The Release of Lead During Pregnancy of Women Exposed to Lead From a Primary Smelter in Northern Idaho

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We, the undersigned, have read this Clinical Study and have heard the oral defense. We agree to accept this study as part of the requirements for the Master of Nursing Program, Family Nurse Practitioner track.

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ABSTRACT

The Evaluation of Lead Released During Pregnancy by Women Exposed to Lead from A Primary Smelter in Northern Idaho

Research indicates that lead stored in the bones of women may be released during periods of high stress such as menopause, pregnancy, and long bone fractures. For over 100 years, the people living in the Silver Valley of Northern Idaho, especially within the area of the Bunker Hill Superfund Site, received long term, intense exposure to lead, cadmium, arsenic and zinc. This limited study evaluated the data of a subgroup of the Prenatal Lead Screening Program, of the Panhandle Health District to determine if lead was being released during pregnancy. The highest lead level found in the mothers was 4 μg/dL. The highest cord blood level in the newborn was 2 μg/dL. In comparing the data with various risk factors for lead poisoning, neither a significant release of lead, nor a correlation between risk factors and lead levels was found.
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CHAPTER ONE

Introduction

Childhood lead poisoning is one of the most common, totally preventable pediatric health problems faced in the United States today (Centers for Disease Control, 1991). While lead is a very useful element in the industrialized world, it has no use in the human body. Lead is an element that causes long term physiological and cognitive effects in the body. Because the body of a child grows rapidly, the effects of lead are more noticeable and devastating in children. These effects are particularly damaging to the central nervous system and the hemopoietic system of the developing fetus (Brown, Bellinger & Matthew, 1990). Once a person is exposed to lead it is either excreted quickly from the body, or deposited in the bones over a period of time, becoming a "bone burden," and a source of re-exposure (CDC, 1991). During pregnancy, the developing fetus obtains calcium and other nutrients from the mother to grow. The release of calcium from the bones enables lead stored as a bone burden in the mother to be released (Silbergeld, Schwartz, & Mahaffey, 1988). This release of lead causes a re-exposure of the mother as well as an acute exposure to the developing fetus (Silbergeld, 1986).

Problem

People living in the Silver Valley area of Northern Idaho, and specifically those living within the Bunker Hill Superfund Site (a 21 square mile area encompassing the communities of Pinehurst, Page, Smelterville, Wardner, Kellogg and Elizabeth Park) have a particularly unique exposure to lead. For over 100 years, heavy metal mining and the related smelting activities played a significant part in the economic picture of the area.
For many years the emissions from the smelter contaminated the air, soil and some of the water supplies with many elements such as cadmium, zinc, arsenic and most notably lead. (Landrigan, & Baker, 1981). The Childhood Lead Screening Program, conducted by the Panhandle Health District in Kellogg, identified that the average lead level for the people living in this area during the early 1970's was about 40 μg/dL. The average lead level for children living in Smelterville was 65 μg/dL (Panhandle Health District, 1995). A study conducted in August of 1974 by Landrigan and Baker (1981), found that 385 (41.9%) of the 1-9 year old children in the study areas had blood lead levels of 40-79 μg/dL. An additional 41 (4.5%) had blood lead levels greater than 80 μg/dL. In the area closest to the smelter, in the town of Smelterville, 170 (98.8%) children had blood lead levels greater than 40 μg/dl, with one child having a blood lead level of 164 μg/dL. At that time, the level of concern for lead poisoning was 40 μg/dL (U.S. Dept. of Health and Human Services, 1991). The current level of concern for children is 10 μg/dL (CDC 1991). Occupational Health and Safety Administration (OSHA) considers 40 μg/dL to be the level above which an employee should be removed from the exposure site (United States Department of Health and Human Services, 1991). As a result of constant exposure to contaminants, many people who were living in the Superfund area as children during the 1970's may be carrying a bone burden of lead in their bodies. During pregnancy, women carrying a bone burden of lead may mobilize the lead causing re-exposure to themselves as well as their developing fetuses (Silbergeld et al, 1988).

The Childhood Lead Screening Program at the Bunker Hill Superfund Site in Kellogg, Idaho has been in existence since 1974. The program has focused upon lead
exposure to infants and children ages 9 months to 9 years of age. An extension of the Childhood Lead Screening program is the Prenatal Lead Screening Program, that began evaluating lead levels in pregnant women in 1989. The Childhood Lead Screening program is funded by the Agency for Toxic Substances and Disease Registry (a federal agency affiliated with the Centers for Disease Control and the United States Public Health Service). The screening program is administered by the Idaho State Office of Environmental Health and Safety, and is implemented by the Kellogg Office of the Panhandle Health District. Initial data gathered during the first four years of the Prenatal Screening Program has been inconsistent in regards to obtaining required blood specimens. Despite inconsistent sampling, early data indicated that lead is not being released during pregnancy in this population. The purpose of this study is to evaluate the data collected by Panhandle Health District Prenatal Lead Screening Program from February 1, 1995 to January 31, 1996, regarding the extent of lead released during pregnancy by women who may carry a body burden of lead. This time frame was chosen because protocol changes made would help in obtaining consistent sampling. Subjects in this project were pregnant women who lived in the Bunker Hill Superfund Site as children during the early 70's, and who may or may not be current residents of that area. Also included were women who were pregnant and currently living in the Bunker Hill Superfund site. The blood lead levels during the first and third trimester of pregnancy and at delivery were evaluated to determine the extent of lead release during pregnancy.
Significance to Nursing

Nursing, particularly Public Health Nursing, plays a significant role in preventing illness and injury. Health intervention to break pathways of exposure by toxic substances is one of the most effective and cost efficient methods of prevention available. Primary, secondary and tertiary interventions which include patient education about interventions, as well as referral to medical resources for possible chelation therapy, are important roles for nursing. Educating the family about sources of exposure, methods of breaking pathways of exposure, and dietary instruction to aid in the excretion of the substance is essential to reduce lead levels and prevent lead related effects from occurring in the developing fetus. Educational needs are established while taking a patient history, evaluating risk factors and conducting prenatal counseling.

