CONCENTRATION OF LEAD IN IMPORTED PLASTIC TOYS, SAFETY TO CHILDREN AND ASSOCIATED FACTORS IN LUSAKA CITY, ZAMBIA

By

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Dissertation submitted as partial fulfilment of the requirement for Masters of Public Health (MPH) Degree in Environmental Health

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DECLARATION

I Doreen Sakala, declare that the work presented in this thesis entitled **Concentration of lead in imported plastic toys, safety to children and associated factors in Lusaka city, Zambia** is to the best of my knowledge and belief my own work and that it is original. The dissertation has never been presented anywhere in whole or in part for the award of a degree in any university and all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

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APPROVAL

The University of Zambia has approved this dissertation of Doreen Sakala as fulfilling the partial requirement for the award of the degree of Masters of Public Health in Environmental Health.

EXAMINERS

Name________________________________Signature_______________Date____________

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ABSTRACT

Lead poisoning has been a constant public health concern because children absorb more lead compared to adults. The resulting health effects are irreversible and include decreased cognitive functions development and death. Lead exposure to children is in various ways and one of the ways is use of toys contaminated with lead. The allowable international standards for Lead in plastic toys is 90 ppm and this study established levels ranged from 0.001 to 2,100 ppm. The study used an analytical cross-sectional design in which 108 toys were collected from 18 randomly selected stores in Lusaka City. The toys were subjected to X-ray Fluorescence using Nilton gun machine to determine lead concentration. Stata version 12.0 was used for statistical analysis. Bivariate regression was used to test for association between independent and dependent variables at $P < 0.05$. Toys with lead levels above the recommended international standard of 90 ppm constituted 18.5% (20) of the total sample while 81.5% (88) toys had lead concentration within the standard. The concentration of lead had a median of 0.001 ppm and (IQR 0.001 – 60.5 ppm). Toys for children above the age of 2 years had higher lead levels of 105 ppm compared to those for children below 2 years with levels of 9.75 ppm. Toys in the mid-range cost category of 16 -25 ZMK had higher levels of 232.5 ppm compared to toys in the low and high cost category of 2-15 and 36-190 ZMK. Lead levels were high in multi coloured toys (102 ppm) compared to the mean for single colours Toys of animal shape had higher lead levels of 105.5 ppm compared to toys in the miscellaneous and repetitive shape categories which had 90 and 0.001 ppm respectively. However, the association between these factors (colour, type, cost, child age category of the toy) and the concentration of lead in the toys was not statistically significant with $P > 0.05$. This study established that 18.5% of the toys were above the acceptable limit of lead, with some toys having lead levels 23 times higher than the internationally acceptable standard of 90ppm. There is therefore urgent need for regulatory bodies (ZEMA and ZABS) to develop standards and policy on lead in toys to ensure protection of children from lead poisoning.

DEDICATION

To God who has walked with me through life. In loving memory of my Mother Ms Sarah Sakala and to my grandmother Mrs Elizabeth Sakala for inspiring me to get education, my sister Sarah for giving me the reason to go on and my entire family for their encouragements during my studies.

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May the Almighty God bless you all abundantly.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABBREVIATIONS

CDC	:	Centre for Disease Control
CPCC	:	Consumer Protection and Competition Commission
CPSC	:	Consumer Product Safety Commission
CSO	:	Central Statistical Office
EU	:	European Union
FDA	:	Food and Drugs Act
ISO	:	International Standards Organisation
IQ	:	Intelligence Quotient
PHA	:	Public Health Act
PVC	:	Polyvinyl Chloride
SI	:	Statutory Instrument
UNEP	:	United Nations Environmental Programme
UNZA	:	University of Zambia
USA	:	United States of America
WHO	:	World Health Organization
ZABS	:	Zambia Bureau of Standards
ZEMA	:	Zambia Environmental Management Agency

CHAPTER ONE
INTRODUCTION

1.1 Background

Lead is a highly toxic metal that can lead to serious health defects in both children and adults at different exposure levels (Gati et al 2014). It is a naturally occurring element found in the earth's crust extracted though mining (Greenway, 2009). Products that contain lead include; batteries, pipes, toys, jewellery, cosmetics, ammunition and paint (Weidernhamer and Clement 2007). According to Chandrashekar and Koppa (2014), human exposure to lead includes ingestion of lead contaminated food, contaminated water supplied from Lead pipes, skin surface contact through use of cosmetics and ingestion of flakes from leaded paint. Lead in plastic toys increases malleability and stabilizes the chlorine molecules in the Polyvinyl Chloride (PVC) material, thereby reducing auto digestion of the PVC material during the life span of the toy (Omolaoye et al, 2010). Health effects of lead in toys include but not limited to, decreased cognitive functions and physical development, Anaemia, cancer and death (Naicker, 2012).

Studies conducted globally and within the African region Omolaoye et al (2010), Gati, et al (2014), Montgomery, and Mathee (2007) and Sindiku and Osibanjo (2011) have reviewed presence of lead in both locally made and imported plastic toys Mateus and Bonilla, (2014), Kumar and Pastore, (2007) and Decharat et al (2013 with some toys exceeding the allowable international standards on lead in plastic toys.

Notwithstanding what has been done on global and regional levels, Zambia lacks information on studies conducted on lead in imported plastic toys and there are currently no standards on lead in toys. However, international standards, the Consumer Product Safety Commission prescribes 90ppm of lead concentration in toys as acceptable limit. Zambia currently does not have legislation on Lead in toys and this makes it difficult to enforce and monitor the quality of toys imported into the country.

Monitoring of lead in toys has been a challenge in most developing countries due to lack of legislation and standards (Kumar and Pastore 2007). However, countries that have conducted studies on lead in plastic toys have influenced development of legislation and policy on monitoring for lead in both locally made and imported toys.

This study therefore aims to determine safety of imported plastic toys to children in relation to concentration of lead in selected stores of Lusaka city, Zambia and compare with set international standards.

1.2 Statement of the problem

Toys are a part of every child's development; however, the chewing and sucking habits of children as they play with toys exposes them to the risk of lead poisoning especially if the toys contain lead (Omolaoye et al, 2010). The importance of assessing lead levels in plastic toys is because toys could contain lead added for malleability, corrosion resistance and durability of paint. Therefore, children need to be protected from exposure to risk of lead poisoning and the likely effects of playing with lead contaminated toys (Pastore and Kumar, 2007).

Zambia imports toys from various countries, yet there is no legislation that addresses the safety of toys and this maybe a risk to the health of the children. Zambia has conducted studies on lead poisoning in Children from environmental lead contamination but there are no studies done on risk of lead poisoning from products like toys. Such related studies include a study by Mbewe et al (2015) which revealed high levels of lead in children who reside near the Kabwe Lead Mine but there are no studies on lead in toys and the likely effects.

1.3 Significance of the Study

Toys contaminated with lead are a great concern to Public Health as they can lead to irreversible health damage to children (Naicker, 2012). According to Kumar and Pastore, (2007), exposure to lead through toys is associated with chronic health effects in children such as reduced cognitive functions and Anaemia. This study therefore, aims to determine the presence of lead in imported plastic toys sold in selected stores of Lusaka city, critical in influencing development of legislation, policy and standards on lead in toys. Implementation of such legislation will ensure routine surveillance at points of entry and strengthen inspection measures and testing of such products. This will ultimately strengthen the country's knowledge on various exposure routes for lead to protect children who are a high-risk group. The study will also assist in creating public awareness on Lead in the toys imported into the Country. The parents will be sensitized on the risk of lead exposure to their children through use of toys and the possible health consequences resulting from the use of lead contaminated toys.

