ASSESSMENT, VIEWS AND CHALLENGES OF ZINC AND IRON FORTIFICATION OF LOCALLY MILLED MAIZE FLOUR SOLD IN NAIROBI, KENYA

BY
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A THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTERS IN PUBLIC HEALTH IN HUMAN NUTRITION (MPH)

DEPARTMENT OF HEALTH, POLICY, MANAGEMENT AND HUMAN NUTRITION

MOI UNIVERSITY

OCTOBER 2020
DECLARATION

DECLARATION BY CANDIDATE

I the undersigned declare that this thesis is my original work and to the best of my knowledge has not been presented for the award of a degree in any university. No part of this thesis should be reproduced in whole or part without the permission of the author and/or Moi University.

Ireen Kathure Mutuma

SPH/PGH/NC/1010/2015

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DEDICATION

I dedicate this work to my Family.
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<tbody>
<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
</tr>
<tr>
<td>AAS</td>
<td>Atomic Absorption Spectroscopy</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylene Diamine Tetra acetic Acid</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organization</td>
</tr>
<tr>
<td>G (g)</td>
<td>Grams</td>
</tr>
<tr>
<td>GAIN</td>
<td>Global Alliance for Improved Nutrition</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
</tr>
<tr>
<td>GoK</td>
<td>Government of Kenya</td>
</tr>
<tr>
<td>HA</td>
<td>Hectare</td>
</tr>
<tr>
<td>IREC</td>
<td>Institutional Research and Ethics Committee</td>
</tr>
<tr>
<td>KDHS</td>
<td>Kenya Demographic Health Survey</td>
</tr>
<tr>
<td>KEBS</td>
<td>Kenya Bureau of Standards</td>
</tr>
<tr>
<td>KNMS</td>
<td>Kenya National Micronutrient Survey</td>
</tr>
<tr>
<td>KPHS</td>
<td>Kenya Population and Housing Census</td>
</tr>
<tr>
<td>KS EAS</td>
<td>Kenya Standard, East African Standard</td>
</tr>
<tr>
<td>MG</td>
<td>Micrograms</td>
</tr>
<tr>
<td>MoU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MT</td>
<td>Metric Tonnes</td>
</tr>
<tr>
<td>NaFeEDTA</td>
<td>Sodium Iron Ethylene Diamine Tetra acetic Acid</td>
</tr>
<tr>
<td>nm</td>
<td>Nanometers</td>
</tr>
<tr>
<td>ODK</td>
<td>Open Data Kit</td>
</tr>
<tr>
<td>PPM</td>
<td>Parts per million</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for Social Sciences</td>
</tr>
<tr>
<td>SANAS</td>
<td>South African National Accreditation System</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Name</td>
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<td>---------</td>
<td>--------------------------------</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>WFP</td>
<td>World Food Program</td>
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<td>WHO</td>
<td>World Health Organization</td>
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DEFINITION OF TERMS

**Food Fortification**

As defined by WHO (2006) is the process of deliberately adding essential micronutrients, (Minerals including trace elements and Vitamins) to food irrespective of whether the nutrients were there before processing or not, with an aim of improving their nutrition quality.

**Iron**

Iron is an essential mineral in the body. Iron is responsible for transportation of oxygen in the body.

**Zinc**

Zinc is an essential mineral in the body. Zinc is a constituent of many enzymes, enabling chemical reactions to proceed at normal rates.
ABSTRACT

Introduction: Low nutrient intake of Zinc and Iron is a global problem affecting the health and social economic wellbeing of world population. There is an advocacy for food fortification as one method of dealing with these two serious micronutrient deficiencies. Kenya has not been left behind. A legal notice of June 2012 made fortification of maize flour with zinc and iron mandatory for all maize millers. Limited studies have been done to evaluate compliance to the Kenyan gazette notice on micronutrient fortification standards for maize flour.

Objectives: Assessment of Iron and Zinc concentration in maize flour, consumers views and miller challenges on fortification of locally milled maize flour, sold in Nairobi, Kenya.

Methods: A cross sectional survey approach was used. The study was carried out in Nairobi County, Kenya. 35 Samples of fortified maize flour were randomly purchased to give a representative sample. Atomic Absorption Spectrometry was used to analyze amounts of Zinc and Iron in the maize flour samples. 384 consumers were interviewed from Nairobi County. Four maize flour millers and a Kenya Bureau of standards personnel responded to the questionnaire. Zinc and iron levels were compared against recommended fortification standards. Data on consumers was extracted, entered on excel spreadsheet and imported into R statistical software package for analysis. Data is presented in prose, charts, and tables.

Results: From the study, of the 35 samples analyzed, overall, 14.29% of the samples met the minimum legal requirement of zinc and iron. The amount of iron ranged between1.08 ppm to 19.02 ppm against a minimum of 15ppm, the amount of zinc ranged from 10.64ppm to 56.25ppm against a minimum of 20ppm. Pearson’s correlation between zinc and iron fortification, was negative at a coefficient of 0.487787. Of the respondents who had knowledge on fortification, 61 % were female. There existed a positive relationship (p-value = 0.0248) between knowledge of fortification and age bracket. Consumers believed fortification improved their health at 66%. Major reasons given for fortification non-compliance were corruption and cost at 40% and 30% respectively. Although the media played a major role in creating fortification awareness at 41 %, 62.9% of respondents were not aware of the mandatory maize flour fortification with Iron and Zinc. Of the four millers interviewed, it was clear, there are no government incentives to support the mandatory fortification.

Conclusion: The study showed that Maize flour available for public consumption in Nairobi County is not adequately fortified. Consumer knowledge on mandatory fortification to be increased. Millers are not adequately prepared to fortify maize flour adequately.

Recommendations: The fortification process to be integrated into the overall food safety mechanisms to ensure conscious and constant monitoring during production. Consumer awareness to be created on the benefits of consuming fortified foods. The government to routinely publish the list of products that are complying and taking disciplinary actions on millers who do not comply. Government incentives such as subsidized costs of laboratory analysis would ensure increased monitoring.
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CHAPTER ONE: INTRODUCTION

1.1. Background

Micronutrients, that is, Vitamins and Minerals are important for human growth and development. Micronutrient deficiency is widespread throughout the world, with negative health and economic consequences. The World Health Organization estimates that more than two billion people are deficient in vitamins and minerals such as Iron and Zinc. (Das, et al., 2013).

Iron is a vital micronutrient responsible for oxygen circulation in the body, improved immune system and general energy of the body. (Abbas pour et al., 2014) Populations feeding on Iron deficient diets are likely to have health issues such as iron deficient anemia which in turn affects the wellbeing of a person and the productivity of a person and community. (Horton and Ross, 2003).

Zinc is an essential micronutrient, whose roles in the body include cell division, functional immune system, cell growth and break down of carbohydrates. Its deficiency results in stunted growth and acute diarrhea in children, dysfunctional immune system, slow wound healing and infertility in men. (Prasad, 2020).

Though micronutrient deficiencies affect entire populations, the most vulnerable groups are children, women and the elderly. The WHO estimates around 24.8% of the world population to anemic due to iron deficiency. In developing countries every second pregnant woman and about 40% of preschool children are anemic. (World Health Statistics, 2016). The 2011 Kenyan micronutrient survey indicated an overall
26.0% iron deficiency in the Kenyan population. Zinc deficiency affects nearly two billion people in the developing world (Prasad, 2012). In Kenya, the burden of zinc deficiency is high, with school going children being at 80.2%, non-pregnant women at 82.3% and men at 74.8 %.(KNMS, 2011).

Food fortification is defined as the process of adding vitamins and minerals to foods. It is a preventive food-based approach aimed at preventing diseases, strengthening immune systems and improving productivity and cognitive development. Over the past century, fortification has been effective at reducing the risk of nutrient deficiency diseases such as beriberi, goiter, pellagra, rickets (Dwyer et al. 2015) and to correct widespread inadequate nutrient intake with the associated deficiencies. This is achieved by adding small and safe amounts of minerals and vitamins in staple foods consumed by a given population. Fortification has been identified as a cost effective nutritional intervention, improving the diets of millions of people world over (Sue Horton, 2006a). Successful fortification programmes world over include, salt fortification with iodine, milk and margarine fortification with Vitamin A and D, and flours fortification with vitamins and minerals.(Chadare et al., 2019).

If micronutrient deficiencies in Kenya are not addressed, they will affect the country’s economic development hence affect its potential to reduce poverty ahead of Vision 2030. According to the Kenya National Nutrition Action Plan-2012-2017, food fortification is one of the High Intervention Nutrition Interventions in addition to exclusive breastfeeding, timely complementary feeding, iron Folate, vitamin A and zinc supplementation, hand washing, deworming, and management of moderate and severe acute malnutrition. (Kenya; Nutrition Action Plan, 2012-2017,)
Studies on compliance to legal requirements of flour fortification in different countries have revealed compliance such as the study done in the Dominican Republican 2013 and noncompliance in others (Yusufali, Sunley, de Hoop, and Panagides, 2012).

Although maize flour fortification became a legal requirement in Kenya in 2012, there are limited studies to evaluate compliance of fortified maize flour sold to the public with the fortification requirements. A study on compliance to fortification among selected ASEAN (Association of South East Asian Nation) countries, revealed the need for constant regulatory monitoring systems for effective results of fortification programs (Van den Wijngaart, et al., 2013). Another study on regulatory monitoring (van den Wijngaart et al, 2013), revealed lack of adequate fortification to meet the set standards for salt and wheat flour fortification in some ASEAN Countries.

1.2. Problem Statement
To reduce the burden of Iron and Zinc deficiency in Kenya, maize flour fortification was made compulsory for millers in Kenya in June 2012 (Kenya Gazette Legal notice, No 62, 2012). All commercially milled maize flour is expected to be fortified with iron and zinc as per the legal notice. This will enable the children to grow and develop to their full potential and improve the overall wellbeing of the population. Inadequate fortification affects the availability of the added micronutrients to consumers of fortified products thus not achieving the full benefits of fortification in vitamin and mineral deficiencies expected from the maize flour fortification programs. It is important to ensure that the food vehicle consistently contains adequate amounts of nutrients at the point of sale for effective impact.
According to Africa Maize Strategy 2017-2026, though maize flour is the primary cereal consumed in Africa, less than 30% of the industrially milled maize flour is fortified. Poor legislation on enforcement and follow up mechanisms is one of the major challenges facing fortification programs. This is majorly due to lack of political support and commitment. Lack of adequate research on product development, best technological processes and marketing also poses a challenge to the success of fortification initiatives.

This would focus on more fortification vehicles, stability of nutritional elements such as vitamins and the quality aspects of the product to ensure overall acceptability of the end product. The cost of fortification equipment, premixes and quality control processes also possess a great challenge to fortification, mostly to small millers.

Thus the this study sought to evaluate the levels of Iron and Zinc in fortified, commercially produced maize flour, available for sale to the Kenyan population, as per the standards stipulated in the Kenyan Gazette Notice, no 62 of June 2012.