Literature Review

The literature review will look at several aspects of lead poisoning, particularly in their relation to pregnancy and the developing fetus. The review will look at the historical aspect of lead poisoning, the relationship between diet and lead absorption, the toxic effects of lead, fetal exposure, methods of exposure, course of action, and finally the effect of lead contamination on the Silver Valley area of North Idaho.

Historical Aspect

Human lead toxicity has been studied for many years. A century ago, milk was given to factory workers to protect them from the ill effects of lead (Mahaffey, 1981). From 1920 to 1940, studies were conducted with diets of varying levels of calcium and phosphorus in an attempt to increase excretion of lead from the body. Calcium and
vitamin D were used therapeutically in acute cases of lead poisoning (Mahaffey, 1981).

Studies show that several nutritional factors can affect the absorption and toxicity of lead:
(a) a diet high in calcium decreases the absorption of lead from the gastrointestinal track
(b) a diet low in fat decreases the absorption of lead, (c) a diet low in iron allows greater
absorption of lead which can lead to anemia (Mahaffey, 1981). Lead absorption on an
empty stomach is greater than when food is present, suggesting that more frequent meals,
especially in children, will reduce lead absorption (Goyer 1993). Dietary counseling
during pregnancy should include recommendations to limit coffee and alcohol, as these
substances are associated with increased maternal lead levels, and encourage eating
regular meals. (Brown, 1990). While dietary supplements of calcium, iron and folic acid
are associated with decreased maternal lead levels, commercial preparations of bone meal
and dolomite can be quite heavily contaminated with lead and should not be used (Brown,
1990).

**Toxic Effects of Lead and Fetal Exposure**

Many studies demonstrated the toxic effects of lead poisoning. The effects of lead
on the kidneys, nervous system and bone marrow, as well as the hematopoietic system
indicated reasons for lead exposure concerns. An investigation in Buffalo, New York,
between November 1987 and April 1988, showed that umbilical cord bloods in 802 infants
ranged from zero to 20 μg/dL with an mean of 3.8 μg/dL. (Shucard, Shucard, Patterson
& Guthrie, 1988). This same study covered 49 townships in and around Buffalo, and
found their results to be comparative between Buffalo and the other forty-eight townships.
Approximately 41% of the newborns studied had cord blood levels between 0-3 μg/dL,
and that more than 60% had measurable cord blood levels (Shucard et al., 1988). More recent studies by Needleman (1990) and others established that lead can affect the cognitive abilities of people, especially of children, in quantities as low as 10 μg/dL or less. Studies by Belinger, Leviton, Waternaux, Needleman, & Rabinowitz (1987) showed that infants who had cord blood levels ≥ 10 μg/dL scored lower on developmental tests up through two years of age than infants whose cord blood level was ≤ 10 μg/dL. Because of these studies, the Centers for Disease Control lowered the "level of concern" for lead toxicity from 25 μg/dL to 10 μg/dL (CDC, 1991). Children and the developing fetus have the greatest risk for damage due to lead poisoning for three major reasons: (a) their bodies are in a stage of rapid development and thus more susceptible to damage; (b) a child's body can absorb 35-50% of the lead ingested as opposed to adults who only absorb approximately 7-15% of the lead ingested; and (c) the hand to mouth habits of babies puts them at greater risk for exposure (CDC, 1991). The fetus is subject to whatever is happening in the mother's body. Acute or constant lead poisoning of the mother exposes the fetus to lead. Several studies have shown that the placental barrier does not restrict movement of lead from the mother to the fetus (Landrigan, 1989). While some studies indicate the cord blood level is a direct indication of fetal exposure to lead (Shucard et al., 1988), Silbergeld (1986) suggests that three models exist in determining lead exposure to the fetus. These models are: (a) the levels of the mother are greater than the levels of the fetus; (b) the maternal exposure and the fetal exposure are equivalent; and (c) the levels of the fetus are greater than that of the mother. Current research suggests that serum lead levels are a more accurate indicator of fetal risk to lead poisoning than whole blood levels.
The use of serum levels is thought to be more accurate than blood lead levels because serum contains free and ionized lead that is more available to fetal circulation than lead that is bound to the red blood cells (H. Hu, personal communication, 1995), and (M. Rabinowitz, personal communication, 1995).

Methods of Exposure

Lead enters the body in one of two ways; ingestion and inhalation. Children are more likely to obtain lead poisoning by ingestion because of their hand to mouth activities. Adults are more likely to obtain their exposure by inhalation. Occupational exposure occurs in industry such as battery or radiator salvage, smelters or when welding metal that has leaded paint on it. For many people, the major source of exposure is from leaded paint in homes. Although lead was removed from paint in the early 1970's, many older homes have lead based paint buried under layers of other paint. Restoring old homes appears to be quite fashionable today. If remodeling is not done correctly with attention to the potential environmental hazards, the residents of the home, and/or the persons doing the renovation can receive significant exposure to lead dust. Auto exhaust is less of a hazard now due to reduced consumption of leaded gas. Other sources of lead include lead water pipes, some home remedies such as Azarcon and pay-loo-ha (used for gastric distress in Central and South America), as well as some East Indian dyes used in makeup, improperly glazed and fired pottery, and hobbies in which lead is used.
Course of Action

Once lead enters the body, it has a half-life in the blood stream of approximately 30 days (ATSDR, 1994). If the body is unable to excrete lead through the urine or feces, it will then begin to distribute into the soft tissues. Since the body tends to maintain balanced levels of elements within its system, as blood levels drop, the lead in the soft tissues will mobilize back into the blood stream, to be excreted. However, if the body continues to be exposed to a source of lead, or nutrition is poor, the lead will remain in the soft tissues, and ultimately move into the bones for long term storage. Lead, which does not easily mobilize from bone, has a half life of over 20 years. Consequently, just because a person's blood lead level is low, does not mean the person is not carrying a body burden of lead. Studies by Wittmers, et al (1988), showed that during adolescence, the lead tended to be stored in the trabecular bone of the vertebral bodies; after body growth ceases, lead tends to accumulate in the long bones, particularly the femur and tibia. A recent investigation by Silbergeld, et al (1988) provided evidence that bone lead can be mobilized into the circulation during periods of bone demineralization. Demineralization events include pregnancy, lactation, and osteoporosis (in both women and men). Mobilization also occurs with fractures of the long bones, when calcium demands are high during the healing process of the bones.

