ASSESSMENT OF THE QUALITY OF FIXED DOSE QUININE SULFATE TABLETS SOLD IN BUSHENYI BASED ON THE BP SPECIFICATIONS

BY

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A RESEARCH REPORT SUBMITTED TO THE SCHOOL OF PHARMACY OF KAMPALA INTERNATIONAL UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF BACHELOR'S DEGREE OF PHARMACY

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DECLARATION

I, **KANDOLE RICHARD**, declare that this research report is a result of my own efforts and has never been submitted to any institution of higher learning for the award of a bachelor's degree in Pharmacy. The views herein are my own, unless stated, and where such has been the case, acknowledgement or reference has been quoted.

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APPROVAL

This research report has been submitted for examination with the supervision and approval of:

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DEDICATION

I dedicate this research report to my dear father Dr.TedsonKandole who has played such a crucial role in my life, financially, morally and spiritually. I haveable to reach this final step because of his unconditional love and support in every kind of way. May the good Lord abundantly reward and bless him for their great love and support and encouragement.

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I would like to extend my gratitude to my supervisor Mr. Ivan Ibanda and co-supervisorfor his support, guidance and for all the assistance he gave me towards making the undertaking of this research report possible.

LIST OF ABBREVIATIONS

DDIP – Drug Development and Industrial Pharmacy

CDC – Centers for Disease Control

WHO – World Health Organization

BP – British Pharmacopoeia

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

WHO defines a poor quality drug as the one that fails to meet pharmacopoeial standards of quality. It can be a counterfeit drug or a substandard drug or a degraded drug.

The poor quality of drugs is a vast and under reported problem, particularly affecting poorer countries. It is an important cause of unnecessary morbidity, mortality, and loss of public confidence in medicines and health structures. The prevalence of poor quality drugs appears to be rising, for instance, it has been estimated that of up to 15% of all sold drugs are of poor quality, and in parts of Africa and Asia the figure exceeds 50% (Robert *et al.,* 2007).

Counterfeit drugs are products deliberately made to resemble a brand name pharmaceutical. They may contain no active ingredient or contain ingredientsinconsistent with the package description. Substandard drugs are found even amongcheaper products, than counterfeit drugs which are common among more expensivedrugs, because some manufacturers wish to avoid costly quality control and good manufacturing practices (CDC, 2006).

The quality of commercially available drugs varies greatly among countries. Due to lackof regulations and poor quality control practices in some countries, the amount of activeingredients can be inconsistent (CDC, 2006).

Poor formulation techniques can affect the release ofactive ingredients from a tablet, with some tablets releasing very little, if any drug. Somedrugs may be contaminated with other substances. Poor storage conditions, especially inwarm and humid tropical environment may contribute to chemical degradation of many pharmaceuticals (CDC, 2006).

Tablets are prescribed widely and are a very effective means of providing drugs to patients. A basic assumption is that when a tablet is used by the patients, the drug from the tablet is released, dissolves, and is absorbed promptly and consistently into system circulation (Yeka, 2009).

The drug quality is needed for this to be a valid assumption. In addition, many drugs are absorbed appropriately while others are incompletely absorbed, due to factors relating to the drug, dosage form, and human physiology in the gastrointestinal tract. Optimal and consistent absorption of such drugs needs to be assured for the best therapeutic outcomes (Jouan, 2005).

Bioequivalence is an important consideration in several key situations involving batch to batch consistency, innovator to generic product therapeutic equivalence, and situations where a marketed product undergoes changes in certain aspects including formulation manufacturing processes and dosage strength (Gomes M.F, 2009).

Bioequivalence testing is considered as the surrogate for the chemical evaluation of the therapeutic performance of drug products. Pharmaceutically equivalent drug product are formulated to contain the same amount of active ingredient in the same dosage form and meet the same compendia or other applicable standards, but they may differ in characteristics such as shape, scorings, configuration, release mechanisms, packing, excipients, expiration time and within certain limits (FDA, 2003).

Pharmaceutical equivalence of drugs may be established by *in vitro* studies based on measurements intended to reflect the rate and extend to which the active pharmaceutical ingredient become available at the site of action. Based on the general consideration that *in vitro* drug dissolution test is predictive *in vivo* performance, *in vitro* drug dissolution test for immediate release tablets and capsules are used among other things, to ensure conformity of drug products to official or set specifications(B. J. Achan J 2007).

Poor quality medicines can either be Sub-standard drugs that are manufactured legitimately but contain inferior ingredients or too little API or can be counterfeited drugs that contain no API or wrong one (John Hopkins University, 2014).

Studies have also shown that poor quality pharmaceutical products have plague the Sub-Saharan Africa and South east Asia with about 660,000 death each year due to poor quality antimalarial drugs (John Hopkins University, 2014).

Poor quality drugs have also been shown to increase drug resistance e.g.chloroquine has been used for decades to treat malaria in Africa but has currently become almost useless in the malaria therapy *Adapted from a journal solving Africa's counterfeiting problem*

Malaria is a tropical parasitic disease caused by theprotozoa plasmodia. Four species are responsible for humanmalaria: *P. falciparum, P. ovale, P. vivax*and *P. malariae.*Of these, *P falciparum* is the most dangerous and accounts for the vast majority of malaria deaths, particularly in tropical Africa. Globally, 300–500 million clinical cases of malaria occur annually, out of which more than 1 million people die of the disease. Children below 5 years of age and pregnant women are most affected (WHO, 1999).

Malaria is a leading cause of low birth weight among infants, and contributes to a high rate of maternal death. Early diagnosis with prompt and effective treatment is one of the strategies for anti-malarial intervention inendemic countries (WHO, 1999). However, drug resistance may decreasethe efficacy of the anti-malarial drug therapy.The World Health Organization (WHO) in 1999 and 2001 developed and recommended artemisinin-based combination therapy in the management of acute uncomplicated P. *falciparum* malaria.

Most Africancountries south of the Sahara have adopted this policy. Despite this, the traditional anti-malarial drug 'quinine'still has a place in anti-malarial chemotherapy. Forexample, according to the National Anti-Malarial Policy of Nigeria, parenteral quinine is indicated in the management of severe malaria, while oral quinine is recommended in the management of acute uncomplicated malaria in pregnancy.

1.2 Statement of the problem

Poor quality medicines present an enormous public health challenge (WHO, 2006). No area of the world is unaffected, but mounting evidence shows that the problem is disproportionately severe in developing and emerging market countries, which also have a high burden of infectious diseases. In poor countries, like Uganda, essential and life-saving drugs used to treat infectious diseases such as tuberculosis and malaria are often the drugs under threat (Bate and Boateng, 2007). According to CDC (2006), in 1999, in Cambodia counterfeit antimalarial drugs were responsible for the deaths of at least 30 people every day.

