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July 2, 2014

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RE: Butte Priority Soils Operable Unit Public Health Study, Phase 1 Report

Dear Ladies and Gentlemen:

Enclosed for your review and approval is the Butte Priority Soils Operable Unit Public Health Study, Phase 1 Report. The health study detailed in the enclosed report has been conducted in accordance with the U.S. Environmental Protection Agency (EPA)-approved work plan dated May 2013 and titled, “Butte Priority Soils Operable Unit: Public Health Study Remedial Design Work Plan, Phase 1 Study.” The study work plan was prepared as a deliverable under the U.S. Environmental Protection Agency (EPA) Unilateral Administrative Order (UAO) for “Partial Remedial Design/Remedial Action Implementation and Certain Operation and Maintenance at the Butte Priority Soils Operable Unit/Butte Site” (EPA Docket No. CERCLA-08-2011-0011). Butte-Silver Bow County (BSB) and Atlantic Richfield Company (AR), as Group 1 responsible parties under the UAO, have been working together and in consultation with EPA, the Montana Department of Environmental Quality, the Agency for Toxic Substances and Disease Registry, the Butte Citizens' Technical Environmental Committee, and members of a Butte health studies Citizens' Advisory Committee to prepare the enclosed report.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Dan Powers, R.S.

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Butte Priority Soils Operable Unit
Public Health Study
Phase 1

Prepared for:
Butte Silver Bow County and Atlantic Richfield Company
Butte, Montana

Prepared by:
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Seattle, Washington

Date:
July 2014

Project Number:
3032503A

ENVIRON

Preface

This report presents the results of the first phase public health study for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County. This study was conducted with the oversight of a technical working group that provided direction for the study scope, reviewed the work plan, commented on technical memoranda and webinars as the study was conducted, and reviewed the study report. Working group members are listed below (some members did not participate for the full study period):

- U.S. Environmental Protection Agency – Dr. Susan Griffin and Nikia Greene
- Montana State Department of Environmental Quality – Lisa DeWitt and Joe Griffin
- Agency for Toxic Substances and Disease Registry – Dr. Michelle Watters and Capt. Dan Strausbaugh
- Butte Silver Bow Health Department – Dan Powers and Eric Hassler
- Atlantic Richfield Company – Dr. Cord Harris
- Butte Citizen's Advisory Committee – Jay Cornish, Helen Joyce, Dr. Merle Benedict, Dr. John Pullman, Shannon Holland, and Dr. Richard Rossi
- Butte Citizens' Technical Environmental Committee – Dr. Steve Ackerlund

Comments received from the public on a draft work plan were also considered in development of the study.

The study was carried out and this report has been prepared by ENVIRON International Corporation on behalf of the responsible parties, Atlantic Richfield Corporation and Butte Silver Bow County. Funding was provided by Atlantic Richfield. ENVIRON's primary technical team included study director Dr. Rosalind Schoof, Project Manager Dina Johnson, Emma McConnell, Cynthia Van Landingham, Dr. Alexa Gallagher, Alma Feldpausch, Amy Kephart and Dr. Linda Dell.

Public Health Statement

The Butte Priority Soils Operable Unit Health Study presents the results of the first phase in a series of public health studies that looks at the effectiveness of the Residential Metals Abatement Program (RMAP) for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana.

This Superfund Study Focuses on Assessing Lead Exposures

This health study evaluates blood lead data collected from Butte children from 2003 through 2011, although additional information about RMAP assessments and abatements was also considered. Concentrations of lead in the blood represent lead exposures from all sources (environmental and non-environmental). In this study, blood lead data are evaluated to understand:

- how lead exposures in Butte have changed over this time period,
- how they compare to blood lead levels for areas outside of Butte, and
- what factors in Butte might be contributing to differences in blood lead levels within Butte and between Butte and other reference areas.

The understanding gained is applied toward making recommendations for improving the RMAP.

The Study Focus on Blood Lead Ensures Consideration of All Sources of Lead Exposure in Butte, including Superfund-related Sources

Lead exposures of children are a concern in all U.S. communities. Many lead sources and risk factors are linked to higher blood lead levels in children. Sources found in most communities include lead in house paint (from before 1978), lead in plumbing (pipes, brass fittings, and solder), and lead in various products such as toys, lead glazed ceramic dishware, and old mini-blinds. Other sources may include lead related to hobbies such as making fishing sinkers or bullets, and working with stained glass. Higher blood lead levels have been found at homes where batteries are recycled or where parents bring home lead on clothes contaminated at work. Risk factors are characteristics that make a person more likely to have higher blood lead levels. For example, higher blood lead levels are associated with poverty, race, age, and other demographic and social and economic factors. Lead exposures and average blood lead levels have declined dramatically since the 1970s because many lead uses in products have been discontinued; however, individual children may still be found with higher than expected blood lead levels.

In Butte, lead in soil and dust from wastes generated by historical mining operations is also a concern and is the main reason for the Superfund activities. Because there are so many sources of lead exposure in all communities, and because of the variation in blood lead levels with other risk factors, it is difficult to point to any one source contributing to blood lead levels in a group of children. Despite this, the study takes into account the many sources of lead exposure and uses several approaches to evaluate whether the RMAP has been effective in contributing to reductions in lead exposures and to identify possible improvements to the RMAP.

Blood Lead Levels in Butte have Declined Dramatically

Blood lead levels in Butte children have dropped dramatically since 2003. Average levels for 2010 of 1.6 µg/dL were less than half of the levels for 2003, of 3.5 µg/dL. The percent of blood lead levels above 10 µg/dL declined by about the same amount. The percent of blood lead levels above 5 µg/dL dropped by an even greater amount, decreasing from 34 percent in 2003 to 10 percent in 2010.

Butte Blood Lead Data were Compared to Data from a Reference Population Adjusted to Reflect the Butte Community

Butte blood lead levels were compared to blood lead levels for an outside “reference” population to understand how Butte children differ from children in non-mining communities over the same time period. For reference blood lead levels outside of Butte, we used data representative of levels in U.S. children that are collected as part of the National Health and Nutrition Examination Survey (NHANES). When comparing two different populations for blood lead, it is standard scientific process to consider how the characteristics of the two populations compare, how these characteristics might influence blood lead levels, and how this might affect our comparison. In this study, we made adjustments to the NHANES dataset to make the U.S. data more similar to Butte in terms of important risk factors, including poverty status, racial make-up, and the wide-spread presence of older homes.

This study found that average blood lead levels decreased throughout the study period both in Butte and in the NHANES reference population. Average blood lead levels were higher in Butte children compared with the reference children from 2003 through 2008, but during 2009 and 2010 the average levels were the same. This means that blood lead levels were declining faster in Butte than in the reference population. The specific factors causing the higher rate of decline in Butte cannot be conclusively proven based on this analysis, but the factors could include ongoing RMAP response efforts and reductions in other lead exposure sources.

Blood Lead Levels were also Compared Across Butte Neighborhoods

As part of this study, we examined blood lead levels in different Butte neighborhoods to see if there were differences in lead exposures. Blood lead levels decreased rapidly over time in all Butte neighborhoods. However, during the study period children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The difference between neighborhoods was similar to the difference reported in a 1990 lead exposure study conducted in Butte. The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats.

Management of Lead Exposures in Butte

Once a child with an elevated blood lead level is identified in a screening program such as the Women, Infants, and Children program in Butte, the first step is to test the child again to confirm the elevated level. Once a child is confirmed to have an elevated blood lead level, the Butte Silver Bow County (BSB) Health Department follows up with a home visit to interview the family and further test the home to identify the source of lead exposure. Until 2013, 10 micrograms lead per deciliter blood (µg/dL) was used as the trigger for follow up home visits. Starting in 2013, 5.0 µg/dL became the trigger for follow up.

According to BSB Health Department's annual reports of clinical and educational interventions, confirmed blood lead results exceeding 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department's RMAP has identified a variety of suspected causes of elevated blood lead levels in Butte, including environmental lead concentrations, toys, dishes, and batteries.

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 that reason, this study could not directly evaluate if abatements reduced blood lead levels in Butte children. However, review of the RMAP activities and seasonal differences between blood lead levels for children living in Uptown and the Flats suggests that both soil and paint might be contributing to higher outdoor lead exposures in Uptown.

The RMAP Continues to be an Important Community-Wide Mechanism for Identifying and Reducing Lead Exposures in Butte

Along with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures from a variety of sources. Based on the findings of this study, our primary recommendation is that the RMAP should be continued. Substantial progress has been made in reducing lead exposures in Butte, but many properties are yet to be assessed. To the extent possible, BSB should 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). BSB should also continue to seek opportunities to promote community participation in the RMAP, especially in residents of Uptown where increased exposures and risk factors are evident.

We support BSB's 2013 change to follow up when children's blood lead levels are greater than 5 µg/dL. Reducing the level that triggers an assessment should increase the effectiveness of lead abatement efforts in Butte. Because it is often difficult to identify specific causes of moderately elevated blood lead levels (i.e., in the range of 5-10 µg/dL), we also recommend improved procedures for electronic data collection and maintenance to enable increased tracking and follow-up of children with elevated blood lead levels. In addition, we recommend other improvements to the RMAP that could improve future assessments of lead exposures and support periodic re-evaluation of the RMAP's effectiveness.

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Acronyms and Abbreviations

ACCLPP	Advisory Committee on Childhood Lead Poisoning Prevention
AR	Atlantic Richfield Company
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	Blood Lead Level
BPSOU	Butte Priority Soils Operable Unit
BSB	Butte Silver Bow County
CAC	Butte Citizens' Advisory Committee
CDC	Centers for Disease Control and Prevention
CTEC	Butte Citizens' Technical Environmental Committee
EPA	U.S. Environmental Protection Agency
GM	Geometric Mean
GSD	Geometric Standard Deviation
IWH	Institute for Work and Health
LCL	Lower Confidence Limit
LEAP	Lead Education and Abatement Program
LSMEANS	Least Squares Means
µg/dL	Micrograms lead per deciliter
MDEQ	Montana State Department of Environmental Quality
MDPHHS	Montana Department of Public Health and Human Services
MLE	Maximum Likelihood Estimation
NHANES	National Health and Nutrition Examination Survey
PIR	Poverty Income Ratio
RMAP	Residential Metals Abatement Program
ROS	Regression on order statistics
UCL	Upper Confidence Limit
WIC	Women, Infants, and Children

Glossary of Terms

Accuracy: The degree to which a measurement reflects the true quantitative value of a variable.

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.

***A Priori* Design**: A design based on deductive reasoning.

Autoregressive Covariance Structure: Measurements farther apart in time are assumed to be less correlated than observations closer in time.

Binning Procedure: Individual bins, defined by a specific set of values for each combination of the variables, such as non-Hispanic whites with a PIR ≤ 1.75 and a house made before 1940. The bins were used in conjunction with estimated Butte data to calculate frequencies for each variable combination, first with Butte data, then NHANES data.

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.

Chi Square test: Hypothesis test used when the distribution of the test statistic is a chi-square distribution. A chi-square test was used to determine if the slopes of regression models were the same.

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

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

Continuous Variable: Quantitative variables representing data with an infinite number of possible values between two data points.

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

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

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 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 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 is included.

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

Extrapolation: To use data in a known interval to make inferences about the values in an unknown interval (Merriam Webster 2013b).

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

Geometric Mean (GM): A measure of central tendency that is typically used when the underlying data is log-normally distributed. The geometric mean is the equivalent of the nth root of the product of n sample values (Merriam Webster 2013c).

Geometric Standard Deviation (GSD): A factor which 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 which represents the frequency distribution of data.

Imputation: A statistical method replacing missing data with substituted values.

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

Interaction Terms: Terms which are added to a model to help determine whether the simultaneous influence of two independent variables on a third (dependent) variable is not additive. For example, sex and age may indicate changes in the dependent variable but if the changes over age are also dependent on the sex (e.g. go up with age in females and down with age in males) then the interaction term is needed.

Least Squares Mean (LSMEANS): Estimated population marginal means based on a group within the model and adjusted for the other covariates in the model (SAS Institute 2013a).

Linear Mixed Model: Allows for multiple patterns of correlation to be modeled and is used to account for repeated measurements and correlated nature of data (Seltman 2013).

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

Log Transformed data: Data for which the logarithm was taken of each observation.

Maximum Likelihood Estimation (MLE): A procedure of finding one or more parameters of a function such that the known likelihood distribution for the function is at a maximum. This procedure is a standard method used in statistics for parameter estimation and inference statistics (Helsel 2005).

Mean: The average value of a set of numbers.

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

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

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.

Natural Log: A logarithm with the base e.

Non-detect: A number below the lowest value which 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 Ration (PIR): 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.

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).

Regression on Order Statistics (ROS): A method of determining possible values for left-censored data (non-detects) in a data set. This method uses a regression line that is fit to the normal scores of the order statistics for the uncensored observations (the detected values) and then fills in values extrapolated from the straight line for the observations below the detection limit.

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 to not 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).

Surrogate Indicator: A substance or compound which can suggest the presence of another.

T-Test: A test which can measure the difference between two groups' mean responses (SAS Institute 2013b).

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 which modifies the influence of a record on the overall fit of the parameters of a model to the data.

Executive Summary

A series of public health studies are called for in addressing the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana. Remediation activities in BPSOU have included a Residential Metals Abatement Program (RMAP) administered by Butte Silver Bow County (BSB) to address potential exposures to lead, arsenic, and mercury in residential areas of Butte. The primary study objective to be addressed by the Superfund health study is the review and evaluation of available RMAP data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed. To date, lead has been the primary focus of activities conducted under the RMAP.

This report presents the result of the first Superfund health study. As part of the scoping process for the Superfund health study, "non-Superfund" health concerns were also identified by residents. The non-Superfund studies will be reported separately.

Blood Lead Data are used to Assess Lead Exposures

Consistent with the RMAP focus, this phase of the Butte health study focuses on lead. For many years, the BSB Health Department has collected blood lead data that could be used to support an assessment of Butte lead exposures. Concentrations of lead in the blood provide a reliable measure of lead exposures from all sources (environmental and non-environmental).

Many sources and risk factors are associated with higher blood lead levels in children. In addition to lead from historical mining operations, sources include lead in paint, plumbing, and various consumer products such as toys, lead glazed ceramic dishware, and old mini-blinds, as well as lead associated with hobbies such as making fishing sinkers or bullets, and stained glass. Elevated lead blood lead levels have been found at homes where batteries are recycled or where parents bring home lead on clothes contaminated at work. Higher blood lead levels are also associated with poverty and other demographic and socioeconomic factors. Lead exposures and blood lead levels have declined dramatically since the 1970s as many lead uses have been discontinued; however, individual children may still be found with elevated levels.

The Study Evaluated Two Primary Lines of Evidence

The study was focused on evaluating two primary lines of evidence. For the first, we compared Butte blood lead levels with those in other parts of the U.S. to understand whether lead exposures in Butte are high relative to other areas while accounting for some other common factors that might influence blood lead levels in both areas. For the second, we evaluated whether lead exposures are different in different Butte neighborhoods to better understand some of the factors within Butte that may still be contributing to higher blood lead levels in some residents. The study focused on children from 12 to 60 months of age because children in this age range typically have higher blood lead levels and are more sensitive to the effects of lead compared with older people. 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.

Blood lead levels in Butte children have declined dramatically since 2003. Average values for 2010 were less than half of the values for 2003, with geometric means having declined from 3.5 µg/dL in 2003 to 1.6 µg/dL in 2010. The percent of blood lead levels above 10.0 µg/dL declined by a similar magnitude, while the percent of blood lead levels above 5 µg/dL declined by an even greater margin, decreasing from 33.6 percent on 2003 to 9.5 percent in 2010.

Comparison of Butte Blood Lead Levels with a U.S. Reference Population

Blood lead data representative of levels in U.S. children are collected as part of the National Health and Nutrition Examination Survey (NHANES). These data were used to develop a reference dataset for this study, adjusting 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[1], poverty levels and races in the Butte study population. Butte blood lead data were then compared to the NHANES reference dataset to assess if Butte children are affected by Superfund sources in addition to lead exposure sources present in non-Superfund communities.

The NHANES is conducted over two year periods. This study examined four two-year periods for which both NHANES and Butte data were available: 2003-2004, 2005-2006, 2007-2008 and 2009-2010. Average blood lead levels were found to be higher in Butte children compared with the NHANES reference dataset during the first three test periods, i.e., during 2003-2004, 2005-2006, and 2007-2008. This difference disappeared for Butte children tested during 2009-2010. For that time period there was not a statistically significant difference between blood lead levels in Butte children and the NHANES reference dataset (see Figure ES1).

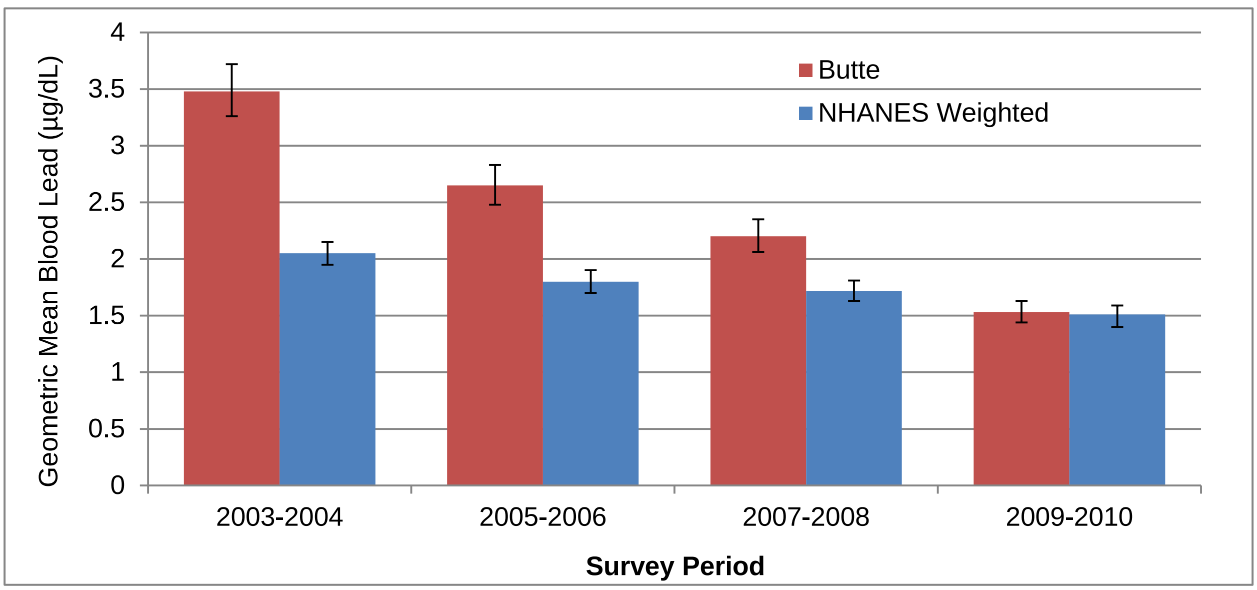


Figure ES1: Modeled Geometric Mean Blood Lead Levels for Butte Compared to the Adjusted NHANES Data by Test Year with 95% Confidence Intervals

[1] Throughout the study, the term "house" refers to any residential dwelling, including single family homes as well as multifamily housing complexes and "house age" refers to the range of years within which the house was built.

The lack of a significant difference between Butte and the NHANES reference dataset during the 2009-2010 reflects a greater rate of decline in Butte blood lead levels during the prior time periods. The specific factors causing the higher rate of decline in Butte cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts, as well as reductions in other lead exposure sources or risk factors.

As described by the Centers for Disease Prevention and Control, "persistent differences between the mean BLLs of different racial/ethnic and income groups can be traced to differences in housing quality, environmental conditions, nutrition, and other factors." (CDC 2013b) To the extent that we were not able to adjust the reference population for all lead exposure risk factors present in Butte, we cannot specify the causes of differences between Butte and reference population blood lead levels in earlier study periods.

Butte Neighborhood Blood Lead Level Comparison

The second part of this study examined blood lead levels in different Butte neighborhoods to see if there were differences in lead exposures. A study conducted during 1990 found that overall blood lead levels of Butte children were not elevated when compared to national blood lead levels; however, the study did find that blood lead levels were higher in the Uptown area of Butte compared with some neighborhoods in the Flats. In this study the 2003-2010 Butte blood lead data were also examined to assess any differences by neighborhood. 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 blood lead levels were compared.

During all four study periods (i.e., 2003-2004, 2005-2006, 2007-2008, and 2009-2010) children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The magnitude of the neighborhood differences was similar to the difference observed in the 1990 study (Figure ES2).

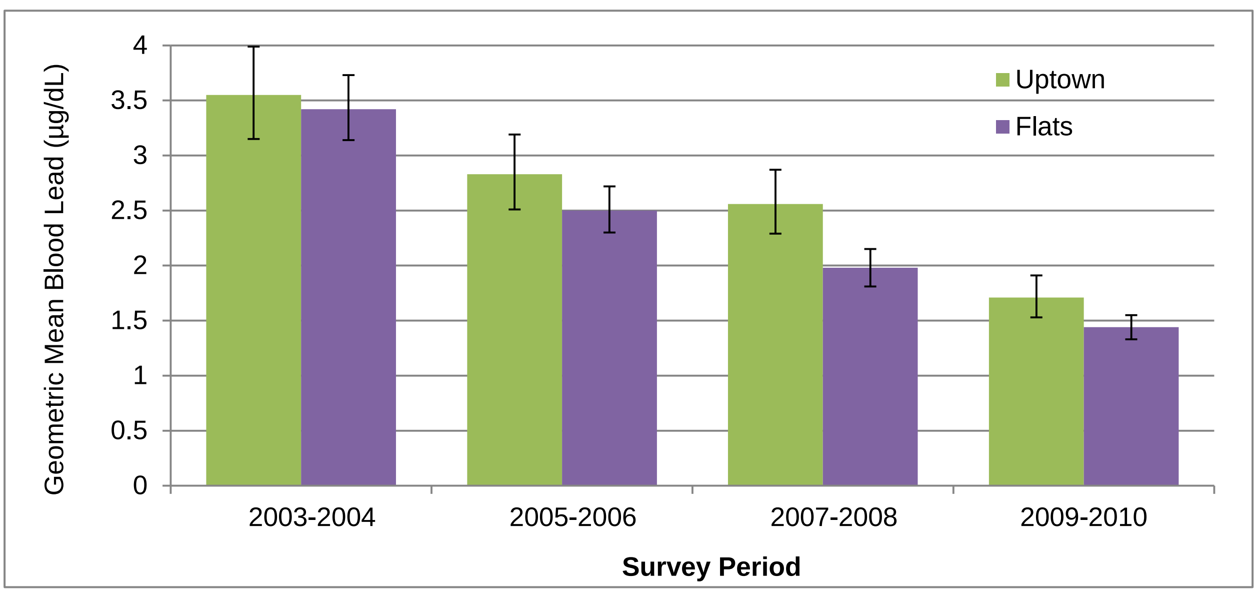


Figure ES2: Modeled Geometric Mean Blood Lead Levels for Uptown vs. the Flats by Test Year with 95% Confidence Intervals

The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats.

Management of Lead Exposures in Butte

During the 2003 through 2010 study period, the Centers for Disease Control and Prevention (CDC) recommended 10 micrograms lead per deciliter blood (µg/dL) as a blood lead "level of concern" when based on a confirmed venous blood draw. This level of concern was used as a risk management tool by the BSB Health Department to identify children who might have elevated lead exposures so that actions to reduce such exposures could be initiated. Children with confirmed venous blood lead results exceeding 9.9 µg/dL were referred for case management, including home visits when appropriate, intensive education for the family, environmental investigation and follow up blood lead testing.

According to BSB Health Department's annual reports of clinical and educational interventions, screening blood lead results confirmed to exceed 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department identified a variety of suspected causes of elevated blood lead levels in these children. Starting in 2013, home visits were scheduled for all children with blood lead levels of 5.0 µg/dL or higher, consistent with a new blood lead reference level issued by the CDC.

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 that reason, this study could not directly assess if abatements reduced blood lead levels in Butte children. However, most RMAP activities occurred in the Uptown neighborhoods with similar frequency of interior/exterior house paint and yard soil abatements. In the Flats, the number of paint abatements exceeds 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.

Recommendations

Coupled with other extensive source remediation activities in Butte, the RMAP has been an important community-wide mechanism for identifying and reducing lead exposures from a variety of sources. Based on the findings of this study, our primary recommendation is that the RMAP should be continued. Substantial progress has been made in reducing lead exposures in Butte, but many properties are yet to be assessed. To the extent possible, BSB should build upon community interactions via the RMAP to further promote exposure reduction education and outreach, including exposure reduction related to non-Superfund sources (i.e., house paint). BSB should also continue to seek opportunities to promote community participation in the RMAP, particularly among residents of Uptown where increased exposures and risk factors are evident.

In 2013, BSB changed the trigger for follow up of children's blood lead levels to greater than 5 µg/dL. Reducing the level that triggers an assessment should increase the effectiveness of lead abatement efforts in Butte. It should be noted that it is often difficult to identify specific causes of moderately elevated blood lead levels (i.e., in the range of 5-10 µg/dL), and for that reason, we also recommend improved procedures for electronic data collection and maintenance to facilitate increased tracking and follow-up of children with elevated blood lead levels.

Several other recommendations relate to collection of blood lead data that could be used in the future to assess the effectiveness of continued efforts to reduce lead exposures. We recommend restoring blood lead testing procedures that produce reliable results at a detection limit of 1 μg/dL or lower (a new method began in late 2011 has a detection limit too high to calculate mean values for blood lead levels). We also recommend improving the consistency with which complete blood lead records are collected, regardless of blood lead testing referral source (i.e., RMAP vs. WIC vs. pediatrician). To the extent legally possible, BSB should also consider collection of additional information from blood lead tested individuals that will improve interpretation of lead exposure trends going forward (e.g., race, maternal education, household income level). These changes would allow for an update of this study in the future to assess RMAP effectiveness.

1 Introduction

This document presents the results of the first phase in a series of public health studies for the Butte Priority Soils Operable Unit (BPSOU) Superfund site in Silver Bow County, Montana (hereafter, the "Butte health study"). This phase of the Butte health study focuses on analyses of Butte Silver Bow (BSB) County blood lead data compiled from 2003 through 2010 to determine if lead exposures by residents differ between the study area and a comparable population or across neighborhoods within the study area. These primary analyses are supplemented by consideration of available Butte environmental data as well as other blood lead data for communities outside of Butte. Collectively, these analyses are designed to support an evaluation of the effectiveness of ongoing remediation and residential metals abatement efforts in the study area that have occurred since the early 1990s. Based on these analyses, recommendations are included regarding potential improvements to current remediation/abatement approaches.

1.1 Study Background and Development Process

This health study has been conducted in accordance with the U.S. Environmental Protection Agency (EPA)-approved Butte health study work plan dated May 2013 (ENVIRON 2013a). The primary study objective to be addressed by the health study is the review and evaluation of available Residential Metals Abatement Program (RMAP) data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed. To address the study objective, the approved study plan proposed to focus on analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels (BLLs) in Butte children. More specifically, the plan called for examination of the blood lead data to assess whether changes in community-wide exposures are evident based on the following lines of evidence:

- The distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated.

  and

- Statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP in BLLs across Butte neighborhoods.

As discussed in the EPA-approved work plan, if the lines of evidence support a finding that improvements to the RMAP are necessary to identify and mitigate potentially harmful exposures to sources of lead, arsenic, and mercury in the Butte community, then response actions appropriate to addressing identified RMAP deficiencies would be proposed for further investigation.

The focus of this study phase was developed after consideration of a range of possible studies and concerns expressed by Butte citizens during community meetings conducted early in the process. The final plan for this study was developed with technical input and collaboration with representatives from EPA, the Montana State Department of Environmental Quality (MDEQ), BSB Health Department, the Agency for Toxic Substances and Disease Registry (ATSDR), Atlantic Richfield (AR), and the Butte Citizens' Technical Environmental Committee (CTEC).[2] Public comments received during the draft study work plan public comment period, which occurred from late 2012 through early 2013, were also considered in finalizing the study work plan for this study.

Health studies for communities affected by environmental contaminants can start either with evaluation of exposures or of disease rates. If a study beginning with evaluation of exposures reported elevated exposures, the next step would be to recommend ways to reduce exposures, and the results could also guide design of future studies of disease rates to focus on diseases possibly related to those specific chemical exposures. Other studies looking broadly at disease rates may be a useful supplement to exposure studies, but in most cases such studies are not as sensitive as focused exposure studies. Both kinds of studies were considered prior to developing the study summarized in this report, which focuses on the evaluation of available lead exposure data in Butte. Additionally, a study of cancer incidence and mortality was also requested and subsequently conducted by the Montana Department of Public Health and Human Services (MDPHHS) early in the study planning process. The MDPHHS study was conducted independently. A summary of the MDPHHS study that was presented in the approved work plan (ENVIRON 2013a) is reproduced in Appendix A to this study report along with a copy of the publically-available MDPHHS study (MDPHHS 2012).

Once the focus of the study was approved in the final work plan, execution of the study design was sequenced to present information on key development steps to the study Working Group members from EPA, MDEQ, ATSDR, CTEC, BSB, and AR. Members of the Butte Citizens' Advisory Committee (CAC) were also invited to each Working Group meeting. The CAC is comprised of technically qualified community members who were appointed by the BSB Board of Health early in the work plan development process to provide input to the study design and implementation process. A summary of the topics presented at each Working Group meeting is provided below along with interim study deliverables for which Working Group review and comments were sought prior to the submission of each deliverable to EPA for approval in consultation with MDEQ:

- Working Group Meeting #1 web-based presentation and conference call on July 17, 2013 included:
  - Proposed preliminary delineation of neighborhoods (study subareas) within the Butte study area to support evaluation of BLL differences across Butte over the study time period.
  - Review of key factors to consider in selecting a reference blood lead dataset for comparison to the Butte blood lead data.
  - Proposed selection of the National Health and Nutrition Examination Survey (NHANES) blood lead dataset as the reference dataset for use in the study and preliminary

[2] Participation by the CTEC representative began during the public comment period for the draft study work plan, after the study focus was selected.

discussion of some of the weighting adjustments that might be needed to ensure the national data were comparable to the Butte data.

– Review of the Butte blood lead database development and documentation process.

- Technical Memorandum Deliverable - Proposed Reference Blood Lead Data for Use in the Butte Health Study (ENVIRON 2013b):

– Submitted for EPA approval, in consultation with MDEQ, on August 20, 2013.

– Approved by EPA, in consultation with MDEQ, on September 3, 2013.

- Working Group Meeting #2 web-based presentation and conference call on October 30, 2013 included:

– Proposed statistical approaches for use in addressing the study's two primary study questions.

- Working Group Meeting #3 web-based presentation and conference call on December 5, 2013 included:

– Review of preliminary study results for each of the study's two primary study questions.

- Working Group Meeting #4 conference call on February 5, 2014 included:

– Review of comments received from Working Group and CAC review of internal draft study report and discussion of comment resolution and associated draft report revisions to be made prior to formal submittal of revised draft report to EPA in consultation with MDEQ.

- Draft Final Study Report Deliverable (ENVIRON 2014):

– Submitted for EPA approval, in consultation with MDEQ, on February 28, 2014.

The Working Group also participated in planning for the draft final report public meeting, review and response to public comments on the draft final report, and development of revisions to the draft final report that are reflected in this document. The response summary for comments received on the draft final report is provided in Appendix B.

1.2 Focus on Butte Lead Exposure Data

EPA's goal in managing Superfund sites is to ensure that chemical exposures are kept low enough to prevent increases in disease rates. EPA conducts assessments that predict potential risks for people expected to be most highly exposed and most susceptible to adverse health effects. EPA then sets cleanup goals expected to protect sensitive members of the population. For BPSOU, EPA reviewed data for multiple chemicals in soil and dust and determined that the primary chemicals of concern were lead, arsenic and mercury, and set cleanup levels for all three chemicals. BPSOU cleanup efforts for arsenic, lead, and mercury have been underway for more than 20 years. AR has conducted much of the cleanup outside of residential areas, and BSB has been leading residential yard and home metals abatement efforts.

The current RMAP and its predecessor program led by BSB have also included a biomonitoring program in which over 3,000 blood lead samples have been collected from Butte children over the past ten years. Arsenic and mercury biomonitoring have also been offered under this program since 2010 but only when environmental sample concentrations in soil or dust[3] are high enough to warrant such testing. Because the environmental concentrations were seldom high enough to offer such testing, there are no comparable arsenic and mercury biomonitoring data. Additionally, RMAP data collected through May 2013 suggest that elevated lead is more prevalent in Butte than elevated arsenic and mercury. For instance, 89 percent of all properties with at least one lead and/or arsenic sample result that exceeded a yard soil action level were due to lead alone. For homes where an indoor dust action level was exceeded (including attics or basements), 44 percent were due to lead alone while less than 1 percent was due to arsenic alone. In all of the RMAP soil and dust samples, there were only two properties with yards exceeding the mercury action level and six with indoor dust exceeding the action level. All of those properties also had lead exceedances.

Using the available blood lead data to assess exposures in Butte is desirable because 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.[4] 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.

1.3 Overall Study Approach

As discussed in the approved work plan for this study, the principal question to be addressed by this study is:

> Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?

As described above, the study design focuses on lead. The study design includes statistical examination of two lines of evidence to evaluate the principal study question. The first line of evidence looks at whether the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. The second line of evidence looks at whether statistically significant differences in BLLs across Butte neighborhoods, measured in conjunction with the RMAP, are reduced relative to differences documented in pre-RMAP BLLs across Butte neighborhoods.

A multi-step process is used to develop a separate multivariable statistical model to address each line of evidence. Supplemental analyses of available environmental and other data augment interpretation of model outputs and help guide identification of a range of possible recommendations or response actions for further consideration to ensure ongoing effectiveness of the RMAP.

[3] Dust includes indoor (living space) dust and attic dust, when exposure pathways for attic dust are identified.
[4] Blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure.

1.4 Report Organization

This report provides a detailed summary of all of the data, methods, analyses and results associated with addressing the principal study question and its dual lines of evidence. To the extent that information relied on this study was included in the approved study work plan (ENVIRON 2013a) or in the approved technical memorandum for selection of the study reference blood lead (ENVIRON 2013b), it has been referenced throughout this report, but may or may not be re-summarized herein. Deviations from the procedures stated in the work plan and this report are provided in Appendix C. Organization of the remainder of this report is as follows:

- Section 2 – The Butte blood lead database is described along with data refinements and treatments applied to the data to prepare it for use in the study's statistical models.
- Section 3 – Factors influencing BLLs are described.
- Section 4 – Development of the statistical model to assess the first line of evidence (comparison to NHANES) is presented including further data adjustments, assumptions, methods, results, and conclusions.
- Section 5 –Development of the statistical model to assess the second line of evidence (differences in BLLs across Butte neighborhoods) is presented including further data adjustments, assumptions, methods, results, and conclusions.
- Section 6 – Supplemental analyses conducted to augment interpretation of the findings from both primary study analyses are described and results presented.
- Section 7 – Overall study conclusions are summarized and discussed including preliminary identification of proposed response actions or other recommendations for improved effectiveness of the RMAP toward reducing Butte metals exposures.
- Section 8 – References cited in the study are listed.

2 Butte Blood Lead Data

As described in the approved work plan (ENVIRON 2013a), blood lead data used in this study originated from BSB Health Department blood lead testing records. The majority of the blood lead records came from patients recruited for regular blood lead testing through the Women, Infants, and Children (WIC) program in Butte.[5]

In June 2012, blood lead data from hard copy records maintained by the BSB Health Department were compiled by a team of individuals authorized by the BSB Health Department to access the confidential information. Compilation of the BSB Health Department blood lead testing records resulted in a blood lead database containing 7,278 blood lead records with collection dates ranging from 1992 to 2012, although only very limited data were available prior to 2002. Entry of each hardcopy record into the electronic database was double-checked by an individual from the compilation team who had not entered the original data.

Most, but not all records compiled included a patient's blood lead result, test date, age at test date, gender, address, and test method. Individuals represented in the database included infants, children, and adults with age at time of testing ranging from 1 month to 70 years. The database included results from both capillary (finger or heel stick) and venous (whole blood) sample collection methods. The majority of blood lead samples had been submitted for laboratory analysis with a detection limit of 1.0 µg/dL; however, in December 2011, the BSB Health Department 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 are 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 blood lead levels that are much higher than most children's levels. 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."

The BSB Health Department records did not include house age[6] information for each individual tested. When it could be located, this information was later added to the database from land survey and property tax data (See Appendix D). 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.

2.1 Refinement of the Blood Lead Database to Support this Study

Refinement of the full blood lead database compiled from BSB records and augmented by property age and census tract assignments was necessary to ensure a complete set of records for use in the health study. Figure 1 depicts the process for blood lead record refinement. Initial

[5] The qualification for WIC is 175% of the federal poverty level or below. However, county blood lead records include those from WIC clients as well as from individuals referred via the RMAP and local physicians.

[6] Throughout the study, the term "house" refers to any residential dwelling, including single family homes as well as multifamily housing complexes and "house age" refers to the range of years within which the house was built.

database refinement excluded records that lacked one or more of the following key pieces of information: test result, participant birthdate, a physical street address for participant's residence at time of testing (i.e., P.O. Box was not sufficient), and participant gender. The remaining 6,608 "complete" records were then further refined as follows:

- Records were excluded for individuals tested at ages that fell outside of the study age range of 12 to 60 months.
- Records obtained by use of the LeadCare II device were excluded as these lacked sufficient sensitivity and precision to support study objectives.
- Records were excluded if they were associated with addresses that were outside of the Butte study area delineated by Silver Bow County Census Tracts 1 through 8.

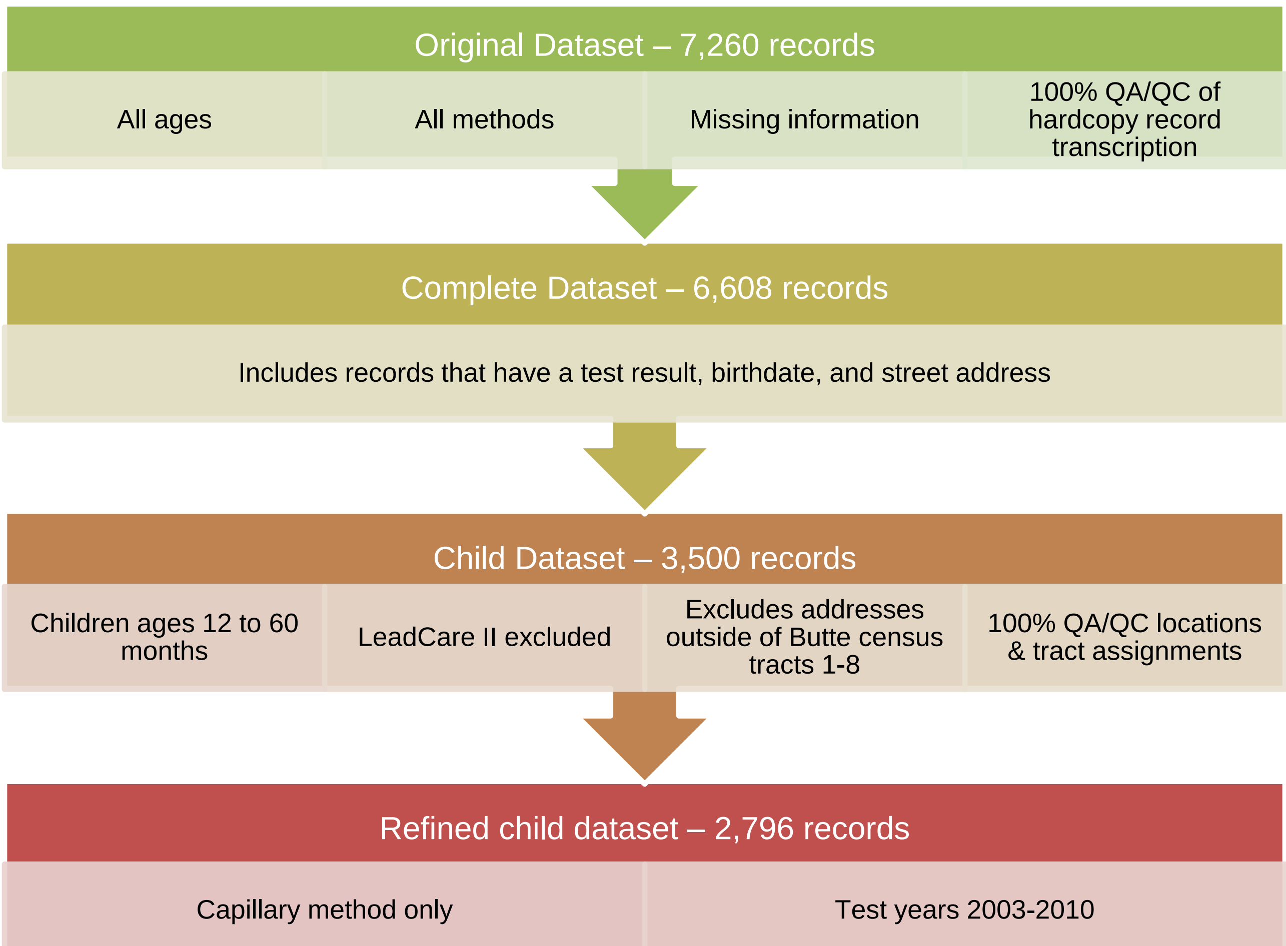


Figure 1: Outline of the Data Refinement Process

Completion of these refinements resulted in a base dataset including 3,500 records that corresponded to the 2002 through 2011 time period. Of these records, most were obtained via capillary sample collection; only 108 were based on venous sample collection. Venous samples in this dataset were most likely collected as confirmatory samples following elevated blood lead results from less invasive, capillary sampling. However, linkages of the capillary and venous data in the BSB records were not evident in most cases. To avoid potential bias in the study analyses that might be introduced by counting both capillary and confirmatory venous results as independent measures for a given individual, all venous records were excluded from the refined child dataset. While studies of simultaneous collection of venous and capillary blood lead samples have shown good correlation, a key concern with the use of finger stick sample collection versus venous sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Consequently, data collected by finger stick is likely to be biased high compared with data collected by venous samples; in other words, blood lead concentrations determined from capillary samples might be higher than those based on venous samples. Exclusion of venous data may include cases where a capillary result was reported as elevated and venous data confirmed that the blood lead was actually not elevated. This also might result in overestimation of blood lead levels for the Butte study participants. However, the potential impact of these potential sources of bias in the overall study analyses is overestimation of blood lead levels in Butte, which is a conservative outcome and more acceptable than including the venous data without more details as to if or how each result relates to other specific capillary results.

Following these refinements, a total of 3,392 records remained in the dataset. Records supporting model development to address the two primary study questions were further limited to test years 2003 through 2010. This ensured alignment with available test years in the NHANES dataset and provided sufficient sample sizes for comparison of trends over time and across neighborhoods in the Butte dataset. Data for 2002 included only 125 records compared to 300 or more records for each of the other years. Data for 2011, which consisted of 470 records from January through early December, were not included in the main statistical models, but were retained in the database and used for supplemental study analyses. With the exclusion of the 2011 data, a total of 2,796 records remained in the refined child dataset.[7]

2.2 Specific Data Treatments Applied to the Study Data

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. These are discussed below.

2.2.1 Log-transformation of Blood Lead Data

Initial evaluation of blood lead data for the refined dataset used histograms to understand how the blood lead results were distributed for the study population. Data were plotted first examining all of the records together and then grouping the records into four 2-year periods. Additional plots were examined based on child gender and child test age groups (12-35 months, 36-50 months). Based on P-P plots, histograms (example shown in Figure 2), and examining values for "skewness", the data fit a lognormal distribution. In other words, the majority of the data fall on the low end of the distribution and very few data points fall in on the highest end of the distribution. This distribution is common for blood lead data with the majority of people having very low BLLs and fewer people having levels that are several times higher. Most

[7] A single capillary blood lead result reported in 2008 with a detection limit different from the other records (3 µg/dL rather than 1 µg/dL) was removed from the refined child dataset to result in 2,796 records.

statistical tests require data to fit a "normal" or Gaussian distribution for valid application. In order to transform the data from the lognormal distribution to the normal distribution, the natural log of each record must be calculated. This transformation was performed on the Butte dataset in order to make the data suitable for use in common statistical tests.

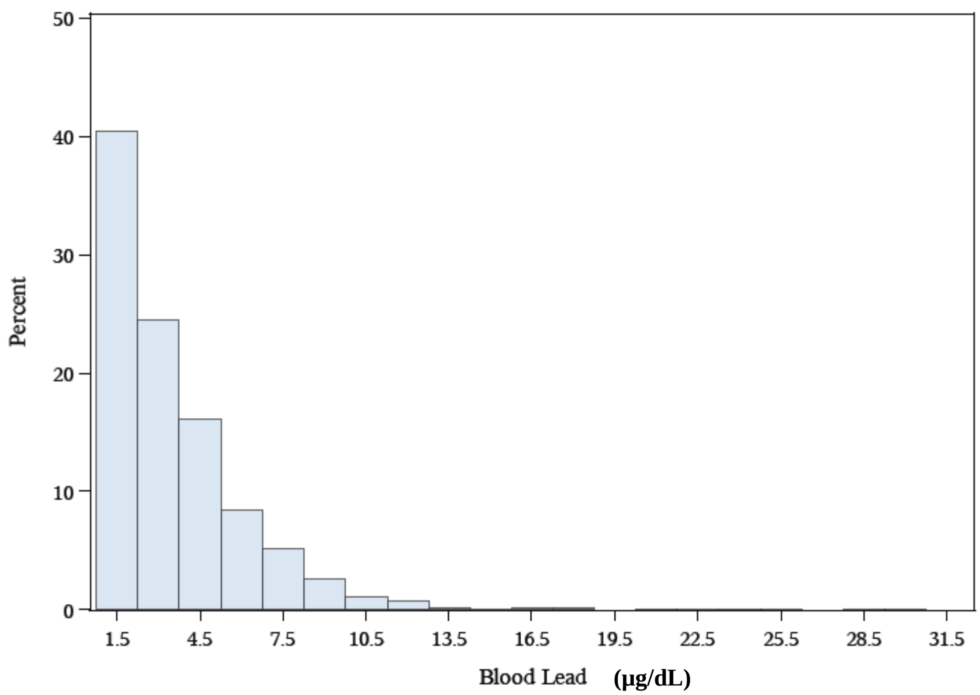


Figure 2: Blood Lead Distribution for Butte (2003-2010)

2.2.2 Handling Non-Detect Blood Lead Data

When a blood lead result is reported as "not-detected" or "non-detect," the blood lead concentration is known to be below the detection limit for the sample analysis, though the exact concentration cannot be determined. The 2,796 blood lead records in the refined child dataset have a detection limit of 1.0 µg/dL and 364 were reported below the detection limit, with a higher proportion of non-detected values in the more recently collected data.

There are a number of accepted options for adjusting the non-detects for use in statistical analysis, including: no action (where all non-detects are replaced with the detection limit); replacement with zero; replacement with half the detection limit; replacement with detection limit divided by the square root of two; maximum likelihood estimation (MLE); extrapolation; and imputation. Replacing the non-detects with the detection limit will cause the results to be higher than they actually are, while replacing the non-detects with zero will produce artificially low values. The other options may come closer to approximating the true values below the detection limit, and the more sophisticated methods of MLE, extrapolation, and imputation are ideal when the computational expertise exists to use them.

To assess the effect of different data treatment options on the Butte data, the following four treatment methods were compared:

- Replacing the Butte non-detects with the detection limit.
- Replacing the non-detects with the detection limit divided by the square root of two.
- Imputing the non-detects with values from a known blood lead distribution.
- Extrapolating the non-detects from the known values in the Butte dataset.

Blood lead results reported at a concentration less than or equal to 1 µg/dL from the NHANES data for 2003 through 2010 supplied the known blood lead distributions used for the imputation method. Analytical methods employed for NHANES are highly precise resulting in very low detection limits ranging from 0.25-0.28 µg/dL. In fact, during the 2003 through 2010 survey years, only one non-detect value is reported in the NHANES blood lead data. Imputation from the NHANES data assumes that the distribution of BLLs less than 1 µg/dL for the Butte population is similar to the same distribution for the NHANES population. Given this assumption, for each two-year test period, the distributions of NHANES data less than or equal to 1 µg/dL were estimated using Oracle Crystal Ball. Then SAS Version 9.3 (SAS Institute Inc., Cary, NC, U.S.) was used to generate random samples from the appropriate distribution to impute a value for each Butte non-detect from the same two-year test period. In this manner, values that were represented more frequently in the NHANES data would be selected for replacement of Butte non-detect values more often.

In contrast to imputing Butte non-detects from the known NHANES distribution at or below 1 µg/dL, the final option extrapolates the Butte non-detect values from the population distribution of known Butte blood lead concentrations (i.e., the detected Butte data) using the EPA statistical software ProUCL's (Version 5.0, USEPA, Atlanta, GA) lognormal regression on order statistics (ROS) function for non-detect imputation. Values for non-detects were extrapolated/assigned from the Butte distribution of values from the same test year.

Employing each of the four non-detect treatment options, geometric mean BLLs were calculated for the Butte study data by two-year period. As shown in Figure 3, differences between each method are slight. The 2009-2010 test period had more non-detects than the other periods, and therefore, the treatment methods had larger effects on the geometric mean BLL. Although all options are scientifically justifiable and reasonably simple to execute, the extrapolation method was deemed most appropriate in that it utilizes known data from the Butte dataset. Therefore, the extrapolation method was selected for use in the study.

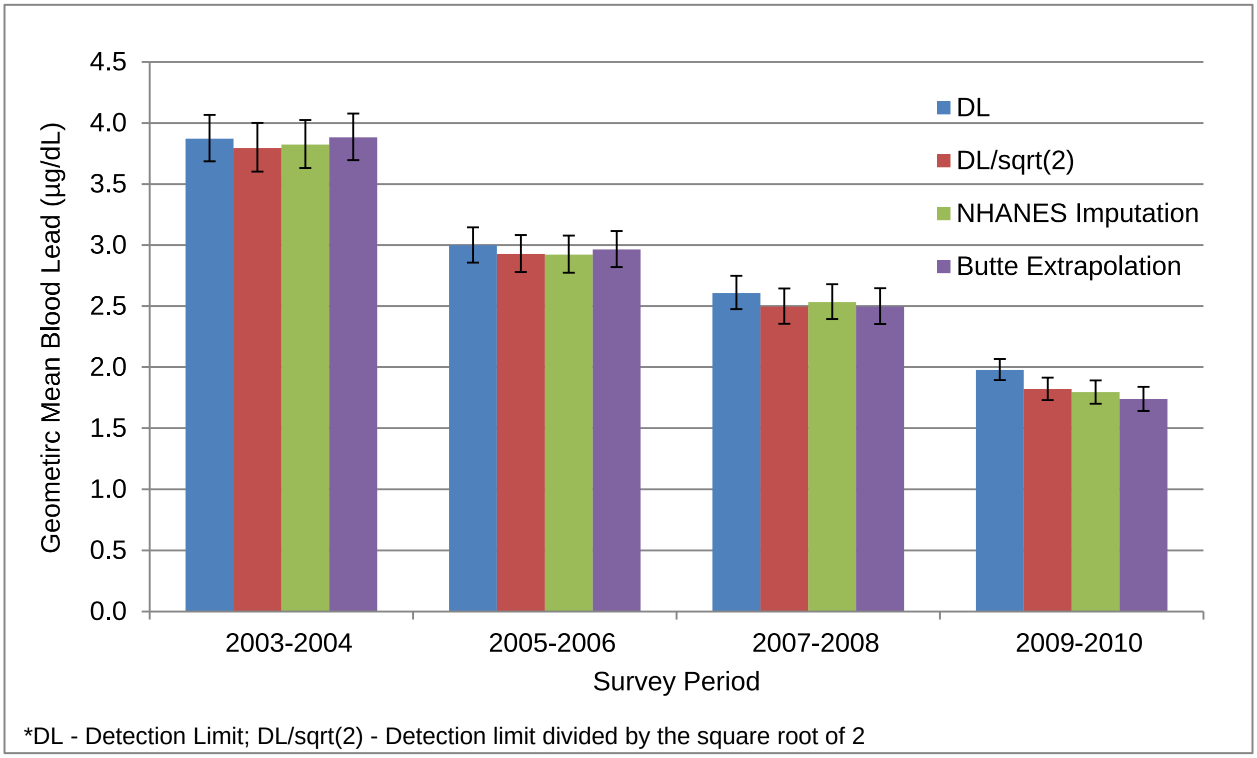


Figure 3: Comparison of Geometric Mean Blood Lead Estimates for Different Non-Detect Treatment Options

2.2.3 Statistical Treatment of Repeat Blood Lead Measurements for Individual Participants

The 2,796 records in the refined child dataset come from 1,697 unique children because study participants were often tested several times. Some children may have been tested annually during well child visits to the clinic, while others may have had repeat tests for other reasons. Multiple blood lead results from a single child cannot be considered statistically independent from each other because of common exposure conditions, as well as behavioral and physiological characteristics. Statistically it would be inaccurate to use multiple results from one child as though they are completely independent; however, if subsequent tests on individuals were removed from the dataset entirely, a significant amount of data would be lost. To keep these repeat measurements in the dataset, “mixed” models were used that could account for any interdependence in the repeat records. See sections 4.3 and 5.3 for additional details on the models.

