

UNIVERSITY OF THE WITWATERSRAND



FACULTY OF HEALTH SCIENCES

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**Title: OCCUPATIONAL LEAD EXPOSURE AMONG LEAD BURNERS IN A
COPPER MINING COMPANY, ZAMBIA.**

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine - Exposure Science.

Research Report, Johannesburg, 2024.

DECLARATION

I **Kasyimbi Pauline Hayumbu with the student ID number 2500440**, declare that this research project entitled "*Occupational lead exposure among lead burners in a copper mining company, Zambia*" is my own, unaided work undertaken under supervision of Dr Keretetse and Dr. Ndaba. It is being submitted in partial fulfilment for the degree of Master of Science in Medicine - Exposure Science at the School of Public Health, University of the Witwatersrand, Johannesburg. This work has not been submitted before for any degree or examination at any other University. The author designed the study, conducted data collection as well as data analysis and write-up of this research report. As per the plagiarism policy, a plagiarism declaration form is signed and attached as Appendix A.



13th August, 2024

To my mentors and family for their unfailing support as well as the Almighty God for
His providence.

PRESENTATIONS ARISING FROM THIS STUDY

Poster Presentation: University of the Witwatersrand School of Public Health Research Day and Consortium for Advanced Research Training in Africa Conference, 14th and 15th September 2023 – WITS School of Public Health, Parktown Education Campus, Johannesburg.

Oral Presentation: Konkola Copper Mine Safety Health and Environment Briefing, 17th November 2023 – Virtual meeting on Webex Cisco Systems, Inc. platform.

Oral Presentation: Occupational Health Research Collaborative Mini-Conference and New Partnership for Africa's Development Workshop, 29th February 2024 – Copperbelt University School of Graduate Studies, Kitwe.

ABSTRACT

Enlisted among the World Health Organisation's (WHO) 10 chemicals of major public health concern and causing 0.6% of the global disease burden, lead exposure occurs through multiple routes. Downward lead exposure trends have been reported yet Zambian literature is scanty. This study characterised exposure among lead handlers at a Zambian copper mine by comparing external occupational exposure with the internal lead body burden. The study was University of the Witwatersrand (Wits) Medical - Human Research Ethics Committee (HREC), Tropical Diseases Research Centre (TDRC) - HREC, and Zambian National Health Research Authority (NHRA) approved. Historical (n=51) and current (n=39) blood lead internal exposure values, versus multi-route current external occupational exposure assessment was conducted. The samples in the external assessment were palmar wipes (n=53), surface wipes (n=27), breathing zone air (n=37), and room air (n=5) to determine lead concentration. Convenience sampling was done. South African National Accreditation System (SANAS) - accredited laboratories performed chemical analyses. Jeffrey's Amazing Statistics Program (JASP) software was used with 5% Alpha level of significance with 95% Confidence Interval to perform statistical analysis. Descriptive tests, Test for normality, Chi-square, Kruskal-wallis, Student T, Analysis of Variance (ANOVA), and Bayesian analyses were done. Most of the data was not normally distributed. International reference standards were adopted since Zambia has none. The mean age of participants, all male, was 41 years with median exposure duration of 10 years. Mean blood lead was 1.61 units higher than the Occupational Health and Safety Administration's (OSHA) recommended value (10 µg/dL). The personal and room air time weighted average (TWA) values were below the OSHA recommended value (0.05 mg/m³), National Institute for Occupational Safety and Health (NIOSH) recommended value (0.1 mg/m³), and American Conference of Governmental Industrial Hygienists (ACGIH) recommended value (0.05 mg/m³). No reference standards for dermal and ingestion routes were available. Health risk exposure assessment findings were: Dermal chronic daily intake (CDI = 6.76x10⁻¹¹ mg/kg/day), Oral (CDI = 5.97x10⁻³ mg/kg/day), and Inhalation (CDI = 4.20x10⁻² mg/kg/day). All pathways showed low risk for adverse health effects with hazard quotient (HQ) less than one. This study showed that the highest pathway contributing to lead exposure was inhalation although air sampling was within

exposure limits. The internal body burden of lead was in exceedance of the recommended standard value but below the action and suspension levels following occupational exposure. Thus contributing to the field of Exposure science by considering all exposure pathways and routes of the entry of lead in an occupational setting. The findings of this study provide the basis for the development of intervention strategies to mitigate occupational lead exposure and prevent negative health impacts.

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NOMENCLATURE

ACGIH –	American Conference of Governmental Industrial Hygienists
ALE –	Anticipated Lead Exposure area
BEI –	Biological Exposure Index
BLL –	Blood Lead Level
CDC –	Centers for Disease Control and Prevention
CDI –	Chronic Daily Intake
CNS –	Central Nervous System
CSF –	Cancer Slope Factor
DALY –	Disability Adjusted Life Year
EBL –	Elevated Blood Lead
EPA –	Environmental Protection Agency
HREC –	Human Research Ethics Committee
HI –	Hazard Index
HQ –	Hazard Quotient
ILCR –	Incremental Lifetime Cancer Risk
ICP-AES –	Inductively Coupled Plasma Atomic Emission Spectrometry
KCM –	Konkola Copper Mines plc.
LOAEL –	Lowest Observed Adverse Effect Level
NMAM –	NIOSH Manual of Analytical Methods
NIOSH –	National Institute for Occupational Safety and Health
NOAEL –	No Observed Adverse Effect Level
OEL –	Occupational Exposure Limit
OSHA –	Occupational Safety and Health Administration

Pb –	Lead
PEL –	Permissible Exposure Limit
PPE –	Personal Protective Equipment
REL –	Recommended Exposure Limit
SANAS –	South African National Accreditation System
TDRC –	Tropical Diseases Research Centre
TLV –	Threshold Limit Value
TWA –	Time-weighted Average
UK –	United Kingdom
USA –	United States of America
U.S. EPA –	United States Environmental Protection Agency
WHO –	World Health Organization
ZAR –	South African Rand

GLOSSARY

Bayes factor	The ratio of two marginal likelihoods: the likelihood of the data under the null hypothesis and the likelihood of the data under the alternative hypothesis.
Biomonitoring:	Biomonitoring is the repeated measurement of certain exposure-related chemical/biochemical markers in biological samples of subjects, e.g. urine, blood, hair, nails, exhaled air or exhaled breath condensate.
Cauchy:	A continuous, infinitely divisible probability distribution.
Disability-adjusted life years:	The number of age-standardised disability-adjusted years lost per 100,000 persons due to a given risk.
Environmental exposure:	An interaction between an exposure stressor and exposure receptor in the non-occupational setting.
Exposure assessment:	The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed.
Exposure science:	Human exposure science studies human contact with chemical, physical or biological agents occurring in their environments, and advances knowledge of the mechanisms and dynamics of events either causing or preventing adverse health outcomes.
Far-Field Compartment:	Any location or environment that is distant from the use of a considered product, to and from which chemical transfers occur and within which removal processes occur. Far-field compartments include environmental media (e.g. 'ambient air', 'freshwater' like rivers and lakes, or 'soil'), biota (e.g. agricultural crops, wild animals and plants), or technological systems (e.g. waste water treatment plants and landfills).
Medical surveillance:	The analysis of health information to look for problems that may be occurring in the workplace that require targeted prevention.
Near-Field compartment (workers):	Any indoor or near-consumer location or environment within the vicinity of the use of a considered product ('user' environment), to and from which chemical transfers occur and within which removal processes occur. Near-field

	compartments include indoor air, consumer products and objects themselves, and their surfaces (e.g. 'skin surface layer' for products applied on top of the skin surface, or 'article interior' for products like flooring materials).
Para occupational exposure:	Exposure to work pollutants transferred to the home environment by family members exposed to work pollutants.
Posterior:	The distribution which represents knowledge about the value of parameters after having observed the data in Bayesian statistics.
Prior:	The distribution which represents uncertainty about the value of the parameters before having observed the data in Bayesian statistics.
Spatial:	Relating to space. In this write-up, relating to location.
Temporal:	Relating to time.
Temporospatial:	Relating to space and time.

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CHAPTER ONE – INTRODUCTION

1. INTRODUCTION

1.1 Background

Lead is a widely used nonferrous metal that occurs naturally in the earth's crust. Its anthropogenic sources include fossil fuels, extraction of minerals from ores, and manufacture of, and use of lead-containing products like paint (1–6). Thermal as well as physicochemical properties of lead including strength and insolubility, though advantageous, are such that harmful emissions may be released. Lead and lead compound anodes are traditionally used during copper electrowinning because lead forms a non-corrosive protective oxide layer that facilitates the conduction of the electrolysis circuit (7). The final stage of copper processing, whether electrowinning or refining, may involve the use of lead materials and lead-burning activities such that release of undesirable lead levels may occur. The presence of these fumes is an occupational and environmental hazard (1–6,8,9). Various worker groups at the Konkola Copper Mine (KCM), are referred to as Lead burners. This may be a misnomer since the company eliminated most lead-burning activities in the year 2006. The workers may rather be referred to as Lead handlers, the titles lead burner and lead handler are used interchangeably in this report. The specific job descriptions are listed in section 2.1. Lead handlers are at risk of lead exposure (8). It may be assumed that each worker at different times, sites, and during various lead handling tasks, present unique lead exposure scenarios (9). Two company sites were studied that is Nchanga and Nkana. Konkola KCM site only served as a source of historical biomonitoring data because it is now closed.

During copper electrolysis, the impure copper cathodes are placed in cells containing an electrolyte solution (1,2). These cells were lined with lead to prevent corrosion until the year 2006 when the lining material was changed to a polymer material that does not contain lead. Rather, along with the copper cathode, lead anode sheets are used during electrolysis which gradually wear off with fragments falling to the base of the cells. KCM Tank house lead handlers are regularly exposed to lead because their job description (operators) involves clearing electrolyte sludge from the cells. Lab assayers are exposed to flux and foil forms of lead, which involves heating the lead in furnaces among other procedures. Additionally, the lead handlers give history of fabricating lead equipment for use during copper refinery such as flotation devices in tanks as a marker

of how full the tank is. The refinery has lead-lined tanks which require maintenance repairs using sheets of lead and heat from time to time.

As the oldest known occupational health hazard, lead exposure can cause irreversible adverse health effects that affect multiple systems in man (3,4). These effects are illustrated in Figure 1.1 below. In the non-occupational setting, certain subpopulations are more susceptible to the detrimental effects of lead, especially children (3–6). In the occupational setting, adults are susceptible to developing acute and long-term detrimental health effects. A multi-pronged approach to preventing workers' adverse health effects by minimising exposure through contact with lead is therefore very important (7–9). Rather than mere compliance with standards, other initiatives may effectively reduce occupational lead exposure. Biomonitoring of lead as a marker of occupational exposure lies within the broader spectrum of lead emission and exposure prevention (4). Air versus dermal/ingestion sampling, using filters and surface wipes respectively, serve as key exposure assessment sampling strategies in a wide range of workplaces (10). This is the approach used in this study. Determination of lead exposure among non-lead handling workers in the mining company is beyond the scope of this study. Pre-, and post-lead handling measurement approach may suffice to illustrate lead exposure extent.

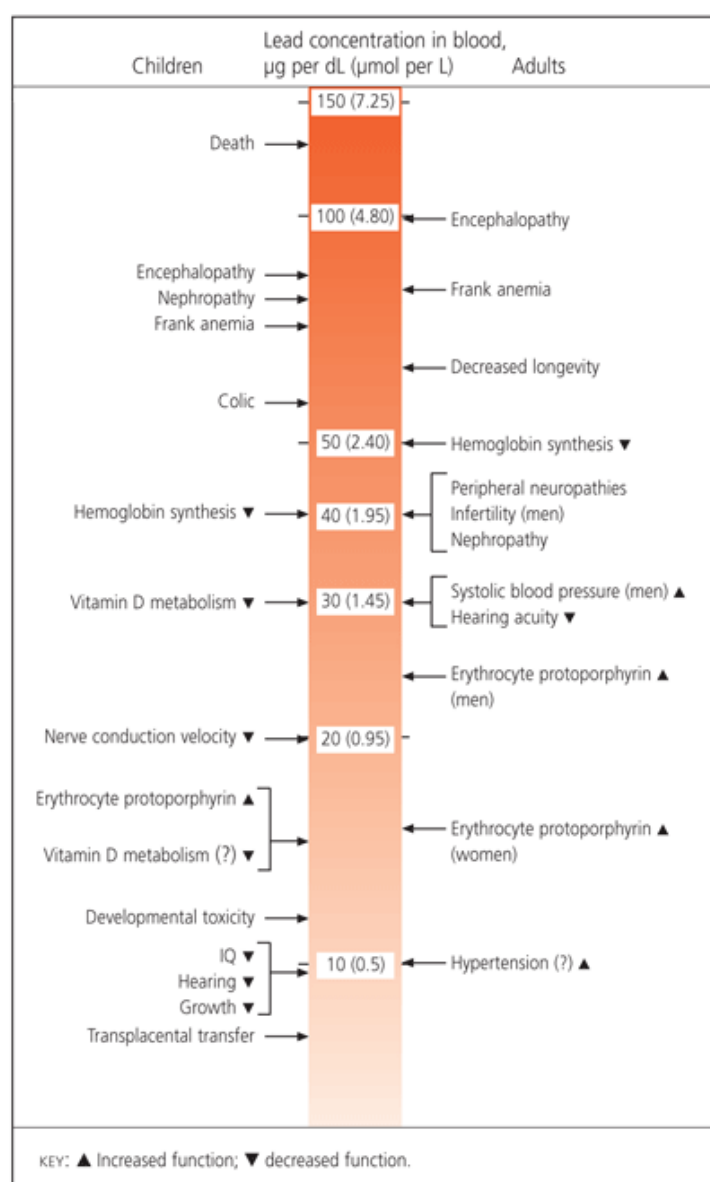


Figure 1. 1 Health effects of occupational lead exposure Source: Staudinger et al. 1998 (7)

1.2 Literature review

1.2.1 Lead use and exposure-induced health outcomes

The current wide application of lead in several industries seems indispensable as the elimination of all lead products may not be possible (3,11,12). Lead causes harm to susceptible target organs including the eyes, digestive tract, nervous system, reproductive system, blood, kidneys, and gingival tissue (7,9,13). Lead, particularly lead salts, are also likely carcinogens (3,14).

Studying the relationship between lead intake and blood lead may provide a well-rounded, reliable means of internal and external exposure assessment (15). Because anthropogenic activities are a major source of lead in the environment, studying this relationship among exposed individuals in the occupational setting may reveal findings necessary to prevent further exposure (4,7,16,17). International reference standard values from various organisations in the United States of America (USA) defined for blood lead levels (BLLs), serve as a powerful resource (14). These include, but are not limited to the NIOSH, ACGIH, and OSHA. BLLs are the most used approach in public health surveillance and general clinical biomonitoring. Not only that, they are the best available marker of exposure for both current and recent events (3,18). This method however does not reflect the total body burden and if used alone, is inadequate to assess day-to-day lead exposure fluctuations, nor can it determine the efficacy of implemented controls (3,4,14,18).

The World Health Organization (WHO) formulated the lowest observed adverse effect levels (LOAELs) at given BLLs for certain health effects of lead in adults such as haematological and central nervous system (CNS) conditions (4). Such associations between exposure (dose) and outcomes show the extent to which exposure assessment-generated information may be directly applied (14). At lower BLLs, the relationship between lead in air takes a curvilinear pattern (14). For instance, approximately $1\mu\text{g}/\text{m}^3$ inhaled lead results in a blood concentration of about $16\mu\text{g}/\text{L}$ in adults (14). For dermal transfers however, several factors are implicated in the process of lead adherence to skin and a loading value of $1.3\text{ mg}/\text{cm}^2$ was proposed by Hemmen and Brouwer (19,20).

Evidence shows that lead may be harmful at BLLs previously thought to be harmless (14,21,22). A small concentration of lead exposure over time may result in significant liver, bone, and/or brain bioaccumulation (23). There is growing awareness of adverse health effects at BLLs less than $10\mu\text{g}/\text{dl}$ while effects have also been reported to occur at BLL $5\mu\text{g}/\text{dl}$ and less (4,24). The CDC declared no safe BLL in children (4). The concept of take-home lead from work, which may put children living in households of lead-exposed workers, is beyond the scope of this report. A study on exposure and

effects from a mixture of heavy metals in developing nations cited that chronic exposure to low dose heavy metals may result in toxicity, since hepatotoxicity has been reported in rats (25).

1.2.2 Occupational lead exposure

For over 2,000 years, lead has been recognized as an occupational health hazard in various industries (7). The United Kingdom (UK) government highlights inhalational, ingestion and dermal contact with lead as potentially significant. It also recommends that occupational exposure be regulated using action and suspension BLLs (26). The USA's OSHA has equally defined Biological Exposure Indices (BEIs) for worker suspension as well as acceptable reference ranges. Such policies coupled with rigorous medical surveillance of lead exposure are invaluable in protecting the health of workers and have been implemented in the US for almost three decades (4,17,21,27). The past several years have shown a downward trend in lead exposure levels in several developed nations. Low-level lead exposure still remains an occupational and environmental concern (9,21,28).