1.4 Research question

What are the levels of lead in imported plastic toys sold in stores of Lusaka city, Zambia?

1.5 Research Objectives

General Objective

To determine the concentration of Lead in relation to safety of imported plastic toys to children and associated factors in Lusaka city, Zambia.

Specific objectives

i. To determine lead levels in imported plastic toys and compare with set international standards
ii. To determine the association between concentration of Lead in plastic toys and selected independent variables

CHAPTER TWO
LITERATURE REVIEW

2.1 Overview

The literature in this study focused on the use of lead in plastic toys, the internationally acceptable standard of lead in plastic toys, acceptable limit of lead in blood and the health effects on the children and concludes by stating the gaps in literature. The concern for lead poisoning in Children is due to their playing practices and habits of chewing and sucking on toys. Literature explains the several studies done on lead in plastic toys and the likely effects of lead on the health of children. Most of the studies especially in developing countries are based on internationally set standards for lead in toys. However, there are gaps in the literature regarding local studies on lead in toys. This study therefore aims to explore literature on lead in plastic toys, likely effects on the health of the children and the internationally acceptable standards for lead in toys.

2.2 History of Lead use

Lead is a silver-grey metal that naturally occurs in the environment in coal and ore with other metals such as copper, Zinc and Silver (Naicker 2012). It has been used for several purposes dating back as far as the Roman empire, ancient Greece and Spain more than 3000 BC (Greenway, 2009). Lead in Roman times was mainly used in water reticulation pipes during plumbing and as an additive in wine. The word plumbing comes from the Latin word plumbum which means Lead and gave lead its chemical formula Pb (Parsons and McIntosh 2010). The authors further explain that properties of lead that include softness, corrosion resistance and durability makes it a good additive in the manufacture of plastic toys. The flexibility of lead allows plastic toys to retain to their normal shape when compressed without breaking (Kumar and Pastore, 2007).

2.2.1 Lead in plastic toys

The global market accounts for US $105 billion in toys with highest consumption in developed countries, Kumar and Pastore (2007). The authors explain that there is however little information on the market share for developing countries due to lack of regulation and monitoring on use of toys. It is however important to note that there is increasingly high toy consumption in developing countries with countries like China being major exporters. Meanwhile, Schmidt (2008) emphasizes that even though developed countries like the USA are a large toy consumer; toy manufacturing is externalized with more than 70% of the toys manufactured in China where there are no proper safety controls. The author explains that product safety and quality is not guaranteed, as there is reliance on voluntary safety testing by manufacturers. Furthermore, Weldernhamer (2008) also emphasizes that some countries sometimes use recycled battery waste in the manufacture of toys thereby increasing the lead content of the toys. CDC (2004) which have documented cases of lead poisoning in children after swallowing toy jewelry from India evidences this statement.

Lead is used as an additive in paint to increase durability on surfaces and leaded paint can be used to paint toys (Greenway, 2009) and paint containing lead can be a source of poisoning for children when used on toys as well as on walls (CDC, 2013). This is consistent with the study on use of leaded paint in South Africa where Mathee (2007) explains that paint scrapings taken from toys widely used by children and procured from major supermarkets and stationery shops across South Africa, reviewed high lead levels of up to 145, 000 µg/g. Some of the toys were locally manufactured and others were imported in to the country from Asia.

Bright colored pigments in form of metal stabilizers are added to paint for toys in order to attract children because the brighter the toy, the more a child is likely to be attracted to it and play with it (Kumar and Gottesfeld 2008). However, Omolaoye et al (2010) explain that the metal stabilizers used in the paint pigments are not bound to the plastic material of the toy and hence leach out during playing and sucking of the toys. The authors therefore explain that toys made of plastic material may put children at a greater risk of possible exposure to lead poisoning if the lead is present in the toys. CDC, (2012) explains that in some cases, jewelry toys have been found to contain high levels of lead. The authors explain that in the United States of America, a toy medallion necklace manufactured in India contained 388,000 mg/kg of lead and blood lead level of the child who swallowed the medallion was 123 µg/dl, more than 12 times the allowable limits of lead in blood. Tests conducted to ascertain lead levels in similar medallions across the USA reviewed high lead levels and this prompted a recall of 1.4 million medallion necklaces manufactured in India (CDC, 2012).

According to Kumar and Pastore, (2007), studies have shown a relationship between colour of toy, country of manufacture, cost of toy, child-age category of the toy and type of toy in relation to the concentration of lead. In a study on lead in plastic toys in India, Kumar and Pastore, (2007) found that the cheaper the toy, the higher the lead levels it had compared to toys that had higher prices. The authors further state that most of the toys were for the age category of children under the age of six, which is a high-risk age group for lead poisoning. In another study on lead in paints used for toys in Colombia by Mateus and Bonilla (2014), findings indicated higher concentrations of lead in brown paint and locally manufactured toys.

Phthalates are also known to contribute to the addition of lead to plastic toys (Johnson et al, 2010). The authors define Phthalates as esters of phthalic acid used as plasticizers to soften PVC products such as toys and other children products like teethers. Phthalates also make the toy to return to its original shape when compressed. However, phthalates are easily broken down in the presence of heat and sunlight, hence lead is added to enhance durability. Countries like China have been known to make half of the world's toys with phthalates and the other half without in order to save money (Johnson et al 2010). It is most important to note that countries like China make bigger contribution to the world toy market (Schmidt 2008). The author explains that use of substandard raw material in toy manufacturing has led to some toys having lead above the limits and in a competitive market where consumers expect low prices for toys; manufacturers tend to use low cost raw materials that may be contaminated with various heavy metals including lead. Greenway (2009) also explains that a recall of about 1.8 million toys imported from China into the USA was due to high concentrations of lead.

2.2.2 Effects of Lead on Human Health

Lead exposure to children from toys is an emerging concern and presence of lead in toys may be one of the exposure pathways for lead poisoning in children (Gati et al 2014). Parsons and McIntosh (2010) state that children are more at risk of lead poisoning from toys due to their chewing and sucking practices as they play with toys and that they have a high gut absorption capacity, which is about 50% compared to adults who have 15%. UNEP (2013) states that children aged one to six years are more at risk of ingesting lead through contaminated soils and other products and hence more at risk of lead poisoning. Furthermore, children with iron deficiency Anaemia have increased lead absorption capacity (Naicker, 2012) and that the most common effects of lead in children is mental retardation and decreased growth, cancer and death. According to WHO (2010), children are more susceptible to lead poisoning due to more life years compared to adults thus, there is high likelihood of developing delayed consequences of lead poisoning such as dementia and poor cognitive development.

CDC (2013) has set the allowable limits of lead in blood to 10µg/dl. However, scientists and physicians have argued and stated that there are no safe levels for lead in blood, even the lowest levels have effects on health (Sindiku, & Osibanjo 2011). One of the major effects of lead is poor cognitive functions and UNEP (2013) explains that lead interferes with rapid brain development leading to asymptomatic impairment of neuro behavioral functions at doses low enough to produce clinical symptoms. Studies on association between lead and IQ have shown that children who did not have any symptoms had a four to five-point deficit in mean verbal IQ compared to children in the same environment with lower lead levels (WHO, 2010). Furthermore, Naicker (2012) in a Cohort from Birth to Twenty study in South Africa, states that lead can affect the endocrine system, which is responsible for hormone release and development leading to delayed puberty, breast development, and pubic hair development and as well as short stature, which can be a precursor for obesity later in life. The author explains that studies have shown that delayed puberty can lead to physical and psychological problems in both girls and boys and low levels of oestrogen in girl's due to lead can increase risk of depression later in life.