2.2.4 Butte Blood Lead Summary Statistics

Summary statistics for the refined Butte dataset are presented in Table 1.These data represent screening BLLs, not confirmed venous results. These data also include repeat measurements.

Table 1: Butte Blood Lead Summary Statistics						
Year	**N**	**GM (µg/dL)**	**GSD (µg/dL)**	**95th percentile (µg/dL)**	**% ≥ 5.0 µg/dL**	**% ≥ 10.0 µg/dL**
2003	351	3.49	2.01	9.10	33.6	3.4
2004	319	4.36	1.76	9.51	44.8	4.4
2005	312	3.35	1.83	8.60	24.7	2.6
2006	326	2.63	1.93	7.03	16.0	1.8
2007	342	2.44	2.16	7.90	16.1	2.0
2008	324	2.55	2.15	9.15	20.1	4.0
2009	361	2.01	2.10	6.80	10.8	1.4
2010	461	1.55	2.42	6.60	9.5	1.5
N – Sample Size; GM – Geometric Mean; GSD – Geometric Standard Deviation						

As shown in Table 1, blood lead levels in Butte children have dropped dramatically since 2003. Geometric mean BLLs for 2010 (1.55 µg/dL) were less than half of the levels for 2003 (3.49 µg/dL). The percent of BLLs above 10.0 µg/dL declined by a similar magnitude, decreasing from 3.4 percent to 1.5 percent. The percent of BLLs above 5 µg/dL declined by an even greater margin, decreasing from 33.6 percent in 2003 to 9.5 percent in 2010.

3 General Factors Influencing Blood Lead Levels

Lead exposures of children are a concern in all U.S. communities. Many sources and risk factors are associated with higher blood lead levels in children. Sources found in most communities include lead in house paint (from before 1978), lead in plumbing (pipes, brass fittings and solder) and lead in various consumer products such as toys, lead glazed ceramic dishware, and old mini-blinds, as well as lead associated with hobbies such as making fishing sinkers or bullets, and stained glass. Elevated lead blood lead levels have been found at homes where batteries are recycled or where parents track home lead on clothes contaminated at work. Higher blood lead levels are also associated with poverty and other demographic and socioeconomic factors. In Butte, lead in soil and dust that originates from wastes generated by historical mining operations is also a concern and is the primary reason for the Superfund activities.

BLLs have declined precipitously in all U.S. populations since the 1970s with implementation of the ban on lead additives in gasoline and paint, along with control of lead in plumbing, canned foods, and other sources. Nevertheless, a variety of factors continue to be associated with differences in BLLs across the nation. These include demographic factors such as gender, age, and race/ethnicity, as well as a variety of socioeconomic factors such as income level and maternal education. To the extent that such information was available for both Butte and the reference dataset (NHANES), these general factors have been considered in the models developed to address the principal study question, in order to differentiate them from factors unique to Butte.

3.1 Sample Year, Season, Age and Gender

Three primary factors considered in model development are the year in which the sample was collected, the season in which the sample was collected, and the age of the subject tested. BLLs may also vary by gender, but this is not currently a significant factor for all age cohorts based on national data.

As noted above, BLLs have declined over the past few decades and continue to decline, albeit at a slower rate in recent years. In addition, BLLs in young children have long been known to be highest in summer and early autumn (Hayes et al. 1994). This pattern has been assumed to be associated with greater exposure to soil containing lead, due to more time spent outside and to more soil tracked and blown into the house during the summer months. A recent study of BLLs in Detroit area children has confirmed that this pattern still occurs; with late summer BLLs averaging between 11 percent and 14 percent higher than BLLs measured in January (Zahran et al. 2013). A preliminary analysis of the Butte dataset (not presented) suggested that a similar trend was present among Butte children.

It has also been consistently observed in the U.S. that on average young children between the ages of 1 and 3 years have the highest BLLs among children (Jones et al. 2009; CDC 2013b). Figure 4 shows the continued decline in BLLs in successive birth cohorts, as well as the decline in BLLs as each birth cohort gets older. Blood lead data collection focuses on young children because their BLLs are higher than other age groups and because young children are more sensitive to the impacts of lead than are older children and adults. Preliminary analyses of all available Butte blood lead records[8] confirm that BLLs have been trending down over the period from late 2002 to late 2011, and that BLLs are higher in 1 to 5 year old children compared with older children and adults living in Butte (Figure 5).

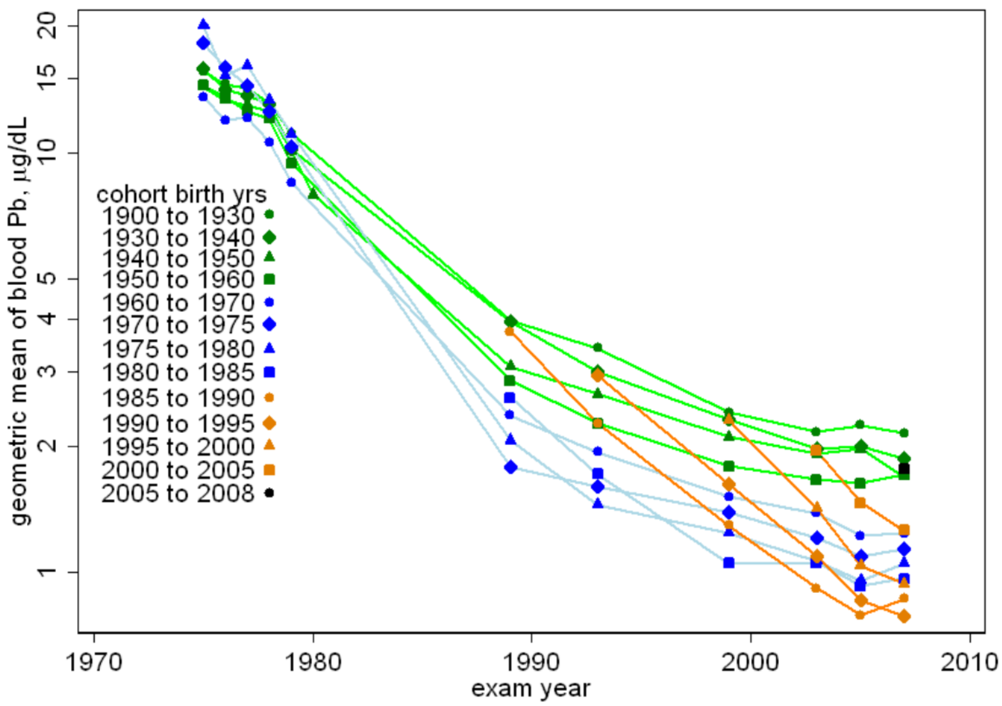


Figure 4: Decline in Blood Lead in Different NHANES Birth Cohorts (USEPA 2013a)

[8] Excluding LeadCare II records

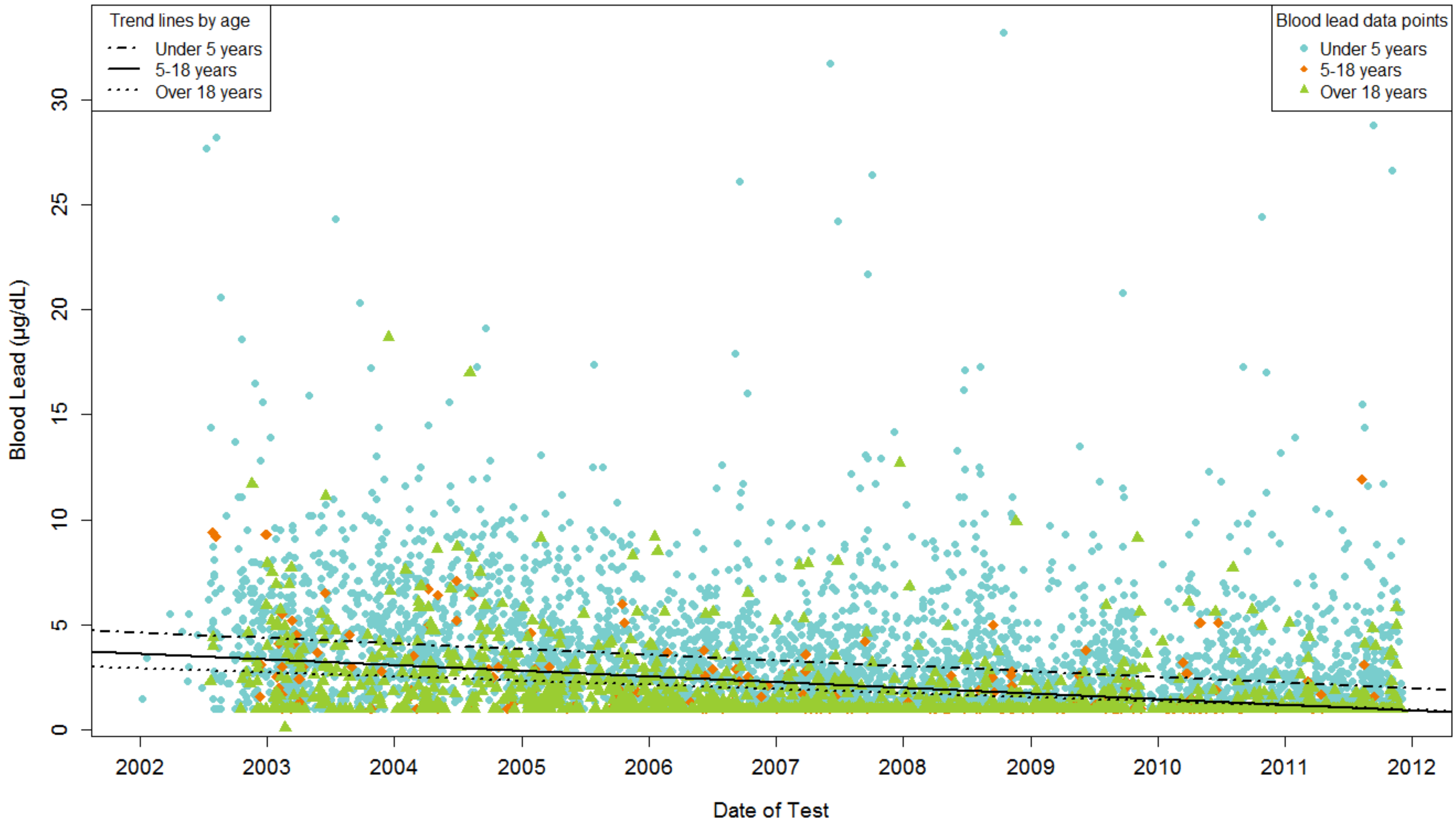


Figure 5: Butte Blood Lead over Time by Age Group for Individuals Aged 1 Year or Older (excluding LeadCare II Results)

BLLs also vary by age within the 1 to 5 year old cohort. Even as BLLs have declined over time, the ages with peak average BLLs have consistently remained from 1 year up to 3 years (Jones et al. 2009; CDC 2013b).In contrast, there have not been consistent gender-related differences in BLLs in young children in the U.S during the past ten years. Figure 6 illustrates these factors for the NHANES dataset for two time periods (2003-2006 and 2007-2010).

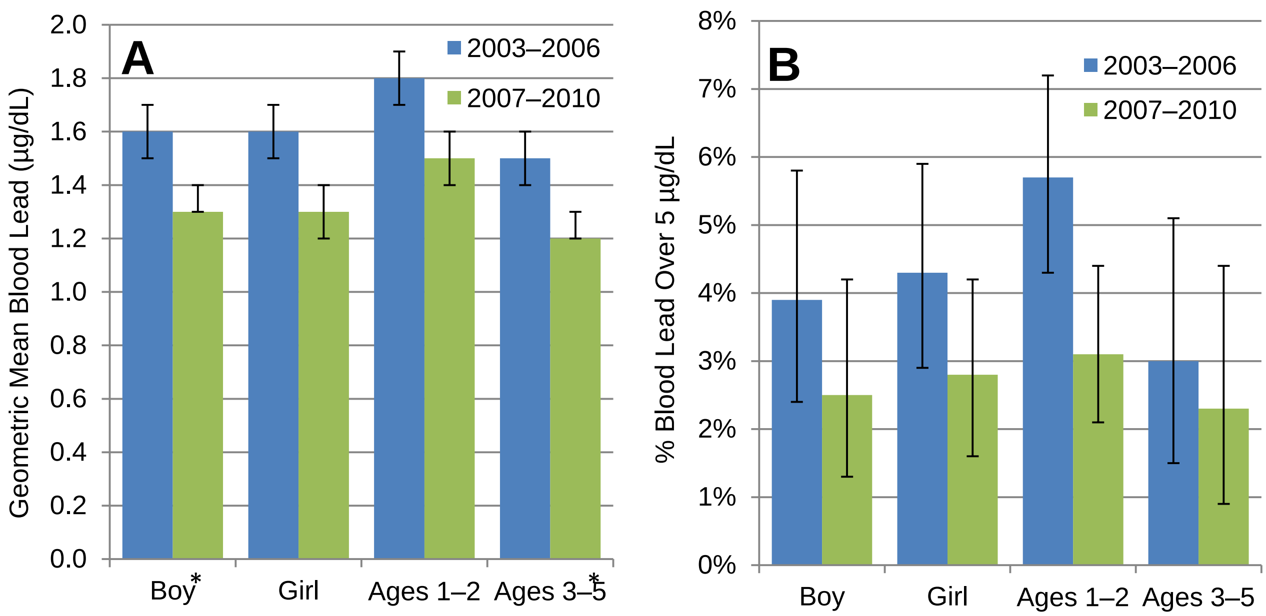


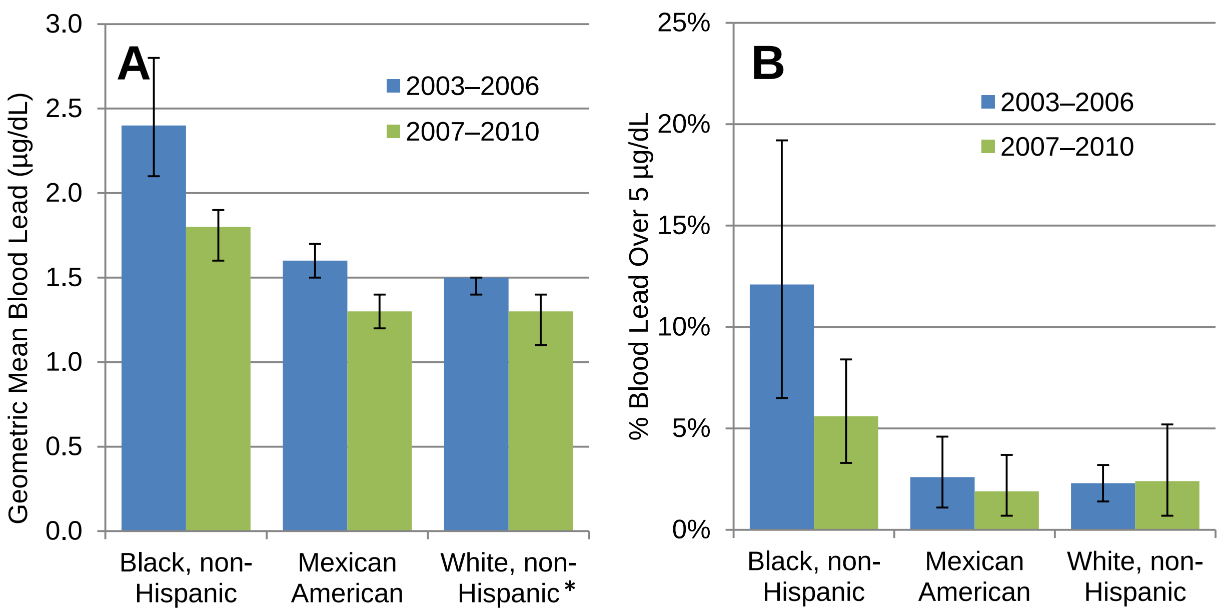
Figure 6: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by Gender and Age Group from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

3.2 Demographic and Socioeconomic Factors

Demographic and socioeconomic factors such as race/ethnicity, income level, educational attainment of mother, and housing status have been correlated with BLLs in children and are important to consider in comparing BLLs for different groups when possible (Sargent et al. 1995, CDC 2000, Gee and Payne-Sturges 2004, CDC 2013b, Jones et al. 2009).

The relative importance of these factors is likely to vary over time. For example, while the difference in BLLs between non-Hispanic black children vs. non-Hispanic white children is still significant, the magnitude of the difference has decreased substantially over time (CDC 2013b). Jones et al. (2009) and CDC (2013b) provide summaries of trends in the primary demographic and socioeconomic factors for U.S. children from 1988 through 2010, as summarized below.

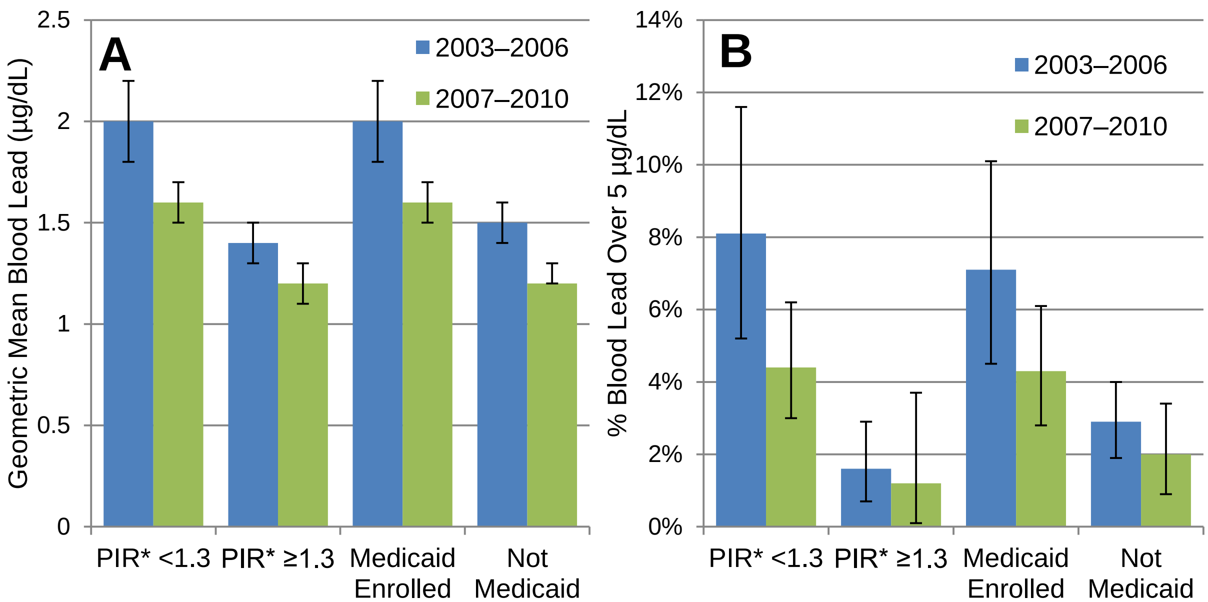
Race/Ethnicity – Race continues to be a significant risk factor for elevated BLLs with the highest levels on average reported for non-Hispanic black children. Figure 7 illustrates race and ethnicity differences in geometric mean BLLs and percentage of BLLs greater than 5 µg/dL from a national dataset for two time periods during the past decade. As shown in Figure 7, average BLLs are higher in non-Hispanic black children, and the percent of these children with BLLs greater than 5 µg/dL is more than twice as high as the percent of non-Hispanic white and Mexican children with elevated BLLs.



*The upper confidence limit equal to the mean is due to rounding

Figure 7: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by Race/Ethnicity from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

Poverty status – Children living in poverty have higher BLLs compared with children in wealthier households. Two measures are used in national studies to assess poverty status: the poverty to income ratio and Medicaid enrollment. The poverty to income ratio (PIR) is the total family income divided by the federal poverty level specific to family size, year, and state of residence. Figure 8 compares geometric mean BLLs and percentage of BLLs greater than 5 µg/dL for children from low income households (defined as a PIR of less than 1.3) with those from higher income households. This figure also compares BLLs for children enrolled in Medicaid with those not enrolled. Both of these measures of poverty status are associated with higher mean BLLs and substantially higher percentages of children with BLLs greater than 5 µg/dL



*PIR - Poverty to Income Ratio
**The lower confidence limit equal to the mean is due to rounding

Figure 8: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by PIR and Medicaid Status from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

House age[9] – Older housing in the U.S. is associated with higher BLLs for a variety of reasons, including the historical use of exterior and interior paint with added lead and higher frequency of lead plumbing lines and fixtures in older homes. Lead paint is primarily a concern when the paint condition deteriorates, so poverty status and living in rental housing are related factors that may contribute to greater exposure to lead paint in older housing.

[9] Throughout the study, the term “house” refers to any residential dwelling, including single family homes as well as multifamily housing complexes and “house age” refers to the range of years within which the house was built.

Lead content of paint was reduced over several decades prior to its ban in the U.S. in 1978. Figure 9 shows the influence of house age on average and elevated BLLs for several categories, including when house age information was missing. As can be seen from this figure, the percent of children with elevated BLLs is markedly higher for those living in U.S. housing built prior to 1950.

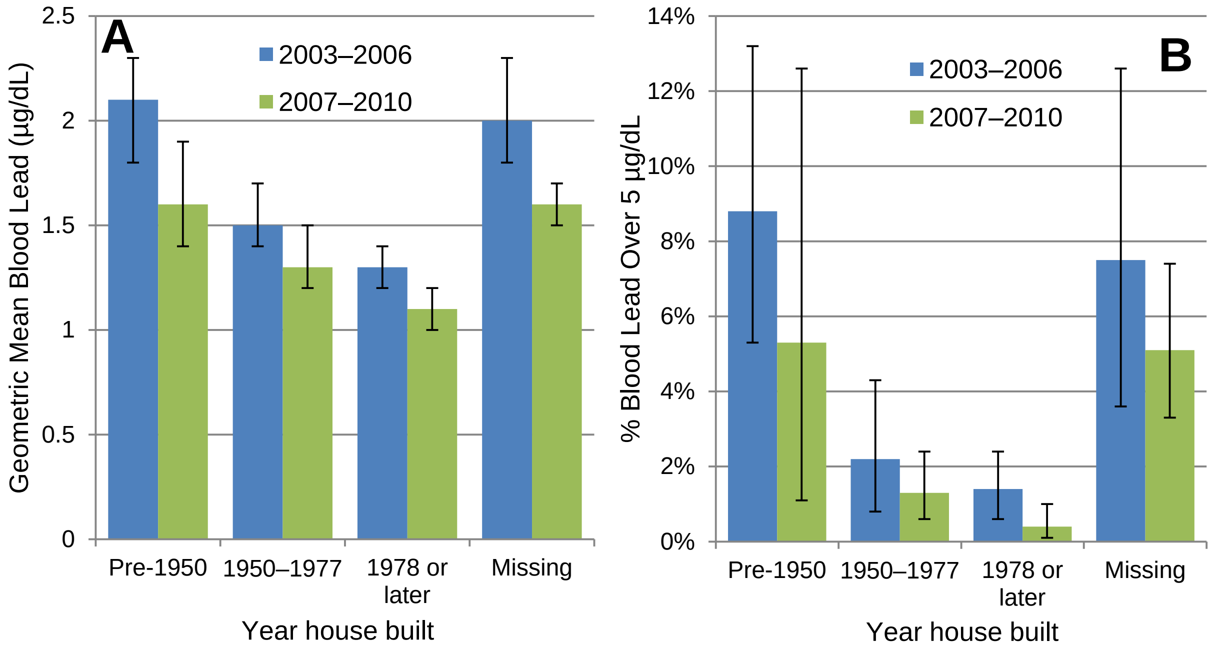


Figure 9: Geometric Mean Blood Lead (A) and Percent Blood Lead over 5 µg/dL (B) by House Age from U.S. Children Ages 1 to 5 Years with 95% Confidence Intervals (CDC 2013b)

4 Butte vs. NHANES Comparison

As described in section 1, two lines of evidence are evaluated in this study to address the principal study question. The first line of evidence evaluated in this study addresses whether or not the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. The NHANES dataset was proposed as the reference population for use in this study as detailed in a technical memorandum (ENVIRON 2013b) submitted to EPA on August 20, 2013. NHANES was proposed based on the availability of a large blood lead dataset for the sample years and age ranges included in the Butte dataset, as well as the ability to correct for several factors that are strongly associated with BLLs. EPA, in consultation with MDEQ, approved selection of NHANES for this study on September 3, 2013. The approved technical memorandum is included as Appendix E to this report.

The remainder of this section describes factors considered in development of a statistical model to compare the Butte and NHANES datasets and details the model development process. Model results are also presented along with a summary of overall conclusions from this analysis.

4.1 Key Factors that Influence BLLs that were Considered in Development of the Butte vs. NHANES BLL Comparison

The Butte vs. NHANES comparison seeks to understand how the BLLs of the children in Butte compare to a reference dataset from the national population across the same time periods and test ages. The NHANES program assesses the health and nutrition of the U.S. population across all age groups. The surveys enroll approximately 10,000 participants across the nation for every two-year survey period, collecting extensive health and dietary information, venous blood lead results, and demographic information.[10]

The NHANES data are reported for two-year time periods. Blood lead data in NHANES for 2003-2004, 2005-2006, 2007-2008, and 2009-2010 are available for comparison to Butte blood lead data for the same time periods. From these years, the NHANES data was limited to 2,937 records from children matching the study age range (12-60 months) who had a blood lead record. The characteristics of the NHANES child blood lead data are summarized in Table 2.

[10] More information about this program may be found at: http://www.cdc.gov/nchs/nhanes.htm

Table 2: Characteristics of NHANES Child Blood Lead Data

2-Year Survey Period	Blood Lead Sample Size	Age Range (months)	Number of Non-detects	Collection Method
2003-2004	753	12-60	0	Venous
2005-2006	806	12-60	0	Venous
2007-2008	676	12-60	0	Venous
2009-2010	702	12-60	1	Venous

When comparing the Butte data to the NHANES data, the goal was to determine if factors that are unique to Butte explain differences between BLLs of children in this area compared to children outside of Butte. To ensure meaningful comparisons, it is important to consider how Butte and the other population compare in terms of common factors that influence BLLs, but are not unique to Butte. When population differences are apparent, investigators commonly use weighting procedures to better match the reference population to the study population. Adjusting for population differences in this way is not unique to this study. In fact, the CDC applies weights to the NHANES data to make it representative of the U.S. population (CDC 2013a).

Key factors influencing BLLs were described in section 3 and include gender, age, and test year, as well as demographic factors such as racial composition, poverty level, and house age. To the extent that information about these factors is available for blood lead records in the Butte and NHANES datasets, such information can be used in model development to weight the NHANES data to be comparable (in terms of demographics and other non-blood lead factors) to the Butte data. Gender, child age and house age are available for individual records in both datasets. Specific test dates are available for Butte, but for NHANES the test date falls within a two-year time period.[11] Poverty and race data are not available for individual records in the Butte dataset as they are for NHANES. However, as described in the following two sections, there is sufficient information about the Butte community and test population to support consideration of these factors in the population comparison. Once differences between the Butte and NHANES data were considered with respect to study variables, weights were calculated for each variable to determine the variables that were most different between the two populations (see section 4.3.2). Final weights were then applied to the NHANES data in statistical model analyses that compared Butte to the NHANES data using standard weighting procedures in SAS Version 9.3 (SAS Institute Inc., Cary, NC), the statistical software used in this study (see section 4.3.3 and Appendix F).

A summary of specific differences between the two datasets is provided below.

4.1.1 Poverty Data Differences

Poverty to income ratios, or PIR, are available for most records in the NHANES dataset, but poverty level information for the Butte data was not requested at the time of sample collection.

[11] NHANES records include a variable for the six month period within each two-year period that the data were collected, allowing for comparison between samples taken November 1 – April 30 (winter/spring) and samples taken May 1 – October 31 (summer/fall).

For children in the NHANES dataset who were missing poverty information, PIR values were imputed from the other NHANES records with known PIRs. In the Butte sample population, the majority of the records were collected through the WIC program from residents who qualified for the assistance by being at or below 175 percent of the federal poverty level, the WIC eligibility threshold. Other individuals tested via Butte's WIC program may have been referred by a private physician or the RMAP. In these cases, the individual's WIC status may or may not have been known. However, based on communications with BSB and WIC staff, the proportion of individuals tested who were not known to qualify for WIC is very small. Therefore, the assumption was made that the vast majority of the Butte blood lead records (90-95 percent) correspond to children from families with household incomes at or below 175 percent of the federal poverty level. This WIC eligibility threshold is equivalent to a PIR of 1.75 in the NHANES dataset. The relationship between WIC eligibility and PIR provides a basis for comparing the two datasets in terms of poverty level. As described further in section 4.3.2.6, a sensitivity analysis was used to test the relative impact of different poverty assumptions for the Butte study population prior applying the weights in the statistical model.

4.1.2 Differences in Racial Composition

Unlike the NHANES dataset, record-specific racial data for the Butte dataset is not available. As summarized in Table 3 below, estimate data from the U.S. Counties Census are available for Butte-Silver Bow County and may be used to infer the racial composition of the Butte dataset. More specific data on racial composition by census tract are not available except with the 2000 and 2010 full census data. A review of the full census data by tract did not suggest that the racial composition was substantially different from the county-wide estimates.

Table 3: Racial Composition for Butte-Silver Bow County

Race/Ethnicity	2003-06	2007-10
Non-Hispanic white	92.4%	91.9%
Non-Hispanic black	0.2%	0.3%
Hispanic or Latino origin	3.1%	3.5%
Other race- including multiracial	4.2%	4.4%
Source: U.S. Counties Census estimates for 2003-2010		

The racial composition of the NHANES blood lead dataset is summarized in Table 4 and shows a much more diverse racial composition in contrast to Butte.

Table 4: Race/ethnicity for NHANES Blood Lead Data from 2003-2010

Race/Ethnicity	2003-06	2007-10
Non-Hispanic white	28%	28%
Non-Hispanic black	28%	18%
Mexican American	33%	26%
Other Hispanic	6%	10%
Other race - including multiracial	6%	6%

For the purposes of this study, it was assumed that the racial composition of Butte-Silver Bow County as a whole is the same as the racial composition of the Butte blood lead data population. Based on this assumption, the NHANES population could be weighted to make it more racially comparable to the Butte population.

4.2 Other Differences Between the Butte and NHANES Blood Lead Data

In addition to factors that may influence BLLs in the general population, other differences between how blood lead data are collected and analyzed in the Butte and NHANES datasets are important. For instance, the method of recruiting participants for each dataset differs. The majority of participants in the Butte dataset represent individuals enrolled in the WIC program. Households with income at or below current WIC income guidelines are offered WIC services free of charge, including annual testing for blood lead. A smaller proportion of the overall Butte dataset is represented by individuals referred for blood lead testing through a primary care physician or the RMAP, some of whom may also qualify for enrollment in WIC. Poverty rates for WIC eligible individuals are likely to be higher than the general Butte population. Individuals living at higher poverty levels are more likely to live in older housing that is associated with increased sources of potential lead exposure.

The NHANES program recruits participants using a complex, multistage probability sampling design that intentionally oversamples subpopulations of interest within a given survey period. As a result, prior to using NHANES data for analyses of national BLL trends, the CDC applies weights to the raw NHANES data to be representative of the U.S. population.

In addition to recruitment differences, the blood lead sample collection and analytical methods for Butte and NHANES also differ. In Butte, blood lead data were collected onto filter paper from capillary samples typically obtained from a child’s finger. Sample data of this type is considered appropriate for blood lead screening, but must be confirmed by venous sampling when elevations are suspected. While venous confirmation was conducted in Butte when screening results exceed 9.9 µg/dL, venous data were excluded from the Butte dataset used in this study as described in section 2.1. In contrast, the NHANES blood lead data are all based on venous blood draws. A key concern with the use of finger stick sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Such external contamination could bias Butte sample results high compared to NHANES sample results. However, correlation coefficients between capillary and venous methods have been reported to range from 0.96-0.98 in paired testing (Schlenker et al. 1994) and Butte WIC sample collection methods include preparation of the skin location using laboratory-provided wipes that are designed to reduce the potential for external lead contamination. Additionally, the laboratory used for the Butte blood lead data reports:

> “The correlation between paired, simultaneously drawn extraction method filter paper and venous samples is >.970. Additionally, undetected-elevated and, falsely-elevated rates may be considered clinically insignificant. These findings are documented by three published, peer-reviewed studies involving 363 paired, simultaneously drawn extraction method filter paper and venous sample comparisons.” (Yee et al. 1995; Srivuthana et al. 1996; and Yee 1997)

In addition to sample differences, there are also analytical differences between the Butte and NHANES data. The analytical method sensitivity of Butte blood lead measurements is lower than that of the NHANES data as reflected in higher detection limits for Butte than for NHANES. As discussed in section 2.2.2, unknown blood lead concentrations below the Butte detection limit (1 µg/dL) were extrapolated from the known distribution of blood lead concentrations in the Butte dataset to improve comparability of the Butte and NHANES datasets given these analytical differences.

4.3 Butte vs. NHANES Model Development

The Butte vs. NHANES comparison required a statistical model that allowed for the comparison of BLLs (the dependent variable) between the Butte and NHANES sample populations of children 12-60 months of age while accounting for other independent variables that can influence blood lead, as described in section 3.

The software used to perform these statistical analyses was SAS Version 9.3 (SAS Institute, Inc., Cary, NC). Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of the data. The “MIXED” procedure in SAS was used for all of the models because it is able to handle these repeated/correlated data as well as data with a different number of measurements per subject. When using the SAS “MIXED” procedure, a covariance structure or specification about how the measurements are related over time was chosen. An autoregressive covariance structure was used in the models, meaning that measurements farther apart in time are assumed to be less correlated than observations closer in time. The SAS “MIXED” procedure provides f-tests from the “Type 3 Tests of Fixed Effects,” which were used to determine the overall significance of variables, as well as partial t-tests from the “Solution for Fixed Effects,” which were used to determine the significance of the different levels/categories of each variable compared to a reference. Additionally, a “Least Squares Means” (LSMEANS) statement was used to calculate geometric means and 95 percent confidence intervals for all categorical variables.

The first step of the model development was generating the univariate statistics. Univariate analysis examined each independent variable individually to determine whether it influenced the dependent variable, BLL. Based on the results from the univariate analysis, a fully adjusted multivariable model was built. An *a priori* decision was made that the fully adjusted model would include all variables that were significant ($p<0.05$) before weighting in the univariate analysis. In a fully adjusted model, the effects of each independent variable on BLLs are examined after adjusting for all of the other variables included in the model.

Before running the fully adjusted model, the Butte vs. NHANES comparison required a weighting procedure to ensure that the NHANES population demographics more closely matched the Butte sample population’s demographics (section 4.3.2). This procedure necessitated determining which of the available variables should be used to weight the NHANES records. Variables for which NHANES values vary most from corresponding Butte values were selected for weighting, and the final weights were applied to the NHANES data using standard SAS weighting procedures.

Interaction terms of interest were then examined in the fully adjusted model. The final model was then stratified based on data source, Butte or NHANES. Once stratified, adjusted geometric mean BLLs for each independent variable included in the model were presented for a side-by-side comparison of Butte and NHANES.

The process and information used to develop the final stratified statistical model for the Butte vs. NHANES comparison is presented below.

4.3.1 Identification of Significant Variables for Inclusion in the Model

The first step in building the Butte vs. NHANES comparison model required identification of independent variables that should be included in the model. Univariate statistical analyses were performed to determine the significance of each independent variable with regard to its influence on blood lead. Table 5 summarizes the details for each variable examined for the Butte dataset. Table 6 summarizes the details for each variable examined from the NHANES dataset. For each variable in the univariate analysis, models produced estimates and p values from t-tests, as well as geometric mean BLLs with a 95 percent confidence interval around the mean.

Table 5: Results from Univariate Analysis for Butte Data in Butte vs. NHANES Comparison

Variable	N	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	2796	0.96	0.94	0.99	0.0020*
Child gender					
Male	1441	2.68	2.55	2.81	Reference
Female	1355	2.31	2.20	2.43	<0.0001*
Year house built					
Missing	991	2.40	2.28	2.53	<0.0001*
Post 1977	111	1.67	1.44	1.95	<0.0001*
1960 to 1977	153	2.21	1.94	2.52	0.0007*
1950 to 1959	158	2.23	1.95	2.56	0.0018*
1940 to 1949	244	2.37	2.13	2.63	0.0035*
Pre 1940	1139	2.81	2.67	2.95	Reference
Test year					
2003-2004	670	3.79	3.57	4.02	<0.0001*
2005-2006	638	2.90	2.73	3.08	<0.0001*
2007-2008	666	2.43	2.30	2.58	<0.0001*
2009-2010	822	1.69	1.60	1.78	Reference
Test season					
Winter/Spring	1414	2.29	2.19	2.39	<0.0001*
Summer/Fall	1382	2.71	2.59	2.83	Reference

*Statistically significant ($p \leq 0.05$)
N – Sample size; GM – Geometric mean; GSD – Geometric standard deviation; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

Table 6: Results from the Univariate Analysis for NHANES Data in Butte vs. NHANES Comparison

Variable	N	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	2937	0.94	0.92	0.96	<0.0001*
Child gender					
Male	1510	1.68	1.62	1.73	Reference
Female	1427	1.7	1.64	1.76	0.58
Child race/ethnicity					
Non-Hispanic White	882	1.52	1.46	1.59	Reference
Hispanic	917	1.49	1.44	1.55	0.48
Non-Hispanic Black	715	2.34	2.24	2.45	<0.0001*
Other Race	176	1.68	1.53	1.84	0.062
Year house built					
Missing	1023	1.96	1.88	2.03	<0.0001*
Post 1977	868	1.33	1.27	1.39	<0.0001*
1960 to 1977	397	1.51	1.42	1.61	<0.0001*
1950 to 1959	244	1.68	1.55	1.81	<0.0001*
1940 to 1949	113	1.73	1.55	1.95	<0.0001*
Pre1940	292	2.38	2.21	2.55	Reference
Test year					
2003-2004	753	2.14	2.05	2.24	<0.0001*
2005-2006	806	1.69	1.62	1.76	<0.0001*
2007-2008	676	1.69	1.61	1.77	<0.0001*
2009-2010	702	1.31	1.25	1.37	Reference
Test season					
Winter/Spring	1389	1.5	1.45	1.55	<0.0001
Summer/Fall	1548	1.88	1.82	1.94	Reference

*Statistically significant (p ≤ 0.05)
N – Sample size; GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

The univariate statistics from the Butte dataset are significant for all variables: child test age, child gender, year house built, test year, and test season (Table 5). The NHANES univariate results (Table 6) show that the majority of the variables are significant. For race, the black population has significantly higher BLLs than the reference (non-Hispanic whites). The other races do not differ from the reference significantly. Child gender differences are not significant in the NHANES dataset (p=0.58). The F-tests from the univariate analyses were performed to determine which variables were significant for inclusion in the fully adjusted model.[12] The p values from the F-test results for the Butte univariate models, the NHANES univariate models, and the univariate models with Butte and NHANES data combined are presented in Table 7. Because child race/ethnicity data was not available for individual records in Butte, it was not included as a variable beyond the univariate analysis, though it was retained for consideration in the NHANES weighting.[13] All other variables were significant in the Butte and/or NHANES datasets and significant when the datasets were combined. Therefore, they were all included in the fully adjusted model.

Table 7: Results from F-test for all Variables in Univariate Analysis for Butte vs. NHANES

Variable	p Value – Butte Only	p Value – NHANES only	p Value – Butte and NHANES Combined
Child test age	<0.002*	<0.0001*	<0.0001*
Child gender	<0.0001*	0.58	0.012*
BLL source (NHANES or Butte)	-	-	<0.0001*
Year house built	<0.0001*	<0.0001*	<0.0001*
Test year	<0.0001*	<0.0001*	<0.0001*
Test season	<0.0001*	<0.0001*	<0.0001*

*Statistically significant ($p \leq 0.05$); BLL – Blood lead level; NHANES results are not weighted

4.3.2 Weighting the NHANES Data

As stated in section 3, there are many factors that can affect BLLs. When comparing the Butte data to the NHANES national data, the goal was to determine if factors that are unique to Butte are causing a difference in the BLLs of the children in this area. In order to see this, it was important to decrease the influence of any other differences that might be present between the Butte population and the NHANES population. For example, the Butte dataset contains children who have higher poverty overall than the NHANES dataset. Poverty is known to be related to higher BLLs. If these two datasets were compared without adjusting NHANES for this variable, it would be difficult to explain whether BLL differences between Butte and NHANES were related to poverty level differences or other factors.

Recruitment for NHANES includes diverse subpopulations and geographical areas of the U.S. and varies by survey period, oversampling certain populations of interest in different years. The CDC provides “weights” to apply to the NHANES dataset to make it representative of the nation. Similarly, for the purposes of this study, the NHANES population needs to be adjusted using weights to make it representative of the Butte population.

Once final weights were calculated for selected variables (i.e., those most different between the two populations), the weights were then applied in the statistical model analyses on the NHANES data using standard weighting procedures in SAS.

[12] For variables with only two categories, such as gender, the results of the F test are the same as the p values presented in the univariate results tables.
[13] Outside of the model, race was considered in generating the weights for NHANES, section 4.3.

The demographic variables considered for weighting were child test age, child gender, test season in which the blood test was done, age of house, child ethnicity, and a YES/NO indication of poverty. Data for each of the variables were available for each of the NHANES records.[14] For the Butte records, data were available for all but two variables: poverty and race. Estimation of Butte data for these variables was necessary prior to evaluating all variable weights for possible inclusion the Butte vs. NHANES comparison model. Weights evaluated for each of these variables are described in the following sections along with assumptions and information used to estimate Butte poverty and race data for the weighting evaluations summarized below and in section 4.1.

4.3.2.1 Child Test Age Data Weights

Weights were determined for the NHANES data based on child test age distribution from the Butte population. As shown in Table 8, the weights are not very different from one. Given the similarity of data distributions for this variable, weighting NHANES for child test age was determined to be unnecessary.

Table 8: Weights for NHANES Based on Butte Age Distribution

Child Test Age (months)	Year group	Weight*
12-35	2003-2004	0.92
36-60		0.85
12-35	2005-2006	0.78
36-60		0.80
12-35	2007-2008	1.0
36-60		0.91
12-35	2009-2010	1.2
36-60		1.1

*Weight - ratio of Butte to NHANES counts

4.3.2.2 Child Gender Data Weights

Weights were determined for the NHANES dataset based on the child gender distribution from the Butte dataset (Table 9). The weights are not very different from one for any of the groups given the similar distributions of gender data for both datasets. Therefore, weighting based on this variable was determined to be unnecessary.

[14] A subset of NHANES records (n=163) were missing poverty information. For these records, poverty was imputed using a uniform distribution to avoid excluding NHANES children missing poverty information.

Table 9: Weights for NHANES Based on Butte Gender Distribution

Gender	Year group	Weight*
Female	2003-2004	0.94
Male		0.84
Female	2005-2006	0.69
Male		0.89
Female	2007-2008	0.96
Male		1.0
Female	2009-2010	1.3
Male		1.1

*Weight - ratio of Butte to NHANES counts

4.3.2.3 Test Season Data for Weights

Weights were determined for NHANES based on the test season distribution from the Butte dataset (Table 10). The weights are not very different from one. Therefore, weighting based on this variable was determined to be unnecessary.

Table 10: Weights for NHANES Based on Butte Distribution for Test Season

Season	Year group	Weight*
Winter/Spring	2003-2004	1.1
Summer/Fall		0.69
Winter/Spring	2005-2006	0.86
Summer/Fall		0.73
Winter/Spring	2007-2008	1.0
Summer/Fall		0.96
Winter/Spring	2009-2010	1.1
Summer/Fall		1.2

*Weight - ratio of Butte to NHANES counts

4.3.2.4 House Age Data Weights

House age data collected for Butte and NHANES were categorized as shown in Table 11 based on the year the house was built. Rather than excluding children missing year house built information, a separate missing category was created.

Table 11: Percent Year House Built Distribution for Blood Lead Records from Butte

Year house built category	2003-06	2007-10
Missing	35.2	35.6
Post 1977	3.4	4.4
1960-1977	6.0	5.0
1950-1959	6.4	5.0
1940-1949	7.8	9.5
Pre1940	41.1	40.5

As shown in Table 12, the resulting weights for NHANES based on this distribution of year house built in Butte are very different from one, suggesting the importance of adjusting the NHANES data for year house built in the statistical model.

Table 12: Weights for NHANES Based on Butte Year House Built Distribution

Year house built	Year group	Weight*
Missing	2003-2004	0.72
Post 1977		0.15
1960-1977		0.34
1950-1959		0.54
1940-1949		2.0
Pre 1940		3.9
Missing	2005-2006	0.89
Post 1977		0.076
1960-1977		0.38
1950-1959		0.79
1940-1949		1.3
Pre 1940		4.0
Missing	2007-2008	1.2
Post 1977		0.11
1960-1977		0.34
1950-1959		0.61
1940-1949		3.0
Pre 1940		3.5
Missing	2009-2010	1.1
Post 1977		0.21
1960-1977		0.50
1950-1959		0.64
1940-1949		2.6
Pre 1940		4.2

*Weight - ratio of Butte to NHANES counts

4.3.2.5 Race Data Weights

Child race in the Butte records was inferred from the census data as described in section 4.1.2. Specifically, it was assumed that the Butte study population's racial composition was identical to that of BSB County as a whole. County level data (U.S. Census Bureau 2010) were then used to calculate the relative percentages of each race category for two four-year periods, 2003-2006 and 2007- 2010 (Table 13). The Butte race distribution based on these percentages was then used with the NHANES race distribution to calculate race weights. As shown in Table 13, the race weights are very different from one. The smallest weight is 0.0057 for the black, non-Hispanic group from 2005-2006, while the largest is 3.4 for the white, non-Hispanic group from 2009-2010. As reflected by these weights, the racial distribution in NHANES is very different from Butte for every test year group supporting adjustment of the NHANES data for this variable in the statistical model.

Table 13: Weights for NHANES Based on Butte Racial Distribution

Race	Year group	Weight*
Other/multiracial	2003-2004	0.67
Hispanic		0.080
Black, non-Hispanic		0.0057
White, non-Hispanic		2.9
Other/multiracial	2005-2006	0.56
Hispanic		0.061
Black, non-Hispanic		0.0065
White, non-Hispanic		2.6
Other/multiracial	2007-2008	0.82
Hispanic		0.082
Black, non-Hispanic		0.013
White, non-Hispanic		2.8
Other/multiracial	2009-2010	0.71
Hispanic		0.098
Black, non-Hispanic		0.019
White, non-Hispanic		3.4

Source: U.S. Counties Census estimates for 2003-2010
*Weight - ratio of Butte to NHANES counts

4.3.2.6 Poverty Data Weights

As described in section 4.1.1, poverty designations for children in the Butte dataset were inferred based on an assumption that the majority of the children tested (90-95 percent) were WIC eligible and that WIC eligibility status was equivalent to a PIR value in NHANES of 1.75. Prior to applying weights for poverty, a sensitivity analysis was performed to evaluate the relative significance of assuming 90 or 95 percent of the Butte study population were WIC eligible. As shown in Figure 10, the weighting assumptions do not significantly change the NHANES geometric mean BLLs by two-year period. Therefore, for the final weighting, the 95 percent assumption was used.

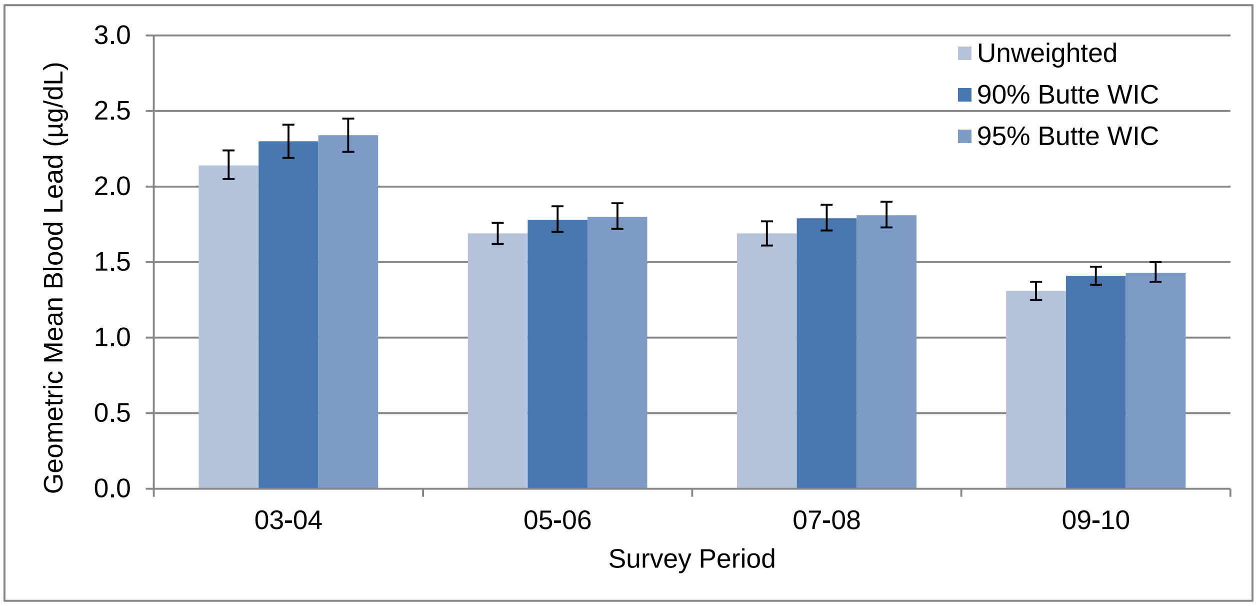


Figure 10: NHANES Geometric Mean Blood Lead and 95% Confidence Intervals for NHANES Weighting Scenarios Where 90% or 95% of Butte Sample Qualifies for WIC (PIR ≤ 1.75)

Table 14 summarizes poverty weights calculated based on an assumption that 95 percent of the Butte study population was WIC eligible. The lowest weight (0.11) corresponds to the lesser poverty category (PIR >1.75) for the 2005-2006 test period. The highest weight (1.8) is calculated for the greater poverty category (PIR ≤1.75) for the 2009-2010 test period. Evaluation of these weights supports adjustment of the NHANES data in the statistical model to account for the difference in distributions of poverty data between Butte and NHANES.

Table 14: Weights for NHANES Based on Estimated Butte Poverty Distribution

Poverty Category	Year group	Weight*
PIR ≤1.75	2003-2004	1.3
PIR >1.75		0.14
PIR ≤1.75	2005-2006	1.3
PIR >1.75		0.11
PIR ≤1.75	2007-2008	1.5
PIR >1.75		0.15
PIR ≤1.75	2009-2010	1.8
PIR >1.75		0.19

*These weights assume that 95 percent of the Butte sample falls in the PIR ≤1.75 category; Weight - ratio of Butte to NHANES counts
PIR ≤1.75 corresponds to greater poverty, while PIR >1.75 corresponds to lesser poverty.

4.3.3 Selection of Final Variable Weights for Inclusion in the Model

Variable weights evaluated in section 4.3.2 support prioritization of NHANES weighting for the following variables: race/ethnicity, year house built, and poverty category. The year the house was built was considered the most significant variable with respect to affecting BLLs given the proportion of the Butte study population living in homes built while lead paint and lead pipe were still commonly in use. Therefore, the following four weighting scenarios were examined:

1. year house built weighting only;
2. year house built weighting combined with poverty weighting;
3. year house built weighting combined with race/ethnicity weighting; and
4. a combination of weighting for year house built, race/ethnicity, and poverty.

The first step in calculating weights was to determine, for each weight scenario, how frequently different “bins” of data occurred in each dataset (Butte and NHANES). For the weighting scenario that included only house age, bins represented the different year house built categories (e.g., pre-1940, 1940-1949, etc.). For the other weighting scenarios, bins represented every combination of variable categories. For example, for the weighting scenario combining poverty, race, and year house built, a single bin might be represented as the frequency of all records defined by the poverty category for PIR >1.75, the non-Hispanic white race category, and the pre-1940 year built category. Once the frequencies of records for all bins were determined, final weights were calculated as the ratio of the Butte frequencies to the corresponding NHANES frequencies. The final weights were then applied to the NHANES data in the model using standard statistical procedures in SAS (defining a weight variable). Since this effort was undertaken to match the NHANES records more closely to the Butte records, the Butte data is un-weighted which is equivalent to each Butte record having a weight of one. Thus, if the final weights of the NHANES records are added across all the NHANES records in the dataset, the sum equals the count of records in the Butte blood lead database.

The four weighting scenarios were evaluated in the fully adjusted model as described below.

4.3.4 Building the Fully Adjusted Model and Examination of Interaction Terms

Incorporating the significant variables from the univariate analysis that were available in both datasets, the fully adjusted model was built to examine the association between each independent variable and the geometric mean BLL while simultaneously controlling for the other independent variables that may be affecting blood lead. Child test age, child gender, child year house built, test year, test season, and source (Butte or NHANES) were all included in the model. This model used a weighted regression. Weighted regression treats the weight as a multiplier for the record so that a record with a weight of X is treated as if X identical records existed in the dataset. All Butte records have a weight equal to one. The model was repeated for each the four NHANES weighting scenarios described in section 4.3.3 and the preferred scenario was selected.

After choosing the preferred weighting scenario and examining the fully adjusted model results, interaction terms were also added to the model and examined. The addition of an interaction term to a model helps to tell whether the relationship between two variables, such as BLL and test year, varies according to a third variable, such as source (NHANES or Butte). In this example, the source and test year represent two variables that can be included as an interaction term in the model.