In the context of lead exposure, exposure limits are available for air assessments but not the dermal and ingestion exposure routes (20). The reference standards for lead in air are 0.05mg/m³ (OSHA, ACGIH) or less than 0.1mg/m³ (NIOSH-CDC). As with blood in lead, there seems to be no consensus regarding reference values from different institutions.

The key determinant of lead release into the workspace is generation of respirable lead fumes and inhalable dust particles (12,14,29). Not all workers in workplaces where lead is used are necessarily at risk and therefore no occupation may by default be classified as more or less hazardous even though some are more risky compared to others (7). Controls such as a buffer zone between lead-use areas and non-lead use areas, personal protective equipment (PPE), worker education, adherence to international and government environmental as well as health safety policies, among others, additively yield much desired protection (6,9).

Studies provide unanimous evidence that males are at a much higher risk of exposure (7,9,11,17,30). In Canada, welders, followed by police officers were the most exposed workers as of 2016 (11) while in Britain the top industrial sectors as of 2021 were smelting, refining, alloying and casting; lead battery manufacture; as well as work with metallic lead and lead-containing alloys (17). A USA study highlighted battery manufacturing, chemical industry, and construction work as major industries and occupations associated with lead overexposure (7,21). This USA decade-long survey established a 94.7% rate of occupational overexposure among 37 states. Corporate failure to comply with set exposure prevention standards as well as workers' poor hygiene practices may increase likelihood of lead exposure leading to elevated blood lead levels among lead-burner workers (31). About 15.6% of the working population in the UK were deemed at risk of inadvertent ingestion of hazardous substances, of which metals were the highest ranked substance group (1.5 million workers), followed by pathogens (32).

A 2019 review of lead exposure sources in different countries across the world revealed that both lower- and middle-income, as well as high-income countries have the burden of curbing the legacy of exposure. The former however have the additional challenge of enforcing regulations and/or lack of regulations. Unique sources of lead were observed in Nigeria (electronic waste, paint), Mexico (glazed ceramics, water), India (cosmetics, unconventional medicines), China (electronic waste, emissions), France (imported ceramics, cosmetics), Australia (dust, imported toys), and USA (industrial legacy of lead exposure) (33). Even though there is considerable evidence for environmental lead exposure in West Africa, three Nigerian occupational lead exposure studies revealed mean BLL findings of 39.00 µg/dl, 155.42 µg/dl, and 50.37 µg/dl for Nkpor, Oshodi, and Port Harcourt respectively (25). A study in South Africa highlighted the need to investigate lead exposure in the growing informal occupational sector and by extension in many other African developing countries (34). Key sources of lead in South Africa and Zambia include lead in petrol (phased out in the year 2006), subsistence fishing using melted lead, lead ammunition use, and mining (35,36).

1.2.3 Lead exposure pathway

Media of our ambient environment known to be sources of lead include the atmosphere, water, soil, dust, and food, among others. As a result of this distribution, there are multiple exposure routes posing a challenge in deciding the appropriate prevention approach (14,37). The exposure routes include inhalation, ingestion and dermal contact (13). Of these, the most common is inhalation followed by ingestion for adults but the opposite may be true in children (11,14,38). In the context of occupational exposure, inhalation is commonly considered the most potentially toxic, followed by skin contact and then ingestion. Some reasons ingestion exposure may be considered negligible include that hazardous substance ingestion is thought to only result from intentional reasons; the low bioavailability of many materials; and/or less proportion of mass of material taken into the body compared to other routes (32). Seemingly minor routes of exposure such as lead in dust or soils must not be neglected. The major exposure pathways i.e. inhalation, dermal, and ingestion, may result in uptake by other minor routes indirectly such as swallowing inhaled particles (14).

The WHO Air Quality Guidelines therefore assume a corrected, higher 50 µg/L value of blood lead resulting from 1µg/m³ lead in the air (14). This caters to a multi-route uptake since it may not be feasible to quantify exposure from all possible pathways. Thus exposure measurement findings in one pathway may be extrapolated to describe the situation in other relevant pathways (14). Multi-route exposure assessment prevents exposure scenario information loss (18,39).

Ingestion route may be the least understood due to the fact that quantifying the mass taken into the gastrointestinal tract cannot be practically measured. Focusing on preceding exposure pathway steps may be more revealing. First, lead exposure potential may be confirmed by surface area (wipe) analysis and then hand contamination, as was proposed in the current study. A good correlation is assumed between ingested lead and hand-mouth contact (32,40). Other than the hand wipe system, oral lead may be detected from peri-oral wipes, saliva samples, mouth rinse

samples, and under nail scrapings (32,40). Evidence exists correlating raised blood lead levels with ingestion of lead (32,40).

As shown in figure 1.2, the common exposure routes for lead are ingestion, inhalation and dermal contact (4,7,19). Ingestion lead exposure has traditionally been measured by determining the concentration of lead in the material ingested. Exposure limits therefore exist for lead in certain media such as soil, and water. For instance, the limit for lead in soil by U.S. EPA and Zambian standards are 400 mg/kg and 200 mg/kg respectively (28,40,41). Dermal lead can be assessed using removal and non-removal methods. The use of wipes for example, is a removal method. On the other hand, qualitative rather than quantitative methods may be used. The former type of assessment only confirms whether a particular sample contains the substance of interest. Further, sampling data may be processed using model functions such as those provided by the U.S. EPA for given exposure scenarios (19,20). Lead in air may be measured using media placed in a sampling pump over a specific period of time. The dermal and air sampling media are appropriately transported, then subjected to chemical analyses and lead concentration determined (4,7,14,35). This concentration is typically converted to 8-hour weighted average that may then be compared with standard reference values.

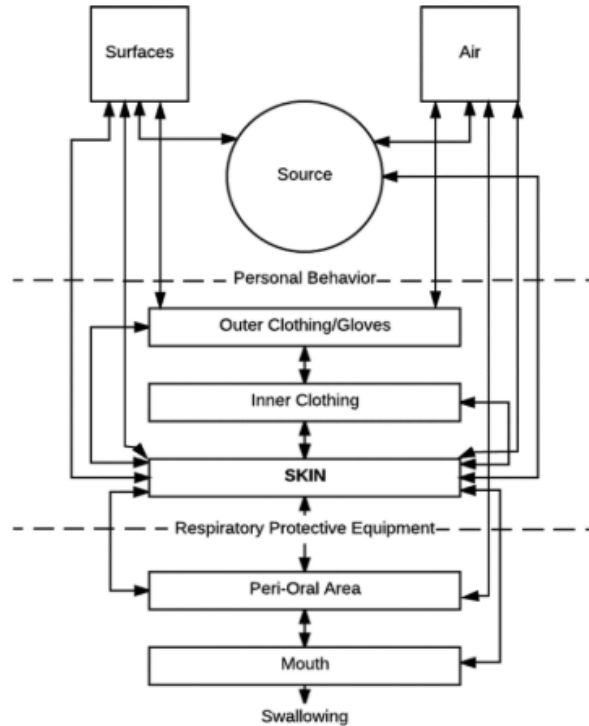


Figure 1.2 Relevant Exposure Pathways Source: Sahmel et al 2022 (19)

Factors affecting absorption may be substance-related (in this case lead), or receptor-related (workers). Organic lead is more easily absorbed (4). Inter-worker variable characteristics include: respiratory/gastrointestinal tract anatomy, skin/mucous membrane integrity, body weight, behavioural e.g. use of personal protective equipment, presence of comorbidities, individual toxicokinetics and toxicodynamics. Other determinants of exposure dose are task related number of contact with lead and duration of exposure, as well as physical form of lead used. Other known confounders are smoking (3,4,19,30). Inhalational occupational lead exposure has been reported to be responsible for the highest corresponding BLLs compared to ingestion and dermal contact (11,14,38). Lead in bone depicts chronic, rather than acute exposure and the expected body burden in bones is beyond the scope of this report (4). Health risk assessment may be determined by filling exposure assessment measurements and literature-sourced parameters in formulae to obtain indices such as HQ, HI, CDI, and ICLR (40). This is illustrated in section 2.4.3.2.

1.2.4 Exposure and Health Risk Assessment

Human metal exposure assessment may be done within the near- or far-field compartments. In the former approach, hazard sources are found indoors. Further, either analytical determination of metals in biological samples correlated with environmental assessment or, mathematical modelling to show multimedia environmental contamination may be done. The former may demand more resources, time and increased sensitivity to detect low metal concentrations. Models and simulations may, on the other hand be too simplistic with unacceptable levels of uncertainty considering that metal kinetics are specific (23).

Multi-route exposure assessment is recommended to avoid underestimating exposure. Dermal exposure may be of more concern compared to inhalational lead exposure because the latter is more obvious and has received more attention in the design of current exposure prevention controls. After lead is loaded on the skin, the primary route of exposure is argued to be ingestion through hand to mouth contact, more than the dermal or inhalation routes. Inhalation may be the highest route however. Determinants of absorbed dose include skin integrity, chemical lipid solubility, and personal activity but the amount of lead that would be biologically available is unclear (19,20). A review hypothesised a workplace scenario of inorganic lead worker aggregate exposure by route to be: ingestion - 46%; dermal – 0%; and inhalation – 54%. Inorganic lead compounds have such low dermal permeation resulting in negligible contribution whereas up to 70% inhaled lead may be absorbed into blood (32). Socio-economic-demographic as well as activity-time-personal behaviour exposure-related information provides clarity (6,7,9). Establishing the most contributing exposure pathway is key to efficacious mitigation (6).

Health risk may be characterised by calculating several indices based on observed, and evidence-based parameters. The exposure assessment body of knowledge continues to be updated with functions by which to quantify hazard risk as well as improve the accuracy with which exposures are linked to health effects. In the context of heavy metal exposure and/or toxicity, assessment may be classified as carcinogenic versus non-carcinogenic. According to the international agency or

research on cancer, lead as a probable carcinogen, is a Group 2A hazard with an assigned cancer slope factor (CSF) of 8.5 kg/day/mg. Lead exposure potentially may cause bladder, stomach, and lung cancer (42,43).

Hazard Quotient (HQ), hazard index (HI), incremental lifetime cancer risk (ILCR), and in the context of exposure pathway analysis, chronic daily intake (CDI) may be calculated. A recent West African study characterising heavy metal exposure via the dermal route revealed the following decreasing order of health risk based on CDI mean values: mercury, lead, cadmium. They additionally cited that the ILCR for lead was not significant and can be neglected (44). Similarly, a human health risk assessment study in Zambia of lead exposure through ingestion of cow milk determined health risk effects to be negligible with respect to the CDI, HQ, and ILCR values observed as cited in section 1.2.6 below (40). In another study from multiple states in Nigeria, lead HI for ingestion, inhalation, and dermal contact exposure pathways was determined to be 2.641, exceeding the USA's Environmental Protection Agency (EPA) acceptable threshold of one. Clinical effects may be observed in experimental animal populations when HI exceeds the given threshold (45).

Lead exposure assessment studies may be conducted among exposed individuals using air or dermal sampling techniques with corresponding biological markers of exposure such as urine, blood, and hair assays. Samples may be collected from various environmental media such as air, water, soil, dust, surfaces, and other solids. A sample from clean sources may be required as a reference too. Biomarkers may not reflect effects of, but rather the extent of exposure (3,4,14,46). Combining exposure measurements with markers of exposure yields the most meaningful and useful preventive information (18).

A U.S. EPA 1999 report cites that owing to their lipophilic nature, making them more easily absorbed in human tissue, the more toxic forms of lead are alkyl-lead compounds (47). Their organic nature may make them more bioavailable. NIOSH Manual of Analytical Methods (NMAM) however, details methods of detecting lead

compounds and elemental lead but not alkyl lead compounds. The manual provides succinct exposure assessment guidelines but other literature suggests adopting less complex alternatives for metal determination. This involves use of accurate, rapid, inexpensive electrochemical sensors adapted for both biological and environmental on-site monitoring (19,39,48). Further, statistical methods may be applied to predict BLLs in correlation with particular exposure pathways as well as explain any observed variability in BLLs (49). These regression methods are beyond the scope of this research.

1.2.5 International Reference Standards

Various institutions and nations have developed regulatory standards on acceptable lead exposure. For lead in air the following time-weighted average values over an 8-hour work shift apply: OSHA - 0.05 mg/m³ NIOSH - <0.1 mg/m³; and ACGIH - 0.05 mg/m³ (4,14,50,51). Standards for air lead exposure have been established but those for ingestion and dermal routes are unavailable, to our knowledge. It is postulated that ingestion route data is under-reported because no standard exposure-characterising metrics exist. Safety limits of lead intake through ingestion and dermal routes, despite evidence of exposure through the same, have yet to be fully characterised (32). A dermal exposure assessment for metallic lead transfer from source-to-skin, and skin-to-skin, among other methods revealed geometric mean ranges of 0.48 - 1.01 µg/cm² and not detected – 0.23 µg/cm² respectively. Significant variability has been observed in published values for dermal transfer efficiency from 0% to 157% (19).

The USA's NIOSH general population case definition of elevated blood lead level (EBL) is 10 µg/dL, which has been reducing over time due to evidence of the occurrence of negative health outcomes at lower BLLs (3,17,21). Descriptive indices for permissible lead exposure therefore continue to be revised as shown in section 2.3.4.1 below. In as much as NIOSH, OSHA, ACGIH international reference values may be adopted, there is a need to recognise differences in applicability of the same but evidence is lacking in our setting (24). Inferences obtained from exposure assessment findings may vary depending on the exposure scenario and the

distribution of the data from a statistical point of view (52). Elimination of exposures causing EBLs remains the aim of Public Health sectors globally (7–9).

1.2.6 The local setting

There is a paucity of data on occupational lead exposure in this region of the world. The main source of lead contamination in Zambia is mining. Kabwe Town hosted a lead mine for 90 years until 1994 and is polluted (29). In copper mining areas, however, lead emissions may comparably be negligible (38). A 2014 assessment in Kabwe on soil revealed exceedance of both the U.S. EPA and Zambian standards. In this assessment, the geometrical mean concentration of lead in soil was 1,470 mg/kg whereas U.S. EPA and Zambian standards are 400 mg/kg and 200 mg/kg respectively (53). BLL research data in the non-occupational setting, particularly in children from Kabwe, is rather plentiful due to the history of a lead mine in the town (28,38,53). One such study had a 100% exceedance of the WHO's 5 µg/dL limit among children (53). A study more representative of the Kabwe population conducted among 0-69 year-olds revealed a mean BLL of 11.9 µg/dL. Among the 4,730 participants, 72% had BLLs in the range 5-45 µg/dL, with 0-5 year-olds having the highest BLL mean of 18.2 µg/dL (28).

A probabilistic health risk assessment to evaluate lead exposure through ingestion of cow milk was conducted in Kabwe among children and adults. The parameters highlighted were CDI, target HQ, and ILCR compared with reference values defined by the U.S. EPA as well as the Joint FAO/WHO Expert Committee on Food Additives (JECFA). CDI, target HQ, and ILCR ranges for adults were 1.75×10^{-7} to 1.49×10^{-6} , 1.07×10^{-3} to 3.41×10^{-3} , and 2.31×10^{-8} to 3.18×10^{-8} respectively. The oral reference dose for CDI is 3.57 µg/kg/day. Target HQ safe limit is one (>1). The acceptable safe ILCR value is 1.0×10^{-6} to 1.0×10^{-4} (40). These parameters may similarly be calculated for other exposure routes and applied for holistic risk assessment.

1.3 Problem Statement

Lead is responsible for 0.6% of the global burden of disease yet exposure to it is completely preventable. Exposure may be underreported in underdeveloped nations (25,35,53). As a foodborne metal, lead has high disability-adjusted life years (DALYs) per 100,000 population. The median global number of foodborne illnesses observed in a 2015 study following lead exposure was 583,569 with no deaths recorded but 5,243,184 DALYs – 95% uncertainty intervals (54). In Zambia, environmental studies characterising lead exposure have been conducted but lead occupational exposure evidence is lacking (28,35,40). Lead occupational exposure assessment is a relevant exercise because significant exposure has been reported elsewhere in the occupational setting (7,18,30).

To our knowledge, lead-burner work exposure profiles in Zambia are lacking. Prevalence estimates show the highest occupational lead exposure occurs among lead welders (11,18). The mechanisms of exposure among welders and lead burners may be comparable, the latter perform fabrication activities while lead assayers use flux and foil lead forms in furnaces (11). Globally, ingestion of lead, arsenic, cadmium, and methylmercury was estimated to cause over 56,000 deaths, one million illnesses and at least nine million DALYs in 2015 (54). A 2019 toxicology profile for lead cited the effects of occupational lead exposures from 15 studies with various parts of the world. Illustrated in this profile are effects to various human systems following lead exposure, as well as mortality outcome. The average All-cause mortality calculated as Relative Risk (six cohorts/ studies), Standardised Mortality Ratio (7 cohorts/ studies), Adjusted Hazard Ratio (5 cohorts/ studies) values were 1.35, 1.09, and 1.15 (4). An article on heavy metal exposure in developing nations highlighted the occurrence inordinate lead toxicity in poorer nations such as a 2010 epidemic of lead poisoning in Nigeria where at least 163 deaths occurred among artisanal miners (25). Thorough health-hazard evaluation requires both workplace environmental risk assessment and medical evaluations of exposed workers (18,19).