Mobilization of lead, even in low amounts, can cause significant toxic levels of lead in the body. Mobilization of lead during pregnancy exposes the fetus to the toxic effects of lead. How much lead is mobilized during pregnancy is subject to a number of factors. Elements such as available dietary calcium required to meet the needs of the developing
fetus, and the presence of zinc and iron, play a significant role in lead mobilization (Rabinowitz, 1994). Adequacy of kidney function affects the levels of lead in the bloodstream, whether lead is present due to acute exposure or if it is being mobilized from body stores. Kidneys which are functioning well compete with the placenta to rid the body of lead, thus sparing the fetus (Rabinowitz, 1994). A study in Port Pirie, Australia indicated lead toxicity caused an increase in premature delivery as well as spontaneous abortions. Other studies conducted throughout the world have failed to show a similar correlation (ATSDR, 1993). Premature births and other related problems in pregnancy have been associated with maternal blood lead levels ranging from 30-40 μg/dL (Blackman 1994). A "safe range" has not been established for neonatal blood lead levels. At the present time it is recommended that a level of < 10 μg/dL be attained (M. Rabinowitz, personal communication 2/96)

**Effects of Lead on the Silver Valley**

As mentioned before, the most common source of lead poisoning occurring today is exposure to deteriorating lead paint. However, the people living in the Silver Valley area of northern Idaho have an additional, significant source of exposure. Due to 100 years of mining activity, and in particular significant environmental contamination during the early 1970's, residents of the Silver Valley area were exposed to high doses of lead as well as cadmium, zinc and arsenic from a primary lead smelter. The average lead emissions from the smelter were estimated to be approximately 10 metric tons per month from 1955 to September of 1974 (Landrigan & Baker, 1981). A fire in the main baghouse (a filtering system for the smoke from the smelter), caused an increase in emissions to 35.3
metric tons per month (Landrigan & Baker, 1981). This increase in emissions caused not only an increase in air lead levels, but also created an increase in soil levels to around 9000 ppm (normal, uncontaminated soil is less than 100 ppm) (Landrigan & Baker, 1981). The average lead level of children living in Smelterville was 65 μg/dL in 1974, with an overall average of 40 μg/dL. The smelter was shut down in December 1981. Blood lead levels monitored over the past 20 years, are now showing an average level of 6 μg/dL (Panhandle Health District Data, 1994). Because of long term exposure, people who lived in the Silver Valley area during the time of environmental pollution, potentially carry a lead burden in their bones. For women of childbearing age, pregnancy is accompanied by the potential of mobilizing bone lead, and exposing the developing fetus. The risk factor of a body burden of lead for this population must be addressed when providing health care to adults, children, and pregnant women. Since many of the toxic effects of lead do not present outwardly until levels are over 25 μg/dL (CDC, 1991), damage may be missed if screening is inadequate. A physician with only a few at risk patients in his/her practice, may overlook the possibility of a body burden of lead and the potential effects of lead on the fetus. Low lead levels in the current non-pregnant adult population can falsely reassure the practitioner concerning lead poisoning. Physicians who practice in areas of environmental risk should be alert to these hazards and continue with appropriate screening tests. The wealth of information about the toxic effects of lead poisoning on the developing fetus supported the development of the present lead screening program.
CHAPTER TWO

Research Design and Data Collection Method

Research Questions

Research questions raised by this project include the following:

1. To what extent is lead released during pregnancy in pregnant women living in the Silver Valley?
2. To what extent does a previous exposure to lead affect blood lead levels during pregnancy?
3. Did the age of the mother at delivery have an affect on the amount of lead released during pregnancy?
4. Did the parity of the mother have an affect on the amount of lead released during pregnancy?
5. Was there a correlation between the mother's lead levels and the number of spontaneous abortions?
6. To what extent did environmental factors such as ages of homes, or a home in a past smelter community effect lead levels?
7. Is there a correlation between childhood blood lead levels and the release of lead during pregnancy?
8. Is there a significant difference in blood lead levels drawn at different times during the pregnancy?
Research Design

This was a descriptive, longitudinal study. The intent of the project was to evaluate the effectiveness of the screening program of Panhandle Health District's Lead Program in determining if women who had constant exposures during childhood released lead during pregnancy. Concurrently, women who experienced environmental contamination of lead as well as zinc, cadmium and arsenic, were also followed to evaluate acute exposures.

Data Collection Procedures

To determine the extent of lead released into the blood stream during pregnancy, three samples were obtained from each subject. Each sample consisted of 3 ml's of blood. The first sample was obtained during the first trimester at the same time that the subject's physician obtained other routine blood samples. The second specimen was obtained during the third trimester in conjunction with additional routine blood work. The third sample was umbilical cord blood and obtained at the time of delivery along with other cord blood samples. In this way, the subjects were not subjected to any additional blood draws.

The specimens were obtained in 3 ml, lavender top, blood collection tubes containing EDTA and have been certified as "lead free". The tubes were supplied by ESA Laboratories, Inc. in Maine, a nationally approved lab for analyzing heavy metals. The same laboratory analyzed blood lead specimens for the Childhood Lead Screening Program and the Prenatal Lead Screening Program conducted by the Panhandle Health District at the Bunker Hill Superfund Site since 1985. Blood specimens obtained from the
cooperating physicians and laboratories in the community were collected twice a week by Panhandle Health District Lead Health Intervention Program, and shipped to ESA Laboratones for analysis. Results from the analysis were returned to the Lead Health Intervention Program. A copy was then sent to the individual subjects and their physician, along with a letter of explanation (Appendix B). Blood specimens were identified by patient name and number. Confidentiality was maintained by use of an identifying number for all statistical calculations and reporting of data.