Results of the fully adjusted model including selection of the final weighting scenario are presented below.

4.3.4.1 Fully Adjusted Model without Interaction Terms

The fully adjusted model was run using each of the four weighting scenarios to determine how each scenario changed the geometric mean BLLs from the original un-weighted data (Figure 11). When the NHANES data were weighted to match Butte on house age and poverty (scenario 2), the resulting geometric mean BLLs were higher than the un-weighted data. This weighting scenario emphasizes the children in NHANES who have higher poverty and who live in homes more likely to contain sources of lead. When the combination of all three variables was used (scenario 4), the geometric mean BLLs generally dropped. Adding race to the weighting (scenarios 3 and 4) emphasizes the white population in NHANES, who typically have lower BLLs than the other races. Ultimately all three variables (scenario 4) were used to weight NHANES because they were all significantly different between Butte and NHANES and when they were combined, they didn't appear to significantly skew the NHANES data in one direction.

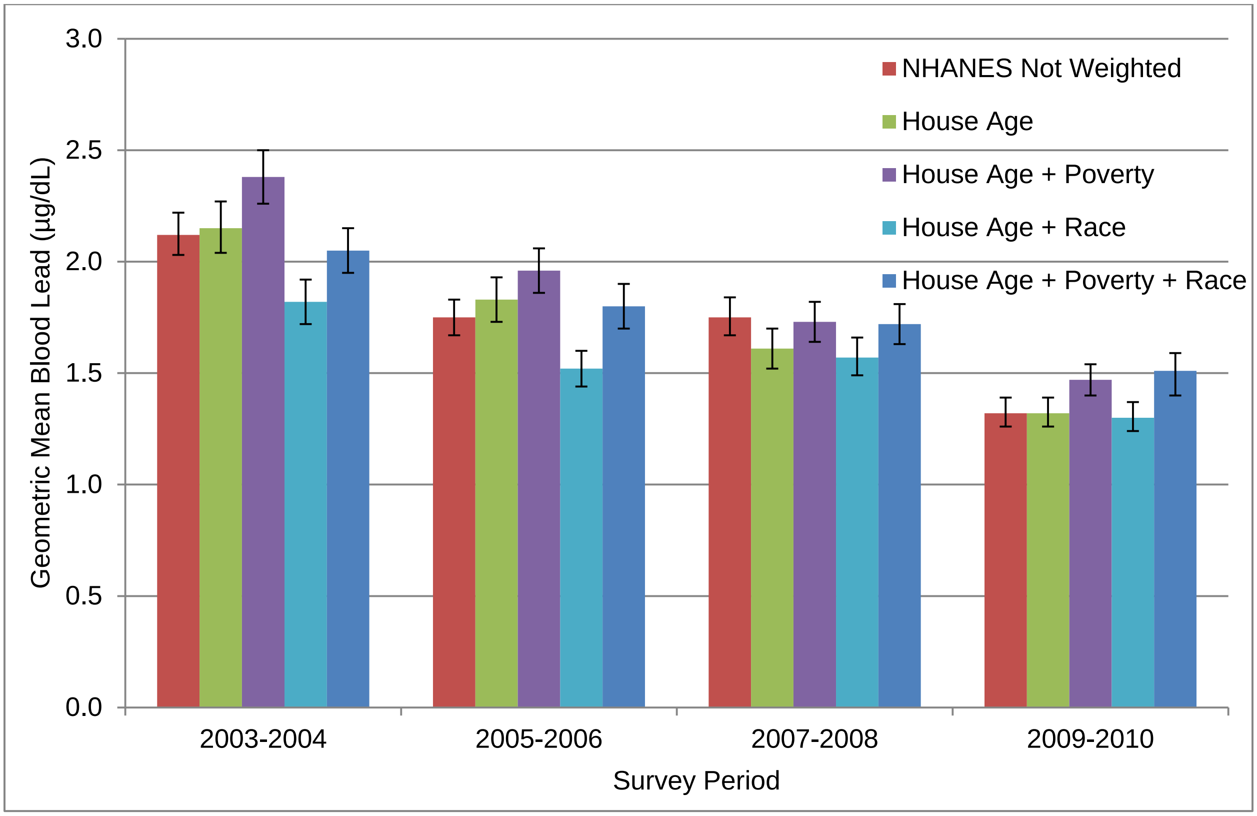


Figure 11: Geometric Mean and 95% Confidence Intervals Comparing Four NHANES Weighting Scenarios and NHANES without Weights (from Butte vs. NHANES Stratified Model) with 95% Confidence Intervals

In the fully adjusted model with NHANES weighted for house age, poverty, and race, all data from Butte and NHANES (after weighting) were combined to determine if differences between these two datasets could be detected statistically. Table 15 summarizes the initial results of the fully adjusted model without inclusion of any interaction terms. For this model, child test age was treated as a continuous variable and all other independent variables as categorical.

Table 15: Results from Full Linear Mixed Model Combining Butte and NHANES Datasets

Variable	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p value
Child test age (estimate)	0.94	0.93	0.96	<0.0001*
Child gender				
Female	2.02	1.95	2.09	0.083
Male	2.07	2.00	2.13	Reference
Source				
Butte	2.34	2.27	2.42	<0.0001*
NHANES (adjusted)**	1.78	1.73	1.84	Reference
Year house built				
Missing	2.02	1.96	2.09	<0.0001*
Post 1977	1.63	1.49	1.78	<0.0001*
1960 to 1977	1.92	1.78	2.07	<0.0001*
1950 to 1959	1.98	1.84	2.14	<0.0001*
1940 to 1949	2.14	2.02	2.27	<0.0001*
Pre1940	2.71	2.63	2.79	Reference
Test year				
2003-2004	2.68	2.57	2.79	<0.0001*
2005-2006	2.20	2.11	2.29	<0.0001*
2007-2008	1.95	1.87	2.03	<0.0001*
2009-2010	1.52	1.46	1.57	Reference
Test season				
Winter/Spring	1.83	1.77	1.89	<0.0001*
Summer/Fall	2.28	2.21	2.35	Reference

*Statistically significant (p ≤ 0.05)
**NHANES data are weighted by race, poverty, and house age
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

After accounting for differences in test year, year house built, test season, child gender and child test age, over all test years, the geometric mean in Butte of 2.34 µg/dL was significantly higher than the geometric mean of 1.78 µg/dL in NHANES (p<0.0001).

4.3.4.2 Examine Interaction Terms

Because a primary aim of the study was to determine if BLLs changed differently over time in Butte compared to NHANES, an interaction term for test year and source was added to the model.

When this interaction term was included in the model, it was found to be significant ($p < 0.0001$). In order to explore this interaction, the model was stratified by source, allowing for comparisons between Butte and NHANES according to the other variables in the model.

4.3.5 The Final Model (Stratified by Source – Butte vs. NHANES)

The final statistical model for the Butte vs. NHANES comparison was stratified by source (Butte vs. NHANES) to examine the influence of each of the remaining independent variables on BLL for Butte compared to NHANES. To determine whether the rate of decline in BLLs over time is different in Butte than NHANES, the coefficients and standard errors for test year (treated as a continuous variable) from the Butte adjusted model and the NHANES adjusted model were used to calculate a Chi-squared test statistic. This test statistic with one degree of freedom was then compared to the Chi Square distribution to determine if the null hypothesis that the coefficients were the same could be rejected at a significance levels of $\alpha = 0.05$.

4.4 Butte vs. NHANES Comparison Model Results

Table 16 summarizes the results of the final stratified model for the Butte vs. NHANES comparison. For both the Butte dataset and the NHANES dataset, model-generated geometric mean BLLs and confidence intervals are presented. The influence of each independent variable (i.e., test year, house age, child test age, child gender, or test season) on BLL is presented after adjusting for the influences of all the other variables. Confidence intervals may be compared, across each variable category for Butte and NHANES to provide an indication of whether geometric mean BLLs for each source are statistically different. However, additional statistical comparisons of results for Uptown and the Flats were performed using a t-test with p values comparing groups also shown in Table 16.

Table 16: Final Results for Butte vs. NHANES Model Stratified by Source

	Butte				Adjusted NHANES**				Comparison[‡]
Variable	**GM/ Estimate (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**	**GM/ Estimate (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**	**p Value**
Child test age (estimate)	0.97	0.94	0.99	0.0040*	0.92	0.90	0.94	<0.0001*	0.0006*
Child gender									
Female	2.22	2.11	2.34	<0.0001*	1.80	1.73	1.87	0.056	<0.0001*
Male	2.51	2.38	2.64	Reference	1.72	1.65	1.79	Reference	<0.0001*
Year house Built									
Missing	2.5	2.38	2.62	<0.0001*	1.65	1.59	1.72	<0.0001*	<0.0001*
Post 1977	1.84	1.6	2.11	<0.0001*	1.45	1.30	1.61	<0.0001*	0.011*
1960 to 1977	2.25	2	2.54	<0.0001*	1.63	1.48	1.79	<0.0001*	<0.0001*
1950 to 1959	2.36	2.09	2.67	<0.0021*	1.67	1.53	1.83	<0.0001*	<0.0001*
1940 to 1949	2.45	2.23	2.69	<0.0016*	1.84	1.70	1.98	<0.0001*	<0.0001*
Pre1940	2.9	2.77	3.04	Reference	2.47	2.37	2.57	Reference	<0.0001*
Test year									
2003-2004	3.48	3.26	3.72	<0.0001*	2.05	1.95	2.15	<0.0001*	<0.0001*
2005-2006	2.65	2.48	2.83	<0.0001*	1.8	1.70	1.90	<0.0001*	<0.0001*
2007-2008	2.2	2.06	2.35	<0.0001*	1.72	1.63	1.81	<0.0001*	<0.0001*
2009-2010	1.53	1.44	1.63	Reference	1.51	1.44	1.59	Reference	0.89
Test season									
Winter/Spring	2.13	2.03	2.24	<0.0001*	1.56	1.48	1.66	<0.0001*	<0.0001*
Summer/Fall	2.62	2.49	2.75	Reference	1.98	1.91	2.06	Reference	<0.0001*

*Statistically significant ($p \leq 0.05$)
**NHANES results are weighted for house age, poverty, and race
[‡]p value comparing GM in NHANES to the GM in Butte
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit-less.

By source, BLL trends are generally similar for Butte and NHANES except for child gender. General trends common to both groups include:

- lower BLLs in the most recent study periods;
- higher BLLs for children aged 12 to 35 months at the time the test was taken than for children aged 36 to 60 months;
- lower BLLs when tested in the winter/spring than in the summer/fall season; and
- higher BLLs for children living in older homes.

For gender, Butte has lower BLLs in females than males. The opposite is true for NHANES, with females having higher BLLs than males.

Across source, in the adjusted model, geometric mean BLLs in Butte are significantly higher than in NHANES for all house age categories, in both the summer/fall and winter/spring, and in both males and females. BLLs decline with an increase in child's age at testing in both populations, but the decline in Butte (3 percent) is lower than in the NHANES population (8 percent). Significant declines in BLLs over time (i.e., with increasing test year) were evident for both populations. For 2003-2004, 2005-2006, and 2007-2008, geometric mean BLLs were higher for Butte than for NHANES (Figure 12). However, for 2009-2010, the means are not significantly different, suggesting that the decline in BLLs has been faster in Butte over the study period. By 2009-2010, controlling for the influence of all other variables, the geometric mean BLL for Butte was 1.53 µg/dL, compared to 1.51 µg/dL for NHANES. The p value confirmed that the difference was not significant for this test period (p=0.89).

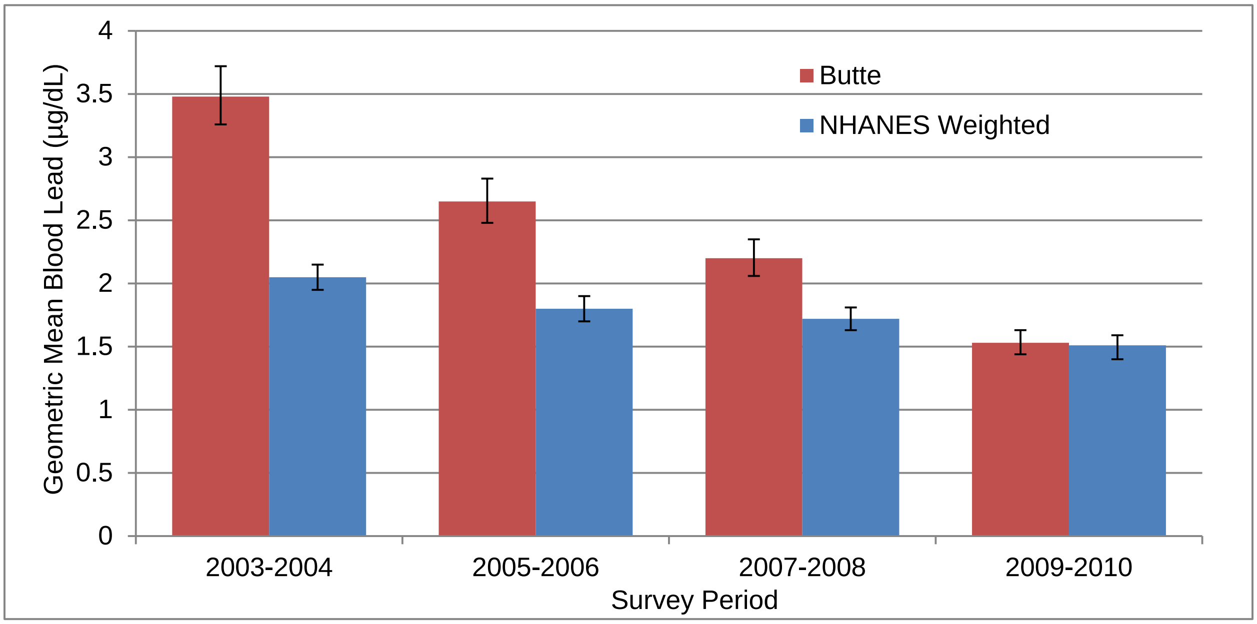
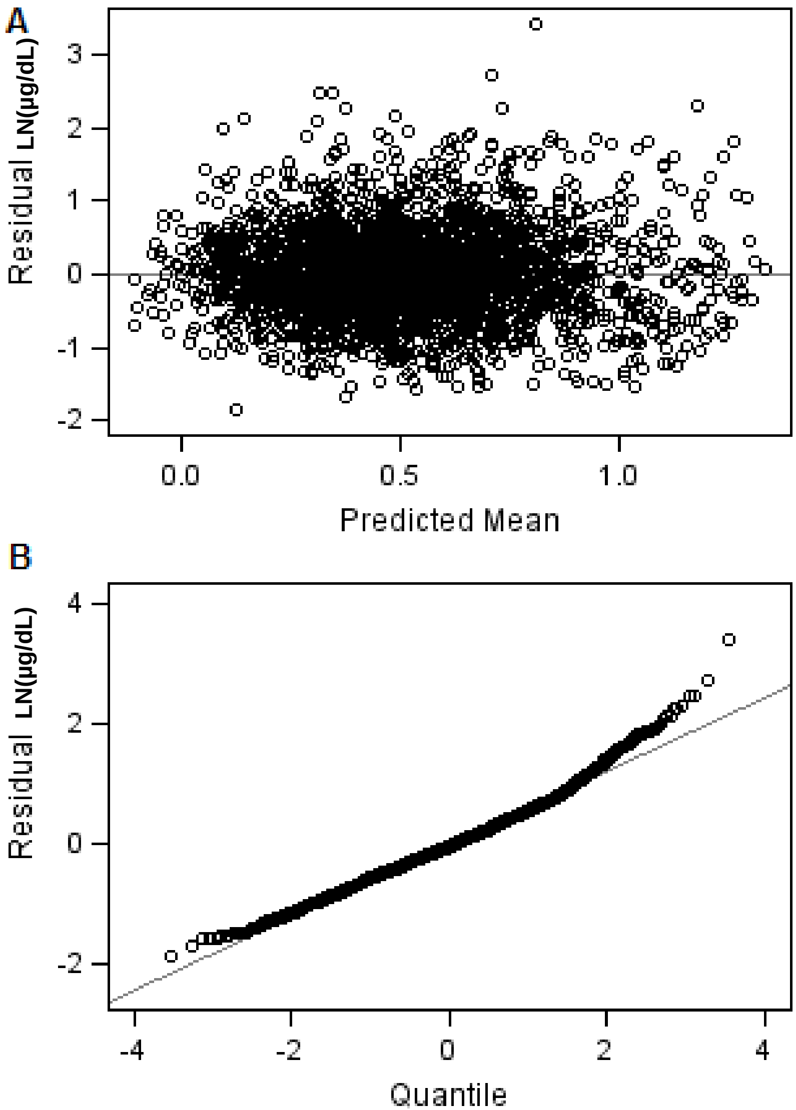


Figure 12: Modeled Geometric Mean Blood Lead Levels for Butte Compared to the Adjusted NHANES Data by Test Year with 95% Confidence Intervals

The Chi-squared test further confirmed that the rate of BLL decline from 2003 through 2010 is statistically greater for Butte than it is for NHANES (p<0.0001). In Butte, geometric mean BLLs have declined by 24 percent over each two-year period while in NHANES BLLs have declined by 9 percent.

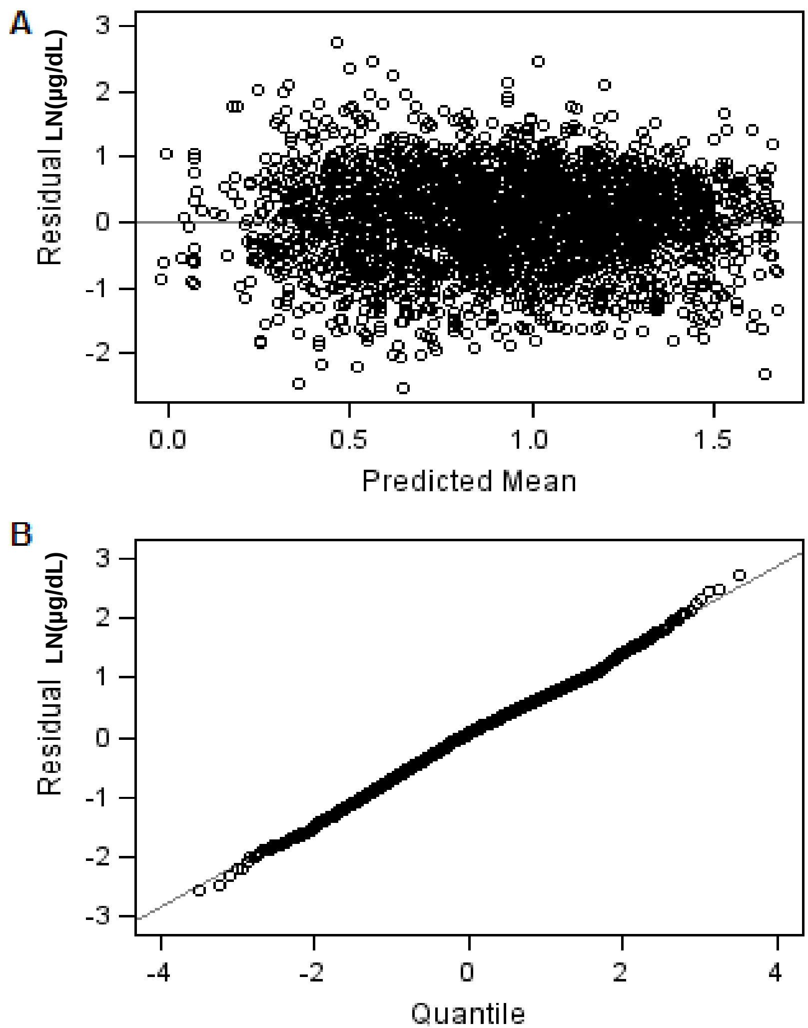
Residual plots of the NHANES and Butte data from the final stratified model were generated to examine how well the model fit the data (Figure 13 and 14). A model with a good fit is more likely to accurately predict the geometric mean BLLs. Residuals are the difference between the model-predicted BLLs and the BLLs from the raw data. The BLLs that the model predicts should not always be higher than or lower than the BLLs from the raw data. Such a skew in the residuals would suggest a poor fitting model and would show up in the residuals plot as having a pattern (e.g., a majority of the residuals would be negative) vs. being randomly distributed. For a good fitting model, the residuals should be distributed randomly, without a clear pattern.

Figure 13A and 14A show a random distribution of residuals around the predicted mean for the weighted NHANES dataset and the Butte dataset, respectively. The general alignment with residuals along the quantile (Figure 13B and 14B) also suggests the model is a decent fit for the weighted NHANES dataset and the Butte dataset, respectively. The tails of the plot in Figure 13B lift slightly from the quantile suggesting that there is still a mild right skew to the data after log transformation. However, the mild skew is not expected to substantially alter the results.



Data are log transformed prior to analysis. Data have been weighted by house age, poverty, and race.

Figure 13: Residuals Plots for the NHANES Blood Lead Levels from the Butte vs. NHANES Stratified Model



Data are log transformed prior to analysis

Figure 14: Residuals Plots for the Butte Blood Lead Levels from the Butte vs. NHANES Stratified Model

4.5 Summary and Conclusions

Development of the Butte vs. NHANES statistical model allowed for the comparison of BLLs (the dependent variable) between the Butte and NHANES sample populations, while accounting for other independent variables that can influence blood lead but may not be unique to either population. Key variables influencing BLLs that were considered during model development included gender, child age, test year, race, poverty level and house age. Tests using univariate statistics confirmed that all of these variables had significant associations with BLLs. Model development considered all variables in building a fully adjusted model and then interaction terms. Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of those data.

A key step was development of weighting factors to determine how the statistical distribution of NHANES values for each variable differed from the distribution of that variable within the Butte dataset. Based on this analysis, it was determined that the full model did not need to include weighting factors for child gender, child age, test year or test season because the two datasets were similar with regard to the distribution of these factors. In contrast, race, poverty level, and house age were all determined to be variables for which weighting factors were needed to support the population comparison. The weighting scenarios for these three variables were compared to determine how they changed the geometric mean BLLs for NHANES from the original un-weighted NHANES data. Ultimately, a combination of all three variables was used to weight NHANES because the distribution of each was substantially different between Butte and NHANES, and it was important to ensure that the overall weights reflected the influence of each variable on BLLs.

The final statistical model for the Butte vs. NHANES comparison was stratified by source (Butte vs. NHANES) to examine the influence of each of the remaining independent variables (test year, child test age, child gender, year house built, and test season) on BLL for Butte compared to NHANES. Additionally, a Chi-squared test was used to examine the rate of BLL decline for Butte compared to NHANES. Based on t-tests, BLLs in Butte are significantly higher than in NHANES for all variable categories except for children tested in 2009-2010. In both populations, BLLs declined over time during the study period. For 2003-2004, 2005-2006, and 2007-2008, geometric mean BLLs were higher for Butte than for NHANES. However, for 2009-2010, the means were not significantly different. Controlling for the influence of all other variables, the geometric mean BLL for Butte during 2009-2010 was 1.53 µg/dL compared to 1.51 µg/dL for the adjusted NHANES dataset.

The final model indicates that based on examination of geometric mean BLLs and confidence intervals, Butte BLLs exceeded those from the reference population from 2003 through 2008. However, due to a greater rate of decline in Butte BLLs over time, Butte BLLs no longer exceeded those of the reference population during the 2009-2010 period. The specific factors causing the higher rate of decline in Butte BLLs cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts. It should also be noted that some factors known to be associated with BLLs could not be accounted for in this study (for example, maternal education).

One way to evaluate the extent to which factors other than the Butte environment may be influencing BLLs for the study population is to look at how well the adjusted NHANES dataset compares to the NHANES data on which the current CDC blood lead reference value, 5 µg/dL, is based. The CDC reference value represents the 97.5th percentile of BLLs for the national population of children ages 1 to 5 based on children surveyed from 2005-2006 and 2007-2008. For the current study, NHANES data for these same survey periods were adjusted to make the NHANES population more similar to the Butte study population with regard to racial composition, poverty threshold, and residential make-up of house ages for children tested. These variables were selected for weighting NHANES data in the statistical model due to their importance as risk factors for elevated BLLs and because the distributions of data for each variable differed most from the corresponding Butte distributions. Thus, the adjusted NHANES data for 2005 through 2008 represent the national population of children surveyed with emphasis on BLLs for those whose demographic characteristics are most similar to the Butte study population. In contrast to the reference value, which is based on 2.5 percent of national children with BLLs greater than 5 µg/dL, when these same national data are adjusted to create a reference population that better matches the Butte study population demographics, the proportion of children in the reference population with BLLs greater than 5 µg/dL is much higher (10.3 percent adjusted reference population vs. 2.5 percent unadjusted, national population). This finding highlights the importance in the current study of adjusting for the potential influence of race and other socioeconomic risk factors associated with elevated BLLs when comparing the Butte blood lead data to blood lead data from a reference population.

5 Butte Neighborhood Comparison

As described in section 1, two lines of evidence are evaluated in this study to address the principal study question. The second line of evidence looks at whether statistically significant differences in BLLs across Butte neighborhoods, measured in conjunction with the RMAP, are reduced relative to differences documented in pre-RMAP BLLs across Butte neighborhoods. RMAP activities have been conducted throughout the study period, 2003-2010. Blood lead data reflecting pre-RMAP exposures within Butte are available from a 1990 exposure study conducted by the BSB Health Department and the University of Cincinnati (BSBHD/UC 1992). The 1990 exposure study identified statistically significant differences across selected areas of Butte that were related to house age and proximity to mining sources. These findings led the investigators to recommend development of a program in Butte to identify and address residential lead exposures from all sources, even though BLLs in Butte at that time were not found to be elevated relative to national data (BSBHD/UC 1992).

The current RMAP and its predecessor programs in Butte arose out of the 1990 exposure study recommendation and have been actively seeking to reduce residential exposures since about 1994. Blood lead data collected via RMAP were not collected in a similar manner or for the same purpose as the 1990 exposure study, thus the current study not intended to reproduce the 1990 exposure study. However, looking at whether or not differences in BLLs still exist across different areas of Butte and in association with variables, such as house age and proximity to mine sources, provides information that can be used to assess whether the RMAP has been effective in reducing exposures to lead across Butte and whether there are elements of the program that might be revisited to better identify and reduce residential exposures in Butte.

A brief summary of the 1990 exposure study is provided below. The remainder of this section describes the Butte neighborhood comparison model development and results. Supplemental analyses are also presented along with a summary of overall conclusions from the Butte neighborhood analysis.

5.1 Summary of the 1990 Exposure Study

The 1990 exposure study evaluated child BLLs across seven distinct Butte neighborhoods (Areas A-G; Figure 15). The number of children tested within each neighborhood ranged from 11 to 183. Blood lead results for all age groups tested in Butte in 1990 are summarized in Table 17.

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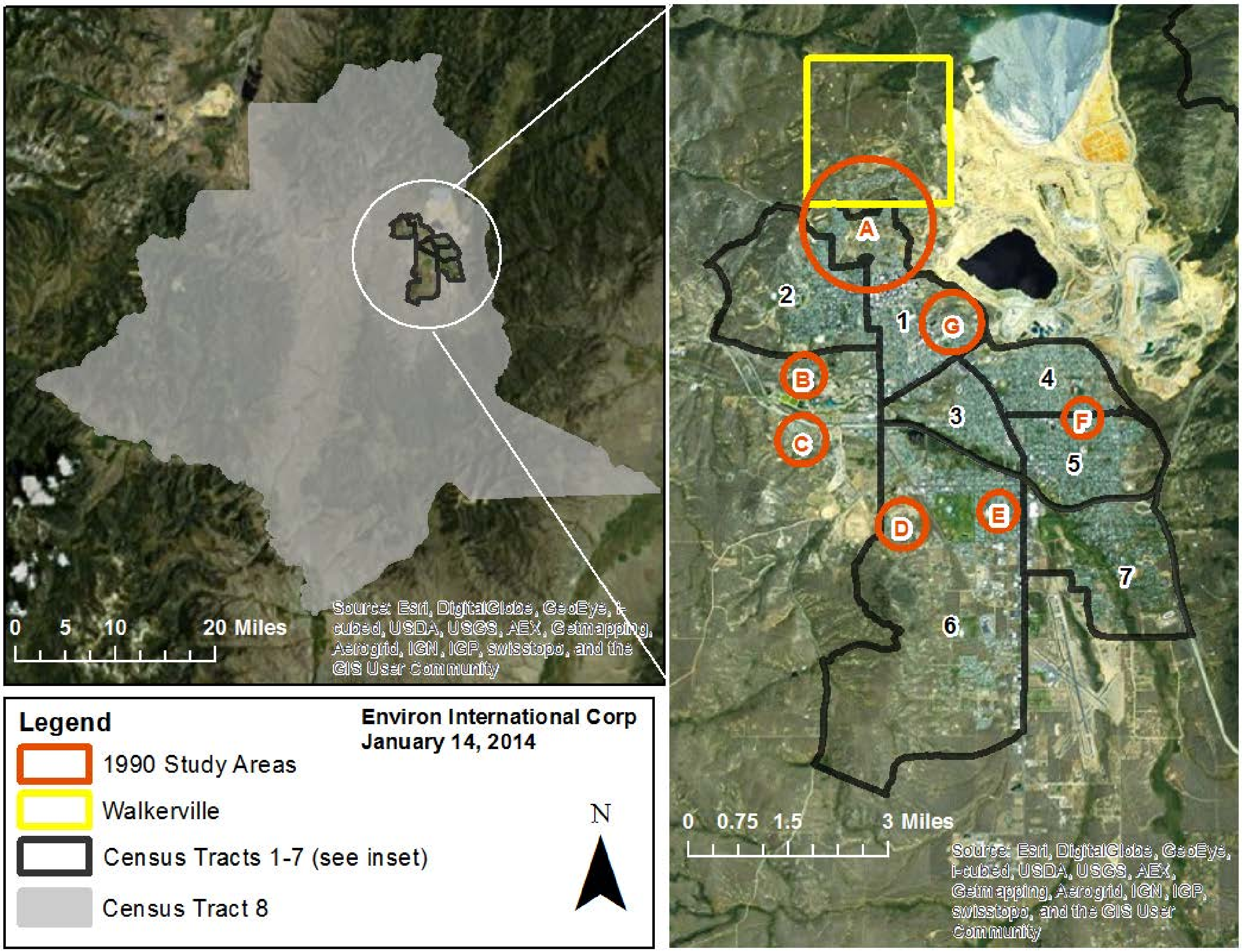


Figure 15: Map of Butte Showing Census Tracts and 1990 Study Areas (BSBDH/UC 1992)

Table 17: Blood Lead Results Reported in 1990 Butte Exposure Study

Statistic	1990 Butte Blood Lead					
	< 72 months*	72 months to 18 years	Adults	Nursing Women	Pregnant Women	All
Sample Size	294	53	48	11	24	430
Geometric Mean (µg/dL)	3.5	3.5	3.1	2.4	2.1	3.4
GSD (µg/dL)	1.8	1.8	1.9	1.6	1.5	1.8
95^{th} Percentile (µg/dL)	10.5	13.6	10.3	5.0	3.3	9.5
Maximum (µg/dL)	25.0	18.0	12.0	5.0	3.5	25.0

GSD- Geometric standard deviation
*Includes infants <12 months old

The study investigators reviewed available soil contamination data for Butte and met with the BSB Health Department 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.

For each neighborhood, the factors potentially influencing BLLs were characterized and 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). Table 18 summarizes the neighborhood characterizations presented in the 1990 exposure study along with blood lead statistics for the children tested. Each of the seven neighborhood areas selected for the 1990 study (Areas A through G) was among the oldest neighborhoods in Butte.

Table 18: Blood Lead Results for Children <72 Months by Neighborhood in 1990 Butte Exposure Study

	1990 Butte Study Areas						
	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
Blood Lead Statistics*							
Number of Participants	183	15	12	11	27	17	13
Geometric Mean (µg/dL)	3.7	2.3	4.6	4.6	2.7	3.0	3.8
GSD (µg/dL)	1.8	1.7	1.9	1.8	1.5	1.5	1.7
95^{th} Percentile (µg/dL)	10.9	4.0	14.5	22.5	5.6	6.5	8.0
Maximum (µg/dL)	25.0	4.0	14.5	22.5	6.0	6.5	8.0
Property Perimeter Soil Lead							
Number of properties	145	10	7	9	21	12	11
Geometric Mean (ppm)	750	250	139	234	151	178	1031
Property Non-Perimeter Soil Lead							
Number of properties	135	9	7	9	19	12	10
Geometric Mean (ppm)	699	358	154	209	136	147	626

*The study also reports on 15 children less than 72 months that were outside of the study areas.
GSD- Geometric standard deviation; ppm – parts per million

The highest average BLLs occurred in Areas A, C, D, G, which were all characterized as medium or high for exposure to waste/tailings and likely presence of lead paint and lead pipe. Specifically, area A was in an area defined by EPA 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 an EPA 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 an EPA Soil Priority Area, was within 1,000 feet of the Clark tailings and former mill, and had houses built in the same time period as 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.

The 1990 exposure study included environmental samples (i.e., yard soil, dust, tap water, lead paint), as well as blood lead samples. Table 18 shows geometric mean blood lead for children in the study and perimeter and non-perimeter soil lead concentrations for each area. Study investigators used the blood lead data and the environmental data to develop a structural equation model of lead exposure pathways. This analysis showed that residence location (i.e., neighborhood area) 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. The indirect effect of soil lead on blood lead was shown to be both small and weak. The investigators concluded that 39 percent of the variability in soil lead concentrations was attributable to lead-based paint, while the remainder (61 percent) 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 home grown produce was shown not to contribute to elevated BLLs.

Based on the findings of this study, the University of Cincinnati investigators, Dr. Bornschein and Dr. Clark, recommended to the BSB 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 EPA in their health risk assessment and cleanup goal development.

5.2 Delineation of Butte Neighborhoods for the Current Study

As described in section 2, more than 3,000 blood lead records are available to assess eight years of Butte child BLLs as compared to a single year evaluated in the 1990 exposure study. The recent Butte data were collected from individuals living in and around the 1990 exposure study areas but are not specifically aligned with those areas. Spatially, the recent data correspond to individuals tested throughout all eight census tracts of Silver Bow County, with the majority of the data encompassed by Census Tracts 1 through 7 and Walkerville, which cluster around the central urban area of Butte. The remainder of Census Tract 8, excluding Walkerville, surrounds this central cluster and extends outward to the more rural perimeters of the county (Figure 15).

Many of the specific mine waste and tailings exposure sources considered during neighborhood selection for the 1990 study have been addressed since that study was conducted, resulting in the reduction or elimination of pathways for exposure to those sources. However, the distribution of recent blood lead data still varies in proximity to active and historical mining areas where contamination still represents a potential for increased exposures relative to areas of Butte more distant from these sources. Based on available census data, house ages (i.e., year built data) and poverty status also vary across different Butte census tracts. Given the abundance of recent data available throughout Butte and the variability across different areas of Butte with regard to factors that might influence BLLs, delineation of neighborhoods for the current study was not limited to areas studied in 1990.

For the current study, the recent blood lead data were first split according to census tracts. The Butte blood lead dataset from the BSB Health Department had limited socioeconomic and demographic data associated with it. However, census data can provide a general indicator of population characteristics for different areas, including data on racial composition, median family income, percent below poverty level, house age group, and population age structure. Census block data were also investigated but found to be more limited than census tract data with regard to the types of summary data that were available. While census data are useful, differences between individuals represented in the census data population and in the Butte blood lead data population are expected. For example, recruitment of many of the individuals represented in the Butte blood lead database is likely to have selected for individuals from the WIC-eligible population. These individuals are likely to have greater poverty and live in the oldest housing in Butte.

The majority of the data points fell within Census Tracts 1-7, with very sparse data in Tract 8 (except for Walkerville). Census Tract 8 encompasses rural areas and is significantly larger than the other tracts combined (Figure 15). Several participants' homes within Census Tract 8 are located near the boundaries of Census Tracts 1-7. For these houses, satellite imagery showing the layout of roadways and clustering of houses was assessed to judge whether these Tract 8 houses appeared to be distinct neighborhoods or proximal extensions of neighborhoods associated with other tracts. A distance of approximately 500 meters around Census Tracts 1-7 was found to encompass many of the Census Tract 8 homes that appeared to be part of the same neighborhoods as the other tracts. Using geospatial analysis tools, a 500 meter buffer was applied to the outer perimeter of Census Tracts 1-7 to capture the proximal Census Tract 8 houses (Figure 16). Applying this buffer, blood lead data for individuals residing within neighboring houses were grouped with data from other residential areas that are likely to share similar characteristics (e.g., house age, socioeconomic level, etc.) and proximity to common sources of lead within the local environment.

Neighborhoods N1 through N7 were then delineated for the statistical model based on the addition of records captured from Census Tract 8 in the buffer around Census Tracts 1 through 7, respectively. The only exception to the applied buffer was at the boundary between Walkerville and the northern border of N1. A significant number of blood lead records are available for the Walkerville area. These records correspond to some of the oldest homes in Butte (dating back to 1875), where the likely presence of lead-based paint and lead pipe is expected to be high. Despite the smaller population of Walkerville, more properties have been sampled for metals and abated there than in neighborhoods N3 through N7 combined. Additionally, this community sits at a higher elevation than the majority of Butte, distinguishing it geographically from the rest of the study area. Given this, a decision was made to delineate Walkerville as a separate neighborhood (N8) from all other neighborhoods in the statistical model. Seventy-nine data points that fell both in the 500 meter buffer of Tract 1 and in the Walkerville boundary were assigned to N8. Additionally, 30 data points that fell just south of Walkerville but within the N1 buffer area were also reassigned to N8 based on input from the Working Group.

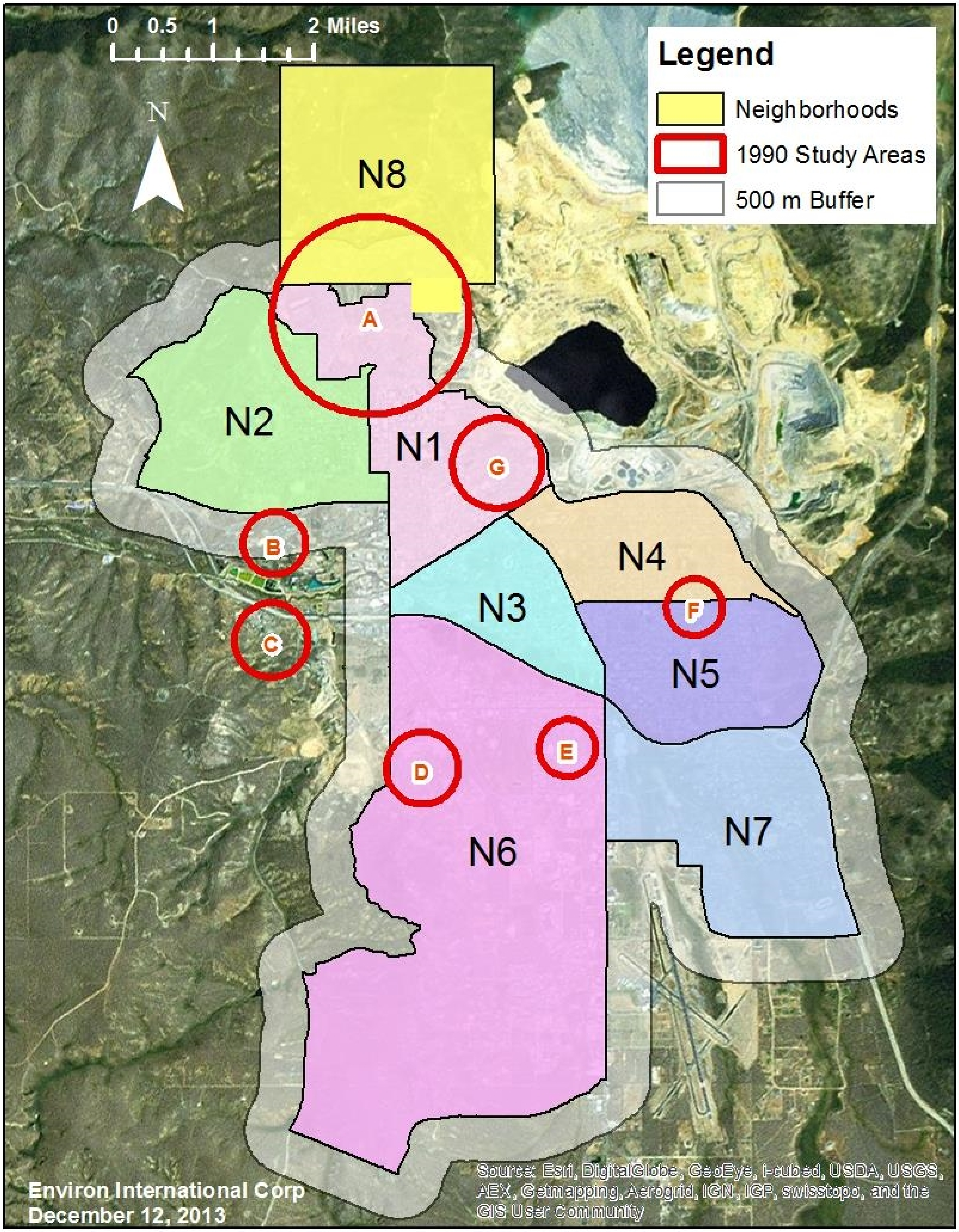


Figure 16: Map of Butte Showing 500 Meter Buffer around Census Tracts and 1990 Study Areas (BSBDH/UC 1992)

For blood lead records between 2003 and 2010, 72 records from 41 houses within Census Tract 8 that were not encompassed by neighborhoods N1 through N8 were excluded from the statistical model for the Butte neighborhood comparison given that these blood lead records were not clustered together or proximal to the other eight neighborhoods delineated. However, these 72 records were included in the statistical comparison of Butte blood lead data to the reference blood lead dataset (section 4). Summary statistics for these data are included in Table 19.

Table 19: Summary Statistics for 72 Blood Lead Records Excluded from the Butte Neighborhood Comparison

Statistic	Mean	SD	Median	Minimum	Maximum
BLL (µg/dL)	2.3 (GM)	2.3 (GSD)	2.7	<1	17.4
Age (years)	2.6	1.1	2.4	1	4.8

GM – Geometric mean; SD – Standard deviation; GSD - Geometric standard deviation

For the 2003 through 2010 time period, a total of 2,724 blood lead records are available for neighborhoods N1 through N8 combined. An additional 452 records are also available from 2011. The 2011 records were used to confirm BLL declines in one statistical model as well as for supplemental analyses in section 5.5. Sample sizes by neighborhood and year are shown in Table 20. The locations of neighborhood study areas evaluated in 1990 are shown in comparison to neighborhoods N1 through N8 in Figure 16.

Table 20: Sample Size by Neighborhood and Year for 2003 through 2011

Year	N1	N2	N3	N4	N5	N6	N7	N8	Total
2003	102	40	32	51	29	69	4	16	343
2004	79	42	38	44	21	61	7	16	308
2005	84	29	27	41	18	79	12	13	303
2006	76	35	37	30	27	84	14	16	319
2007	83	50	33	49	26	72	17	7	337
2008	93	56	21	31	24	66	17	11	319
2009	96	49	26	56	30	71	13	11	352
2010	121	55	37	63	39	93	13	22	443
2011*	131	64	42	57	31	97	15	15	452

*2011 data were only used in models to confirm trends seen in prior years and used outside of the model for supplemental analyses.
N1 – Neighborhood 1

5.3 Butte Neighborhood Model Development

The Butte neighborhood analysis necessitated development of a statistical model that allowed for comparison of BLLs (the dependent variable) from children 12-60 months of age for neighborhoods N1 through N8 while accounting for other independent variables that can influence BLLs (factors described in section 3). The software used to perform these statistical analyses was SAS Version 9.3 (SAS Institute Inc., Cary, NC).

Because many children in Butte have repeated BLL measurements, linear mixed models were used to account for the correlated nature of the data. The "MIXED" procedure in SAS was used because it is able to handle repeated/correlated data, as well as data with a different number of measurements per subject. When using the "MIXED" procedure, a covariance structure or specification about how the measurements are related over time was chosen. For the Butte neighborhood analysis, an autoregressive covariance structure was used, meaning that measurements farther apart in time are assumed to be less correlated than observations closer in time. The SAS "MIXED" procedure provides F-tests from the "Type 3 Tests of Fixed Effects" which were used to determine the overall significance of variables, as well as partial t-tests from the "Solution for Fixed Effects" which were used to determine the significance of the different levels/categories of each variable compared to a reference. When multiple comparisons were made, Tukey's multiple comparison tests were applied. Additionally, a Least Squares Means (LSMEANS) statement was used to calculate geometric means and 95 percent confidence intervals for all categorical variables.

The first step of the model development was generating the univariate statistics. The univariate statistics examined each independent variable individually to determine whether it influenced the dependent variable: the BLLs.

Based on the results from the univariate analysis, a fully adjusted multivariable model was built. In the fully adjusted model, the effect of each independent variable on BLLs was examined after adjusting for all of the other variables included in the model. An *a priori* decision was made that all variables that were significant ($p<0.05$) in the univariate analysis would be included in the fully adjusted model. Interaction terms of interest were then added to the fully adjusted model. Finally, the fully adjusted model was stratified, first by neighborhood (N1–N8) and then by two groupings of neighborhoods. This section describes the process and information used to develop the final stratified statistical model.

5.3.1 Identification of Significant Variables for Inclusion in the Model

The first step in building the Butte neighborhood comparison model involved identifying which independent variables to include in the model. A univariate statistical analysis was conducted to evaluate the significance of several independent variables with regard to their individual influence on blood lead. Table 21 summarizes the details for each variable examined and the results of the univariate analyses. For each variable examined in the univariate analysis, estimates and p values from t-tests, as well as geometric means and 95 percent confidence intervals around the means were calculated. The estimates do not have units,[15] while the geometric mean of BLLs and confidence intervals have units of µg/dL.

From Table 21, the statistically significant p value for child test age (a continuous variable) means that as child test age increases, the BLLs decrease (p=0.0033). The p values for the categorical variables compare each category within that variable to a reference category. In general, the category with the largest sample size was chosen as the reference for each variable examined. For these estimates, the p value shows whether the BLLs for a given category are significantly different from the reference. For instance, the BLLs in neighborhoods N3, N4, N5, N6, and N7 are significantly lower than those in neighborhood N1 (Table 21). However, there is no evidence to suggest that the BLL in neighborhoods N2 or N8 are different than the BLL in neighborhood N1 (p=0.84 and 0.43, respectively).

[15] Estimates below one represent a decline in BLLs with increasing test year or increasing child test age for those variables, while estimates above one represent an increase in BLLs. An estimate of 0.88 for test year indicates that BLLs are declining 12 percent per year.

Table 21: Results from Univariate Analysis for Butte Neighborhood Comparison

Variable	N**	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value
Child test age (estimate)	2724	0.96	0.94	0.99	0.0033*
Child gender					
Male	1408	2.69	2.56	2.82	Reference
Female	1316	2.32	2.21	2.44	<0.0001*
Neighborhood					
N8	112	3.10	2.63	3.64	0.43
N7	97	1.91	1.62	2.24	<0.0001*
N6	595	2.12	1.98	2.27	<0.0001*
N5	214	2.18	1.95	2.44	<0.0001*
N4	365	2.34	2.14	2.55	<0.0001*
N3	251	2.51	2.26	2.79	0.020*
N2	356	2.92	2.68	3.19	0.84
N1	734	2.89	2.72	3.07	Reference
Year House built					
Missing	945	2.40	2.27	2.54	<0.0001*
Post 1977	96	1.69	1.43	1.99	<0.0001*
1960 to 1977	152	2.23	1.96	2.54	0.0012*
1950 to 1959	158	2.23	1.95	2.56	0.0019*
1940 to 1949	244	2.39	2.15	2.65	0.0061*
Pre 1940	1129	2.81	2.67	2.95	Reference
Test year					
2003-2004	651	3.80	3.58	4.04	<0.0001*
2005-2006	622	2.89	2.72	3.06	<0.0001*
2007-2008	656	2.44	2.30	2.58	<0.0001*
2009-2010	795	1.71	1.62	1.80	Reference
Test season					
Winter/Spring	1369	2.30	2.20	2.40	<0.0001*
Summer/Fall	1355	2.73	2.61	2.85	Reference

*Statistically significant ($p \leq 0.05$)
**The N differs from the univariate results for Butte presented in Table 5 because it excludes the 72 samples from Census Tract 8 that were not assigned to a neighborhood and were dropped from that analysis.
N – Sample size; GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit.
Estimates are unit-less

An F-test was used to also determine p values for each variable as a whole, not by category, as in Table 21.[16] All significant variables from this F-test were incorporated into the fully adjusted model (Table 22).

Table 22: Results from F-test for All Variables from the Univariate Butte Neighborhood Analysis

Variable	p value from F-Test
Child test age	0.003*
Child gender	<0.0001*
Neighborhood	<0.0001*
Year house built	<0.0001*
Test year	<0.0001*
Test season	<0.0001*

*Statistically significant ($p \leq 0.05$)

5.3.2 Building the Fully Adjusted Model and Examination of Interaction Terms

The fully adjusted model incorporated all of the significant variables from the univariate analysis (child test age, child gender, neighborhood, year house built, test year, and test season). This model then examined the association between each independent variable and geometric mean BLLs, while simultaneously controlling for the other independent variables that may affect the BLLs.

At this stage of model development, interaction terms were added to the model and examined. The addition of an interaction term to the model helps to determine whether the association between two variables (BLL and test year, for example) varies according to a third variable (neighborhood). Here, for instance, a significant interaction term would provide evidence that BLLs were declining faster over the years in one neighborhood compared to another.

Results of the fully adjusted model, with and without inclusion of interaction terms, are presented below.

5.3.2.1 Fully Adjusted Model without Interaction Terms

Table 23 summarizes the initial results of the fully adjusted model, which treated child test age data and test year data as continuous variables and all other independent variables as categorical. After adjusting for the other variables in the model, statistically significant results indicate the following trends:

- declining BLL with increasing test year;
- declining BLL with increasing child test age;

[16] For variables with only two categories, such as gender, the results of the F test are the same as the p values presented in the univariate results tables.

- lower BLLs in females than in males; and
- lower BLLs in winter/spring than summer/fall.

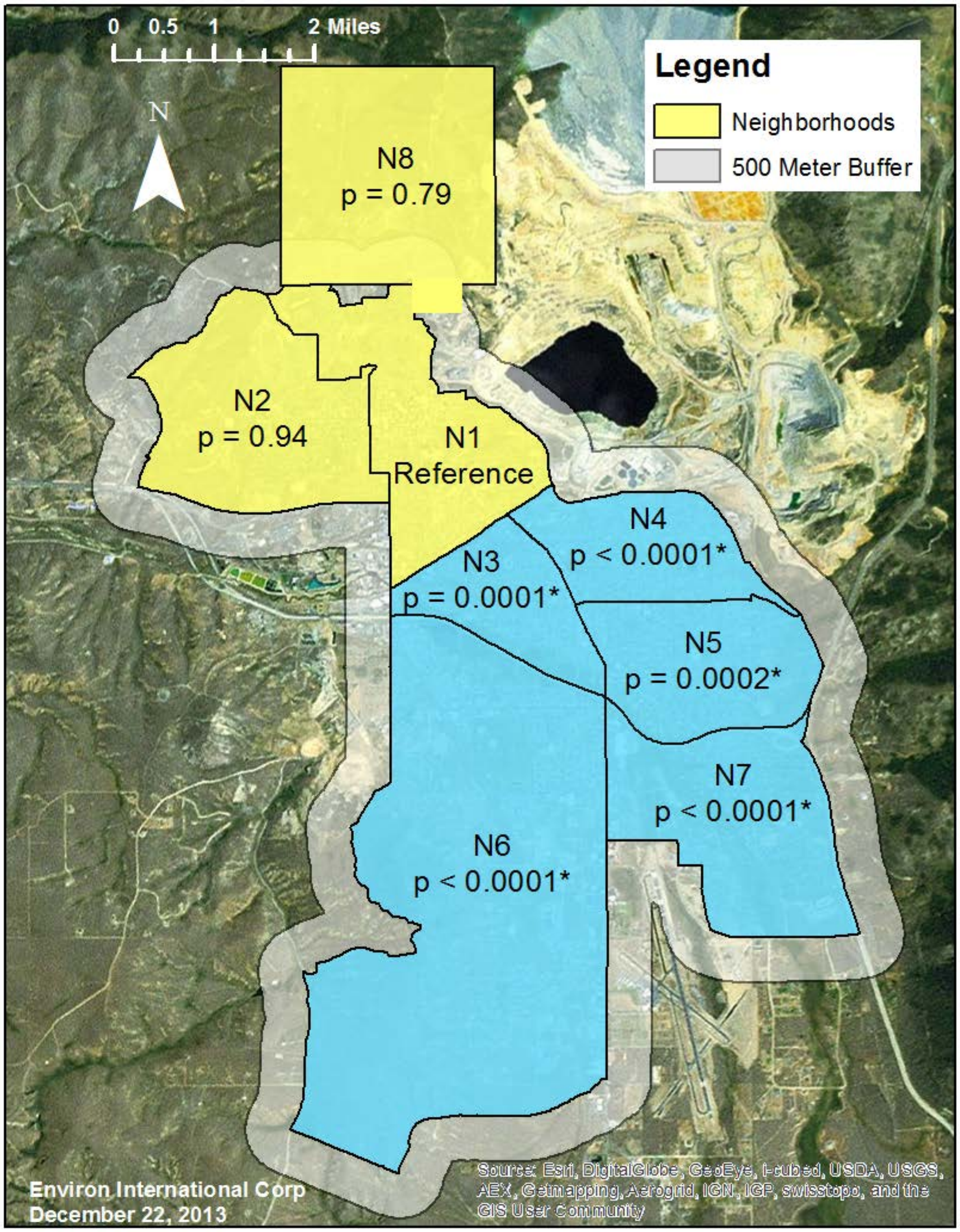
BLLs for children in all year house built groupings (1940-49, 1950-59, 1960-77, 1978 and later, and “missing”) were lower than BLLs from participants in homes built prior to 1940 (the reference category for the house age variable). As discussed in section 3, older housing is associated with higher BLLs for a variety of reasons, thus the model results for BLLs based on different house age categories are as expected for any population.