1.4 Justification

Very little is known on occupational lead exposure in Zambia and previous studies focused on environmental exposure (28,38,53,54). An assessment by the Yale Center for Environmental Law and Policy in the year 2022, assigned Zambia an Environmental Performance Index (EPI) global score of 41.70 out of 100, reflecting a lead exposure DALY rate above the 50th percentile. In Sub-Saharan Africa, Zambia's EPI score ranked 20th out of 46 countries for lead, as a marker of heavy metals. Lead was chosen for the EPI assessment due to paucity of global data (55). The current study will provide lead exposure profiles of workers exposed to lead during copper refinery at a mine in Zambia. The resulting information may guide intervention strategies to mitigate occupational lead exposure and prevent the negative health impacts thereof.

1.5 Research Question

To what extent and through which possible route(s) are lead burners at a copper mining company in Zambia exposed to lead?

1.6 Aim

To determine the extent of personal occupational lead exposure among lead burners at a copper mining company in Zambia.

1.7 Objectives

- I. To assess personal and work environment lead in air among lead burners of Konkola Copper Mine (KCM) in 2023.
- II. To estimate dermal lead contamination at the KCM workplaces in 2023 and describe the potential for incidental lead ingestion.
- III. To describe the 2023 and historical trends of KCM lead-burner blood lead levels.

CHAPTER TWO- METHODOLOGY

2. METHODOLOGY

This was a cross-sectional study that incorporated use of historical biomonitoring BLL values. No other information from worker medical records was used.

2.1 Study population

Study data was collected from the mining company's lead-handling staff between 26th June and 16th August 2023. Both sites studied had refinery tank houses where copper electrolytic production takes place using lead anodes. One of the sites additionally runs a chemical analytical laboratory where lead assaying is done. The company had a total of 37 exposed company workers in addition to several contracted workers at the time of data collection. Not only that, retrospective analysis of available medical records and BLLs provided additional historical study information. A total of 77 worker's BLLs were assessed, some workers had several serial BLL measurements while others only had one. Historical BLL measurements were from the years 2001 to 2022. Job descriptions included: general operator, crane operator, copper sheet slitter, supervisors and assayers. These do not necessarily burn lead but the misnomer is due to company history when they used to burn lead while lining copper refinery electrolysis cells regularly until the year 2016. The same workers have been assigned new roles except for the Nkana tank house workers who are still lead burners. All workers were males. The standard shift is 8 hours but workers' duration of labour is task based because of lead exposure risk.

2.2 Materials and Methods

2.2.1 Study area

Zambian copperbelt provinces (namely, Copperbelt and North-Western) have extensive copper reserves. These constitute the southern part of the extensive Katanga Basin copper reserves of the Central African Copperbelt of Democratic Republic of Congo and Zambia. Figure 2.1 is a map of Zambia showing, among other Copperbelt Province mining towns, the KCM mine sites in Chingola Town and Kitwe City. At the former, there is a smelter plant with copper electrowinning tank houses

while at the latter, there is a copper refinery. The lead exposure assessment of this study was conducted from both places.

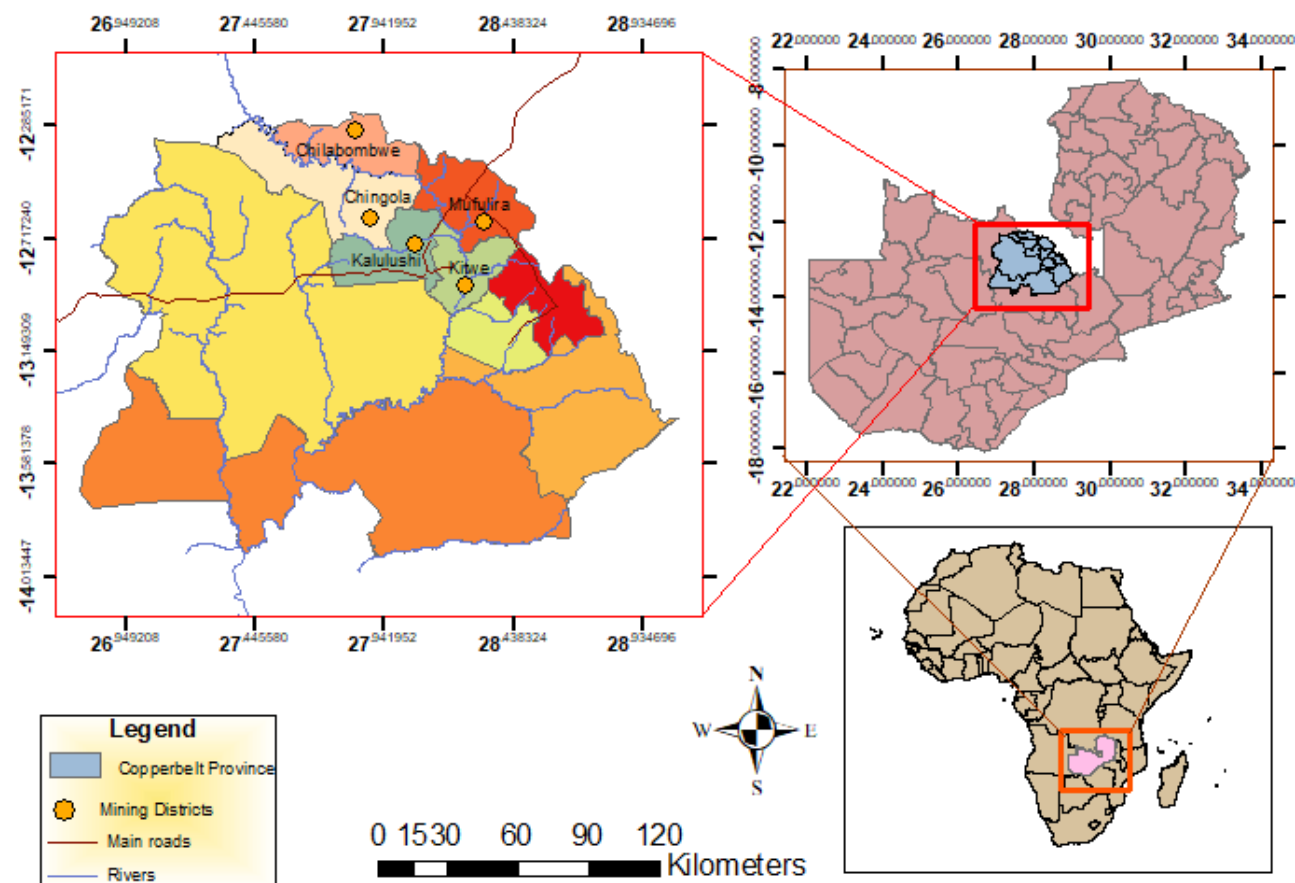


Figure 2.1 Mining districts in the Copperbelt Province of Zambia

The actual work environment for lead handling activities was used to collect air filter personal samples for task-based periods rather than a normal 8-hour shift per worker. The exposure controls put in place include: presence of substitution controls (lining of copper electrolysis cells with polymer material instead of lead), engineering controls (dilution ventilation), administrative controls (task-based labour rather than standard 8-hour shifts, personal hygiene concerning hand-washing and use of ablution facilities, lockers, designated feeding place, diet supplements - milk), as well as personal protective equipment (use of polyvinyl chloride gloves, respirator or mask, overalls, and safety boots).

The exposure scenario is such that lead handlers report at their respective sites in personal clothing and then change into company-provided personal protective equipment. The tank house electrolysis process involves the use of lead: antimony alloy (97%:3%) anodes and copper cathodes in cells containing a non-lead electrolytic solution. The cells are lined with a non-lead polymer material. One means of exposure is when removing and disposing of moist sludge containing lead flaked off from the lead anode during electrolysis. Assayers, on the other hand, analyse samples of various metals using two forms of lead: foil and flux. They take at least a tea and lunch break per day during which they are expected to leave the work area and feed from either of two designated feeding places: a green area within the tank house/refinery or cocoa house/kitchen. The closest feeding area is located about 50 metres from the lead-handling facility. Drink bottles were however seen in use while working within the electrolysis cells area. They take off contaminated PPE after work, followed by a quick shower, then put on clean clothing. Figure 2.2 illustrates a simplified potential exposure process flow chart of the scenario.

2.2.1.1 Nchanga Smelter

The Nchanga Smelter in Chingola Town has one tank house and 37 permanent company lead-handling workers. Several additional men work in this lead-handling sector as contracted staff. Of these, those designated as operators directly handle lead while working through processes including desludging tank house cells and pulling copper cathodes out of electrowinning electrolytic cells among other activities. Other staff do not directly handle lead such as supervisors, control room staff, foremen, kitchen, security, and crane operators.

2.2.1.2 Nkana Refinery

The Nkana Refinery in the City of Kitwe has 12 workers designated as lead handlers. Of these, some analyse lead in the form of flux and foil at the company's laboratory. The job titles of those who handle lead in the laboratory are assayers and analysts. The site equally has refinery electrolytic cells manned by those designated as lead-burners who also perform occasional lead fabrication maintenance activities such as

lining steel tank interior surfaces with lead sheets and other lead-welding tasks apart from those performed by their Nchanga Smelter tank house counterparts.

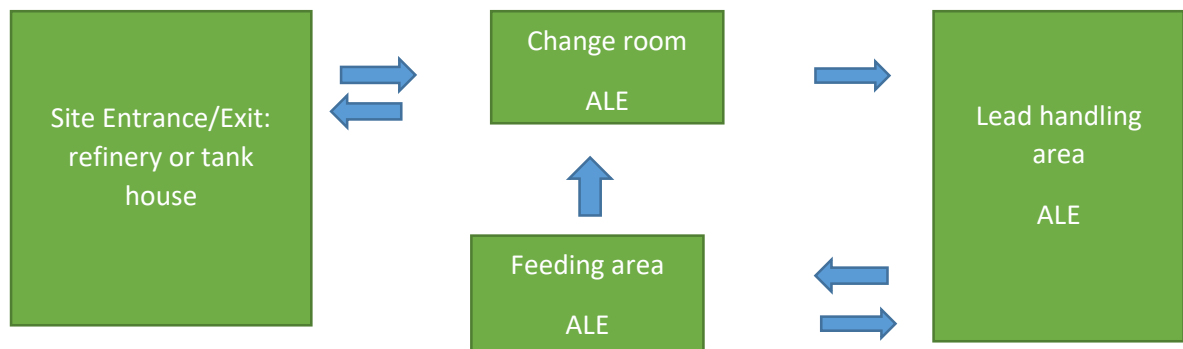


Figure 2.2 Anticipated lead exposure (ALE) areas

Data collection was conducted in a real-world normal working environment for the lead burners. Figure 2.3 below illustrates how the air sampling unit was used.



Figure 2.3 Illustration of air sample collection pump on worker's waist

2.2.2 Description of the lead-burner work environment

Before data collection, a walkthrough survey of the copper mine lead-handlers section was done. A group of eight lead handlers and administrative staff were interviewed about the work process. The selected staff were those located at both the Nkana Business Unit and Nchanga site of the company even though same refinery process occurs at both sites. No other criteria were considered in selecting the staff interviewed. The interviews and walk through at the site were conducted prior to data collection to make the data collection process objective as well as guide the concept of the research rather than yield data for analysis and reporting. The interview consisted of open-ended questions regarding lead handling activities performed, frequency of exposure, use of personal protective equipment, and anticipated adverse health effects following lead exposure. The walkthrough survey and lead burning department revealed information on the number of people at risk, exposure prevention policies, frequency of exposure, possible exposure routes and/or scenarios, workspace layout, as well as practices involving a variety of lead handling activities.

2.2.3 Sampling

Convenience sampling was conducted for both exposure assessment and biomonitoring.

2.3 Questionnaire data and sample collection

2.3.1 Field-based exposure data

Self-administered questionnaires were completed by the lead-handling workers of the mining company to obtain their demographic information, work shift patterns, type and duration of lead-handling activities, perceived lead-exposure risk, as well as personal behaviour. A total number of 57 workers participated in the study, all males, currently employed in the two sites of the company where copper refinery takes place as well as data for 19 workers who are no longer in the company. The workers who are no longer working with the company were not contacted, did not consent to participate in the study, and therefore did not respond to the questionnaire. Thirty-nine workers participated in blood collection, 38 in personal air sampling, 53 for dermal wipes while

30 area surface wipe samples including field blanks were collected. The variation in the numbers is due to the shift-working pattern which meant the workers could not all be pooled at one time. Another reason is limited resources.

2.3.2 Lead air sampling instruments and methods

Sampling equipment used included a personal respirable dust sampling media i.e. cellulose ester membrane filter in a cassette filter holder and a personal sampling pump with flexible connecting tubing.

2.3.2.1 Area air sampling

Area samples (eight) and personal breathing zone samples (thirty-seven) as well as field blank samples (four) were taken. A limited number of air filters were allocated for area, control, and personal samples.

2.3.2.2 Personal air sampling

Workers who were available on-shift during scheduled sample collection time, and had consented to the study participated in the process. The sampling process involved the following steps:

- i. Placement of calibrated personal pumps with a representative sampling train in line. The occupational health technician explained the sampling process, and attached the sampling pump to the worker's waist and the sampling head to their overall within the breathing zone (Figure 2.3 and 2.4). The sampling method was according NIOSH 7303 and 9105 NMAM guidelines (39). Metal analysis was conducted by the inductively coupled plasma method.
- ii. Pre- and post-sampling flow rate measurement was done to ensure that the average flow rate during sampling was about 1.7 L/min while targeting a total sample size of at least 200 L and no more than 2000 L for time-weighted average (TWA) measurement.
- iii. The filter loading dust was not to exceed 2 mg (56).

After placement of the air sampling equipment on the participant, they went about their normal work for the entire shift. Air and wipe samples were collected over the course of 3 days with average overall air sampling time as 226 minutes, average air flow rate of 1.710 litres per minute. The pumps were mounted within the breathing zone of the workers as illustrated in figure 2.4 below. Area air sampling involved placing the pump in respective sites over the period of a normal shift. The sites included the lead cathode storage yard, electrolysis cell units, electrolysis cells' control room, starter sheet loading bay, tank house checkpoint, analytical laboratory, guardroom, and tank house administrative office. Field blanks were collected by placing the filter in the pocket of certain staff, randomly, without being connected to a pump. After the sampling period, the filter cassettes were removed from the pump and transported at room temperature to an external SANAS-accredited lab for chemical analysis.



Figure 2.4 Lead air-sampling setup in the work environment

2.3.3 Lead wipes

To determine surface and dermal contamination by lead and its compounds, the following field equipment were required:

- i. Plastic 50 mm x 70 mm ziplock bags per wipe placed into releasable hard-walled 50 mL plastic sample containers per participant or surface.
- ii. SKC Ghost lead wipes: disposable towelettes, individually wrapped, with not significant background lead levels and pre-moistened.
- iii. Disposable latex powdered plastic gloves
- iv. Tape wipe template: 30 cm x 30 cm
- v. Tape measure
- vi. Masking tape

The sampling process involved the principle investigator donning on a pair of gloves, then placing a 30 cm x 30 cm template over the area sampled for surface sampling. To ensure no contamination occurred from the gloves to the wipes, an unused glove was transported in a Ziploc plastic bag to the analysing laboratory for detection of lead. For dermal sampling, the sampling area was not measured but the entire palmar surfaces of both hands were wiped in an 'S' pattern. A wipe was removed from its package and unfolded, folded into quarters and the surface wiped with firm pressure. One person performed this procedure to prevent inter-operator variability.

For area sampling, the sample was collected by covering the entire surface area using an overlapping 'S' pattern first with horizontal strokes followed by vertical 'S' strokes over the same area after folding the initially exposed side of the wipe-in. A third wipe over the surface around the perimeter but within the template was done after folding the wipe one more time to reveal an unexposed surface. Each wipe was placed into a clean 50 mm x 70 mm ziploc plastic bag folded in all exposed sides. Then multiple bags: two per participant, three and four per surface, were placed in hard-walled 50 mL plastic sample containers. The container was sealed securely and appropriately labelled. The template was cleaned between wipe sampling and gloves were discarded to prevent cross-contamination. Field blanks (five) were prepared by placing unexposed wipes into sample containers straight from their packaging. All were couriered to a SANAS-accredited laboratory for analysis (57).