The proliferation of generics of fixed dose quinine tablets in Uganda with variable prices is raising suspicion of difference in quality. In Uganda,quinine tablets in the market areavailable in various strengths from both local and foreign manufacturers. Drug quality is a source of great concern worldwide, particularly in many developing countries. Use of the substandard and counterfeit drugs endangers lives and wastes scarce resources. It appears that poor quality of fixed dose quinine tablets is linked to development of drug resistant strain of *Plasmodium parasites* which causes malaria. Evidence abounds on the circulation of poor quality drugs in tropical areas of the world (WHO, 1990). Counterfeiting of drugs and circulation of unlicensed drugs may be a major concern in a land locked country like Uganda. The quality of these antimalarials if not properly safeguarded may lead to therapeutic failure in patients and the development of drug resistance. This study was therefore aimed at assessing the quality of the fixed dose quinine tablets based on the British Pharmacopoeia.

1.3 Justification of the study

Some of the consequences of using poor quality/substandard antimalarial drugs are;

a) Loss of therapeutic effect and treatment failure (Bate and Boateng, 2007).
b) Complications and mortality due to malaria and toxic components of the drugs(Kelesidis et.al 2007).
c) High burden of malaria leading to mortality and morbidity (Kelesidis*et al.*, 2007).

Poor quality medicines are part of a broader phenomenon of substandard pharmaceuticals–medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases (WHO, 2006).

Studies done in Nigeria and Pakistan have highlighted the bioequivalence of some brands of quinine tablets and other pharmaceuticals (Muhammed *et al.*, 2016; Shuaibu, 2010). But there appears to be little information on the quality of quinine published in Uganda. Lack of this information on the quality of drugs may lead to serious health implications, waste scarce resources and contribute to drug resistance. The importance of having information on the quality and bioequivalence of drug products include: it generates data that will aid in drug policy making, promote consumer trust in health system, help to strengthen the drug quality assurance system, strengthen law enforcement, enhance cooperation among stake holders, increase the

availability of inexpensive quality assured drugs and raise awareness of the problem of counterfeits or substandard drugs among health professional and consumers. Quality of quinine is of great importance for efficacy and safety during treatment. This is good to ensure efficacy, prevent adverse drug reactions, reduce development of resistance and therefore maintain health care costs at all levels.

1.4 General objectives

To assess the quality of branded fixed dose quinine tablets sold at pharmacies in Bushenyi, Uganda in relation to the BP specifications.

1.5 Specific objectives

i. To determine the weight variability of the commonly used brands of quinine sold at pharmacies in Bushenyi, Uganda based on the BP specifications.

ii. To determine the friability of the selected quinine tablets based on the BP specifications.

iii. To determine the crushing strength (hardness) of the selected quinine tablets based on the BP specifications

iv. To determine the disintegration time of the quinine tablets sold at pharmacies in Bushenyi, Uganda based on the BP specifications.

v. To determine the drug content of the selected quinine samplesbased on BP specifications.

1.6 Research questions

Do the selected brands of fixed dose quinine tablets conform to the quality specified by the BP for weight variation, friability, disintegration time, hardness, drug content and thickness variation?

1.7 Scope of the study

This study will focus on the quality of fixed dose quinine 300mg tablets available in community andwholesale pharmacies in Bushenyi,Uganda. The study also will make insight into existence or otherwise substandard quinine tablets in the study area.

CHAPTER TWO

2.0LITERATURE REVIEW

2.1 Overview of the quality of drugs available on the market

Poor quality/substandard medicines represent an enormous public health challenge (WHO, 2006). Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way, in the form of tablets or capsules that look right, but which do not contain the correct ingredients and, in the worst case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality.

Poor quality medicines range from random mixtures of toxic substances to inactive, useless preparations. Occasionally, there can be ''high quality'' fakes that do not contain the declared active ingredients. In all cases, contents of counterfeits are unreliable because their source is unknown or vague and always illegal. Fake drugs can cause harm and sometimes lead to death (WHO, 2006).

Literature review was done to ascertain the extent of the problem of poor quality/substandard drugs. The information gathered through literature review flows from the global perspective, regional perspective and national perspective respectively.

Globally, in developed countries the percentage of poor quality drugs is estimated at 1% while in specific regions of the world, e.g. Asia and Africa the overall percentage is significantly higher than the global market average (Aria, 2008).

In India, in 2002 pharmaceutical companies suggested that in India's major cities, 1 in 5 medicines sold was a fake (WHO, 2002). A survey in Southeast Asia, showed that among 104 tablets presented as the antimalarial drug artesunate, 38% did not contain any artesunate(Newton *et al.*, 2001).

According to CDC (2006), in 1999, in Cambodia poor quality antimalarial drugs were responsible for the deaths of at least 30 people daily.

Regionally, a study conducted in 6 countries in most severely malarious parts of Africarevealed that 35% (73/210) of tested samples of antimalarial drugs were substandard(Bate *et al.*, 2008).

In Burkina Faso, a study on substandardantimalarial drugs showed that 32/77 (42%) samples were of poor quality, of which 2810 samples failed the visual inspection, 9 samples had substandard concentrations of theactive ingredients, 4 samples showed poor disintegration, and 1 sample contained none ofthe stated active ingredients (Tipke*et al.*, 2008).

According to the American Journal ofTropical Medicine and Hygiene 2004, in Cameroon fifty (38%) of 133 Chloroquine, 52(74%) of 70 quinine, and 10 (12%) of 81 antifolates had either no active ingredient, aninsufficient active ingredient, the wrong ingredient, or unknown ingredient(s). The studyresults of antimalarial drugs bought in Ghana, Kenya, Nigeria, Rwanda, Tanzania showed that 35% contained too little active ingredient or failed to dissolve,rendering them ineffective (Times online 2008). In six African countries a study wasconducted on the quality of antimalarial drugs which were on sale, and it revealed that 16 of 42 tested drugs (38%) on the Kenyan market were ineffective in treating the disease (IRIN Africa, 2008).

2.1 Overview about tablets

A tablet consists of one or more drugs (Active Pharmaceutical Ingredients) as well as a series of other substances (excipients) used in the formulation of a complete preparation. In the European Pharmacopoeia (2011), tablets are defined as 'solid preparations each containing a single dose of one or more active substances'.

Tablets are obtained by compressing uniform volumes of particles or by another suitable manufacturing technique, such as extrusion, molding or freeze-drying (lyophilization).They are intended for oral administration. Some are swallowed whole, some are chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated.Thus, a variety of tablets exists, and the types of excipients and also the way in which they are incorporated in the tablet vary(Aulton and Taylor 2013).