Also in Table 23, the model compared Butte neighborhoods N2 through N8 to the reference neighborhood, N1. Geometric mean BLLs for N2 and N8 (2.74 µg/dL and 2.65 µg/dL, respectively) were not statistically different from N1 (2.70 µg/dL). All other neighborhoods (N3 through N7) had statistically lower BLLs than N1. The geometric mean BLLs for N3-N7 ranged from 1.83 µg/dL (N7) to 2.20 µg/dL (N4). These results are shown spatially in Figure 17.

Table 23: Results for Butte Neighborhood Comparison from Fully Adjusted Model

Variable	GM/Estimate (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value
Child test age (estimate)	0.97	0.95	1.00	0.030*
Child gender				
Female	2.17	2.05	2.30	0.0004*
Male	2.42	2.28	2.56	Reference
Neighborhood				
N8	2.65	2.28	3.09	0.79
N7	1.85	1.59	2.16	<0.0001*
N6	2.04	1.90	2.19	<0.0001*
N5	2.15	1.93	2.38	0.0002*
N4	2.20	2.02	2.40	<0.0001*
N3	2.18	1.96	2.42	0.0001*
N2	2.72	2.50	2.97	0.94
N1	2.70	2.53	2.90	Reference
Year house built				
Missing	2.45	2.32	2.59	0.011*
Post 1977	1.90	1.63	2.21	<0.0001*
1960-1977	2.34	2.07	2.64	0.038*
1950-59	2.32	2.04	2.63	0.032*
1940-49	2.15	1.93	2.39	0.0001*
Pre1940	2.68	2.55	2.82	Reference
Test year (estimate)	0.88	0.87	0.89	<0.0001*
Test season				
Winter/Spring	2.08	1.97	2.20	<0.0001*
Summer/Fall	2.53	2.39	2.67	Reference

*Statistically significant ($p \leq 0.05$)
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit. Estimates are unit less.



*represents statistically significant p value; p values based on fully adjusted model (Table 23)

Figure 17: Comparison of Geometric Mean BLLs for Neighborhoods N2 through N7 with N1 as Reference

Pairwise comparisons of all combinations of year house built categories were also conducted to assess differences between categories. Tukey's multiple comparisons tests were used to calculate p values for these pairwise comparisons (Table 24). Based on this analysis, BLLs for individuals tested while living in houses built from 1940 to 1949[17] and after 1977 are statistically lower than BLLs for individuals tested while living in houses built prior to 1940. Additionally, BLLs from individuals where year house built data were missing were statistically higher than BLLs for individuals tested while living in houses built after 1977.

Table 24: Pairwise Comparisons of Year House Built Categories from Butte Neighborhood Comparison

Year Built Category	GM for Category (µg/dL)	Comparison Category	GM for Comparison Category (µg/dL)	p Value	Conclusion
Missing	2.45	Post 1977	1.90	**0.017***	"Post 1977" BLLs < "Missing" category BLLs
		1960-1977	2.34	0.98	No significant difference
		1950-59	2.32	0.97	
		1940-49	2.15	0.22	
		Pre1940	2.68	0.11	
Post 1977	1.90	1960-1977	2.34	0.26	No significant difference
		1950-59	2.32	0.34	
		1940-49	2.15	0.76	
		Pre1940	2.68	**0.0004***	"Post 1977" BLLs < "Pre1940" BLLs
1960-1977	2.34	1950-59	2.32	1.0000	No significant difference
		1940-49	2.15	0.91	
		Pre-1940	2.68	0.30	
1950-59	2.32	1940-49	2.15	0.94	No significant difference
		Pre1940	2.68	0.26	
1940-49	2.15	Pre1940	2.68	**0.0013***	"1940-49" BLLs < "Pre 1940" BLLs

*Statistically significant ($p \leq 0.05$) comparison between year built categories
BLL – Blood lead level; GM – Geometric mean.

Tukey's method was also used to evaluate pairwise neighborhood comparisons (Table 25). These results confirmed that there are no statistically significant differences in BLLs for individuals tested while living in neighborhoods N1, N2, and N8. BLLs corresponding to neighborhoods N3 through N7 are also not statistically different from each other. As shown in Figure 18, neighborhoods N1, N2, and N8 are clustered together in the "Uptown" area of Butte. The Uptown area is most proximal to the higher elevation areas of Butte where past and current

[17] Note: 195 out of 244 blood lead tests (80 percent) for this year house built category correspond to a single housing complex. This housing complex is located in N1 and blood lead records from this complex represent 96 percent of the records in N1 for this year house built category.

mining activities are concentrated. Consistent with increased mining activities, documented mineralized zones occurring throughout the bedrock and at the surface are also more prevalent in the Uptown area (Weed et al. 1897). South of Uptown, “the Flats” area corresponds to neighborhoods N3 through N7. Elevations in the Flats are lower than in Uptown. Mineralized zones are also far less prevalent in the Flats consistent with decreased historical and active mining activities in the Flats, relative to Uptown.

Table 25: Pairwise Comparisons of Neighborhoods from Butte Neighborhood Comparison

Neighborhood	GM for Neighborhood (µg/dL)	Comparison Neighborhood	GM for Comparison Neighborhood (µg/dL)	p Value	Conclusion
N8	2.65	N7	1.85	**0.021***	N8 BLLs > N7 BLLs
		N6	2.04	**0.034***	N8 BLLs > N6 BLLs
		N5	2.15	0.30	No Difference
		N4	2.20	0.36	
		N3	2.18	0.34	
		N2	2.72	1.0	
		N1	2.70	1.0	
N7	1.85	N6	2.04	0.94	No Difference
		N5	2.15	0.77	
		N4	2.20	0.48	
		N3	2.18	0.65	
		N2	2.72	**0.0003***	N2 BLLs > N7 BLLs
		N1	2.70	**0.0002***	N1 BLLs > N7 BLLs
N6	2.04	N5	2.15	0.99	No Difference
		N4	2.20	0.83	
		N3	2.18	0.96	
		N2	2.72	**<0.0001***	N2 BLLs > N6 BLLs
		N1	2.70	**<0.0001***	N1 BLLs > N6 BLLs
N5	2.15	N4	2.20	1.0	No Difference
		N3	2.18	1.0	
		N2	2.72	**0.012***	N2 BLLs > N5 BLLs
		N1	2.70	**0.0045***	N1 BLLs > N5 BLLs
N4	2.20	N3	2.18	1.0	No Difference
		N2	2.72	**0.0057***	N2 BLLs > N4 BLLs
		N1	2.70	**0.0010***	N1 BLLs > N4 BLLs
N3	2.18	N2	2.72	**0.011***	N2 BLLs > N3 BLLs
		N1	2.70	**0.0037***	N1 BLLs > N3 BLLs
N2	2.72	N1	2.70	1.0	No Difference

*Statistically significant ($p \leq 0.05$) comparison between geometric mean BLLs at two neighborhoods
BLL – Blood lead level; GM – Geometric mean.

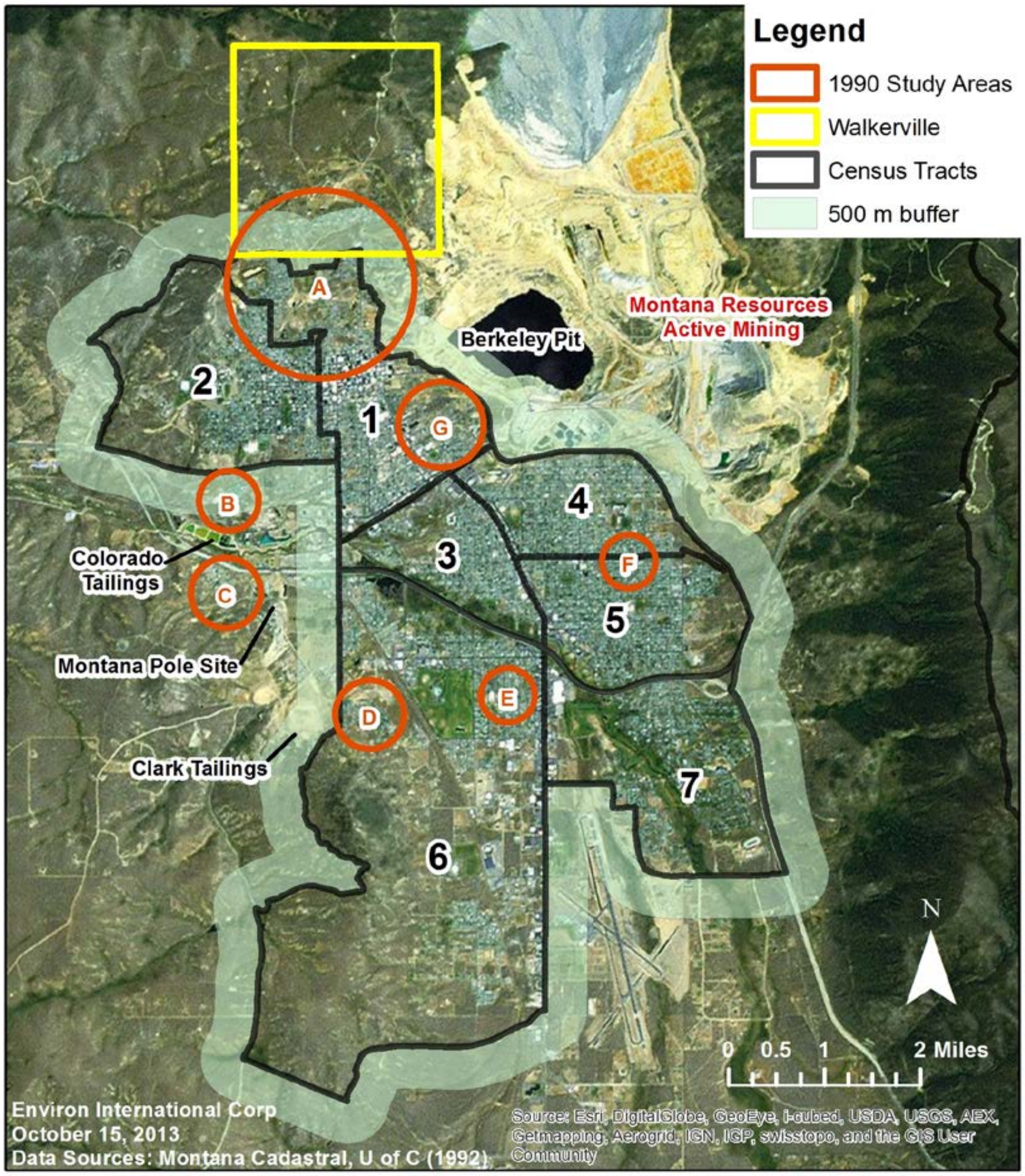


Figure 18: Map of Butte Showing Mining Areas

The fully adjusted model was run first with child test age as a continuous variable. However, as discussed in section 3, it has been consistently observed in the U.S. that young children between the ages of 1 and 3 years have the highest BLLs on average (Jones et al. 2009; CDC 2013b). Therefore, child test age was also set as a categorical variable comparing child test ages 12 to 35 months to child test ages 36 to 60 months. For this portion of the analysis, test year was also grouped into four categories (2003-04, 2005-06, 2007-08, 2009-10), and neighborhoods were grouped by area (i.e., Uptown and the Flats).

Consistent with results in Table 7, the results for this analysis showed the same significant effects (Table 26). The highest geometric mean BLL (3.54 µg/dL) corresponded to the 2003-04 test period, and geometric mean BLLs declined with each later test period. The geometric mean

BLL for children tested at ages 12 to 35 months was significantly higher than for children in the 36 to 60 month test age category (p=0.0002). The geometric mean BLL in Uptown was statistically higher than for the Flats (p<0.0001).

Table 26: Results from Fully Adjusted Model with All Variables as Categorical

Variable	GM (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	p Value
Child test age (months)				
12-35	2.54	2.42	2.66	0.0002*
36-60	2.29	2.17	2.42	Reference
Child gender				
Female	2.28	2.16	2.41	0.0004*
Male	2.55	2.42	2.69	Reference
Neighborhood				
The Flats	2.14	2.04	2.25	<0.0001*
Uptown	2.72	2.57	2.88	Reference
Year house built				
Missing	2.54	2.42	2.67	0.0003*
Post 1977	1.96	1.68	2.27	<0.0001*
1960-1977	2.43	2.16	2.74	0.0092*
1950-59	2.48	2.20	2.80	0.026*
1940-49	2.28	2.07	2.51	<0.0001*
Pre1940	2.87	2.75	3.01	Reference
Test year				
2003-2004	3.54	3.31	3.78	<0.0001*
2005-2006	2.69	2.52	2.88	<0.0001*
2007-2008	2.24	2.10	2.39	<0.0001*
2009-2010	1.58	1.49	1.68	Reference
Test season				
Winter/Spring	2.18	2.07	2.29	<0.0001*
Summer/Fall	2.67	2.53	2.81	Reference

*Statistically significant compared to reference category (p ≤ 0.05)

GM – Geometric mean; LCL – Lower confidence limit; UCL – upper confidence limit.

5.3.2.2 Examine Interaction Terms

As noted earlier, interaction terms are added to a model to help determine whether the relationship between two variables (for instance, BLL and test year) vary according to a third variable (for instance, neighborhood). The interaction between neighborhood and test year was examined in the model to assess whether the effect of test year on BLLs differed between the individual neighborhoods (N1 through N8). For this interaction term, test year was treated as a continuous variable and the interaction term was found to be significant when added to the model (p <0.022). These results suggest an influence of test year on BLLs that varies by individual neighborhood.

A similar interaction was also examined using an interaction term based on continuous test year and neighborhood grouping (i.e., Uptown and the Flats); however, the addition of this interaction term to the model was not significant (p=0.15). [18]

5.3.3 Final Statistical Model (Stratified by Uptown vs. the Flats)

The final statistical model for the Butte neighborhood comparison was stratified by Uptown and the Flats to examine the influence of each of the remaining independent variables (child test age, child gender, year house built, test year, and test season) on BLL for Uptown vs. the Flats. Stratification of the model based on individual neighborhoods (N1 through N8) was initially conducted; however, sample sizes were too small for some variables on an individual neighborhood basis. Sample sizes for Uptown vs. the Flats do not fluctuate greatly over the four time periods evaluated in this study (Table 27).

Table 27: Sample Sizes for Uptown and The Flats by Two-Year Period

Years	Uptown	The Flats
2003-2004	295	356
2005-2006	253	369
2007-2008	300	356
2009-2010	354	441

To determine whether the rate of decline in BLLs over time is different in Uptown than the Flats, the coefficients and standard errors for test year (treated as a continuous variable) from the adjusted model were used to calculate a Chi-squared test statistic. This test statistic with one degree of freedom was then compared to the Chi Square distribution to determine if the null hypothesis that the coefficients were the same could be rejected at a significance levels of α = 0.05. Results of these analyses are summarized below.

5.4 Butte Neighborhood Comparison Model Results

Table 28 summarizes the results of the final stratified model for the Butte neighborhood comparison. For each neighborhood area or “source” considered in the stratified model, geometric mean BLLs and confidence intervals are presented. The influence of each independent variable (i.e., child test age, child gender, test year, house age, or test season) on BLL is calculated by the model while accounting for the influences of all the other variables. Confidence intervals may be compared across each variable category for Uptown and the Flats to provide an indication of whether BLLs for each area are statistically different. Statistical comparisons of results for Uptown and the Flats were also performed using a t-test with p values comparing the neighborhood groups (Table 28).

[18] Interaction terms were also considered for year house built and neighborhood, as well as test year as a categorical variable and neighborhood group. Both treatments lacked sufficient statistical power for the significance of the term to be estimated.

Table 28: Results from Stratified Model with P Values Comparing Uptown to the Flats

	Uptown				the Flats				Comparison**
Variable	**GM (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**	**GM (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p Value**	**p Value**
Child test age (months)									
12-35	2.67	2.43	2.94	0.087	2.34	2.19	2.49	0.0033*	0.026*
36-60	2.48	2.25	2.75	Reference	2.11	1.97	2.26	Reference	0.012*
Child gender									
Female	2.42	2.18	2.68	0.0073*	2.13	1.98	2.28	0.031*	0.044*
Male	2.74	2.49	3.02	Reference	2.32	2.16	2.48	Reference	0.0086*
Year house built									
Missing	3.16	2.9	3.43	0.87	2.15	2.02	2.29	<0.0001*	<0.0001*
Post 1977	1.69	1.19	2.39	0.0006*	1.85	1.57	2.19	0.0002*	0.49
1960-1977	2.55	1.91	3.41	0.14	2.18	1.91	2.48	0.012*	0.32
1950-59	2.73	2.14	3.48	0.22	2.18	1.9	2.51	0.020*	0.086
1940-49	2.48	2.22	2.77	0.0002*	2.42	1.96	2.99	0.47	0.92
Pre1940	3.18	2.98	3.4	Reference	2.62	2.46	2.79	Reference	<0.0001*
Test year									
2003-2004	3.55	3.15	3.99	<0.0001*	3.42	3.14	3.73	<0.0001*	0.61
2005-2006	2.83	2.51	3.19	<0.0001*	2.5	2.3	2.72	<0.0001*	0.085
2007-2008	2.56	2.29	2.87	<0.0001*	1.98	1.81	2.15	<0.0001*	0.0007*
2009-2010	1.71	1.53	1.91	Reference	1.44	1.33	1.55	Reference	0.018*
Test season									
Winter/Spring	2.29	2.07	2.52	<0.0001*	2.05	1.92	2.19	<0.0001*	0.086
Summer/Fall	2.9	2.63	3.2	Reference	2.41	2.25	2.57	Reference	0.0023*

*Statistically significant ($p \leq 0.05$)
** p value comparing GM in Uptown to the GM in the Flats
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit.

After adjustment for other variables in the model, BLL trends are generally similar for Uptown and the Flats. General trends common to both neighborhood groups include the following:

- BLLs are lower in the later study periods (Figure 19). In Uptown, BLLs decline from a mean of 3.55 µg/dL in 2003-2004 to a mean of 1.71 µg/dL in 2009-2010. In the Flats there is a decline as well, from 3.42 µg/dL in 2003-2004 to 1.44 µg/dL in 2009-2010.

- BLLs are lower for children aged 36 to 60 months at the time of test than for children aged 12 to 35 months.
- BLLs are lower for females than for males.
- BLLs are lower for children tested in the winter/spring than in the summer/fall season.

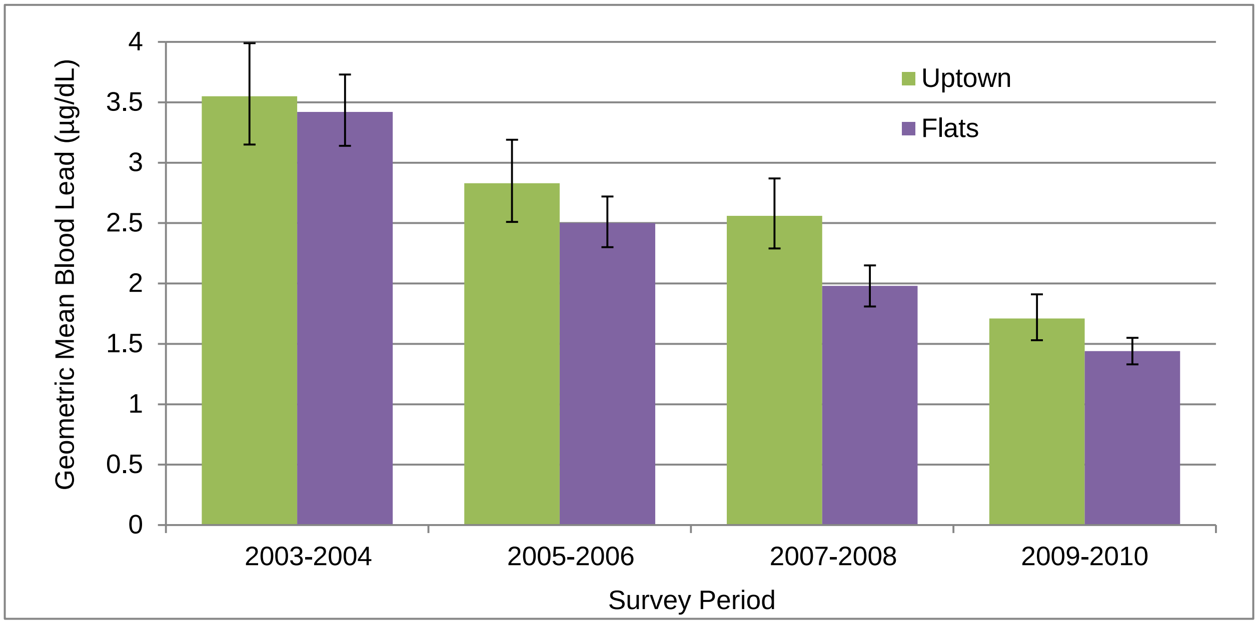


Figure 19: Modeled Geometric Mean Blood Lead Levels for Uptown vs. the Flats by Test Year with 95% Confidence Intervals

In both the Flats and Uptown, BLLs tend to increase as house age increases. In the Flats, children living homes built prior to 1940 have mean BLLs that are significantly higher than those of children living in homes built in 1950 or later. In Uptown, BLLs from children living in pre-1940 homes are significantly higher than those of children living in homes built from 1940 to 1949 or from 1978 and later.

Comparing across neighborhood groups, geometric means in Uptown tend to be higher than geometric means in the Flats. Specifically, BLLs in Uptown are significantly higher than in the Flats for:

- the two most recent test periods of 2007-2008 and 2009-2010;
- children tested in the summer/fall;
- children of both age categories and genders; and
- children living in homes built prior to 1940 or in homes of unknown ages (i.e., the missing category).

Controlling for the influence of all other variables, BLLs for children living in houses built after 1939 were not statistically different between Uptown and the Flats. BLLs for Uptown and the

Flats were also not statistically different for the earliest two test periods and the winter/spring test season.

Based on the results of the Chi-squared test, the rate of BLL decline from 2003 through 2010 is not statistically different (p=0.069) for Uptown and the Flats. In Uptown, BLLs have declined at a rate of 11 percent per two-year period compared to a decline of 14 percent in the Flats.

5.5 Summary and Conclusions

Statistical models were built to compare BLLs across Butte neighborhoods while accounting for other independent variables that can influence BLLs. Child test age, child gender, year house built, child neighborhood, test year, and test season were included in the models after determining the significance of each variable in the univariate analysis. Results of a fully adjusted model were examined along with the model stratified by neighborhood area, Uptown and the Flats. In both the fully adjusted model and the stratified model, statistically significant results indicate the follow trends:

- BLLs declined over time during the study periods examined.
- BLLs for children aged 36 to 60 months at the time of test were lower than for children aged 12 to 35 months.
- BLLs in females were lower than in males.
- BLLs for children tested in the winter/spring were lower than in the summer/fall season.

Overall, the final stratified model suggests BLLs in Uptown are higher than in the Flats when accounting for the influence of other variables, and these differences are frequently statistically significant. There is also a consistent trend with regard to declining BLLs over time for both areas of Butte, and, despite the higher BLLs in Uptown, the rate of decline is not statistically different between the two areas.

Uptown BLLs were significantly higher than BLLs for the Flats during the summer/fall test season when the greatest exposures to outdoor sources are expected, but BLLs were not different between these areas during the winter/spring test season when outdoor exposures are more limited. This suggests that outdoor sources of lead exposures may contribute more to BLLs for residents of Uptown than for the Flats. In this study, the model does not include variables for specific sources of lead exposure within the indoor and outdoor environment that are present in Butte, therefore, it is not possible to identify which outdoor source or sources might be responsible for the higher BLLs in Uptown during warmer months. We do know that Uptown is spatially located in closer proximity to areas in Butte where past and ongoing mining activities have been concentrated. We also know that naturally-occurring mineralized zones are more prevalent in these areas and that most of the oldest homes in Butte, which are most likely to have lead paint, are located in Uptown. Each of these conditions could contribute to the seasonal BLL difference identified between Uptown and the Flats.

To assess whether the decline in BLLs for both Uptown and the Flats continued beyond 2010, available Butte blood lead records collected in 2011 were added to the model, and blood lead data for each two-year study period were compared to the 2011 test year. For both the Flats and Uptown, 2011 data were not statistically different from data for 2009-2010 (see Appendix G for complete summary of the model results with 2011 data added), while each of the three earliest test periods is statistically different from 2011. Comparison of 2011 data for Uptown and the Flats using a t-test supports the earlier finding that BLLs in Uptown are statistically higher (Appendix G).

During the study period, the CDC recommended 10.0 µg/dL as a blood lead "level of concern" when based on a confirmed venous blood draw. This level of concern was used as a risk management tool by the BSB Health Department to identify children who might have elevated lead exposures so that actions to reduce such exposures could be initiated. Children with confirmed venous blood lead results exceeding 9.9 µg/dL were referred for case management, including home visits when appropriate, intensive education for the family, environmental investigation and follow up blood lead testing. According to BSB Health Department's annual reports of clinical and educational interventions, screening blood lead results confirmed to exceed 9.9 µg/dL declined from 1.4 percent in 2003-2004 to 0.1 percent in 2010. The Health Department identified a variety of suspected causes of elevated blood lead levels in these children. Starting in 2013, home visits were scheduled for all children with blood lead levels of 5.0 µg/dL or higher, consistent with a new blood lead reference level issued by the CDC.

Analysis of the percentages of Butte children with BLLs above the CDC level of concern during the study period (10 µg/dL) and in comparison to the current reference level (5 µg/dL) was not included in the neighborhood comparison statistical model, but was evaluated outside of the model. The same Butte blood lead data used in the model were used for the analysis of percentages; however, to address repeat measures, only the first measurement for each individual within the full study time period was included. This approach differs from how repeat measures were accounted for in the statistical model and was necessary because including repeat measures in the percentage of results that exceed 5.0 or 10.0 µg/dL would limit how well those percentages could be compared to values for other datasets.[19] Figure 20 shows the percentage of Butte blood lead results greater than the current CDC reference value for five time periods from 2003 to early December 2011. Figure 21 has the equivalent results for the percentages of BLLs greater than or equal to the prior CDC level of concern (10.0 µg/dL).

[19] In particular, since exposure reduction follow up in Butte was initiated during the 2003-2010 study period only when a confirmed blood lead result exceeded CDC's former level of concern, 10.0 µg/dL, children tested with results between 5.0 and 10.0 µg/dL, who were not referred for follow up, but may have continued to be retested periodically and would, therefore, contribute to an increase in the percentages above 5.0 µg/dL. Similarly, Butte children tested multiple times with results below 5.0 µg/dL would contribute to a decrease in the percentages that would also limit the value of comparisons to other data (i.e., national data).

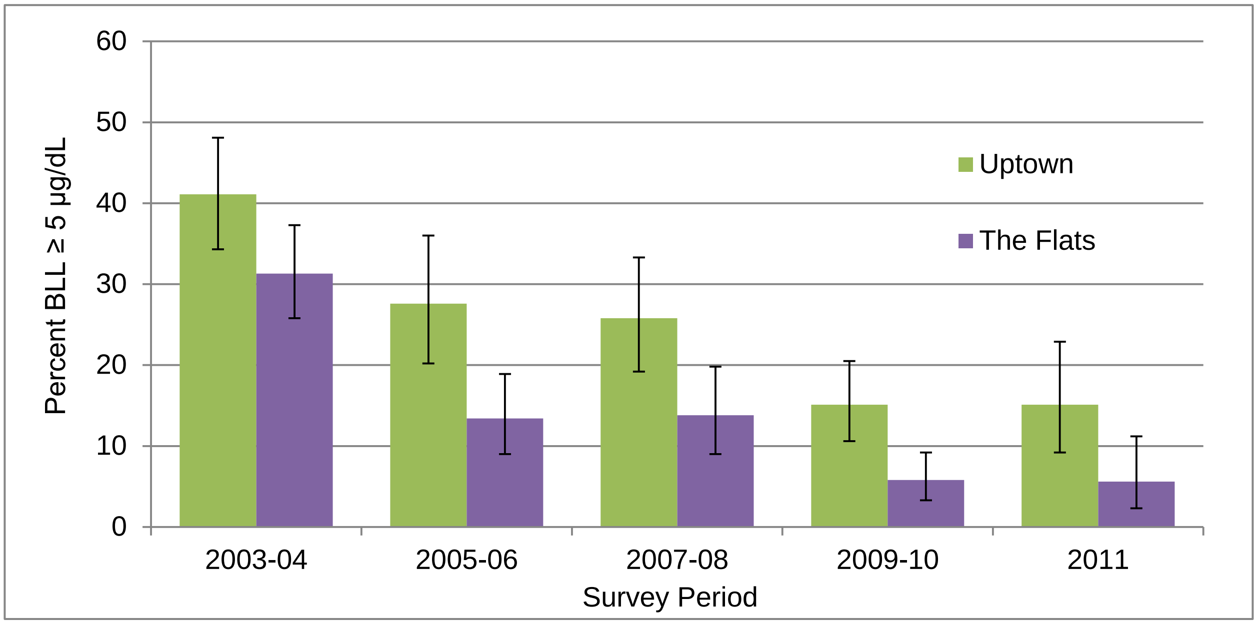


Figure 20: Percentage of Blood Lead Levels ≥ 5.0 µg/dL over Time for Uptown vs. the Flats with 95% Confidence Intervals

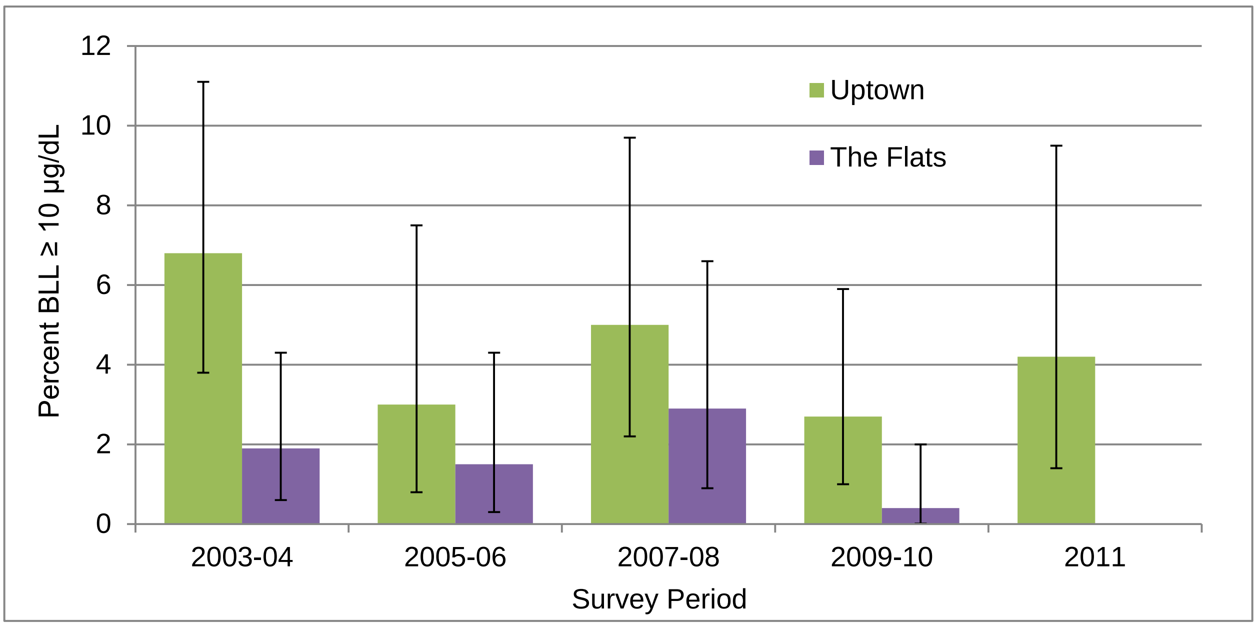


Figure 21: Percentage of Blood Lead Levels ≥ 10.0 µg/dL over Time for Uptown vs. the Flats with 95% Confidence Intervals

Consistent with the model analysis, these data suggest that higher overall BLLs in Uptown continue to be evident even with the significant decline in BLLs over time. For both Uptown and the Flats, there has been a dramatic decline in the percent of children tested with BLLs greater than 5.0 µg/dL from the earliest study test period (2003-2004) to the most recent test period (2009-2010) (Figure 20). The percent of children in Uptown with BLLs greater than 5.0 µg/dL declined from 40.6 to 15.1 percent for the 2003-2004 to 2009-2010 test periods, respectively. In the Flats, the percent greater than 5.0 µg/dL declined from 31.0 to 5.1 percent, respectively. In both areas, the percentages that exceed the CDC reference value did not decline further from the 2009-2010 test period compared to 2011.

Because BLLs greater than 10.0 µg/dL are less common, the percentages of the records above this level have fluctuated over the survey periods (Figure 21). In Uptown, the percentage has decreased from 6.8 percent to 4.2 percent above 10.0 µg/dL from 2003-2011. In the Flats, a smaller percentage of records were above 10.0 µg/dL. In the earliest survey period (2003-2004), 1.9 percent of records were above this level, and in 2011 there were no records elevated to 10.0 µg/dL. Additionally, from the most recent study period of 2009-2010, the distribution of BLLs in Uptown and the Flats is shown in Figure 22, with lines marking the values above 5.0 and 10.0 µg/dL.

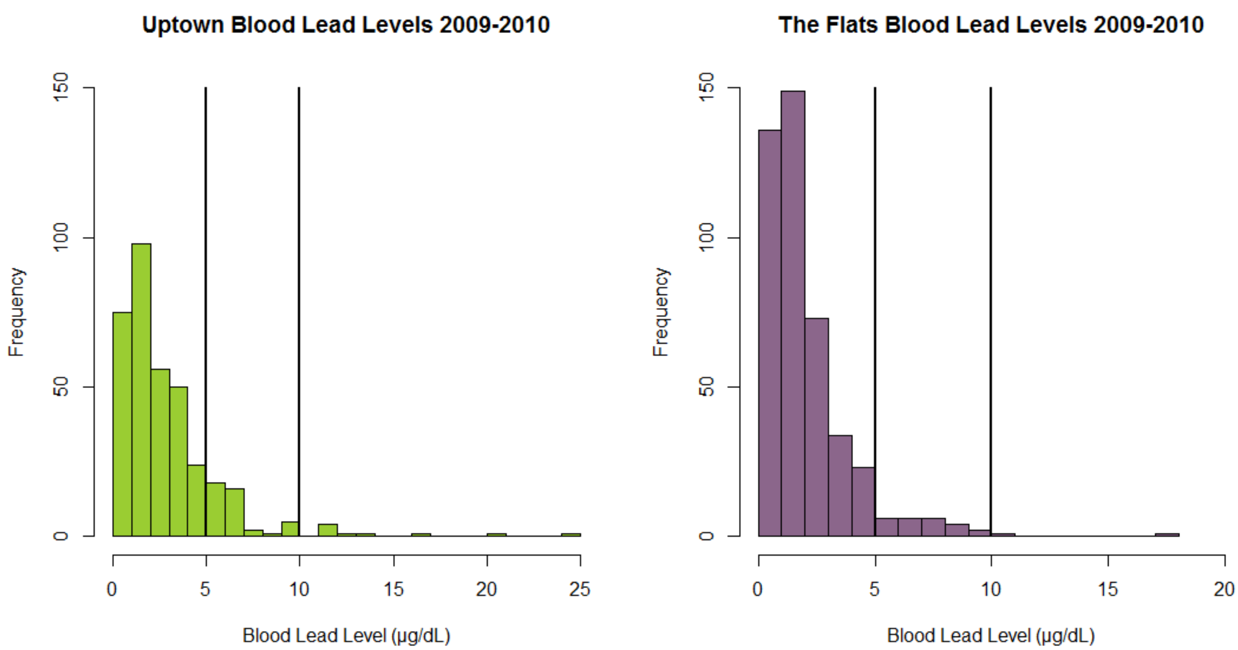


Figure 22: Blood Lead Frequency Distributions for Uptown and the Flats for 2009-2010

As with the current study, BLL differences across different areas of Butte were also identified in the 1990 Butte exposure study (summarized in section 5.1). There are considerable differences between the study design for the 1990 study vs. the current study (e.g., study purpose, geographic areas sampled, distribution of samples over all Butte neighborhoods, recruitment of the target populations, etc.), which limit direct comparison of study results. In addition, only summary data are available for the 1990 study, which prevents robust statistical comparisons of these data to the current study. Nonetheless, some additional information may be gained by looking at the magnitude of BLL differences across Butte neighborhoods in 1990 in comparison to the most recent test period (2009-2010) in the current study. While the 1990 study did not group neighborhood data by Uptown or the Flats as in this study, these areas are approximated by Areas A and G and Areas E and F, respectively, from the 1990 study. Table 18 provides summary statistics for these areas from the 1990 study, which can be used to calculate the percent difference in BLLs for the combined Areas AG vs. combined Areas EF. Geometric means for each area combined were weighted to account for significant differences in sample sizes. Area AG had a geometric mean BLL 30 percent higher than Area EF based on samples collected during August and September 1990. This compares to 38 percent higher geometric mean BLLs in Uptown vs. the Flats based on data collected during the 2009-2010 summer/fall season. Recognizing the limits to this analysis described previously, these values confirm that despite the dramatic decrease in BLLs in Butte, the difference between Uptown and the Flats persists.

6 Consideration of Supplemental Information

As described in the preceding sections, statistical analyses supporting the Butte neighborhood comparison and the Butte comparison to NHANES focused on blood lead data for Butte and NHANES without consideration of other kinds of exposure information, such as available environmental data. Similarly, comparison of the Butte data to a reference population focused on NHANES following approval of this dataset for use in the primary study analyses. However, interpretation of the primary study analyses was supplemented by consideration of environmental data from the RMAP and of available blood lead data identified during the process of selecting NHANES as the blood lead reference dataset for this study.

6.1 Consideration of RMAP Environmental Data

BSB maintains a database of residential metals sampling and abatement information as part of the RMAP. While the RMAP environmental database contains thousands of records documenting extensive assessment and abatement activities conducted within the study area, a relatively small subset of all study area properties include both blood lead and abatement records, which limited analysis of the two datasets to a neighborhood basis, rather than property-specific basis. Details about the RMAP database and its consideration in this study are summarized below.

BSB provided this database to ENVIRON in June of 2013. 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 between February 1992 and May 2013 throughout the RMAP area. BSB also publishes “Annual Construction Completion” reports that summarize RMAP activities conducted each year and/or planned for subsequent years. As of 2013, the program has sampled approximately 2,340 of 3,646 properties (64 percent).

The database includes records for 7,340 soil/dust samples (from 1,850 unique parcels), 899 paint samples (from 812 unique parcels) and 711 abatements (from 519 unique parcels). A total of 168 Butte blood lead records from the refined child dataset evaluated in this study correspond to properties that were abated through all years of the RMAP (based on matching address). These include abatements of interior dust and/or paint (including basements and attic dust) and exterior paint and/or yard soil. Of these blood lead records, 126 occurred after abatement took place at the property, 34 took place before abatement occurred, and 8 occurred at some time during the abatement process (i.e., in cases where multiple abatements had occurred at a single property). However, 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 at WIC 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 BSB.

Consideration of the environmental data contained in the RMAP was accomplished by linking each RMAP property to one of the eight study neighborhoods in Butte (N1 through N8; see Appendix D for details). While only a small number of blood lead records match the RMAP records on a property-specific level, RMAP summary statistics are based on all records available for a given neighborhood. Counts of RMAP activities for each neighborhood area (Uptown and the Flats) were then compared to provide an indicator of the intensity of exposure reduction activities conducted within each area of Butte over a specific timeframe. As shown in Figures 23 and 24, the vast majority of the RMAP activities occurred in the Uptown neighborhoods (N1, N2, N8), which are geographically closer to historic mining and ongoing mining associated with Montana Resources operations (Figure 19). Naturally-occurring mineralization is also more prevalent in Uptown than in the Flats, as well as an increased prevalence of older housing.

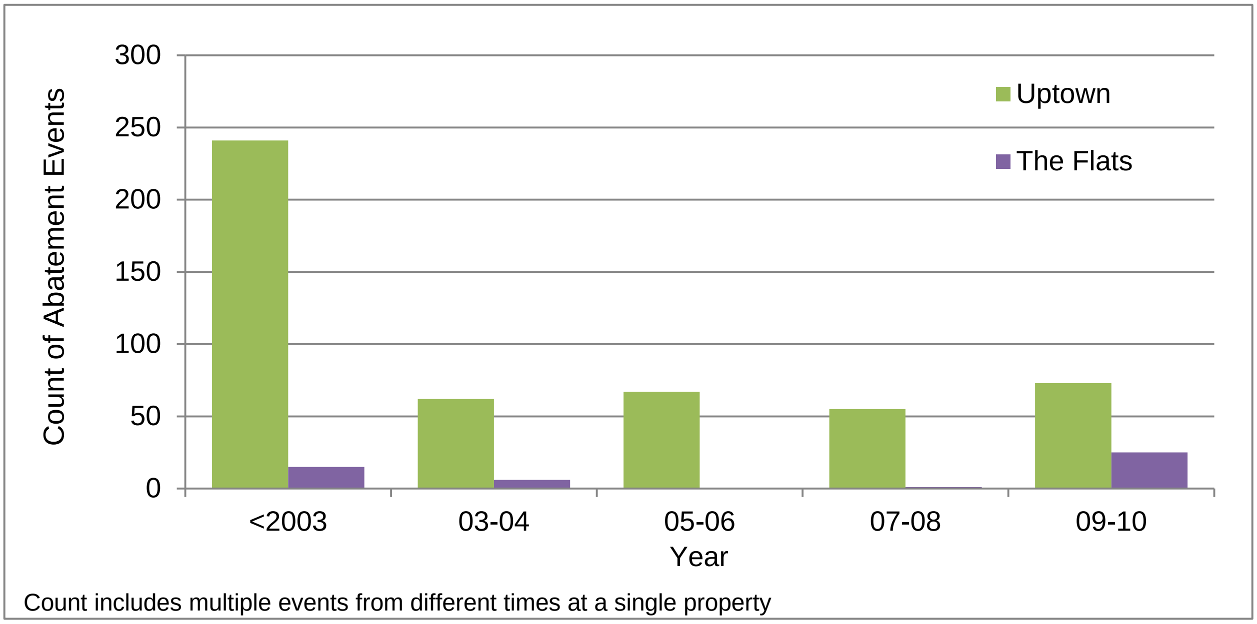


Figure 23: Count of All RMAP Abatement Events (Soil, Dust, Paint) over Time for Uptown vs. the Flats

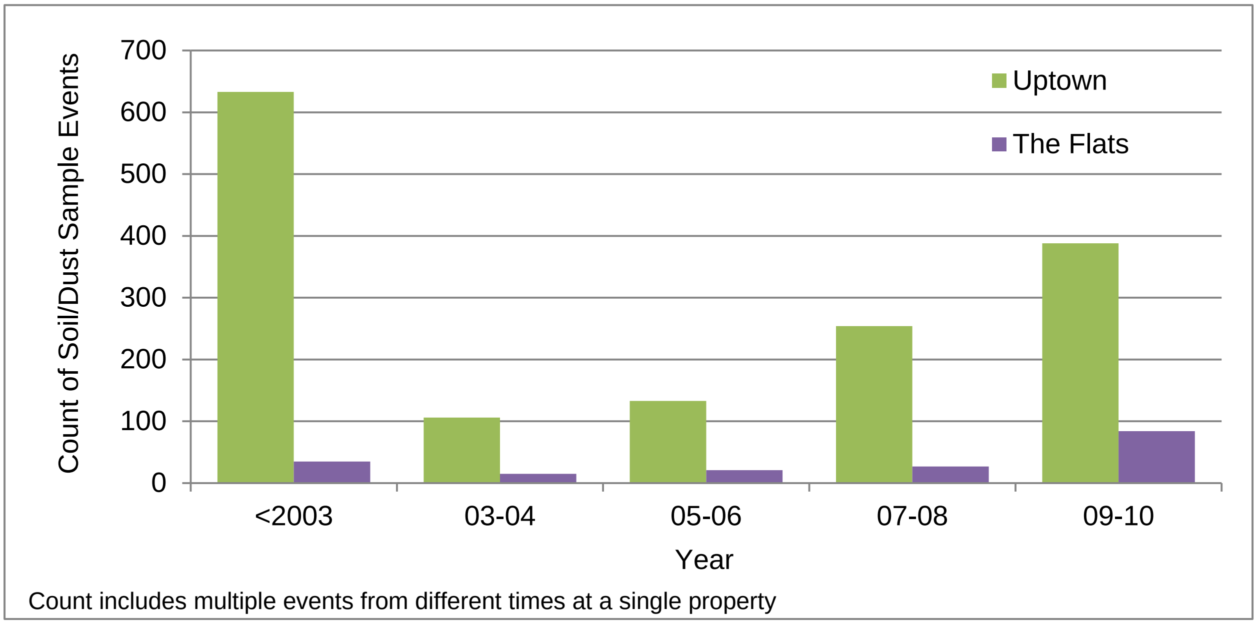


Figure 24: Count of RMAP Soil/Dust Sampling Events over Time for Uptown vs. the Flats

A trend toward increased sampling over time is evident for both areas. For Uptown, a total of 881 sampling events occurred from 2003 to 2010 versus 633 sampling events prior to 2003. 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.

Prioritization of properties addressed by RMAP is detailed in section 5.0 of the final RMAP (BSB/AR 2010), which states:

> "Residential properties shall be remediated if sampling data indicate that action levels for yard soil or interior living space dust are exceeded or for indoor air when mercury concentrations exceed the mercury vapor action level."

and,

> "The Program utilizes a prioritized approach which addresses affected and sensitive populations as a priority; however, BSB will attempt to access every property within the BPSOU and Adjacent Area, and shall carry out abatement where required by the assessment results."

The data represented in Figures 23 and 24 reflect higher numbers of abatements relative to sampling events for both Uptown and the Flats prior to 2003 (38 and 43 percent, respectively) than during the study period (29 and 22 percent, respectively). As the program prioritized properties that had the highest potential for exposures and most sensitive populations, finding a higher rate of abatements prior to 2003 is not unexpected. It is notable, however, that 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 since then, 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. Looking at these abatements more carefully, Figures 25 and 26 show the numbers of yard soil abatements and paint abatements over time for both areas. Based on these data, the proportion of paint to yard abatements is higher in the Flats than in Uptown where the ratio is closer to one. The results of the Butte neighborhood comparison model suggested that outdoor lead exposures in Uptown, including from older houses, might contribute to the higher BLLs for Uptown relative to the Flats. These RMAP abatement data further support the potential that both soil and paint are contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil to overall exposures appears to be lower.

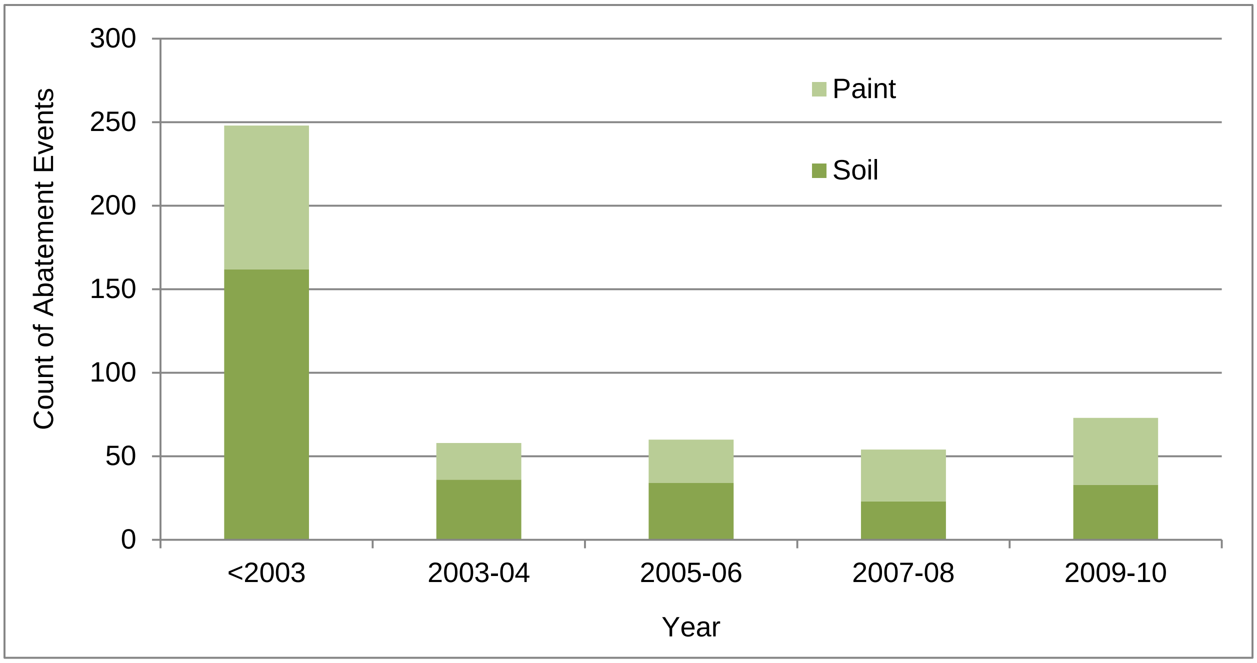


Figure 25: Abatement Events in Uptown by Type

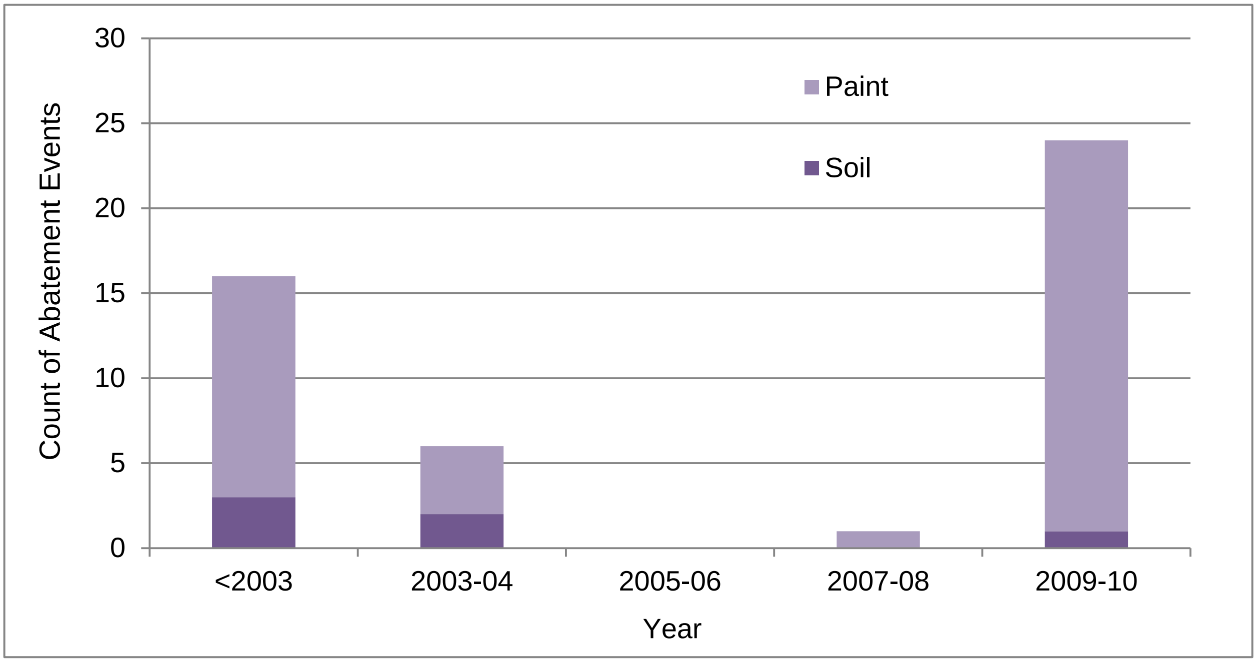


Figure 26: Abatement Events in the Flats by Type

6.2 Consideration of Community-Based Blood Lead Data

In addition to NHANES, several other community-based blood lead data sources were researched and evaluated prior to selecting NHANES for use in the health study. As described in the reference data technical memorandum (ENVIRON 2013b; Appendix E), the reference blood lead data source proposed for use in the study was intended to support assessment of whether or not the distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated. As discussed in section 4 and in the approved reference data technical memorandum, examination of the comparability of factors that may influence BLLs across datasets is an important consideration for selection of a reference blood lead data source. Such factors include demographic characteristics (e.g., gender, age, income level, etc.), age of housing stock within the community, blood lead testing and analytical methodologies, as well as whether or not a potential reference dataset has a Superfund site history similar to Butte.