Figure 2.5 Lead surface sampling with SKC lead dust wipes over 30 cm x 30 cm area

2.3.4 Lead exposure biomonitoring

2.3.4.1 Understanding BLLs

The NIOSH – CDC BLL Reference Guide values as defined by various institutions provides a means to understand BLLs. Consider that in 2017-2018 USA Adults BLL was 0.855 $\mu\text{g}/\text{dL}$ (24). The Council of State and Territorial Epidemiologists, California Department of Public Health (CDPH), and American College of Occupational & Environmental Medicine (ACOEM) reference value is 3.5 $\mu\text{g}/\text{dL}$ (24). CDC's NIOSH-funded Adult Blood Lead Epidemiology and Surveillance (ABLES) state-based database has a limit of 5 $\mu\text{g}/\text{dL}$ (21,24). The USA National Toxicology Program (NTP) bimonthly test threshold and Michigan Occupational Safety and Health Administration (MOSHA) removal threshold is 10 $\mu\text{g}/\text{dL}$ (24). MOSHA & ACOEM return to work following 2 consecutive BLLs value is less than 15 $\mu\text{g}/\text{dL}$ (24). ACGIH worker adverse health effect BLL level is 20 $\mu\text{g}/\text{dL}$ (24). OSHA's serious exposure to be handled by inspection limit is 25 $\mu\text{g}/\text{dL}$ while their return to work following 2 consecutive BLLs value is 40 $\mu\text{g}/\text{dL}$. MIOSHA, ACOEM & CDPH's medical removal value is 30 $\mu\text{g}/\text{dL}$ whereas OSHA's medical removal limit is between 50-60 $\mu\text{g}/\text{dL}$ (24). British Control of Lead at Work (CLAW) regulations action and suspension levels are 50 $\mu\text{g}/\text{dL}$ and 60 $\mu\text{g}/\text{dL}$ respectively (27).

2.3.4.2 Venous BLL sample collection

Venous blood was collected by the mining company's occupational health nurses at designated site clinics in adherence to standard venepuncture health and safety procedures. No more than 5 mL of blood was collected per participant and immediately placed into purple top EDTA tubes. The blood samples were neither spun, separated, nor frozen but stored at 7 °C in a fridge until they were couriered with ice packs to the South African branch of a SANAS-accredited laboratory where the samples were processed with a detection limit of 0.4 µg/dL.

2.3.4.3 Historical BLL data collection

To collect historical blood-lead data for the company's lead-handling staff over time, reference was made to the blood-lead levels database maintained by the company's Occupational Health Department. All lead-handling workers undergoing blood lead exposure medical surveillance between June 2006 and January 2023, regardless of demographic characteristics were considered for inclusion. No data parameters were considered relevant to warrant worker exclusion. Additionally, available historical BLL-related medical records were reviewed without incorporating exposure-related details in the presented results section of this report due to high occurrence of missing values. Sex and age, where available, were the only details collected from the medical records. Considering that the company's biannual biomonitoring exercise for workers exposed to lead started in the year 2006, a worker who was working in the company at the time and participated in the current survey was expected to have up to historical 33 BLLs. We found 20 workers with one historical BLL, one with four historical BLLs, one with five historical BLLs, one with six historical BLLs, and two with eight historical BLLs. All the historical BLLs encountered were below the reference level of 50 µg/dL and one value at action level of 30 µg/dL. All these BLLs were analysed with no anticipated bias, except for the large number of missing historical BLLs.

2.3.4.4 Statistical Analyses

Apart from descriptive analyses, Bayesian alternative of Independent T-Test for the comparison of BLLs between current and historical, as well as Nchanga tank house Nkana tank house and Nkana analytical laboratory sites was conducted. For the

hypothesis test, under the null hypothesis we expect an effect size (δ) of zero. Thus, we define $H_0: \delta = 0$. The alternative hypothesis is two-sided, $H_1: \delta \neq 0$, and prior to observing data, we assumed that δ was distributed as a Cauchy distribution with scale $r = 0.707$. This is further clarified in the results section.

2.4 Chemical analysis

2.4.1 Lead concentration analysis

2.4.1.1 Air

The Inductively Coupled Argon Plasma, Atomic Emission Spectroscopy (ICP-AES) technique was used for chemical analysis. The reagents used were 1.25 mL concentrated hydrochloric acid (HCl) and 1.25 mL concentrated nitric acid (HNO₃) to produce a final 25 mL solution of 5% HCl and 5% HNO₃. The elements in the 25 mL acid determined calibration and the measurement limit of quantification (LOQ) range was up to 50,000 ug/sample (0.07 ug/mL) while the estimated limit of detection was 0.023 ug/mL. The minimum sampling air volume needed to obtain the OSHA PEL at the given LOQ at a sample digestion volume of 25 mL was 35 L. On the other hand, the maximum sampling volume per sample, with the stated sample LOQ (50,000 ug) was 100,000 L. The wavelength selection on the ICP-AES was specific to lead and the instrument used by a SANAS-accredited laboratory with background correction according to spectral wavelength shift. Precision was not evaluated.

The ICP-AES spectrometer was calibrated according to the manufacturer's recommendations using standards of a matrix of the 2 acid preparations described above. Standards and reagent blanks were analysed every 10 samples while media blanks were analysed every 20 samples. A set of 2 laboratory control samples was analysed every 40 samples for a given matrix for either air or wipe specimens. Recoveries were checked with at least two spiked media blanks per 10 samples.

To obtain the lead concentration (C), in the volume of air sampled or amount of lead absorbed onto the wipe and digested (V) in litres, the following parameters are needed: instrument sample solution concentration (C_a ug/mL), instrument average media blank (C_b ug/mL), the volume of sample solution (V_a mL), and media blank volume (V_b mL) as illustrated in Equation 1 below:

$$C = \frac{(C_a V_a - C_b V_b)}{V} \text{ mg/m}^3 \quad \text{Equation 1}$$

Thirty-seven personal air samples were collected from workers' breathing zones along with four control samples, and eight area samples from anticipated lead exposure points. Time-weighted averages were calculated illustrating the total lead exposure concentration during an 8-hour entire shift. The parameters used were total lead concentration (C) and time taken per shift (T). See Equation 2 below:

$$TWA = \frac{(C_1 T_1) + (C_2 T_2) + (C_3 T_3) + \dots + (C_x T_x)}{\text{Total time}} \quad \text{Equation 2}$$

2.4.1.2 Dermal and Surface

Composite lead dust wipe samples were collected, two for dermal wipes and an average of three for area wipes. Blank field wipes were also collected in addition to analysis of an unused glove to rule out lead contamination from the same. A total of 84 measurements were available for analysis for workers' hands and potential lead exposure areas from both study sites. Following combination of NIOSH 7303 and OSHA ID-125G, samples were digested using hydrochloric and nitric acid, cooled, and diluted with ultrapure water. Blanks and samples were analysed with Inductively coupled plasma, atomic emission spectroscopy (ICP-AES) to determine the lead content. The resulting absorbances were used to calculate the lead concentrations of the samples (56).

2.4.1.2 Blood

The BLL analysis, for both current and historical samples, was conducted in the analytical services section of a SANAS-accredited laboratory using atomic absorption spectrometry (AAS).

A search of lead-burners' historical medical surveillance records yielded 83 BLL values from various years. Some of the workers had serial measurements in their records over time, others are no longer working for the company, a few had no accessible medical records at the time of data collection and only participated in the current BLL

analysis. Overall, 75 workers' BLL values were available for statistical analysis. There were no excluded values and 21 workers in the current lead measurements had historical BLL medical records. No other tests were conducted on the blood apart from chemical analysis for lead.

2.4.2 Statistical analysis

A total of 57 workers consented to participate in the study and filled in self-administered questionnaires. The data was checked for completion, and missing values. Variables with missing information were removed from the analysis. At this point, each participant had an assigned number which was tallied with the questionnaire number. Not all questionnaire responders participated in the biomonitoring exercise due to the reasons stated in the methodology section 2.3.1, however, 21 had historical BLLs which were analysed. Similarly, not all questionnaire responders participated in each of the occupational lead exposure sampling exercises in the work environment mainly due to the mismatch of the workers' shift timetable versus scheduled sample collection times.

All data were entered into Microsoft Excel spreadsheets from data collection tools which consisted of paper-based questionnaires, paper-based field data collection forms and electronic lab reports. Data cleaning, and coding were conducted before exportation to the selected statistical software. Data analysis was further conducted by objective. Descriptive statistics were run on the data, frequencies for categorical variables, and measures of spread for continuous variables depending on the type of data distribution. A test of normality was conducted before descriptive analyses using Shapiro-Wilk for the latter. The Chi-Squared tests were done on work site and job description variables, as well as the duration of exposure.

For environmental lead contamination, the variables job/task description, air media- and dermal/surface lead mass in a given volume (concentration) were analysed using Kruskal-Wallis test. The student T-test and Bayesian analyses were used to determine the need for action from both historical and current BLLs. Analyses of variance

(ANOVA) were also performed as well as Student T-tests to determine exceedance of recommended exposure limits for blood in lead. Bayesian ANOVA was performed against a null model to predict the risk of increased lead contamination by site given the data collected. Bayes factor was set to 10, compared to the best model, and credible interval of 95%. The statistical platform was JASP software version 0.16.1 with an Alpha level of significance was 5%. A breakdown of the analysis according to study objectives is given below.

To assess personal workplace lead exposure, area air and personal air average 8-hour values were weighted and then contrasted. Shapiro Wilk normality test indicated the need for a non-parametric T-test. The median 8-hour averaged air lead concentration was subjected to the Wilcoxon signed-rank test with the OSHA and ACGIH reference standards for lead in air exposure assessment value of 50 $\mu\text{g}/\text{m}^3$. Additionally, exposure health risk assessment for CDI, HQ, as well as ILCR was performed using published formulae and parameters as elaborated in section 2.4.3 below.

The following data analyses were conducted to estimate dermal lead contamination at the KCM workplaces and to describe the potential for incidental lead ingestion. Descriptive statistics for median and interquartile range was done following Shapiro Wilk normality test which indicated the need for a non-parametric T-test. The result for lead wipe concentration was significant with a p-value <0.001 according to Wilcoxon signed-rank test. Due to lack of explicit exposure limit standard values for dermal and ingestion routes, compliance inferential statistical analysis was not possible. Rather, exposure risk assessment for these routes was determined using CDI, HQ, as well as ILCR indices.

To describe current and historical trends of KCM lead-burner blood lead levels, the cumulative measurements were first subjected to a test of normality using Shapiro Wilk. Other descriptive statistical tests included mean with standard deviation for normally distributed data, and median with interquartile range for log normal data. Chi-

Squared tests as well as T-tests were further performed for comparison of observed values with certain exposure risk variables and exposure limits, respectively. Blood lead levels were not sub-categorised for analysis. Instead, Box plots and Bayesian ANOVA-yielded QQ plots were generated to illustrate the spread and distribution of the same as shown in the results section. Blood lead levels served as the sole marker for disproving or confirming lead exposure at levels warranting action to prevent further exposure.

2.4.3 Health risk assessment

Having estimated the environmental lead concentration anticipated to result in inhalational and dermal exposure, dose estimates of the amount of lead taken in by the at-risk mine workers with respect to time were evaluated.

2.4.3.1 Hazard Identification

The U.S. EPA has classified lead as a probable human carcinogen (group C category under the 1986 guidelines). CDI, HQ, and HI values were determined for the main exposure routes. Further breakdown of the above parameters according to exposure pathway as well as total risk are detailed in the following section.

2.4.3.2 Exposure assessment

Equations 3, 4, and 5 below as sourced from U.S. EPA were used to determine the CDI (mg/kg/day) through ingestion, dermal, and inhalation routes. Parameters fused in were: concentration (C mg/L), surface area (SA cm²) of skin available for contact, permeability coefficient (K_p cm/hour), dermal absorption factor (ABS), daily average intake (DI L/day), exposure time (ET h/event), annual exposure frequency (EF days/year), exposure period (EP years), unit conversion factor (CF L/cm³), body weight (BW Kg/person), average time (AT days), the content of inhalable particulates in air (PM₁₀ mg/m³), daily air inhalation rate (DAIR m³/day), retention fraction of inhaled particulates in body (PIAF), the fraction of soil-borne particulates in air (FSPO). Table 2.1 shows assumed input parameters for different pathways.

$$CDI_{\text{ingestion}} = \frac{C \times DI \times ABS \times EF \times EP}{BW \times AT} \quad \text{Equation 3}$$

$$CDI_{\text{dermal}} = \frac{C \times SA \times K_p \times ABS \times EF \times ET \times CF \times EP}{BW \times AT} \quad \text{Equation 4}$$

$$CDI_{\text{inhalation}} = \frac{C \times PM_{10} \times DAIR \times PIAR \times FSPO \times CF \times EF \times EP}{BW \times AT} \quad \text{Equation 5}$$

The workers' Pb HQ was estimated as a ratio of the calculated CDI to reference doses (RfD) through oral, dermal, and inhalation pathways. The RfD values are 3.5×10^{-3} , 5.25×10^{-4} , and 3.52×10^{-3} mg/kg/day, respectively (42). The HI was calculated as a sum of the three HQ values. Further, the carcinogenic risk was calculated by multiplying the CDI by U.S. EPA CSF for lead. The lead CSF values are 8.50×10^{-3} , 8.50×10^{-6} , 4.20×10^{-2} for oral, dermal, and inhalation exposure routes, respectively. The safe risk range is from 10^{-6} to 10^{-4} according to U.S. EPA (45).

Table 2. 1 Exposure parameter values for exposure risk assessment
Source: Wang et. al. 2017 and Mohammadi et. al. 2019 (42,58)

Parameter (Unit)	Values		
	Ingestion	Dermal	Inhalation
Daily average intake (ug/day)	2.2		
Skin surface area (cm ²)		1800	
Permeability coefficient (cm/hour)		0.001	
Exposure time (Hour/event)		0.58	
Exposure frequency (Days/year)	365	350	350
Exposure period (year)	70	30	30
Conversion factor (L/cm ³)		0.0001	
Body weight (Kg)	70	70	70
ABS (All)	0.001	0.001	0.001
Average time (Days)	25550	25550	25550
PM ₁₀			0.15
Daily air inhalation rate (m ³ /day)			14.5
Retention fraction of inhaled particulates in body			0.75
Fraction of soil-borne particulates in air			0.5

To determine the concentration of lead ingested by the study population the approach by Cherrie et al., 2006 was adopted (32). Surface area wipe lead analysis essentially serves as a confirmation of lead in workers' microenvironment. The standard summative (bilateral) palmar surface area of an adult male is 155.7 cm² (59). The mean palmar wipe lead concentration obtained from laboratory analysis was thus divided by palmar surface area to determine surface loading in µg/cm². We assumed the worker made an average of 5 hand-mouth contacts per hour, with 5% palmar-oral contact area (10 cm²) per event and, a transfer efficiency of 10%. The mass transfer value was calculated as a product of surface load, contact area, contact frequency per hour, number of hours (8 in a normal shift), and transfer efficiency. The lead ingestion mass transfer value obtained was used to calculate chronic daily intake and other probabilistic health risk values including carcinogenic risk and hazard quotient. Respective lead concentration values for dermal and personal inhalation routes were similarly used to calculate the above-stated EPA chemical exposure health risk parameters and findings are discussed in succeeding sections of this report (32,40,56,60).

2.5 Ethical considerations

Ethical approval was sought from the University of the Witwatersrand Medical Human Research Ethics Committee (certificate number: M220931) as well as Tropical Diseases Research Centre Human Research Ethics Committee (certificate number: TDREC104/11/22) in Zambia prior to conducting the study. Additionally, both the Zambian National Health Research Authority (NHREB0002/05/02/2023) and Konkola Copper Mine Management approved the study before commencement. Appendix B includes the ethics clearance certificates.

2.5.1 Access to Participants

The researcher was granted permission to assess internal and external lead exposure among workers who handle lead for the stated mining company. This included access to workers' medical records in view of the lead biomonitoring program already in place. Notice of this was given in writing from the Chief Executive Officer. Departmental heads and the company's occupational health staff facilitated interaction between the principal investigator and the workers.

2.5.2 Informed Consent

Copies of the study information sheet as per approved research protocol, as well as informed consent sheet were distributed to prospective participants at the beginning of the study. Participants were informed that they did not have to participate in the study if they so wished, they could withdraw at any point during the study, and did not risk losing their job thereby. The study aim, activities and risks were explained verbally and participants given time to read through before individually signing the consent sheets which were returned with the completed paper-based questionnaire. For historical medical records, it was not feasible to obtain consent from the workers who are no longer at KCM but access was granted by KCM.

2.5.3 Beneficence and Risk of Harm

It was explained to participants that except for pain from venous blood collection, participants would not experience physical discomfort and harm during the study. Collection of biological samples was conducted at the health facility with medical supplies adequate for emergency care in case of any casualty. The Zambian Kwacha equivalent of ZAR 70 was given to each consenting participant as proposed in the study protocol. In case a member of the team of investigators had to be reached, their contact details were provided to the participants, as well as those for the local TDRC, and University medical human research ethics committee.

2.5.4 Anonymity and Confidentiality

Each participant was assigned a unique identifier for the purpose of this study rather than their name. A participant log sheet, linking both worker names and unique study identifier, were kept in a safe lockable place away from the company, and only accessed by the study principal investigator. The completed questionnaires were safely transported and stored whereas all soft copy information is kept on a password-protected computer.

CHAPTER THREE – RESULTS

3. RESULTS

3.1 Demographics

The study population comprised only adult males. See Table 3.1 below for other study participant characteristics. It shows characteristics of study participants from both sites. Table 3.2 however, distinguishes these characteristics according to the company business units. Of the 57 participants, 12 (21.05%) were from Nkana Refinery, the age range was 28 to 58 whereas mean age was 41.1 years. Nineteen (33.33%) lead handlers had no demographic details recorded since only their historical medical surveillance for blood lead levels were assessed. Current versus historical BLL values were analysed separately as well as collectively. About 40.35% of the workers showed knowledge of all the three main routes lead may enter the human body. On the other hand, 3.51% do not think lead may enter the body through the skin, air or oral pathways.