The different categories of tablets include; coated tablets (including film coated and sugar coated tablets), soluble tablets, dispersed tablets, effervescence tablets, and chewable tablets, tablets for use in the mouth including sublingual and buccal tablets.

2.2 Quinine

This is a quinolone methanol, which is the main alkaloid of Cinchona species. It is a levorotatory stereo isomer of quinidine and it is available in different salt forms which include hydrochloride, sulphate, dihydrochloride, bisulphate etc. Quinine has been used clinically in parenteral treatment of severe malaria andoral treatment of resistant falciparum malaria. Although, decreasing sensitivity to quinine has been detected in areas of South East Asia, the strains of *P. falciparum* from Africa are generally sensitive to quinine (Adegbolagun 2011).

Quinine is a rapidly acting blood schizontocide with activity against *Plasmodium falciparum*, *P. vivax*, *P. ovale* and *P. malariae*. It is active against the gametocytes *of P. malariae* and *P. vivax* but not against *P. falciparum* gametocytes. It has no activity against exoerythrocycticforms (Shasun, 2007).

2.3.0 Quality control parameters of quinine tablets as by the BP

2.3.1 The weight variation

Weight variations of the tablets produced is a relatively common problem of the tableting process. But each tableting process aims at producing tablets with a constant weight. The actual cause for this problem is the lack of weighing systems that are sufficiently fast to weigh or dose the required weight for each single tablet (Bano *et al.*, 2011).

Since this is not possible, each tablet press doses a certain amount of powder into the die and this powder is then pressed into tablets by the upper and lower punch. This means that a volume is dosed, but the quality requirement is the weight. Hence, weight variations in a limited extent are quite normal due to variations in the density of the powder material and to a partially incomplete filling of the dies (Bano *et al.*, 2011)..

The pharmacopoeias specify the acceptable level of weight variations. If the weight variations are too high the level of active ingredient in each tablet might be too high or too low and then the tablets don't comply with the specifications any more (Shargel *et al.*, 2005).

Tablet is designed to contain a specific amount of a drug in a specific amount of tablet formula. To check whether tablet contain a proper amount of drug, weight of tablet should be routinely measured (Bano *et al.*, 2011).

When 20 tablets are used and their average weight calculated,a minimum of 18 tablets should not deviate from the average weight by more than 5% and a maximum of 2 tablets should not deviate from the average weight by more than 10 %(BP, 2013).

2.3.2 The friability

Friability is the percentage loss of weight by a tablet due to mechanical action on its surface (BP, 2009). Doubling the quantity of magnesium stearate in the granulation in a given tablet strength decreases the maximum tablet hardness that could be obtained, and for the other tablet strength increased friability (DDIP, 1994).

Friability testing is used to evaluate the ability of tablet dosage form to withstand abrasion during packaging, handling and shipping (Remington, 1975).According to the BP 2013, the friability of tablets should not be greater than 1%.

2.3.2 The disintegration time

Disintegration time test measures the time required under a given set of conditions for a group of tablets to disintegrate into a particles. Tablets failing to disintegrate and release the API could be fatal to patients who need prompt medical treatment. Disintegration of the solid oral dosage form, together with the dissolution and permeability of the API, are important factors that determine the oral absorption of the API from a solid oral dosage form and ultimately determines the product's fate regarding its efficacy (Shargel *et al.*, 2005).

Tablets can disintegrate equally rapidly with or without disintegrating agent, thus allowing no comparison between disintegrating agents. Excess binders, lubricants and too much hardness increases disintegration time of tablets (DDIP, 1994).

Disintegration tests evaluate if the solid oral dosage form will break into smaller particles and ensure the increase in effective surface area from which the API can be released. (Shargel *et al.*, 2005).

For compressed uncoated tablets the testing fluid is waterat 37 ± 0.5^0 C, but in some cases the monographs direct that simulated Gastric fluid be used (Remington, 1975) , but in some cases the monographs direct that simulated Gastric fluid be used. The norm for disintegration testing of immediate release oral solid dosage forms is to use water as medium, at 37 ± 0.5°C, with a specification of 15 minutes (BP, 2013).

2.3.4 Hardness testing

Tablet hardness is the force (load) required to break a tablet. Because the hardness of a tablet directly relates to all other physical parameters, it is a fast and efficient test that indicates whether specifications such as disintegration time and friability will be met. It is therefore essential, that hardness measurement is done correctly – and that the equipment used to test tablet hardness guarantees repeatable results (Scheuniger, 2011).

Hardness testing assesses the ability of tablets to withstand handling without fracturing or chipping (Ngwulukaet *al.*, 2009). It also measures the resistance of tablets to abrasion or breakage under conditions of storage, transportation and handling before usage (Remington, 1975). Hardness of 4 - 15kgF is the acceptable limit (Ogah *et al.*, 2002).

2.3.4 The drug content

Granulation is a commonly used route in pharmaceutical product development to increase dissolution rate, flow ability, density of API, better distribution of API for low dose formulations, or in the case of multi-particulate systems to provide for a solid core for coating a release modifying polymer (Martinez *et al.*, 2001).

However, when granules are added to a blend formulation, problems of poor drug content may arise due to a combination of factors such as non-ideal granule characteristics (particle size, assay distribution), low tablet dose, particle size differences with excipients, and segregation during manufacturing operations (Krenzlin *et al.*,2011).

The chemical content of quinine sulphate tablets is determined using a non- aqueous titration with color indicator end point determination using 5%w/v crystal violet indicator (B.P. 2001). The chemical content obtained in the study should not be either below or above the official specification of 95-105%w/w (B.P. 2001).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

This study was experimental; four different brands of quinine sulphate tablets, with labeled contents of 300mg per tablet were obtained from different retail pharmacies and drug shops in Ishaka and other areas which was representative of the brands available within Bushenyi district.

3.2 Study site

This research was carried out at the Pharmaceutics laboratory of the School of Pharmacy of KIU-WC located in Ishaka town, Bushenyi district in Uganda. The school's campus is located in the town of Ishaka, in Bushenyi District, Western Uganda, approximately 330 kilometres (210 mi), by road, southwest of Kampala, Uganda's largest city and capital. The campus is also referred to as Kampala International University Western Campus, to distinguish it from Kampala International University Main Campus, located in Kansanga, Makindye Division, Kampala. The coordinates of Kampala International University's Western Campus are:0°32'19.0"S, 30°08'40.0"E (Latitude:-0.538611; Longitude:30.144444).

3.3 Determination of sample size

A total of 600 tablets were used for the study and 150 tablets from each brand were selected for the entire study.

3.4 Selection criteria

3.4.1 Inclusion criteria

Only quinine sulphate 300mg within their shelf lives was used in the study. The selected brands were from the NDA approved list of drugs. All the tablets were examined for white sugar coating with similar shapes, thickness and diameter.