The search for blood lead data from potentially comparable communities was a challenging exercise in that blood lead data were often limited or not available for communities with characteristics most closely aligned with those of Butte. Ultimately, only the NHANES data source was deemed suitable for use in the study to address the primary study objectives. However, as stated in the reference data technical memorandum: “Additional comparative analyses using subsets of some of the other reference data sources identified may also be useful for interpreting the distribution of BLLs in Butte and these will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds.” Accordingly, available raw community data obtained during the conduct of this study were re-evaluated to determine whether any could be meaningfully compared to the distribution of BLLs in Butte. Summary data (geometric means without associated confidence intervals) were available from Lake County, Colorado for 2006-2010 and from Bunker Hill, Idaho for 2007-2009, and though these were considered, the lack of information about data treatments and test population characteristics associated with these summary data limit how useful they are for interpreting the distribution of BLLs in Butte.

De-identified raw blood lead data were available only for two other datasets overlapping with the Butte study data test years and child ages. One dataset was provided by the Head Start program in Kalispell, Montana and is limited to the 2010 test year. The Kalispell data are limited to 151 children who reside in Flathead County. As with Butte, these data are from capillary sampling with a detection limit of 1.0 µg/dL. It is unknown whether any of these data represent repeat measurements for the same child. Individual results only include date of sample collection and analytical result, and do not include the age (although the likely range is 36 to 60 months) or gender of the child. Unlike Butte, Kalispell is not associated with a Superfund site and Kalispell has no known major industrial point-sources of lead. Newer housing stock in Kalispell is not comparable to distribution of home ages in Butte-Silver Bow County, with 20 percent built before 1950 in Kalispell vs. 48 percent in Butte. However, poverty levels in the tested population for the Kalispell data are likely to be higher than for the Butte dataset. This is because the income qualification for WIC in Butte is a family income equal to or less than 175 percent of the poverty level; whereas the income qualification for Head Start in Kalispell is 100 percent of the poverty level. Given these differences/uncertainties and the important influence of both poverty and house age on BLLs, it was determined that statistical comparison of the Kalispell and Butte datasets would not be useful for interpreting the distribution of BLLs in Butte.

The other raw dataset was provided by the East Helena Superfund Lead Education and Abatement Program (LEAP) and is limited to a single month, September, of the 2008 test year. The East Helena dataset is comprised of blood lead results for approximately 80 children tested at ages 1 through 5 years who resided in Lewis and Clark County. Repeat measurements are included for some children, test date is missing in a few cases, and month age or dates of birth are not included, so it is possible that some of the children tested at the age of 5 years would be outside of our study age range. This population of children lives within the area of influence of a former lead smelter and had other demographic differences from the Butte population as detailed in the reference data technical memorandum (ENVIRON 2013b). The detection limits for these data are 0.5 and 2.0 µg/dL; however, the records considered not-detected are not distinguished in the dataset. Given the availability of only a single month of data for comparison, as well as other uncertainties associated with the East Helena dataset and comparability of the tested population to the Butte study population, it was determined that statistical comparison of the Kalispell and Butte datasets would not be useful for interpreting the distribution of BLLs in Butte.

7 Conclusions and Recommendations

As described in section 1.3, the principal question to be addressed by this study is:

> Do environmental and biomonitoring data collected for the RMAP support a finding that the program has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community and, if not, what actions can be taken to improve the efficacy of the RMAP?

To address this question, this study focused on characterizing the distribution of Butte BLLs in comparison to a selected reference population (NHANES) and across Butte. With consideration of nearly 3,000 blood lead records collected from Butte children from 2003 through 2010, the primary and supplemental analyses detailed in this report were conducted to support two lines of evidence. First, whether or not the distributions of BLLs in the Butte community and in a reference population are similar over the same period evaluated. Second, whether or not statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP in BLLs across Butte neighborhoods. As detailed in the approved study work plan, evaluation of these two lines of evidence may yield one of four possible outcomes related to the following hypotheses pairs:

The null and alternative hypotheses for first line of evidence (H1) are:

$H1_0$: BLL distributions within the study population are significantly higher than BLL distributions for the comparison population based on statistical comparisons of data collected over the same time period.

$H1_A$: BLL distributions within the study population are not significantly higher than BLL distributions for the comparison population based on statistical comparisons of data collected over the same time period.

The null and alternative hypotheses for the second line of evidence (H2) are:

$H2_0$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are still evident based on more recent BLL data.

$H2_A$: Statistically significant differences in BLLs between specific neighborhoods evaluated in 1990 are no longer evident based on more recent BLL data. Unless the data analysis provides conclusive information to reject the null hypotheses for the alternative hypotheses, we assume that the null hypotheses are true.

Based on the Butte vs. NHANES comparisons described in section 4, the distribution of BLLs for Butte children are significantly higher than corresponding BLLs for the reference population (NHANES) for three of the four time periods evaluated in this study. However, for the most recent time period evaluated, 2009-2010, statistically significant differences between Butte and NHANES BLLs did not persist. Thus, this study does not provide conclusive information to reject the null hypothesis, $H1_0$, for all time periods considered except the most recent time period.

The lack of a significant difference between Butte and the NHANES reference dataset during the 2009-2010 reflects a greater rate of decline in Butte blood lead levels during the prior time periods. The specific factors causing the higher rate of decline in Butte cannot be determined based on this analysis, but such factors could include ongoing RMAP response efforts, as well as reductions in other lead exposure sources or risk factors.

Further, supplemental consideration of the frequency of blood lead results for the adjusted NHANES data for 2005-2008, the timeframe that corresponds to the NHANES data underlying the CDC blood lead reference value, suggests the potential significance of older housing and increased poverty levels in Butte on higher BLLs and supports the importance of matching blood lead risk factors such as house age, poverty, and race when seeking to explain BLL differences between two populations.

Based on the Butte neighborhood analyses described in section 5, statistically significant differences in BLLs across different Butte neighborhoods are evident over the study period evaluated. During all four study periods (i.e., 2003-2004, 2005-2006, 2007-2008, and 2009-2010) children living in neighborhoods in Uptown were found to have higher average blood lead levels than children living in the Flats. The magnitude of the neighborhood differences was similar to the difference observed in the 1990 study. Thus, this study does not provide conclusive information to reject the null hypothesis, $H2_0$.

Although the results of this study suggest a marked trend in declining BLLs in Butte over four consecutive two-year periods from 2003 through 2010, as with the 1990 lead exposure study conducted in Butte, geometric mean BLLs in Uptown were consistently higher than corresponding BLLs in the Flats and the differences were statistically significant across almost all variable categories considered in the final stratified model. The difference between Uptown and the Flats was greater during the summer when outdoor exposures would be greatest. This suggests that for Uptown children, outdoor sources of lead exposures may be more important than for children living in the Flats. Increased prevalence of older housing and mineralized zones in Uptown, as well as closer proximity to past and ongoing mining areas may all contribute to increased outdoor exposures to lead in Uptown relative to the Flats. Supplemental evaluation of the RMAP abatement data further supports the potential that both soil and paint are contributing to higher lead exposures in Uptown, while in the Flats, the relative contribution of soil to overall exposures appears to be lower. Despite the higher BLLs in Uptown vs. the Flats, the rate of decline in BLLs across all of Butte has been considerable over time and is not statistically different between Uptown and the Flats.

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. Based on the findings of this study, we recommend BSB consider the following to assure the RMAP's continued effectiveness in identifying and reducing lead exposures in the Butte Priority Soils Operable Unit:

1. Continue to follow the CDC recommendations for confirming screening blood lead test results by venous sampling if greater than 5 µg/dL and update the screening value used when/if the CDC reference value is updated in the future. We understand that the WIC program began referring children with BLLs above 5 µg/dL for confirmation testing during March 2013. The results of the confirmation testing should be included in the blood lead database to ensure that appropriate follow up occurs.

2. 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. The ability to characterize the trends is needed to continue to track the effectiveness of the RMAP.

3. Improve procedures for electronic data collection and maintenance to facilitate increased tracking and follow-up of individuals over time who have confirmed BLLs exceeding the CDC reference value. Documented procedures and instructions are needed to ensure consistency over time and with staff changes. Consistency will support better tracking and follow up.

4. 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.

5. 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.

6. Improve the consistency with which complete blood lead records are collected, regardless of blood lead testing referral source (i.e., RMAP vs. WIC vs. pediatrician). Currently, blood lead records are only consistently compiled from RMAP and the WIC program, with other records being added on an ad hoc basis. A program to ensure that records are also obtained regularly from all doctors and clinics would provide a more robust view of BLLs in Butte and would facilitate tracking of children tested multiple times.

7. To the extent legally possible, consider collection of additional information from blood lead tested individuals that will improve interpretation of community BLL trends going forward (e.g., race, maternal education, household income level). Due to the strong correlation of some of these factors on BLLs, interpretation of differences in BLLs was limited by the lack of child-specific information on factors such as poverty levels and race. Maternal education is another factor known to be correlated with BLLs that we were not able to examine in this study. A review of relevant factors and evaluation of the feasibility of collecting additional socio-economic and demographic information should be considered.

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Appendix A

Summary of Silver Bow County Cancer Incidence and Mortality Study (MDPHHS 2012)

Summary of Silver Bow County Cancer Incidence and Mortality Study (MDPHHS 2012)

As part of the first phase of the Superfund-related health studies and to address broader community concerns, the Working Group identified the need for an update to and expansion of a 2001 ATSDR review of Silver Bow County cancer incidence rates compared to similar data for Montana and the U.S. (ATSDR 2002). The 2002 ATSDR analysis focused on cancer outcomes associated with exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury. Update of the ATSDR study aligns with public health study activities specified in the RMAP and was prioritized to address heightened concerns about elevated cancer mortality rates in Butte expressed by community members during public listening sessions.

The updated study was conducted by the MDPHHS and included consideration of the most common cancers, as well as cancers associated with exposure to metals present in Butte. The health study Working Group did not provide input to or comment on the state's report (MDPHHS 2012). The MDPHHS study (2012) is attached along with the ATSDR (2002) study. A summary of the MDPHHS (2012) approach and findings is provided below.

In May 2012, MDPHHS, evaluated cancer incidence and mortality among BSB residents using data from Montana death records and the Montana Central Tumor Registry (MCTR). Cancer incidence and mortality rates among BSB residents were compared to state and national rates to assess whether or not cancer is elevated in BSB. Cancers which are diagnosed or treated among Montana residents are required, by state law, to be reported to the MCTR. Similarly, all deaths which occur among Montana residents are also to be reported to MDPHHS. It is estimated that MDPHHS has records of over 95% of all cancers and deaths which occur among Montana residents.

According to MDPHHS, the best way to assess the effects of environmental exposure on cancer risk in humans 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 actually a general term which 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 specific heavy metals of concern in BSB are lung and bronchus cancer, bladder cancer, kidney cancer, and liver cancer.

ATSDR Agency for Toxic Substances & Disease Registry Public Health Assessments & Health Consultations

HEALTH CONSULTATION

SILVER BOW CREEK/BUTTE AREA
BUTTE, SILVER BOW AND DEER LODGE COUNTIES, MONTANA

INTRODUCTION

In June 2001, the Montana Department of Public Health and Human Services (MDPHHS) requested that the Agency for Toxic Substances and Disease Registry (ATSDR) evaluate cancer incidence data for Silver Bow County. The MDPHHS and Silver Bow County Health Department have had reports of possible cancer excesses from residents and physicians in the area for many years. This analysis focused on cancer outcomes associated with exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury.

Historically, elevated environmental levels of numerous heavy metals have been found in Silver Bow County soils as a result of mining and milling practices in the area. The Silver Bow Creek/Butte Area National Priorities List (NPL) site is an extensively contaminated site located in Silver Bow and Deer Lodge Counties. ATSDR has issued numerous documents related to this NPL site including health assessments, site review and updates, and health consultations. The agency has also conducted various health studies and exposure investigations in the Silver Bow area.

The purpose of this data review is to compare cancer incidence rates from Silver Bow County with similar data at the State and national levels. This ecologic analysis does not include any exposure information. Instead, it relies solely on cancer incidence data from state and national cancer registries and population demographic data from the U.S. Census Bureau.

MATERIALS/METHODS

The Montana Central Tumor Registry provided cancer incidence data to ATSDR in the summer of 2001. This data described all newly diagnosed cases occurring in Silver Bow County and the entire state of Montana during the twenty-one year period from 1979 to 1999. Specific cancer sites analyzed included the urinary bladder, kidney, liver, lung, prostate, and skin. Skin cancers used in this analysis included malignant melanomas as well as nonmelanomas. These outcomes were chosen because of their reported associations with arsenic exposure [1]. Mercury is not considered a human carcinogen and therefore did not influence the choice of cancers being analyzed [2]. There is limited information on the potential for lead to cause cancer so this contaminant also had little influence on the cancer sites analyzed [3].

Standardized incidence ratios (SIRs) were calculated using two comparison groups. The comparison groups included the entire state of Montana and a representative portion of the United States population. The Montana Central Tumor Registry provided cancer incidence data for the state of Montana for the years 1979 to 1999. Cancer incidence data for the United States were obtained from the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) program. The SEER program collects and publishes cancer incidence and survival data from 11 population-based cancer registries and three supplemental registries covering approximately 14 percent of the U.S. population. The SEER data used for comparison in this analysis included cancer incidence from 1989 to 1998.

Cancer incidence data for Silver Bow County and the two comparison populations were standardized using four age groupings; 20-54, 55-64, 65-74, and 75 and over. These predefined age groupings are used in publicly available SEER datasets. Age standardization eliminated the effects of age differences among residents of Silver Bow County, the state of Montana, and the United States as a whole. Cancer incidence rates for the state of Montana were adjusted using 1990 Census Bureau data. United States (SEER) incidence data were adjusted using the standard 1970 U.S. population.

RESULTS

Skin cancer was the only outcome that demonstrated elevated rates when compared to both Montana and U.S. reference populations (Table 1, Table 2). The SIR for all persons age 20 and over when compared to the state of Montana was 1.23 (95% CI, 1.04-1.44) and compared to the U.S. population was 1.24 (95% CI, 1.05-1.45). There were also elevated SIRs within multiple age-specific categories for skin cancer when compared with both reference populations.

Other cancer outcomes including urinary bladder, kidney, and lung demonstrated elevated rates in some age-specific categories but these elevations were not consistent when compared with both reference populations. Liver and prostate cancer rates were not elevated when compared with either reference population.

DISCUSSION

A previous ecologic analysis of skin cancer rates in Silver Bow County and neighboring Deer Lodge County by Wong et al. failed to show any significant increases in cancer morbidity [4]. However, their analysis used only six and one-half years of cancer incidence data (1980 to mid-1986) and this analysis looked at cancer incidence over a much longer time frame (1979-1999). Wong et al. identified all skin cancer cases through area pathologists and dermatologists, a less effective method compared with the use of data obtained from the state's central tumor registry. Case ascertainment in this analysis should be significantly increased through the use of registry data.

There are numerous limitations to this ecologic analysis including the potential for in- and out-migration of cases, a lack of exposure data, and no 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). This analysis measured skin cancer incidence in aggregate instead of distinguishing between the two distinct forms of this disease, malignant melanoma and nonmelanoma. Nonmelanoma is the only type of skin cancer that has been associated with arsenic exposure [5]. However, none of these limitations should consistently bias SIRs towards positive or negative associations.

Another limitation in interpreting the apparent elevation in skin cancer incidence is the demographic difference between Silver Bow County and the U.S. comparison population. Both malignant melanoma and nonmelanoma skin cancers are much more common in white populations. There is a higher percentage of Caucasians in Montana in contrast to the U.S. Therefore, some increase in skin cancer in the Montana population can be expected when compared to the total U.S. population. However, the demographics of Silver Bow County and Montana are fairly similar so this does not explain the elevated SIRs generated through comparisons with state cancer incidence data.

The process for age-adjusting cancer rates in Silver Bow County and Montana were similar as was the time frame for comparison (1979-1999). In comparing Silver Bow County with U.S. rates, there were some discrepancies. The analysis used different time frames of cancer incidence data for Silver Bow County (1979-1999) and the U.S. reference population (1989-1998). Also, there was a difference in the age-adjustment process with the U.S. reference group standardized using the 1970 U.S. population. These discrepancies in age standardization were unavoidable since NCI does not provide the raw data collected through the SEER program.

Even with these limitations and the minor differences in age standardization methods, there appears to be a slight increase in skin cancer incidence in this area of widespread arsenic contamination. Historically, skin and lung cancer have been the most prevalent cancer outcomes associated with arsenic exposure in the public health literature. Unfortunately no dose estimates were available for this analysis so the slight increase in skin cancer incidence cannot be evaluated against potential arsenic exposure in the area.

CONCLUSION

The data indicate a slightly elevated incidence of skin cancer in Silver Bow County when compared with age-standardized rates at the State and national level. No other cancer outcomes were consistently elevated when compared with these two reference groups. The slight increase in skin cancer incidence cannot be directly attributed to soil arsenic contamination in the area since no exposure assessments were included in this analysis.

RECOMMENDATIONS

1. Evaluate melanoma and nonmelanoma skin cancer incidence separately since only nonmelanoma skin cancers are associated with arsenic exposure.
2. Educate local citizens on ways to reduce or eliminate exposure to ambient arsenic contamination.
3. Educate local physicians on the symptoms, effects, and treatment regimes for arsenic exposure.
4. Consider reviewing pre-1979 cancer statistics to determine if cancer incidence was elevated prior to the time frame used in this analysis.

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TABLES

Urinary Bladder Table 1.

Standardized Incidence Ratios using the Montana Population as a Reference, 1979-1999

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	1	11.2	0.09	0.00	0.50
55-64	18	23.6	0.76	0.45	1.21
65-74	90	50.5	**1.78¶**	1.43	2.19
75+	68	61.7	1.10	0.86	1.40
20+ (all ages combined)	177	147.0	**1.20¶**	1.03	1.40

Kidney

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	9	12.5	0.72	0.33	1.23
55-64	15	14.9	1.00	0.56	1.56
65-74	30	22.9	1.31	0.88	1.81
75+	34	18.6	**1.83¶**	1.27	2.48
20+ (all ages combined)	88	68.9	**1.28¶**	1.02	1.56

Liver

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	2	1.8	1.11	0.12	4.01
55-64	5	2.0	2.50	0.81	5.83
65-74	6	4.9	1.22	0.45	2.67
75+	10	5.9	1.69	0.81	3.12
20+ (all ages combined)	23	14.6	1.58	1.00	2.36

Lung

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	57	40.2	**1.42¶**	1.07	1.84

55-64	127	110.6	1.15	0.96	1.37
65-74	210	194.2	1.08	0.94	1.24
75+	159	148.5	1.07	0.91	1.24
20+ (all ages combined)	553	493.5	**1.12¶**	1.03	1.22

Prostate

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	11	14.5	0.76	0.38	1.24
55-64	87	91.5	0.95	0.76	1.03
65-74	212	232.3	0.91	0.79	1.04
75+	209	213.5	0.98	0.85	1.12
20+ (all ages combined)	519	551.8	0.94	0.86	1.02

Skin

Age Categories	Observed	Expected	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
65-74	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

Table 2.

Standardized Incidence Ratios using the U.S. population (SEER) as a Reference, 1979-1999

Urinary Bladder

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	1	15.2	0.07	0.00	0.37
55-64	18	28.5	0.60	0.37	1.00
65-74	90	62.8	**1.40¶**	1.15	1.76
75+	68	76.3	0.89	0.69	1.13
20+ (all ages combined)	177	182.8	0.97	0.83	1.12

Kidney

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	9	14.9	0.60	0.28	1.03
55-64	15	18.8	0.80	0.45	1.23
65-74	30	29.0	1.04	0.70	1.43
75+	34	27.0	1.26	0.87	1.71
20+ (all ages combined)	88	89.7	0.98	0.79	1.20

Liver

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI

20-54	2	5.2	0.39	0.04	1.39
55-64	5	7.0	0.71	0.23	1.66
65-74	6	12.3	0.49	0.18	1.06
75+	10	13.6	0.74	0.35	1.35
20+ (all ages combined)	23	38.2	0.60	0.38	0.90

Lung

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	57	53.2	1.07	0.81	1.39
55-64	127	118.4	1.07	0.89	1.28
65-74	210	226.7	0.93	0.81	1.06
75+	159	195.0	0.82	0.69	0.95
20+ (all ages combined)	553	593.3	0.93	0.86	1.01

Prostate

Age Categories	Observed	Expected	SIR	Lower 95% CI	Upper 95% CI
20-54	11	51.5	0.21	0.11	0.35
55-64	87	251.5	0.35	0.28	0.42
65-74	212	668.9	0.32	0.28	0.36
75+	209	666.2	0.31	0.27	0.36
20+ (all ages combined)	519	1638.25	0.32	0.29	0.34

Skin

Age Categories	Observed	Expected	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
65-74	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

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Cancer Incidence in Silver Bow County, Montana, and the United States

MONTANA
CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION BUREAU

Figure 1. Age-adjusted incidence rate of all-site cancer, Silver Bow County, Montana and the U.S.

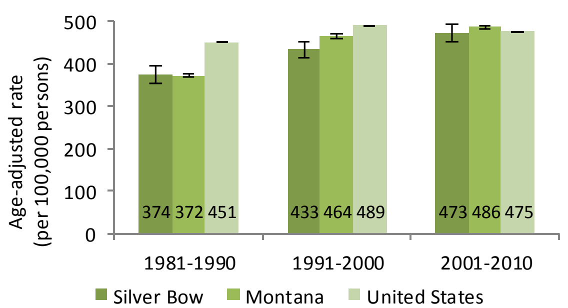
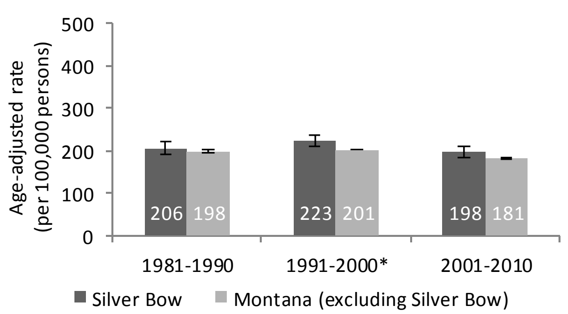


Figure 2. Age-adjusted mortality rate of all-site cancer, Silver Bow County and Montana



Cancer is a common disease in Montana and the United States. Approximately, 5,000 Montanans are diagnosed with cancer each year. A person can develop cancer for many reasons: genetics, environmental exposures, and life style behaviors (such as cigarette smoking, drinking alcohol, etc.). Unfortunately, however, it is often difficult to determine the exact cause for an individual's cancer.

The State of Montana has very complete data on cancer incidence. Cancer incidence is the number of newly diagnosed cancer cases each year. This data comes from the Montana Central Tumor Registry (MCTR). State law requires every case of cancer that is diagnosed or treated in Montana be reported to the MCTR (Montana Code Annotated 50.15.7). The MCTR has been collecting cancer data since 1979. The MCTR is very complete, over 95% of all cancer cases are in the registry.

Cancer incidence data for Montana and Silver Bow County was provided by the Montana Central Tumor Registry. Caner incidence data for the United States was provided by the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) program. Data on cancer mortality was provided by the Montana Office of Vital Statistics. All incidence and mortality rates in this report are age-adjusted to the U.S. Standard Million Population.

The incidence of cancer for all sites was the same among residents of Silver Bow County compared to the residents of the state of Montana (Figure 1). The U.S. all-site cancer incidence rate was higher than both Silver Bow County and Montana during the diagnosis period of 1981-1990 and 1991-2000 (Figure 1). The U.S. incidence rate was the same as Silver Bow County and Montana during the diagnosis period of 2001-2010 (Figure 1).

Mortality due to cancer (all-site) was the same in Silver Bow County as the rest of Montana for the periods 1981-1990 and 2001-2010 (Figure 2). The all-site cancer mortality rate for the period 1991-2000 was higher in Silver Bow County than the rest of Montana (Figure 2).

MT Cancer Surveillance & Epidemiology Program

1400 E Broadway

Helena, Montana 59260-2951

(406) 444-0064

http://www.dphhs.mt.gov/publichealth/cancer/datastatistics.shtml

MONTANA
Department of Public Health & Human Services

May 2012

Figure 3. Incidence of prostate cancer among residents in Silver Bow County, Montana, and the U.S.

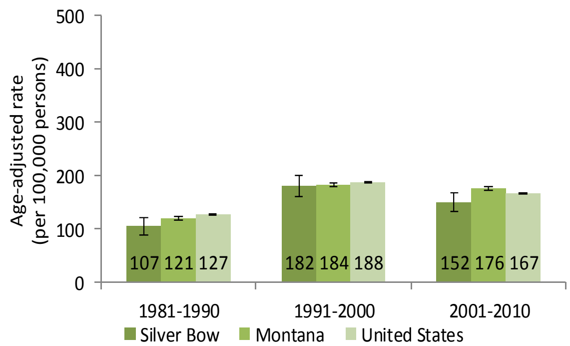


Figure 4. Incidence of breast cancer among female residents of Silver Bow County, Montana, and the U.S.

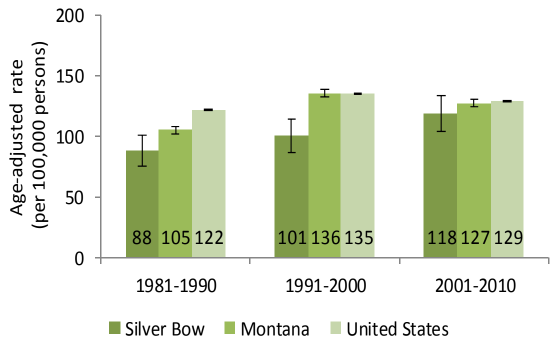


Figure 5. Incidence of colorectal cancer among residents of Silver Bow County, Montana, and the U.S.

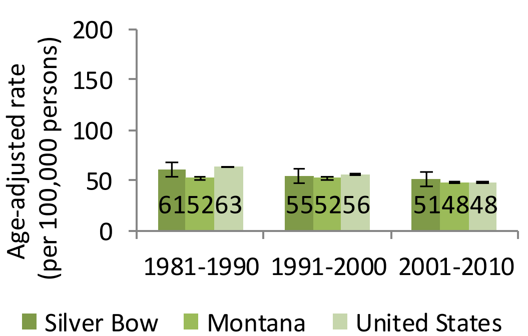
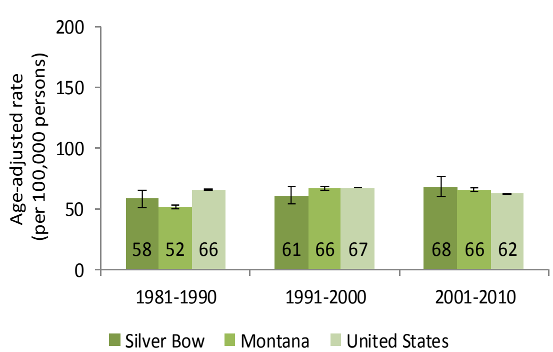


Figure 6. Incidence of lung & bronchus cancer among residents in Silver Bow County, Montana, and the U.S.



Incidence of the Most Common Cancers

The most common types of cancer in Silver Bow County are also the most common in Montana and in the United States. None of these cancers (except for lung cancer) are known to be affected by the heavy metals or chemicals of concern in Silver Bow County. Lung cancer is also associated with arsenic exposure. However the majority of lung cancer cases are caused by cigarette smoking (87% of cases among men and 74% of cases among women).

Prostate Cancer Incidence

Prostate is the most diagnosed cancer in Montana and in the US. The incidence of prostate cancer among residents of Silver Bow County was the same as Montana and the United States for the time intervals 1981-1990 and 1991-2000 (Figure 3). From 2001-2010, the incidence rate in Silver Bow County was lower than Montana (Figure 3).

Female Breast Cancer Incidence

The incidence of female breast cancer among residents of Silver Bow County was lower than Montana and the United States for the time periods 1981-1990 and 1991-2000 (Figure 4). From 2001-2010, the incidence rate in Silver Bow County was the same as Montana and the United States (Figure 4).

Colorectal Cancer Incidence

The incidence of colorectal cancer among residents of Silver Bow County was the same as Montana and the United States for all three time intervals (Figure 5).

Lung & Bronchus Cancer Incidence

The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time intervals (Figure 6).

Mortality of the Most Common Cancers

Prostate Cancer Mortality
Mortality due to prostate cancer among residents of Silver Bow County was the same as Montana for all three time intervals (Figure 7).

Female Breast Cancer Mortality
Mortality due to female breast cancer among residents of Silver Bow County was the same as the rest of Montana for all three time intervals (Figure 8).

Colorectal Cancer Mortality
Mortality due to colorectal cancer among residents of Silver Bow County was higher than the rest of Montana for all three time intervals (35% higher in 1981-90, 50% higher in 1991-00, and 50% higher in 2001-10) (Figure 9).

Lung & Bronchus Cancer Mortality
Mortality due to lung & bronchus cancer was the same among residents of Silver Bow County as the rest of Montana for all three time intervals (Figure 10).

Figure 7. Mortality of prostate cancer among residents in Silver Bow County and Montana

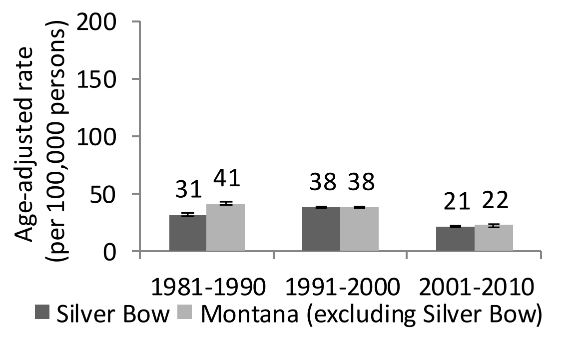


Figure 8. Mortality of female breast cancer among residents of Silver Bow County and Montana

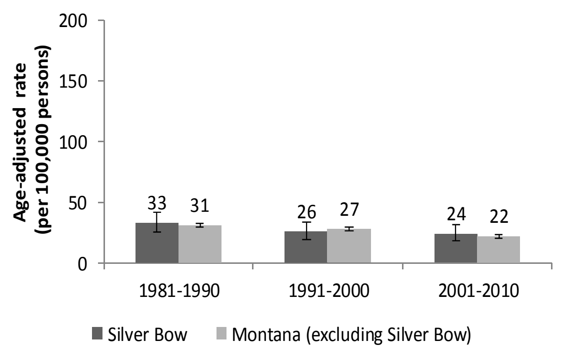


Figure 9. Mortality of colorectal cancer among residents of Silver Bow County and

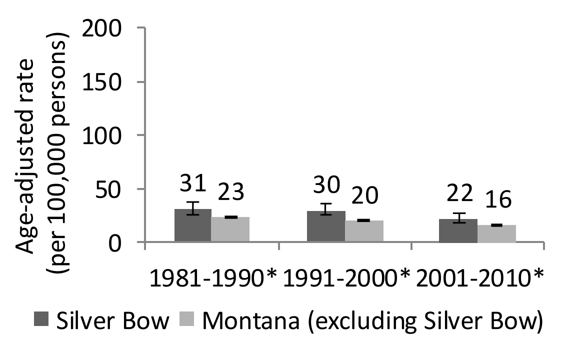


Figure 10. Mortality of lung & bronchus cancer among residents in Silver Bow County

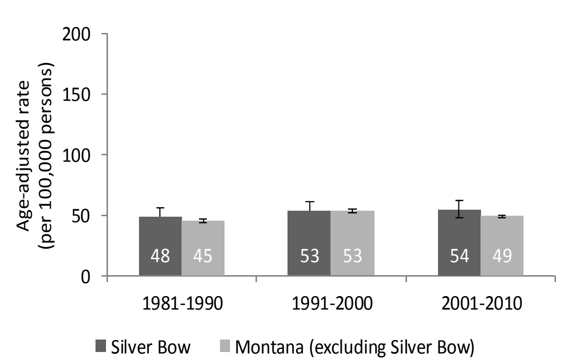


Figure 11. Incidence of bladder cancer among residents of Silver Bow County, Montana, and the U.S.

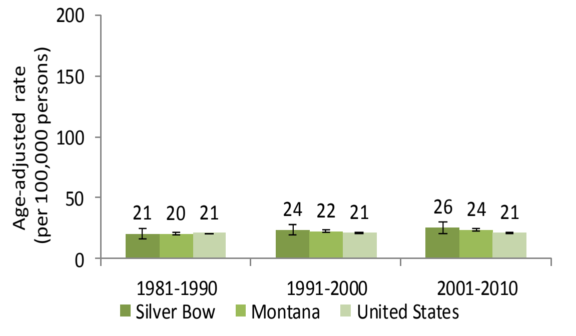


Figure 12. Mortality of bladder cancer among residents of Silver Bow County and Montana

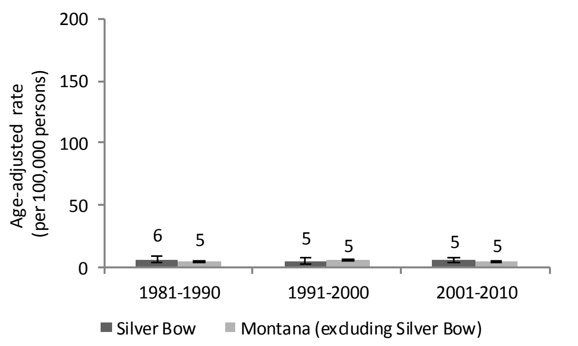
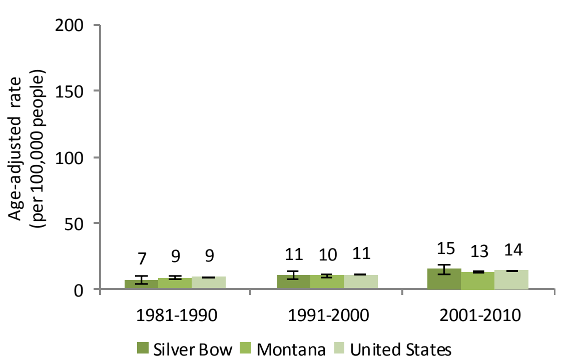


Figure 13. Incidence of kidney cancer among residents of Silver Bow County, Montana, and the U.S.



Cancers associated with Environmental exposures

Assessing cancer risk of humans due to exposure to environmental compounds requires the review of multiple scientific studies. These studies assess cancer risk in humans, animals, and in the laboratory. National and international agencies use the results of these studies to classify environmental compounds as to their cancer-causing potential. The International Agency for Research on Cancer (IARC) and the Agency for Toxic Substances and Disease Registry (ATSDR) have classified the carcinogenicity of the following heavy metals and chemical of concern in Silver Bow County:

Arsenic: *Carcinogenic to humans (Group 1)*
Inorganic Lead: *Probably carcinogenic to humans (Group 2A)*
Organic Lead: *Not classifiable as to its carcinogenicity to humans (Group 3)*
Metallic Mercury & Inorganic Mercury: *Not classifiable as to its carcinogenicity to humans (Group 3)*
Methylmercury compounds: *Possibly carcinogenic to humans (Group 2B)*
Pentachlorophenol (PCP): *Possibly carcinogenic to humans (Group 2B)*

Arsenic Exposure

Cancers known to be associated with arsenic exposure (via food or water contamination) include lung & bronchus, bladder, kidney, and skin cancer (squamous cell carcinoma). Squamous cell carcinoma of the skin is not a reportable cancer by Montana State Law. The MCTR does not have complete data on the incidence of this type of skin cancer, therefore it is not reported here.

Lung & Bronchus cancer

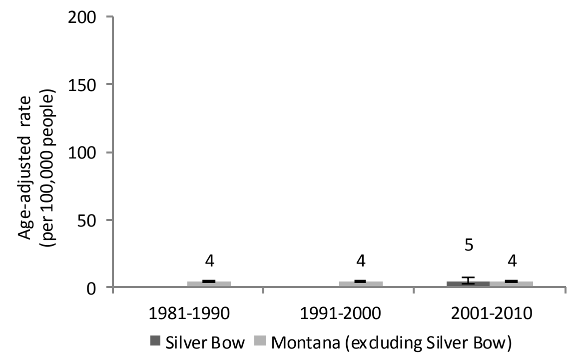
The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time periods (Figure 6). Mortality due to lung & bronchus cancer was the same among residents of Silver Bow County and as the rest of Montana for all three time intervals (Figure 10).

Bladder Cancer

The incidence of bladder cancer among residents of Silver Bow County is the same as Montana and the United States during each of the three time periods (Figure 11). Mortality due to bladder cancer was the same in Silver Bow County as the rest of Montana for three time intervals (Figure 12).

Kidney Cancer
The incidence of kidney cancer among residents of Silver Bow County is the same as Montana and the United States during each of the three time periods (Figure 13). There were too few deaths due to kidney cancer in Silver Bow County during the time intervals 1981-90 and 1991-00 to compute a rate (14 and 16 deaths, respectively). From 2001-2010 mortality due to kidney cancer in Silver Bow County was the same as the rest of Montana (Figure 14).

Figure 14. Mortality of kidney cancer among residents of Silver Bow County and Montana



Pentachlorophenol (PCP) Exposure

Pentachlorophenol is possibly carcinogenic to humans (Group 2B). There is inconclusive evidence of cancer in humans. However, increases in liver, adrenal gland, and nasal tumors have been found in lab animals. Cancers of the adrenal gland and the nasal cavity had too few cases in Silver Bow County to report.

Liver Cancer
The incidence of liver cancer was the same among residents of Silver Bow County, Montana and the United States during the time intervals of 1991-00 and 2001-10 (Figure 15). There were too few cases of liver cancer during the1981-90 time interval to calculate a rate. There were too few deaths due to liver cancer in Silver Bow County to calculate a rate during all three time intervals. The mortality rate of liver cancer in Montana remained the same during all three time intervals (Figure 16).

Figure 15. Incidence of liver cancer among residents of Silver Bow County, Montana, and the U.S.

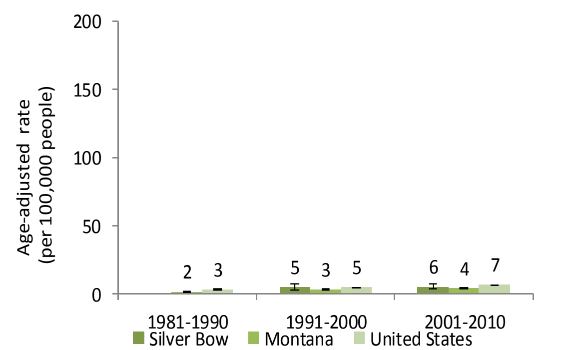
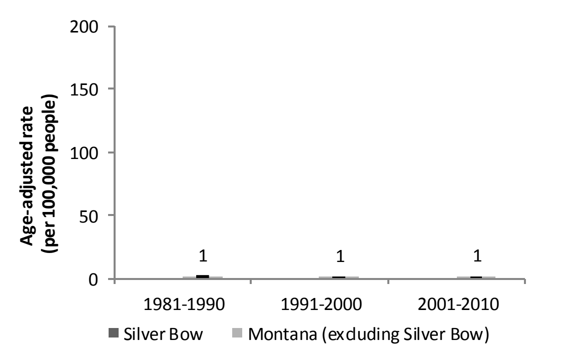


Figure 16. Mortality of liver cancer among residents of Silver Bow County and Montana



Appendix B

Response Summary for Comments Received on the Draft Final BPSOU Public Health Study, Phase 1 Report

Response Summary for Comments Received on the Draft Final Butte Priority Soils Operable Unit (BPSOU) Public Health Study, Phase 1 Report

Conduct of the Butte Priority Soils Operable Unit Public Health Study, Phase 1, (hereafter, "the Butte health study") included a release of a draft final report for public review and comment. The draft final report was released by EPA on February 28, 2014 commencing a 60-day public comment period that ended on April 29, 2014. Additionally, during a public meeting held at the Mining City Center's Copper Auditorium on April 9, 2014, study investigators and collaborators provided more information about the study and were available to answer questions from community members. Questions posed by community members attending the public meeting were responded to by the study representatives during the "Question and Answer" portion of the meeting or during one-on-one interactions with the study representatives during the "Open House" portion of the meeting. Comment cards were also made available during the meeting for those wishing to submit comments in writing.

A total of four individuals submitted written comments on the ("draft final report") in relation to the Butte health study public comment period. One of these commenters submitted suggestions for edits to the draft final report. Another commenter submitted two comment sets, each with unique questions to be addressed. The third commenter submitted a single comment on a comment card at the April 9, 2014 public meeting. The final commenter submitted a total of 19 separate sets of comments; however, many of the same comments or comment themes were repeated throughout the submittals.

To ensure responses to individual commenter's comments are easily located, comment responses provided below are grouped by individual commenter. Original comment submittals are provided as Attachment 1 to this response summary. Names of each commenter have been omitted from this summary and Attachment 1.

Commenter 1: This commenter submitted comments via an email that suggested the following revisions to the Public Health Statement included at the beginning of the draft final report:

1. "After the first three bullets, consider a concluding statement like, 'The understanding gained is applied toward making recommendations for improving the RMAP program.'"

Response: Suggested revision has been made.

2. "Your second header, 'Blood lead levels provide…' is not addressed by the text. That is, you don't explain why blood lead is a good indicator of exposure. Also, too, the goals and standards are brought in rather late in the summary, and could be brought into a new paragraph here that addresses the header. I would add that there is no known beneficial effect of exposure, that the goal is no exposure but that there are standards (5 for CDC, 10 for EPA). The text is good, but maybe needs a different header."

Response: To better represent the content presented in that section, the header has been revised to: "The Study Focus on Blood Lead Ensures Consideration of All Sources of Lead Exposure in Butte, including Superfund-related Sources."

3. "Third header, revise to: '…Levels in Butte Have Declined…'"

Response: Suggested revision has been made.

4. "Page iii, second full paragraph, last sentence. Edit to: '…cannot be identified conclusively proven based on this analysis…reductions in other lead exposures achieved through other government programs.'"

Response: The sentence has been revised to: "The specific factors causing the higher rate of decline in Butte cannot be conclusively proven based on this analysis, but the factors could include ongoing RMAP response efforts and reductions in other lead exposure sources."

5. "Header on page iv, revise to: 'The RMAP ~~has been~~ continues to be and important…'"

Response: The phrase has been changed to "The RMAP continues to be an important…"

Commenter 2: This commenter submitted two sets of comments via email. Comments sought information about a variety of concerns in Butte, including:

1. "I could not look at all of the references, so excuse me if this was answered. What are the other concerns that will degrade (have degraded) the health of citizens? Lead seems to be the focus of the report. What about arsenic, mercury and other metals in the environment? Is asbestos an issue? Specifically, lead paint is unrelated to mining. What are mining related issues and how well do we understand them? And attempt to control them?"

Response: The commenter's questions align well with information presented in section 2 of the EPA-approved work plan for the Butte health study, which details the study basis and design, including a summary of broader concerns raised by the public during scoping for the Butte health study, how those have or are being addressed. Specifically, the approved work plan described how:

> *…implementation of the public health studies will occur in an iterative manner with subsequent phases of proposed study to be guided by the findings of prior phases (Figure 1). As part of planning for the initial study phase, the Working Group identified two primary goals to be considered in design of the public health study. The first goal relates to Superfund and is to evaluate whether the RMAP has been effective in identifying and mitigating potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. The second broader goal is to review community health concerns or actions to help BSB focus on pathways to improve public health. This work plan focuses on the first study goal. Specifically, related to the Superfund program and aligned with public health study activities specified in the RMAP, the Working Group team identified evaluation of available RMAP blood lead biomonitoring data collected through 2011 as a priority for inclusion in the first phase of the public health studies.*

…With regard to the second goal (i.e., to review community health concerns or actions to help BSB focus on broader public health improvement efforts), the Working Group identified the following needs:

- *An updated evaluation of cancer incidence and mortality rates in Silver Bow County compared to state and national levels, including cancers associated with environmental exposures to contaminants of concern in Butte. This evaluation supports the Superfund-related health studies described in the UAO.*
- *A series of fact sheets addressing topics of interest to the Butte community. Some of these fact sheets directly support the Superfund-related health studies efforts, while others support efforts being conducted outside of the Superfund health studies.*
- *A focused air quality study in response to specific community concerns that do not relate to Superfund.*

With regard to the last bullet above, the approved work plan further described:

… During initial planning team discussions and community outreach sessions, a number of health concerns (e.g., asthma prevalence and poor air quality) were identified by members of the Butte community. For phase 1, evaluation of long-standing concerns by BSB residents regarding air quality in the Summit Valley is planned. Because management of regional air quality issues and other environmental conditions related to many of these public health concerns rests with BSB and/or MDEQ outside of the Superfund program, portions of the periodic public health studies that address these concerns will be designed and implemented under BSB's leadership as part of a separate process from the Superfund health studies.

Appendix C to the approved work plan included an outline of the air quality study BSB is leading; however, the commenter is encouraged to contact Dan Powers, Assistant Health Director with BSB Health Department (406-497-5025 or dpowers@bsb.mt.gov) for more information about this separate study. The approved work plan is also available at: http://www2.epa.gov/region8/butte-priority-soils-operable-unit-public-health-study-remedial-design-work-plan-phase-1

2. "Were I to reside here for 30 years, living a healthy lifestyle, am I at increased risk to certain diseases that are environmentally related? COPD? Cancer? Mercury poisoning???? If the answer is unknown, what measures are underway to learn it?"

Response: Your question is not easily answered as many diseases are associated with multiple risk factors. Susceptibility to diseases also varies across different individuals. In addition to the Superfund health study activities, other public health evaluations are ongoing to identify and respond to concerns. Having your property evaluated by BSB's Residential Metals Abatement Program is an important action that you can take as a citizen to help ensure that elevated lead, arsenic, and mercury in residential soil/dust are identified and addressed.

Regarding mercury, what we can tell you is that only a limited number of properties with elevated mercury levels have been identified in the Butte area, and those have been remediated. While there are other sources of exposure to mercury, mercury from historic mining in Butte has been addressed at residential properties.

Regarding cancer, as noted in the draft final health study report (p. 2 and Appendix A), a study of cancer incidence and mortality conducted by the Montana Department of Public Health and Human Services (MDPHHS) included consideration of the most common cancers, as well as cancers associated with exposure to metals present in Butte. The MDPHHS study provided an update to and expansion of a 2001 ATSDR review of Silver Bow County cancer incidence rates compared to similar data for Montana and the U.S. (ATSDR 2002). The 2002 ATSDR analysis focused on cancer outcomes associated with exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury. Original copies of both studies are included as Appendix A to the draft final report. Based on its 2001 review, ATSDR (2002) concluded:

> *The data indicate a slightly elevated incidence of skin cancer in Silver Bow County when compared with age-standardized rates at the State and national level. No other cancer outcomes were consistently elevated when compared with these two reference groups. The slight increase in skin cancer incidence cannot be directly attributed to soil arsenic contamination in the area since no exposure assessments were included in this analysis.*

The more recent MDPHHS study (2012) reported that the incidence of cancer for all sites (i.e., not a specific cancer site, e.g., lung) was the same among residents of Silver Bow County compared to the residents of the state of Montana and that both were the same or lower than the all sites cancer incidence for the U.S. over three time periods spanning from 1981 to 2010. For mortality due to cancer (all sites), the rate for Silver Bow County was the same for the rest of Montana for 1981-1990 and 2001-2010, but the county rate was slightly higher for the 1991-2000 timeframe evaluated. Further, MDPHHS reported:

> *The most common types of cancer in Silver Bow County are also the most common in Montana and in the United States. None of these cancers (except for lung cancer) are known to be affected by the heavy metals or chemicals of concern in Silver Bow County. Lung cancer is also associated with arsenic exposure. However the majority of lung cancer cases are caused by cigarette smoking (87% of cases among men and 74% of cases among women)….*
>
> *Prostate is the most diagnosed cancer in Montana and in the US. The incidence of prostate cancer among residents of Silver Bow County was the same as Montana and the United States for the time intervals 1981-1990 and 1991-2000… From 2001-2010, the incidence rate in Silver Bow County was lower than Montana…*
>
> *The incidence of female breast cancer among residents of Silver Bow County was lower than Montana and the United States for the time periods 1981-1990 and 1991-2000 ...*

From 2001-2010, the incidence rate in Silver Bow County was the same as Montana and the United States...

The incidence of colorectal cancer among residents of Silver Bow County was the same as Montana and the United States for all three time intervals…

The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time intervals…

According to MDPHHS, the best way to assess the effects of environmental exposure on cancer risk in humans 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.

3. "What approaches and attitudes are present among the business leaders, technologists and citizens that would tend to prevent the [pollution] and cleanup that the area faces from a history of, what I must assume, was irresponsible mining practices? Note, I am aware that much particulate [pollution] of the air is caused by coal and wood burning in homes during winter, and forest fires in the summer. Please feel free to criticize my causal assumption. Hindsight is always clearer."

Response: This comment is really focused on questions that are beyond the scope of the Butte health study. However, there are other efforts underway to address broader community concerns, including those related to Butte air quality. We suggest the commenter contact Nikia Greene at EPA or Dan Powers at BSB Health Department to further explore the commenter's question and to promote a more meaningful dialogue regarding this topic.

4. "has the level of lead decreased in the environment over the same time period as measured in public and private spaces. Clearly the blood levels show a decrease, but do they indicate its decrease in the environment? Blood levels are one measure, but let's add other measures. True, the presence of Pb in blood indicates its presence in the environment of those individuals. I suggest that all city parks and playgrounds be tested for metals at least annually, if not twice a year. If these tests have been done, please report them. Is there a test that can be applied to biological samples. For example, tree rings should contain a history of both water and air contaminants. Old and young trees are cut down [every] year. It would seem that tests by area of the city might be informative. I suggest that vegetables and fruits that are grown for consumption should be tested as well. If nothing else, a sample of produce from the public gardens adjacent to the Hummingbird restaurant should be tested annually. I am unfamiliar whether other potential test sites of this nature exist. It is conceivable that a controlled test

garden(s) within the area could be created and maintained by some entity. Another testing location would be the soil on selected trails, abandoned and converted railroad beds and otherwise in all directions of Butte."

Response: Blood lead is a biomarker of exposure to lead that an individual may contact in their environment, which would include both public and private spaces, and from products they use and food they consume. Blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure. Using the available blood lead data to assess exposures in Butte is desirable because blood lead levels provides 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. A decline in blood lead levels for the Butte health study population over time is consistent with extensive programs to reduce sources of lead exposures, including remediation of mine sources, as well as other sources common to all communities. There are thousands of samples of soil from around Butte that document lead concentrations in soil. Soil concentrations are not expected to change because the sources have been controlled. In addition, there are institutional controls programs in place in Butte to address potentially significant soil disturbance events, should these occur. Lead does not typically accumulate in plants, so there is not a need to monitor trees or other plants.

5. "Is there no way of attributing the presence of Pb (and other metals) to mining operations as opposed to the other cited Pb sources? The results of the above paragraph's testing may provide a hint to this."

Response: All communities have multiple sources that contribute to lead exposures. In addition to lead-based paint and socio-economic risk factors potentially influencing blood lead levels in Butte, the draft final report also notes proximity to past and ongoing mining areas as a potential contributor to differences in blood lead levels between different areas of Butte (i.e., Uptown and the Flats). However, as noted in response to the prior comment, blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure. When an individual with an elevated blood lead level is referred to BSB's RMAP staff for a property/home assessment, attempts are made to identify the specific source(s) of lead contributing to the elevated blood lead level, whether it is related to mining, consumer products, lead-based paint, or other sources. Notably, the cleanup in Butte has addressed lead in soil from lead-paint and other lead sources along with mining-related lead in soil as part of the Superfund cleanup and RMAP.

6. "Having submitted these suggestions, I still commend all who worked on the existing study for a job well done. As always, studies beget studies."

Response: Comment acknowledged. The community concerns received at the conclusion of the study will be considered in crafting future health study needs. Thank you for your participation.

Commenter 3: This anonymous comment was received on an index card submitted at April 9, 2014 public meeting.

1. "Why isn't the public more involved with the Citizens Technical Env. Committee CTEC should involve the public. (For the people?!?)"

Response: Note: Given the comment received was directed toward CTEC, the comment was referred to CTEC. The following response was prepared directly by CTEC in response to this comment.

Despite CTECs efforts to highly publicize the public meeting on this health study, disappointingly, only two members of the general public turned out. CTEC does wish to be more consistently effective in involving the broader public at important times. Levels of public involvement through CTEC have changed over the years as the issues have evolved. At times, when public concern was high, better turnout at public meetings has occurred. During long stretches between those times, we should appreciate that a small core of individuals serving on the CTEC board have been monitoring and responding to Superfund project developments. There are many needs and opportunities for volunteering in the community, and CTEC recognizes that everybody can't make time for every issue. While CTEC would welcome more involvement, it has been challenging to keep people engaged over many years and where controversy and technical complexity are often involved, and we are open to specific ideas on how we might be more effective. This first health study had a narrow, technical focus to it, and we were not surprised that it attracted more limited public interest and involvement. Moving forward, CTEC is considering public forums during the scoping process that we hope will make future health studies more responsive to public needs and interests. The details on how we will achieve this outcome have yet to be determined; however, it is our expectation that efforts like this will generate more public interest and involvement in the next phase of the health study.

Commenter 4: This commenter submitted 19 separate sets of comments via email, totaling 90 pages of comments. To guide review of the comment responses, please note the following:

- Comments within and among the different submittals often repeated comment themes, many of which had been raised during the public comment period for the Butte health study work plan and were already addressed in the response to comment summary for that work plan. In such cases, responses summarized below refer the commenter to prior responses. Similar comments are considered together in development of a single response to each theme for simplicity.
- A number of comments received were presented as lists of topics or phrases without clear linkages to the draft final report, the Butte health study methodology, or its findings. Comments lacking relevance to the study are noted as such in responses below.
- Many comments lacked sufficient information or context that would allow for a response without inference. If it was necessary to infer what the commenter might have meant by a specific comment, that comment was not addressed in this response summary.