Table 3. 1 Demographic characteristics of study participants

Characteristic	Variable Distribution	Measure of spread	Range
Age in years	Normal : p(Shapiro-Wilk = 0.410)	Mean (SD) 41.1 (7.0)	30
Age groups	n	%	Min – Max [28 - 58]
20- <30	3	5.3	
30- <40	21	36.8	
40- <50	25	43.9	
50- <60	8	14.0	
Total	57	100	
Exposure in years	Non-normal : p(Shapiro-Wilk < 0.001)	Median (IQR) 10 (0.75 - 33)	32.25
Exposure Duration groups	n	%	Min – Max [0.75 – 33]
< 5	5	8.8	
5 - <10	21	36.8	
10 - <20	25	43.9	
20 - <29	3	5.3	

>30	3	5.3	
Total	57	100	
	Subcategory	n (%)	
Job Title	Operator Supervisor Assayer Analyst Lead burner	24 (40.4) 10 (17.5) 3 (5.3) 8 (14.0) 13 (22.8)	
Site	Nchanga Smelter Nkana Refinery	45 (21.05) 12 (78.95)	
Personal protection use*	Gloves Mask Goggles Avoid skin contact Use less lead Good hygiene Dilution ventilation Perform activities according to manual Other**	56 (98.3) 53 (93.0) 53 (93.0) 52 (91.2) 40 (70.2) 52 (91.2) 20 (35.1) 34 (59.7) 13 (22.8)	
Exposure Pathway	Skin	49 (86.0)	
Knowledge level	Oral	24 (42.1)	
	Air	52 (92.2)	
Substance use	Alcohol use at the time of survey	30 (52.6)	
	Smoking at the time of survey	11 (19.3)	
Trained on lead-handling	Yes	17 (29.8)	
	No	40 (70.2)	
Feed from a designated place	Yes	51 (89.5)	
	No	6 (10.5)	
Contaminated work wear stays on site	Yes	37 (64.9)	
	No	18 (31.6)	

*Numbers and percentages do not add up as participants were likely to have used more than one method of protection/used a combination of methods.

**Other forms of personal protection other than those listed because the given list was not exhaustive. Other include wearing overalls, respirators or helmets.

Table 3. 2 Occupational Exposure Characteristics by study site

	Nchanga	Nkana	Total	P values
Job, n (%)	45 (59.21)	12 (15.79)	57	-
Mean Age - years (Range)	41 (28-58)	42 (37-48)	41 (28-58)	0.785
Mean lead handling duration - years (Range)	11.89 (2-33)	10.99 (0.75-23)	11.70 (0.75-33)	0.703
Lead handling training				0.765
Yes	13 (22.81%)	4 (7.02%)	17 (29.82%)	
No	32	8	40	
Use designated eating place				0.181
Yes	39 (68.42%)	12 (21.05%)	51 (89.47%)	
No	6	0	6	
Smoking				0.057
Yes	11 (19.30%)	0 (0%)	11 (19.30%)	
No	34	12	46	
Alcohol				0.780
Yes	24 (42.11%)	6 (10.53%)	30 (52.63%)	
No	21	6	27	
Do not take work clothes home				0.062
Yes				
No	27 (47.37%)	10 (17.54%)	37 (64.91%)	
	18	2	20	

3.2 Personal and area air lead exposure

The mean measured air lead concentration was 2.82 $\mu\text{g}/\text{m}^3$ for area samples, and 6.63 $\mu\text{g}/\text{m}^3$ for personal air samples. The highest recorded measurement was a personal reading of 96 $\mu\text{g}/\text{m}^3$ averaged over an 8-hour period. OSHA and ACGIH reference standards for lead in air exposure assessment value of 50 $\mu\text{g}/\text{m}^3$. T-test result for recorded mean was not significant with a p-value of 1.000. Table 3.3 illustrates the number of samples collected from personal sampling, area sampling and mean air concentration of lead by site with reference to exposure limit. Figures 3.1, and 3.2 show the distribution of lead in air concentration for area samples, personal samples, and combined number of samples respectively. The p value for a Chi squared test comparing mean air lead mass concentration for the various sites was significant (<0.001).

Table 3. 3 Mean lead air sampling by site

Collection site	Personal sample n (%)	Area sample n (%)	Mean personal and area air lead mass concentration ug/m ³ (min - max)	Number of samples above action level (30 µg/m ³) n (%)	OSHA and ACGIH Pb in air PEL Reference standard (µg/m ³)
Nchanga tank house	30 (52.6)	6 (10.5)	5.70 (1.63-96.00)	1*** (2.7)	50 (action level: 30**) [Source: (7)]
Nkana Refinery	4 (7.0)	0 (0.0)	3.98 (2.75-7.20)	0 (0.0)	
Nkana laboratory	3 (5.3)	2 (3.5)	9.33 (2.71 – 21.52)	0 (0.0)	
Total	37 (64.9)*	8 (14.0)	5.95 (1.63-96.00)	1 (2.7)	

*Out of 50 air samples, 37 were personal, 8 were area and 5 were control samples

**Initiate medical surveillance if exposed for more than 30 days in a year

***This was a personal air sample

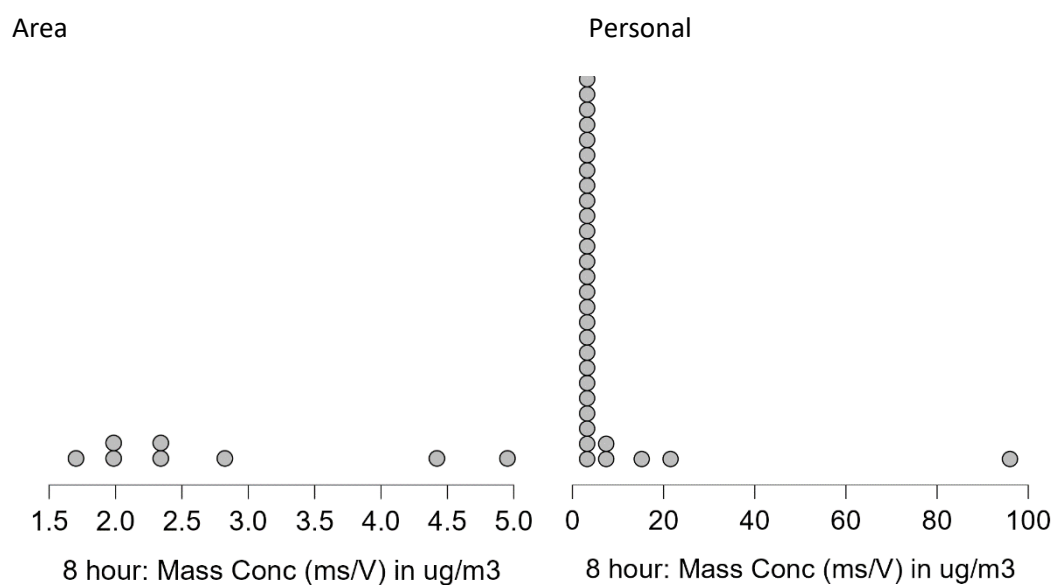


Figure 3. 1 A display of readings of mass concentration for samples from area sampling (left) and personal samples (right), showing distribution of readings.

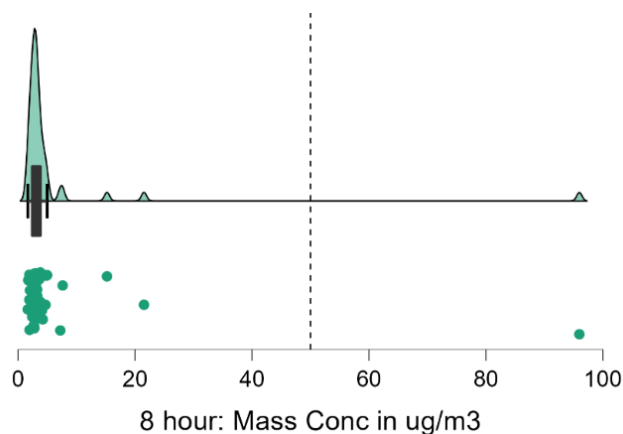


Figure 3.2 An illustration of values for mass concentration of lead from all samples (personal and area sampling).

3.3 Surface and dermal lead contamination

The average observed lead mass from all wipes was 2.22 mg/sample. The mean lead mass observed for blank wipe, dermal wipe, unused glove, and surface wipe values were 0.01 mg, 0.74 mg, 0.02 mg, and 5.45 mg, respectively. The highest recorded mass per set of three wipes was an area sample of 37.60 mg and among dermal wipes, 7.70 mg per pair of wipes. The former translates to maximum values of 37.60 mg per 900 cm² (41.78 µg/cm²) for area samples, and 7.70 mg per 155.7 cm² as assumed palmar surface area (49.45 µg/cm²) (59). The mean lead surface wipe concentration values according to study site are illustrated in Table 3.4 below. Note that the dermal wipe concentration presentation has been omitted because no actual palmar surface area measurements were conducted among study participants. Figure 3.3 further illustrates the findings.

Table 3. 4 Mean lead wipe concentration by work site

	Nchanga tankhouse	Nkana tankhouse	Nkana laboratory	Total
Dermal: n (%)	46 (54.76)	3 (3.57)	4 (4.76)	53 (63.10)
Surface: n (%)	16 (19.05)	5 (5.95)	6 (7.14)	27 (32.14)
Mean lead surface wipe mass - µg/cm² (Min - Max)	49.11 (0.38-21.28)	0.76 (0.21-2.18)	17.73 (0.03 – 41.78)	5.95 (6.61-106.67)

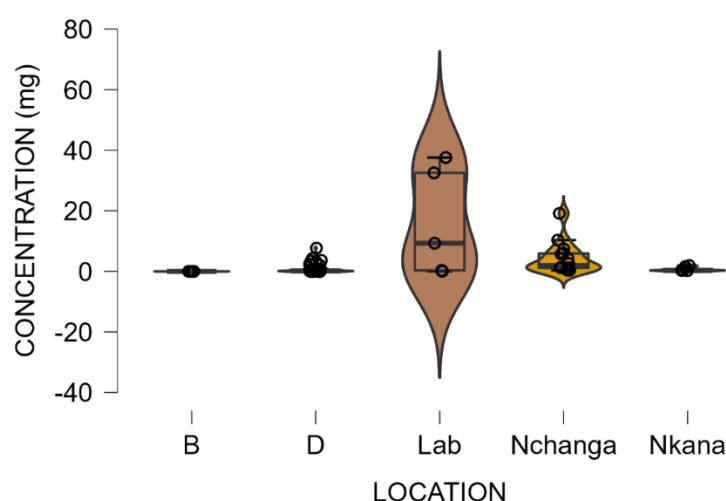


Figure 3. 3 Mean lead wipe mass by site (B=blank; D=dermal)

3.4 Current and historical blood lead levels

A total of 69 individual's BLLs were analysed, Shapiro-Wilk p value was 0.385 inferring a normal distribution. The descriptive findings include mean 11.61 $\mu\text{g/dl}$ (SD 4.81) and range 2.50-34.00 $\mu\text{g/dl}$. No statistically significant difference in mean BLLs between the workers at the Nchanga Smelter (12.86 SD 5.00 $\mu\text{g/dL}$) and Nkana Refinery (9.09 SD 4.66 $\mu\text{g/dL}$) was observed. Table 3.5 shows total BLLs, historical as well as current by job title and by site. Box plots, plus Bayesian ANOVA-yielded QQ plots illustrate the distribution of the same in Figures 3.4 and 3.5, respectively. The box plot in figure 3.4 illustrates the average BLLs observed from Konkola (historical), Nchanga (tank house historical and current), as well as Nkana (refinery tank house and analytical laboratory, historical and current). Nchanga site recorded the highest value but no outliers were observed overall. The median BLL average at Konkola was higher than Nchanga while the lowest median value was from Nkana. The figure 3.5 illustrates quantile-quantile plots where the fit does not align with the theoretical quantiles. This suggests that the distributions may not be normal which may be expected in field exposure assessment studies. The limited number of quantiles plotted make it difficult to derive a definitive answer about whether the sample and theoretical quantiles have similar distributions especially in the case of the first two plots. If we had more quantile values to plot, the graphs would have been more informative.

Table 3. 5 Historical and current BLLs by job title

	Combined BLLs (mean µg/dL +/-SD)	Current BLLs (mean µg/dL +/-SD)	Number of Current BLLs exceeding 10 µg/dL
Distribution	normal (p*-value 0.306)	normal (p*-value 0.385)	
BLLs	N = 57 11.54 +/- 4.58 min-max: 3.07-23.80	N = 39 11.66 +/- 5.52 min-max: 2.50-26.45	23 (59.0%)
Job title groupings			
Analyst (N = 9)	N = 5 (10.29 ±7.82) min-max: 3.53-23.80	N = 4 (11.08 ±8.80) min-max: 3.53-23.80	1 (25.0%)
Assayer (N = 5)	N = 3 (12.84 ±7.68) min-max: 7.76-21.68	N = 2 (8.46 ±3.09) min-max: 6.27-10.64	1 (50.0%)
Lead burner (N = 20)	N = 11 (10.82 ±4.83) min-max: 3.07-17.57	N = 9 (8.30 ±3.35) min-max: 2.5 -12.5	4 (44.4%)
Operator (N = 35)	N = 20 (11.61 ±4.70) min-max: 4.56-22.22	N = 15 (12.57 ±5.72) min-max: 4.56-26.45	10 (66.7%)
Supervisor (N = 18)	N = 10 (13.7 ±4.23) min-max: 5.44-18.92	N = 8 (13.86 ±4.35) min-max: 5.57-19.22	7 (87.5%)
Total	69	37	23
Worker site			
Nchanga smelter N = 38	N = 38 (12.86 +/- 5.00) min-max: 3.53-23.80	N = 29 (13.09 +/- 5.49) min-max: 3.53-26.45	20 (69.0%)
Nkana Refinery N = 12	N = 12 (9.09 +/- 4.66) min-max: 3.57-17.57	N = 10 (7.53 +/- 3.08) min-max: 2.50-10.96	3 (30.0%)
Total	50**	39***	23
Site mean BLL Student T-test	p= 0.710 95% Confidence interval for difference of means: 9.58 -12.89 µg/dL Goodness of fit mean: 0.05		

*Shapiro-Wilk p-value

**17 historical BLLs were observed from a non-operational site: Konkola

***2 current (2023) BLLs were assigned an unspecific site: Other

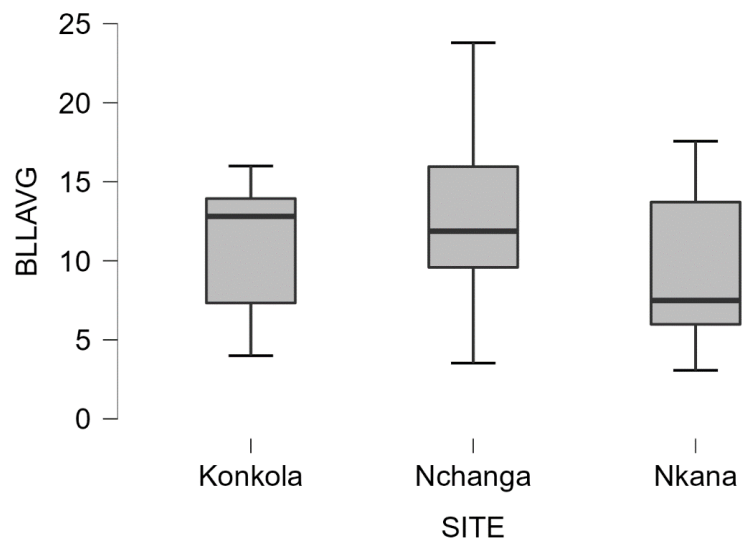
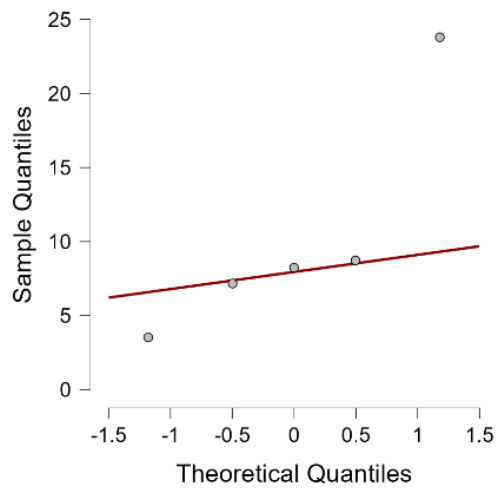
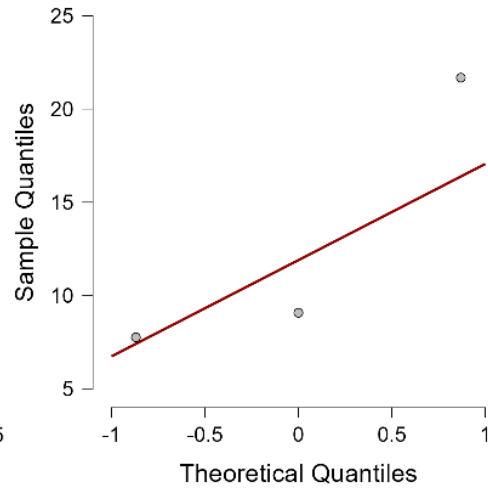