Naicker, (2012) further explains that childhood lead exposure is also associated with increased hyperactivity, inattentiveness, and conduct disorder, failure to graduate from high school, delinquency, drug abuse and incarceration, reduced brain size on MRI examination in adults, and kidney dysfunction. The author states that even with chelation, neuro behaviors associated with lead poisoning in early childhood are persistent and irreversible. Other health effects of lead include extensor muscle palsy with wrist and ankle drop and lead induced clinical anaemia especially in children with iron deficiency (WHO, 2010) and weakening of the immunity leading to various illnesses (Greenway, 2009).

2.3 Gaps in Literature

Zambia has conducted several studies on Lead poisoning and lead contamination in soil, water, food and air emissions. However, there is lack of information on lead exposure to children through toys. Furthermore, there is also lack legislation on lead in toys. This study will therefore add to the body of knowledge on lead exposure pathways and help in influencing development of legislation and standards on lead in toys, which will ultimately help to protect children from lead poisoning through use of toys.

CHAPTER THREE

METHODOLOGY

3.1 Study Design

This research was an analytical cross sectional study.

This study design provided a snapshot on the concentration of lead in imported plastic toys sold in selected stores at a specific point in time and in a specific geographical location, which is Lusaka city.

3.2 Study setting and study population

The study population was new plastic toys imported on to the Zambia market in Lusaka City. The toys were sampled from different stores across Lusaka city. Lusaka, the capital city of Zambia covers an area of 360 Km^2 and has a population of 2.4 million and characterized by rapid population growth at 4.7% with most of the population living in Peri urban areas (CSO 2010). Lusaka is the center of both commerce and Government in Zambia and connects to the four main parts of the country mainly by road. Zambia and in particular Lusaka is seeing an increase in the middle-class population in terms of income, this has resulted into high consumption rate of goods and services. Demographic distribution includes the high class composed of high income, middle income as well low-income population mainly residing in the high-density compounds with poor access to amenities like proper stores and shopping areas. The central location of Lusaka in relation to other cities of Zambia supports high trade activities with most major retailers of toys located in the city. Different types of toys are imported into the country and sold in Lusaka and other parts of the country, therefore most people from other towns buy toys for sale from stores in Lusaka.

3.3 Sample size and sampling procedure

Since there was lack of information on studies conducted on lead in plastic toys in Zambia and studies in Africa equally did not have statistically derived sample size and the samples were purposively collected, therefore sample size calculation was based on a mean and standard deviation from a similar study conducted by Mateus and Bonilla

(2014) on the presence of lead in paint of toys sold in stores of the formal market of Bogotá, Colombia.

It was therefore assumed that in Zambia, the mean lead levels will be at 2.50 ppm (SD 0.5). This translated into a minimum of 96 toys using the formula for a single mean.

$$n = \frac{Z^2\sigma^2}{e^2}$$

$$\frac{(1.96)^2 * (0.5)^2}{(0.1)^2} = 96$$

Where n = sample size,

Z = 1.96 at 95% confidence interval

σ = standard deviation

e = margin of error

Factoring in a 10% non-response rate, the sample size will increase to 108 toys.

3.4 Inclusion and exclusion criteria

The study only included new imported plastic toys sold in stores in Lusaka. New plastic toys sold on the streets and markets were not included since the assumption is that new plastic toys sold on the streets and markets were purchased from the stores already included in the sampling frame. The focus for this study was new imported toys so as to understand lead content as an intrinsic component of the toy such as malleability which makes it a good additive in toy manufacture.

3.5 Data collection, management and storage

3.5.1 Sampling techniques

To create a sampling frame, this study identified 37 toy stores in Lusaka. The stores were located within the Central Business District shopping malls as well as stores situated on the Eastern, Western, Southern and Northern part of the City. From the 37 stores identified a total number of 18 stores were randomly selected by simple random sampling. The toys were then stratified into three strata namely miscellaneous, repetitive and animal shape. Two toys were purchased from each of the three strata in the 18 selected stores. For each toy purchased details such as country of origin, cost, colour, type and what age of child the toy is meant for was collected. To avoid secondary contamination each toy was packed in a clear plastic and photographed before transportation to the laboratory at the Zambia Bureau of standards (Appendix A).

3.5.2 Sample analysis

Lead concentration in plastic toys was measured using a Nilton X-Ray Fluorescence (XRF) gun (XL3t 950, Thermal Scientific, Tewksbury, USA). Before use the gun was calibrated according to manufacturer's manual. A clean flat surface was used where all the analysis was conducted. Toys were then removed from the clear plastics and subjected to XRF. The smaller toys or parts of toys were placed inside the equipment whereas bigger toys, direct measurement was conducted by pointing the gun at the toy and readings tabulated in part per million (Greenway 2009). The results were compared to the set international standards. This approach was helpful and had an effect on the final reading of the lead levels. Examples of toys subjected to this approach were cars. The body of the car, tyres and chassis were tested separately and results revealed that high lead concentration was mainly on tyres and chassis. The machine gave a reading that was recorded as the concentration of lead in that particular toy in parts per million (Greenway 2009). Concentration of lead was recorded and compared with the set international standards.

3.5.3 Data collection tools

Data Sampling form (Appendix B) and camera.

A data sampling form was generated in order to record information such country of origin, type of toy, child age category of the toy, colour and cost of toy. The other information on the form was results from the laboratory analyst, name of the analyst and the date the samples were submitted to the laboratory. A digital camera was also used to take photographs of the toys that were collected in all the stores.

3.5.4 Selected Study variables

Table 1 shows the variables used in this study.

Table 1: Study variables

Type of Variable	Variable	Indicator	Measurement scale
Dependent	Lead in toys	Levels of Lead in toys (Above and below the standard)	Categorical
Independent	Color of toy	Red, green, Multi colored & others	Nominal
Independent	Country of origin	China, South Africa, Not Indicated & others	Nominal
Independent	Type of toy	Repetitive shapes (building blocks, letters), Animal shapes Miscellaneous (cars, airplanes, dolls, toy jewelry)	Nominal
Independent	Cost of toy	2-15 ZMK 16-25 ZMK 26-35ZMK 36-190 ZMK	Ordinal

Independent	Child- age category	Below 3 years Above 3 years	Categorical

3.5.6 Data management and storage

After collection data was entered by the researcher into an excel spread sheet and kept on a laptop with a secured password to avoid access by other persons and for backup, a copy was kept on CD and External hard drive. During analysis, data (names of stores) was de-identified by using codes

3.6 Data Analysis

Statistical analysis of the measured data was analysed using Stata version 12.0 for descriptive statistics and bivariate logistic regression to test for association between dependent and independent variables at $P < 0.05$. Lead values were graphically presented for each variable as categorical variables in form of bar charts and frequency table.

3.7 Ethical Consideration

The purpose of the study was explained to the storeowners (Appendix C) and informed consent was sought from the storeowners before purchase and collection of toys from the stores (Appendix D). Participation in the study was voluntary and the storeowners were free to withdraw from the study at time with no negative consequences. In order to ensure confidentiality, stores were de-identified using codes during analysis and dissemination of the results. Data was stored on a CD and external hard drive for backup just in case the computer developed a problem that could have led to loss of information. Study results were also be availed to Storeowners from whom samples will be collected.