Setting

The setting of the project was the Silver Valley region of northern Idaho, specifically the Bunker Hill Superfund Site. This particular site was chosen for several reasons: (1) the area has a 20 year history of data collection of environmental and blood lead levels; (2) it has a current Lead Intervention program in place; (3) data on blood lead levels were available on a large quantity of the exposed population; (4) a screening program for blood lead levels of pregnant women was approved by the Agency for Toxic Substances and Disease Registry, the State of Idaho Bureau of Environmental Health and Safety, Boise State University, and Panhandle Health District four years ago; and (5) many physicians who practice in this area have a working knowledge of lead toxicity, and have completed a course on heavy metals sponsored by the ATSDR.

Population Sample

Subjects were selected through a three-question screening tool that was used by seven physicians of Obstetrics and Gynecology in Coeur d'Alene, Idaho, as well as three Family Practice physicians who provide obstetrical care in the Silver Valley area of
northern Idaho. The criteria for pregnant women to participate in the screening program were as follows:

1. The subjects must currently live within the Bunker Hill Superfund Site; OR
2. The subjects must have lived in the Superfund Site as a child; OR
3. The subjects must have participated in a childhood lead screening program.

The size of the total sample population was anticipated to be 100 women, and the goal was to have at least half of them having been exposed to lead as a child. (The Kellogg office of the Panhandle Health District has recorded blood lead levels or Erythrocyte Protoporphyrin levels for children in the Superfund Site for the past 20 years.) For this portion of the total project, subjects were accepted during the time of February 1, 1995 to January 31, 1996, to meet the requirements of a clinical project for a Master of Nursing program. The Panhandle Health District Lead Intervention Program will continue to gather data through the fall of 1996 to complete analysis of data from all subjects who participate in the program.

Human Subjects

Each potential subject was given a packet containing a letter of explanation, a brief two-page questionnaire requesting demographics and other information to assess their risk for lead exposure, and a consent form in triplicate. (See Appendix A). The questionnaire and a copy of the consent form was sent to the Lead Health Intervention Program in Kellogg, for use as a subject record. A copy of the questionnaire and the consent form was retained by the physician. The original copy of the consent form was
given to the patient. A copy of the consent form accompanied the physician's prenatal record that was supplied to the delivering hospital's Labor and Delivery department. This record alerted hospital personnel to the subject's involvement in the Lead Project. The subject's medical chart and the prenatal record had a special sticker applied to them to identify the subject as a participant in the Prenatal Lead Project (See Appendix A). This identifier helped to remind the physician that additional blood specimens were needed.

Stickers were also applied to all the blood collection tubes for identification as part of the Prenatal Lead Project. Stickers were applied to the specimen tubes before being supplied to the physicians, hospitals and labs to prevent use of the wrong tubes to collect the blood specimens. The questionnaires and consent forms were kept in individual file folders, in a locked cabinet at the Kellogg Office of the Panhandle Health District. Keys to the cabinet are retained by the public health nurse assigned to the program and the director of the Lead Health Intervention Program. The files in the computer are identified by a number supplied by the software system, and access limited by password. A master log was kept to correlate the ID number with the patient; this log was kept under lock and key in a separate cabinet.

Data Analysis

Risk data and blood sample results were entered into a PC computer system using Epi-Info®, version 6.02, a software system designed by the Centers for Disease Control and the World Health Organization. Epi-Info was designed to track epidemiology studies and provide statistical analysis of the data. Calculations for the descriptive analysis and
risk factors was performed on the first trimester levels. Descriptive analysis yielded mean, median, mode, frequency, percentile, and chi-square analysis of some data. As part of the larger study, these data may also be analyzed by TerraGraphics of Moscow, Idaho, which is the Risk Management Contractor for the Idaho State Office of Environmental Health and Safety. TerraGraphics has conducted the statistical analysis of all data obtained from the Bunker Hill Superfund Site. Upon receipt of the questionnaire and consent form, a letter was sent to the subjects thanking them for agreeing to participate in the study (Appendix B). They also received a packet of information about lead poisoning.

If the lead levels were elevated above 10 μg/dL, the public health nurse conducted a home visit to determine the presence of an acute exposure. Information was given regarding methods of breaking pathways of lead exposure. Physicians were alerted by the public health nurse if the levels were elevated. Physicians were also provided information regarding levels of concern, and treatment modalities.

The time period for this study was February 1, 1995 to January 31, 1996. A total of twenty women participated in the Prenatal Lead Screening Program during this time period. Of these 20 women, 2 were unable to complete the screening program after the first trimester due to spontaneous abortions. Only two women had all three blood lead levels obtained (first and third trimester and cordblood; however, seven of the twenty will deliver over the next six months, and are not yet due for their third trimester samples. These women will continue to be followed by Panhandle Health District Lead Intervention Program until their delivery.
The age range for the group was 16 to 35 years; the mean age was 24 with a SD of 1.259 (Figure 1). Age did not play a significant role in the release of lead. Residency within the Superfund site during childhood was fairly even, nine lived here as a child, and eleven did not (Figure 2). Residence does not appear to be a significant variable. Their residences were distributed between Elizabeth Park, Kellogg, Kingston, Pinehurst, Smelterville and Wardner (Figure 3).

This area contains a large number of old homes, and the question always arises about the risk of lead paint as an exposure source. Approximately 55% of the subjects lived in homes over 20 years of age, and 27% lived in homes over 30 years of age (Figure 4). Of the ten subjects living in homes over 20 years of age, the highest blood lead level was 3 \( \mu g/dL \).

Approximately 10% of the women had lead related hobbies, while 30% ate fish from the Coeur d'Alene River and 35% ate locally grown vegetables (Figure 5). The subject with a blood lead level of 4 \( \mu g/dL \) did eat fish from local streams, and locally grown vegetables, resided in the Silver Valley all of her life, and additionally her husband cast his own bullets and sinkers.

Blood lead levels in the first trimester ranged from \(<1 \mu g/dL\) to 4 \( \mu g/dL \), with a mean level of 1.95 \( \mu g/dL \) (Figure 6). At the time of this report only five women had third trimester levels drawn. The mean lead level of the third trimester blood was 1.8\( \mu g/dL \), with a range of one to 4\( \mu g/dL \) (Figure 7). The cord blood levels obtained to date ranged from \(<1 \mu g/dL\) to 2 \( \mu g/dL \), with a mean level of 1.25 \( \mu g/dL \) (Figure 8). Please note that
it is not possible to calculate a result of <1 µg/dL, and the lab does not report 0 µg/dL. Those with <1 µg/dL were counted as 1 µg/dL.