Figure 3. 4 A box plot of average mean BLLs by work site

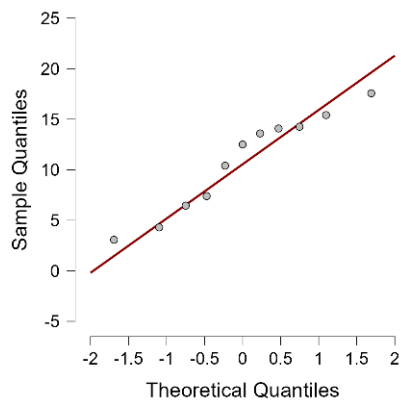
Analyst



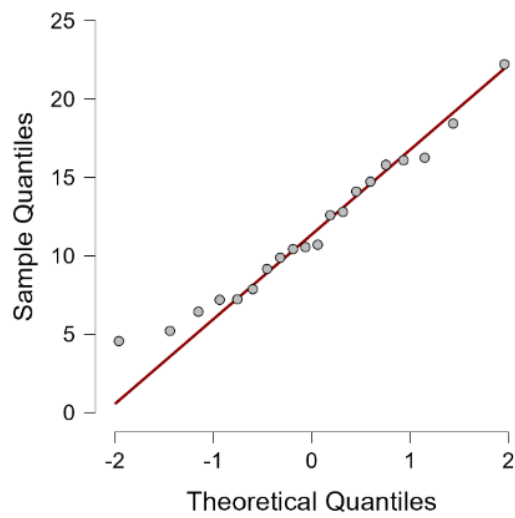
Assayer



Lead burner



Operator



Supervisor

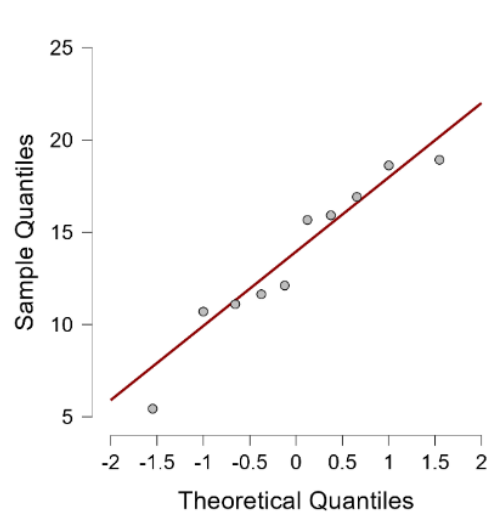


Figure 3. 5 BLL Sample quantile Q-Q Plots by job title

A Bayesian alternative of Independent T-Test for the comparison of BLLs between current and historical, as well as the two sites revealed positive effect sizes but Bayes Factor values were not significant. These are illustrated serially in Figures 3.6 to 3.11. For the hypothesis test, under the null hypothesis we expect an effect size (δ) of zero. Thus, we define $H_0: \delta = 0$. The alternative hypothesis is two-sided, $H_1: \delta \neq 0$. The alternative hypothesis was true with median [CI] values highlighted below. Of note, separate temporal, and spatial median values were negative while the combined temporospatial median value was positive. This reflected lower BLLs for the current versus historical BLLs, and lower BLLs observed at Nchanga compared to Nkana sites.

We found Bayes factors of $BF_{10} = 0.269, 0.827, \text{ and } 0.36$ for temporal, spatial, and temporospatial analyses respectively. This infers that the observed data are approximately 0, 1, and 0 times more likely under H_1 than H_0 . This result indicates weak evidence of H_1 . The pizza plots of the prior and posterior plots in figures 3.6, 3.8, and 3.10 illustrate this finding.

For temporal, spatial, and temporospatial analyses respectively: assuming prior odds of 1-to-1 for H_1 and H_0 , our observed data updated these odds to 0.269-to-1, 0.827-to-1, and 0.36-to-1 in favour of H_1 . This is equivalent to a posterior model probability of $p(H_1|\text{data}) = 0.212, 0.453, \text{ and } 0.265$.

Of interest is the posterior distribution for δ , the population-level effect size. Under H_1 , δ was assigned a Cauchy prior with scale $r = 0.707$. The posterior distribution for δ had median values [central 95% credible interval ranges] of -0.135 [-0.494 to 0.218], -0.315 [-0.703 to 0.060], and 0.194 [-0.184 to 0.581]. Qualitative assessment of the evidence for H_1 with respect to temporal, spatial, and temporospatial Bayesian analyses was moderate, anecdotal, and moderate respectively as revealed by Bayes Factor Robustness checks.

Bayesian Independent Samples T-Test for BLL Bayes Factor (BF_{10}) value was 0.269 (0.026% error), with respect to biomonitoring over time. See figures 3.6 and 3.7 below.

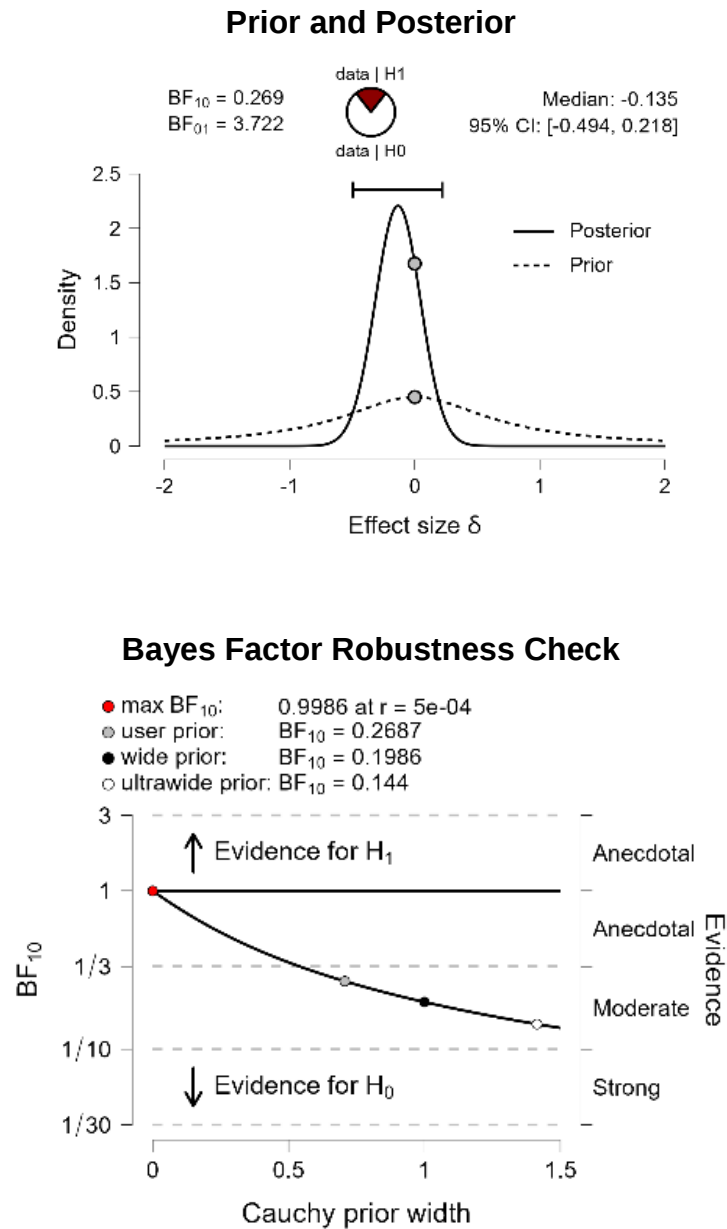


Figure 3. 6 An illustration of two BLL Inferential plots with respect to time of lead exposure

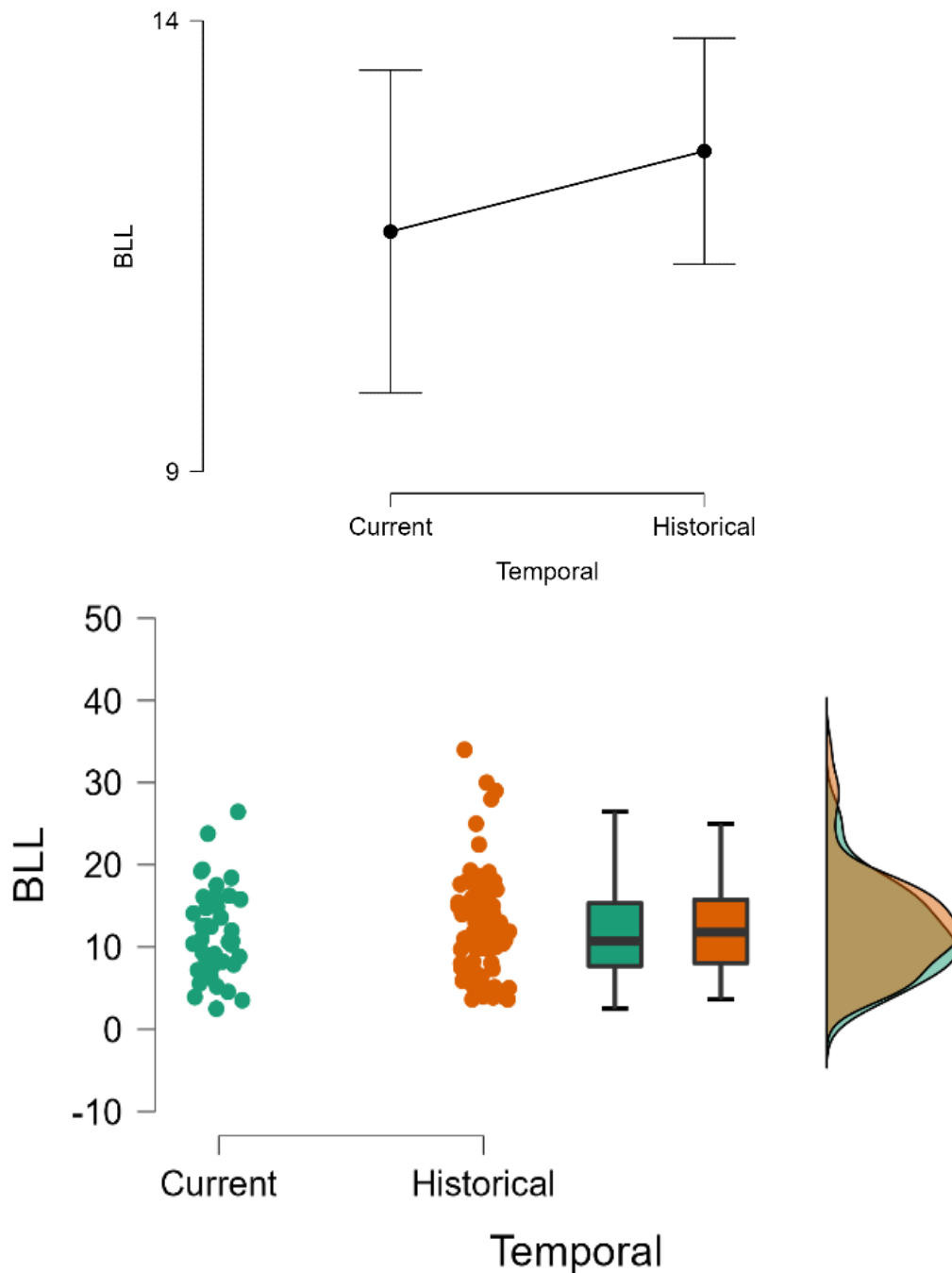


Figure 3. 7 An illustration of Current and Historical BLL Descriptive plots

Bayesian Independent Samples T-Test for BLL Bayes Factor (BF_{10}) value was 0.827 (0.014% error), with respect to biomonitoring at the two studied sites. For spatial comparison between Nchanga Smelter and Nkana Refinery measurements inferential plots are clustered as Figure 3.7 below. Additionally, descriptive plots are illustrated in Figure 3.8 below.

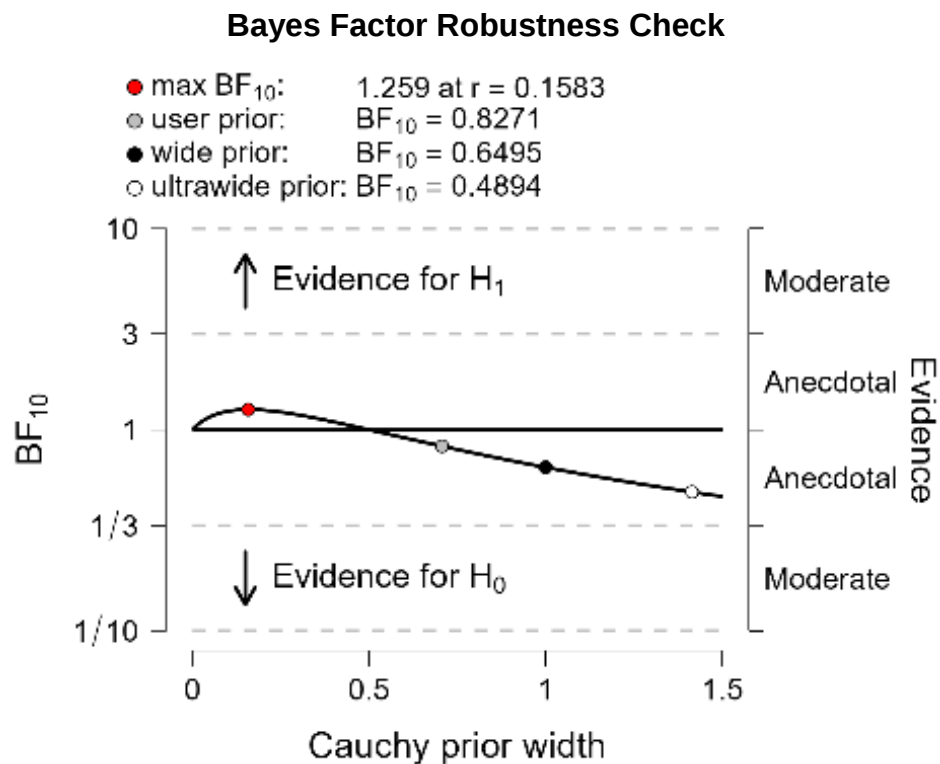
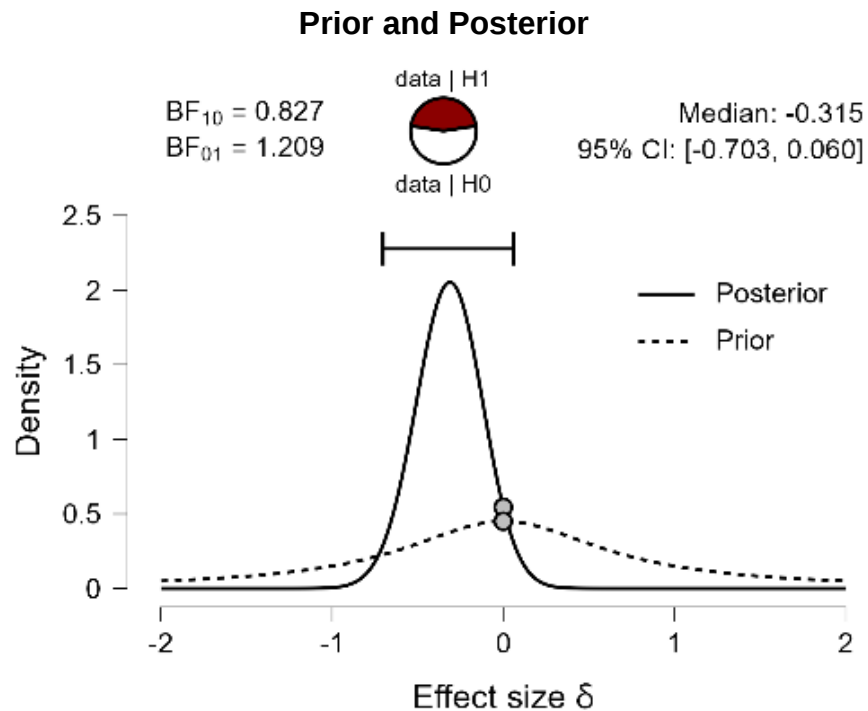


Figure 3. 8 An illustration of two inferential plots of BLLs with respect to location of lead exposure