The benefits of the study are that the information collected in this study may help in creating awareness among store owners that the toys they sell to the general public may not be safe to the health of the children

The study posed psychological risks to the store owners due to anxiety on outcome of the results. There were also economical risks because in the event that legislation is developed on control and monitoring of lead in toys, contaminated toys would be disposed of, and traders would need to buy toys from other sources which maybe more expensive hence reducing profit margins. To reduce these risks, storeowners were assured that their stores would be de-identified and the results would not be connected to any particular store.

Currently, Zambia has no legislation that bans the importation and sale of toys with high lead levels. For stores whose toys had higher Lead than the standard, the store owners were informed and information provided on the health effects of high lead concentration in toys to children and they would have to make an informed decision on whether to continue selling the toys or not. ZABS was also informed as standard developers to initiate and expedite the process of developing standards on lead in plastic toys to prevent continued exposure of children to lead, through strengthened monitoring and control processes.

The research protocol was subjected to review for ethical approval by ERES Converge

CHAPTER FOUR
RESULTS

4.1 Characteristics of sample

Sampling of toys was done in various stores across Lusaka city. Zambia has in the recent past seen a defined social class in regards to income and expenditure. Stores that were randomly selected for purchase of toys cater for all social classes that exist in Zambia. The type of stores sampled included large and medium sized supermarkets and small stores. These stores sell variety of merchandise and they include clothes, foot wear, household furniture and appliances, food and beverages, electronics. It should be noted that most stores in Zambia do not exclusively sell toys unless for a few countable ones. These stores have been selling toys for a long period in Zambia especially in Lusaka city, with 10 having been in the business for more than 20 years, 7 for less than 12 years and 1 store has been selling toys in Lusaka City for less than 2 years. There is variation in the type of clientele for these stores, 5 stores are mainly for the upper class, 3 for the middle class, 6 are for the mixed classes and 4 are the lower class. Since the total sample was 108 toys, 6 toys were purchased from each store

4.2 Levels of Lead in Toys in Lusaka City

Lead concentration ranged from 0.001 to 2110 ppm with a median of 0.001 ppm and an interquartile range of 0.001 to 60.5 ppm as shown in Figure 1 whereas Table 2 shows lead levels in toys. Low lead toys are within international standard for lead concentration of 90ppm (CPSC 2008) and high lead exceed the standard. Toys that were above the acceptable limit of 90ppm were at 18.5% while those that were below the acceptable limit were at 81.5% and Figure 1 shows the distribution of lead levels in the toys.

Table 2: lead concentration levels for toys in Lusaka, Zambia

Lead Levels	**Frequency**	**Percent (%)**
Low Lead (0 to 90 ppm)	88	81.5
High Lead (90 to 2110 ppm)	20	18.5
Total	**108**	**100**

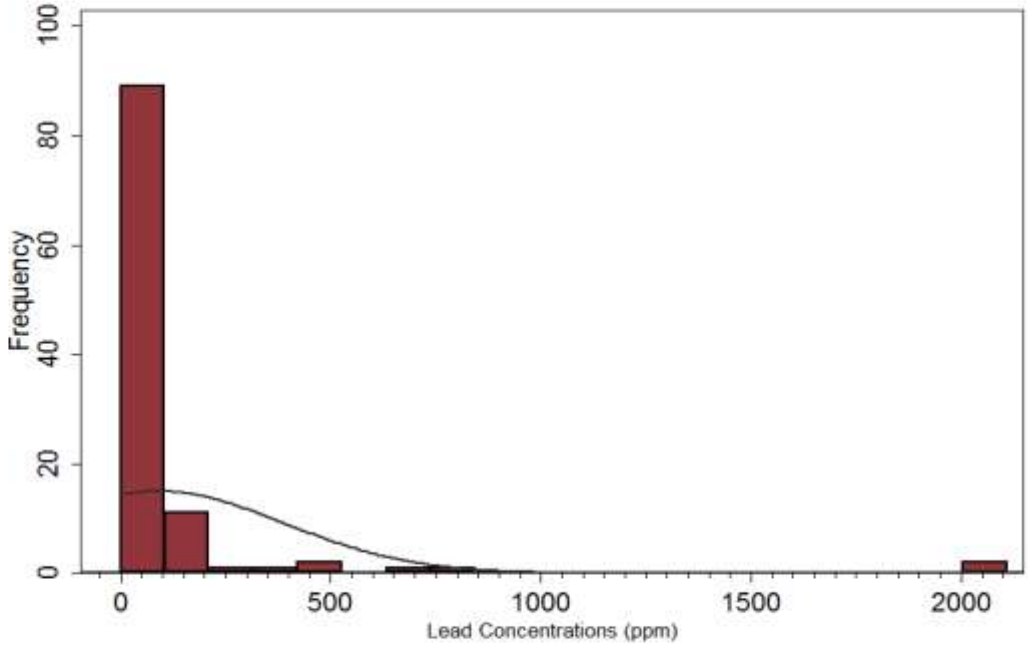

Figure 1. Statistical distribution of lead concentration in toy

18.5% of the toys had Lead concentration above the set standard, 17.6% had Lead concentration within standard of 90ppm, while 63.9% had undetectable lead levels of 0.001 ppm

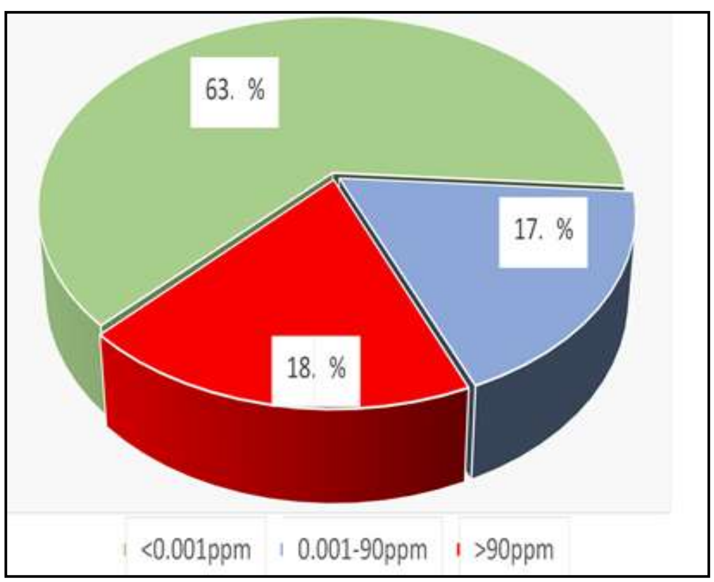

Figure 2: Proportion of lead by concentration in all toys

Toys for children above the age of 2 years had high lead levels compared to toys for children below 2 years as shown in figure 3 below

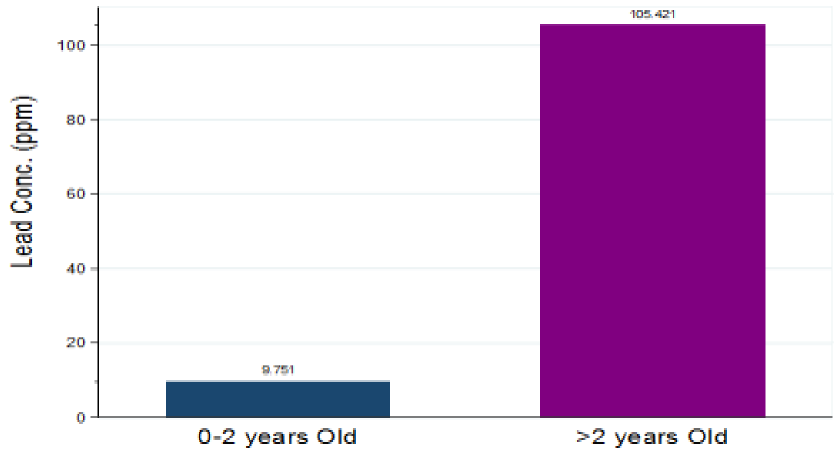

Figure 3: Lead levels according to child age category of toy

Miscellaneous and Animal shaped toys had the highest lead content at 90 ppm and 105.6 ppm, respectively as shown in the figure below.