Commenter #4 Comment Response Summary

1. BPSOU Action Levels – In 7 of 19 comment submittals, the commenter expressed concerns regarding the adequacy of BPSOU remedy and the need for updating the soil lead action level for consistency with CDC's blood lead reference value, 5 micrograms per deciliter. The

commenter asserted that the prior BPSOU risk assessments were flawed, that BPSOU action levels are not protective of human health, and that the action levels ignore environmental justice. The commenter requested confirmation that properties addressed by RMAP were considered safe for residents.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 1.B.1, 1.B.2, and 1.B.3 presented in Table 1 and comments 2.A.2, 2.C.4, 2.C.5, 2.C.9, 2.D.1, 2.E.12, 2.E.13, 2.F.9, 2.F.14, 2.G.1, and 2.G.2 of Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013. Once a property has been addressed by RMAP, it is considered safe for families who reside there. In addition to cleanup of soils where action levels are exceeded, as part of the residential access agreement covenants, the program includes provisions for future development and maintenance of addressed properties to ensure long-term integrity of the work completed. As part of the RMAP cleanup process, measures are also taken to ensure underlying soils that may exceed action levels are indicated with visual markers prior to backfilling excavated soils at the surface.

2. Public Involvement – In 10 of 19 comment submittals, the commenter asserted that the health study process has failed to include meaningful public involvement.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.B.1 through 2.B.12 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

3. Environmental Justice – In 12 of 19 comment submittals, the commenter requested that EPA comply with environmental justice commitments. The commenter asserted that health study ignores environmental justice concerns with regard to the study involvement process and study design. Commenter asserts that risk assessments conducted for the study area also did not address environmental justice concerns and that the proposed plan and preferred alternative for BPSOU are null and void as a result.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.C.1 through 2.C.14 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013. In addition, please see response to Comment #1 above regarding the adequacy of BPSOU action levels and prior studies.

We disagree with the commenter's assertions that the health study has ignored the environmental justice concerns of low-income citizens in Butte. The Butte study population blood lead data were compiled from county blood lead records including those from Butte's Women, Infants, and Children

(WIC) program clients as well as from individuals referred via the RMAP and local physicians. The majority of the blood lead records came from patients recruited for regular blood lead testing through WIC. The qualification for WIC is 175% of the federal poverty level or below. In addition, census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level. Thus, relative to the broader Butte population, the Butte study population is expected to represent Butte's low-income citizens who are likely at higher risk for blood lead exposure. While it is most appropriate to focus the study on this portion of the Butte population that is at greatest risk for lead exposure, it is recognized that doing so reduces the generalizability of the Butte health study findings to the portions of the Butte population that are at lower risk for lead exposure based on socioeconomic factors.

We note also the lack of relevance for the commenter's assertions that Butte health study has failed to consider the health effects and disease outcomes of lead exposure on low-income citizens. As detailed in response to Comment # 9 below, the purpose of the study is not to evaluate health/disease outcomes; this applies to the general Butte population as well as specific subpopulations (e.g., low-income citizens).

4. Peer Review – In 9 of 19 comment submittals, the commenter requested independent peer review of the health study prior to finalization. The commenter asserted that EPA has reneged on promise of an independent peer review. Comments assert that methodological issues identified by the commenter support the need for independent peer review. Comments assert that journal publications will not satisfy need for independent peer review.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.D.1 through 2.D.10 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

5. Precautionary Principle – The commenter asserted that the Precautionary Principle needs to be incorporated into the health study.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.H.1 and 2.H.2 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

6. Bioavailability – The commenter questioned whether the health study should look at hair and nail samples to determine the bioavailability of chemicals of concern and asked why bioavailability data has not been correlated with chemical concentrations in attics and yards. This commenter asserted that the lead and arsenic found in homes is more bioavailable than in tailings dust.

Comment Response: The commenter appears to confuse biomonitoring with bioavailability in these comments. The bioavailability of lead in Butte soils was measured in several different animal studies and found to be very low. The bioavailability of lead in Butte dust was not measured; therefore, the default value in EPA's IEUBK model of 30% was used to be conservative. With regard to biomonitoring for lead, the U.S. Centers for Disease Control and Prevention (CDC 2013) states: "Blood lead measurement is the preferred method of evaluating lead exposure and its human health effects." A comment submitted during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan also asserted that hair and fingernail sampling for arsenic should be part of the study as these give a better picture of chronic exposures in Butte. A response to this comment was provided in the final approved work plan. Please see response to comment 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

7. <u>Synergistic and Cumulative Effects</u> – In 4 of 19 comment submittals, the commenter asserted that the health study fails to consider synergistic and cumulative effects of exposure to toxics in Butte, which is a shortcoming of the study.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.C.8, 2.C.13, 2.G.2, and 2.G.7 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

8. <u>Incidence and Mortality Studies</u> – In 7 of 19 comment submittals, the commenter asserted that other recent studies in Butte have found that disease rates for chemicals of concern in Butte are steady or increasing and that the health study should look at disease incidence and mortality instead of exposure data.

Comment Response: We disagree with the commenter's assertion regarding the findings of recent studies of disease rates in Butte and the preference for health outcome data versus exposure data in Butte. The commenter is referred to response to Comment #2 for Commenter 2 above regarding the findings of recent mortality and incidence studies in Butte. Regarding the preference for health outcome data versus exposure data in Butte, similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.F.1 through 2.F.21 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

9. <u>Study Purpose</u> – The commenter asked: "What exactly, in as succinct a statement as possible, is the purpose of Phase 1 of the Health Study?"

Comment Response: The purpose of the Butte health study is described on pages ii, xv, and 1 of the February 2014 Draft Final Report. For clarity, the purpose is also summarized below.

The purpose of the study is to evaluate the effectiveness of ongoing remediation and residential metals abatement efforts in the study area that have occurred since the early 1990s and to identify areas of potential improvements to current remediation/abatement approaches based on that evaluation. Toward that end, the EPA-approved study design focuses on assessing lead exposures represented by several years (2003 through 2011) of available blood lead data collected from Butte children.

Specifically, this study employs a descriptive cross-sectional analysis of blood lead data and other factors that may influence blood lead levels in children to characterize the following:

- how Butte blood lead levels represented in the available data have changed over this time period,
- how blood lead levels in the Butte study population compare to blood lead levels for a demographically-similar reference dataset that does not have Butte's Superfund history, and
- what factors in Butte might be contributing to differences in blood lead levels across the Butte study population and between Butte study population and the reference blood lead dataset.

Other available RMAP data for the same study period are considered in the study, secondary to the primary analyses of blood lead data. Recommendations are included regarding potential improvements to current remediation/abatement approaches that may be indicated based on interpretation of the results from these analyses.

To further assure clarity regarding the study purpose, we also note that the purpose of this study was <u>not</u> to address questions of causality or to evaluate health outcomes associated with the blood lead levels characterized for the Butte study population. Numerous "methodological problems" asserted by this commenter relate to causation and/or health/disease outcome studies. These comments, therefore, are not relevant to this study and are not addressed in this response to comment document.

10. <u>Study Focus on Lead</u> – In 4 of 19 comment submittals, the commenter questioned the focus of the study on lead and/or asserted the need for consideration of other toxics in Butte.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.G.1 through 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

11. <u>Availability of Raw Study Data</u> – In 3 of 19 comment submittals, the commenter requests that the raw data used in the study be made available to the public for verification of study findings.

Comment Response: The raw data used in the Butte health study includes personally identifying information about individuals whose blood lead records were used in the study. Such information is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules and cannot be released to the public. Requests for de-identified data used in the study (or other existing biomonitoring data) would have to be reviewed and approved by the Butte Silver Bow County Health Department. Support for such requests would include why the data are requested and a protocol for how data would be used and protected. Due to the HIPPA Privacy Rules, verification of the de-identified records against the raw data would not be possible; however, the commenter is assured that each piece of information from the raw data that was compiled from original paper records into an electronic database was checked by a second team member to assure accurate transfer of the original data.

12. Scope of Future Studies – The commenter asked what the scope of future studies will be and whether these will include medical monitoring of chronic exposure to all toxics of concern in Butte.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.A.1, 2.A.2, 2.A.4, 2.A.12, 2.B.3, 2.B.4, 2.F.1, 2.F.2, 2.F.3, and 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

13. Focus on Acute vs. Chronic Exposures – In 2 of 19 comment submittals, the commenter asserted that the study focuses on acute exposures when focus on chronic exposures is needed.

Comment Response: The Butte health study focuses on blood lead data as a biomarker for exposure. According to the CDC, blood lead data “reflect both recent intake and equilibration with stored lead in other tissues, particularly in the skeleton” (http://www.cdc.gov/biomonitoring/Lead_BiomonitoringSummary.html). Further, by including hundreds of blood lead samples collected over a nine year period, the Butte health study presents a long term view of ongoing lead exposures in Butte. The Butte health study does not seek to identify sources of lead exposure contributing to the blood lead result for a given individual within the study population or to identify whether such sources might have been contacted by the individual over a short (i.e., acute) or long (i.e., chronic) period of time. Such endeavors are not necessary to address the study objectives.

14. Prediction Intervals and Confidence Intervals – The commenter asserted the following as a methodological concern with the Butte health study: “Using confidence intervals when prediction intervals are warranted.” The commenter also asked: “On what bases were the confidence and prediction intervals determined?” This commenter also questioned how the Butte health study avoided problems with failure to quantify the degree of precision or imprecision in confidence intervals.

Comment Response: Prediction intervals are the estimate of the interval in which the future observations will fall. For this study we were attempting to estimate the population mean of the current and past populations, so confidence intervals are the appropriate metric to use. While prediction intervals were not used, all confidence intervals given in the report have been defined as to their precisions (e.g. 95% confidence interval of a geometric mean).

15. Regression on Residuals – The commenter asserted the following as a methodological concern with the Butte health study: “Problems with regression on residuals.”

Comment Response: Residuals were used only to determine normality as for the regression analysis, the error terms should be normally distributed.

16. Representativeness of Study Population – The commenter asserted the following as a methodological concern with the Butte health study: “Failure to show the representative nature of the population sampled in Butte.”

Comment Response: The sampled population is not representative of Butte as a whole since the samples came mainly from the Women, Infants, and Child (WIC) population. The WIC-based sample population over-represents individuals within the population who fall within lower income levels, which historically has corresponded to over-prediction of the average blood lead levels for the general population.

17. Variable Selection Methods – The commenter asserted the following as a methodological concern with the Butte health study: “Assuming linearity is preserved when variables are dropped. One common mistake in using ‘variable selection’ methods is to assume that if one or more variables are dropped, then the appropriate model using the remaining variables can be obtained simply by deleting the dropped variables from the "full model" (i.e., the model with all the explanatory variables). This assumption is in general false. Cook and Weisberg (1999) Applied Regression Including Computing and Graphics, Wiley.”

Comment Response: The methodological concern asserted by the commenter is not relevant to the Butte health study. No statistical selection method (stepwise, forward or backward) was used. Each variable was tested separately and then together for use in the models.

18. Regression Model Use – The commenter asserted the following as a methodological concern with the Butte health study: “Using a regression model without knowing the subject.”

Comment Response: The methodological concern asserted by the commenter is not relevant to the Butte health study. The subject is known. Linear regression is used in the study to determine a mean blood lead level after adjusting for race, poverty index level and housing age.

19. Problems with Stepwise Model Selection Procedures– The commenter asserted the following as a methodological concern with the Butte health study: “Problems with Stepwise Model Selection Procedures ‘... perhaps the most serious source of error lies in letting statistical procedures make decisions for you.’ ‘Don't be too quick to turn on the computer. Bypassing the brain to compute by reflex is a sure recipe for disaster.’ Good and Hardin, Common Errors in Statistics (and How to Avoid Them), p. 3, p. 152.”

Comment Response: The methodological concern asserted by the commenter is not relevant to the Butte health study. Stepwise model selection (a statistical selection method) was not used in the analyses on these data.

20. Common Mistakes in Multiple Regression– The commenter noted five points under the heading, "Common Mistakes in Multiple Regression Avoided in the Health Study?"

Comment Response: The relevance of the commenter's five points to specific methods used in the Butte health study is not clear. However, with regard to study methods, we note: 1) that residuals were tested for normality; 2) outliers were looked for, but because we had no reason to assume that any outliers were not part of the overall population, they were not removed; 3) plots were examined for fit; 4) stepwise regression was not used in this study; and 5) errors were not confused with residuals.

21. Estimating vs. Predicting– The commenter asserted the following as a methodological concern with the Butte health study: "Confusing 'estimating' with 'predicting'."

Comment Response: Predicting refers to something that has yet to occur. In this study, population means are estimated based on a sample from that population.

22. Consideration of Prior Studies– The commenter asked the following with regard to methodological concerns with the Butte health study: "How were prior studies used to determine which variables to include in the modes and study?" The same commenter also asked: "What role did prior studies of exposure, disease rates and mortality rates play on the development of the first phase of the Butte Health Study? What was superior about the methodology used in Phase I of the Butte Health Study as compared to the methodology used in other studies of exposure, disease rates/incidences and mortality? Why should we have more confidence in the methodology used in this study as compared to the methodology used in previous studies related to the health effects of the toxics of concern in Butte?"

Comment Response: Based on numerous publications, we know that certain demographic characteristics can be predictive of blood lead levels. These were the variables explored in the Butte health study for correlations to the measured blood lead levels in NHANES and in Butte. Prior studies of exposure, incidence and mortality were described in the study work plan and in the draft final report. The commenter is also referred to response to Comment #8 in this response summary and response to Comment #2 for Commenter 2 above. The Butte health study is not an incidence or health outcome study, thus, comparison of its methodology with such studies is not appropriate.

23. Bias– The commenter asserts that the Butte health study is or may be subject to several types of bias that should be addressed.

Comment Response: The commenter's assertions that Berkson's bias and collider bias are issues with the Butte health study are not well-founded as neither of these types of bias are relevant to the study methodology. Similarly, the commenter asserts that the study fails to adequately deal with 18 different biases the commenter lists. Of these, only two (informational and selection bias) are of potential relevance to the study. Bias in an epidemiological study can broadly be categorized as either information or selection bias. Information bias is the term used to define the potential error introduced into a study when the outcome/ dependent variable (here, BLL levels) or independent variables/covariates (year, house age, season, etc.) for study subjects are misclassified. In the Butte Health Study, concerns about information bias are minimal. The majority of the variables used including year of BLL test, season of BLL test, age of the child at the time of the test, and gender of the child are unlikely to have been recalled or reported incorrectly in the WIC client records from which the information was obtained. Neighborhood was not self-reported, but mapped to a census tract by the researchers using the child's address. House age was also not self-reported, but obtained from land survey and property tax databases using property addresses reported in WIC client records. Additionally, house age information was missing for approximately 35% of children (945/2724), but rather than dropping these children, they were included in the analysis with a missing house age category. BLL measurements for all children in the study were obtained by the capillary method using the same procedure and technique alleviating concerns that changes or differences across groups in how the samples were collected or analyzed explain any of the results.

Selection bias, the second broad category of bias, occurs when systematic differences exist between individuals selected into the study and individuals not selected into the study. The Butte Health Study used blood lead records collected by the Butte Silver Bow Health Department as part of the RMAP and WIC programs. The specific years of data, 2003 to 2010, and specific age ranges, 12 to 60 months, selected for evaluation in the study were carefully considered as detailed in section 2 of the draft final report. The intent of the study was to examine the relationship between several factors (year, neighborhood, house age, child's age, sex, season) and blood lead levels and we have no reason to suspect that the way these records were collected or selected for use in this study would have led to a distortion of the relationships between these factors and BLLs. Importantly, though, the use of this data source, in which the majority of the children were WIC participants and for which census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level, may limit the generalizability of these findings to the entire Butte population. The generalizability of a study refers to the populations to which it is appropriate to apply the study's findings. The Butte Health Study provides important insight into the blood lead levels of children living in Butte, but it should be noted that the study population is likely drawn from a population of lower socioeconomic status than the Butte population in general and, because lower socioeconomic status correlates with higher blood lead concentrations, the concentrations may not be representative of Butte children overall. The commenter is also referred to responses to Comment #3 and #27 for additional discussion of the generalizability of the Butte study population to the overall population of Butte.

24. <u>Confounding</u>– The commenter questions how the Butte health study methodology addresses/eliminates confounding problems related to interpretation of the etiology of cases.

Comment Response: Confounding problems related to interpretation of the etiology or cause of cases are not relevant to this study. As noted in response to Comment #9, the purpose of this study was <u>not</u> to address questions of causality or to evaluate health outcomes associated with the blood lead levels characterized for the Butte study population. With respect to the study methodology, adjusting the models for age, sex, season, etc. was conducted to avoid potential confounding of model results due to these variables. These and other potential factors that might influence interpretation of study results are discussed in the draft final report.

25. Laboratory Quality – The commenter expresses concern about false-negative sampling errors with capillary blood lead sampling and asks: "What assurance does the public have that labs that do the sampling and analysis are certified and reliable?"

Comment Response: The analytical laboratory that performed the analysis of blood lead samples represented in the Butte dataset holds all required certificates and licenses, and successfully participates in required proficiency testing programs (see http://tamaracmedical.com/). As described in the draft final report, a key concern with the use of finger stick sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Such external contamination could result in a rate of higher false positives or otherwise bias Butte sample results high compared to NHANES sample results. However, correlation coefficients between capillary and venous methods have been reported to range from 0.96-0.98 in paired testing (Schlenker et al. 1994) and Butte WIC sample collection methods include preparation of the skin location using laboratory-provided wipes that are designed to reduce the potential for external lead contamination. The laboratory used for the Butte blood lead data reports: "The correlation between paired, simultaneously drawn extraction method filter paper and venous samples is >.970. Additionally, undetected-elevated and falsely-elevated rates may be considered clinically insignificant. These findings are documented by three published, peer-reviewed studies involving 363 paired, simultaneously drawn extraction method filter paper and venous sample comparisons." (Yee et al. 1995; Srivuthana et al. 1996; and Yee 1997)

26. Failure to Reduce Random Variation – The commenter asks how the study addresses problems with failure to reduce random variation.

Comment Response: Random variation in a population is not something we can avoid nor should try to reduce when doing this type of study. The confidence intervals estimated take the variance in the population into consideration.

27. Conceptual Framework Problems – The commenter asserts that four "conceptual framework problems" including failure to adequately characterize the external population, the target population, and the Butte health study population.

Comment Response: Characterization of the Butte study population and the reference population, NHANES, is provided in the draft final report, with additional detail in the EPA approved Technical Memorandum – Proposed Reference Blood Lead Data for Use in the Butte Health Study, which is included as Appendix D to the draft final report. For the Butte study population, county blood lead records include those from Butte's Women, Infants, and Children (WIC) program clients as well as from individuals referred via the RMAP and local physicians. The majority of the blood lead records came from patients recruited for regular blood lead testing through WIC. The qualification for WIC is 175% of the federal poverty level or below. In addition, census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level. Thus, relative to the broader Butte population, the Butte study population is likely at higher risk for blood lead exposure due. While it is most appropriate to focus the study on the portion of the Butte population that is at greatest risk for lead exposure, doing so reduces the generalizability of the study findings to the portions of the Butte population that are at lower risk for lead exposure based on socioeconomic factors.

28. Case/Control Study Issues – The commenter asserts that the Butte health study methodology suffers from issues related to overmatching and selection of controls, assessment of reliability problems, assessment of validity problems, and misclassification problems. A reference cited quoted pertains to overmatching in studies relating exposure and disease. In a later comment, the commenter also notes: "Failure to do any case-control studies."

Comment Response: Comments pertaining to case/control studies are not applicable to the health study which is not a case/control study and does not evaluate the relationship between exposure and disease. Further, considering the study research questions and available data, case-control study designs/approaches would not be appropriate.

29. Causality Methodology Problems – The commenter asserts that the Butte health study methodology suffers from "serious causality methodology problems that are visible in the Study" and need to be addressed.

Comment Response: Comments pertaining to causality studies are not applicable to the Butte health study which does not evaluate causation. The study was descriptive by design and there are no causal inferences to be made. This study can only look at statistical correlations between certain factors (age, sex, house age, neighborhood), but no conclusions are drawn about "causation." This methodology is appropriate for a study in which blood lead levels are the response and where other variables are evaluated as predictors of blood lead levels among the study group. Even if the study were evaluating an etiological hypothesis, causal inferences cannot be made based on a single study. The Hill criteria cited by the commenter are considered across a body of epidemiological literature to evaluate evidence for making causal inferences. The Hill criteria are not applicable to the Butte health study methodology.

30. Blood Lead Instrumentation/Detection Levels – The commenter asserts: "The issue of whether or not the instrumentation/detection level used in analyzing the blood lead data is adequate needs to be addressed. Is the current detection level set at too high a bar? Do the current detection limits used in Butte adequately address whether or not adverse health effects are occurring in Butte children?"

Comment Response: Consideration of blood lead instrumentation and detection limits was a key part of the data refinement process used to develop the blood lead database used in the Butte health study. During the study data collection timeframe (2003 through 2010), blood lead samples had been submitted for laboratory analysis with a detection limit of 1 µg/dL, which is sufficiently sensitive for evaluation of the distribution of blood lead levels in a population relative to the CDC blood lead level of concern (10 µg/dL) that was applicable from 2003 through 2010, as well as the current CDC blood lead reference value (5 µg/dL). As noted in the draft final report, in December 2011, the BSB Health Department 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 are elevated. However, for the purposes of this study, it was determined that records obtained by use of the LeadCare II device lack sufficient sensitivity and precision to support the study objectives and could not be used. This is why the study excludes LeadCare II data from analyses of the 2011 data in comparison to the 2003 through 2010 data. Recommendations made in the draft final report include BSB's continued adoption of the CDC recommendations for confirming screening blood lead test results by venous sampling if greater than 5 µg/dL and update the screening value used when/if the CDC reference value is updated in the future. Recommendations also include re-initiating blood lead testing procedures that produce reliable screening results at a detection limit of 1 µg/dL or lower given that blood lead levels in Butte are now low enough that trends in blood lead levels cannot be discerned using testing procedures with higher detection limits (e.g., the LeadCare II analyzer). The ability to characterize the trends is needed to continue to track the effectiveness of the RMAP.

With regard to the above, it is important to clarify that blood lead data used in the health study represent a biomarker of exposure, not health effects. Therefore, the commenter's question about whether or not the current detection limits used in Butte adequately address the occurrence of adverse health effects is not relevant to this study. That said, the BSB Health Department confirms via venous sampling and laboratory analysis all LeadCare II screening results if equal to or greater than 5 µg/dL, thus accelerating the timeframe for follow-up of cases with suspected elevations of blood lead and providing a more precise and sensitive measure of blood lead for that individual.

31. Long Latent Periods – The commenter asserts the Butte health study methodology fails to "deal with the problem of long latent periods."

Comment Response: This comment is not relevant to the health study; long latency periods are not a subject of this study.

32. Lack of Covariate Data – The commenter asserts a "lack of covariate data."

Comment Response: Several covariates are included in the Butte health study models as detailed in the draft final report.

33. Rare Outcome Events – The commenter asserts: "Methodology not suited to rare outcome events in non-clinical populations."

Comment Response: There are no rare outcomes associated with the Butte health study population.

34. Cross-Sectional Studies – The commenter asserts the Butte health study fails to do any cross-sectional studies.

Comment Response: The commenter's assertion is not correct. The study is cross-sectional in nature.

35. Genetic, Space-Time Cluster, and Time Trend Studies – The commenter asserts the Butte health study fails to do any genetic studies, space-time cluster studies, and time trend studies.

Comment Response: Considering the study research questions and available data, such study designs/approaches would not be appropriate.

36. Ecologic Inference Making – The commenter asserts: "Poor ecologic inference making."

Comment Response: Ecologic inference making is not relevant to the Butte health study approach.

37. Gene-Environment Interaction – The commenter asserts: "Poor consideration of gene-environment interaction."

Comment Response: Considering the Butte health study research questions and available data, such consideration would not be appropriate.

38. Bayesian Modeling – The commenter asserts: "Phase I suffers from the failure to do Bayesian modeling."

Comment Response: Bayesian modeling was not necessary to address the Butte health study research questions.

39. Population Randomization – The commenter asserts: "Given that there is no randomization in the populations studied imbalances in the characteristics of those exposed can occur."

Comment Response: This would not have been an appropriate way to address the Butte health study research questions. Randomizing lead exposure would be unethical.

40. Cohort Studies – The commenter asserts methodology issues related to cohort studies.

Comment Response: These comments are not relevant to the Butte health study, which is not a cohort study.

Appendix C

Deviations from the Statistical Analysis Procedures

Deviations from the Statistical Analysis and Quality Assurance Procedures

ENVIRON staff followed the procedures outlined in the Butte Priority Soils Operable Unit Public Health Study Phase 1 report. The following list summarizes deviations from these procedures:

- Five blood lead records were mistakenly excluded from the statistical models. These study methods state that records were examined for children aged 12-60 months (corresponding to 1.00 to 5.07 years within the database). Due to the complexity of the analysis, it did not seem reasonable to attempt to add these few records. From the Butte EBLP Database, these records are shown in Table 1.

Table 1: Blood Lead Records Incorrectly Excluded from the Butte Statistical Analysis

Test_ID	Indiv_ID	Loc_ID	Test_number	Test_year	Test_date	Age_num	Pb_txt
1087	234	5395	1	2009	17-Sep-09	5.00	<1.0
6722	4133	6497	5	2010	03-Feb-10	5.01	<1.0
2871	1715	7607	3	2004	09-Feb-04	5.02	1.5
1351	418	2016	1	2004	12-Oct-04	5.02	2.5
3585	2180	1842	4	2004	07-Apr-04	5.04	6.7

Appendix D

Environmental Blood Lead and Property Database Development

Contents

1 Introduction

This document is intended to describe the process by which blood lead records from the Butte Silver Bow (BSB) County Health Department were used to build a confidential blood lead database that was coupled with property information and de-identified for use in the Butte Priority Soils Phase 1 Public Health Study. The de-identified database used in the study is referred to as the Environmental Blood Lead and Property database (EBLP).

This process is covered in the following sections:

- Types of data used in developing the blood lead database (section 2)
- Method of database development (section 3)
- Final structure of the EBLP (section 4)
- Subsets of the data used in the Butte health study (section 5)

Section 6 of this document reviews a second database of environmental data used in the Butte health study that was provided by the BSB Residential Metals Abatement Program (RMAP[1]).

2 Data Types and Sources

The following section describes the sources of the blood lead and property age information included in the EBLP, as well as the environmental information used in supplemental analysis.

2.1 Blood Lead

Blood lead levels and corresponding personal information were obtained by hand-entering hard copy medical records into Microsoft Excel spreadsheets. This work was performed by ENVIRON International Corp. (ENVIRON) and Pioneer Technical Services (Pioneer) personnel at the BSB Health Department in June 2012. A grand total of 7,278 blood lead records corresponding to approximately 2,500 properties were electronically compiled with test dates ranging from 1992-2012.

The BSB Health Department switched from handwritten blood lead test recordkeeping to compiling blood lead records electronically in 2010. At that point, only hardcopy summary sheets corresponding to electronically recorded records were retained. The summary sheets did not contain addresses or complete personal information. During post-processing of the compiled data in the database, these data gaps were identified and summarized with a request to the Health Department in August 2012 for completion of the missing information for these records. In response to this request, in February 2013 the Health Department provided updated information which was then incorporated into the confidential blood lead database, including addresses, names, genders, birthdates and a few new blood lead results.

[1] The RMAP, through the US Environmental Protection Agency, was designed to reduce exposure of residents of the Butte Priority Soils Operable Unit Superfund site to sources of lead, arsenic, and mercury contamination.

Due to the way the medical files were organized and examined by ENVIRON and Pioneer personnel, many duplicate blood lead records were discovered during database development. Every effort has been made to remove duplicate records; however, it is possible that some remain.

ENVIRON worked with the Health Department to ensure the completeness and accuracy of blood lead records, including correct personal information on individuals. During database development, it was necessary to determine records corresponding to distinct individuals. This was accomplished by using the “DISTINCT” function in Access, selecting individuals unique by first name, last name, gender, and birthdate.

2.2 Property Year Built Data

Property year built data for each blood lead record were not provided in the Health Department records, but were of interest for the Butte health study. Therefore, as available, year built data were added to the database from property records obtained from the Montana Cadastral, a state-wide online repository for land survey and property tax data from federal, state, and local governments. A Microsoft Access database for Silver Bow County was downloaded from the Cadastral website in August 2012.[2] These data were generated by the Montana Department of Revenue Computer Assisted Mass Appraisal (CAMA) system. Documentation available on the Montana Cadastral website provided background on the database, which was used to find appropriate year built information for structures on tax parcels.

Although the Montana Cadastral provides information for many locations and structures, not all of the blood lead records could be matched to locations in the repository, and, in some cases, year built data were not provided in the repository even when matched to blood lead record addresses.

2.3 Environmental

BSB maintains an RMAP database, which contains environmental data tracked in conjunction with Superfund-related RMAP activities. The June 2013 version of the database was provided by the BSB Management Information System (MIS) Department. This database includes information on 2,174 properties sampled for metals and/or abated from February 1992 to May 2013. Although some of these properties match to blood lead records, most do not (see section 6.1 of the Butte Priority Soils Phase 1 Public Health Study). Because of this, information from the RMAP database is not incorporated into the EBLP database, but can be linked to data in the EBLP database. Additional development of this database is described in section 6 of this report.

3 Blood Lead Database Development

Before coding the blood lead database to protect confidential information, property year built information had to be added from the source described in section 2.2. Then the geographic location of the residence related to each blood lead record was determined to allow for assignment to a neighborhood in Butte. By assigning each record to a neighborhood in the

[2] Note, the Montana Department of Revenue migrated this information to Microsoft SQL Server in 2013 and no longer updates the Access databases or provides them for download.

Butte health study, identifying address information was able to be omitted. This section describes the general processes involved in adding the house year built data and de-identifying the blood lead records to create the final EBLP database.

Development work unfolded in four main phases:

1. Address Standardization
2. Address Matching
3. Geocoding
4. Neighborhood Assignment

During development phases, the data were housed in a Microsoft Access database, Microsoft Excel was used for QA/QC tracking, and ESRI ArcMap 10.1 was used for geographical information systems (GIS) analysis. This full process, including 100% QA/QC was performed only on the blood lead records for children ages 12-60 months with a gender, birthdate, and physical address in Butte.

3.1 Address Standardization

The three types of data (blood lead, property year built, environmental) were related to each other by common street address. Prior to linking the addresses, it was necessary to standardize each address to ensure that all were represented in a similar format and using common nomenclature. Because the Montana Cadastral repository provided the most comprehensive list of addresses and originated from local government land records, this source provided the backbone for the standardization process. For each data type, the addresses from each source were preserved in their original form, but a copy of the address was stripped of extraneous characters such as periods and put into a standard format. This format was based on simple rules such as changing all numerical street names to words (e.g., "1st" to "First"). Additionally, when an apartment complex had separate unit numbers, these were removed from the standardized address and only the street number and name were used to designate a unique location.

3.2 Address Matching

Using Microsoft Excel matching functions and manual inspection, addresses converted to a standard format were matched across data sources. To accomplish matching, further standardization rules were set based on:

1. The dominant format type represented across all addresses.
2. The preferred format recognized by Google Maps.
3. The preferred format recognized by GIS software (ArcMap 10.1).

For some streets, a global change could be implemented (e.g., every address on a particular street could be converted from "Ave" to "St"), while others depended on the street number (e.g., "Phillips" might be converted to "Phillips Ave" or "Phillips St" depending on the house number).

Two addresses would only be confirmed as matches if they both plotted in the exact same spot in Google Maps. Confirmation was determined from visual inspection by alternating between the separate Google Maps webpages containing each address. If both addresses plotted in the same spot, the webpage looked the same no matter which page was active.

3.3 Geocoding

To assign a blood lead record to a neighborhood, it was necessary to identify the physical location of the individual tested on a map. Neither the RMAP data nor the blood lead records contained geospatial information other than addresses, so geocoding was necessary. Geocoding is the process by which the latitude and longitude (or "XY coordinates") of a location are assigned to an address. This section describes the geocoding sources used and examples of issues encountered during the QA/QC process.

3.3.1 Geocoding Sources

Shapefiles (geospatial vector data files) from Montana Cadastral (January 2013) provided the polygon shapes for every tax parcel in Butte-Silver Bow. After calculating coordinates for the centroid of each tax parcel polygon with ArcMap, this shapefile became our primary source in the geocoding process.

The Cadastral shapefiles were created from PLSS (Public Land Survey System) coordinates and legal land descriptions obtained from three sources:

- Bureau of Land Management Geographic Coordinate Data Base (GCDB),
- Montana Department of Revenue CAMA, and
- Private research conducted in areas not covered by the GCDB and CAMA.

For blood lead or environmental addresses which did not match to a tax parcel in the shapefile, a GIS geocoder was used. ArcMap geocoded the addresses using the North American Address Locator (June 2012 update), which is a composite of nine locators using a street network as the primary reference data type. For addresses that did not plot using the Cadastral shapefile or GIS geocoder, Google Maps and the Cadastral shapefile were used as references to manually investigate and plot the locations in GIS. Butte addresses that could still not be reconciled or were not for a home location (e.g., P.O. boxes) were then put into a general Butte category.

3.3.2 Geocoding QA/QC

As stated at the beginning of section 3, 100% QA/QC of address locations was completed for only a subset of blood lead records from children. During the QA/QC process, issues identified were resolved as follows:

- <u>A blood lead address with house number, street, and "Butte, MT 59701" plotted in the generic center of town</u>.
  Research on Google Maps and a search of the Cadastral data either found the address was located in a different town (e.g., Anaconda) or could not be plotted to a level of accuracy greater than Butte, MT. Such cases were assigned to the general Butte location category.

- An address did not have a directional prefix.
  In some cases, the geocoder picked a directional prefix for an address that lacked this detail. For example, an address on “Platinum” may have plotted on “E Platinum” rather than “W Platinum.” Manual inspection using the Cadastral shapefile and Google Maps either confirmed the geocoded result, its alternate, or determined the address could not be plotted to a level of accuracy greater than Butte, MT. In the last case, the address would then be assigned to the general Butte location category.

3.4 Neighborhood Assignment

The confidential blood lead data were grouped together by designated neighborhoods to be used in the EBLP database to protect the confidentiality of individuals identifiable at a property level. Preliminary neighborhood designations aligned with the eight census tracts for BSB. This section describes the neighborhood assignment process using GIS and resolution of issues encountered during QA/QC.

3.4.1 Preliminary Grouping

Upon completion of geocoding, census tracts were used to delineate preliminary neighborhood boundaries. ArcMap used shapefiles obtained from the 2010 U.S. Census to assign plotted address points to census tracts. This was accomplished using the “Select by Location” function and “Field Calculator” tool for each census tract, 1-8. Butte addresses that could not be geocoded to an accuracy of at least street level were assigned to the general Butte category. Addresses outside of the Butte census tracts were assigned to the “Other” category.

3.4.2 Preliminary Grouping QA/QC

Examples of issues discovered during QA/QC of neighborhood grouping and the actions taken to resolve each are described below:

- An address point geocoded to multiple parcels of the same address in the Cadastral shapefile.
  Locations were required to be accurate to the census tract level. In cases where an address geocoded to multiple parcels all within the same census tract, then any set of those coordinates were deemed accurate. For an address with parcels in two different census tracts, the final location match was determined by consulting physical feature information (e.g., one tax parcel contained structures while the other had vacant land) and Google Maps.
- An address point was assigned to more than one census tract by ArcMap.
  In some cases, the address plotted in the middle of the street due to street-based GIS geocoding instead of within a tax parcel; and the middle of the street location coincided with the boundary of two census tracts. For these instances, the tax parcel shapefile and Google Maps were consulted to determine which side of the street the address was located, and thus which census tract it should be assigned to.
- An address contained a house number and street but plotted only to the level of street.
  In these instances, it was necessary to determine whether the entire street was in the same census tract or split by a census tract boundary. If it was split, the Cadastral shapefile was used to place the address on a street location closest to the house number

provided. In some cases, a house number fell outside the existing range of house numbers on the street and plotted at the beginning or end of the street, depending on which side of the range it fell. In these cases, Google Maps and parcel data were used to determine the most accurate location for the address.

3.4.3 Final Neighborhood Assignment

The decision process behind final neighborhood assignments is described in more detail in the BSB Health Study Report. This section describes the technical tools used to perform these final assignments. Using the "Buffer" tool in Arc GIS, a 500 meter buffer was placed around Census Tracts 1-7 and used to reassign points from Census Tract 8 into a neighborhood they were adjacent to, creating neighborhoods N1-N7. Additionally, a shapefile downloaded from the Montana State Library provided a boundary for the city of Walkerville sourced from the Montana Department of Transportation/Planning/Data & Statistics Bureau. This shapefile was used to define neighborhood N8. In GIS, the "Select by Location" function, manual selection of points by location, and the Field Calculator tool were used to reassign points into the final neighborhoods. Refinements made in ArcMap during this process were updated in the final EBLP database.

4 Database Design

The EBLP database was designed to allow for the extraction of blood lead and property age data subsets for use in statistical models developed for the Butte health study. This section describes the structure of the database. Figure 1 provides the Relationships table from the EBLP database and includes six of the tables listed in the data dictionary. Relationships show the way that data from one table relate to data from another table. For example, tbl_Individuals and tbl_Results are related by the field "Indiv_ID," which is common to both. The relationships are "one-to-many" (represented by the symbols "1" and "∞"). The data dictionary (Table 1 and section 4.1) further describes the fields in each of the tables visible in Figure 1. In order to protect personal information, names, birthdates, addresses, and geospatial data do not appear in the EBLP database. Unique identifiers are used in the place of specific locations and individuals.

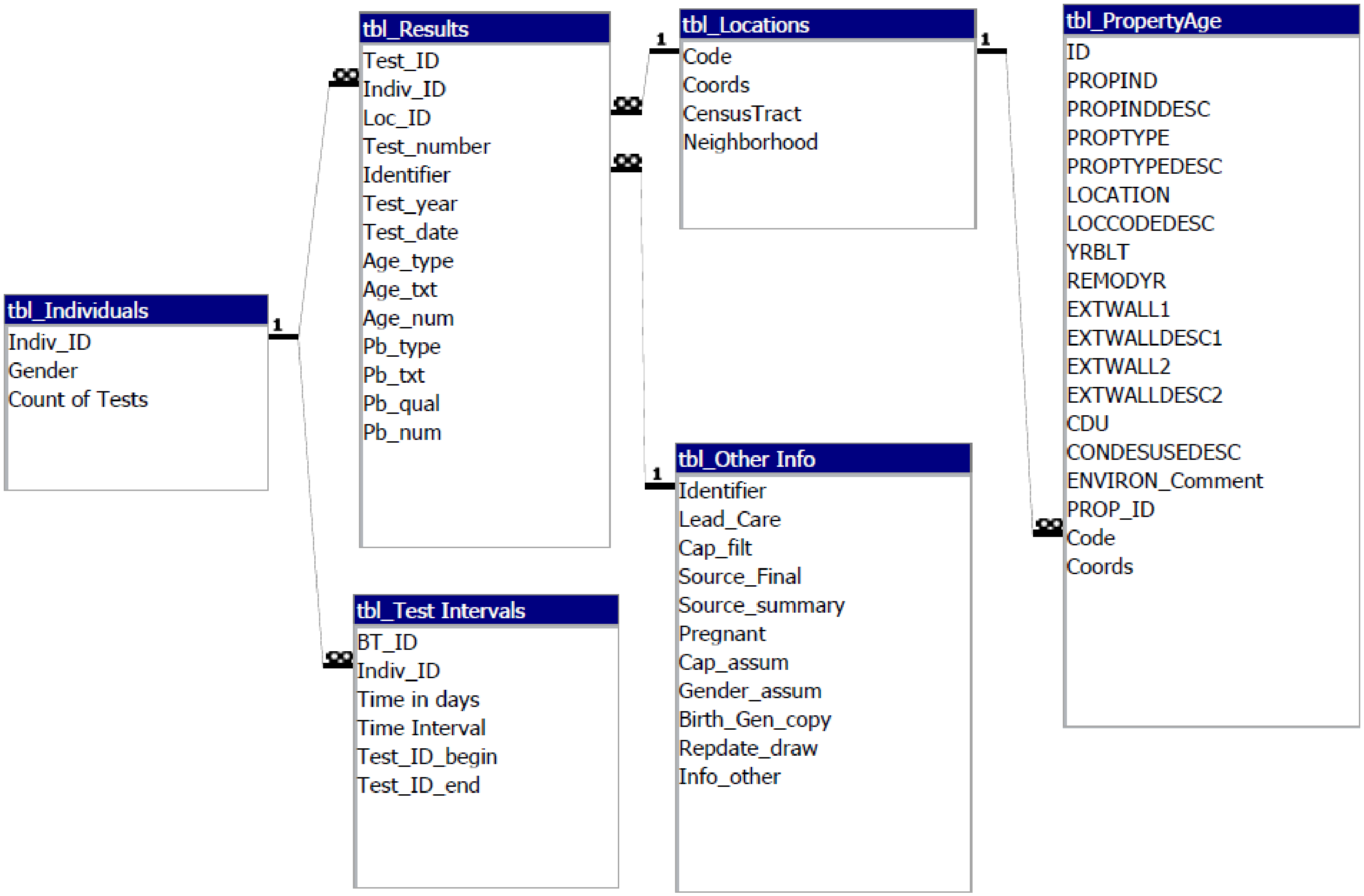


Figure 1. Relationships Table for the EBLP Database

Table 1. Descriptive Data Dictionary for the EBLP Database					
Table	**Field**	**Key**	**Format**	**Decimals**	**Description**
tbl_QueryList	Query_ID	Primary	AutoNumber		Unique identifier for a query
	Query_title		Text		Title of the query
	Query_desc		Memo		Description of the query
tbl_Individuals	Indiv_ID	Primary	Number	Auto	Unique identifier for an individual with a blood lead result
	Gender		Text		Male (M) or Female (F)
	Count of Tests		Number	Auto	Number of blood lead results
tbl_Locations	Code	Primary	Number		Unique identifier for a standardized address - the key between the coded and uncoded versions of the blood lead database
	Coords		Text	Auto	Does the standardized address have map coordinates (Null as Yes or "No")?
	CensusTract		Text		The general location of a standardized address - specific to the level of a 2010 census tract or "Butte General," "Other," or Unassigned "UNA"
	Neighborhood		Text		The neighborhood assignment from the census tract (1-8). A value of 0 corresponds to addresses in census tract 8 or "Butte General" that will be retained for the NHANES comparison
tbl_OtherInfo	Identifier	Primary	Number	Auto	Unique identifier for a blood lead record used in preliminary versions of database (is not unique to a test result in all cases)
	Lead_Care		Text		Blood draw collected using the Lead Care II method (Y or N)?
	Cap_filt		Text		Blood draw collected using filter paper: Y, N, or UNK (Unknown)?
tbl_OtherInfo	Source_Final		Text		Data source for the blood lead record: WIC (Women, Infants, and Children Program)or other provider.
	Source_summary		Text		Entered from summary sheet (Y or N)? No means data came from a full medical file.

Table 1. Descriptive Data Dictionary for the EBLP Database					
Table	**Field**	**Key**	**Format**	**Decimals**	**Description**
tbl_OtherInfo	Pregnant		Text		Yes (Y) if the patient was pregnant.
	Cap_assum		Text		Yes (Y) if the blood lead result was assumed to be capillary - default assumption when medical record did not clearly state.
	Gender_assum		Text		Yes (Y) if gender not provided in medical record but assumed based on name.
	Birth_Gen_copy		Text		Yes (Y) if birthdate/gender added from other record with the same name
	Repdate_draw		Text		Yes (Y) if the report date of the blood lead result was used as the blood draw date due to an incomplete/unclear medical record.
	Info_other		Text		Other information from the medical file - mainly related to pregnancy status.
tbl_PropertyAge	ID	Primary	Number	Auto	Unique identifier for a property age record added by Access during import from the Montana Cadastral source.
	PROPIND		Text		Code for residential improvement indicator
	PROPINDDESC		Text		Code description for PROPIND
	PROPTYPE		Text		Code for property type that best describes the specific property type of the subject parcel based on actual present day use
	PROPTYPEDESC		Text		Code description for PROPTYPE
	LOCATION		Text		Code for the type of neighborhood in which the subject property is located
	LOCCODEDESC		Text		Code description for LOCATION
	YRBLT		Number	Auto	Original year of construction
	REMODYR		Number	Auto	Refers to the year of the last extensive remodeling, i.e., remodeling which significantly alters the "effective age" of the dwelling.

Table 1. Descriptive Data Dictionary for the EBLP Database					
Table	**Field**	**Key**	**Format**	**Decimals**	**Description**
tbl_PropertyAge	EXTWALL1		Text		Code for predominant wall construction type
	EXTWALLDESC1		Text		Code description for EXTWALL1
	EXTWALL2		Text		Code for predominant exterior finish type
	EXTWALLDESC2		Text		Code description for EXTWALL2
	CDU		Text		Composite rating code for depreciation of the structure
	CONDESUSESDESC		Text		Code description for CDU
	ENVIRON_Comment		Text		Rationale for ENVIRON exclusion provided or updates/edits made to records by ENVIRON
	PROP_ID		Number	Auto	Unique identifier for a property age standardized address used in preliminary versions of the blood lead database.
	Code	Foreign	Number	Auto	Unique identifier for a standardized address - the key between the coded and uncoded versions of the blood lead database
	Coords		Text		Does the standardized address have map coordinates (Y or N)?
tbl_Results	Test_ID	Primary	AutoNumber		Unique identifier for a blood lead result
	Indiv_ID	Foreign	Number	Auto	Unique identifier for an individual with a blood lead result
	Loc_ID	Foreign	Number	Auto	Unique identifier for a standardized address - the key between the coded and uncoded versions of the blood lead database
	Test_number		Number	Auto	Test occurrence for an individual in chronological order
	Identifier	Foreign	Number	Auto	Unique identifier for a blood lead record used in preliminary versions of database (is not unique to a test result in all cases)
	Test_year		Number	Auto	Year number of the test occurrence
	Test_date		Date/Time		Full date of the test occurrence

Table 1. Descriptive Data Dictionary for the EBLP Database					
Table	**Field**	**Key**	**Format**	**Decimals**	**Description**
tbl_Results	Age_type		Text		Infant <1yr, "Child" 1-<5yr, "Older than 5" ≥5yr
	Age_txt		Text		Age at blood draw in years (text format)
	Age_num		Number	2	Age at blood draw in years (number format)
	Pb_type		Text		Whether the blood test was capillary or venous
	Pb_txt		Text		Blood lead result in µg/dL (text format)
	Pb_qual		Text		Text qualifiers for blood lead results, such as "<" for non-detects
	Pb_num		Number	1	Blood lead result in µg/dL (number format)
tblTestIntervals	BT_ID		Number	Auto	Unique identifier for the Interval records
	Indiv_ID		Number	Auto	Unique identifier for an individual with a blood lead result
	Time in days		Number	Auto	Time between two test occurrences in days
	Time Interval		Text		Indicates which two chronological tests the time in days describes; "BT" is for "between" (e.g, BT1_2 is the time between test occurrence 1 and 2 for an individual)
	Test_ID_begin		Number	Auto	The unique Test ID that corresponds to the first test in the Time Interval (e.g., would be the Test ID for test 1 of a BT1_2 time interval)
	Test_ID_end		Number	Auto	The unique Test ID that corresponds to the second test in the Time Interval (e.g., would be the Test ID for test 2 of a BT1_2 time interval)

4.1 Data Dictionary

The EBLP database is a Microsoft Access relational database containing seven tables, as described in Table 1.

- **tbl_QueryList** catalogs every query in the database including the title and a description.
- **tbl_Individuals** includes information specific to a distinct individual, such as gender and count of blood lead tests. Indiv_ID is the primary key.
- **tbl_Locations** includes information specific to a distinct location by address, such as which census tract (i.e., neighborhood) an address is assigned to and if XY coordinates have been obtained for it. Code is the primary key, which goes by Loc_ID when it behaves as a foreign key in tbl_Results.
- **tbl_OtherInfo** houses other information collected about blood lead records during the transcription process. Identifier is the primary key. This key was the unique identifier for blood lead records during preliminary phases of the project and is not unique to a test result in all cases.
- **tbl_PropertyAge** contains information on properties in Silver Bow County. Every field except ID, ENVIRON_Comment, PROP_ID, Code, Coords, and Census Tract came from querying and exporting data from the Montana Cadastral repository discussed in section 2.2. Information types include house age (YRBLT), wall construction material (EXTWALL1), and exterior finish types (EXTWALL2).
- **tbl_Results** includes blood lead results, age of the individual at test, test date, test type, and foreign keys that allow this table to relate to the other tables. Test_ID is the primary key, while Indiv_ID relates it to tbl_Individuals, Loc_ID relates to tbl_Locations, and Identifier relates to tbl_OtherInfo.
- **tbl_TestIntervals** includes the results of internal analysis performed to understand how much time typically passed between blood lead tests for an individual. It does not have an established relationship to the other tables, evidenced by its absence in Figure 1, although the table does relate to tbl_Individuals by Indiv_ID.

5 Blood Lead Subset Characterization

Using existing queries in the EBLP database, subsets of blood lead data were extracted for statistical analysis. This section describes how the subsets of blood lead data are defined based on record characteristics.

Due to more limited blood lead record availability prior to 2002, the EBLP database only includes blood lead results (tbl_Results) that are from the year 2002 forward and only those which are defined as “complete” records (see below). All blood lead data originally transcribed on-site was retained electronically in the confidential blood lead database[3] whether it is included in the EBLP database or not. Not all of the blood lead results have corresponding property information.

Complete records (from “tbl_Results”; n=6,608) are defined as containing all of the following:

- Blood lead result, capillary or venous
- Physical Address (not a P.O. Box)
- Birthdate
- Gender

The Capillary base dataset (from query “Capillary Base Dataset”; n=3,392) is defined as complete records meeting the following criteria:

- 12 to 60 months of age at time of testing
- Test methods other than Lead Care II
- Locations corresponding to a Butte neighborhood or the general Butte area
- Capillary blood lead results

An additional query “Dataset for Neighborhood Comparison” (n=2,724) refines the data for the neighborhood comparison to include:

- Results from years between 2003 and 2010
- A detection limit of 1 µg/dL
- Locations corresponding to neighborhoods N1-N8

The data for the NHANES comparison are refined from query “Dataset for NHANES Comparison” (n=2,796) to include:

- Results from years between 2003 and 2010
- A detection limit of 1 µg/dL

[3] This information can only be accessed by individuals who have signed a confidentiality agreement with BSB

6 Environmental Database Review

The environmental database was used for supplemental analyses in the Butte health study. In order to prepare it for analysis, QA/QC was performed, in addition to a geocoding process to assign the records to the study neighborhoods.

6.1 Initial QA/QC of Environmental Database

The environmental database provided by BSB County underwent QA/QC to the extent possible. Attempts were made to confirm the records in the database against the BSB Annual Construction Completion reports; however, there were fewer total records in the database than in the Annual Reports and the discrepancy was unable to be reconciled with available resources. Additional QA/QC involved the identification and removal of approximately 100 duplicate records in the sampling and abatement tables in the database that were confirmed to be duplicated due to operator error (e.g., an employee of the county entered data for a property twice).

6.2 Geocoding Environmental Database

In order to analyze the RMAP data in the context of the study, the 2,147 parcel records within that database needed to be assigned to a neighborhood. This process was similar to that described in section 3. However, in the EBLP database, address was used to link the records to the tax parcel data which provided a spatial location. For the environmental database, an identifier known as a “geocode” was provided and could act as the link the tax parcel information, which then provided geographic coordinates. A geocode is one way that parcels are identified by governments; it is made up of seven sets of numbers pieced together as one 17-digit long number. CAMA guidance documents are available on the Cadastral website for more information. The objective of this phase was to correctly match the geocodes of RMAP records to the geocodes in the tax parcel shapefile, which contains coordinates for plotting the data.

For the majority of the RMAP properties, geocode information provided in the RMAP database was linked to tax parcel data (from Montana Cadastral) in order to assign the RMAP data to a study neighborhood. For a few properties with a geocode that could not be matched to a tax parcel, or with an incomplete geocode, standardized address was used to assign the properties to a neighborhood. A county representative assisted in correcting several geocodes that had changed over the course of the RMAP data collection period. After corrections were made, the database contained 7340 soil/dust samples from 1850 unique parcels, 899 paint samples from 812 unique parcels, and 711 abatement records from 519 unique parcels. These data were used in the Butte health study for supplemental analysis.

Appendix E

Technical Memorandum
Proposed Reference Blood Lead Data
for Use in the Butte Health Study

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8, MONTANA OFFICE
FEDERAL BUILDING, 10 W. 15th STREET, SUITE 3200
HELENA, MONTANA 59626

Ref: 8MO

August 29, 2013

Dan Powers
Butte-Silver Bow Health Department
25 West Front Street
Butte, MT. 59701

Re: Approval for Technical Memorandum - Proposed Reference Blood Lead Data for Use in the Butte Health Study, (August 20, 2013)

Dear Mr. Powers

The U.S Environmental Protection Agency (EPA), in consultation with the Montana Department of Environmental Quality (DEQ), approves the use of the proposed reference blood lead data (NHANES) described in the Technical Memorandum mentioned above.