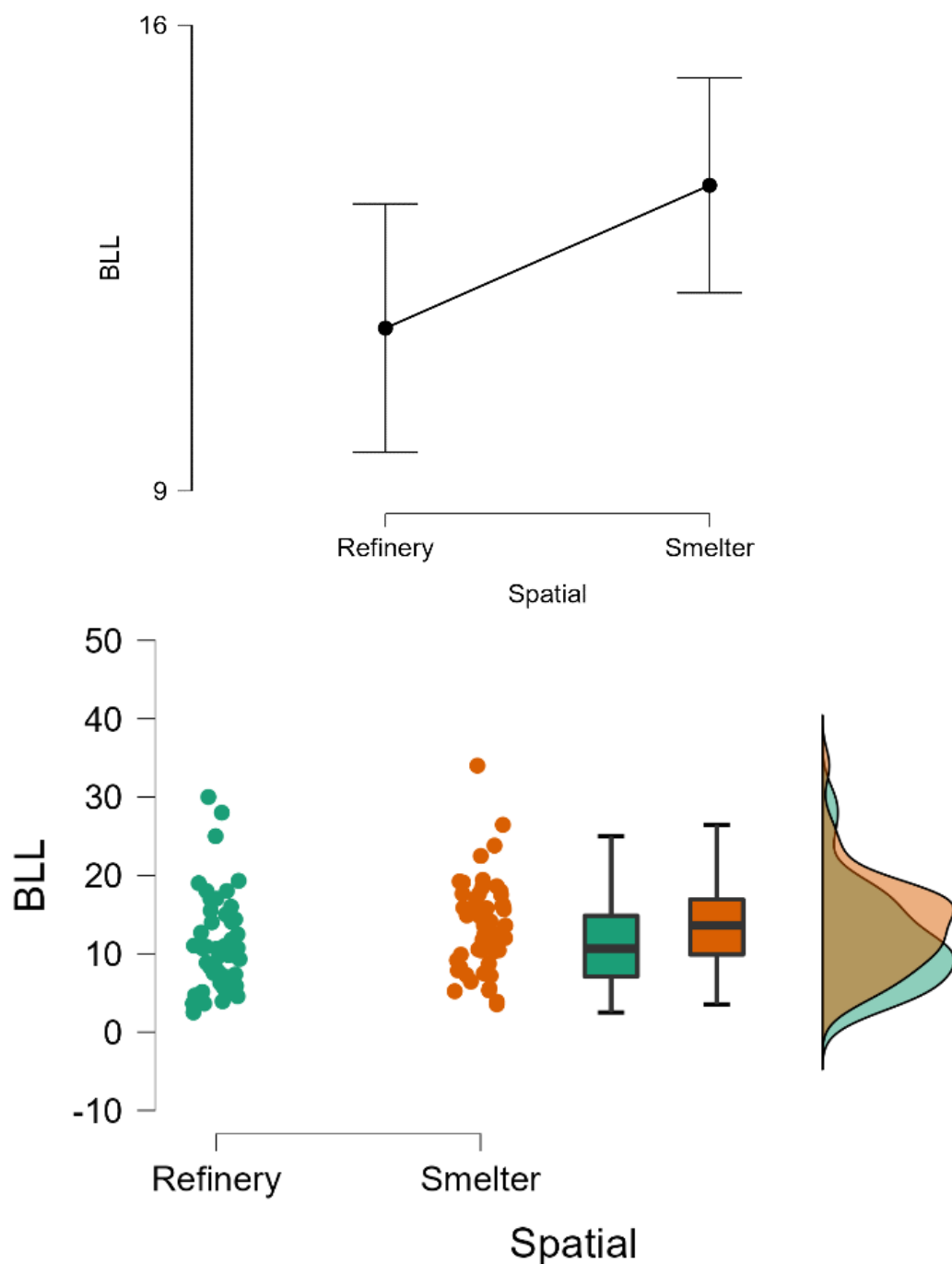


Figure 3. 9 An illustration of two descriptive plots of blood lead levels with respect to location

Bayesian Independent Samples T-Test for BLL Bayes Factor (10) value was 0.360 (0.019% error), with respect to biomonitoring at the sites over time. For spatial comparison between the old and new tank house measurements inferential plots are clustered as Figure 3.10. Additionally, descriptive plots are illustrated in Figure 3.11 as follows.

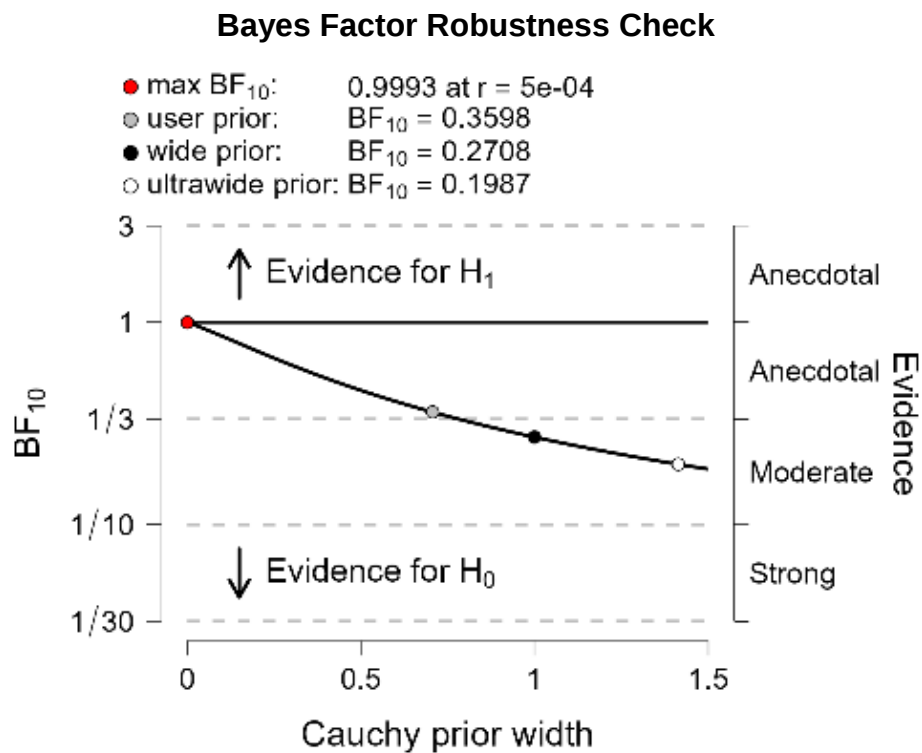
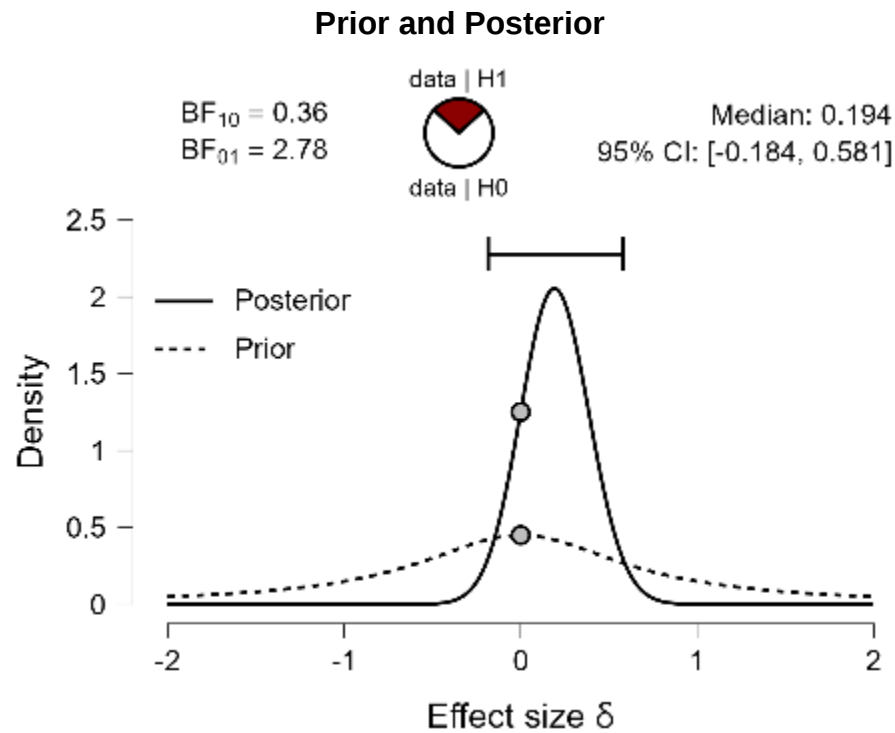


Figure 3. 10 An illustration of two inferential plots for BLLs with respect to time and location of lead exposure

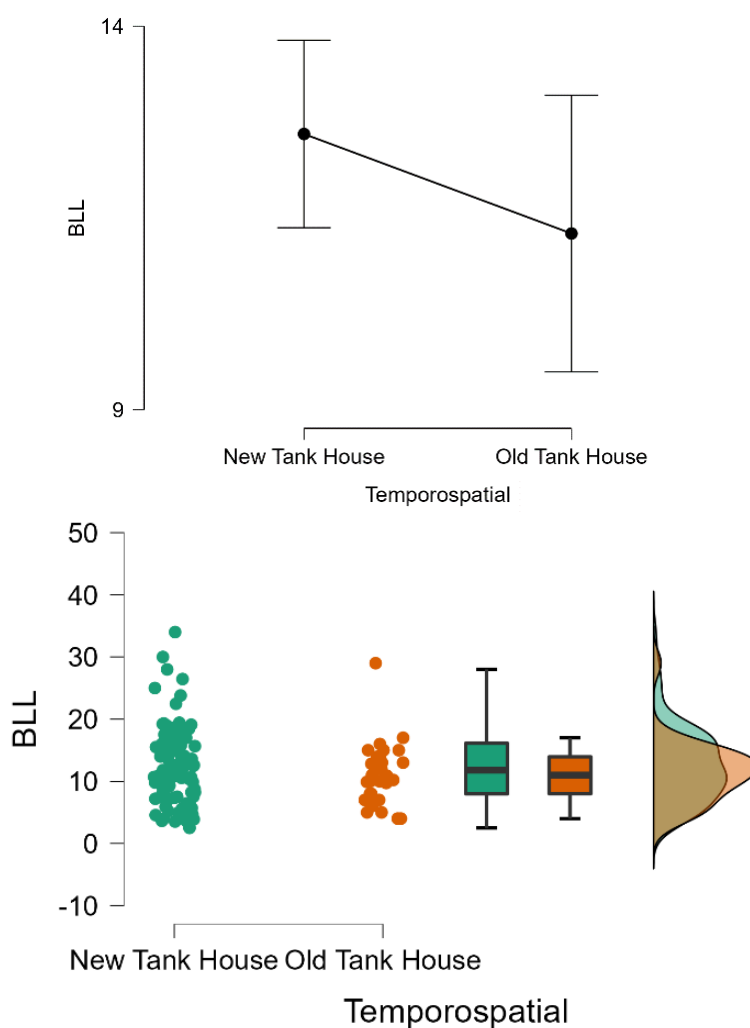


Figure 3. 11 An illustration of plots describing distribution of blood lead level results with respect to both time and location

3.5 Occupational health risk evaluation

Having determined the mean lead concentration for personal air and dermal samples. Occupational health risk assessment using EPA formulae for chronic daily intake, hazard quotient and carcinogenic risk was done. The estimates are illustrated in Table 3.6 below. Non-carcinogenic hazard index for the three exposure routes was 0.01, viz. each of the three hazard quotients were less than one.

Table 3. 6 Worker occupational risk evaluation

PATHWAY	CDI (mg/kg-day)	Percentage of total CDI	HQ	CR	Percentage < reference dose
Oral	5.97×10^{-3}	12%	1.70×10^{-3}	1.45×10^{-5}	100%
Dermal	6.76×10^{-11}	0%	1.29×10^{-10}	1.09×10^{-2}	100%
Inhalation	4.20×10^{-2}	88%	1.12×10^{-2}	5.00×10^{-4}	100%

CHAPTER FOUR - DISCUSSION

4. DISCUSSION

4.1 Field-based lead exposure assessment

The mining company under study has been collecting laboratory-reported blood lead levels for exposed workers. In the developed world, state health departments and/or health institutes are known to pool such information for future preventative purposes (4). These forms of surveillance date back to the 1940s with a database created having measurements from 1987 onwards in the USA (21,30). Our study population had medical surveillance data from 2001. Employed adults in various lead-emitting industries including mining and ore-smelting traditionally undergo serial biomonitoring of BLLs (3,8,21,30,51,61). Biomonitoring may be paired with environmental assessment to establish clear exposure pathways and/or causality. Literature cites listless exposure assessments approaches for lead in air, skin, as well as ingestion considering that lead transfer occurs between various environmental media (3,8,21,30,51,61). These external routes of human lead uptake, coupled with internal BLLs were investigated. All participants were adult males working in the refinery section of a copper mining company with mean age 41 years (3,8,21,30,51,61).

A USA study comparing production versus non-production lead surface contamination using wipes reported lead contamination of up to 25,000 $\mu\text{g}/\text{cm}^2$ with geometric mean 709 $\mu\text{g}/100\text{cm}^2$ and 470 $\mu\text{g}/100\text{cm}^2$ respectively (10). The current study determined arithmetic mean values of 41.78 $\mu\text{g}/\text{cm}^2$ for area samples, and 49.45 $\mu\text{g}/\text{cm}^2$ for palmar wipes. Of note, the former study used wipes on porous surfaces when the recommended method for clothing and carpet is vacuum. The current study sampled firm flat surfaces only. Despite existing U.S. EPA lead surface contamination clearance criteria for public buildings and homes where children live, as well as a standard guide for metals and metalloids for worker protection, the lack of clear standards by organisations such as NIOSH and OSHA remain a challenge for defining surface exposure (10). For reasons of cost, technical restraint, time, colorimetric testing may be more advantageous whereas qualitative tests prove more useful during adherence confirmation assessments (10).

4.2 Lead concentration from various exposure pathways

There is evidence that lead is mainly transmitted through inhalation, ingestion, and dermal routes in descending order for adults. It is cited that 50-70% of lead will be absorbed into blood when inhaled depending on the particle size. The dermal permeation rate is very low potentially resulting in negligible skin uptake. A review by Cherrie et al., 2006 suggests the following uptake proportions by route for aggregate lead exposure: ingestion (46%), inhalation (54%), and dermal (0%) (32). A study in China however identified food consumption as representing 90% of toxic metal exposure compared to other routes (62). This may particularly be true for child populations as they are more likely to ingest large amounts of lead, have immature detoxification, and their ingested absorption of lead into blood occurs at a higher rate (3,6,10,32). This is substantiated by age-dependent fractional lead absorption modelling results as described in a toxicological profile for lead compiled by Agency for Toxic Substances and Disease Registry.

A study in various US worksites revealed that for workers in the lead sheet or plate installation and removal sector, mean personal lead air concentration was 614 $\mu\text{g}/\text{m}^3$ with a corresponding mean BLL of 28 $\mu\text{g}/\text{dL}$ (30). By contrast, copper smelter workers' mean personal lead air concentration was not recorded but mean BLL observed was 33 $\mu\text{g}/\text{dL}$ (30). In an Iraq air assessment for lead emissions, mean lead air concentration was illustrated to vary between seasons. This substantiates the theory for temporal variation in lead exposure (63). Another study in Korea suggested correlation between lead in air and BLL demonstrating how when the atmospheric lead concentration reduced, lower BLLs were observed (9).

Literature cites that airborne lead may be significant in occupational settings and that inhalation is a dominant pathway (4,51). This tallies with the present study findings of 12% oral, 0% dermal, and 88% inhalation. This pattern is similar to the findings of Cherrie et al., 2006 except for the increased gap between oral and inhalation routes in the current study rather than an almost equal percentage in the sited study. There may have been underestimation of the dermal and ingestion pathways due to lack of organic lead detection tools as well as limited published standard measurement

guidelines. The need to define metrics for chemical ingestion and dermal uptake exposure assessment is apparent. Complex interactions between lead dose, particle size, protective equipment use, tasks performed, and personal behaviour determine external exposure and must be accounted for. Further, genetics and exposure compartment issues including time, bioavailability, pharmacokinetic issues determine internal exposure dose (4,32,43,51,64).

4.3 Dose Estimates of lead in blood from occupational exposure

It is argued that lead handling workers at the mining company under study are exposed to high levels of lead through various uptake routes. The current study shows workers have blood lead levels above certain international BLL reference ranges such as the ACOEM 3.5 µg/dL, ABLES 5 µg/dL, and OSHA reference range, NTP, as well as MOSHA removal of 10 µg/dL (24). Our findings however did not exceed the biological exposure index of occupational exposure suspension level as detailed in section 2.3.4.1. Literature in occupational health support that lead exposure continues to decline but workers who handle lead have remarkable lead body burden (24,30,65). Lead burners, and those working at refineries are known to be susceptible to high lead exposures because their work environment is potentially contaminated with lead. The extent of risk may not be as high as in the case of lead smelting and battery manufacturing (16). Prevalence estimates of worker lead exposure in Canada as of 2016 rank the following industries as top 4: specialty trade contractors, public administration including workers handling lead ammunition, repair and maintenance, then fabricated metal production (11,30).

British CLAW regulations similar to USA standards, emphasise distinctions between male and female exposure as well as age stratification (27). In the year 2009/10 51 out of 7162 individuals among British workers undergoing medical surveillance were suspended of which 3.4% were females (27). There is no evidence of worker suspension at the KCM but positive history of medical action recommending removal from lead handling tasks was encountered. For the smelting/ refining/ alloy/ casting British job sector, as of the year 2009/10, 30.2% of the males recorded BLLs less than 10 µg/100mL with the odds of BLL above 10 µg/100mL increasing by 2% per

year (27). By contrast, our study reported 40.4% of the participants in 2023 to have BLLs above 10 µg/dL. Considering that KCM medical surveillance only started in 2006, it may be expected that the British Medical surveillance system with values from 1992/93 would be more efficient at preventing occupational lead exposure reducing the odds of recording raised BLLs (27). A China study provides evidence for dose-response relationship between cumulative occupational lead dust/fume exposure and lead poisoning (66). A recent study in South Africa revealed median BLL of 2.1 µg/dL among artisanal pot makers with interquartile range 1.7-2.5 µg/dL (67). This low exposure may be traced to the physicochemical properties of the pot material and pot making process rather than effective hygiene practices.