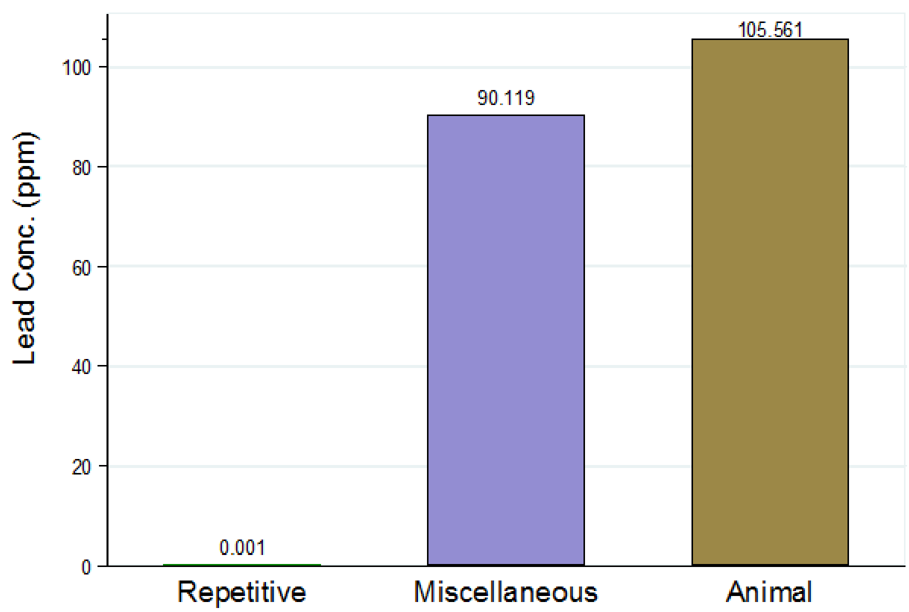

Figure 4: Lead concentration according to shape of toys

Lead levels for multi colored toys was high at 102.7 ppm while single colored toys had lead level at 54 ppm which is below the standard as shown in figure 5 below

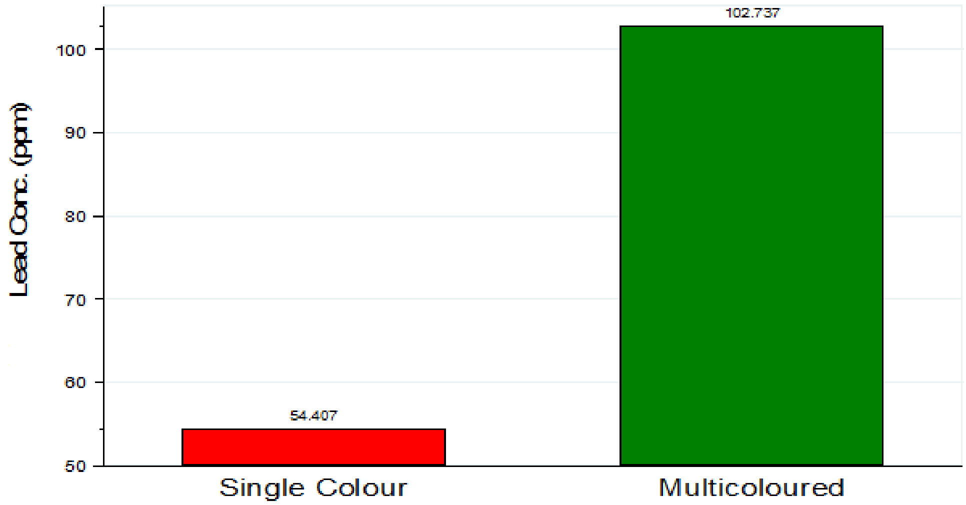

Figure 5: Lead concentration classified according to colour

The toys in the mid-range price of 26-35 ZMK had higher mean lead levels of 232.9 ppm compared to toys that were cheaply and highly prices, 2-25 ZMK and 36 – 190ZMK that had mean levels below 90ppm as shown below in Figure 6.

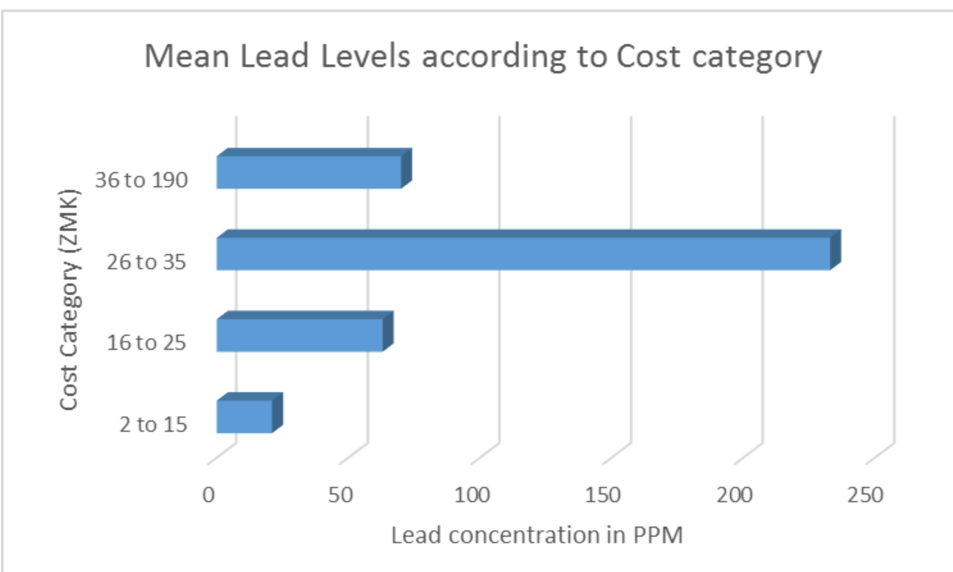

Figure 6: Lead concentration according to Cost of the toys

4.3. Factors associated with lead concentration

Table 3: Factors associated with lead levels in Lusaka city

Bivariate			
Variable/	**No (%)**	**P-value**	**Unadjusted OR**
Toy type			
Miscellaneous	71(65.7%)	0.356	1.00
Repetitive	8(7.4%)	0.977	1.00
Animal	29(26.9%)	0.283	1.02
Child age category of toy			
<2years	20(18.5%)		
>2years	88(81.5%)	0.205	3.9
Cost of toy			
2- 15	32(29.9%)		
	23(21.3%)		1.8
16-25		0.445	
	24(22.2%)		2.5
26-35			1.5
	29(26.9%)	0.206	
36-190			
		0.564	
Colour of toy			
Single	32(29.6%)		
coloured	76(70.4)		1.3
Multi		0.616	
coloured			

4.3.1 Type of toy

Bivariate regression analysis was used to test for association between the dependent and the independent variable. For toy type, higher lead levels were found in toys that were animal shaped compared to toys in the miscellaneous and the repetitive shapes category that had levels below the cut-off point. However, the P- value > 0.05 indicates that there was no association between Concentration of lead and the type of toy and the wide confidence interval indicates that results are not statistically significant and that there is a chance that the results could have been found by chance and that there is no difference between type of toy and lead levels and this is also demonstrated by unadjusted OR of 1.00.