1.3. Justification

Fortification initiatives all over the world have evolved over time and some programmes have been very successful. In the US, salt fortification with iodine had very positive results in the goiter belt, where incidences of goiter among children dropped from 35% to 2.6% between 1924 and 1935. (Fletcher et al., 2004).

Other countries with successful fortification initiatives are Guatemala with Vitamin A fortification of sugar. Costa Rica has improved iron status on women and children after
Iron and other micronutrients fortification program. In Chile, fortification of wheat flour with folic acid has seen a reduction in incidences of neural tube defects. (Martorell and de Romaña, 2017)

Maize flour fortification alone does not end micronutrient deficiencies but if it is done to set standards in combination with other strategies such as exclusive breastfeeding and diet diversification, it can impact positively on the reduction of health conditions that result from micronutrient deficiencies (Lawrence, et al, 2016),(Chadare et al., 2019). Fortification increases the availability and absorption of the micronutrients added hence reduces the effects of micronutrient deficiencies resulting in a healthy population. Despite the increased costs of maize flour milling due to fortification, the health benefits outweigh the costs incurred. (Method et al., 2015).

In 2008, the Kenyan Government included fortification in Kenya’s National Food Security and Nutrition Policy as a strategy for addressing national food and nutrition security. All maize flour millers in Kenya are expected to fortify their maize flour with micronutrients including Zinc and Iron according to Foods Drugs and Chemical Substances Act.2012 and to monitor to ensure adequate amounts of micronutrients are added to the maize flour before distribution. Maize flour is a preferred fortification vehicle because of its stability on adding micronutrients and that it is consumed by around 78% of the Kenyan population. (Markets, 2020). In Nairobi County that has an estimated population of 4.4 million people (KPHS, 2019), commercially milled maize flour is the preferred source of starch (Onyango, et al, 2016).

If fortification standards are not adhered to, there will be need to review monitoring policies .This will ensure every packet of maize flour with the fortification logo, meets
the stipulated levels of micronutrients (Method et al., 2015). A study to identify barriers and good practices in monitoring of fortified foods in some ASEAN countries revealed that, there exists evidence of non-fortification and under fortification among products claiming to be fortified (Van den Wijngaart et al., 2013).

Though maize flour fortification with Iron and Zinc is compulsory in Kenya, there are limited studies done to assess the amount of micronutrients available to the consumers at the point of sale.

1.4. Research Question
What are the levels of Iron and Zinc in maize flour available for sale, and the public views on maize flour fortification in Nairobi County?

1.5. Broad Objective
Assessment of nutrient concentration, consumer views and miller challenges on iron and zinc fortification of locally milled maize flour, sold in Nairobi, Kenya.

1.6. Specific Objectives
The objective of the study was to.

1. Determine adequacy of Iron and Zinc concentration in locally milled maize flour sold to the public in Nairobi County.
2. Assess views on iron and zinc fortification from Nairobi residents.
3. Document challenges of maize flour millers’ in fortifying maize flour with Iron and Zinc.
CHAPTER TWO: LITERATURE REVIEW

2.1. Maize Production in Kenya

Maize also known as \textit{(Zea mays)} is consumed by more than a billion people in the world (Suri and Tanumihardjo, 2016). Maize is a staple food in Kenya grown in small and large-scale farms with an estimated production of 2,850,000 metric tons in July 2016 (Table 2.1). The Galana/Kulalu Food Security Project, located in Kilifi and Tana River counties covering 1.78 million acres is meant to increase maize production by 2017. (National Irrational Board, 2016). Maize is the backbone of food security in Kenya mostly grown in the rift Valley, Central, Coastal and Parts of the Eastern regions of the country. In Kenya Maize is widely used for cooking local dishes such as Stiff porridge \textit{(ugali/sima )}, Porridge \textit{(Uji)}, Maize and beans \textit{(makande/ githeri)} and mashed maize and beans sometimes mixed with bananas, or vegetables or English potatoes \textit{(Irio)} and can also be eaten on the cob, boiled or roasted.

Commercially, maize is used in the industrial production of starch, corn oil, animal feeds and maize flour. Currently the country Kenya does not produce enough maize and has to import maize from neighboring countries. Kenya imports maize mostly from the East African community. Maize flour is generated from maize by dry milling.
Table 1: Kenyan maize production, imports and distribution.

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<tr>
<td>USDA Official</td>
<td>New Post</td>
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<tr>
<td>Area Harvested (1000 HA)</td>
<td>1650</td>
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<td>1700</td>
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<tr>
<td>Beginning Stocks (1000 MT)</td>
<td>415</td>
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<td>210</td>
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<td>Production(1000 MT)</td>
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<td>TY Imports (1000 MT)</td>
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<tr>
<td>Total Supply(1000 MT)</td>
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</tr>
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<td>FSI Consumption(1000 MT)</td>
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<tr>
<td>Total Consumption(1000 MT)</td>
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<tr>
<td>Ending Stocks(1000 MT)</td>
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<td>215</td>
<td>255</td>
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<tr>
<td>Total Distribution(1000 MT)</td>
<td>3960</td>
<td>3965</td>
<td>4010</td>
</tr>
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(Grain and Feed Annual Nairobi Kenya, 2016.)

**Key**

**USDA**-United States Department of Agriculture

**TY**-Trade year

**FSI**-Food, Seed and Industrial use (production of flour

**MT**-Metric Tones
2.2. Nutrient Content of Maize

Maize is a source of carbohydrate (63.4 g/100g), protein (7.94 g/100g), Fat (4.5g/100g) and fibre (9g/100g). It is also a source of vitamins and minerals. 100g of whole, dry, white variety maize contain, Calcium-24 mg, Iron -2.6mg, Magnesium-75mg, Phosphate-367mg, Potassium-226mg, Sodium-12mg, Zinc-1.88mg, Se-8mg, Thiamin 0.25mg, Riboflavin 0.1mg, Niacin- 2mg and Folate -71mcg. (Kenya-Food-Composition-Tables-2018).

Most of the minerals are found in the bran and germ and hence are lost during milling of maize (Suri and Tanumihardjo, 2016b). Maize flour fortification replaces the lost minerals without affecting the organoleptic quality of the product (Van Bockstaele, et al, 2016).

2.3. Micronutrient Deficiencies

A deficiency in intake of essential micronutrients that is, vitamins and minerals affects efficient energy metabolism and other functions of the human body. The effects are severe and widespread in many parts of the world. They cause extensive burden on individuals with issues poor mental and physical development, with general losses in productivity and potential. (Ritchie and Roser, 2017). This in turn creates a burden on health services, education systems and families caring for children who are disabled or mentally impaired (Black, 2014). In 2000, the World Health Report identified Vitamin A, iodine, Iron, and Zinc deficiencies among the world’s most serious health risk factors.
The WHO estimates that 30 percent of women globally are anemic. Studies by the World Bank have shown that countries whose populations suffer from micronutrient deficiencies encounter economic losses as high as 5 percent of gross domestic product (GDP) (Mannar, et al., 2004). Most of the 1.62 billion people currently affected by anemia are women or young children. According to WHO, the three worldwide micronutrient deficiencies are Iron, Iodine, Zinc and Vitamin A, with Iron being the most deficient (WHO, 2009).

Malnutrition affects Kenya's economic and social development. This affects its potential to reduce poverty, ahead of the country’s Vision 2030 goal of transforming Kenya into a globally competitive and prosperous nation with a high quality of life. (GoK 2015). About 26 percent of Kenyan children under five are stunted, while 8 percent are severely stunted (2014, KDHS). In Kenya, over 80% of children under five do not get adequate amounts of Vitamin A.

2.4. Iron and Zinc Deficiencies

2.4.1. Iron

Iron is very important for human development. Its benefits include improved blood levels and circulation in the body, healthy pregnancies and increased energy. It is also needed by babies for brain development and general growth. (Jill Kohn, MS, RDN, LDN, 2017). (Jill Kohn, et al, 2017)

Iron deficiency results in impaired physical and cognitive development such as attention span, intelligence and sensory functions among children (Jáuregui-Lobera, 2014). There is increased child and maternal deaths (Abu-Ouf and Jan, 2015) and
decreased productivity due to ill health (Bhandari and Banjara, 2015 hence reduced school performance in children and a cycle of poverty (Atinmo Tola, et al, 2009). The Recommended Dietary Allowance for Iron based on age is, 7-12 months-11mg, 1-3yrs-7mg, 4-8yrs-10mg, 9-13yrs-8mg, 14-18yrs-15mg and above 19yrs-18mg (Office of Dietary Supplements - Iron,2018).Dietary sources of iron are red meat, fish and poultry for heme iron while fruits and vegetables such as spinach, kale and soya provide non-heme Iron (Dieticians of Canada, 2016).

Iron deficiency is caused by diets low in iron, diets that contain compounds that inhibit Iron absorption such as high levels of phytates (Grases, Prieto, and Costa-Bauza, 2017). Parasite infections especially among school going children also contribute to Iron deficiencies (Stoltzhus et al., 1997). There is an increased requirement such as women due to menstruation and adolescents due to expansion of total blood volume (Beard, 2000). Pregnancy and breastfeeding increases iron requirement in women (Marangoni et al., 2016). Malaria which is common in Kenya also contributes to iron deficiency (Nyakeriga et al., 2004).Poverty, where food availability is affected, nutritional illiteracy (Arya and Devi, 1991) and poor absorption in the gut (Scalbert et al, 2002) contribute to iron deficiency.

WHO reports zinc is one of the most common nutrient deficiencies in the world affecting an estimated 2 billion people. The latest WHO report on micronutrient deficiencies (2018) estimates that 243,187,000 non-pregnant women of child-bearing age have anemia related to iron deficiency. In total, 800,000 (1.5%) of deaths worldwide are attributable to iron deficiency. According to the Kenyan micronutrient survey done in 2011, there is overall 26.0% iron deficiency in the Kenyan population.
Measures taken to combat Iron deficiencies are effective when they are effectively combined (Fernando E. Viter, 1998). These mostly involve exclusive breast feeding up to the age of six months (Griffin and Abrams, 2001), diet variation to include foods rich in iron especially animal products, giving of supplements to expectant mothers (P.K. Chawla and R. Puri), deworming of school going children and food fortification (Kenya; Nutrition action plan). A study carried out in rural areas of Shimoga, Karnataka, India (BAL, et al, 2015), and shows fortification as a successful intervention programme for anemic children.

2.4.2. Zinc

Zinc is a vital micronutrient for general growth and for normal neurological function. It is needed for normal pregnancy outcomes, optimal child health and physical growth (Prasad, 1998), (Hambidge, 2000). Breast milk is a source of zinc for babies but the availability declines after first few months of breast feeding. (Brown et al., 2009). (Aumeistere et al., 2018).

Zinc deficiency is connected with many diseases that affect the functionality of the human body. (Jurowski et al., 2014) Effects of zinc deficiencies include diarrhea in children and infants. There is loss of appetite, low immunity, hair loss/hair thinning. Leaky guts affecting micronutrient absorption could also be associated with Zinc deficiency (Hambidge, 2000). Acne or rushes, delayed sexual maturation and mental disorders are also effects of zinc deficiency. (DiGirolamo, 2016).