3.4.2 Exclusion criteria

All tablets containing quinine sulphate in combination with other active substances or out of their self-life. Quinine tablets manufactured using other official compendia other than the BP were not be used.

3.5 Laboratory analysis

The quinine sulphate tablets were bought from some of the pharmacies and drug shops in Ishaka and other areas in Bushenyi District. A given number of tablets were randomly selected from each of the four brands of quinine sulphate and specific tests were performed on them.

3.5.1 Assay of quinine by non-aqueous titration method

0.300 g of powdered tablet was dissolved in a mixture of 10 ml of *chloroform and* 20 ml of *acetic anhydride.*The resultant solution was titrated with *0.1 M perchloric acid in presence of 5% crystal violet indicator*, determining the end-point by color change of the indicator from purple to blue. Each1 ml of *0.1 M perchloric acid* was equivalent to 24.90 mg of C40H50N4O8S.For each brand 10 tablets were used and the percentage assay for each of 10 tablets was obtained. The average percentage assay for the 10 tablets was calculated and then their compliance with specification of the BP was obtained.

3.5.2 Weight variation test

Twenty tablets from each of the three brands were weighed individually using weighing balance. The average weights of the tablet were calculated as well as their percentage deviation from the average weight. The expected deviation from the mean for the individual weights was not to be more than the appropriate allowed deviation of 5%.

3.5.3 Disintegration time test

The disintegration apparatus (BJ-I disintegration tester) was heated and maintained at 37 ± 1° C. A disintegrating medium of distilled waterwas used. Twenty four tablets of each brand were selected and six tablets were used at once and placed in each of the cylindrical tubes of the basket and then connected to the disintegration apparatus. The time taken to break each tablet to disintegrate was recorded and the average disintegration time for twenty four tablets will be calculated and recorded. The test was carried out for twenty fourtablets from each of the brands and mean disintegration time of each brand was calculated. The disintegration time is the time taken where no particles of the tablet remains on the basket assembly of the apparatus (Usman *et al.*, 2011).

3.5.4 Hardness test

YD-I tablet hardness tester was used to carry out this test.). The crushing strength of seventy six individual tablets per brand was determined by random selection and placing each tablet between the jaws of the hardness tester and then applied by adjusting the knob of the tester until the tablet integrity failed. The average mass per force exerted on tablets was calculated and results were recorded in (N)

3.5.5Friability test

Twenty tablets from each brand were weighted and subjected to abrasion using a tablets friability tester at 25 revolutions per minute. The tablets were then weighted and compared with their initial weight and percentage friability was calculated.

3.6 Data analysis

The experimental data obtained on the selected brands was entered into Microsoft Excel where it was cleaned and sorted before being imported into STATAv14.2. The data was summarized as Mean±SEM and the Relative Standard Deviations were determined. To detect for statistical differences amongst the brands, one-way ANOVA (Analysis of Variance) was performed at a 5% level of significance and p values less than or equal to 0.05 were considered statistically significant. Bonferroni was employed as a post hoc test to detect the sources of significant differences in the means.

3.7 Ethical considerations

The different brands of quinine sulphate tablets selected were coded throughout the study process. Their identities were not revealed to any other third party other than the researcher involved as the brands were coded with letters A, B C, and D.

CHAPTER FOUR

4.0 RESULTS

4.1Weight variation

From the results in table 1, brand **D** had the highest relative standard deviation, while brand **A** had the lowest relative standard deviation. Also from the results in table 1, brand **B** had the highest average weight while **A** had the lowest average weight. The results obtained were within the calculated ranges. This means that they complied with the required specifications.

The p value is less than 0.05 therefore the differences in the weights of the individual brand tablets are typically variable.

Table 1: Weight variation test results for brands A, B, C and D obtained using the procedure for the BP

Brand code (n = 20)	Mean ± SEM; Weight (mg)	RSD (%)	P value	Range (mg)	
				A	B
A	408.85 ± 0.80	0.87	**<0.0001**	408.85±20.44	408.85±40.89
B	744.35 ±5.82	3.50		744.35±37.22	744.35±74.43
C	598.55 ±1.92	1.44		598.55±29.93	598.55±59.85
D	475.50 ± 4.91	4.62		475.50±23.78	475.50±47.55

Range A = Mean ± (5%XMean) and B = Mean ± (2X5%XMean).

4.2 Friability

From the results in table 2 below, brand D had the highest friability while B and C had the lowest friability. Brands A and D did not comply with BP specifications while brands B and C complied.

Table 2: Friability test results for brands A, B, C and D obtained using the BP procedure

Brand code	Initial weight(W1)	Final weight(W2)	(W1-W2)g	Friability[(W1-W2)/W1]X100%	Compliance with BP
A	8.103	8.021	0.082	1.01	No
B	14.925	14.922	0.003	0.02	Yes
C	12.028	12.016	0.012	0.10	Yes
D	9.558	9.389	0.169	1.80	No

4.3 Hardness test

From the results in table three below, brand B had the highest average crushing strength/ hardness of 16.89kg/F while brand D had the lowest average crushing strength of 6.92kg/F. Brand B had an extremely high crashing strength value as compare to brands A, C and D. Three brands A, B and C passed the test while brand B failed the test. The asterisk shows the mean that is significantly different from all the others after the post hoc testing. The obtained values were statistically different from each other ($p<0.0001$) although brand B failed the test.

Table 3: Hardness test results for brands A, B, C and D obtained using a procedure for the BP

Brand code (n=76)	Crushing strength, Mean±SEM (kg/F)	Relative SD (%)	P value
A	11.28 ± 0.13		**<0.0001**
B	16.89 ± 0.11*		
C	8.70 ± 0..09		
D	6.92 ±0.04		