Fourteen subjects reported current residence in the Superfund site, and six did not. Of the fourteen subjects currently living in the Superfund Site, the highest level was 4 µg/dL; and of the six not currently residing, their highest level was 2 µg/dL (Chi sq. = 4.02, df = 3, and p = 0.25953158) (Figure 9). All of the nine who lived in the Silver Valley as a child, had some level of blood lead, but the highest amount was 4 µg/dL. Of the eleven who did not live here as children, the highest was 3 µg/dL. It does not appear that residency at the time of childhood is a significant variable (Chi square = 4.76, df = 3, and p = 0.19008523). (Figure 10)

Thirty six percent reported this was their first pregnancy, and one woman reported that this was her fifth pregnancy. Blood lead levels compared to parity were not significant (Figure 11). Five (25%) of the women had 1 or 2 previous spontaneous abortions (SAB's), and one reported a history of an ectopic pregnancy (Figure 12). According to Pernoll and Garmel (1994) more than 25% of all gestations end in spontaneous abortion.

The Health District had recorded childhood blood lead levels for four of the subjects. The average blood lead level was 28.6 µg/dL. One subject, had a childhood lead level ranging from 68 to 19 µg/dL over a 6 year period. Her current lead level was 4 µg/dL; her bone lead level was 5.96 µg/g bone. She was one of two subjects who aborted during the study, and the only one to have had a K X-ray fluorescence (K-XRF) measurement of bone lead. (I have not been able to find information regarding "normal ranges" or "levels of concern" for bone lead.)
Discussion and Implications

In evaluating the data, a determination was made of the risk factors whether residence, parity, age, previous lead levels or hobbies had any effect on the blood lead levels during pregnancy or the cord blood levels at birth. The levels in the women studied were considerably less than anticipated considering their exposure to lead as children. Even though the number of participants for this study was low, the findings are of tremendous interest. It is not possible to do a trend comparison or other statistical evaluation of the blood lead levels between the group prior to 1993 and the current group being studied because the laboratory changed analysis methods in 1993. Their reporting ability changed from a confidence level of 5 μg/dL to a confidence level of 1 μg/dL. Consequently, in the group of women screened between 1989 and 1993, anyone with a level of <5 μg/dL was arbitrarily assigned a value of 4 μg/dL. The limited data does not show an increase in blood lead levels due to risk factors; however, it is possible to see that the twenty women screened in this study are continuing the same trend of low blood lead levels during pregnancy despite living in a contaminated site currently or as children.

Possible Threats to Validity

1. Mortality or desire to withdraw from the project. There were two cases of spontaneous abortion, one during and one after the first trimester, causing the subjects to withdraw from the screening program.

3. The blood sample could be obtained in the wrong type of test tube causing an invalid result. Tubes that were certified "lead free" were provided to the physicians and
labs by ESA Laboratory, and were marked with a bright pink sticker identifying them as "Prenatal Lead Study". 

4. Questionnaire incompletely filled out or consent form not signed. The physician's office staff reviewed the questionnaire with the subject as part of their risk assessment. If data were missing the public health nurse contacted the subject by phone, mail, or in person.

5. Errors in data entry in the computer program. Data values were rechecked with an assistant for accuracy.

6. Inappropriate laboratory evaluation. ESA Laboratories is nationally certified to conduct physiological heavy metal evaluations, participates in the CDC certification program and is used by numerous institutions. It has been the laboratory of record for the Bunker Hill Superfund Site Childhood Lead Screening Program for 10 years.

7. Subjects not understanding the laboratory results mailed to them. The letter containing the laboratory results contained an explanation of the findings as well as encouragement to contact their physician or the Health District for an explanation of the results. Physicians were also given written materials on lead poisoning, interventions to prevent or mitigate poisoning and medical treatment modalities. The levels of concern for blood lead were established by using the guidelines provided by the Centers for Disease Control.

8. Break in confidentiality. All files are kept under lock and key with very limited access. Computer data are preserved by password access.
9. Lack of interest in the screening program either by the physicians and/or their staff, or by the potential subjects. Due to the 20 year history of being "studied" by an assortment of agencies, there is considerable apathy within the community about being involved in another study or screening program for lead poisoning. There is also a large segment of the population who feel that too much fuss is made over the situation. This played a significant role in the lack of participants.

10. Difficulty in getting appropriate number of samples. Unlike larger institutions where the subjects have all their samples obtained in the same location, this program worked with eleven physicians and their staffs, a separate lab and 2 hospitals located some 37 miles apart. The coordination of these entities was a major stumbling block resulting in substantial loss of data.

11. Application of data results. These data should not be applied outside this population as the characteristics of this sample are not easily replicated. The results may have some value for other smelter communities such as Trail, B. C. and Port Pire, Australia.

Implications

It is hoped that the information obtained will be helpful to those who provide prenatal care, and will guide them in the care of women with a history of lead exposure. It is very important for physicians to counsel their patients regarding adequate nutrition during, especially calcium and iron during any pregnancy. It is especially important to counsel them if they are at risk for exposure to lead. Blood lead samples drawn at intervals during a pregnancy may prove to be inefficient in providing the information
needed regarding risks to the developing fetus. If so, then perhaps this study will help to stimulate the search for a more appropriate and cost effective method. Based on the results of this study, the formal Prenatal Screening program was suspended. Panhandle Health District will continue to offer the service of blood lead testing and counseling to obstetrical patients as well as continuing the Childhood Lead Screening Program. The results of this one study were consistent with the 65 women previously screened since 1990. The highest blood lead level recorded over the past 6 years was 8 µg/dL. This subject moved to the area from Texas, and her exposure source was unknown.

This project will be submitted for publication so that additional research may be stimulated, as well as encouraging nurses to learn about lead intervention programs. However, before submitting the paper, it must receive approval of the ATSDR, the Idaho State Office of Environmental Health, and Panhandle Health District. All slides, posters, data and materials are property of the afore mentioned agencies.