The recommended daily allowance for Zinc varies with different groups. Babies 7-12 months-3mg, 1-3yrs-3mg, 4-8yrs-5mg, 9-13yrs-8mg, Teens-9to 11mg, adult men-
11mg, adult women-8mg, during pregnancy-11-12mg and when breastfeeding-12-13mg.(National Institutes of health.)

Main causes of Zinc deficiencies are gastrointestinal surgery because zinc is absorbed and excreted for the intestines (Semrad, 1999).Vegetarian diets have lower bioavailability of Zinc than diets with omnivorous diets (Foster M, Samman S, 2015) this creates a risk of Zinc deficiency among the vegetarians. Alcohol interferes with Zinc absorption (Dinsmore W. et al, 1985).

Inadequate Zinc intake greater than 25% is considered an elevated public health concern, according to Conclusions of the Joint WHO/UNICEF/ Interagency Meeting on Zinc Status Indicators (de Benoist, et al, 2007). In Kenya, the burden of Zinc deficiency is high with about 80.2 % of school going children, 68.3 % in pregnant women and 74.8 % of men having Zinc deficiency (The Kenya National Micronutrient Survey, 2011).

In 2012, during the 65th World Health Assembly (World Health Assembly, 2012,), a comprehensive plan for the improvement of maternal, infant and young child nutrition was endorsed with targets to be achieved by 2025. These targets included a 50% reduction in the number of women of reproductive age affected by anemia with respect to the estimated number for 2011(Brancan et al., 2014).Countries that have successfully implemented food fortification have reduced the effects of micronutrient deficiencies. A case in point is a study in Costa Rica, on effectiveness of evaluation of the food fortification program, indicated a decline in anemia in women and children. It also indicated iron status in children improved after fortification (Martorell et al., 2015).
In Kenya, the High impact Nutrition interventions were developed by the Kenyan Government in its effort to realize the millennium development goals. These interventions include: exclusive breastfeeding, timely complementary feeding, iron, Folate, vitamin A and zinc supplementation, hand washing, deworming, food fortification and management of moderate and severe acute malnutrition (Kenya National Nutrition Action Plan.2012-2017).

2.5. Food Fortification

Fortification as defined by World Health Organization refers to the practice of deliberately increasing the content of an essential micronutrient that is, vitamins and minerals (including trace elements) in a food, irrespective of whether the nutrients were originally in the food before processing or not. This is done so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health.

Fortification has been referred to as a successful tool to correct micro-nutrient shortages and associated deficiencies (Dwyer et al., 2015). The addition of micronutrients is done during the industrial processing of the food. The foods that qualify for fortification are limited by several factors. According to a study ‘Public health aspects of food fortification; a question of balance’ (Fletcher, Bell, and Lambert, 2004), these factors include technological properties of the food which are mostly moisture, pH of the food and Oxygen permeability. These lead to unacceptable taste and appearance, as well as cost and consumer expectations (Fletcher, et al, 2004). Fortification of maize flour and corn meal with a single or multiple micronutrients is a public health intervention that
aims to improve vitamin and mineral intake, micronutrient nutritional status, health and development of the general population (Sue Horton, 2006b).

2.6. History of Food Fortification

Fortification began between the First and the Second World Wars (1924-1944). Food items fortified were; salt with Iodine, vitamins A and D added to margarine, vitamin D added to milk, and vitamins B1, B2, niacin, and iron added to flours and bread. This was done was to reduce deficiencies or restore micronutrients lost during processing of the food (Dunn Michael L., et al, 2013).

In 2009, the World Health Organization released recommendations for such fortification, with guidelines on the addition levels for iron, folic acid, vitamin B12, vitamin A, and zinc (Table 2) at various levels of average daily consumption (Randall et al, 2012). According to the WHO, fortification of maize flour has been done for many years in several countries in Americas and Africa. Examples of such countries are Costa Rica on reduction of neural tube defects following fortification programs (Chen and Rivera, 2004). An increase in folate levels was reported in Tanzania in women of reproductive age after large scale folic fortification programs were implemented (Noor et al., 2017). Fortification can be mandatory or voluntary.

2.7. Process of Maize Flour Fortification

Fortification is done through fortification technology. It can be done en masse at the processing point targeting the entire population. An example is fortification of maize flour that is consumed by the entire population. Fortification can also be targeted fortification which is done targeting specific groups such as infants. This can be achieved by fortifying only infant foods.
For any fortification programme to be a success these factors are essential. The fortificant should be effective, bio-available, acceptable, and affordable (FAO/WHO 2001). Food is fortified based on the consumption habits of a country or a community. The staple food of a community such as maize or wheat serves as the best fortification vehicle for that community (Darnton-Hill, 1998), (Mahshid Lotfi et al, 1996). Foods that are commonly fortified are salt, flours, rice, bread, milk products, breakfast cereals and oil.

Maize flour fortification is common because it is a staple food in many parts of the world. Maize flour fortification is done after the milling process (Gwirtzet al., 2013) during which most micronutrients are lost. This is because the outer layers of the maize and the germ that contain the micronutrients are removed during milling.

Fortification is done using a powdered blend that has minerals and vitamins. The blend is called a premix. The premix does not affect the taste, smell or texture of the product. The amount of micronutrients added to maize flour is calculated based on the dietary requirements of the population (WFP, Fortification Standard operating procedure, 2009).

Losses during production, storage and cooking are also factored in when calculating the amount of micronutrients to add. The premix has free flowing micronutrients and of similar particle size to avoid separation of the added micronutrients. The equipment for fortification is designed such that a known quantity of premix is added to a known
amount of flour. This can be by batching system where premix is added per batch or can be by continuous mixing.

The fortification process has to be consciously monitored during production to ensure uniform spread of micronutrients in the end product. The fortification machine called the feeder also has to be monitored periodically during production to ensure it is discharging adequate amount of premix during production. (Bryan McGee, 2008), (Head, et al, 2014).

2.8. Food Fortification with Iron

Iron fortification is majorly done on cereals though other products such as milk have been successfully fortified with iron. A variety iron fortificants are used in flours, including sodium iron EDTA, ferrous fumarate, elemental iron powders and ferrous sulphate. (R. F. Hurrell, 2002), (Hurrell, et al, 2010). Iron is very reactive and it causes organoleptic changes in products colour (green to bluish in cereals) and taste due to rancidity (Mehansho, 2006). Hence some fortificants such as iron sulphate have a high bioavailability of Iron but they are not suitable for flour fortification. (FAO1997).

Sodium ethylenediaminetetraacetic acid (NaFeEDTA) is commonly used with iron in flour fortification because it increases the amount of iron available from iron fortified flour (Hurrell, 2002). In addition it does not support lipid oxygenation which can affect the taste of the food (WHO 2006). (Kongkachuichai, et al, 2007).

2.9. Food Fortification with Zinc

Fortification of staple foods with Zinc has been found to improve the health of populations (Shah et al., 2016). Adding Zinc to food does not affect absorption of other
minerals such as zinc (Whittaker, 1998). The main Zinc fortificants are zinc sulfate, zinc oxide with EDTA, zinc oxide, or sodium-zinc EDTA. Zinc oxide is used for maize flour fortification because of the convenience of its small particle size and inertness and has little effect on food shelf life (Rosado, 2003), (Kantha Shelke, et al, 2006).

2.10. **Storage of Fortified Maize Flour**

The minerals added to maize flour (Iron, Zinc and calcium) are stable during the production, transportation, storage (Kuong et al., 2016) and cooking of fortified flour. This is unlike the vitamins that are lost in the chain. (Dunn et al, 2014) A study done in Mexico (Rosado et al, 2005)on storage fortified corn flour for 90 days indicated over 90% retention of Iron added and no changes on the amount of Zinc added to the flour.(Dunn et al, 2014).

2.11. **Benefits of Food Fortification**

There are many benefits of fortification in comparison to the costs of fortification. The cost benefit ratio is estimated to be 8.7:1(Horton, et al., 2003:2006).Fortification is an economical option for delivering micronutrients to populations both poor and wealthy compared to supplementation (Sue Horton, 2006).

A study in South Africa, revealed a significant effect in reducing anemia and improving iron status and motor development of infants fed on fortified maize meal porridge (Faberge et al, 2005). Micronutrient deficiencies that are seasonal due to emergency related factors such as drought, war and other natural calamities can be addressed by fortified foods (Prinzo and Benoist, 2002).
Unlike supplementation that is done for individual micronutrients, several micronutrients can be added to a product at the point of manufacture by multiple micronutrient fortification (Mehansho et al., 2003) thus a sustainable venture if well implemented and the process monitored (García-Casal, 2014).

2.11.1. Benefits of fortifying food with Iron

According to Food Fortification Initiative Economic Progress, there is a big saving in fortification with iron compared to the amount spent in reducing Iron deficiency anemia prevalence. Childhood anemia is associated with mental retardation (Hurtado, et al, 1999), hence a drop in adulthood earnings, affecting the economic status of an individual and community at large (S. Horton and Ross, 2003). Iron fortification increases the amount of iron available during pregnancy, reducing the number of maternal deaths due to iron deficiency anemia (Leite, 2016).

2.11.2. Benefits of fortifying food with Zinc

Zinc fortification can increase dietary zinc intake and total daily zinc absorption. Zinc is used by several enzymes in the body (Joseph E Coleman, 1992). A study done on the elderly (Mocchegiani et al., 2013), indicates an adequate intake of Zinc results in improved immunity due to its requirement for the activity of many enzymes. Zinc contributes to improved growth of the male reproduction system (El-Tawil, 2003), (Biswajit Roy, 2013). Zinc contributes to improved vision (Newsome, 2008) and reduced gastrointestinal illnesses such as diarrhea (Roohani, et al, 2013).
2.12. Food fortification guidelines

In 2009, the World Health Organization released recommendations for fortification of maize and wheat flour. The guidelines were on compounds to be added for different micronutrients and the level of nutrient to be added in parts per million (ppm) by estimated average per capita availability (g/day) (Table 2.1). The micronutrients to be added are Iron, folic acid, vitamin B12, vitamin A and zinc at various levels of average daily consumption (Randall, et al, 2012). These guidelines are a resource for governments and agencies implementing or considering food fortification.
Table 2: WHO recommendations for wheat and Maize flour fortification.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Flour Extraction Rate</th>
<th>Compound</th>
<th>Level of nutrient to be added in parts per million (ppm) by estimated average per capita wheat flour availability (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt;752 g/day</td>
</tr>
<tr>
<td>Iron</td>
<td>Low</td>
<td>NaFeEDTA</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrous Sulfate</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrous Fumarate</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Electrolytic Iron</td>
<td>NR3</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>NaFeEDTA</td>
<td>40</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>Low</td>
<td>Folic Acid</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Cyanocobalamin</td>
<td>0.04</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>Low</td>
<td>Palmitate</td>
<td>5.9</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Zinc Oxide</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zinc Oxide</td>
<td>100</td>
</tr>
</tbody>
</table>

For fortification programs to be effective, fortification needs to be supported by adequate food regulations and labeling, quality assurance and monitoring to ensure compliance and desired impact (Mannar, et al., 2004). Global recommendations for fortification are based on levels that will not affect the product's taste, smell, or appearance.