Sincerely,

Nikia Greene
Remedial Project Manager
US EPA Region 8

cc: (email only)
Dan Dennehy; BSBC
Rick Larson; BSBC
Molly Maffei; BSBC
Tom Malloy; BSBC
Jon Sesso; BSBC
Eric Hassler; BSBC
Dan Powers; BSBC
Gordon Hart; Paul Hastings for BSBC
Lindy Hanson; ARCO/BP
Loren Burmeister; ARCO/BP
Cord Harris; ARCO/BP
Lorri Birkenbuel; ARCO/BP
Marci Sheehan; ARCO/BP
Marcus Ferries; BP

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Jill Kelley, ARCO/BP Counsel
Jean Martin; Counsel ARCO/BP
William Duffy; attorney for ARCO/BP
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Pat Sampson; PTS for ARCO/BP
Mike Borduin; PTS for ARCO/BP
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Don Booth; for ARCO/BP
Gary Honeyman; UP
Robert Bylsma; Counsel for UP
John Gilmour; Jgdpc for UP
Bill Jackson; Jgdpc for UP
David Smith; BNSF
Leo Berry; BKBH for BNSF
Robert Lowry; Kelrun for BNSF
John Ashworth; Kelrun for BNSF
Brooke Kuhl; Counsel for BNSF
Chuck Soule; Kennedy Jenks for BNSF and UP
Bob Andreoli; Patroit/RARUS
R. Schellig; Counsel for Patriot/RARUS
Becky Summerville; Ddmllaw for Inland Properties Inc.
Dawn Maack; Dmllaw for Inland Properties Inc.
Henry Elsen; EPA
Sara Sparks; EPA
Joe Vranka; EPA
Nikia Greene; EPA
David Shanight; CDM for EPA
Jared Hautamaki; EPA
Ken Brockman; BOR
James Freeman; DOJ
Mary Capdeville; State counsel for DEQ
Joe Griffin; DEQ
Larry Scusa; DEQ
Lisa Dewitt; DEQ
Bill Kirley; DEQ
Rob Collins; State NRD Program
Ted Duaime; MBMG
Nick Tucci; MBMG

Technical Memorandum
Proposed Reference Blood Lead Data
for Use in the Butte Health Study

Butte, Montana

Prepared by:
ENVIRON International Corporation
Seattle, Washington

Date:
August 2013

Project Number:
3032503A

ENVIRON

Contents

1 Introduction

As detailed in the U.S. Environmental Protection Agency (EPA)-approved Butte health study work plan, the primary study objective to be addressed by the health study is the review and evaluation of available Residential Metals Abatement Program (RMAP) data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. To address the study objective, the approved study plan focuses on analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels (BLLs) in Butte children[1]. More specifically, examination of the blood lead data will be conducted to assess whether changes in community-wide exposures are evident based on the following lines of evidence:

- Statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP differences in BLLs across these same neighborhoods.

and/or

- The distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated.

As discussed in the EPA-approved work plan, if the lines of evidence support a finding that improvements to the RMAP are necessary to identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community, then response actions appropriate to addressing identified RMAP deficiencies will be investigated and proposed.

In support of the second line of evidence, this technical memorandum proposes a reference blood lead data source for use in comparison to the Butte blood lead data. Examination of the comparability of factors that may influence BLLs across datasets is an important consideration for selection of a reference blood lead data source. Such factors include demographic characteristics (e.g., gender, age, income level, etc.), age of housing stock within the community, blood lead testing and analytical methodologies, as well as whether or not a potential reference data set has a Superfund site history similar to Butte. The intent of this technical memorandum is to detail the process used to assess a variety of potential reference data sources and summarize the outcome of that process leading to a recommendation for use of a primary reference data source to best support comparisons of the distribution of BLLs in the Butte community and in a reference population over the same periods given consideration of such factors.

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[1] As noted in the approved work plan, young children (ages 1 to 5 years) are most susceptible both to lead exposures and also to adverse effects of lead. Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Therefore, focusing on this population provides the most effective means of detecting any elevation of lead exposures in affected neighborhoods. This focus on young children is also protective of all persons including older children and adults.

Two categories of data sources were considered to identify potential reference blood lead data sets. One source investigated was Montana communities with various characteristics comparable to Butte (e.g., size, urbanization, age of housing stock, socioeconomic status) that also have sufficient blood lead data from some or all of the years for which Butte data are available. The second source category was national blood lead data from the National Health and Nutrition Examination Survey (NHANES). For investigation of this source, our analysis involved determining the feasibility of adjusting available NHANES data to create an NHANES-based reference population with characteristics similar to Butte. In conducting research on these sources, it was understood that identification of one or more reference data sources that could be matched perfectly to the Butte data with respect to all factors that may influence BLLs would not be feasible. Both kinds of data sets were found to offer different advantages and disadvantages; however, community-based data are subject to significant limitations in the availability of data for the time periods and ages of interest, whereas the NHANES database was not subject to these limitations. Therefore, we recommend use of the NHANES database as the primary blood lead data reference source for comparison to the Butte community in the health study. Additional comparative analyses using subsets of Butte data with some of the community data sources may also be useful for interpreting the distribution of BLLs in Butte. Such supplemental analyses will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds.

This memorandum summarizes the processes used, possible reference data identified, and details the rationale for proposed use of the NHANES blood lead data source. Proposed statistical approaches for study data analyses to support examination of Butte blood lead data in comparison to appropriate reference population data will not be finalized until approval of this technical memorandum and the proposed primary reference data source by EPA in consultation with the Montana Department of Environmental Quality. However, in anticipation of such approval, this memorandum details specific data adjustment and weighting steps that would be necessary to ensure comparability of the datasets, particularly with regard to those factors that are known to affect BLLs. Given the importance of these factors in selection of appropriate blood lead reference data, this memorandum is organized with an overview of these factors first, followed by findings of our research and evaluation of specific data sources leading to recommended use of the NHANES data source for development of the reference data sets.

2 Consideration of Factors Influencing the Comparability of Blood Lead Datasets

This section provides a review of factors known to correlate with and/or to affect BLLs as well as those which may affect interpretation of blood lead measurements. Examination of the comparability of these factors across datasets is a crucial element to guide our reference population selection and study design. Specifically, an assessment of factors that may influence the comparability of different blood lead datasets must include consideration of factors that could be contributing to an observed effect. It is also important to characterize the sampling and analytical methods used to measure BLLs and the associated detection limits as these may also influence meaningful comparison of two blood lead datasets.

In assessing lead exposures in Butte, we start by characterizing the population for whom we have data and then identifying additional factors that may affect BLLs in that population. The majority of the data in the Butte database are from young children between 12 and 60 months of age. The majority of sample dates range from late 2002 through late 2011. The primary sampling method was finger stick/capillary tube with an analytical detection limit of 1 µg/dL. Additional key characteristics for this population include racial/ethnic profile (predominantly non-Hispanic white) and house age (many neighborhoods with very old housing). The ways in which these and other factors may affect the comparability of potential reference blood lead datasets to Butte data are described below.

2.1 Comparability Based on Sampling and Analytical Methods

A critical factor to examine in selecting reference data is the analytical method used and the associated detection limits. Different whole blood sampling methods (i.e., venous sample vs. finger stick with capillary tube or filter paper) and analytical methods are used in different programs. A key concern with the use of finger stick sample collection vs. venous sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Consequently, data collected by finger stick is likely to be biased high compared with data collected by venous samples.

Detection limits may vary widely and reproducibility may also vary. Detection limits have declined over time during the past few decades; however, current regulations still allow ±4 µg/dL laboratory error in blood lead proficiency testing programs, and variations in test results of ±2 µg/dL are normal and are well within the acceptable lab error (Binns et al. 2007, ACCLPP 2012). The lowest detection limits are typically associated with venous samples and graphite furnace atomic absorption spectrometry (GFAAS) or inductively coupled plasma mass spectrometry (ICP-MS).

For blood lead analyses for the NHANES, detection limits have been 0.3 µg/dL or less over the past decade, whereas most capillary samples are analyzed by methods with a detection limit of 1 µg/dL. A kit called the LeadCare II point of care device, also being used by some programs, has a detection limit of 3 µg/dL. As BLLs have continued to decline, use of higher detection limits results in large numbers of samples falling below the detection limit, and may prevent accurate characterization of population blood lead distributions and means. Disparities in detection limits may also affect population comparisons. For the purposes of this study, data collected using the LeadCare II device is not useable because the detection limit is too high to allow for an assessment of the blood lead distribution in the datasets.

2.2 Comparability Based on Factors Influencing Blood Lead Levels

Blood lead levels have declined precipitously in all U.S. populations since the 1970s with implementation of the ban on lead additives in gasoline and in paint, along with control of lead sources in plumbing, canned foods and other sources. Nevertheless, a variety of factors continue to be associated with higher BLLs. These include demographic factors such as gender, age and race/ethnicity, as well as a variety of socioeconomic factors such as income level and maternal education.

2.2.1 Sample Year, Age and Gender

Two primary factors to be considered in designing lead exposure comparison studies are the year in which the sample was collected and the age of the subject. Blood lead levels may also vary by gender, but this is not currently a significant factor for all age cohorts based on national data.

As noted above, BLLs have declined over the past few decades, and continue to decline, albeit at a slower rate. It has also been consistently observed in the U.S. that on average young children between the ages of 1 and 3 years have the highest BLLs. These trends are both illustrated in Figure 1, which shows the continued decline in BLLs in successive birth cohorts, as well as the decline in BLLs as each birth cohort gets older. Consequently, comparisons of BLLs must ensure that the subject populations are matched in terms of sample year and subject age.

Much available blood lead data focuses on young children because their BLLs are higher than other age groups. Preliminary analyses of the Butte dataset confirm that BLLs have been trending down over the period from late 2002 to late 2011, and that BLLs are higher in 1 to 5 year old children compared with older children and adults (Figure 2).

Blood lead levels also vary by age within the 1 to 5 year old cohort. Even as BLLs have declined over time, the ages with peak average BLLs have consistently remained 12 to 36 months. This factor indicates that it will be necessary to ascertain if a reference dataset has the same age structure as the Butte dataset. In contrast, during the past ten years in the U.S. there have not been consistent gender-related differences in BLLs in young children. Figure 3 illustrates these factors for a national dataset for two time periods, i.e., from 2003 – 2006 and from 2007 - 2010.

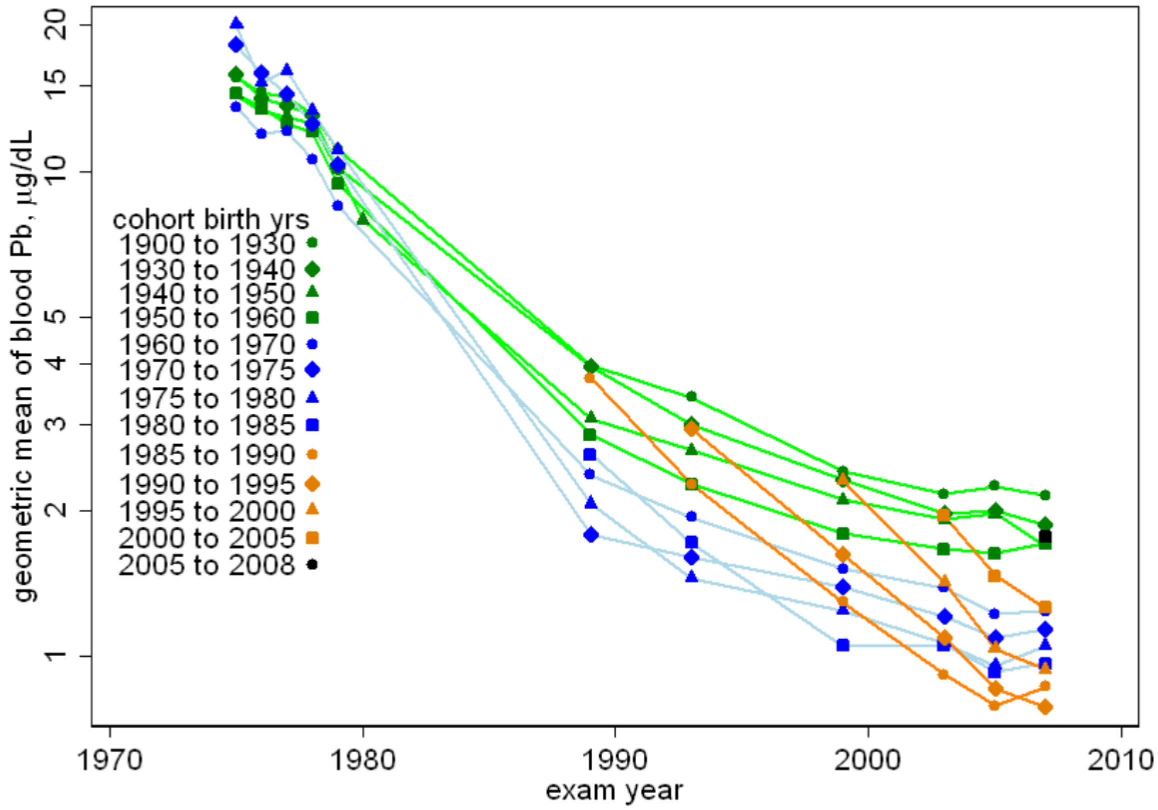


Figure 1. Decline in Blood Lead in Different NHANES Birth Cohorts (source: USEPA 2013a)

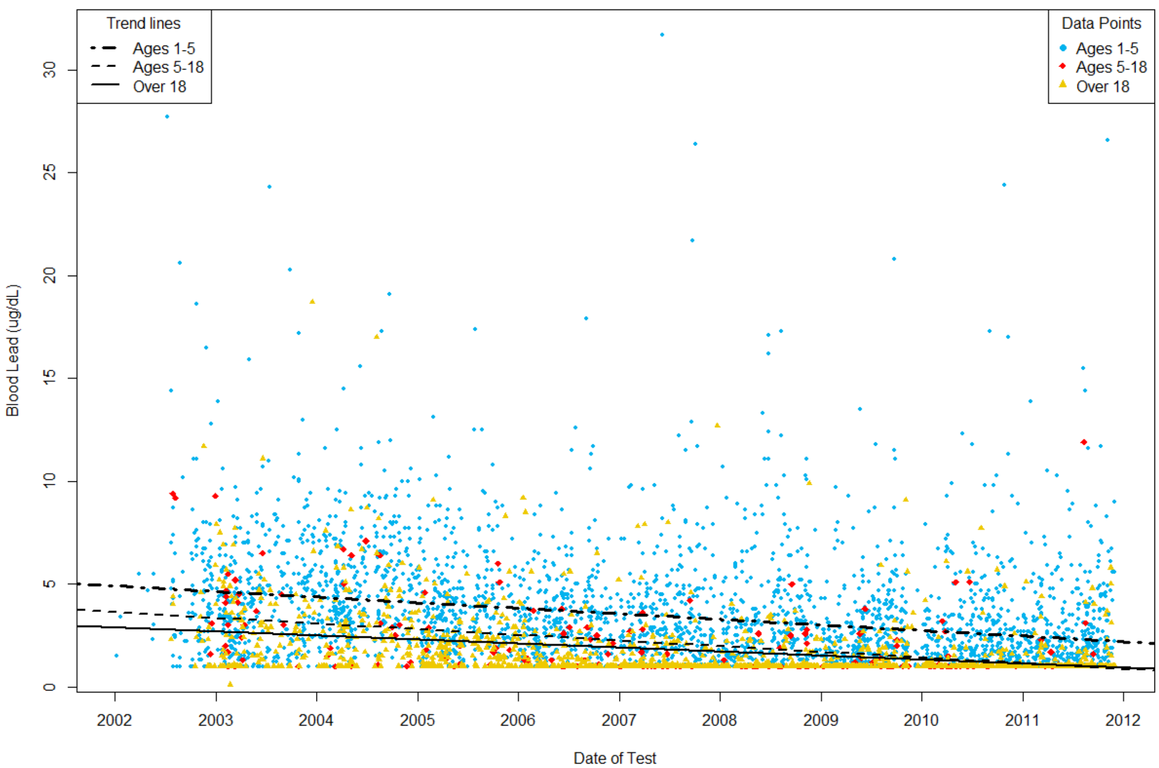


Figure 2. Butte Blood Lead over Time by Age Group for Individuals Aged 1 Year or Older (Excluding Lead Care II Results)

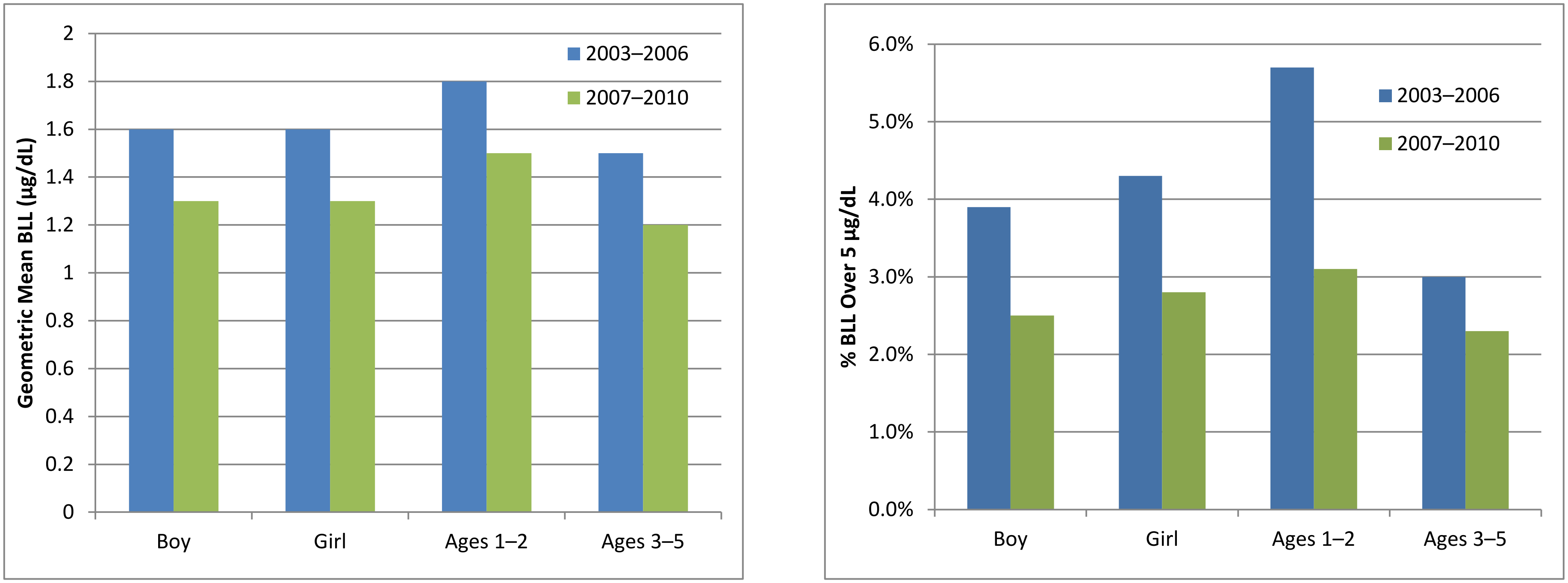


Figure 3. Blood Lead by Gender and Age Group from U.S. Children Ages 1 to 5 (From U.S. Centers for Disease Control and Prevention [CDC] Morbidity and Mortality Weekly Report April 5, 2013)

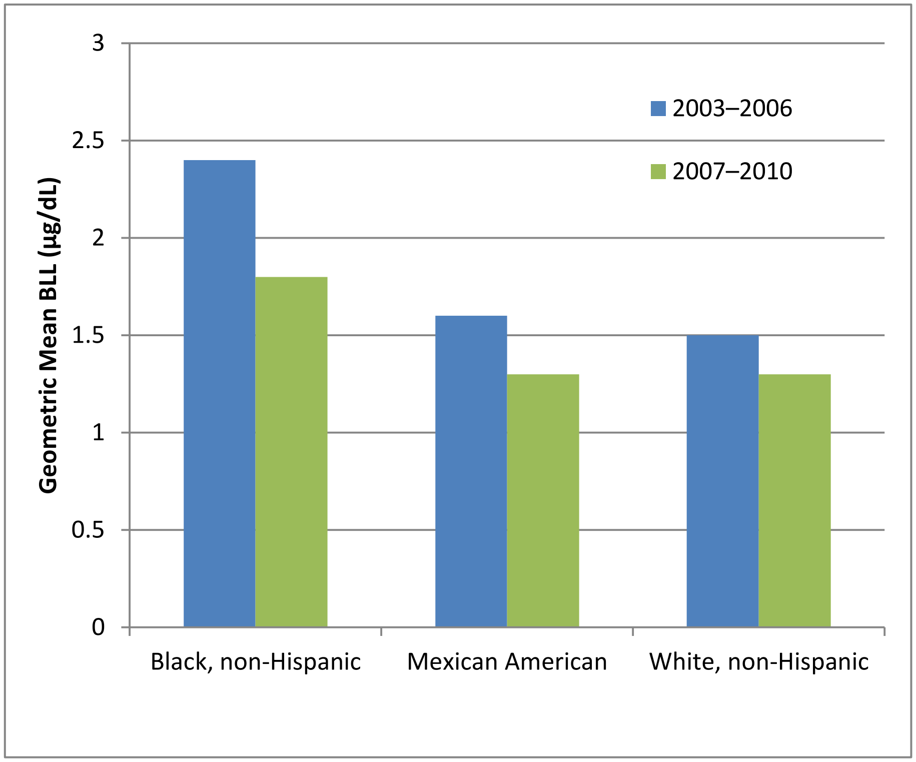
2.2.2 Demographic and Socioeconomic Factors

Demographic and socioeconomic factors such as race/ethnicity, income level, educational attainment of parents and housing status have been correlated with BLLs in children and are important in identifying appropriate comparison communities for the Butte health study (Sargent et al. 1995, CDC 2000, Gee and Payne-Sturges 2004, CDC 2013a, Jones et al. 2009). BLLs also are known to vary with season. The relative importance of these factors may be expected to vary over time. For example, while the difference in BLLs between non-Hispanic black children vs. non-Hispanic white children is still significant, the magnitude of the difference has decreased substantially over time (CDC 2013a). Jones et al. (2009) and CDC (2013a) provide summaries of trends in the primary demographic and socioeconomic factors for U.S. children from 1988 through 2010. Factors considered during identification of possible reference populations for Butte are described below.

Race/Ethnicity – As described above, race continues to be a significant risk factor for elevated BLLs with the highest levels on average reported for non-Hispanic black children. Figure 4 illustrates race and ethnicity differences in geometric mean BLLs and BLLs greater than 5 µg/dL for a national dataset for two time periods during the past decade. As shown in Figure 4, average BLLs are higher in non-Hispanic black children and the percent of these children with BLLs greater than 5 µg/dL is more than twice as high as the percent of white, non-Hispanic and Mexican children with elevated BLLs.

Poverty status – Children living in poverty have higher BLLs compared with children in wealthier households. Two measures are used in national studies to assess poverty status: the poverty to income ratio and Medicaid enrollment. The poverty to income ratio or PIR is the total family income divided by the federal poverty threshold specific to family size, year and state of residence. Figure 5 compares geometric mean BLLs and BLLs greater than 5 µg/dL for children from low income households (defined as a PIR of less than 1.3) with those from higher income households, and also compares BLLS for children enrolled in Medicaid with those not enrolled. Both of these measures of poverty status are associated with higher mean BLLs and substantially higher percent of children with BLLs greater than 5 µg/dL

House age – Older housing is associated with higher BLLs for a variety of reasons, including the historical use of exterior and interior paint with added lead and higher frequency of lead plumbing lines and fixtures in older homes. Lead paint is primarily a concern when the paint condition deteriorates, so poverty status and living in rental housing are related factors that may contribute to greater exposure to lead pain in older housing. Lead content of paint was reduced over several decades prior to its ban in 1978. Figure 6 shows the influence of house age on average and elevated BLLs for several categories of house age. As can be seen from this figure, the percent of children with elevated BLLs is markedly higher for those living in houses built prior to 1950.



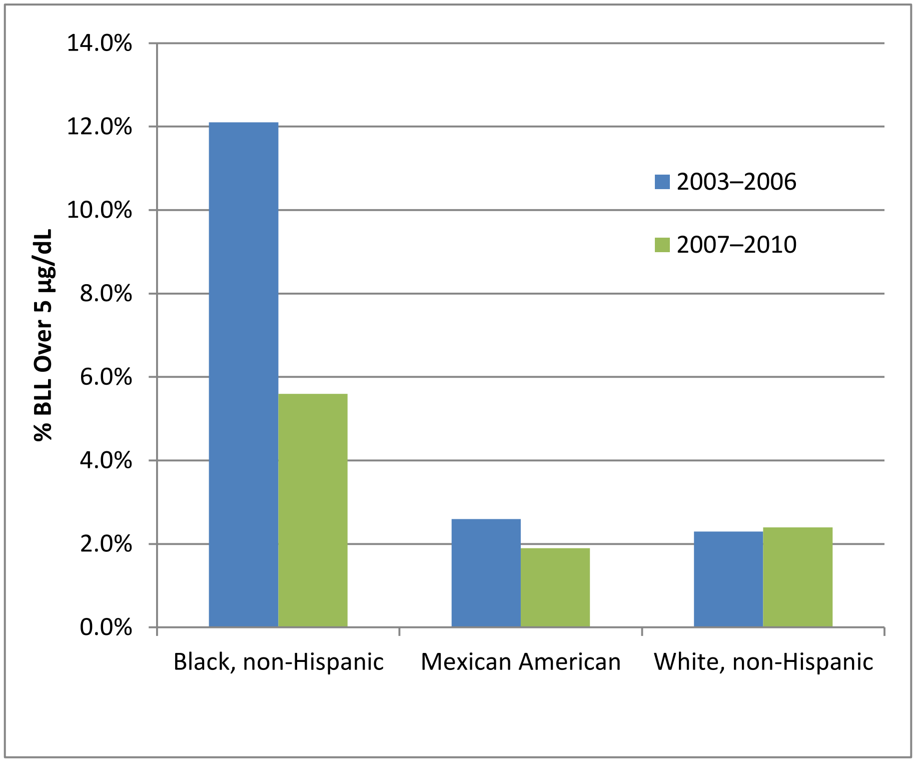
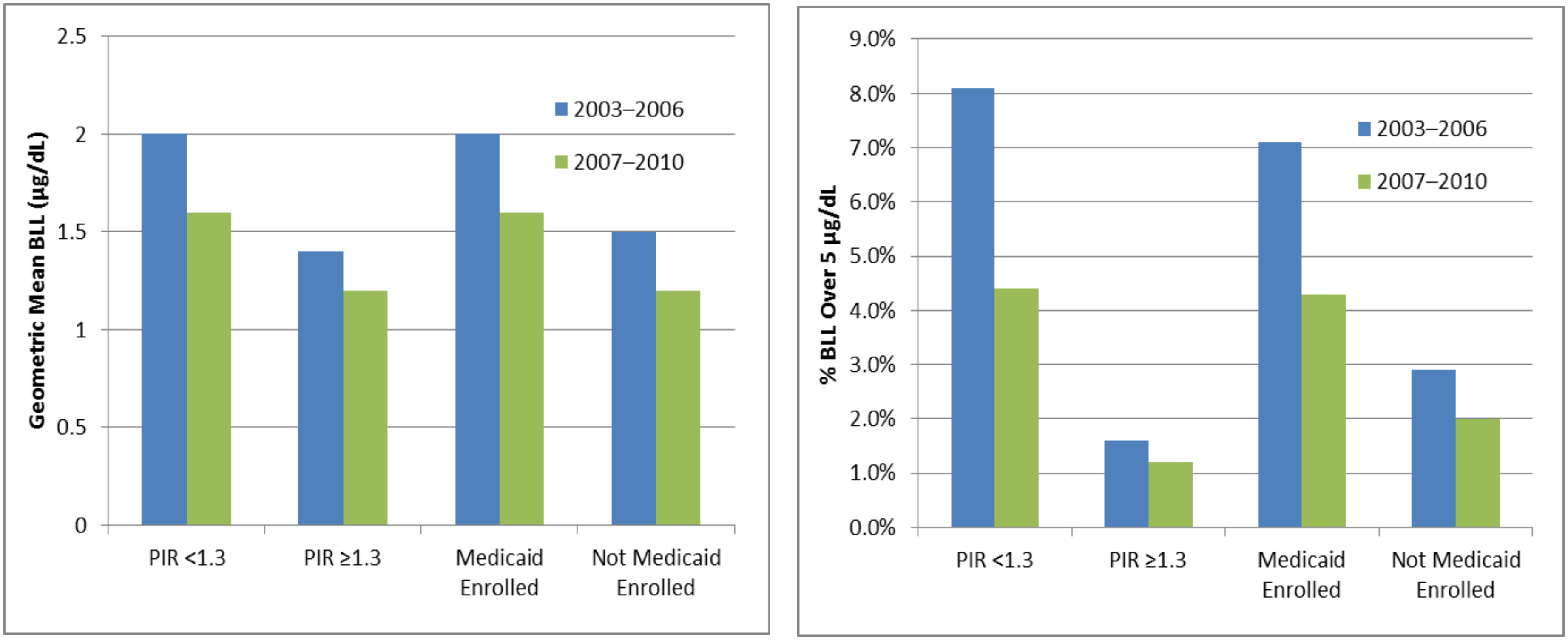


Figure 4. Blood Lead by Race/Ethnicity from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)



PIR = Total annual family income/
Federal poverty threshold specific to family size, year, and state of residence.

Figure 5. Blood Lead by PIR and Medicaid Status from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)

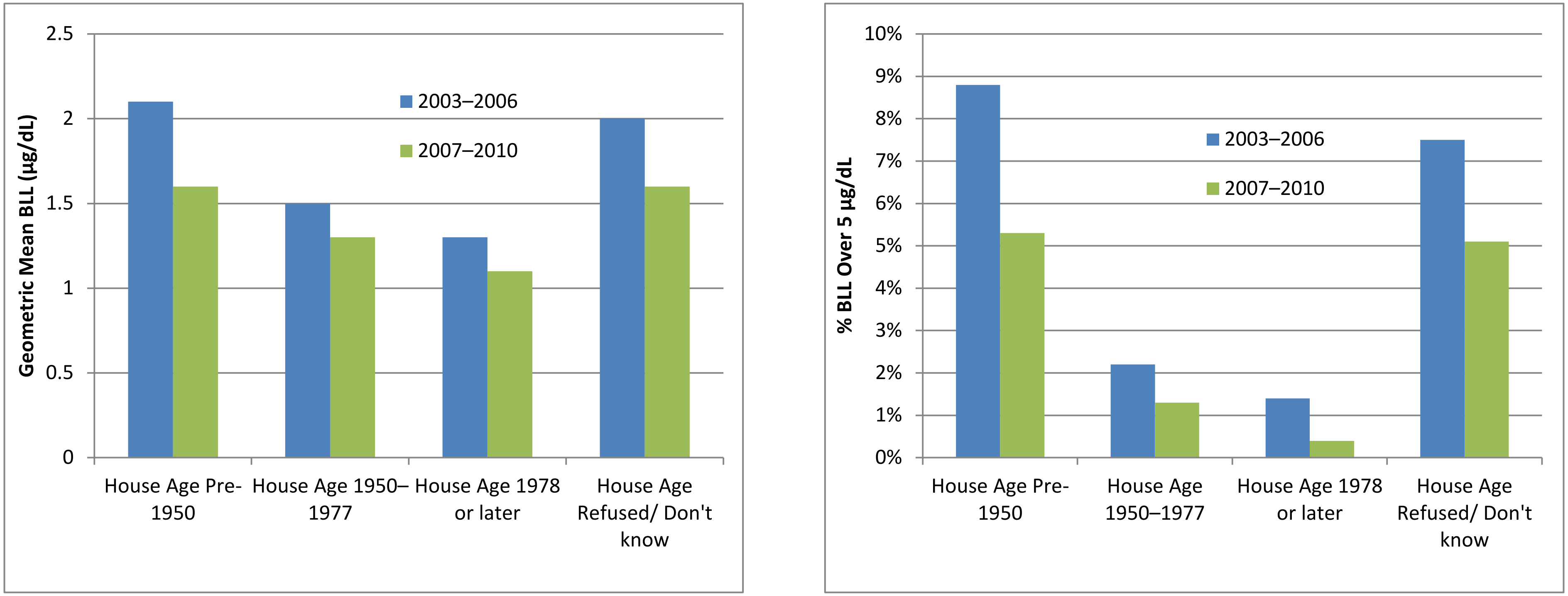


Figure 6. Blood Lead by House Age from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)

Season – BLLs in young children have long been known to be highest in summer and early autumn. This pattern has been assumed to be associated with greater exposure to soil containing lead, due to more time spent outside and to more soil tracked and blown into the house during the summer months. A recent study of BLLs in Detroit area children has confirmed that this pattern still occurs; with late summer BLLs averaging between 11% and 14% higher than BLLs measured in January (Zahran et al. 2013). A preliminary analysis of the Butte dataset suggests that the variation may be even greater among Butte children.

All of the factors described above have been shown to have a substantial impact on BLLs, and are evaluated in the identification of a reference population.

3 Identification of Possible Reference Communities

This section includes a description of the methods used to identify possible reference communities and methods for acquisition of blood lead data, followed by summaries of key communities that had relevant blood lead data, including Flathead, Gallatin, Lewis and Clark and Yellowstone Counties in Montana, and Lake County, Colorado and Shoshone County, Idaho. Communities are identified as counties because data were generally managed by and available from county health departments.

3.1 Methods for Identifying Reference Communities

Identification and evaluation of publically-available blood lead datasets for Montana communities and other communities in the mountain west considered similarities between Butte and potential reference communities with regard to the following:

- urbanization level,
- demographics,
- socioeconomic characteristics,
- time periods of blood lead data sampling,
- ages of individuals represented by blood lead data.

Differences in level of urbanization have been shown to relate to differences in health statistics. For example, death rates generally increase with decreasing urbanization across multiple age groups, for both genders (Ingram and Franco 2012). It is thought that this and other observed health disparities between urban and rural communities reflect differences in demographic, economic, physical, social, and environmental characteristics, in addition to differences in access to and characteristics of available health care resources (Ingram and Franco 2012).

To facilitate the examination of urbanization level impacts on health, the National Center for Health Statistics (NCHS) developed the 2006 Urban-Rural Classification Scheme for Counties, which assigns counties to one of four metropolitan or two nonmetropolitan urbanization categories. There are 56 counties in Montana, including Butte-Silver Bow County. Due to the level of effort involved with online and phone research to identify the existence and characteristics of blood lead data for each of these counties and/or individual communities within them, we first narrowed the potential list of communities by comparable urbanization level. The NCHS classifies Silver-Bow County as a “micropolitan” area because it contains at least one urban cluster of 10,000 – 49,999 inhabitants present in a nonmetropolitan area (Ingram and Franco 2012). Other Montana counties designated as micropolitan include Flathead, Gallatin, Hill, Jefferson, and Lewis and Clark (Ingram and Franco 2012).

The NCHS designations provide more classifications for metropolitan than nonmetropolitan counties and the focus is on population size of urban clusters, independent of economic base and other factors that may influence health characteristics, such as housing stress and type of economy. To further explore nonmetropolitan counties with similar characteristics, additional refinement of rural classifications was sought.

The U.S. Department of Agriculture Economic Research Service (ERS) provides rural classification codes for the six NCHS-designated micropolitan counties, shown in Table 1 (USDA 2009, 2013). The ERS 2013 Rural-Urban Continuum Code (RUCC) further classifies nonmetropolitan counties according to population density as well as proximity to metropolitan areas, a measure of urban influence. Of the six NCHS-designated micropolitan counties, four counties, including Silver Bow, are similarly designated as RUCC code 5, nonmetropolitan counties with an urban population of 20,000 – 49,999, not adjacent to a metropolitan area[2]. The nonmetropolitan counties with similar urbanization to Silver Bow County, i.e., Flathead, Gallatin, and Lewis and Clark, were the focus of further characterization to assess the potential for comparability of factors that may influence blood lead data and also for availability of blood lead data.

Demographic and socioeconomic information specific to Silver Bow, Flathead, Gallatin, and Lewis and Clark Counties was obtained from the ERS and U.S. Census Bureau to characterize factors potentially influencing BLLs.

ERS assigns typology codes to each county to identify differences in economic and social characteristics. ERS codes for economic dependence, housing stress, and nonmetropolitan recreation status, shown in Table 1, relate to factors that can directly or indirectly influence blood lead, and may be considered in identifying strengths and weaknesses of potential reference populations. U.S. census demographic (e.g., gender and age distributions) and socioeconomic (e.g., educational attainment, income, and poverty) data are provided in Table 2 to further characterize potential reference population characteristics. In addition, Table 3 provides housing data obtained from the U.S. census, which represent an important factor associated with lead exposure in children.

Consideration of the urbanization level, demographics, and socioeconomics helps us identify and characterize communities that may be suitable reference populations for the Butte health study. Together, the NCHS, ERS, and census information provide us with quantified measures for cross-community comparisons that allow us to best match non-mining-related risk factors influencing BLLs. However, identified communities also must have publicly-available blood lead data to compare with Butte BLL data. Also, if blood lead data are identified, consideration of the time period during which the data were collected, collection and analytical method, and age range of the sampled population also must be evaluated for comparability to the Butte database.

3.2 Methods for Acquisition of Blood Lead Data

Following identification and characterization of counties with levels of urbanization similar to Silver Bow County as Flathead, Gallatin, and Lewis and Clark Counties, we sought to identify sources of blood lead data in each of these counties. Initially, the Montana Department of Public Health and Human Services (MDPHHS) was contacted in an effort to access state-wide data from which to obtain blood lead data for the target counties. However, it was reported that no state-wide blood lead statistics are publicly available (Cannon 2013, Helgerson 2013, Zanto

[2] Hill County is classified as a nonmetro county with an urban population of 2,500-19,999 not adjacent to a metro area; Jefferson County is classified as completely rural or less than 2,500 urban population not adjacent to a metro area.

2013). Like many other states, Montana has lacked funding for enforcement of reporting and centralized management and storage of blood lead data for Montana residents and little data is voluntarily reported to the state. In addition to few resources available to provide testing at the county and state levels, it was reported that many physicians are not recommending blood lead testing because lead exposure is not viewed as a current concern for most children under the age of six (Cannon 2013).

As discussed in the community summaries in the following section, lack of resources was often cited as a limitation to providing access to blood lead data, as well as being a limitation for general recording, storage, and management of data that is received from laboratories and health practitioners. The absence of Montana blood lead monitoring data is confirmed by the CDC's Childhood Lead Poisoning Data, Statistics, and Surveillance Program, which includes tested and confirmed elevated BLLs by year for children up to age 7 years beginning in 1997. Such summaries are provided for many states, but not for Montana (CDC 2013b). Similarly, other nearby states do not report blood lead data to the CDC, including Idaho, Wyoming, Colorado, North Dakota, and South Dakota, among others. Thus, finding blood lead data for comparable communities in neighboring states also presents a challenge. Once it was determined that a state-wide database could not be queried, we contacted county- and city-level organizations and/or agencies that would potentially collect and store child blood lead data.

In addition to seeking out local blood lead data sources, we opportunistically followed up on leads provided during conversations with MDPHHS staff, such as summary data for the 2012 Healthy Homes Study conducted by MDPHHS and focused collection efforts associated with Superfund clean-up in Butte, Libby, and East Helena, Montana. In such cases, we followed up on leads even if the data pertained to a county not previously identified as having a similar level of urbanization (i.e., Libby - Lincoln County), incompatible sample years (i.e., Healthy Homes Study participant counties), or influence of lead-emitting industrial sources (i.e., East Helena – Lewis and Clark County). Some summary data were obtained in this manner; data that are potentially suitable for use are described in the following community summary section.

Outside Montana, we were directed to the state of Colorado's Environmental Public Health Tracking Childhood Lead Poisoning Indicator Data, which includes summary blood lead testing information for children born between the years 2008 and 2011 and tested prior to their third birthday. The online database provides query results only for screening rate, number of children with confirmed and unconfirmed BLLs greater than 10 µg/dL, and number of children with BLLs less than 10 µg /dL. The raw blood lead data underlying these testing statistics are not readily available online. We contacted the Colorado Department of Public Health and Environment in an effort to obtain these data but were informed that data are not stored in a format that can be easily shared and there are no available resources that can be dedicated to manually retrieving data and/or removing confidential information (Kuhn 2013). Instead, we were referred to staff at the Lake County Blood Lead Program, due to the existence of a long-term blood lead surveillance program associated with the California Gulch Superfund Site near Leadville. Data obtained from Lake County are described in the following community summary section.

3.3 Community Summaries

A summary of demographic and socioeconomic characteristics, available blood lead data obtained from county and local-level organizations, and data suitability is provided for Butte-Silver Bow and each focus county, i.e., , Flathead, Gallatin, and Lewis and Clark. In addition, community profiles are provided where blood lead data were opportunistically obtained for communities outside the focus counties. These additional areas include Yellowstone County (Billings), Montana, plus Lake County, Colorado, and Shoshone County, Idaho. Blood lead data also were explored for Montana Healthy Homes Study participant counties, Globe, Colorado, and Rocky Mountain Arsenal, Colorado but no useful data were obtained from these locations; therefore, community summaries are not provided.

3.3.1 Butte-Silver Bow County, Montana

To assess the suitability of other Montana communities for comparison with Butte, we must first understand Butte economic, demographic, and social characteristics. These characteristics change over time, including over the study period ranging from 2002 to 2011. But, for the purpose of evaluating comparison communities, only more recent census (U.S. Census 2013) and ERS (USDA 2009, 2013) data are evaluated and presented in Tables 1 to 3.

Silver Bow County is home to roughly 34,000 people, 33,000 of whom live in Butte, and nearly 6 percent of County residents are under the age of 5 years. Ninety percent of Butte-Silver Bow residents have earned their high school diploma or equivalency and the median household income is roughly $40,000. In Butte-Silver Bow County, 16 percent of people live below the poverty level, which was defined as an annual income of $22,314 for a family of four in 2010 (U.S. Census 2011). The percentage of people living in poverty is higher in Butte-Silver Bow County (16 percent) than in Montana (14.6 percent) or the U.S. (14.3 percent) (U.S. Census 2013). Additionally, 40 percent of families with children less than five years old within Butte have incomes below the poverty level (U.S. Census 2013). The area addressed by the RMAP, which is the subject of this initial health study, includes the areas within Butte that have the highest percentages of families with incomes below the poverty level.

ERS does not classify Silver Bow County as a housing stress area, which would indicate that 30 percent or more of homes had one or more of the following conditions: incomplete plumbing or kitchens, cost 30 percent or more of occupants' income, and/or more than one person in residence per room (USDA 2009). Nearly half of Silver Bow County's total housing stock (16,675 units) was constructed prior to 1949 and roughly 80 percent of Butte housing was constructed prior to the ban of lead in paint in the late 1970's. Of the total housing units, 35 percent are not owner-occupied. Non-owner occupied housing (i.e., rental units) typically represents homes that are less likely to be maintained in good repair, which can be a concern when lead-based paint and plumbing are present (Sargent et al. 1995, Jacobs et al. 2002, Lanphear 2005).

Since 1989, the CDC has identified Medicaid-eligible children between the ages of 1 and 5 years as having an increased risk of lead exposure and targeted Medicaid-eligible children for preventive and screening measures, including blood lead testing (CDC 2009). Enrollment in Special Supplemental Nutrition Program for Women, Infant, and Children (WIC) and/or Head

Start is used as a proxy for Medicaid-eligible children and often, a partnership between CDC and WIC and/or Head Start is formed to facilitate blood lead screening and reporting to CDC.

In the Butte-Silver Bow County area, blood lead data are available for WIC-enrolled infants and children up to age 5 years as well as pregnant women for the years 2002 to 2011. The County health department has created a database to facilitate evaluation of blood lead data for the Butte health study, and will provide between 150 (2002) and nearly 500 results (2011) collected annually. Most data were from samples collected by capillary tube (i.e., droplets from a foot- or finger-prick). Samples collected prior to 2011 were analyzed by a fixed laboratory yielding a detection limit of 1 µg/dL and after 2011, samples were analyzed using a portable instrument that yielded a detection limit of 3 µg/dL. Each blood lead result is paired with gender, age, ethnicity, and residence location data. Summary statistics for the Butte-Silver Bow County blood lead database are provided in Table 4.

3.3.2 Flathead County, Montana

Flathead County, like Silver Bow County, is classified as having a services-dependent economy. Approximately 91,000 people reside in Flathead County and 19,700 of whom reside in micropolitan statistical area of Kalispell. As shown in Table 2, similar proportions (6 percent) of residents in Flathead and Silver Bow Counties are under the age of 5 years. A slightly higher proportion (92 percent) of Flathead residents has earned their high school diploma or equivalency than in Silver Bow County (90 percent). Flathead's annual per capita income of $25,300 is greater than that of Silver Bow, which also has a greater proportion of residents living below the federal poverty level (16 percent in Silver Bow compared to 13 percent in Flathead).

Flathead County is designated as both a housing stress and nonmetropolitan recreation area; designations which may be inter-related in that the sub-standard housing conditions may be attributable to recreational homes (see Table 1). As shown in Table 3, Kalispell itself has newer housing stock than Butte, with 51 percent of the total housing (9,100 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. Although Kalispell has a higher percentage of non-owner occupied housing (42 percent), the housing stock is younger and, therefore, less likely to present risks from historic lead sources (i.e., paint, plumbing).

The Flathead County Community Health Services Department advertises on-going, free lead screening of capillary blood samples, but blood lead data are not readily accessible (White and Stouts 2013).

Kalispell's Northwest Montana Head Start Program tests all children for BLLs and maintains some records in an electronic database. The program's Health and Nutrition Manager shared 199 de-identified, individual capillary data collected for years 2010 and 2011 (Napier 2013). However, individual results do not include the age or gender of the child, only date of sample collection and analytical result (detection limit of 1 µg/dL). Blood lead data collected prior to 2010 was collected, but the data is not readily available in a useable format.

Strengths of Kalispell-Flathead County as a reference population include:

- Similar education, median income, and poverty level,
- Similar services-based economy,
- No known major industrial point-sources of lead.

Weaknesses of Kalispell-Flathead County as a reference population include:

- Younger total population than in Butte but this is not expected to impact BLL comparisons for children under age 5 years, Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available blood lead data from Northwest Montana Head Start for 2010 and 2011 are not consistent with Butte study time-frame and do not include age and gender associated with individual results,
- Northwest Montana Head Start blood lead data collected prior to 2010 is archived, but not available in a useable format for external use.

3.3.3 Gallatin County, Montana

Gallatin County has a government-dependent economy, in contrast to the services-dependent economies of both Silver Bow and Flathead Counties. Approximately 90,000 people reside in Gallatin County, 37,000 people of whom reside in the micropolitan of Bozeman. Similar to Butte, five percent of Bozeman's residents are under the age of five years, as shown in Table 2. Disparities in socioeconomics can be viewed in Table 2. For example, nearly all Gallatin County residents (96 percent) have earned their high school diploma or equivalency compared to 90 percent in Silver Bow. Also, Gallatin's annual per capita income of $27,800 exceeds that of Silver Bow and 13 percent of Gallatin residents live below the poverty level, compared to 16 percent in Silver Bow.

Gallatin County is classified as a housing stress area by ERS. It is possible that the housing stress designation is correlated with its designation as a nonmetropolitan recreation county, where rudimentary recreational homes (i.e., cabins) may be common (see Table 1). As shown in Table 3, Bozeman itself has a much newer housing stock than Butte, with only 44 percent of the total housing (16,900 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. Although Bozeman has a higher percentage of non-owner occupied housing (55 percent), the housing stock is younger and may be less likely to present risks from historic lead sources (i.e., paint, plumbing).

The Human Resource Development Council (HRDC) provides Head Start educational services to low-income children ages 3 to 5 years in Gallatin, Park, and Meagher Counties. As part of HRDC's educational services, blood lead screening is conducted annually. For the past four to five years, HRDC has used the LeadCare II system for screening enrolled children; prior to that capillary testing was conducted. HRDC has indicated that they can provide BLL data for enrolled children, but data have not yet been received and years during which samples were collected is not yet known; conversations with HRDC are on-going (Origer 2013).

Strengths of Bozeman-Gallatin County as a reference population include:

- No known major industrial point-sources of lead,
- Blood lead data for children ages 3 to 6 years expected to be available from HRDC Head Start.

Weaknesses of Bozeman-Gallatin County as a reference population include:

- Differences in demographics and socioeconomics reflect younger population, higher income, and lower poverty rate than in Butte-Silver Bow,
- Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available Head Start blood lead data includes LeadCare II-analyzed data which are of limited utility.

3.3.4 Lewis and Clark County, Montana

Lewis and Clark County is home to the state capitol of Helena; the County is characterized by a government-dependent economy as opposed to a services-dependent economy. Approximately 63,400 people reside in Lewis and Clark County, 28,000 of whom live in the capital city of Helena. Like Silver Bow County, six percent of Lewis and Clark County residents are under the age of five years. Additional differences and similarities between demographic and socioeconomic characteristics can be viewed in Table 2. For example, 95 percent of Lewis and Clark residents have earned their high school diploma or equivalency compared to 90 percent in Silver Bow, and Silver Bow's annual per capita income is substantially lower than that of Lewis and Cark County.

The ERS does not classify Lewis and Clark County as a housing stress area. Approximately 70 percent of Helena's total housing stock (14,000 units) was constructed prior to the ban of lead in paint in the late 1970's, compared to Butte's 80 percent (Table 3). Further consideration of homes built prior to 1949, a period when lead content in paint was even greater than the period prior to 1979, reveals that roughly 30 percent of Helena's housing was constructed prior to 1949 compared to nearly 50 percent in Butte (Table 3). Thus, the age differences in Helena's housing stock compared with Butte's housing stock become more pronounced with consideration of pre-1950 housing. Helena has a greater percentage of non-owner occupied, and possibly less well-maintained, housing compared with Butte; however, on a county-level Lewis and Clark County has a lower percentage of non-owner occupied houses compared with Silver Bow County.

Blood lead data were collected from East Helena children age 6 months to 6 years for the years 1995 to 2011 in association with the East Helena Lead Education and Abatement Program (LEAP), which was established as part of the East Helena Superfund Site investigation and remediation effort. The blood lead data represent children living in an area impacted by a lead smelter that operated for well over 100 years, from 1888 to 2001. LEAP was established in 1995, the smelter closed in 2001, and lead abatement activities continued through 2010. U.S. EPA reports that BLLs have declined since the program's inception (USEPA 2013b). Prior to 1985, BLLs in only one-third of the children were below 10 µg/dL, whereas during the period 2000 to 2004 BLLs in 97 percent of children were at or below 4 µg/dL (USEPA 2013b).

De-identified LEAP blood lead data for all program years 1995 to 2011 are not available due to resource constraints preventing acquisition and transmittal of de-identified data[3]; however, de-identified data for approximately 140 children tested in September 2008 were readily available and provided by LEAP staff (Williams 2013). These data include BLL, age of child, date of blood test, and in some cases, yard soil lead levels or notes regarding date of yard soil remediation. The samples were collected using venous draws and depending on the laboratory conducting the analysis, the limit of detection is either 0.5 µg/dL or 2 µg/dL. Table 4 provides a summary of the September 2008 LEAP data, including age range, sample number, collection method, etc.

Strengths of Helena-Lewis and Clark County as a reference population include:

- Similar proportion of children below the age of 5,
- Similar housing stock age as for Butte, when considering homes constructed prior to 1979 but this similarity diminishes when considering pre-1950 construction,
- Blood lead data exists for East Helena children (up to 6 years) for years 2002 to 2011,
- De-identified, raw data for 140 children tested in 2008 have been provided by LEAP,
- Available blood lead data were analyzed in a fixed laboratory.

Weaknesses of Helena-Lewis and Clark County as a reference population include:

- Median income for Helena is 30% higher than in Butte and percentage of people living below poverty level is 3% lower, but these differences may not hold when focusing on East Helena community for whom we have blood lead data,
- 10% fewer owner-occupied homes, resulting in higher percentage of homes that are potentially less well-maintained than in Butte,
- Additional research may be needed to more clearly define socioeconomic and demographic characteristics of residents within the East Helena Superfund Site, represented by the LEAP BLL database,
- Blood lead database represents child population living within the area of influence of a former lead smelter,
- Blood lead database for entire program not available at this time (only 140 results from September 2008 available) due to resource limitations at LEAP / Lewis & Clark County Health Department.

3.3.5 Yellowstone County, Montana

Yellowstone County is a metropolitan county assigned an RUCC code of 3, representing metro areas of fewer than 250,000 people. The county population of 148,000 is dependent on a service-based economy similar to the Butte-Silver Bow area. Most of the county's residents, approximately 103,000 people, reside in Billings. The proportion of county residents under the age of 5 years (7 percent) is slightly higher than in Silver Bow County. As shown in Table 2, 92

[3] No annual summary reports describing number of samples analyzed each year were available. Much of the data is archived hard-copy, which would include patient name, address, etc.

percent of Yellowstone County residents have earned their high school diploma or equivalency compared to Silver Bow's 90 percent. Also, the annual per capita income is greater than that of Silver Bow and fewer of Yellowstone County's residents live in poverty (11 percent compared to Silver Bow's 16 percent).