4.3.2 Child age category

Higher lead levels were found in toys for children above the 2 years compared to toys for children below the age of 2 years but the test for association with the dependent variable had a P value > 0.05 indicating that there was no association between the child age category of the toy and the concentration of lead. Furthermore, the wide confidence interval also indicated no statistical association, nevertheless, unadjusted OR of 3.9 means that the toys in this category were 3.9 times more likely to contain high lead.

4.3.3 Cost of toy

The toys were ordered into cost categories and the results from the chi square test showed that there was no association between the cost of the toys and the concentration of lead as evidenced by P-value of > 0.05 and wide confidence intervals. However, unadjusted OR indicated that toys priced between 26 -35 (ZMK) were 2.5 more likely to contain high lead, even if the results were not statistically significant.

4.3.4 Colour of toy

Toys were grouped into single and multi-colour categories, with multi coloured toys having more lead than the single coloured toys. The unadjusted OR indicated that the multi coloured toys were 1.3 times more likely to contain lead than the single coloured toys. However, the wide confidence interval and P-value of >0.05 showed that the results were not statistically significant.

Overall even if lead levels were found in the toys under the various categories, lack of statistical significance of the results indicates that there is no association between the concentration of lead in a toy and the independent variables which are colour, cost, type of toy and child age category of toy. This further illustrates that there is 5% that results were merely found by random chance.

CHAPTER FIVE
DISCUSSION

The aim of this study was to determine the safety of imported plastic toys to children in relation to lead poisoning. Lead poisoning is public health concern especially in children due to long term irreversible effects that a child exposed to lead would experience. The safety of the toys imported into Zambia is not known with regards to presence of lead. Hence the research study was conducted to ascertain the safety of these toys.

This study established that lead is present in the plastic toys imported into Zambia with 18.5% of the toys having lead above the recommended limits and 17% having presence of lead even if it was in low concentrations and 63% having lead levels below 0.001 ppm.

5.1 Type of toy

The toys were stratified into three strata; miscellaneous shapes which included toys such as Barbie dolls, cars, airplanes, kitchen and garden tools; animal shapes which included all toys of animal shape; and repetitive shapes which included toys such as building blocks and numbers and letters. Lead levels were measured according to the shape of the toy. This study showed that toys that were in the miscellaneous and animal shape categories had high lead content compared to toys in the repetitive shape category with mean levels of 105.5, 90 and 0.001 ppm respectively. However, animal shaped toys had the highest lead levels of 105.5 ppm. Under the miscellaneous stratum, high lead levels were found mostly in cars compared to other toys. Parts of the car that had high lead levels were tyres and the chassis. It should be noted that the highest lead levels which was about 30 times the allowable levels of lead in toys was a car and the lead was in the tyres. However, comparing the miscellaneous to the animal shapes, high lead levels were observed in animal shaped toys. According to Sindiku and Osibanjo (2011), lead is the most commonly used stabilizer in the manufacture of plastic products as it is cheap and readily available. While Kumar and Pastore (2007) explains that lead as a metal has properties of softness and when added to a toy it increases the softness and strength allowing it to be flexible. Even though the animal shaped toys in this study were made of soft plastic material, this study did not conduct tests to establish the type of materials from which the toys were made, hence the presence of lead in these toys cannot strongly be attributed to use of stabilizer or addition of lead for softness. However, one cannot completely rule out the fact that lead stabilizes the PVC molecules in plastic and hence there is a possibility of adding lead to toys for this purpose. In view of this, a further study in Zambia is recommended which can analyze the type of material the toy is made of and compare with lead levels. The association of lead levels and type of toy was not statistically significant ($p=0.977$) and an odds ratio of 1.02 indicates that there is no difference in the lead levels among the types of toy in this study. However, study is consistent with findings from other studies Kumar and Pastore (2007) and Omolaoye et al (2010) that state that soft plastic toys, are more likely have high lead levels compared to the hard plastic and they further explain that Lead stabilizes the chlorine molecules in the Polyvinyl Chloride (PVC) material, thereby reducing auto digestion of the PVC material during the life span of the toy. Furthermore, Johnsons et al (2010) explains that these stabilizers can leach out during sucking and chewing on toys by children leading to ingestion of lead which increases risk of lead poisoning.

The concentration of lead found in the toys sampled in this study is a Public Health concern owing to the high levels. One of the exposure pathways for lead poisoning in children is through ingestion of lead contaminated food, water and through use of other articles. Therefore, presence of lead in toys as one of the articles in the exposure pathway poses a high risk of lead poisoning in children. WHO (2010) explain that 600,000 children suffer from lead poisoning each year and 143,000 die annually, with the highest numbers of these cases coming from developing countries. This study established that among the toy types, animal shaped toy was found to have higher lead levels compared to other shapes. It was also revealed that the animal shaped toys were made of soft plastic material which gave them a higher possibility of containing lead.

Precautionary principles of legislating and monitoring of toys imported into Zambia need to be applied to avoid exposing children to risks of lead poisoning. An international standard has been set for levels of lead in toys, however presence of lead even in low concentration in toys still poses a risk of exposure to poisoning from repeated use and scientists and physicians have argued that there are no safe blood lead levels because even the lowest concentration can lead to long term health effects especially poor brain development (Omolaoye et al 2010).

5.2 Child age category of toy

Studies have shown that rapid brain development takes place during early childhood and any effects on the brain during this period can have irreversible health effects (WHO 2010). This study established that toys for children >2years old had high lead levels of 105ppm exceeding the allowable limit of 90ppm. The high levels of lead in toys for children > 2years is a matter of concern in public health as this is period when children are likely to use more toys and any metals including lead with effects on their health should not be present in the toys even in low concentrations.

Gati et al (2014) explain that children have a higher lead absorption capacity compared to adults at 50% to 15%. Omolaoye et al (2010), Kumar and Pastore (2007) also argue that this is the age when children are more active and play more with toys and acts of chewing and sucking increase exposure to lead poisoning. Therefore, lead exposure through use of toys, increases the risk of lead poisoning. Effects of lead poisoning can also be noticed later in adult life, for instance, children that have been exposed to lead are likely to have delayed puberty and menarche, poor breast development in females and high risk of depression, delinquency and sometimes high crime tendencies Naicker (2012).

Although the association between lead levels and child age category of the toy was not statistically significant (P=0.439), odds ratio indicated that toys for children >2-year-old category were 3.9 times more likely to have high lead content compared to toys in the <2-year-old category. It is therefore important to ensure that there are controls on the levels of lead in the toys imported on the Zambian market through monitoring at points of entry as well as inland. However policy formulation and development of legislation should precede lead monitoring. As a matter of priority, regulatory bodies such as Zambia Environmental Management Agency and Zambia Bureau of Standards should develop legislation and policy on lead in toys.