For any country considering a fortification standard that exceeds the global recommendations, cooking trials may be needed to ensure that the fortification does not have a negative impact on the final food product. (The Food Fortification of staple foods by BASF, 2015)

2.13. Food Fortification Policy in Kenya

Ministry of Public Health and Sanitation through a Legal Notice no. 62 of 15th June 2012 declared it mandatory to fortify the following food products (Table 23). This aimed at reducing micronutrient deficiencies in Kenya as per the National Food and Nutritional Security Policy (National Food and Nutritional Security Policy 2011). In 2018, this was incorporated into the Kenya Food fortification Strategic Plan.

Table 3: Food fortification in Kenya as per the Kenya Gazette. (Appendix 7)

<table>
<thead>
<tr>
<th>Food product</th>
<th>Micronutrients to be added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheat Flour</td>
<td>Zinc and Iron</td>
</tr>
<tr>
<td>Dry Milled Maize Products</td>
<td>Zinc and Iron</td>
</tr>
<tr>
<td>Salt</td>
<td>Iodine</td>
</tr>
<tr>
<td>Vegetable Fats and Oils</td>
<td>Vitamin A</td>
</tr>
</tbody>
</table>
This was achieved by the Ministry of Health in partnership with Global Alliance for Improved Nutrition (GAIN) (GAIN, 2015), which based its interventions on three important nutrition pillars: Large-Scale Food Fortification, which focuses on millers and traders, multi nutrient supplements to advance home fortification and linking agriculture and nutrition programming.

The aim was to reach 95 percent of the population with fortified vegetable oil and 74 percent of the population with fortified wheat flour. The program began in February 2011; GAIN’s grant ended in September 2015 (http://www.gainhealth.org.) The Ministry of Public Health and Sanitation subsequently signed a Memorandum of Understanding (MOU) with Kenya Bureau of standards (KEBS) to administer the Food Fortification Logo (Appendix 01) and certification of products which fulfill the requirements of the relevant Kenya Standard with respect to Fortification.

The National food fortification programme, through the four years of the implementation 4.7 million people were reached with fortified maize flour, ((Save the children, Kenya, 2015). Kenya has about 25 large scale millers, of these, 18 have a capacity of more than 150 Metric tons per day and the others are medium capacity of 50 to 150 Metric tons per day. The total milling capacity in Kenya at present is about 3,500 Mt/ per day (Lucy Styles, et al, 2016).

Packaged dry milled maize products should be fortified and conform to the requirements specified here below (Table 2.4) according to the legal notice. This study thus sought to confirm whether there is compliance with the fortification requirements for maize four available for public consumption.
Table 4: Micronutrient fortification guidelines in Kenya

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortification compound</th>
<th>Recommended factory average</th>
<th>Regulatory requirements (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Vitamin A plam.SD 0</td>
<td>0.5 ± 0.02</td>
<td>0.2</td>
</tr>
<tr>
<td>Thiamine (Vitamin B1)</td>
<td>Thiamin Mononitrate</td>
<td>4.0± 2.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Riboflavin (Vitamin B2)</td>
<td>Riboflavin</td>
<td>3.5± 2.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Niacin (Vitamin B3)</td>
<td>Niacin amide 2</td>
<td>25±5</td>
<td>15</td>
</tr>
<tr>
<td>Folic acid</td>
<td>Folic acid</td>
<td>1.5±1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Pyrodoxine (Vitamin B6)</td>
<td>Pyrodoxine</td>
<td>5.0±2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Vitamin B12 0.1% WS</td>
<td>Vitamin B12 0.1% WS</td>
<td>0.005±0.002</td>
<td>0.002</td>
</tr>
<tr>
<td>Iron</td>
<td>NaFe EDTA</td>
<td>10±5</td>
<td>5</td>
</tr>
<tr>
<td>Total iron</td>
<td>Total iron</td>
<td>20±5</td>
<td>15</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>30±10</td>
<td>20</td>
</tr>
</tbody>
</table>

These are nine micronutrients, both vitamins are recommended for fortification of different foods in Kenya.

### 2.14. Consumer Awareness on Fortification

Consumers are the central point of any economic activities in a country. Consumer awareness is an act of making sure the consumer or buyer is aware of the information about a product. This empowers the consumers to make the right choices about product. Consumers have a right to correct information about a product. This includes the content, quality and safety of a product. (Nedumaran and Dhanasekaran, 2019).
In Kenya, levels of consumer awareness are noted to vary, based on different bio-demographical factors such as household income, size and area. (Rousseau and Venter, 2015). A study done in Kenya on awareness of fortified sugar in Kenya, (Kennedy et al., 2014), showed factors such as age of consumers, location (urban or rural), to be among factors affecting consumer awareness of fortification.

Mandatory maize flour fortification aims at offering affordable, and convenient mechanism of improving public health nutrition. Consumers need to be aware of the benefits of consuming fortified foods and any effects of fortification on the cost and availability of their food products. Knowledge of the fortification symbol would help customers be on the lookout for fortified foods when shopping. (Drake and Gerard, 2003). Hence the study sought to assess consumer awareness of mandatory maize flour fortification.

2.15. Maize Flour Millers, Challenges in Fortifying with Iron and Zinc

Maize flour fortification in Kenya is expected to be done by all millers. To ensure adequate fortification, there are universal standard procedures to be implemented by millers. These include, having proper fortifying equipment, use of the right premixes, fortification mix inventory records, production records, regular equipment inspection and regular analytical tests to ascertain adequate fortification. (Capacity Building of Small Millers, 2011).

World over, though fortification, has many success stories, it has experienced many challenges and handles especially for the producers of fortified foods. These include;
Cost of production. In addition to capital costs for acquiring fortification equipment such as feeders, there are operational costs such as premixes, labour and packaging. Quality control and quality assurance. This lies with the manufacturer and the government to ensure compliance. The manufacturer bears the costs of micronutrient level analysis, over and above the normal production costs. (Johnson and Wesley, 2010).

To address these challenges, partnerships between millers and governments have been advocated for. The government steps in to finance the initial high finance fortification infrastructure, quality control and quality assurance programmes. Such successful partnerships have been registered in countries such as Morocco and Vietnam. (Wirth et al., 2012).

In Kenya, the 2018-2022 fortification strategic plan was established to provide the national road map to enhance food fortification between 2018 -2022. For a successful fortification programme, the government is expected to carry out regulatory monitoring, certification of premix, external monitoring in factories and importation sites and commercial monitoring at distribution centres and retail stores. (Food Fortification Strategic Plan Final Press Aug 2018.)
2.16. Conceptual framework

![Conceptual framework diagram]

Figure 1: Conceptual framework. Conceptual framework adopted from the UNICEF conceptual framework of malnutrition.

From this frame work, though policies are in place for maize flour fortification as a tool to fight hidden hunger, all stake holders have a role to play and all factors affecting adequate fortification need to be addressed to ensure positive results of the fortification program.
CHAPTER THREE: METHODOLOGY

The research method stipulates the activities and procedures that were undertaken to come up with the findings of the study. It describes in detail the methods used in data collection and analysis to achieve the objectives of the study. The survey intended to establish if the correct amounts of Zinc and Iron are being added to maize flour available for sale to the public by maize flour millers.

3.1. Study Design

A cross sectional survey design was used (Ranganathan and Aggarwal, 2018). This design helped the researcher to collect actionable data that can be used in decision making.

3.2. Study Area

The study was done in Nairobi County in Kenya. The county was purposively selected because maize flour is the preferred source of starch (De Groote and Kimenju, 2012). Nairobi County is one of the 47 counties in Kenya. It is the most populous county with a population of 4.39 million according to the 2019 census. It is the capital and the largest city in Kenya. To ensure a wide geographical coverage of the Nairobi County, the researcher visited different 9 former districts of the Nairobi County seeking for maize flour samples. The districts visited were Westlands, Lang’ata, Kasarani, Dagorreti, Starehe, Kamukunji, Embakasi, Makadara and Njiru.

3.3. Maize Flour Sample Size

Maize flour available for sale in supermarkets and shops in Nairobi County were purchased as samples to meet the minimum acceptable sample size of 30. (Wayne W.,
A total of 35 maize flour brands were collected. Any available maize flour brands were conveniently collected from the shops without repeating a brand, to meet the targeted sample size. This was because of financial hitches which also had a bearing on the logistics of sample collection.

3.4. Consumer Sample Size

The Fisher’s formula (1988), was used to determine the sample size for consumers (Jung, 2014)

\[ n = \frac{z^2pq}{d^2} \]

Where;

- \( n \) is the minimum sample size for a statistically significant sample size.
- \( z \) is the normal deviant at the potion of 95%. Thus \( z = 1.96 \)
- \( p \) = expected proportion = 50%.
- \( d \) = margin of error in estimating \( p \) = 0.05
- \( q \) = 1 - \( p \)

Hence;

\[ n = \frac{1.96^2 \times 0.5(1-0.5)}{(0.05)^2} \]

\[ n = 384. \]

3.5. Maize Flour Millers’ Sample Size

The researcher sought to know the millers’ challenges in maize flour fortification. The researcher contacted all the millers whose samples were collected. Those who responded and accepted to participate in the study were sent the questionnaires. Based
on convenience, those who responded within two weeks were considered for the study. Hence a sample size of four millers was used.

3.6. Inclusion and Exclusion Criteria

3.6.1. Inclusion

Fortified maize flour bearing the fortification symbol.

Maize flour available for sale in shops in Nairobi County.

Consumers above the age of 18 years. Younger shoppers were not included as it was believed they had less shopping experience and would give biased results (Groote et al., 2011).

3.6.2. Exclusion criteria

These parameters made some maize flour samples ineligible for the study. Expired maize flour products and damaged packets of maize flour packets were not picked for the study. Consumers who did not know about maize flour fortification.

3.7. Data Collection Tools

To collect data, the researcher used questionnaires for the consumers and millers, interviews for the consumers with feedback being recorded in the ODK tool kit. Observation was used to check for the fortification symbol on the maize flour samples. Atomic Absorption Spectrometer was used to get the amounts of Iron and Zinc in the samples.
3.8. Data Collection Procedure

3.8.1. Maize flour samples

The study involved sourcing maize flour samples from the market, analysis of the samples in the laboratory. A total of 35 maize flour brands were purchased for the study. To get the 35 maize flour samples, a packet weighing one or two kilograms per brand was randomly purchased as any consumer would shop for flour. No samples were collected directly from millers. This was to ensure that what was analysed was what was actually consumed by the public. For millers who have different brands of maize flour retailing in the shops, only one brand per miller was picked. This was achieved by listing down all brands by a miller and the brand to purchase selected by rolling a dice.

During shopping, the researcher checked for the fortification symbol and the expiry date of the product and picked any packet from the shelves as the shoppers would do. The collected maize flour samples were transferred from their original packaging to brown Kraft paper bags for confidentiality. Each sample was coded for confidentiality and labeled. The labels contained the brand’s code, the collection date and the date of manufacture. The Codes used were Alphabetical letters ((A to AL).