Conclusions

Since the Panhandle Health District did not have bone lead levels on all the subjects, it is assumed that they are carrying a bone burden of lead due to their long exposure history. In actuality, the subjects may not be carrying a significant bone burden. The reason for the low lead levels is not known. The best guess at this point is because of nutrition, although data to substantiate this hypothesis were not obtained as part of the present study. Diets high in calcium prevent mobilization of calcium from the mother's bones, preventing the mobilization of lead as well. It may also be possible that zinc is playing a role in this situation. It is known that zinc is a protective element for lead
poisoning, and since the area is contaminated with zinc, there may be a protective factor involved in either the initial absorption of lead or in its release during pregnancy. It is beyond the scope of this project to answer the question of "why" these women do not have higher lead levels. There are many other factors to be investigated to answer that question. However, it may be difficult to find the answer because of the difficulty in obtaining willing subjects from this particular population. In addition, the low lead levels may indicate that finding the answer to "why" may be a moot point. If this population has not been releasing lead during pregnancy over the past five years, then it would be unlikely that the physicians will want spend much more time looking into a problem that may not exist. Additional study of this population is not recommended.


FIGURES 1-11

Figure 1  Age of Subjects
Figure 2  Number of Participants Who Lived in the Silver Valley as Children
Figure 3  Locations of Those Currently Living in the BHSS
Figure 4  Age of Homes of Subjects
Figure 5  Other Risk Factors for Lead Exposure
Figure 6  Results of First Trimester Blood Lead Levels
Figure 7  Results of 3rd Trimester Blood Lead Levels
Figure 8  Cord Blood Lead Levels
Figure 9  Current Residence and Blood Lead Level
Figure 10 Comparison of Blood Lead Levels and Childhood Residence
Figure 11 Comparison of Blood Pb Levels with Number of Pregnancies
Figure 12 Comparison of Blood Lead Levels and No. of SAB's
**Age of Subjects**

![Bar graph showing the number of subjects by age in years, with a mean age of 23.95 years.](image)

**Number of Participants Who Lived in the Silver Valley as Children**

![Pie chart showing 9 participants who lived in the Silver Valley as children and 11 who did not.](image)
Locations of Those Currently Living in the BHSS

Figure 3

Age of Homes of Subjects

Figure 4
Other Risk Factors for Lead Exposure

Number of Subjects

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceramics Painting</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Stained Glass</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Metal Casting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bullets Cast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Car Batteries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eat Fish</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eat Local Vegetables</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 5

Results of 1st Trimester Blood Lead Levels

Number of Subjects

<table>
<thead>
<tr>
<th>Blood Lead Levels</th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 µg/dL</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 µg/dL</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 µg/dL</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 µg/dL</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean = 1.9 µg/dL, Median = 2 µg/dL

Figure 6
Results of 3rd Trimester Blood Lead Levels

Number of Subjects

Mean = 1.8 μg/dL  Median = 1.0 μg/dL

Figure 7

Cord Blood Lead Levels

Number of Subjects

Mean = 1.25 μg/dL  Median = 1.000

Figure 8
Current Residence and Blood Lead Level

Number of Participants

<table>
<thead>
<tr>
<th></th>
<th>1 µg/dL</th>
<th>2 µg/dL</th>
<th>3 µg/dL</th>
<th>4 µg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>NO</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

Currently Living Within the Bunker Hill Superfund Site

Figure 9

Comparison of Bl. Pb. Levels and Childhood Residence

1st Trimester Blood Lead Level

Number of Participants

<table>
<thead>
<tr>
<th></th>
<th>1 µg/dL</th>
<th>2 µg/dL</th>
<th>3 µg/dL</th>
<th>4 µg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>NO</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

Lived Within the Bunker Hill Superfund Site as a Child

Figure 10
Comparison of Blood Pb Levels with Number of Pregnancies

Blood Lead Levels

Figure 11

Comparison of Blood Pb Levels and No. of SAB's

Figure 12
APPENDIX A

Appendix A contains the information packet, the questionnaire and the consent form used by Panhandle Health District for the Prenatal Lead Screening Program.
PANHANDLE
HEALTH
DISTRICT I
114 West Riverside Avenue
Kellogg, Idaho 83837-2351

PRENATAL BLOOD LEAD PROGRAM

PROTOCOLS

I. IDENTIFICATION

A. When OB patients register, please ask if they:
   1. Live in the Bunker Hill Superfund Site (Pinehurst to Elizabeth Park)
   2. Lived in the Bunker Hill Superfund Site as a child
   3. Know that they were leaded as a child.

B. If any of the above are positive, please ask the patient if they would like to participate in the program, and if so, fill out the Prenatal Questionnaire as well as sign the consent form. We will need these questionnaires and consent forms for our files at Panhandle Health, though you may make a copy for your chart if you like.

C. You will be supplied with bright pink stickers which say "Panhandle Health District, Prenatal Lead Program". Please put a sticker someplace obvious on the chart so it is easy to identify the patient as a participant in the Lead Program (a reminder that specimens need to be drawn, etc.) When it is time to send a copy of the patient's H&P and Prenatal Care Record to Labor and Delivery, please attach a sticker to that copy. This will tell the hospital L&D nurses that a "Cord Blood Specimen" must be obtained. Kootenai Medical Center also requests that you also include a copy of the consent form (page 3 of the triplicate form) to insure that the patient has agreed to obtaining that cord blood sample.

II. BLOOD SAMPLES

The samples consist of 3-4 ml in a lead free purple top tube.

1. Sample #1 should be obtained as early in the first trimester as possible, as this is a baseline level. You may choose to draw this during their initial OB Panel.
2. Sample #2 should be obtained in the third trimester, to determine if lead has been released during the pregnancy.
3. Sample #3 is a cord blood sample taken at delivery to determine risk to the baby.
These samples need to be transported to the Panhandle District Office in Kellogg either by courier, mail, or picked up by someone in this office. We have to have the sample to our contract lab, ESA in Massachusetts, within 7 days of the draw, so it is important that you notify us when you have samples. If you use Alpha Labs to draw/run your prenatal specimens, we have made arrangements with their courier service to bring the specimens to us. When ordering the Lead Level, please be sure to mark on the request "Draw and hold for Panhandle Health District Lead Program". If the draws are done through Shoshone Medical Center, we have also made the same arrangements regarding the draw and hold. The patients are NOT charged for this test; it is covered by the grant when processed through our contract lab, provided they have signed the consent and completed the questionnaire. When obtaining the Cord Blood Samples, the Delivery Nurse will tag the tube with one of the pink stickers to alert the lab to hold it for us.