ERS does not designate Yellowstone County as a housing stress area and Billings has newer housing stock than Butte, with 64 percent of the total housing (46,000 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. However, Billings and Butte have identical proportions of non-owner occupied housing (35 percent). Additional comparisons between the Billings-Yellowstone and Butte-Silver Bow areas can be made using data provided in Tables 2 and 3.

A brief report by the City of Billings regarding Head Start, Inc. blood lead testing of pre-school children indicated that few enrolled children are tested:

> "Head Start, Inc. has been performing lead-testing for children participating in their programs. In 2009, three of the 360 participating children were tested and all three were found to have no elevation in lead. Overall, the incidence of high BLLs in Montana children is 0.27%. The State stopped sending data to the Center for Disease Control in 2006 because there was no data to be sent. The data collected to date in Billings indicates that elevated lead blood levels are not a priority concern." -- in "*City of Billings Annual Action Plan, FY2011-2012, Year Two of the FY2010-2014 Consolidation Plan*" (no date)

Head Start, Inc. staff indicated that many children enrolled in their program are not tested by their physicians because they do not typically find children with elevated BLLs. As a consequence, the physicians do not view lead exposure as a current concern and consider the test unnecessary (McCulloch and Kelker 2013). Head Start, Inc. was willing to share de-identified data collected using LeadCare II from 2011 through 2013 by the Billings Clinic. An additional request for blood lead data collected prior to 2011 has been made, but it is not known if older data are available and if they were collected using LeadCare II or other methods.

Strengths of Billings-Yellowstone County as a reference population include:

- Similar services-based economy,
- No known major industrial point-sources of lead.

Weaknesses of Billings-Yellowstone County as a reference population include:

- Larger population may reflect greater urban area sources of lead than in Butte,
- Dissimilar income and poverty levels and other socioeconomic characteristics,
- Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available blood lead data for Head Start-enrolled children was collected outside the Butte Health Study time-frame and data quality for LeadCare II results is inadequate for use in the study.

3.3.6 Lake County, Colorado

Lake County is a micropolitan area (USDA 2013). Unlike other areas considered, Lake County is assigned a nonspecialized economic dependence RUUC code of 6 (USDA 2013). As shown in Table 2, the urbanization level, demographic, and socioeconomic characteristics of Lake County differ from Silver Bow. For example, the proportion of children under age 5 is 8 percent of the total population, compared to Silver Bow's 6 percent. Also, Lake County's population has a lower (81 percent) educational attainment level than Silver Bow (90 percent) with regard to obtaining a high school diploma or equivalent; although, Lake County's median household and per capita income are nearly identical to that of Silver Bow.

Lake County is designated by ERS as a housing stress area, perhaps due to the presence of recreational homes in surrounding wilderness areas, which would be consistent with the ERS designation as a nonmetro recreation county. As shown in Table 3, Lake County has similarly-aged housing stock as the Butte-Silver Bow area, with 75 percent of the total housing units (4,117 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. When considering homes built prior to 1950, the proportion of Lake County's housing stock in that category is less (40 percent) than that of Butte-Silver Bow (50 percent). Also, Lake County has a similar proportion of non-owner occupied housing (33 percent) as Butte (35 percent).

Lake County is home to Leadville, a historic mining district where the California Gulch Superfund Site is located. Mining impacts have resulted in elevated soil lead levels in residential areas. Nevertheless, data from Lake County were pursued for possible consideration as a reference dataset and annual summary data for the period from 2006 to 2010 for children ages 12 to 72 months were obtained from the county health department,.

A blood lead monitoring program operated by Lake County Health Department was established in 1995 as part of the cleanup agreement for the California Gulch Superfund Site. At that time, the estimated population of Lake County was approximately 6,000, with half of the population residing within Leadville. In 1991, prior to site remediation, a blood lead survey involving 314 children (64 percent of child population) demonstrated that the site-wide geometric mean BLL for Leadville children was 5 to 6 µg/dL, with 8 percent of children exceeding the CDC threshold of 10 µg/dL (USEPA 1999). Between 1999 and 2005, as part of the site cleanup agreement for residential soils, the Lake County Community Health Program worked to reduce soil lead exposures among child residents through its "Kids First" blood lead monitoring and education program. By 2005, the program had achieved its performance goals, but was extended to reduce overall lead exposure through continued education and blood lead monitoring (Lake County Board of County Commissioners 2009).

Individual de-identified blood lead data for child residents of Leadville are not available, but summary data have been obtained for years 2006 through 2010 (Lake County Public Health Agency 2013). Summary data include number of initial and re-tested children ages 12 months to 6 years and average and maximum BLLs for initial and re-test, by year and study area. A summary of all areas combined, by year, is provided in Table 3. All initial tests were conducted using capillary blood samples, re-test results for capillary results greater than 10 µg/dL are based on venous blood draws (Patti 2013).

Strengths of Leadville-Lake County as a reference population include:

- Similar proportion of housing constructed prior to 1979 compared to Butte-Silver Bow; this relationship generally holds for homes built prior to 1950,
- Summary blood lead data are available for children ages 1 to 6 six years,
- Blood lead data were analyzed via fixed laboratory,
- Available summary data were collected within Butte study period.

Weaknesses of Leadville-Lake County as a reference population include:

- Urbanization level and demographic and socioeconomic characteristics differ from those of Butte-Silver Bow,
- Community is located within a mining district with elevated levels of lead in soil,
- Individual blood lead data are not available.

3.3.7 Shoshone County, Idaho

Shoshone County, a nonmetropolitan county, is located in northern Idaho and is assigned an ERS RUCC code of 1 representing a farming-dependent economy (USDA 2009). Shoshone County's population is approximately 13,000, 5 percent of whom are under the age of 5 years. As shown in Table 2, fewer of Shoshone County's residents (82 percent) have earned a high school diploma or equivalent compared to Silver Bow County (90 percent). The per capita income in Shoshone County is slightly lower, reflected also in a slightly greater higher poverty rate.

Shoshone County is not classified as an ERS housing stress area, similar to Silver Bow County, and similar proportions of housing were constructed prior to 1979 though a greater proportion of Shoshone County homes are owner-occupied (see Table 3). The proportion of housing stock built prior to 1950 in Shoshone County is less (40 percent) than that of Butte-Silver Bow (50 percent).

Shoshone County contains the Coeur d'Alene River Basin, which is home to the Bunker Hill Mining and Metallurgical Superfund Site. The site was listed in 1983 due to metals contamination from historic mining activities, and is divided into three areas, the Coeur d'Alene Basin, a 21-mile square "Bunker Hill Box" which includes the populated areas, the non-populated areas of the Bunker Hill Box, and the Coeur d'Alene Basin which includes areas outside of the Box. Lead contamination resulting from historical mining practices led to blood lead monitoring of site residents since the mid-1980's through the Lead Health Intervention Program (LHIP). Summary data for children ages 6 to 72 months of age tested through the LHIP are available for years 2002 to 2010 (PHD 2008, 2009, 2010, 2012). Individual data are stored and managed on behalf of the LHIP by a private company, which must be contracted with directly for data analyses. Data are not stored in a de-identified format that facilitates sharing with outside entities.

Strengths of Coeur d'Alene Basin-Shoshone County as a reference population include:

- Similar proportion of homes constructed prior to 1979 compared to Butte-Silver Bow; this relationship generally holds for homes built prior to 1950,
- Summary blood lead data are available for children ages 6 months to 6 six years,
- Blood lead data were analyzed via fixed laboratory,
- Available summary data were collected within Butte study period.

Weaknesses of Coeur d'Alene Basin-Shoshone County as a reference population include:

- Urbanization level and demographic and socioeconomic characteristics differ from those of Butte-Silver Bow,
- Community is located within a mining district with elevated levels of lead in soil,
- Individual blood lead data cannot be directly accessed because they are not stored in a de-identified format that protects the privacy of the sampled individuals.

Table 1: ERS Rural-Urban Continuum Code and County Typology Codes

State-County FIPS Code	County, State	NCHS Classification	2013 Rural-urban Continuum Code (a)	Economic-dependence County Indicator (b)	Housing Stress County Indicator (c,d)	Nonmetro Recreation County Indicator (c, e)
30093	Silver Bow County, MT	Micropolitan	5	5	0	0
30029	Flathead County, MT	Micropolitan	5	5	1	1
30031	Gallatin County, MT	Micropolitan	5	4	1	1
30041	Hill County, MT	Micropolitan	7	6	0	0
30043	Jefferson County, MT	Micropolitan	9	2	0	0
30049	Lewis and Clark County, MT	Micropolitan	5	4	0	0
30111	Yellowstone County, MT	Small metro	3	5	0	0
08065	Lake County, CO	Micropolitan	7	6	1	1
16079	Shoshone County, ID	Noncore	7	1	0	0

Source: NCHS 2012; USDA 2009, 2013

Notes:

(a) Also known as the Beale Code. 3=County in metro area of fewer than 250,000 population; 5=Nonmetro county with urban population of 20,000 or more, not adjacent to a metro area; 7=Nonmetro county with urban population of 2,500-19,999, not adjacent to a metro area; 9=Completely rural or less than 2,500 urban population, not adjacent to a metro area
(b) 1=Farming-dependent 2=Mining-dependent 3=Manufacturing-dependent 4=Federal/State government-dependent 5=Services-dependent 6=Nonspecialized
(c) 0=no 1=yes
(d) Housing stress (537 total, 302 nonmetro) counties--30 percent or more of households had one or more of these housing conditions in 2000: lacked complete plumbing, lacked complete kitchen, paid 30 percent or more of income for owner costs or rent, or had more than 1 person per room.
(e) Nonmetro recreation (334 designated nonmetro in either 1993 or 2003, 34 were designated metro in 2003) counties--classified using a combination of factors, including share of employment or share of earnings in recreation-related industries in 1999, share of seasonal or occasional use housing units in 2000, and per capita receipts from motels and hotels in 1997.

Table 2: U.S. Census Demographic and Socioeconomic Data

County, State	Population	White, non-Hispanic (one race)	% Male	% Female	Median Age	% Below Age 5 yrs	% Below Age 18 yrs	% Above Age 65 yrs	% High School Grad or Higher	% Bachelor Degree or higher	Per Capita Income	Median Household Income	% People Below Poverty Level
Focus Areas													
Silver Bow, MT	34,200	95	51	49	42	6	21	17	90	23	22,249	40,030	16
Flathead, MT	90,928	96	50	50	41	6	23	16	92	28	25,317	45,588	13
Gallatin, MT	89,513	96	52	48	32	6	21	10	96	45	27,769	51,391	13
Lewis and Clark, MT	63,395	94	49	51	41	6	22	15	95	37	27,121	53,053	10
Blood Lead Data-driven Focus Areas													
Yellowstone, MT	147,972	91	49	51	38	7	24	15	92	29	27,273	50,185	11
Lake, CO	7,010	74	52	48	35	8	25	8	81	22	21,063	40,543	30
Shoshone, ID	12,849	96	51	50	46	5	21	19	83	13	19,717	37,934	17
Micro or Metropolitan Centers within Focus Areas													
Butte, MT	32,982	95	51	50	42	5	21	16	91	23	22,421	40,485	16
Kalispell, MT	19,654	96	48	52	32	9	27	14	91	26	22,301	39,205	17
Bozeman, MT	37,070	93	54	47	27	5	15	8	97	52	25,699	44,412	20
Helena, MT	27,978	94	49	51	41	6	19	16	96	46	28,856	47,749	13

Table 2: U.S. Census Demographic and Socioeconomic Data

County, State	Population	White, non-Hispanic (one race)	% Male	% Female	Median Age	% Below Age 5 yrs	% Below Age 18 yrs	% Above Age 65 yrs	% High School Grad or Higher	% Bachelor Degree or higher	Per Capita Income	Median Household Income	% People Below Poverty Level
Micro or Metropolitan Centers within Blood Lead Data-driven Focus Areas													
Billings, MT	102,982	90	48	52	38	7	23	15	92	31	27,582	47,869	12
Lake, CO	7,010	74	52	48	35	8	25	8	81	22	21,063	40,543	30
Shoshone, ID	12,849	96	51	50	46	5	21	19	83	13	19,717	37,934	17
Source: U.S. Census 2013													

Table 3: U.S. Census Housing Data

County, State	% Owning Home	% Non-owner Occupied Housing	Total Housing Units	*Percent of Housing Constructed (by Year Grouping[a])*								
				2005 or later	2000-2004	1990-1999	1980-1989	1970-1979	1960-1969	1950-1959	1940-1949	1939 or earlier
Focus Areas												
Silver Bow, MT	66	35	16,675	2	3	8	7	11	8	12	7	42
Flathead, MT	72	29	48,141	8	12	19	16	18	7	7	5	7
Gallatin, MT	62	38	41,545	11	17	21	13	17	6	5	3	10
Lewis and Clark, MT	72	28	30,687	7	9	14	12	21	9	7	4	16
Blood Lead Data-driven Focus Areas												
Yellowstone, MT	70	30	63,345	5	8	12	14	22	9	14	6	9
Lake, CO	67	33	4,117	1	6	10	8	18	7	11	2	37
Shoshone County, ID	70	30	7,062	2	2	8	6	15	9	16	11	31
Micro or Metropolitan Centers within Focus Areas												
Butte, MT	65	35	16,243	2	3	9	7	11	8	12	7	41
Kalispell, MT	58	42	9,122	12	10	14	13	14	6	11	7	13
Bozeman, MT	45	55	16,857	14	17	14	11	14	7	7	5	12
Helena, MT	55	45	13,960	5	5	9	10	17	11	11	7	25
Micro or Metropolitan Centers within Blood Lead Data-driven Focus Areas												
Billings, MT	58	42	9,122	12	10	14	13	14	6	11	7	13
Lake, CO	67	33	4,117	1	6	10	8	18	7	11	2	37
Shoshone, ID	70	30	7,062	2	2	8	6	15	9	16	11	31

Source: U.S. Census 2013; [a] Year groupings as reported by source.

Table 4: Summary Information for Potential Reference Populations for which Publicly-Accessible Data are Available

Data Source	Date Range	Sample No.	Age Range (months)	DL	Collection Method	Related to Contaminated Site Monitoring?	Summary Data (Sum)/Raw Data (Raw)?	LeadCare (LC) vs Fixed Lab (Lab)
Focus Areas								
Butte Health Dept., Silver Bow County	2002-2011	3,274	12 – 60	1.0	Capillary	Yes	Raw	Lab
Kalispell Head Start, Flathead County	2010-2011	199	36 – 60	1.0	Capillary	No	Raw	Lab
Bozeman Head Start, Gallatin County	Unk	Unk	36 – 60	3.3	Capillary	No	Unk	LC / Unk
East Helena LEAP, Lewis & Clark County	2008	86	9 – 60	0.5, 2.0	Venous	Yes	Raw	Lab
Blood Lead Data-driven Focus Areas								
Billings Head Start, Yellowstone County	2011-2013	Unk	36 – 60	3.3	Capillary	No	Raw	LC
Lake County, CO	2006	377	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2007	349	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2008	321	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2009	375	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2010	332	12 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2002	368	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2007	8	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2008	18	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2009	18	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2002	103	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2003	75	6 – 72	Unk	Capillary	Yes	Sum	Lab

Table 4: Summary Information for Potential Reference Populations for which Publicly-Accessible Data are Available

Data Source	Date Range	Sample No.	Age Range (months)	DL	Collection Method	Related to Contaminated Site Monitoring?	Summary Data (Sum)/Raw Data (Raw)?	LeadCare (LC) vs Fixed Lab (Lab)
Bunker Hill, ID – Basin, Shoshone Co.	2004	80	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2005	81	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2006	69	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2007	71	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2008	73	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2009	175	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2010	108	6 – 72	Unk	Capillary	Yes	Sum	Lab

Notes:

Unk = unknown

NA = not applicable

4 Development of an NHANES-Based Reference Population

As noted by its name, the National Health and Nutrition Examination Survey (NHANES) is a program designed to assess the health and nutritional status of the U.S. population across all age groups. NHANES is a program within the National Center for Health Statistics, which is part of the Centers for Disease Control and Prevention.

The survey is administered in two-year cycles, with approximately 10,000 nation-wide participants selected for each survey. NHANES can be used to generate population based statistics for specific age groups, as well as for people self-identifying as being Hispanic and/or African American. The two-part survey includes an interview for all participants where demographic, socioeconomic, dietary, lifestyle and health-related questionnaires are administered. Almost all of the participants also participate in a physical examination where medical, dental, and physiological measurements are collected and laboratory analyses are performed on blood and urine samples.

In addition to BLLs, demographic and socioeconomic information is available for NHANES participants. The NHANES became a continuous program in 1999. Information collected from these surveys will be useful in understanding how the Butte community blood lead status compares to that of the rest of the United States, including: demographic information, health insurance status, housing age, income, and blood lead (age 1 year and older).

Strengths of using the NHANES dataset as a reference population include:

- Relevant time frame: Data from NHANES survey years 2001-2002, 2003-2004, 2005-2006, 2007-2008, 2009-2010 can be compiled for comparison with Butte 2002 – 2010 blood lead data,
- Large sample size: Two year sample size ranges from 723 children to 968 children, depending on the survey years,
- Appropriate age-range: Blood lead data represent people ages 1 through adult, allowing for selection of an age range and age distribution consistent with the Butte blood lead data collected among children up to age 6 years,
- High quality data: Venous sample collection with low detection limits allows accurate characterization of BLL distributions. The limit of detection was defined as 0.3 µg/dL in 1999-2000 and 2001-2002, 0.28 µg/dL in 2003-2004, and 0.25 µg/dL in 2005-2006, 2007-2008, and 2009-2010, which is lower than the limit of 1 µg/dL for the Butte blood lead data. The lower limits reported in the NHANES data may need to be adjusted for comparison with the Butte data. Several methods for adjustment of the NHANES data may be considered to reduce bias resulting from lower limits of detection and better align data with Butte analytical methods.

These key characteristics are summarized in Table 5.

Table 5: Summary Statistics for Selected NHANES 2-Year Survey Periods					
2-Year Survey Period	**Sample No.**	**Age Range (months)**	**Percent Detect**	**Collection Method**	**Summary Data (Sum) / Raw Data (Raw)?**
2003-2004	753	12 – 60	100	Venous	Raw
2005-2006	806	12 – 60	100	Venous	Raw
2007-2008	676	12 – 60	100	Venous	Raw
2009-2010	702	12 – 60	100	Venous	Raw

The NHANES dataset also includes critical information that may be adjusted to better match Butte dataset, including:

- Housing characteristics: House age data are linked to individual NHANES blood lead values, and are also available for individual values in the Butte dataset. House age is grouped by categories generally corresponding to changes in lead management policy, such as removal of lead from paint, gas, plumbing, solder in food containers, etc. House age groupings include: before 1940, 1940-1949, 1950-1959, 1960-1977, 1978-1989, and 1990-present. Representation from housing age groups may be matched to that of the wider Butte community.
- Socioeconomic and demographic data: Starting in 2001, NHANES contains the household and family income (as ranges) and a calculated poverty index ratio for the participants in the NHANES surveys. Poverty index, educational attainment of the reference individual for the household, race, health care status, age, and gender data are all available for the NHANES population. Of these factors only age and gender are available in the Butte dataset. Poverty level and race adjustments may be may on a census tract level, while educational attainment and health care status adjustments are not likely to be feasible.

Limitations of using the NHANES dataset as a reference population include:

- Lack of individual sample dates: Individual blood lead data are assigned to 6-month intervals, which may limit the ability to adjust for expected seasonal variation in BLLs.
- No identifying geographic data: Degree of urbanization for NHANES subject residences is not available in the public files. Because the survey method for NHANES is intended to be representative of the U.S. populations, blood lead data cannot be adjusted to represent rural micropolitan communities comparable to Butte.
- Sample selection bias: The volunteer NHANES population may have socioeconomic or other characteristics that are dissimilar from those of the Butte population.

A three step process has been used to determine if the NHANES database can be used to develop a dataset that can be used as a reference population for Butte: First data were selected by year and age range that matched Butte data. The matched sample periods extend from 2003 through 2010. The matched age ranges are 12 months through 60 months.

The second step involved a review and comparison of analytical methods and detection limits. NHANES analytical detection limits were 0.3 µg/dL in 1999-2000 and 2001-2002, 0.28 µg/dL in

2003-2004, and 0.25 µg/dL from 2005 through 2010, which resulted in few to no undetected values in the time period of interest. In contrast, the detection limit of 1 µg/dL for the Butte blood lead data resulted in 6% to 24% of the values being undetected (see Table 6). The lower limits reported in the NHANES data will need to be adjusted for comparison with the Butte data. Several methods for adjustment of the NHANES data are being considered to reduce bias resulting from lower limits of detection and better align data with Butte analytical methods. To align the NHANES and Butte datasets, non-detected values need to be treated comparably. Several methods for adjustment of the NHANES and/or Butte data may be considered to reduce bias resulting from differences in limits of detection. The non-detected values in the Butte dataset can be adjusted by imputing values below the detection limit, or by applying the NHANES rule[4] of replacing the detection limit with the detection limit divided by the square root of 2. Alternatively, all values less than 1 µg/dL in the NHANES dataset could be treated as non-detected values. These values could then be imputed or replaced by the detection limit divided by the square root of 2. A sensitivity analysis could be conducted to determine if the difference in detection limits is a significant factor in the dataset comparison and to guide development of appropriate adjustments.

Table 6: Comparison of Undetected Blood Lead Values for NHANES and Butte Datasets for Four Survey Periods

Dataset	2003-2004	2005-2006	2007-2008	2009-2010
NHANES	0 (0%)	0 (0%)	0 (0%)	1 (0.14%)
Butte	36 (5.6%)	42 (6.8%)	84 (13%)	187 (24%)

The third step included review of the feasibility of making adjustments to reflect differences in various independent variables between the two datasets. We considered age, gender, house age, race/ethnicity, seasons of sample collection, and indicators of poverty. As discussed above, gender has little influence on BLLs in young children, so even if the gender structure of the databases varies, it may not be necessary to make adjustments to align them according to gender. Other factors are described below.

- **Child age structure** – Figure 7 illustrates the child age structure by 6 month intervals for one two year period (2007-2008) of the two datasets. This figure shows that, during this two year period, the Butte dataset includes a higher proportion of children younger than 30 months. Because these children are expected to have higher BLLs than older children, the NHANES dataset will need to be adjusted to align with the Butte dataset age structure. Similar comparisons will be conducted for each survey period.

[4] In all NHANES laboratory data sets, non-detected results are not assumed to be present at the detection limit; non-detected results are assigned a value that is calculated as the lower limit of detection divided by the square root of 2. This substituted value is assumed to represent the midpoint of values falling below the limit of detection.

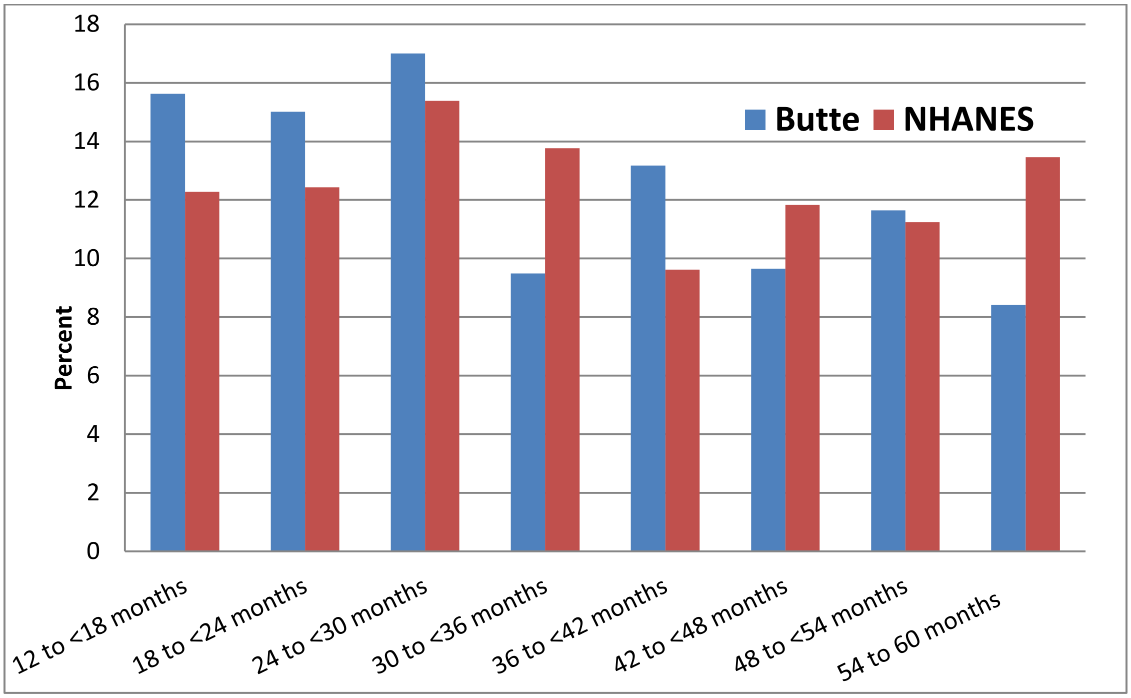


Figure 7. Child Age Structure Comparison for 2007-2008 Survey Period

- **House age** – Figure 8 shows a similar comparison (for the 2005-2006 period) of house age, based on NHANES home age categories. The Butte dataset for this period has a very high proportion of children who live in houses built before 1940 (close to 40%), whereas in the NHANES dataset less than 10% of the children live in such old houses.

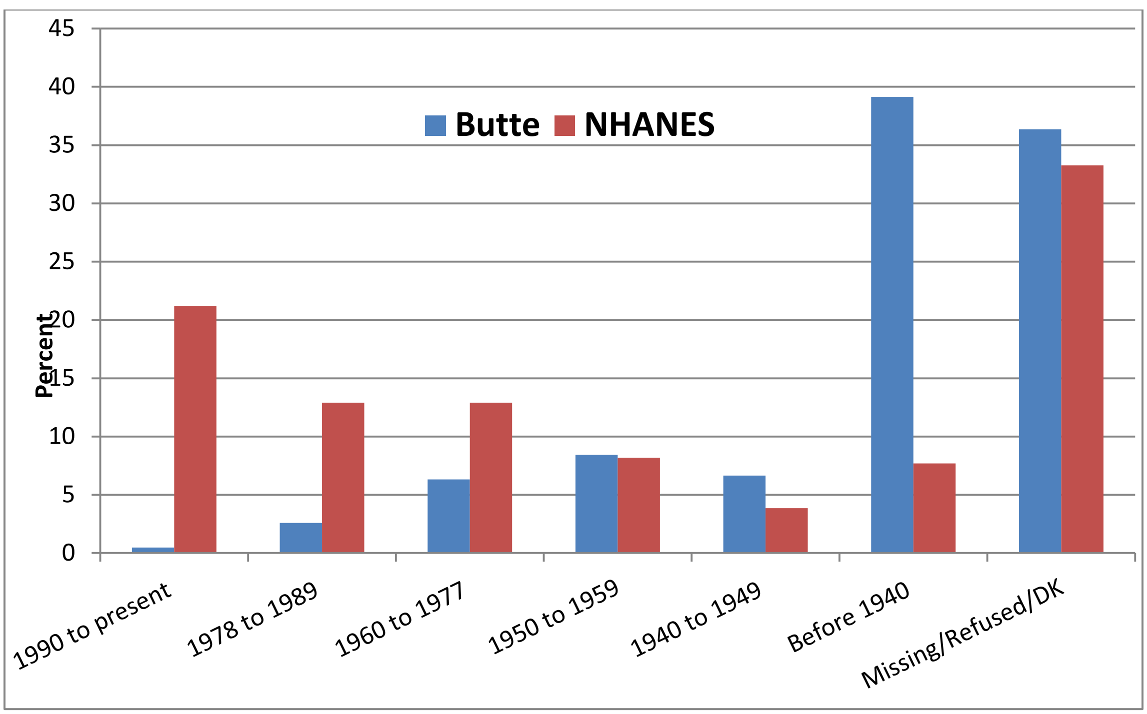


Figure 8. House Age Structure Comparison for 2005-2006 Survey Period

- **Racial/ethnic composition** – Figure 9 illustrates differences in racial/ethnic composition of the two datasets. The Butte dataset records do not indicate race, so a comparison was done by selecting two Butte census tracts. Butte's racial composition is predominantly non-Hispanic while, with very few non-Hispanic blacks.

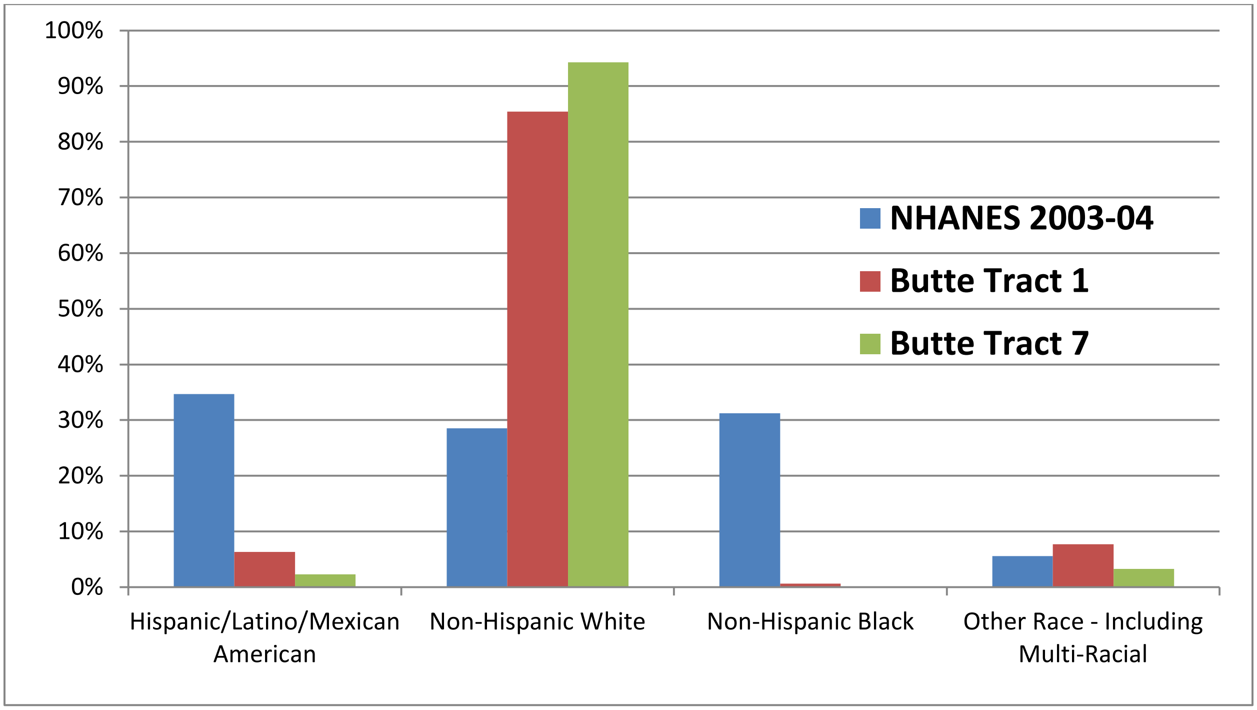


Figure 9. Race/Ethnicity Comparison for 2003-2004 Survey Period

- **Poverty status** – Poverty is another important factor for which the Butte dataset does not have individual records; but for which census tract level data are available. The Butte dataset is heavily weighted to children enrolled in Medicaid, thus biasing the dataset to children from low income families. Consequently, adjustments based on census tract poverty levels may not be valid.

- **Seasonal variations** – Sample dates are included in the Butte dataset, allowing for an analysis of variation in BLLs by season. As described above, preliminary analyses suggest that seasonal variation is an important factor affecting BLLs of Butte children. The NHANES dataset does not include specific sample dates, but samples are assigned to one of two 6 month periods extending from November through April and from May through October. The May through October period is consistent with the period when BLLs are highest, so that information will allow an examination of whether there are significant biases toward one season for another across the two datasets.

In summary, the NHANES dataset will allow for comparisons with the Butte dataset, both by age and by sample dates in six month to two-year increments. The blood lead data selected from the NHANES dataset can be matched to Butte community housing and economic characteristics, using available socioeconomic and housing information. The larger sample size of the NHANES dataset allows for selection of subsets of data that mirror the study years and age range associated with the Butte dataset while preserving sample sizes sufficient to conduct statistical comparisons of data that are also representative of other factors that influence BLLs.

Due to differences in demographics and other characteristics, NHANES blood lead data must be assigned weighting factors to more accurately mirror the Butte population. Applying weighting factors to demographic characteristics (i.e., age, race, gender) aligns NHANES and Butte population characteristics and would allow for use of NHANES data without having to discard any results. In this way, group size differences based on age, race and home age would not influence comparisons between populations. There would still be differences between the two datasets that we would not be able to adjust for, including the likelihood that data from samples collected by finger stick (Butte) would be biased higher than data from samples collected by venous (NHANES), and for reliance primarily on Medicaid enrolled children vs. a nationally representative population. Possible impacts of these residual differences would need to be explored in our analyses.

5 Recommended Reference Blood Lead Data

Based on the availability of a large dataset for the sample years and age ranges included in the Butte dataset, as well as the ability to correct for several factors that are strongly associated with BLLs, we are recommending use of the NHANES database for development of the reference population for Butte. While data collection efforts continue, no suitable comprehensive Montana reference dataset, nor dataset from other mountain states, has been identified to date. Further, experience to date indicates a low probability that any forthcoming data from such communities will provide a suitable reference dataset for use in the study.

The search for blood lead data from potentially comparable communities was a challenging exercise in that blood lead data often are limited or not available for communities with characteristics mostly closely aligned with those of Butte. When blood lead data are available, they typically are associated with Superfund remediation and intervention activities. While these databases may be more comprehensive than other community-based data and may provide some useful insights when compared with the Butte data, they cannot be used to assess how Butte BLLs compare with those of a reference population not affected by historical mining activities.

For many county health departments, staff responsible for supporting blood lead poisoning prevention programs is also responding to communicable disease outbreaks and other public health concerns. These many responsibilities combined with limited staff and funding resources, result in a reduced ability to organize, manage, and store blood lead data that is either collected by the health department or is reported to the health department by area physicians and laboratories. Even in cases where dedicated staff is available to manage blood lead programs, data often are not stored in a format that facilitates analysis and/or de-identification for protection of the sampled individual. For these reasons, acquisition of blood lead data from public health departments, other than Healthy Homes Study data collected using LeadCare System, was very limited.

Among the various data sources considered, Head Start programs appear to provide the most promising prospect for obtaining blood lead data. Federal regulations pertaining to Head Start funding (as well as WIC and Medicaid enrollment) have made testing a priority for many programs. However, Head Start staff often indicated that when children were referred to physicians for testing, the physicians were reluctant to administer the test because they do not view blood lead poisoning as a public health concern – even among Head Start-enrolled children. Head Start staff reports of a low rate of blood lead screening are consistent with findings of a May 2012 survey conducted by MDPHHS. Among Montana medical practitioners who responded to the mail-in survey, less than 28 percent reported that they routinely test Medicaid enrolled children ages 1 to 5 years for lead, 61 percent test only when risk factors[5] are present, and 21 percent of practitioners do not test for lead (MDPHHS 2012). Reasons listed for not performing the required lead screening included a perceived low level of lead exposure in their geographic area and parental refusal of testing (MDPHHS 2012). Nevertheless, some programs appear to be persevering in testing enrolled children for lead exposure and have

[5] Age of child's current home, zip code, address of previous child residence, and standardized assessment questionnaire are factors used by practitioners to determine child's risk for lead exposure.

agreed to provide de-identified data (conversations are on-going; data are expected in early August 2013). However, these data will represent children ages 3 to 6 years. Methods for testing and analysis vary, so it is not yet known if data that do become available would meet data quality requirements for use in the Butte Health Study.

Additionally, in some cases, Head Start and public health programs are using the LeadCare system for on-site capillary blood analysis. This system provides instantaneous results but the limit of detection is not acceptable for use in Butte Health Study analyses. As we continue to follow-up on inquiries for blood lead data, we may find that much of the recent data is not useable because of the increased use of the LeadCare system to screen for blood lead poisoning.

In contrast to the limited and/or uncertain potential for available blood lead data from community sources with characteristics comparable to the Butte blood lead dataset, the NHANES database provides a large blood lead dataset corresponding to the sample years and age ranges included in the Butte dataset. Further, the NHANES database affords the ability to correct for several factors that are strongly associated with BLLs as discussed in sections 2.1 and 2.2. Potential limitations of the NHANES database for comparisons to the Butte data relate to differences between the two datasets for which adjustments are not feasible. For instance, while studies of simultaneous collection of venous and capillary blood lead samples have shown good correlation, capillary blood lead samples may be prone to more external contamination than venous resulting in concentrations that are biased high in comparison to venous. Because the NHANES blood lead data have been collected by venous sampling and the Butte data by capillary sampling, it is possible that blood lead concentrations for the Butte data will be biased high relative to the NHANES data, independent of other factors that might influence blood lead distributions. Similarly, differences between NHANES and Butte with respect to drivers for participant enrollment are also not feasible to account for, but may influence comparability of the two datasets. The Butte participant pool is largely comprised of WIC clients and/or Medicaid enrolled children in contrast to the NHANES survey population which is more likely to include a broader sampling of individuals. As with the sampling differences, participant enrollment differences are also likely to conservatively bias the Butte data high relative to the NHANES data. While the influence of these factors will be important to consider when interpreting statistically significant differences between the Butte and the reference dataset, the potential bias toward higher Butte blood lead concentrations is not outweighed by all of the other strengths associated with use of the NHANES database as detailed in section 4.

Based on all of the above considerations, we recommend use of the NHANES database for development of the reference blood lead dataset for primary use in comparison to Butte blood lead data in the Butte Health Study. Additional comparative analyses using subsets of some of the other reference data sources identified may also be useful for interpreting the distribution of BLLs in Butte and these will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds.

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Appendix F

NHANES Weights from Three Weighting Scenarios

Table 1: NHANES Weighting Results (Weighting for House Age and Poverty)

House Age	Year Group	Poverty Category*	Weight
Missing	2003-2004	<=1.75	0.84
Post 1977		<=1.75	0.27
1960-1977		<=1.75	0.59
1950-1959		<=1.75	0.89
1940-1949		<=1.75	3.41
Pre 1940		<=1.75	5.12
Missing		>1.75	0.19
Post 1977		>1.75	0.01
1960-1977		>1.75	0.04
1950-1959		>1.75	0.06
1940-1949		>1.75	0.23
Pre 1940		>1.75	0.73
Missing	2005-2006	<=1.75	1.07
Post 1977		<=1.75	0.15
1960-1977		<=1.75	0.61
1950-1959		<=1.75	1.50
1940-1949		<=1.75	3.90
Pre 1940		<=1.75	6.49
Missing		>1.75	0.22
Post 1977		>1.75	0.01
1960-1977		>1.75	0.05
1950-1959		>1.75	0.08
1940-1949		>1.75	0.10
Pre 1940		>1.75	0.47
Missing	2007-2008	<=1.75	1.33
Post 1977		<=1.75	0.22
1960-1977		<=1.75	0.47
1950-1959		<=1.75	1.03
1940-1949		<=1.75	4.75
Pre 1940		<=1.75	5.30
Missing		>1.75	0.54
Post 1977		>1.75	0.01
1960-1977		>1.75	0.05
1950-1959		>1.75	0.07
1940-1949		>1.75	0.36
Pre 1940		>1.75	0.47
Missing	2009-2010	<=1.75	1.31
Post 1977		<=1.75	0.37
1960-1977		<=1.75	0.85
1950-1959		<=1.75	0.98

Table 1: NHANES Weighting Results (Weighting for House Age and Poverty)			
House Age	**Year Group**	**Poverty Category***	**Weight**
1940-1949	2009-2010	<=1.75	4.30
Pre 1940		<=1.75	5.57
Missing		>1.75	0.34
Post 1977		>1.75	0.02
1960-1977		>1.75	0.06
1950-1959		>1.75	0.08
1940-1949		>1.75	0.30
Pre 1940		>1.75	0.74
*Weighting assumes that 95% of Butte population falls in the PIR <=1.75 category			

Table 2: NHANES Weighting Results (Weighting for House Age and Race)

House age	Year Group	Race	Weight
Missing	2003-2004	Other	0.62
Post 1977		Other	0.08
1960-1977		Other	0.21
1950-1959		Other	1.34
1940-1949		Other	0.85
Pre 1940		Other	4.07
Missing		Hispanic	0.05
Post 1977		Hispanic	0.02
1960-1977		Hispanic	0.03
1950-1959		Hispanic	0.04
1940-1949		Hispanic	0.21
Pre 1940		Hispanic	0.60
Missing		Black	0.01
Post 1977		Black	0.04
1960-1977		Black	0.03
1950-1959		Black	0.07
1940-1949		Black	0.17
Pre 1940		Black	0.04
Missing		White	5.87
Post 1977		White	0.26
1960-1977		White	0.97
1950-1959		White	1.85
1940-1949		White	4.70
Pre 1940		White	9.61
Missing	2005-2006	Other	0.91
Post 1977		Other	0.04
1960-1977		Other	0.23
1950-1959		Other	0.55
1940-1949		Other	1.72
Pre 1940		Other	5.17
Missing		Hispanic	0.05
Post 1977		Hispanic	0.01
1960-1977		Hispanic	0.02
1950-1959		Hispanic	0.09
1940-1949		Hispanic	0.15
Pre 1940		Hispanic	0.39
Missing		Black	0.01
Post 1977		Black	0.02
1960-1977		Black	0.07
1950-1959		Black	0.05

Table 2: NHANES Weighting Results (Weighting for House Age and Race)			
House age	**Year Group**	**Race**	**Weight**
1940-1949	2005-2006	Black	0.14
Pre 1940		Black	0.08
Missing		White	11.61
Post 1977		White	0.17
1960-1977		White	1.20
1950-1959		White	2.18
1940-1949		White	2.70
Pre 1940		White	8.11
Missing	2007-2008	Other	0.97
Post 1977		Other	0.10
1960-1977		Other	0.32
1950-1959		Other	0.32
1940-1949		Other	1.40
Pre 1940		Other	5.63
Missing		Hispanic	0.09
Post 1977		Hispanic	0.01
1960-1977		Hispanic	0.03
1950-1959		Hispanic	0.06
1940-1949		Hispanic	0.20
Pre 1940		Hispanic	0.38
Missing		Black	0.01
Post 1977		Black	0.02
1960-1977		Black	0.06
1950-1959		Black	0.09
1940-1949		Black	0.33
Pre 1940		Black	1.00
Missing		White	8.43
Post 1977		White	0.30
1960-1977		White	0.81
1950-1959		White	1.31
1940-1949		White	9.98
Pre 1940		White	4.92
Missing	2009-2010	Other	1.13
Post 1977		Other	0.09
1960-1977		Other	0.18
1950-1959		Other	0.54
1940-1949		Other	3.39
Pre 1940		Other	2.99
Missing		Hispanic	0.08
Post 1977		Hispanic	0.02

Table 2: NHANES Weighting Results (Weighting for House Age and Race)

House age	Year Group	Race	Weight
1960-1977	2009-2010	Hispanic	0.04
1950-1959		Hispanic	0.04
1940-1949		Hispanic	0.20
Pre 1940		Hispanic	0.58
Missing		Black	0.01
Post 1977		Black	0.04
1960-1977		Black	0.14
1950-1959		Black	0.14
1940-1949		Black	0.25
Pre 1940		Black	0.08
Missing		White	6.83
Post 1977		White	0.46
1960-1977		White	1.19
1950-1959		White	2.61
1940-1949		White	6.42
Pre 1940		White	7.42

Table 3: NHANES Weighting Results (Weighting for House Age, Poverty, and Race)						
Year Group	**House Year Built**	**Poverty**	**Race**	**Number in NHANES**	**Numbers in Butte***	**Weight**
2003-2006	missing	<=1.75	Other	19	18.4	0.97
	missing	<=1.75	Hispanic	210	13.6	0.065
	missing	<=1.75	Black	190	1	0.0053
	missing	<=1.75	White	45	404.7	9.0
	missing	>1.75	Other	7	1	0.14
	missing	>1.75	Hispanic	59	1	0.017
	missing	>1.75	Black	38	1	0.026
	missing	>1.75	White	9	21.3	2.4
	Post 1977	<=1.75	Other	16	1.8	0.11
	Post 1977	<=1.75	Hispanic	79	1.3	0.017
	Post 1977	<=1.75	Black	42	1	0.024
	Post 1977	<=1.75	White	81	39.5	0.49
	Post 1977	>1.75	Other	19	1	0.053
	Post 1977	>1.75	Hispanic	57	1	0.018
	Post 1977	>1.75	Black	26	1	0.038
	Post 1977	>1.75	White	120	2.1	0.017
	1960-1977	<=1.75	Other	9	3.2	0.35
	1960-1977	<=1.75	Hispanic	57	2.3	0.041
	1960-1977	<=1.75	Black	21	1	0.048
	1960-1977	<=1.75	White	38	69.3	1.8
	1960-1977	>1.75	Other	6	1	0.17
	1960-1977	>1.75	Hispanic	34	1	0.029
	1960-1977	>1.75	Black	25	1	0.04
	1960-1977	>1.75	White	30	3.6	0.12
	1950-1959	<=1.75	Other	3	3.4	1.1
	1950-1959	<=1.75	Hispanic	25	2.5	0.099
	1950-1959	<=1.75	Black	25	1	0.04
	1950-1959	<=1.75	White	14	73.7	5.3
	1950-1959	>1.75	Other	2	1	0.5
	1950-1959	>1.75	Hispanic	20	1	0.05
	1950-1959	>1.75	Black	12	1	0.083
	1950-1959	>1.75	White	24	3.9	0.16
	1940-1949	<=1.75	Other	1	4.1	4.1
	1940-1949	<=1.75	Hispanic	9	3.0	0.33
	1940-1949	<=1.75	Black	7	1	0.14
	1940-1949	<=1.75	White	10	89.5	9.0
	1940-1949	>1.75	Other	3	1	0.33
	1940-1949	>1.75	Hispanic	9	1	0.11
	1940-1949	>1.75	Black	6	1	0.17

Table 3: NHANES Weighting Results (Weighting for House Age, Poverty, and Race)						
Year Group	**House Year Built**	**Poverty**	**Race**	**Number in NHANES**	**Numbers in Butte***	**Weight**
2003-2006	1940-1949	>1.75	White	16	4.7	0.29
	Pre 1940	<=1.75	Other	3	21.4	7.1
	Pre 1940	<=1.75	Hispanic	27	15.8	0.59
	Pre 1940	<=1.75	Black	33	1.0	0.031
	Pre 1940	<=1.75	White	27	471.4	17
	Pre 1940	>1.75	Other	2	1.1	0.56
	Pre 1940	>1.75	Hispanic	8	1	0.13
	Pre 1940	>1.75	Black	7	1	0.14
	Pre 1940	>1.75	White	29	24.8	0.86
2007-2010	missing	<=1.75	Other	18	22.2	1.2
	missing	<=1.75	Hispanic	182	17.6	0.097
	missing	<=1.75	Black	120	1.5	0.013
	missing	<=1.75	White	61	462.7	7.6
	missing	>1.75	Other	4	1.2	0.29
	missing	>1.75	Hispanic	35	1	0.029
	missing	>1.75	Black	22	1	0.045
	missing	>1.75	White	4	24.4	6.1
	Post 1977	<=1.75	Other	16	2.8	0.17
	Post 1977	<=1.75	Hispanic	99	2.2	0.022
	Post 1977	<=1.75	Black	34	1	0.029
	Post 1977	<=1.75	White	64	57.6	0.90
	Post 1977	>1.75	Other	15	1	0.067
	Post 1977	>1.75	Hispanic	62	1	0.016
	Post 1977	>1.75	Black	43	1	0.023
	Post 1977	>1.75	White	95	3.0	0.032
	1960-1977	<=1.75	Other	6	3.1	0.52
	1960-1977	<=1.75	Hispanic	50	2.5	0.049
	1960-1977	<=1.75	Black	15	1	0.067
	1960-1977	<=1.75	White	39	64.6	1.7
	1960-1977	>1.75	Other	9	1	0.11
	1960-1977	>1.75	Hispanic	19	1	0.053
	1960-1977	>1.75	Black	10	1	0.1
	1960-1977	>1.75	White	29	3.4	0.12
	1950-1959	<=1.75	Other	6	3.1	0.52
	1950-1959	<=1.75	Hispanic	33	2.5	0.075
	1950-1959	<=1.75	Black	11	1	0.091
	1950-1959	<=1.75	White	20	64.6	3.2
	1950-1959	>1.75	Other	2	1	0.5
	1950-1959	>1.75	Hispanic	21	1	0.048

Table 3: NHANES Weighting Results (Weighting for House Age, Poverty, and Race)						
Year Group	**House Year Built**	**Poverty**	**Race**	**Number in NHANES**	**Numbers in Butte***	**Weight**
2007-2010	1950-1959	>1.75	Black	7	1	0.14
	1950-1959	>1.75	White	19	3.4	0.18
	1940-1949	<=1.75	Other	2	5.9	3.0
	1940-1949	<=1.75	Hispanic	21	4.7	0.22
	1940-1949	<=1.75	Black	1	1	1
	1940-1949	<=1.75	White	6	124.0	21
	1940-1949	>1.75	Other	1	1	1
	1940-1949	>1.75	Hispanic	4	1	0.25
	1940-1949	>1.75	Black	6	1	0.17
	1940-1949	>1.75	White	11	6.5	0.59
	Pre 1940	<=1.75	Other	5	25.2	5.0
	Pre 1940	<=1.75	Hispanic	37	20.0	0.54
	Pre 1940	<=1.75	Black	9	1.7	0.19
	Pre 1940	<=1.75	White	54	525.6	9.7
	Pre 1940	>1.75	Other	2	1.3	0.66
	Pre 1940	>1.75	Hispanic	7	1.1	0.15
	Pre 1940	>1.75	Black	5	1	0.2
	Pre 1940	>1.75	White	37	27.7	0.75

Appendix G

Model Results for Butte Neighborhood Analysis Including 2011 Data

Table 1: Results from Fully Adjusted Model for Butte Neighborhood Comparison, Including 2011 Data

Variable	GM (µg/dL)	95% LCL (µg/dL)	95% UCL (µg/dL)	P Value
Test year				
2003-2004	3.54	3.31	3.79	<0.0001*
2005-2006	2.70	2.53	2.88	<0.0001*
2007-2008	2.24	2.10	2.39	<0.0001*
2009-2010	1.56	1.47	1.66	0.17
2011	1.65	1.54	1.77	Reference
Neighborhood				
The Flats (N3-N7)	1.96	1.88	2.06	<0.0001*
Uptown (N1, N2, N8)	2.53	2.40	2.67	Reference
House age				
Missing	2.38	2.27	2.49	0.0003*
Post 1977	1.82	1.59	2.09	<0.0001*
1960-1977	2.21	1.98	2.47	0.0020*
1950-59	2.28	2.03	2.56	0.013*
1940-49	2.12	1.93	2.32	<0.0001*
Pre 1940	2.67	2.55	2.79	Reference
Age (months)				
12-35	2.31	2.21	2.42	0.0042*
36-60	2.15	2.05	2.26	Reference
Gender				
Female	2.12	2.02	2.23	0.0008*
Male	2.34	2.23	2.46	Reference
Season				
Winter/Spring	2.04	1.95	2.14	<0.0001*
Summer/Fall	2.44	2.32	2.56	Reference

* Statistically significant ($p \leq 0.05$)
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit

Table 2: Results from Stratified Model for the Butte Neighborhood Comparison, Including 2011 Data

	The Flats				Uptown			
Variable	**GM (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p value**	**GM (µg/dL)**	**95% LCL (µg/dL)**	**95% UCL (µg/dL)**	**p value**
Test year								
2003-2004	3.44	3.15	3.75	<0.0001*	3.59	3.20	4.03	<0.0001*
2005-2006	2.50	2.30	2.72	<0.0001*	2.86	2.55	3.21	<0.0001*
2007-2008	1.97	1.81	2.15	<0.0001*	2.60	2.33	2.91	<0.0001*
2009-2010	1.42	1.31	1.53	0.1588	1.72	1.55	1.91	0.82
2011	1.44	1.30	1.58	Reference	1.87	1.66	2.11	Reference
House age								
Missing	1.99	1.88	2.11	0.6237	2.93	2.71	3.17	<0.0001*
Post 1977	1.72	1.47	2.01	0.0001	1.62	1.20	2.17	0.0002*
1960-1977	1.96	1.74	2.21	0.2044	2.50	1.90	3.30	0.0046*
1950-59	1.97	1.72	2.25	0.2130	2.57	2.03	3.26	0.012*
1940-49	2.23	1.83	2.73	<0.0001*	2.29	2.07	2.55	0.54
Pre 1940	2.38	2.24	2.53	Reference	3.00	2.82	3.20	Reference
Age (months)								
12-35	2.10	1.97	2.23	0.1101	2.52	2.30	2.75	0.061
36-60	1.97	1.84	2.10	Reference	2.36	2.15	2.59	Reference
Gender								
Female	1.95	1.83	2.08	0.0160	2.31	2.10	2.54	0.036*
Male	2.11	1.98	2.26	Reference	2.57	2.35	2.82	Reference
Season								
Winter/Spring	1.89	1.77	2.01	<0.0001*	2.20	2.01	2.41	<0.0001*
Summer/Fall	2.18	2.05	2.33	Reference	2.70	2.47	2.96	Reference

*Statistically significant ($p \leq 0.05$)
GM – Geometric mean; LCL – Lower confidence limit; UCL – Upper confidence limit