The samples were stored in a cool, dry place away from direct sunlight according to the manufacturers’ instructions and transported to the laboratory for analysis. All samples collected were taken to the laboratory for Iron and Zinc analysis, hence the researcher did not do a further sampling. The laboratory conducting the analysis was SaNas accredited. The 35 samples were analysed according to KS EAS 768:2012 requirements for maize fortified milled products.
Atomic Absorption Spectrometry (AAS) was used to analyse for Iron and Zinc in the maize flour samples. This method determines the quantity of elements using absorption of atomic radiation by free atoms in the gaseous state (Butcher, 2005). To ensure a representative sample was collected, each flour sample was thoroughly mixed then a 2 grams sample drawn for each element. The 2 grams maize flour sample was converted to dry ash by putting it in the Muffle Oven at 600-800 degree Celsius for a minimum of four hours. After cooling, the ash was then digested by boiling it in 20% Hydrochloric acid for 30 minutes. The undissolved ash was filtered into a volumetric flask of 50 millilitres and the solution made to the mark (50ml) by adding distilled water. The solution was transferred to the atomic absorption spectrometer to take the readings. The same digestion procedure was used for the two elements, but reading was done separately to get the amount of Zinc (ppm) and Iron (ppm) in the flour samples. Iron measurement was done at a wavelength of 248.3nm and zinc at 213.9nm. The machine was programmed to print out the results of the quantities in the solution in parts per million (ppm). Three readings were taken for each sample and each element.

### 3.8.2. Maize flour consumers

Consumer questionnaires (Appendix 04) were used to collect information from maize flour shoppers. Multi stage sampling was done to get at least 42 maize flour shoppers from each of the former nine districts in Nairobi County in order to get the 384 shoppers required for research. For each of the nine districts, stratified random sampling done to give regions in the district based on social economic status. From each region, simple random sampling was done to pick three supermarkets. With a target of about 15 shoppers per supermarket, the researcher sought permission from
the supermarket market manager to interview shoppers for the purpose of this study only.

Every willing customer who knew about fortification was interviewed at the point of purchasing flour, until the target number was achieved. To administer the questionnaire, the researcher sought consent from the shoppers by introducing herself and the study. Once granted permission, the researcher issued the questionnaire to the shopper, who would fill it in the presence of the researcher. The shoppers were allowed to seek clarity on any questions that were not clear. Others were interviewed by the researcher and their answers keyed into the ODK phone App. Some of the main data collected from consumers included: gender, age, location and frequency of consuming maize flour. It also sought to know their knowledge on maize flour fortification and if they knew the Kenyan fortification logo. The interview took approximately ten minutes to complete.

3.8.3. Maize flour millers

A questionnaire (Appendix 03) was used to get feedback from millers whose brands had been picked for the study. After getting consent, the questionnaires were emailed to them. The response was to be sent back to the researcher in two weeks’ time as agreed during the introduction. For those emailed the questionnaire, constant follow up was done to fill and send it back to the researcher. Four responses were received within the given time frame. Responses were received from three Production managers and one Quality assurance manager.
Questions asked included: production capacity of the facility, access to fortification material, laboratory access and quality control checks and if they use the fortification Logo on their products. Most millers were not willing to participate in the study and termed their production processes as confidential.

The researcher also sought information from Kenya Bureau of Standards (KEBS) being the body mandated to give the fortification Logo through a questionnaire (Appendix 05). The KEBS questionnaire was filled by a laboratory personnel involved in fortified maize flour analysis. Among the questions asked was the support of KEBS to millers fortifying maize flour.

3.8.4. Observation for fortification logo and listed fortificants

Observation was used to identify the products with the fortification logo. All fortificants listed on the maize flour packaging were also observed and listed.

3.9. Data Management and Analysis

3.9.1. Amounts of Iron and Zinc

After examining zinc and iron contents of maize flour from thirty five different millers in the laboratory, data was extracted and entered on excel spreadsheet (version 2016) and imported into R statistical software package for analysis.

Results for the amounts of Zinc and iron in the maize flour samples were compared against minimum set standards in order to determine whether they met the required standards on fortification. Pearson correlation was carried out to determine whether there was any relationship between iron and zinc samples.
3.9.2. Consumer questionnaires

Data from the interviews was entered in an electronic data file as it was received from the field. The consumers’ questionnaire was uploaded on ODK collect App on mobile phones. This made data collection easy and was a factor in environmental conservation since the researcher did not have to print many questionnaires. In addition, after interviewing three hundred and eighty four shoppers, data was entered into an open source software (RED Cap version 7.01) and later imported into R statistical software for analysis. Data collected was cleaned for any questionnaires that were not adequately answered. Statistical analysis was conducted using R statistical software (version 3.2). This was done to get percentages for the different questions in the questionnaire.

3.9.3. Maize flour millers’ questionnaire

No statistical analysis was done on feedback from the miller’s.

3.9.4. Observation

An observation was done on the packs that had the fortification symbol and the minerals listed on the packaging. No statistical analysis was done on findings through observation.

3.10. Data Presentation

3.10.1. Chemical analysis for Iron and Zinc

Data from the analysis of Iron and Zinc in maize flour samples was presented in counts, prose, tables, bar graphs and pie charts.
3.10.2. Consumer questionnaires

Research findings were from consumer questionnaires were presented in counts, prose, tables, bar graphs and pie charts as shown in the texts.

3.10.3. Maize flour millers’ questionnaire

Research findings were presented in prose.

3.11. Ethical Considerations

Approval was granted by Institutional Research Ethics Committee (IREC) (Moi University). Approval number: FAN: IREC 1948 granted on 19th September 2017. (Appendix 06).

Informed consent was sought from the consumers to participate in the interview. Consumer responses were blinded for confidentiality. All samples and the analysis results were coded with the codes known only by the researcher. Data collected was confidentially stored and handled by the researcher only. The filled questionnaires were safely locked up by the researcher for confidentiality. Data entered into the computer was password protected to limit unauthorized access.
CHAPTER 4: RESULTS

This chapter represents the findings of the study based on the three objectives.

4.1. Amount of Zinc and Iron

The first objective sought to find out the amount of Iron and Zinc in the 35 maize flour samples collected for the study. The maize flour samples marked were coded A to AL and the amounts of Iron and Zinc is in parts per million (ppm).

4.1.1. Laboratory results for Zinc

The Sample G had the highest amount of Zinc at 56.25 ppm, while sample C recorded the lowest amount with 10.64 ppm. Table 3, summarises the amount of Zinc in the 35 samples of flour that were analysed.

Table 5: Amount of Zinc in maize flour samples

<table>
<thead>
<tr>
<th>Sample</th>
<th>Zinc (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>52.9</td>
</tr>
<tr>
<td>B</td>
<td>17.34</td>
</tr>
<tr>
<td>C</td>
<td>10.64</td>
</tr>
<tr>
<td>D</td>
<td>47.86</td>
</tr>
<tr>
<td>E</td>
<td>16.68</td>
</tr>
<tr>
<td>F</td>
<td>37.36</td>
</tr>
<tr>
<td>G</td>
<td>56.25</td>
</tr>
<tr>
<td>H</td>
<td>17.88</td>
</tr>
<tr>
<td>I</td>
<td>23.07</td>
</tr>
<tr>
<td>J</td>
<td>52.22</td>
</tr>
<tr>
<td>K</td>
<td>13.78</td>
</tr>
<tr>
<td>L</td>
<td>40.26</td>
</tr>
<tr>
<td>M</td>
<td>20.01</td>
</tr>
<tr>
<td>N</td>
<td>13.98</td>
</tr>
<tr>
<td>O</td>
<td>23.56</td>
</tr>
<tr>
<td>P</td>
<td>40.72</td>
</tr>
<tr>
<td>Q</td>
<td>18.34</td>
</tr>
<tr>
<td>R</td>
<td>34.83</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>Zinc (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>42.04</td>
</tr>
<tr>
<td>T</td>
<td>17.71</td>
</tr>
<tr>
<td>U</td>
<td>17.72</td>
</tr>
<tr>
<td>V</td>
<td>15.71</td>
</tr>
<tr>
<td>X</td>
<td>19.42</td>
</tr>
<tr>
<td>Y</td>
<td>32.7</td>
</tr>
<tr>
<td>Z</td>
<td>35.69</td>
</tr>
<tr>
<td>AA</td>
<td>40.97</td>
</tr>
<tr>
<td>AB</td>
<td>27.42</td>
</tr>
<tr>
<td>AC</td>
<td>17.76</td>
</tr>
<tr>
<td>AD</td>
<td>37.8</td>
</tr>
<tr>
<td>AE</td>
<td>34.47</td>
</tr>
<tr>
<td>AG</td>
<td>46.06</td>
</tr>
<tr>
<td>AI</td>
<td>17.01</td>
</tr>
<tr>
<td>AJ</td>
<td>17.27</td>
</tr>
<tr>
<td>AK</td>
<td>30.96</td>
</tr>
<tr>
<td>AL</td>
<td>48.45</td>
</tr>
</tbody>
</table>
Amount of zinc in Maize Flour Compared to the required standards is presented in figure 2 below. 60% of samples met the minimum zinc standards requirement of =>20 ppm.

Figure 2: Amount of Zinc in maize flour samples compared to the standard
4.1.2. Laboratory analysis of Iron

The amount of Iron in the 35 maize flour samples is summarized in table below. The sample with the highest amount of Iron was sample M with 15.45 ppm, while sample C had the least amount with 6.49 ppm.

Table 6: Amount of Iron in maize flour samples

<table>
<thead>
<tr>
<th>Sample</th>
<th>Iron (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>18.52</td>
</tr>
<tr>
<td>B</td>
<td>9.29</td>
</tr>
<tr>
<td>C</td>
<td>6.49</td>
</tr>
<tr>
<td>D</td>
<td>14.01</td>
</tr>
<tr>
<td>E</td>
<td>11.63</td>
</tr>
<tr>
<td>F</td>
<td>14.87</td>
</tr>
<tr>
<td>G</td>
<td>12.72</td>
</tr>
<tr>
<td>H</td>
<td>10.23</td>
</tr>
<tr>
<td>I</td>
<td>11.09</td>
</tr>
<tr>
<td>J</td>
<td>14.03</td>
</tr>
<tr>
<td>K</td>
<td>9.75</td>
</tr>
<tr>
<td>L</td>
<td>12.79</td>
</tr>
<tr>
<td>M</td>
<td>15.45</td>
</tr>
<tr>
<td>N</td>
<td>12.52</td>
</tr>
<tr>
<td>O</td>
<td>11.23</td>
</tr>
<tr>
<td>P</td>
<td>14.41</td>
</tr>
<tr>
<td>Q</td>
<td>9.9</td>
</tr>
<tr>
<td>R</td>
<td>11.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>Iron (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>9.01</td>
</tr>
<tr>
<td>T</td>
<td>10.86</td>
</tr>
<tr>
<td>U</td>
<td>13.2</td>
</tr>
<tr>
<td>V</td>
<td>12.29</td>
</tr>
<tr>
<td>X</td>
<td>14.39</td>
</tr>
<tr>
<td>Y</td>
<td>11.72</td>
</tr>
<tr>
<td>Z</td>
<td>9.9</td>
</tr>
<tr>
<td>AA</td>
<td>12.26</td>
</tr>
<tr>
<td>AB</td>
<td>19.02</td>
</tr>
<tr>
<td>AC</td>
<td>1.08</td>
</tr>
<tr>
<td>AD</td>
<td>11.24</td>
</tr>
<tr>
<td>AE</td>
<td>16.87</td>
</tr>
<tr>
<td>AG</td>
<td>12.89</td>
</tr>
<tr>
<td>AI</td>
<td>8.83</td>
</tr>
<tr>
<td>AJ</td>
<td>7.41</td>
</tr>
<tr>
<td>AK</td>
<td>10.94</td>
</tr>
<tr>
<td>AL</td>
<td>17.73</td>
</tr>
</tbody>
</table>
Amount of iron (ppm) in maize flour was compared to the required standards (the red horizontal strip). From the 35 samples, 14.29% of them met the minimum iron standards requirement of $\geq 15$ ppm. The comparison of the samples is presented in the figure below.