We will mail the results of these tests to the patient, as well as a copy for your records. We realize it is taking an extra effort on your part as well as your staff, and we are most grateful for that extra effort and that you have agreed to participate in this study. If you have any questions, please feel free to call Kathy Smith RN, PHN or Jerry Cobb Environmental Health Specialist at Panhandle Health District Lead Health Intervention Program - 786-7474.
PRENATAL BLOOD LEAD PROGRAM

Panhandle Health District: Lead Health Intervention Program, in cooperation with your physician, is conducting a limited study to determine the possibility and extent of lead released from bone stores during pregnancy. Previous studies indicate that women who have been leaded in the past, and are carrying lead in their bones, may release that lead during pregnancy and while breastfeeding. This release of lead into the blood stream could put the developing baby at risk.

In order to find out this information, we will need to obtain three blood specimens:

- The first two samples are obtained from the mother during the first and third trimesters, and the third sample is obtained from the umbilical cord at delivery.

To be eligible, you must:

1. Currently live in the Bunker Hill Superfund Site (Pinehurst to Elizabeth Park), OR
2. Lived in the Bunker Hill Superfund Site as a child. OR
3. Have participated in the Childhood Lead Program in the past.

If you wish to participate in this program, please complete the attached questionnaire and sign the consent form. All information will be kept confidential, and no one will be identified in any reports.

Thank you for your cooperation. If you have any questions, please contact Kathy Smith RN, at Panhandle Health District office in Kellogg at 786-7474. I am usually available on Mondays, Wednesdays and Fridays, but please feel free to leave a message and I will return your call as soon as possible.
All information will be kept confidential, and no person will be identified by name in any report.

Please Print:
Name: __________________________________________ Maiden Name: __________________________
Address (street): ________________________________ Social Security # _______________________
Address (mailing): ________________________________ Date of Birth: __/__/____
Physicians Name: ________________________________
Est. Due Date: __/__/____
Phone: ____________________________ Number of Pregnancies: __________
Occupation: ________________________________ Number of Living Children: __________
Partners Occupation: ________________________________ Number of Stillbirths: __________
Do you plan to feed by breast __ or bottle __ Number of miscarriage/abortions __________

1. Do you currently live in the Superfund Area (Pinehurst to Elizabeth Park)? Yes No
   If Yes: Where? How Long?

2. Did you live in the Superfund area as a child? Yes No Where?
   If Yes, for how long? During what years?

3. Have you participated in past lead screening programs? Yes No
   If Yes, during what years (if known)?

4. Have your children ever participated in the Lead Screening Program? Yes No
   If Yes, what years?

5. Do you eat fish from the Cœur d'Alene River? Yes No
6. Do you eat vegetables from locally grown gardens? Yes__ No__

7. How old is the home you live in? 5 yrs. or less? 10 yrs. or more? 15 yrs. or more? 20 yrs. or more? More than 30 yrs.? 

8. Has your yard been remediated (changed out) by the Superfund program? Yes__ No__

9. Is your drinking water from a community water system or private well?

10. Have you done, or are you planning on doing any remodeling of your home? Yes__ No__
     If Yes, then when and what type of remodeling?


10. Please check all hobbies or home occupations below that people living in your household do:

    __ Ceramics  __ Electronics soldering
    __ Tole painting  __ Car battery/radiator salvage
    __ Stained glass  __ Any other hobbies using solder/lead products
    __ Casting bullets or sinkers.

    Do not write below this line

Samples collected:

Sample #1  Collected on__/__/__
           Results of blood lead:__________

Sample #2  Collected on:__/__/__
           Results of blood lead:__________

Sample #3  Collected on:__/__/__
           Results of blood lead:__________

Comments: ____________________________________________________________
           ____________________________________________________________
           ____________________________________________________________

pn ques revised 1/95

2
SILVER VALLEY HEALTH INTERVENTION PROGRAM

Prenatal Blood Lead Monitoring Program

Participant Consent Form

I understand that the Panhandle District Health Department is conducting a free blood lead screening to determine the extent of prenatal exposure to lead. The screening is being conducted with the assistance of the Idaho Department of Health and Welfare and the Centers for Disease Control. Pregnant women who live in Kellogg, Smelterville, Wardner, Page, or Pinehurst may participate.

I understand that there will be three parts to the survey and that my participation is voluntary:

A. Interview — A brief questionnaire will be used to obtain information about possible exposure to lead.

B. Mother’s Blood Sample — A blood sample consisting of 4-5 ml will be taken from the arm of each participant to have tested for blood lead. A sample will be collected as early in the pregnancy as possible and again late in the third trimester. There should be no problem associated with collecting the blood sample, other than slight, temporary discomfort, and the possibility of a small bruise at the site where the needle enters the skin. If a bruise occurs, it will disappear in a few days.

C. Cord Blood Sample — At the time of delivery of your child a 3 ml blood sample will be drawn from the umbilical cord and tested for blood lead.

I voluntarily agree to take part in this screening and consent to be tested. I have been assured that personal identification information will be kept confidential, and that no participant will be identified by name in any report. I understand that this consent form is executed pursuant to all privileges recognized by law. I also understand that I may decline to answer specific questions, and that I am free to withdraw my participation at any time. I understand I will be informed in writing of all results, including any recommendations for follow-up. I understand that I can contact Kathy Smith, R.N. or Mr. Jerry Cobb, Panhandle Health District Department (786-7474) if I have further questions.

My physician’s name is ________________________________ and I am giving my permission to release the result of this survey to him/her.