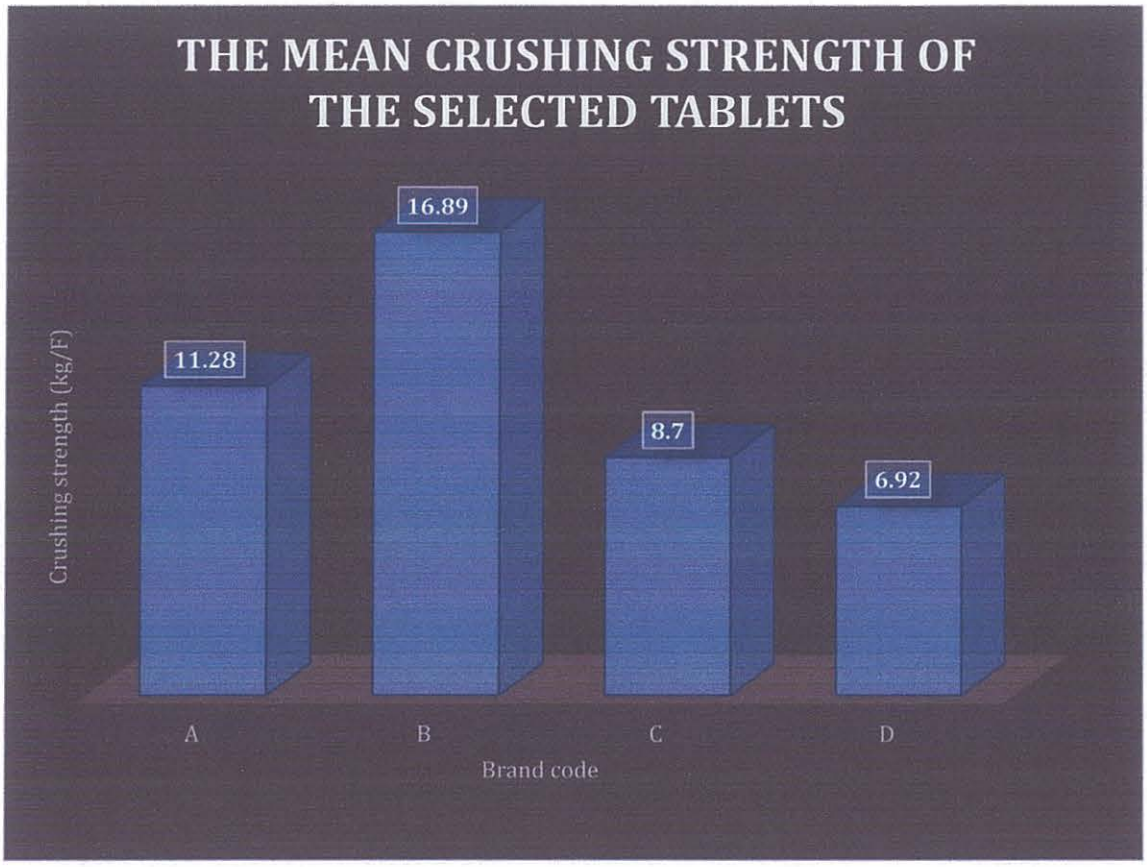

Figure 1: A graph showing the mean crushing strength of the selected brands of quinine tablets

4.4 Disintegration time

From the results in table 4 below, brand B had the highest average disintegration time of 16.5 minutes while brand D had the lowest average disintegration time of 6.5 minute. Three brands A, C and D passed the test while brand B failed the test. The obtained values were statistically different from each other ($p<0.0001$) despite the fact that brand B failed the test.

Table 4: Disintegration test results for brands A, B, C and D obtained using a procedure for the BP

Brand code (n=24)	Disintegration time, Mean±SEM (min)	P value
A	12.4 ± 0.1	**<0.0001**
B	16.5 ± 0.1	
C	10.4 ± 0.1	
D	6.5 ± 0.1	

4.5 Assay of quinine content in the tablets

According to the results in table 5below, brand D had the highest content of quinine (102.5%), followed by brands C and A respectively, while brand B had the lowest content of quinine (93.57%). Brands A, C and D passed the test while brand B failed the test. The obtained values were statistically different from each other ($p<0.0001$) despite the fact that brand B failed the test.

Table 5: Assay test results for brands A, B, C and D obtained using a procedure for the BP

Brand code	Mean±SEM (mg)		P value
(n =10)	Percentage assay (%)	Within 95 – 105 %	
A	100.84 ± 0.28	Yes	**<0.0001**
B	93.57 ± 1.22*	No	
C	101.51 ± 1.80	Yes	
D	102.50 ± 0.48	Yes	

The asterisk shows the mean that is significantly different from all the others after the post hoc testing.

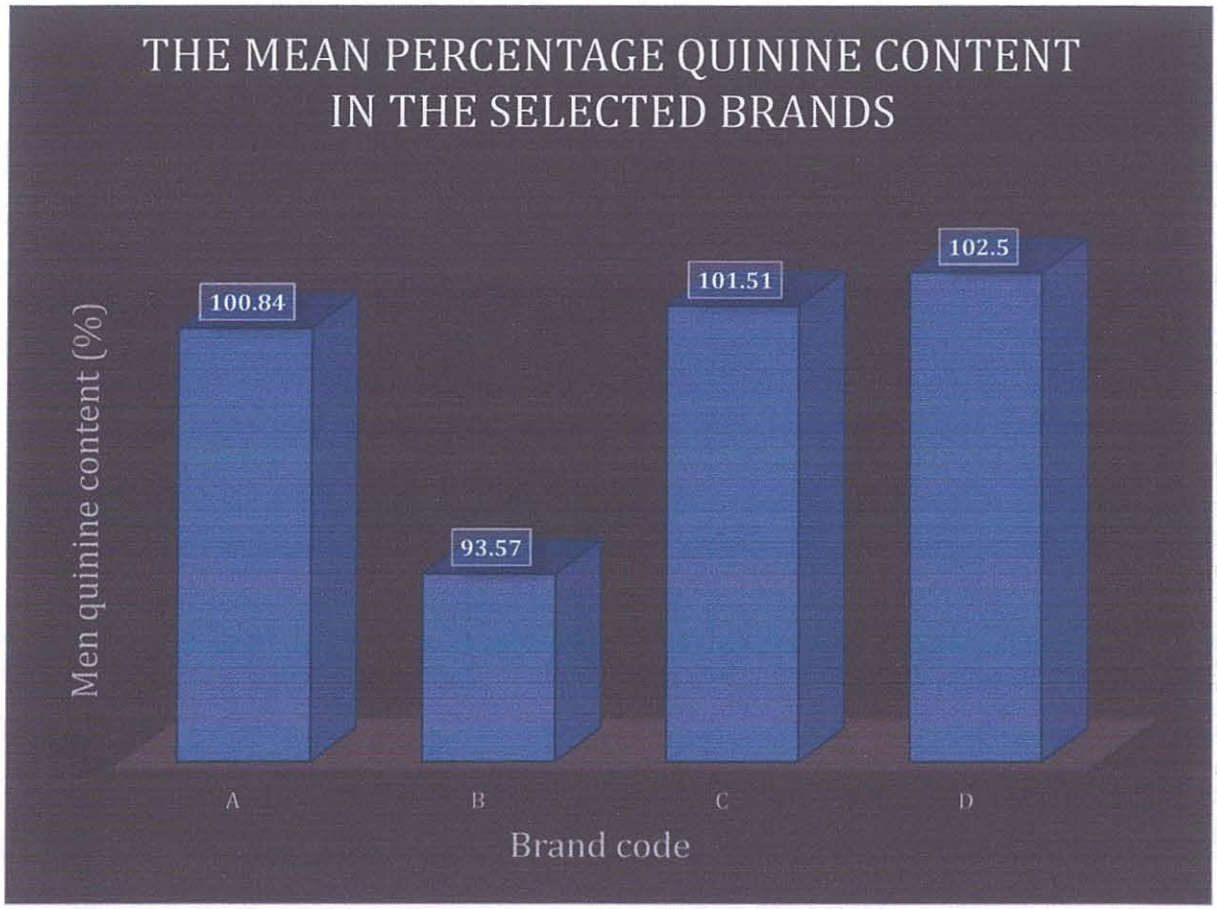

Figure 2: A graph showing the mean quinine content of tablets of selected brands.