**Figure 3: Amount of Iron in maize flour samples compared to the standard.**

![Graph showing iron content in maize flour samples]

4.1.3. **Samples that were both iron and Zinc Compliant**

The distribution of iron and zinc over the required minimum standards on fortification, the minimum amount of Zinc required to be 20ppm and Minimum Iron to be 15ppm. Overall, only 14.29% of the 35 samples were adequately with iron and Zinc as per the set fortification standards. Sample M had the least deviation from the standards for both Iron and Zinc. The highest deviation for Iron was sample A and sample AB had the highest deviation for Zinc. The findings are summarised in the table below.
Table 7: Number of samples that were both iron and Zinc compliant

<table>
<thead>
<tr>
<th>Sample</th>
<th>Zinc (ppm)</th>
<th>Minimum standard</th>
<th>Difference</th>
<th>Iron (ppm)</th>
<th>Minimum standard</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>52.19</td>
<td>20</td>
<td>32.19</td>
<td>18.52</td>
<td>15</td>
<td>3.52</td>
</tr>
<tr>
<td>AB</td>
<td>27.42</td>
<td>20</td>
<td>7.42</td>
<td>19.02</td>
<td>15</td>
<td>4.02</td>
</tr>
<tr>
<td>AE</td>
<td>34.47</td>
<td>20</td>
<td>14.47</td>
<td>16.87</td>
<td>15</td>
<td>1.87</td>
</tr>
<tr>
<td>AL</td>
<td>48.45</td>
<td>20</td>
<td>28.45</td>
<td>17.73</td>
<td>15</td>
<td>2.73</td>
</tr>
<tr>
<td>M</td>
<td>20.01</td>
<td>20</td>
<td>0.01</td>
<td>15.45</td>
<td>15</td>
<td>0.45</td>
</tr>
</tbody>
</table>

The same findings were summarised on the figure below, where only 14.29% samples are within the red cut off lines, indicating compliance.

**Figure 4: Samples complying with Iron and Zinc standards.**
4.1.4. **Pearson's correlation coefficient between iron and zinc**

When Pearson’s correlation was carried out to determine the relation between zinc and iron fortification, it showed a negative correlation coefficient of 0.487787.

![Pearson's correlation between amounts of Iron and Zinc.](image)

**Key**: 0>40-Amount in ppm

A to AL- sample codes.

**Figure 5**: Pearson’s correlation between amounts of Iron and Zinc.
4.2. Consumer Views

The second objective sought to get consumers views on fortification, particularly maize flour fortification. The response rate was 100%. The respondents were interviewed to gauge their views on various issues around fortification.

4.2.1. Gender of respondents

The researcher did a survey of the gender of the consumers who participated in the study. Of the 384 respondents, 234 were female at 61% and males at 39%.

![Figure 6: Gender distribution of the respondents](image-url)
4.2.2. Age distribution of respondents

Figure 4.6, shows age distribution of the respondents who had knowledge on fortification. Of all the respondents, those aged between 31 and 35 years were more knowledgeable on fortification of maize flour at 26% compared to those aged below 30 years and those above 36 years.

![Figure 7: Age distribution of the respondents](image-url)
4.2.3 How consumers obtained knowledge on food fortification

Knowledge on fortification was attained through different channels. A total 41% of the respondents obtained knowledge through the media. Packaging was one of the sources of information at 13.3% whereas a small percentage at 1% of respondents obtained through advertisements. Social media played a role as a source of knowledge on food fortification at 10.5%. The findings are summarised in the figure below.

Figure 8: Source of knowledge on food fortification
4.2.4. Types of food the consumers believed to be fortified

Approximately 37.1% of respondents mentioned maize flour as the main food fortified. 11% did not know any fortified foods. Among other foods that stood out, was salt, sugar, cereals, blue band margarine and milk.

Figure 9: Knowledge on fortified foods.
4.2.5. Knowledge on benefits of fortification

More than half 196/384 (51 %) of those interviewed reported nutrition as the major benefit of fortifying food, followed by health 154/384 (40 %). 9% mentioned fortification is done to improve the quality of the product.

![Figure 10: Knowledge on benefits of food fortification.](image-url)
4.2.6. Number of times the consumers consumed maize flour per week

Majority of respondents reported to consume maize flour meal at least 2 and 3 times per week, 24% and 21% respectively. 8.7% of the consumers mentioned consuming maize flour more than six times a week. The weekly consumption is summarised on figure 4.10 below.

Figure 11: Number of maize flour consumption in a week.
4.2.7. Effects of food fortification on cost of maize flour

Majority 278/384 (72.5 %) of respondents believed fortification affected the cost of maize flour, unlike 27.5 % who said fortification did not affect the cost of maize flour available in the shops.

Figure 12: Effects of food fortification on cost of maize flour
4.2.8. Consumer confidence that millers fortify maize flour

More than half 196/384 (51%) of those interviewed had confidence that maize millers fortify their products with the recommended fortificants.

Figure 13: Respondents confidence in millers fortifying maize flour
4.2.9. Reasons for not fortifying maize flour

Of the respondents 49% lacked confidence that millers fortify their maize flour. The reasons mentioned included corruption at 40%, cost of fortification at 30%, and poor policies at 20%. Lack of resources such as fortification equipment as the reason for lack of adequate fortification was given by 6% of the respondents.

![Figure 14: Respondents reasons for lack of adequate fortification.](image-url)
4.2.10. Consumer awareness of the fortification symbol.

Most 219/384 (57.1%) of the respondents did not know the Kenyan of fortification symbol.

Figure 15: Awareness of the fortification symbol

4.2.11. Reasons for food fortification

A large proportion of the respondents 281/384 (73.3 %) agreed that the major reason for food fortification is for nutritional benefits (Figure 4.15). Other reasons such as legal requirements were given by 15.2%.

Figure 16: reasons for food fortification
4.2.12. Knowledge on mandatory maize flour fortification with zinc and iron

More than half 242/384 (62.9%) of respondents were not aware that millers were required to fortify their maize flour with zinc and iron.

![Knowledge of mandatory maize flour fortification](image)

**Figure 17:** Knowledge of mandatory maize flour fortification.

4.2.13 Association between Variables

In order to find out if there exists any association between fortification variables, statistical tests on the same data were carried out. This involved conducting Pearson’s chi-squared test for a number of variables, and an association between variables with a P value < 0.05 in the analyses was considered significant. There was a significant positive relationship between knowledge of fortification and age. (P-value = 0.024). To create awareness and a culture of consuming fortified foods in order to beat the hidden hunger, age of shoppers should be factored.
There existed a strong positive association (p-value = 0) between knowledge of fortification and Gender. Females seemed to know more about fortification and fortified foods than the males.

There existed a negative association (p-value <0.05) between Knowledge of Foods fortified in Kenya and Gender. This was not a significant association. The outcome of association of variables is summarized in the table below.

**Table 8: Association between variables**

<table>
<thead>
<tr>
<th>Association Variables</th>
<th>Relationship</th>
<th>P Values &lt;0.05</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortification Knowledge and age</td>
<td>Positive</td>
<td>0.024</td>
<td>Significant</td>
</tr>
<tr>
<td>Gender and Knowledge of fortification</td>
<td>Positive</td>
<td>0.0</td>
<td>Significant</td>
</tr>
<tr>
<td>Age and Knowledge of fortified foods</td>
<td>Negative</td>
<td>0.05</td>
<td>Non-Significant</td>
</tr>
<tr>
<td>Gender and Knowledge of fortified foods</td>
<td>Negative</td>
<td>0.05</td>
<td>Non-Significant</td>
</tr>
</tbody>
</table>
4.3. Maize Millers Challenges

During the study, the millers sampled stated that fortification was being done. Continuous fortification technology was used. It was clear from the millers and Kebs there was no government incentives to sustain the mandatory fortification program. According to the millers, fortification did not affect the consumer demand for maize flour.

Millers did not have in house labs capable of testing for the amounts of Iron and Zinc in their product. They have to outsource the services; hence do not have the results in time. The Kenya Bureau of standards had a laboratory that run tests on fortified products. It was reported by most millers that they send their samples for analysis at least once a year.

Through observation it was noted that all flour samples analysed had the fortification symbol. The elements listed on the flour packaging included: Vitamin A, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B6, Vitamin B12, Folate, Iron and Zinc.
CHAPTER 5: DISCUSSION

5.1. The Amount of Zinc and Iron in Fortified Maize Flour

All the maize flour samples collected, had the Kebs Quality standard mark. For the samples analysed, 28/35 (80 %) of the samples were under government subsidy project of reduced flour prices during the 2017 project to ensure sufficient food for the Kenyan population.

On physical observation of the packaging, only 7 out of the 35 of the samples did not have a listing of mineral and vitamins added to the flour on the packaging. It was also noted that packaging played a role in creating fortification awareness at 13.3% after media and training which were at 41% and 26.7% respectively. All the samples picked were within the manufactures’ set expiry dates.

From the study the levels of Iron and Zinc did not meet the minimum levels set in the Kenyan gazette on maize flour fortification, hence not addressing the issue on Micronutrient deficiency as expected. 60% of the samples met the minimum required levels of Zinc of =>20mg/100g. 14.29% had the minimum amounts of Iron of =>15mg/100g. Overall, only 14.29% samples had adequate amounts of Iron and Zinc as per the set fortification guidelines in the 2012 fortification gazette notice. More samples met the zinc requirements at 60% of samples met the minimum zinc standards requirement of =>20 unlike iron at 14.29% of samples met the minimum iron standards requirement of =>15 ppm. With a coefficient of - 0.48 between Iron and Zinc, there was a weak relationship between a company deciding to fortify with the flour with Iron and Zinc. We could assume when a company increases the amount of Iron, it tends to
decrease the amount of zinc or there could be factors in the maize flour products that affect the availability of Zinc compared to Iron (Watzke, 1998). In studies done, joint supplementation of Iron and Zinc does not affect the biochemical status (Walker, et al, 2005) of either of the elements.