All job descriptions exceeded the blood lead reference level, there were more operators and lead burner participants than other workers and these had more exceedances. The highest recorded value of 23.8 µg/dL was from lead analyst for current biomonitoring results and, tank house operator for historical results. These findings may be explained by poor personal hygiene and failure to use provided personal protective equipment. Some workers could not demonstrate knowledge of the routes through which lead enters the human body. That is, 9% did not agree that lead may be inhaled, 14% did not agree that lead may enter the body through skin, 58% did not agree that lead may be ingested, 40.4% showed lack of knowledge for at least one pathway of lead exposure. No initiatives to train them are known to us, this would be a point for improvement on the part of all stakeholders(68). The present study revealed that knowledge levels of exposure risk among participants was poor and no initiatives to train them are known to us, this would be a point for improvement on the part of all stakeholders. No statistically significant difference ($p>0.05$) in mean BLLs between the workers at the Nchanga (Mean 13.1 µg/dL) and Nkana (Mean 7.5 µg/dL) was observed. Zein et al cite that variable exposure levels may be present in different sections of the same organisation. A CDC study highlights lead-burning as potentially causing raised BLLs. Additionally, a 2015 review on lead exposure at various US worksites reported blood weighted average mean values from 1970 onwards to be all above 30 µg/dL in the primary and secondary metal production sector (16,18,30). Mining and smelting are the primary sources of lead exposure in Zambia (38).

No specific occupational lead exposure regulations are present locally. International OSHA, ACGIH, and NIOSH guidelines were used. As of 2021, the WHO Guideline for Clinical Management of Exposure to Lead recommends a BLL of 5 µg/dL but this may not be applicable to occupationally exposed individuals (24). At this observed value, a person needs to be reviewed through exposure analysis and action to prevent further exposure taken. Only 8% of our study participants had overall serial BLL average of less than 5 µg/dL while 59% exceed OSHA blood reference range of 10 µg/dL. Table 3.5 illustrates exceedances observed. Biomonitoring has been part of the company's occupational health policy since the year 2006 and as far back as 2001 for some contracted lead handlers. Analysis of BLLs over time did not reveal a downward trend despite implementation of several lead exposure controls. The small study sample size of 57 individuals' BLLs may explain the absence of significant findings regarding temporal variation in internal lead exposure. Analysis by site was equally not statistically significant ($p>0.05$) for spatial variation in internal lead exposure. This infers similarity in site management, medical surveillance and company policies. The fact that the exceedance pattern is consistent across sites may be explained by poor enforcement of existing lead exposure control guidelines.

There is more literature in the context of environmental lead exposure and lead exposure in child populations. A WHO Environmental assessment cited up to 6.6 times more atmospheric lead emissions due to mining/ smelting/ consumption activities than from natural sources (50). The study however reports inadequate carcinogenicity evidence following lead exposure (50). Our study similarly has unremarkable carcinogenicity evidence.

Factors known to potentially increase lead body burden other than occupational lead exposure, include smoking and drinking (alcohol), among others (4,50). Over the course of five years, a 37% reduction in arithmetic mean BLL was observed whereas a sexual difference was also noted by the WHO among 9933 individuals with women having 4.2 less BLL units than males (50). The latter fact may be explained by the implementation of universally lower exposure thresholds for females and children as

reflected in most lead reference standards while the former validates the idea of temporal variation. The above mentioned WHO assessment for inorganic lead revealed an overall arithmetic mean BLL of 13.9 µg/dL versus 16.2 µg/dL, 19.2 µg/dL, and 19.7 µg/dL values in occupationally exposed individuals, non-drinkers/ smokers, and drinkers/ smokers respectively (50). Lead has been detected in cigarette filters qualifying smoking as a confounder for raised BLLs (50). Among our participants, 19% identified as smokers and 53% drink alcohol, non-occupational lead exposure is therefore plausible but not entirely responsible for the raised BLLs observed.

The CDC-NIOSH reference guide to understanding BLLs shown in Table 3.5 illustrates the values at which various institutions propose action to protect exposed populations. Of note, is the cited USA adult population BLL as of 2018, a value about a dozen times less than our observed mean BLL. The challenge therefore remains, considering the non-essential nature of the metal lead in the human body. In keeping with the fundamental principle of health equity, it would be ideal to lower the average BLL in the studied population to such low levels since no amount of internal lead exposure is considered safe. The reference guide additionally illustrates how particular institutions define varying BLL exposure limits and thresholds. Some values overlap while others, such as the removal level are distinct. The NTP and MOSHA removal level threshold is 10 µg/dL. Meanwhile MIOSHA, ACOEM, and CDPH have a removal threshold value of 30 µg/dL. On the other hand, OSHA has a removal level of 50-60 µg/dL (7,24). This leaves unanswered questions of how such varying values could be arrived at for the same species. At KCM, the upper limit of 60 µg/dL has been adopted as the removal level and BLLs between 2-9 µg/dL are considered normal for non-industrial exposure. Intervals between BLL measurements are beyond the scope of this report.

Zambia has bodies responsible for worker protection. These include the Mine Safety Department (MSD) in the Ministry of Mines and Minerals Development, Zambia Environmental Management Agency (ZEMA) in the Ministry of Green Economy and Environment, as well as the Occupational Health and Safety Institute (OHSI) in the Ministry of Labour and Social Security. The MSD conducts site inspection or hazard surveillance as well as ensures the use of relevant engineering controls, personal

protective equipment, training, hygiene, while OHSI conducts annual medical surveillance without chemical exposure biomonitoring. Zambian occupational health and related laws contain rather dated lead exposure regulations, requiring regular medical surveillance. The regulations also require that workers receive adequate personal protective equipment that include respiratory protection, coverall clothing, and have access to ablution and change-room facilities. Ideally, clean lead-free zones should be separate from contaminated areas. An attempt to maintain these standards was observed in the present study except for worker compliance to the listed controls.

The company covers health surveillance costs including biannual BLL biomonitoring, in case of acute lead toxicity the company has onsite clinics manned by qualified health professionals (who are neither licenced occupational health medicine nor occupational health nurse practitioners). The company has invested in the workers' health to ensure continuity in copper production. Of note, it has had administrative disruption in the recent past which has in turn affected production, thus exposure assessment values obtained do not reflect peak production. A major turn in lead handling was taken by the company in 2006 when electrolytic cells were coated with a non-lead material eliminating the need for regular lead fabrication and maintenance activities in the refinery when the cells were coated with lead. These factors may explain why markedly raised BLLs were not observed. No significant findings may be reported from multivariate regression analysis regarding lead in blood (16,35,40).

4.4 Study limitations

The study's small sample size and reduced number of filters for air pathway limited the statistical power of the study. Particularly, historical medical records were fewer than anticipated with missing demographics in some cases. This may have prevented identification of statistically significant analyses. The same company that has been conducting blood lead biomonitoring was used during the study for logistic reasons, using a new provider of similar calibre (SANAS-accredited) would have allowed for validation of the BLL trend. Lead dust wipe analysis would have been more yielding if on-site qualitative analysis was coupled with the laboratory quantitative analysis conducted. Not only that, a more complex approach to dermal exposure may have

been adopted rather than merely the removal method of palmar wipes considering that sensitivity for lead detection for this exposure pathway is low. Samples had to be shipped across borders, this posed financial constraints and more importantly, potential quality compromise with respect to time between collection and analysis. Other populations such as women and children would not benefit from this study as the findings are not generalizable.

4.5 Study strengths

Study findings are consistent with existing evidence. Also, in view of the fact that no amount of lead in blood is considered safe, this study proved relevant revealing that the exposed population need exposure pathway analysis and prevention interventions. The study design aims to compare internal and external exposure simultaneously. Dose estimates were obtained using standard EPA formulae and are reproducible. This is the first study to produce occupational lead exposure profiles with an attempt at pathway analysis in Zambia, to our knowledge.

CHAPTER 5- SUMMARY AND CONCLUSIONS

5. SUMMARY AND CONCLUSIONS

5.1 Summary

Lead is the oldest occupational health hazard that is known to cause adverse health effects in the following systems: central nervous, haematology, reproductive, and renal systems. Evidence emphasises that there is no safe amount of lead body burden. This warrants rigorous exposure risk assessment where humans continue to be exposed to the metal in its varied forms. Lead may be taken into the body through various routes including, but not limited to oral, dermal, and inhalation. These entry pathways were assessed in the study population of copper refinery lead-handling workers. Findings revealed the presence of lead in workers' microenvironment, that is, work surfaces, breathing zone air, and rather diminutive amounts on palmar skin. The US-EPA defined formulae were applied in determining exposure risk. Results were consistent with existing literature, particularly in the order of exposure risk by pathway, inhalation as highest, followed by ingestion, then dermal. This evidence was in occupational rather than general population environmental health contexts. The mean blood lead level of 11.61 µg/dL observed exceeded the OSHA blood lead reference level of 10.61 µg/dL but was adherent to the standard occupational exposure suspension level of 60 µg/dL. All in all, findings from the simultaneous internal and external lead exposure conducted confirm the postulated exposure pathway scenario(s).

5.2 Conclusion of main findings according to study objectives

5.2.1 To assess personal lead exposure among lead burners of Konkola Copper Mine (KCM)

The study included all lead-handling staff in the company at the proposed copper refinery sites. In the occupational setting, the most likely route of exposure to toxic metals has been reported to be through air. Inhalation pathway risk assessment was conducted by collecting both are and breathing zone samples. Workers were observed to use respirators to prevent exposure with varying levels of adherence. The mean personal lead air value observed was higher than that for area samples. The inference that exposure was activity-based was thus made. This was substantiated by the exposure patterns noted per job title. Analytical laboratory lead assayers were noted

to be most at risk of inhalational lead exposure. Only one of the samples exceeded OSHA, NIOSH, and ACGIH reference standard values for air. Similarly, the chronic daily intake CDI determined was within permissible limits but represented the major intake route compared to ingestion and dermal pathways. Literature has disproportionately more evidence for air lead exposure compared to other pathways.

5.2.2 To estimate dermal lead contamination at the KCM workplaces and describe the potential for incidental lead ingestion.

As highlighted above, there is little evidence regarding dermal and ingestion exposure assessment of lead. Composite palmar wipe samples were collected from both hands of the workers as well as surface wipes from potentially contaminated areas within the two business sites. The mean amount of lead detected on area wipes was higher than dermal wipes by a factor of about seven. This fundamentally validates the assumption that workers are at risk of lead uptake by virtue of working at these sites. Probability estimates deemed dermal exposure to be negligible and ingestion to be second in importance after inhalation consistent with some literature. Standard measurement metrics are otherwise lacking for these pathways.

5.2.3 To describe current and historical trends of KCM lead-burner blood lead levels.

There was no statistically significant difference observed between current and historical trends of blood lead levels among workers. Neither were there statistically significant findings for job type and study site. The overall mean blood lead value was 1.61 units higher than the recommended blood lead level according to OSHA. Of note, inclusion of historical values for job type analysis showed higher mean blood levels exceeding the reference value for all job types compared to current blood lead levels alone where two job types were not in exceedance. This temporal variation may be explained by the copper refinery electrolysis cells' lining lead substitution with polymer material. This control was implemented by the mining company in the recent past. There is potential for correlation regression studies to be performed on the same dataset in relation to the ancillary data collected from questionnaires. Also, an array of other blood tests may be done to assess internal blood lead exposure and its effects such as haemoglobin and erythrocyte protoporphyrin.

5.3 Recommendations

More health laws, coupled with relevant stakeholder sensitisation, starting with exposed workers may bring about reduction in exposure. Local occupational regulations are overdue, with enforcement as in the case of Chinese Law where occupational health violators are subjected to varying degrees of punishment including business closure. Incentivising the system may also help. Without stern enforcement, progress would not be observed (16,30). Additionally, worker education on occupational lead exposure risk, relevant exposure pathways, as well as preventative controls by the company's occupational health and safety department is highly recommended. A review of the existing training program will need to be conducted whereas if none exists, one needs to be designed. This would involve defining the following: scope, content of training, frequency, materials used, and methods. Didactic or simulation approaches may be adopted and tailored to workers' level of education. Content to be prioritised includes health effects of lead exposure, PPE benefits and correct use, protective practices beyond PPE use as well as occupational hygiene exposure assessments (68).

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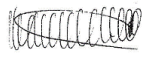
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7. APPENDICES

Appendix A – Plagiarism form

Supervisor signature: 

Co-Supervisor signatures: 

2500440 Research_Report_ updated 01.08.2024.docx			
ORIGINALITY REPORT			
12%	9%	8%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS
PRIMARY SOURCES			
1	wiredspace.wits.ac.za Internet Source	2%	
2	web.archive.org Internet Source	1%	
3	www.cdc.gov Internet Source	<1%	
4	www.mdpi.com Internet Source	<1%	
5	worldwidescience.org Internet Source	<1%	
6	"Toxicological Profile for Lead", ATSDR s Toxicological Profiles Web Version, 2002. Publication	<1%	
7	Ali Akbar Mohammadi, Ahmad Zarei, Saba Majidi, Afshin Ghaderpoury et al. "Carcinogenic and non-carcinogenic health risk assessment of heavy metals in drinking water of Khorramabad, Iran", MethodsX, 2019 Publication	<1%	

Appendix B – Ethics clearance


UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R49 Dr KP Hayumbu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M220931

NAME: Dr KP Hayumbu
(Principal Investigator)

DEPARTMENT: School of Public Health
Medical School
University

PROJECT TITLE: Occupational lead exposure amongst lead burners in a
copper mining company, Zambia

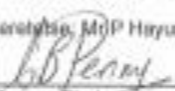
DATE CONSIDERED: 2022/09/30

DECISION: Approved unconditionally

CONDITIONS:

NOTE: If contact information regarding student study participants is required,
please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR: Ms G Keratissa, MJP Hayumbu, Dr N Ndaba

APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL: 2023/02/15

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Research Office secretariat on the 3rd floor, Philip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in September and therefore reports and re-certification will be due in the month of September each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator _____ Date _____

TROPICAL DISEASES
Tel/Fax +260212 615444
NDOLA, ZAMBIA



RESEARCH CENTRE
tdrc-ethics@tdrc.org.zm
P O Box 71769

TDRC RESEARCH ETHICS COMMITTEE
IRB REGISTRATION NUMBER : 00002911
FWA NUMBER : 00003728

TRC/C4/11/2022

21st November, 2022

Dr Kasyimbi Pauline Hayumbu
Principal Investigator
House Number 3V3
Private Bag 49, Chilanga,
Zambia.

Dear Dr Hayumbu,

RE: ETHICAL APPROVAL OF STUDY PROTOCOL

Reference is made to the protocol entitled "Occupational lead exposure among lead burners in a copper mining company, Zambia" TDREC104/11/22.

On behalf of the Chairman of the TDRC Research Ethics Committee (REC), I am pleased to inform you that your protocol was reviewed and granted ethical approval based on conditions below.

The Committee has noted that you will have to interact with the study participants, some of who may not be well conversant with the English language. You are therefore advised to ensure that the information sheet and informed consent form are translated into local language.

You are further advised to obtain Material Transfer Agreement approval from the National Health Research Authority (NHRA) for blood samples you intend to ship to NIOH laboratory for conducting lead analysis.

You are now required to submit your protocol to the NHRA for final approval following the link: <https://www.nhra.org.zm>. A final report to the study should be submitted to the REC Secretariat at the end of the study.

This approval is valid for the period, 21st November, 2022 to 20th November, 2023

The Committee wishes you success in academic work and execution of the study.

Yours faithfully,
TROPICAL DISEASES RESEARCH CENTRE

Sydney Mwanza
DEPUTY SECRETARY – TDRC Ethics Review Committee





NATIONAL HEALTH RESEARCH AUTHORITY

Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA

Chalala Office Lot No. 18961/M, Off Kasama Road, P.O. Box 30075, LUSAKA

Tell: +260211 250309 | Email: znhrasec@nhra.org.zm | www.nhra.org.zm

REF:NHREB0002/05/02/2023

Date: 2nd February, 2023

Principal Investigator,
Dr. Kasyimbi Pauline Hayumbu
C/o Kabwe Central Hospital
P.O. Box 80917,
Kabwe

Dear Dr Hayumbu,

Re: Request for Authority to Conduct Research

The National Health Research Ethics Board (NHREB) is in receipt of your request for authority to conduct research titled "Occupational Lead Exposure Among Lead Burners in A Copper Mining Company, Zambia."

I wish to inform you that following submission of your request to the Board, its review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

1. A Material Transfer Agreement is obtained and cleared by the National Health Research Ethics Board should there be any need for samples to be sent outside the country for analysis.
2. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
3. Progress updates are provided to NHRA Bi-annually from the date of commencement of the study;
4. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
5. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, and all key respondents.

Yours sincerely,

Prof Patrick Musonda
Chairperson
National Health Research Ethics Board