Yes________  No ________

PARTICIPANT

Signature: ____________________________
Address: ____________________________

______________________________

DATE: ______________
ID Number: ____________________________

INTERVIEWER

Signature: ____________________________
Date: ______________

______________________________

DATE: ______________
APPENDIX B

Appendix B contains copies of the letters sent to the subjects and their physicians regarding participation in the program and results of their blood lead levels.
April 1, 1996

Jane Doe
123 Elm St
Anywhere, USA

Dear Jane;

As part of our Prenatal follow-up for the Health District, women who are pregnant and at risk for lead exposure are referred to the Lead Health Intervention Program. We are currently checking the lead levels of women who meet the following criteria:

1. Currently Live in the Bunker Hill Superfund Site Area, OR
   (Superfund site is Pinehurst, Page, Smelterville, Kellogg and Elizabeth Park)
2. Lived in the Superfund area as a child, OR
3. Have participated in the Childhood Lead Screening Program

We have enlisted the assistance of the following physicians to help us obtain this information:

   Dr. Tarnasky, Dr. Ambrose, Dr. Cutting, Dr. Sanderson, Dr. A. Henneberg, Dr. R. Henneberg, Dr. Seeley, Dr. Swason, Dr. Burnett and Dr. Janzen.

If you are seeing one of these physicians and would like to participate in the program, please let them know so you can fill out the appropriate paperwork. If you are not seeing one of these physicians for your prenatal care, but you meet the qualifications listed above and would like to be involved, please contact me at (208) 783-0707.

Sincerely,

Kathy Smith RN
Public Health Nurse
Lead Health Intervention Program
April 1, 1996

Jane Doe
123 Elm St
Anywhere, USA

Dear Jane:

I would like to take this opportunity to thank you for agreeing to participate in this important study. The information we hope to gain will be very helpful in giving the best possible prenatal care to women who have been exposed to lead. I will remind you again that identifying information will be kept completely confidential. Names, addresses, birthdates, and etc. are needed only to make sure the person and the blood sample are matched.

Please find enclosed some additional information about lead: what it is, and what you can do to break the pathways of lead exposure for yourself and your family. I have also included a booklet on remodeling. Often times when a baby is on the way, the family decides to remodel and make room for the new family member. This can be dangerous for the mother and baby if the house is old or in an area where tearing out ceilings and walls could expose the family to contaminated dust and dirt.

If you have any questions about lead, or about the study, please feel free to call me. I am usually available Mondays, Wednesdays and Fridays at this office.

Thank you again for your cooperation.

Sincerely,

Kathy Smith RN, BSN
Public Health Nurse
Lead Health Intervention Program
April 1, 1996

Jane Doe
123 Elm St
Anywhere, USA

Dear Jane;

The test results of analysis of the venous blood sample collected from you as part of the Prenatal Lead Health Program has been received and is as follows:

<table>
<thead>
<tr>
<th>Sample date</th>
<th>Type of Sample</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>xx/xx/xx</td>
<td>Venous</td>
<td>XX µg/dL</td>
</tr>
</tbody>
</table>

Current guidelines recommends that blood lead levels in pregnant women be as low as possible. A level of less than 10 µg/dl is desirable, and 15 µg/dl should not be exceeded. If you have a level of 10 µg/dl or above, you should make specific contact with your physician for advice.

You will note your highest sample is XX µg/dl. As requested, a copy of your results will be provided to your physician.

Sincerely,

Kathy Smith R.N. B.S.N.
Public Health Nurse
Lead Study Program

cc  Jerry Cobb
Environmental Health Specialist Sr.
April 1, 1996

Dr. Jones
345 Oak St
Anywhere, USA

Dear Dr. Jones,

The test results of analysis of venous blood drawn from your patient Jane Doe, part of the Prenatal Lead Health Survey have been received and are as follows:

<table>
<thead>
<tr>
<th>Sample Date</th>
<th>Type of Sample</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>xx/xx/xx</td>
<td>Venous</td>
<td>XXug/dl</td>
</tr>
</tbody>
</table>

Blood lead levels should be as low as possible. A level below 10 ug/dl is desirable, and 15 ug/dl should not be exceeded.

If you have any questions or concerns regarding the results, please do not hesitate to call me at any time. I can be reached at 208-783-0707.

Sincerely,

Kathy Smith R.N. B.S.N.
Public Health Nurse
Lead Study Program
April 1, 1996

Jane Doe
123 Elm St
Anywhere, USA

Dear Jane:

We have received the analysis of the cord blood sample collected from you as part of the Prenatal Lead Health Program, and the results are as follows:

<table>
<thead>
<tr>
<th>Sample Date</th>
<th>Type of Sample</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>xx/xx/xx</td>
<td>Cord Blood</td>
<td>xx µg/dL</td>
</tr>
</tbody>
</table>

Current guidelines recommend that blood lead levels for children be kept as low as possible. A level of 10 µg/dL or less is desirable. If the level is above 10 µg/dL, you should contact your physician for possible further evaluation.

It is important with a new baby, that you continue to be aware of the sources of lead and the steps you need to take to break the pathways of lead exposure. The booklets provided to you earlier in your pregnancy contain useful information; if you have questions, please call us at 208-783-0707. We recommend that you participate in the annual Childhood Lead Screening Program if you continue to live in the Kellogg-Pinehurst Area.

Thank you for your participation in the Prenatal Lead Health Program. The information obtained has been very useful in helping your physician provide good prenatal care.

Sincerely,

Kathy Smith RN
Public Health Nurse
Lead Intervention Program
February 14, 1996

MEMORANDUM

TO: Kathleen Smith, ICNE (5291)

FROM: Paul Whitney, Chair, WSU Institutional Review Board

SUBJECT: Review of Human Subjects Protocol

Your Human Subject Review Summary Form and additional information provided for the proposal entitled "The Evaluation of Lead Released During Pregnancy From Women Exposed to Lead From a Primary Smelter in Northern Idaho," OGRD #NF was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the IRB has approved your human subjects protocol on July 7, 1995.

The IRB approval indicates the IRB's belief that the Human Subjects protocol as presented in the Human Subjects Review Summary Form by the investigator, is designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of human subjects participating in the protocol. This approval is valid for one year from approval date. If any significant changes are anticipated in the study please notify the IRB before implementation.

In accordance with federal regulations, this approval must be kept by the researcher for THREE years after completion of the research.