This means the products available for public consumption are not adequately fortified. The same findings were reported on a post implementation survey carried out in South Africa (Yusufali, Et al, 2012). The low results could be attributed to several factors that affect the fortification process (Peña-Rosas Juan Pablo, et al, (2014) .Such factors include quality of the premixes and the amount of premixes added to the flour. The premixes are imported hence posing the question of the cost of running the fortification program (Fiedler et al., 2014).

5.2. Consumer Views
The second objective sought to get consumers’ awareness on fortification. The researcher sought to know the gender that had more knowledge on fortification and of 70% respondent who had knowledge on fortification, 61 % were female.

There was a positive correlation between gender and knowledge of fortification. With the female shoppers being more, they could the ideal target group for fortification awareness campaigns in an effort to fight micronutrient deficiencies in Kenyan communities. Same findings were reported in a study on sugar fortification in Kenya. (Kennedy et al., 2014). Most shoppers were in ages 31-35 at 25.7%. There was a positive relationship between fortification and age (Linda et al., 2020). This means in creating fortification awareness, age of target group should be factored and this group
could be an ideal target for fortification awareness. 41% of the respondents who knew about fortification obtained knowledge through the media. Meaning, using the current media avenues available in Kenya would impact food fortification awareness among the Kenyan population. (Honka, et al, 2017).

Approximately two fifths (37.1%) of respondents mentioned maize flour as the main food fortified with a consumption of maize flour meals being 2 to 4 times a week. This is can compare to a study done in Kibwezi district, where consumption was reported to up seven times a week. (Kilonzo, 2012). This means maize flour as a fortification vehicle in Kenya, if adequately fortified, a wide population in Nairobi County would have Iron and Zinc in their diets. Among the foods listed by consumers as fortified, the highest was cereals at 37.1% followed by maize flour at 6.1%. Though Salt in Kenya is fortified with Iodine, it was not majorly mentioned at only 3.8%. Only less than 10% mentioned oils and fats to be fortified.

During the study, (73.3%) of respondents agreed that the major reason for food fortification was for nutritional benefits (Griffiths, 2003). More than half, 51% of those interviewed had confidence that millers fortify maize flour, although 72.5% were afraid that fortification would increase the cost of flour.

More than half (51%) of those interviewed had confidence that millers fortify maize flour. Though of the respondents (49%) who lacked confidence that millers fortify their maize flour, mentioned reasons such as corruption at 40%, and costs of production (31%) (Roks, 2014) such as the import of premixes and fortification equipment.
Respondents also mentioned policies at 20% to be the major reasons for not fortifying (Bromage et al., 2018).

From this study 62.9% of respondents were not aware that millers were required to fortify their maize flour with zinc and iron hence cannot put pressure on the producers and policy makers to ensure maximum compliance to the legal requirement. Low levels of awareness of mandatory fortification were also reported in a study carried out in Mongolia and Harbin. (Bromage et al., 2019).

5.3. Maize Flour Millers’ Challenges
The lack of cooperation and response by most millers during the study could be an indicator that they are not confident with their fortification processes. Millers did not have in-house quality control facilities and costs of laboratory analysis are high meaning there were no adequate quality checks. Same findings were mentioned in a report in Tanzania on fortification monitoring. (Food Fortification Regulatory Monitoring Policy Guidance (2018.). This means the amounts of iron and zinc in the flour cannot be verified before being released from the mills to the public. The government can also facilitate establishment of laboratories as an incentive for millers to analyse their products and get real time results during production (Bymolt, 2017). The overall cost of analysis was very high, hence could affect the consistency of monitoring by millers (Mkambula et al., 2018). This could also be due to lack of monitoring of the fortification process by stake holders such as the Government at the point of production hence not taken seriously by the millers (Makhumula et al., 2014).
CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

This chapter outlines conclusions drawn from the study based on the objectives.

6.1. Conclusion

There was fortification of maize flour with iron and zinc but the amount of fortificants in fortified maize flour was way below the recommended standards. Although the government made it a legal requirement (Appendix 07) to have maize flour fortified with iron and zinc, this study reveals that this directive has not been adequately complied with.

Though media was noted to be effective in passing messages on fortification, it was noted that there was still need to create more awareness and increase consumers’ confidence in shopping and consumption of fortified foods.

The Government and all stake holders need to play an active role in monitoring compliance to the fortification standards. As per the study by (Luthringer, et al., 2015) political risk of enforcement and lack of resources for the inspectorate bodies affect the quality of fortification programs. Cooperation from the maize flour millers was very poor. Most millers were not willing to share any details pertaining to fortification.

6.2. Recommendations

From conclusion the study, the researcher recommends:
6.2.1. Recommendations on policy

1. The government to put incentives in place such as cheap and easy to access laboratories for routine and regular monitoring of the products available for public consumption (Luthringer, et al, 2015a).

2. Having a multisectral approach to fortification in Kenya would ensure all stakeholders are accountable to ensuring adequately fortified foods are available for public consumption as per a workshop in South East Asia held to review fortification programs. (Gayer and Smith, 2015)

6.2.2. Recommendations on training

1. Public nutrition education programmes through media to educate the public on fortification.

2. The school curriculum to include to topics that create awareness on benefits of consuming fortified foods.

6.2.3. Recommendations on practice

1. Quality control and quality assurance systems should be improved to ensure compliance to fortification standards set by the government.

2. Legal action to be taken on maize flour millers not complying with the fortification regulation.

6.3. Challenges encountered

A number of problems were encountered during the study. Due to limited financial resources available for this study, it was not possible to analyze all the minerals and vitamins listed on the maize flour packaging. Hence the study focused on Iron and Zinc
micronutrients based on their great effect on public health and that it is mandatory in Kenya to fortify maize flour with the two elements. The other challenges were uncooperative respondents, especially maize flour millers.

6.4. Dissemination

The researcher is working on publishing the findings of this study.
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APPENDICES

APPENDIX 01: LETTER OF INTRODUCTION

College of Health Sciences
P O Box 4606 -30100

ELDORET, Kenya
Tel: 254-053-33104
Fax: 254-053-33041
Telex: 35047 MOIVARSITY
E-mail: mnnangami@gmail.com
Cell phone: +254-733-764-361

February 20, 2017

To Whom It May Concern

Re: Letter of Introduction of Moi University MPH Candidate to Conduct Research

This is to confirm that Ireen Mutuma MPH-2015 in Nairobi Campus is bone fide student of Moi University MPH programme based in Nairobi at Bazaar plaza and is interested in undertaking a research in your organization.

The purpose of this letter is to request your office to authorize her to access relevant data. Her MPH thesis is titled “FORTIFICATION OF MAIZE FLOUR IN KENYA: A SURVEY OF ZINC AND IRON LEVELS AT THE POINT OF PRODUCTION.” She will share the following documents:

(1) Abstract of her proposal signed by her supervisors
(2) Letter of clearance from the Institutional Research and Ethics Committee (IREC)
(3) Any other relevant information
Please do not hesitate to contact the undersigned for any further clarification regarding this communication. The email and phone contacts are provided:
mnnangami@gmail.com; 0724-345-222

Yours sincerely,

Prof. Mabel Nangami,

MPH Programme Coordinator, Nairobi

Cc.

Dean, School of Public Health
APPENDIX 02: LETTER OF INFORMED CONSENT

(Adopted from Moi University College of health sciences / Moi teaching and referral hospital Institutional Research and Ethics Committee (IREC) informed consent form ICF)

Study Title: Maize flour fortification in Kenya: A survey of Zinc and Iron levels at the point of production in Nairobi County, Kenya

Name of the Investigator: Ireen Mutuma

Name of Organization: Moi University

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate) You will be given a copy of the signed Informed Consent Form

Part I: Information Sheet

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study.

Purpose of the study:

The study is being carried out for educational purposes only (Masters’ thesis) and it aims at assessing the state of fortified maize flour in relation to the stipulated fortification guidelines.
**Type of Research**

The study will involve a structured interview with your quality/Technical team leader and collection of flour samples for lab analysis.

**Confidentiality**

All reasonable efforts will be made to keep your protected information (private and confidential. All samples and questionnaires will be coded for confidentiality purposes.

**Part II: Consent of Participant:**

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time.

Name of Participating Company...........................................................................

Name of the Company representative...................................................................

Signature of the company representative..............................................................

Date......................................................................................................................

Name of the researcher..........................................................................................

Signature of the researcher....................................................................................

Date......................................................................................................................
APPENDIX 03: MAIZE FLOUR PRODUCERS QUESTIONNAIRE

Questionnaire NO: ………

GUIDE QUESTIONS FOR MILLERS INVOLVED WITH THE PRODUCTION OF FORTIFIED MAIZE FLOUR.

(Adopted from Two Decades of Food Fortification in Nigeria: Situational Analysis; By Adeniyi Kayode Busari-2013)

Do I have consent for this Interview-Yes / No?

1. Company Name: .................................................................

2. Principal contact person ............................................. Rank.................................

3. Contacts..............................................................................

Production capacity and access to fortification materials

1. Please provide names of maize products from your company: (Optional)
   a..............................................   b..................................................

2. Are your maize products fortified to meet legal requirements?
   Yes (1)_____   No (2) ______

   If Yes, state year of commencement, _________________

   If No, list reasons for non-compliance

3. Does your industry produce fortified product on regular basis all year round?
   Yes (1)______    No (2) ______

   If No, list reasons why plant is unable to produce

4. Does the plant have a dedicated production line for fortification of its products?
   Yes (1)______   No (2) ______

   If yes, is it done in batches________or continuous__________?
5. Does the plant have a functioning fortification department manned with staff?
   Yes (1) ________  No (2) ________
   How Many? ________

6. Does the plant currently have adequate supply of good quality premix for its fortification program on a sustainable basis?
   Yes (1) ________  No (2) ________
   If No, What are the challenges ________________________________ ?

7. Are there Government incentives to industries to sustain the mandatory fortification program?  Yes (1) ______  No (2) ______
   If YES, list these incentives
   a) ________________________________
   b) ________________________________
   If NO, List the incentives you will like Government to put in place
   ________________________________

8. Are the marketing objectives for the consumption of fortified products being met?
   Yes (1) ______  No (2) ______

9. **Iron and Zinc deficiency**
   a) Are the plant personnel aware of **iron** deficiencies and consequences in children?
      Yes (1) ______  No(2) ______
   b) Are the plant personnel aware of **iron** deficiencies and consequences in pregnant women? Yes(1)______No(2)____
   c) Are the plant personnel aware of **Zinc** deficiencies and consequences in children?
      Yes(1)______No(2)____
   d) Are the plant personnel aware of **Zinc** deficiencies and consequences in pregnant women Yes(1)______No(2)____
10. Has the fortification of the product significantly affected consumer demand for the product? Yes (1) _____ No (2) _____

**Laboratory and quality assurance practices**

11. a). Does the plant have laboratory facility for routine tests on fortified products?
Yes (1) _____ No (2) _____

12. Does the plant have access to adequate supply of laboratory reagents/other laboratory consumables in order to perform required tests in a timely fashion?
Yes (1) _____ No (2) _____

13. Select a characteristic that describes your laboratory skills
   a). Qualified
      Yes (1) _____ No (2) _____
   b). Adequate number
      Yes (1) _____ No (2) _____
   c). Adequate training
      Yes (1) _____ No (2) _____
   d) Adequate expertise
      Yes (1) _____ No (2) _____

14. Are routine product test performed during production and results recorded and available for inspection? Yes (1) _____ No (2) _____

15. a). Does your organization routinely inspect equipment for fortification and replace worn-out parts (e.g. spray nozzles) as recommended by the manufacture.
Yes (1) _____ No (2) _____

16. Is routine testing of fortificant (premix) being performed and results recorded and available for inspection? Yes (1) _____ No (2) _____

17. a) Do labels on packaging contain adequate information on fortification?
Yes (1) _____ No (2) _____

    b) Is the production date on the packaging?
       Yes (1) _____ No (2) _____

    c) Is the producers name on the packaging
d) Is the batch number/lot number on the packaging?