CHAPTER FIVE

5.0 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

Weight uniformity of tablets serves as a pointer for good manufacturing practice (GMP) as well as amount of the pharmaceutical ingredient (API) in a product (Ngwuluka, *et al.*, 2009).Weight variations of the tablets produced is a relatively common problem of the tableting process. But each tableting process aims at producing tablets with a constant weight. The actual cause for this problem is the lack of weighing systems that are sufficiently fast to weigh or dose the required weight for each single tablet (Bano, *et al.*, 2011). However, the differences between different brands could be due to variations in percentage of excipients especially diluents, or bulking agents, which is usually the decision of formulation pharmacist (Ibezim, *et al.*, 2008).The pharmacopoeias specify the acceptable level of weight variations. If the weight variations are too high the level of active ingredient in each tablet might be too high or too low and then the tablets don't comply with the specifications any more (Shargel, *et al.*, 2005). When 20 tablets are used and their average weight calculated, a minimum of 18 tablets should not deviate from the average weight by more than 5% from the average (BP, 2013). All the brands complied with the compendia specification for uniformity of weight as the percent deviations from average weight of all the tablets were within the acceptable range. The obtained values were statistically different from each other ($p<0.0001$)

Friability is the percentage loss of weight by a tablet due to mechanical action on its surface (BP, 2009). Doubling the quantity of magnesium stearate in the granulation in a given tablet strength decreases the maximum tablet hardness that could be obtained, and for the other tablet strength increased friability (DDIP, 1994). It can be caused by a number of factors including poor tablet design (too sharp edges), low moisture content and insufficient binders (Pandley, *et al,* 2014). According to the BP 2013, the friability of tablets should not be more than 1%. The friability of brands B and C were within the limits of the BP specification of not more than 1% while brands A and D had their friability values above the specifications of the BP. The above factors must have caused this problem.

Tablet hardness is the force (load) required to break a tablet(Scheuniger, 2011).Because the hardness of a tablet directly relates to all other physical parameters, it is a fast and efficient test that indicates whether specifications such as disintegration time, dissolution time and friability will be met(Pellek and Amum, 2008). If the tablet is too hard, it may not disintegrate in the required period of time to meet the dissolution specifications. Again, if it is too soft, it may not be able to withstand the handling during subsequent processing such as coating or packaging and shipping operations(Scheuniger, 2011). Hardness of tablets can be increased by addition of excess binders, over weight granules, over dried granules, small but dense particles, problems related to lower punch and poor storage conditions (Pellek and Amum, 2008). The BP recommends ahardness of 4 - 15kg/F as the acceptable limit (Ogah, *et al.,* 2002). In this study, tablets of brands A, C and D had average hardness of 11.28kg/F, 8.70kg/F and 6.92kg/F respectively which was in the range of the BP specification and thus passed the hardness test. Brand B had an average hardness of 16.69kg/F which was above the BP specification of 4-15kg/F and thus failed the test. This increased hardness is related to use of excess binders, over weight granules, over dried granules, small but dense particles, problems related to lower punch and poor storage conditions. The obtained values were statistically different from each other ($p<0.0001$).

Disintegration time test measures the time required under a given set of conditions for a group of tablets to disintegrate into a particles.Tablets failing to disintegrate and release the API are not effective to patients who need prompt medical treatment and also can lead to treatment failure and development of resistance (Shargel*et al.*, 2005). Disintegration of the solid oral dosage form, together with the dissolution and permeability of the API, are important factors that determine the oral absorption of the API from a solid oral dosage form and ultimately determines the product's fate regarding its efficacy (Shargel*et al.*, 2005).Tablets can disintegrate equally rapidly with or without disintegrating agent, thus allowing no comparison between disintegrating agents. Excess binders, lubricants and too much hardness increases disintegration time of tablets (DDIP, 1994). The norm for disintegration testing of immediate release oral solid dosage forms is to use water as medium, at 37 ± 0.5°C, with a specification of not more than 15 minutes (BP, 2013).In this study, brands A, C and D had average disintegration time of 12.3mins, 10.5mins and 6.5mins respectively which was within the BP specifications and therefore passed the test. Brand B had the average disintegration time of 16.5mins which was above the BP specifications of not

more than 15 minutes and therefore failed the test.This increased disintegration time for brand B is related to use of excess binders, lubricants and too much hardness. The obtained values were statistically different from each other ($p<0.0001$).

Assay is a measure of drug activity expressed in terms of the amount of API (in percentage) required to produce a response of given strength. This test is done for determining the toxic and therapeutic effect of the drug. The assay of the tablet should comply with the specification because very highly potent drug may give toxic effect & very less potent drug may give sub-therapeutic effect(DDIP, 1994).Granulation is a commonly used route in pharmaceutical product development to increase dissolution rate, flow ability, density of API, better distribution of API for low dose formulations, or in the case of multi-particulate systems to provide for a solid core for coating a release modifying polymer (Martinez, *et al.*, 2001).However, when granules are added to a blend formulation, problems of poor drug content may arise due to a combination of factors such as non-ideal granule characteristics (particle size, assay distribution), low tablet dose, particle size differences with excipients, and segregation during manufacturing operations (Krenzlin, *et al.*,2011). Friability, poor storage condition that exposes the dosage form to microorganisms that degrade the API affects the assay (WHO, 2018). The chemical content of quinine sulphate tablets determined using a non- aqueous titration with color indicator end point determination using 5%w/v crystal violet indicator should not be either below or above the official specification of 95-105%w/w per tablet (B.P. 2001).In this study, brands A, C, and D had their average percentage assay values of 100.84%w/w, 101.51%w/w and 102.50%w/w respectively which were in BP official specification of 95-105%w/w and therefore passed the assay test.Brand B had the average percentage assay of 93.57%w/w which was below the BP official specification of 95-105%w/w and therefore failed the assay test. The low average percentage assay is related to either non-ideal granule characteristics (particle size, assay distribution), low tablet dose, particle size differences with excipients, and segregation during manufacturing operations or friability, poor storage condition that exposes the dosage form to microorganisms that degraded the API. The obtained values were statistically different from each other ($p<0.0001$).