5.3 Colour of toy

This study established that toys in the red, green, and multicolours had high lead levels of 93 ppm, 131 ppm and 102 ppm compared to the international standard of 90ppm while lead levels were undetectable (0.01 ppm) in other colours. In terms of overall mean concentration for colour, multi coloured toys had high lead levels of 102 ppm compared to the single colours that had lead levels of 54 ppm, within the recommended standard. From the findings, this study established that brightly coloured toys contained higher lead levels than less brighter toys. These findings are consistent with a study by Kumar and Pastore (2007) who found that brightly coloured toys such as red were likely to contain high lead content than other colours. Mateus and Bonnila (2013) explain that bright colored paints used on toys were more likely to contain lead and hence increase the lead content in a toy. Another study by Greenway (2009) stated that lead has been known to be used in pigments to add vibrancy of colour to the products and lead chromates are used in pigments that have colors ranging from greenish to yellowish red. The metal stabiliser used in the pigments are not bound to the polymer and any lead added in the paint will leach out during handling of toys like chewing, sucking and exposure to sunlight. This results in the exposure of children to lead, leading to irreversible health impacts Omolaoye (2010).

Despite high lead levels being found in green, red and other multi colored toys, a conclusion cannot be made that the finding is due to lead chromates or paint used in the painting of the toy. This is because studies that showed presence of lead in paint used on toys, analysed the paint separately from the toy by scrapping off the paints Mathee (2007). However, this was not done in this study as toys were analysed as whole without removing the paint. It should however be noted that in other similar studies, the association between colour and lead content was done with single coloured toy. But this study went further to consider multi coloured toys and their association with Lead content and findings reviewed that multi coloured toys had high lead levels compared to some single coloured toys.

Although findings in this study were not statistically significant, (p= 0.616), the odds ratio indicate that multi colored toys were 1.3 times more likely to contain high levels of lead compared to the single colored toys. It is therefore, important to have control measures in terms of monitoring at entry points and inland by subjecting the toys to lead tests as consumers cannot attribute high lead levels in toys to a particular colour.

5.4 Cost of toy

This study established that toys in the mid-range categories costing between ZMK 26 to 35(USD 3 to 4) had the highest lead levels of 232.9 ppm compared to toys in the other cost categories. Study findings in India, Colombia and Ghana by Kumar and Pastore (2007), Gatil et al (2014) and Mateus and Bonnila (2011) showed that toys that were cheaper were more likely to contain high lead than the higher priced toys. The authors attributed the findings to the poor quality raw materials used in the manufacturing of the toys which were likely to affect the lead levels and final cost of the toys and that low-quality raw material, likely from recycled lead waste, will translate into a cheap toy having high lead levels. However, this study established that toys in the midrange category contained higher lead levels of 232.9 ppm, above the recommended standard of 90 ppm compared to toys that had lower and higher prices.

Toys that were low priced had undetectable lead levels of <0.001 ppm while the other categories including the high-priced toys were within the recommended standard. Therefore, it is difficult to associate levels of lead to the cost of the toy as the statistical analysis of the cost of toy and levels of lead was not statistically significant (p=0.684). However, the odds ratio of 1.8 indicates that the toys in the midrange category are 1.8 times more likely to contain high lead levels compared to the other cost categories. This makes monitoring for levels of lead in toys imported into Zambia an important issue for safety of children.

It should be noted that the toys in the midrange cost category are quite affordable to most Zambians, hence larger population is exposed and Naicker (2011) explains that there has been an association between childhood lead exposure and performance in cognitive functions 20 years after levels were measured. Such exposures have been linked to increased hyperactivity, inattentiveness, and conduct disorder, failure to graduate from high school, drug abuse and incarceration. The author further explains that even with chelation, neuro behaviours associated with lead poisoning in early childhood are persistent and irreversible. It therefore important to control and monitor levels of lead in toys imported into Zambia to prevent exposure of children and enhance their safety.

5.5 Country of Origin

The study in Zambia reviewed that all toys that were sampled from the market in Lusaka City were manufactured in China and 18.5% of the toys had high lead levels. The presence of Chinese made toys on the Zambian market is consistent with Schmidt (2008) that countries like China make bigger contribution to the world toy market. Furthermore, Greenway (2009) state that the USA had a 1.8 million toy recall due to high lead levels and that the toys were made in China, while Gati et al (2014) explain that toys originating from China have high lead levels and low prices. Other similar studies in South Africa, Colombia and UNEP equally concluded that Chinese made toys had high lead levels after sampling toys from China and other countries and making comparisons. However, all toys collected in this study were from China, hence it would be inconclusive to state that toys from China have high lead levels, if there were no other countries to compare with and this makes it difficult to attribute presence of lead to toys from a particular country. This calls for Zambia to intensify surveillance measures to monitor lead levels in all toys coming into the country to ensure safety. The fact that all toys were Chinese and there was no country to compare with, a recommendation is made that a bigger study be done that can include more stores and wider area that may likely have toys from other countries to ensure comparison in terms of lead levels.

CHAPTER SIX
CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Lead exposure to children is in various ways and one of the ways is use of toys contaminated with lead. Thus, the objective of this study was to use an analytical cross sectional design in which 108 toys were collected from 18 randomly selected stores in Lusaka City to determine the lead concentration. This study established that lead levels in the toys ranged from 0.001 to 2,100ppm. There was no association between concentration of lead and the selected independent variables such as colour, cost, child age category and type of toy. However, odds ratios of more than 1 indicate that categories of toys that were found with high lead, were more likely to contain higher lead levels than those in categories with low lead levels. This further indicates that there is a risk of exposure to lead among children as they play with the toys and increased risk of lead poisoning.

The fact that Lead was present in the toys imported into Zambia, is a public health concern which needs urgent attention from all players. Creating public awareness on the presence of lead in toys and letting parents know the dangers of lead contaminated toys, will reduce exposure of children to lead poisoning from use of contaminated toys. The study contributes to existing findings on concentrations of lead in toys and it also reveals that the safety of the toys on the Zambian market is compromised and this can lead to Lead poisoning in children with irreversible health damage. There is need to put a system of testing the toys imported into Zambia in order to ascertain their safety on children. This monitoring system needs to be preceded by development of policy and legislation by stakeholders like ZABS and ZEMA. The Ministry of health equally needs to take an active role in active surveillance for lead poisoning in children in the hospitals so as to help provide more information for research that may need to associate the lead poisoning to exposure through toys and other products.

6.2 Study limitation

During laboratory analysis, other metals such as cadmium were also detected, but because it wasn’t a metal of interest, results were not included among the sample results. Cadmium is also a heavy metal and has long term effects on the health of the children. The study was only limited to Lusaka city and did not cover other towns in the country.

6.3 Recommendations

During the laboratory analysis of the toys, other heavy metals were also found that have negative effects on the health of the children. Among the metals found was cadmium that was also in higher than normal concentrations. However, since it was not my metal of interest, it was not considered in the results. It is therefore recommended that levels of cadmium be analyzed in future studies.

The study area was equally small as it only concentrated on Lusaka City and not the rest of the country. It is therefore recommended that the study be extended to other parts of the country.