Yes (1) ______  No (2) ______

e) Are the micronutrients added labeled on the packaging?

Yes (1) ______  No (2) ______

f) Is expiry date labeled on the product?

Yes (1) ______  No (2) ______

g) Is the level of fortification (mg/kg) indicated on the packaging

Yes (1) ______  No (2) ______

18. a) Are fortified products stored properly before they are distributed?

Yes (1) ______  No (2) ______

b) Describe typical storage conditions for fortified products

19. Does your organization believe the inspections, enforcements, enforcement and suctioning process provided by law/regulatory agencies are fair effective?

Yes. (1) ______  No (2) ______

20. a) Does your organization have any collaborative arrangement with Kenya Bureau of Standards for the testing of your product as part of your routine quality assurance processes?  Yes (1) ______  No (2) ______

b) How often? __________

Thank you very much for your time
APPENDIX 04: QUESTIONNAIRE FOR MAIZE FLOUR CONSUMERS

Questionnaire No: ------

I am Ireen Mutuma, a Masters of Public Health, Human Nutrition Student, at Moi University. (PGH/PGH/NC/1010/2015). I am collecting data on shoppers for my, Thesis-Maize flour fortification in Kenya: a survey of zinc and iron levels at the point of production in Nairobi county Kenya. The Information collected is purely for academic purposes.

Is it okay if I ask you a couple of questions on food fortification?

Do I have your agreement to proceed? Yes/No

Shop Location: ________________________________

Gender
Male:__________
Female__________

Age bracket
1) 20-30.
2)30-35.
3)35-40.
4) 40-45.
5) 45-50.
6) 50-60.
7) Above 60.

Occupation: ________________________________

1. Do you know what fortification is? Yes (1) _______ No (2) _______

2. How did you get to know about fortification?

3. Do you know the fortification symbol? Yes (1) _______ No (2) _______

4. Do you know foods that are fortified in Kenya? Yes (1)_______ No (2) ______

Name any__________________________________________________________
5. When shopping, do you look for fortified foods? Yes (1) No (2)

6. How many times do you consume fortified maize flour in a week? 

7. What are the reasons for food fortification?

9. Do you know maize flour fortification with Iron and Zinc is mandatory in Kenya? Yes (1) No (2)

10. Do you think fortification affects the cost of maize flour? Yes (1) No (2)

11. Are you confident that maize millers are fortifying maize flour as per the legal standards? Yes (1) No (2)

   If No, Why?

12. What are the benefits of fortifying maize flour with Iron and Zinc?

   Thank you.
APPENDIX 05: QUESTIONNAIRE TO KENYA BUREAU OF STANDARDS

FORTIFICATION ANALYSIS TECHNICIAN

Do I have consent for this Interview-Yes / No?

1. Company Name: Kenya Bureau of Standards

2. Contacts.................................................................

Government support

3. Are there Government incentives to industries to sustain the mandatory fortification program? Yes (1) _____ No (2) _____

   If YES, list these incentives

   a) _______________________________________________

   b) _______________________________________________

   If NO, List the incentives you will like Government to put in place
   ___________________________________________________________________

4. Do manufacturing companies have any collaborative arrangement with Kenya Bureau of Standards for the testing of your product as part of your routine quality assurance processes?

   Yes (1) _______ No (2) _____

   b) How often? __________

Laboratory and quality assurance practices

5. Does the laboratory facility support routine tests for fortified products?

   Yes (1) _____ No (2) _____
6. Does the laboratory have access to adequate supply of laboratory reagents/other laboratory consumables to perform required tests in a timely fashion?

   Yes (1) _______  No (2) __________

7. Select a characteristic that describes the laboratory technicians.

   a) Qualified    Yes (1) _______  No (2) _______
   b) Adequate number  Yes (1) _____  No (2) ______
   c) Adequate training  Yes (1) _______  No (2) ______
   d) Adequate expertise  Yes (1) _______  No (2) ______

8. Is routine testing of fortificant (premix) performed and results recorded and available for inspection?  Yes (1)______  No (2) ____

9. Are the inspections, enforcements, enforcement and suctioning process provided by law/regulatory agencies are fair effective?

   Yes. (1)__________No (2) ______________

Thank you very much for your time
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORRET

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORRET
Tel: 35471/2/3

Reference: IREC/2017/67
Approval Number: 0001948
19th September, 2017

Irene Kathure Mutuma,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORERT-KENYA.

Dear Ms. Mutuma,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

“Maize Flour Fortification in Kenya: A Survey of Zinc and Iron Levels at the Point of Production in Nairobi County”.

Your proposal has been granted a Formal Approval Number: FAN: IREC 1948 on 19th September, 2017. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 18th September, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

Dr. S. Nyabera
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD
APPENDIX 07: KENYA GAZZETTE

LEGAL NOTICE NO 62. JUNE 2012

Legal Notice No. 62

THE FOOD, DRUGS AND CHEMICAL SUBSTANCES ACT Cap. 254)

IN EXERCISE of the powers conferred by section 28 of the Food, Drugs and Chemical Substances Act, the Minister for Public Health and Sanitation makes the following Regulations:—

THE FOOD, DRUGS AND CHEMICAL SUBSTANCES (FOOD LABELLING, ADDITIVES AND STANDARDS) (AMENDMENT) REGULATIONS, 2012.

Citation

1. These Regulations may be cited as the Food, Drugs and Chemical Substances (Food Labelling, Additives and Standards) (Amendment) Regulations, 2012.

Sub. Leg.

2. The Food, Drugs and Chemical Substances (Food Labelling, Additives and Standards) Regulations (in these Regulations referred to as “the principal Regulations”) are amended in regulation 2 by inserting the following new definitions in their proper alphabetical sequence—

“Food bio-fortification” means addition of nutrients through a process of genetic manipulation to mitigate the dietary deficiency in a food article;

“Food enrichment” means addition of nutrients to replace nutrients lost during processing or addition of nutrients to enhance existing nutrients in a food article;

“Food fortification” means addition of nutrients to bridge the dietary deficiency in a food article;

“Minister” means the Minister for the time being responsible for matters related to public health and sanitation.
3. Regulation 249 of the principal Regulations is amended by renumbering the existing provision as paragraph (1) and inserting the following new paragraph—

(2) Packaged wheat flour shall be fortified and conform to the food requirements specified here below:

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortification Compound</th>
<th>Recommended factory average (mg/kg)</th>
<th>Regulatory requirements mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Vitamin A plam.SD</td>
<td>2+_1</td>
<td>0.5</td>
</tr>
<tr>
<td>Thamin (Vitamin B1)</td>
<td>Thiamin Mononitrate</td>
<td>10+_5</td>
<td>5.0</td>
</tr>
<tr>
<td>Riboflavin(Vitamin B2)</td>
<td>Riboflavin</td>
<td>6+_3</td>
<td>2.5</td>
</tr>
<tr>
<td>Niacin(Vitamin B3)</td>
<td>Niacinamide</td>
<td>60+_15</td>
<td>40</td>
</tr>
<tr>
<td>Folates</td>
<td>Folic acid</td>
<td>1.5+_1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Pyrodoxine (Vitamin B6)</td>
<td>Pyrodoxine</td>
<td>6.5+_3.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Cabalamine (Vitamin B12)</td>
<td>Vitamin B120.1% WS</td>
<td>0.015+_0.005</td>
<td>0.00</td>
</tr>
<tr>
<td>Iron</td>
<td>NaFe EDTA</td>
<td>40+_10</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Total iron</td>
<td>50+_10</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide</td>
<td>40+_10</td>
<td>30</td>
</tr>
</tbody>
</table>

4. Regulation 253 of the principal Regulations is amended—

(a) by deleting the expression “15” appearing in paragraph (1) and substituting therefor the expression “13.5”.

(b) by inserting the following new paragraph immediately after paragraph (2)—

(3) Packaged dry milled maize products shall be fortified and conform to the requirements specified here below—
<table>
<thead>
<tr>
<th><strong>Nutrient</strong></th>
<th><strong>Fortification Compound</strong></th>
<th><strong>Recommended factory average (mg/kg)</strong></th>
<th><strong>Regulatory requirements mg/kg)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Vitamin A plam.SD</td>
<td>0.5±0.02</td>
<td>0.2</td>
</tr>
<tr>
<td>Thiamin (Vitamin B1)</td>
<td>Thiamin Mononitrate</td>
<td>4.0±2.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Riboflavin (Vitamin B2)</td>
<td>Riboflavin</td>
<td>3.5 ±2.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Niacin (Vitamin B3)</td>
<td>Niacinamide</td>
<td>25±5</td>
<td>15</td>
</tr>
<tr>
<td>Folates</td>
<td>Folic acid</td>
<td>1.5±1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Pyrodoxine (Vitamin B6)</td>
<td>Pyrodoxine</td>
<td>5.0±2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Cabalalmine (Vitamin B12)</td>
<td>Vitamin B120.1% WS</td>
<td>0.005±0.002</td>
<td>0.002</td>
</tr>
<tr>
<td>Iron</td>
<td>NaFe EDTA</td>
<td>10±5</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total iron</td>
<td>20±5</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide</td>
<td>30±10</td>
<td>20</td>
</tr>
</tbody>
</table>

Iron NaFe EDTA 10±5 5 15 Total iron 20±5 15 30 Zinc oxide 30±10 20 40

(4) The Minister may, from time to time, amend paragraph (3).

5. Regulation 258 of the principal Regulations is amended—

(a) By re numbering the existing provision as paragraph (1) and

(b) By inserting the following new paragraph—

(2) Vegetable fats and oils shall be fortified with Vitamin A in accordance with the Kenya Standard for Edible Fats and oils KS326-2:2009.

6. The principal Regulations are amended by inserting the following new Regulations immediately after Regulation 318—

319. Where no specifications are set out in any part of these regulations for the fortification of any food articles, but specifications have been established by the joint Food and Agricultural Organization and World Health Organization *Codex*
Alimentarius Commission the Specifications of the Codex Alimentarius Commission shall apply.

320. Labeling of fortified products shall be done in accordance with the relevant Kenyan Standard relating to nutrition.

Dated the 4th June, 2012.

BETH MUGO,

Minister for Public Health and Sanitation.