5.2 CONCLUSION

This study provides objective evidence to answer speculations whether or not poor quality antimalarial drugs exist in Bushenyi and that this poor quality is the cause of treatment failure and development of drug resistance. This has been evidenced by brand B failing to comply with the BP official specifications of hardness, disintegration and assay which are key parameters that determine drug bioavailability and efficacy.The poor quality of drugs could have been either as a result of non-adherence to Good Manufacturing Practices or poor storage conditions exposed to drugs in pharmacies and drug shops.The revelation of the existence of poor quality drugs by this study poses a challenge to the Drug Regulatory Body to enhance its Post-marketingsurveillance programme to ensure and assure constant quality monitoring of drugs thatare found on the Ugandan market, as quality, safety and efficacy are the tenets of everypharmaceutical product.

5.3 RECOMMENDATIONS

i. The Drug Regulatory body (NDA) should have the mini-laboratory facilities in all districts of Uganda.
ii. The Drug Regulatory Body (NDA) and the Medical Council of Uganda should intensify their inspection of both private and public drug outlets.
iii. The Drug Regulatory Body (NDA) should have educational programmes to educate people on the dangers of consuming poor quality or substandard drugs.
iv. The Drug Regulatory Body (NDA) should strictly adhere to preregistrationand post-registration quality control of all pharmaceutical products.

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DE: BIO1202

TT/40	ESE/60	TT/100
35	44	79
29	44	73
33	40	73
31	43	74
26	36	62
28	47	75
31	50	81
32	42	74

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A STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICES OF MOTHERS TOWARDS IMMUNIZATION OF CHILDREN AGED 0-5 YEARS IN MUGWATA VILLAGE GISOZI PARISH MURAMBA SUBCOUNTY KISORO DISTRICT

BY

BAKUNZI DAVID

DCM/0049/143/DU

A RESEARCH REPORT SUBMITTED TO THE SCHOOL OF ALLIED HEALTH AS PARTIAL FULFILLMENT FOR THE AWARD OF A DIPLOMA IN CLINICAL MEDICINE AND COMMUNITY HEALTH AT KAMPALA INTERNATIONAL UNIVERSITY

JULY 2017

DECLARATION

I BAKUNZI DAVID declare that this research report is my original piece of work and that to my knowledge; it has never been presented to any University or academic institution for a similar award. Where other individuals' information has been used, citations have been made and reference provided

RESEARCHER

BAKUNZI DAVID

Signature.....Bakunzi..... **Date**...19...../..07...../...2017....

APPROVAL

This research report has been produced under my supervision and submitted with my approval.

MR MBURUGU MARTIN

Signature..... **Date**.19...../...07.../...2017.....

SUPERVISOR

DEDICATION

I dedicate this research work to my dear and beloved parents Pastor and Mrs. Barere Elisha who made me a visible child today, Mrs Night Bakunzi, my beloved wife who tirelessly supported me from the beginning up to the end, Professor Gerald Paccione, Dr Amit Patel, Dr Noriyuki Murakami, Dr Arash Nafisi, Dr Sam Cohen, Dr Timothy Leupp, Chris Knudson, Dr Kotecha Vijay who supported me financially, Doctors for Global Health, Kisoro District Hospital, my brothers Munyambabazi Joshua, Tumwizere Julius, Bwiringiro Obed, Sebikari Philip, Nemeye Nelson, Ndizeye Robert, Habarulema Benon, Zirunguye Festo, Edson, Zirakwiye Bernard, my sisters Zipporah, Jackline, Jeska, my sister in laws Christine, Flora, Mary Sebikari, Muhawe Flavia, Asiimwe Charity, Mahirwe Topister, Hellena, Ntawiha, Mamiye, Juliet and Nyirabaruta Jovia, My nephew Irakiza Gideon and my nieces Irankunda Annet, Ashimwe Donata and Mujaw'Imana Molly and the rest of my family members. As well as my mother in law Mrs. Hope Tereraho. The family Mr and Mrs Sheba Hanyurwa and my brother in laws Abel, John, Peter and Sam thank you for everything. Also to my old friends Mr and Mrs Birungi Anthony, Budongo Spe, Dr and Mrs Baganizi Michael, Mr and Mrs Musominali Sam, Mr and Mrs Niyonzima Silas, Mildred, Owomugisha Ronah, Mutuzo Topister, Mukiza Joel, Pr Tumwesigye Stevenson, Pr and Mrs Ndimubakunzi Jerome, Mr and Mrs Manishimwe Godfrey, Mabiga family, My uncle Mr Nkunduwenda Anthony My aunties Nyirankumi Peresi, Mukama Sifora and Nyiramponoke Joyce, Mr and Mrs Nkunduwenda Godfrey, Mr and Mrs Hatangimana Steven, Pr and Mrs Twine David Kanyaruju, Pr and Mrs Byaruhanga Saverino, Mr and Mrs Ndikuryayo Japheth, Mr Nzabarinda Charles, Staff Mirembe Guest House, Mr and Mrs Sekabuga Silas, Ndahayo Peter and others who helped me during this academic struggle.

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God bless you so, so much.

LIST OF ABBREVIATIONS AND ACRONYMS

BCG	Bacillus Calmette- Guerine
DPT-Hep+Hib	Diphtheria Pertussis Tetanus HepatitisB+Haemophilus Influenza type b.
EPI	Expanded Program on Immunization.
GIVS	Global Immunization Vaccine Strategy
GVAP	Global Vaccine Action Plan
HSSIP	Health Sector Strategic Investment Plan.
IPV	Inactivated Polio Vaccine.
KAP	Knowledge, Attitude and Practices
MoH	Ministry of Health
OPV	Oral Polio Vaccine
PATH	Project for Appropriate Technologies for Health
PCV	Pneumococcal Conjugate Vaccine
TB	Tuberculosis
UNBoS	Uganda National Bureau of Statistics
UDHS	Uganda Demographic Health Survey
UN	United Nations
UNAS	Uganda National Academy of Sciences
UNEPI	Uganda National Expanded Program on Immunization.
UNICEF	United Nations Immunization Children's Emergency Fund
VPDs	Vaccine Preventable Diseases
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

A fully immunized child;	Is a child who has received all doses of the recommended antigens; that is BCG(1dose), DPT-Hep+Hib (3doses), polio vaccines (3OPVdoses+1IPVdose), Measles vaccine (1 dose), PCV(3 doses), Rota virus vaccine.
A mother;	In this study refers to a female parent or guardian of children.
A vaccine;	This is a biological preparation/antigen which when administered to an individual improves his/her immunity to a particular disease.
Alternative traditional methods of disease prevention;	Any other method used to prevent the vaccine preventable diseases other than immunization
Attitude;	Is a way of thinking about something or behaving towards something.
Doubtful sources of information;	Un trusted sources of information other than medical personnel.
Effective utilisation of immunization services;	To make good use of immunization services available.
Immunization coverage:	Is a proportion of children aged 12-23 months that are fully vaccinated.
Immunization service;	This is the duty or work done by Ministry of Health (MoH) under Expanded Programme on immunization (EPI) to improve the health of the people in relation to immunization.