The focus for this study was brand new toys and not second-hand toys, it is therefore recommended that a another study be done on lead in second hand toys and those from hospital and other day care centers. Zambia imports second hand toys for sale as well as those received as donations for hospitals and social welfare facilities. It important that the lead level in these toys are determined, since some studies have indicated that toys kept in homes and other buildings built before leaded paint was banned in developed countries, were more likely to contain higher levels of lead due to contact with paint in these buildings. The second-hand toys also have a wider population on the market compared to new toys. Areas that are in remote locations of the country with few or no stores that sell toys, are likely to have second hand toys being sold. This means that there are more children being exposed to metals contained in these toys. There is also urgent need for the development of policy and legislation on lead in toys in order to ensure that children are protected from the risk of lead exposure and poisoning.

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APPENDICES

Appendix A: Approval letter for sample analysis from ZABS

Zambia Bureau Of Standards
"For Safety and Quality Assurance"

Lechwe House, Freedom Way - South End
P O Box 50259 ZA 15101, Ridgeway, Lusaka, Zambia
Tel: +260 211 231385 / 227075 / 221386
Telefax: +260 211 238483
E-mail: ceo@zabs.org.zm

The Postgraduate Coordinator – School of Medicine
The University of Zambia
P.O. Box 50110
LUSAKA

Attn: Mrs. C Jacobs

Dear Madam

RE: REQUEST FOR LABORATORY ANALYSIS OF LEAD CONTENT IN PLASTIC TOYS

With reference to the above, your student Doreen Sakala (2015130918) is welcome to carry out her research at the Zambia Bureau of Standards Laboratories, to determine Lead content in imported plastic toys in Lusaka, Zambia.

The analysis will be carried out by our technicians, but the student will be responsible for sample preparation and will be charged a standard testing fee discounted by 20% of the normal charges. Your student will also be expected to provide her own safety clothing and follow standard laboratory procedures and working arrangements.

Yours fully

A. Chipongo

SNR ANALYST-ZAMBIA BUREAU OF STANDARDS

CC: Laboratories Manager

All Correspondence to be addressed to the Director

Border Offices:
Chanida, Chirundu, Livingstone, Nakonde, Kazungula, Mwami, Katima Mulilo

Provincial Offices:
Chipata, Solwezi, Chinsali, Ndola, Kasama, Choma, Mongu, Mansa

Appendix B: DATA SAMPLING FORM

1. Sample No..	2. Date Collected...
3. (a) Product name and description:... (b) Method of collection.. (c) Collector's identity on package and seal...	
4. Reason for collection...	
6. Dealer..	
7. Quantity sampled...	
8. Date collected..	
9. Delivered to...	
10. Date of delivery...	
11. Laboratory..	
12. Records obtained.. (a) Invoice No. and date... (b) Shipping record and date.. (c) Other documents..	

13. Remarks: (a)Country of Origin... (b) Type... (c) Colour... (d) Child- age category.. (e) Cost of sample..
15. (a) Collector's Name (*Print*).. (b) Collector's Signature...
16. (a) Receiver's Name (*Print*)... (b) Receiver's Signature...
17. Sample results remarks.. ....
18. Date results issued...
19. Name of Analyst (*Print)*.. 20. Signature of Analyst..

Appendix C: Information sheet

UNIVERSITY OF ZAMBIA - DEPARTMENT OF PUBLIC HEALTH

INFORMATION SHEET

Study Title: Concentration of Lead and associated factors in imported plastic toys in Lusaka city, Zambia

Purpose of research project

This study is part of my research for my training in Master of Public Health that I am doing with the University of Zambia. T the purpose of the research is to test for Lead in imported plastic toys.

Studies conducted in other countries across the world have reviewed high lead levels in both imported and locally manufactured plastic toys. Nevertheless, Zambia lacks of information on Lead in plastic toys and has no regulations that deal with safety of toys. The importance of assessing the Lead levels in plastic toys is because plastic toys are usually coated with lead to ensure durability of paint, softness of the toys and corrosion resistance.

This study therefore, aims to assess levels of lead in these imported plastic toys with the view of limiting lead exposure to children in order to prevent mental retardation and other health problems.

For me to do this, I have to collect toys from different stores randomly selected across Lusaka. I will buy different plastic toys only from the selected stores.
After collecting the toys, I will take them to the Zambia Bureau of Standards laboratory for testing for presence of Lead.

Why you are being asked to participate?

Participants in this study are those who sell imported plastic toys in stores in Lusaka city and were randomly selected among stores that sell toys in Lusaka city. You have been asked to participate because you fit the description of participants in the study. It is expected that there will be 16 - 18 stores, hence 16- 18 participants in the study.

Procedures

If you agree to participate in this study, I will buy and collect six toys from your store. The toys to be collected will be chosen randomly. Each toy will be recorded, photographed and put in a clean plastic and taken to the laboratory for testing for lead.

Risks/discomforts

There are no physical risks in this study but you may have psychological risks due to anxiety of what will happen to the toys in the store if lead is present. However, your store will not be connected to the results as the results will be presented in general to stakeholders.

Benefits

There are no direct benefits to you for participating in this study. However, you will be able to get knowledge on lead in toys and health effects and be able to contribute to the protection of the lives of children who play with these toys.

Payment

There is no any form of payment for participating in this study.

Protecting data confidentiality

I have put up steps to protect the information I will get from you. The details of your store will be protected, as I will not identify your store by name. The data will be locked in a secure place and copies of data shall be kept on a CD just in case I have a problem with the computer during the period of the study. The results of the study will be published for public knowledge, nevertheless, your store names will not be linked to the results. Feedback on results of the study will be shared with you.

What happens if you do not want to participate in the study?

You are free to decide whether you want to take part in the study or not. This will not bring any problem to you. If this study brings you any discomfort, you are free to withdraw from it at any time.

Whom do I call if I have questions or problems?

If you have complaints about the study, contact me on the address below:

Principal Investigator

Doreen Sakala

UNZA- School of Medicine

Department of Public Health

P.O Box 50110

LUSAKA.

Cell: 0965016188

Email: doliwe56@gmail.com

For Ethical queries, you can call Eres Converge at:

ERES Converge

33 Joseph Mwilwa Road, Rhodes Park, Lusaka

Tel: + 260 955 155633, +260 955 155634, +260 966765 503

Email: eresconverge@yahoo.co.uk

Appendix D: Informed Consent form

UNIVERSITY OF ZAMBIA - DEPARTMENT OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title: Concentration of Lead and associated factors in imported plastic toys in

Lusaka city, Zambia

Principal Investigator: Doreen Sakala

Ethics committee Ref No: 2016- June- 011

I have read the information (or it has been read to me). I understand that the research project is trying to determine the safety of imported plastic toys in relation to Lead content in Lusaka city, Zambia. I have had the opportunity to ask questions about it and any questions I asked, have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

I understand that participation in the study is voluntary and that confidentiality will be maintained. My identity will not be revealed in any way. I also understand that I'm also free to withdraw from the study at any time if I do not want to continue with my participation.

I understand that if I want to talk to the people who are in charge of this research project I can contact Ms. Doreen Sakala on 0965 016188 or Email: doliwe56@gmail.com

If I have any complaints or questions about the research during the study period, I can also call ERES CONVERGE on numbers shown below.

Tel: + 260 955 155633, +260 955 155634, +260 966765 503 or Email eresconverge@yahoo.co.uk

Agreement

I have decided to take part in the study even though I know that I don't have to do it. The researcher has answered all my questions.

____________________	________________________	___________
Print name of Participant	Signature/Thumb print of Participant	Date
__________________	________________	____________
Name of Person obtaining consent	Signature of Person Obtaining Consent	Date
___________________________	_____________	___________
Name of Person interpreting Informed Consent	Signature of person interpreting informed consent	Date