Immunization; The term is used here to refer to the process of making a person immune or resistant to an infectious disease typically by administration of a vaccine.

Knowledge; refers to facts, information and understanding that a Person has acquired either through experience or education.

Partially immunized child; is a child who has received a few doses of a specific vaccines but has not completed a full immunization course for such a given vaccine.

Practice; is the actual use or performance as compared with the idea, intention or rules on which the action is based.

Reliable sources of knowledge about immunization; trusted sources of information about immunization, who are mainly the medical workers.

Vaccine preventable diseases (VPDs); These are diseases of children that can be controlled/prevented by immunizing children. The term VPD is used interchangeably with children killer immunizable diseases.

TABLE OF CONTENTS

ABSTRACT

Immunization involves the process of making children immune or resistant to an infectious disease typically by administration of a vaccine. It is one of the most cost effective public health interventions for reducing child mortality and morbidity hence it is the best investment a country can make to ensure a healthy population. Globally it saves about 2-3 million lives annually and provides one of the least expensive tools for preventing childhood vaccine preventable diseases, avoiding costs of curative care.

The study was a descriptive cross-sectional study on knowledge attitude and practices of mothers towards immunization of children aged 0-5 years in Mugwata village, Gisozi parish Muramba Sub County, Kisoro district.

The general objective was to determine the knowledge, attitude and practices of mothers towards immunization of children of aged 0-5 years.

The specific objectives were; to assess knowledge of the rural mothers about immunization, to study the attitudes of rural mothers towards immunization, and to determine the practices of mothers on immunization of children aged 0-5 years.

Both quantitative and qualitative methods of data collection were employed. A questionnaire with both closed and open ended questions was used and 65 respondents were sampled.

Results: There study observed a high knowledge on immunization, 96.9% of the mothers were able to define immunization appropriately, 93.8% identified benefits of immunization and at least every mother mentioned one immunizable disease. Poliomyelitis and measles were the most known vaccine preventable disease. However, the study revealed that there was lack of knowledge on the correct earliest age and last age for immunization of children 0-5 years of age. Only 66.2% knew the correct earliest age of immunization and only 21.5% of mothers knew the last age of for immunization of children.

The attitude of mothers towards immunization was found to be moderately positive; some respondents had moderate supportive attitudes towards childhood immunization where by only 78.5% believed vaccines to be safe.

The immunization practices of mothers on immunization were inadequate; only 75.4% mothers followed the immunization schedule and 16.9% could bathe children with herbs to prevent measles.

CHAPTER ONE

INTRODUCTION

1.0 Introduction.

This chapter presents the background to the study, problem statement, justification of the study, significance of the study, objectives of the study, research questions and the scope of the study.

1.1 Background to the study.

Immunization is one of the most cost effective public health interventions for reducing child mortality and morbidity hence it is the best investment a country can make to ensure a healthy population, (UNICEF, 2013).

Globally it saves about 2-3 million lives annually and provides one of the least expensive tools for preventing childhood vaccine preventable diseases, avoiding costs of curative care, (PATH, 2014).

The primary goal for active immunization is to protect and prepare the immune system so that it can respond rapidly and specifically to the targeted wild organism, thereby preventing disease colonization and infection. It prevents children from illnesses, disability and death from vaccine preventable diseases including; Poliomyelitis, Measles, Diphtheria, Pertussis, Tetanus, Pneumonia, Rota viral diarrhoea, Tuberculosis, Hepatitis B and Heamophilus Influenza b, (WHO, 2015).

The percentage of infants fully immunized against diphtheria tetanus and pertussis (DPT3) in most developing countries has remained steady at 83% for the last 3 years. According to this report the factors related to low immunization coverage include low education status of mothers, long distances from immunization center in most developing countries,(Bhuwan, Hemnt and Velhal, 2013, WHO 2014)

In other countries like India only 44% of children aged 12-23 months were fully immunized and about 5% did not receive any immunization at all. The factors associated with low immunization

coverage were; long waiting time at healthy facility, fear of children to cry due to painful injections, (MoH and Family welfare Government of India, 2006)

Globally population of about 22.4 million infants is not immunized against childhood killer diseases, (UNICEF, 2011). In Sub-Saharan Africa the immunization coverage among children aged 0-9 months has remained low at 44%. In many African countries For instance Ghana has registered low coverage up to 11.7%, such a coverage is associated with obstacles including; mothers having no time to take children for immunization as most of them are in the garden and long distances to the immunization centers, (WHO, 2012).

In East Africa, countries like Kenya only 77.4% of children aged 12-23 months received recommended vaccines in 2009, (Kenya National Bureau of Statistics, 2009). In Uganda child hood immunization is free of charge. It is one of the 4 priority areas in Uganda Health Sector Strategic Investment Plan (HSSIP, 2010/11-2014/15). Despite the struggle by Uganda government the immunization coverage has not yet reached maximum (UNEPI 2011).

The immunization schedule in Uganda according to WHO is ;At birth: BCG, polio 0, At 6 weeks: polio 1, DPT-Hep+Hib 1, PCV 1, At 10 weeks polio 3, DPT-Hep+Hib 2, PCV2, At 14 weeks: polio 3, DPT-Hep+Hib 3, PCV 3, IPV, At 9 months: measles vaccine, Vitamin A supplements given at 6 months then continuously given after every 6 months till the age of 5 years, and de worming tablets given from 1-5 years.

The immunization coverage rates in Uganda in 2011 were highest in Kampala ,followed by sub-regions of south west , western regions and least in the sub-region of East central , central 1 and 2 and northern regions,(UDHS 2011).

Despite the observed improving coverage rates, Uganda is still the last in immunization performance in East African region, (UNAS, 2014). According to above UDHS report factors related to the low coverage include long waiting time at immunization centers, (Waiswa, 2006).

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1.2 Problem statement

Despite the reported increase in the overall percentage of fully immunized children in Uganda; DPT-HepB+Hib3 84%, OPV 84% and Measles 80% in 2009, the country still performs poorly compared to its regional neighbors,(UDHS, 2011)

For instance the wild polio virus outbreak in districts like Amuru , Moyo and Pader in 2009 and in 2010 in Bugiri district after 13 polio free years.(UNAS, 2014) and 1,497 measles outbreak cases in 2012-2014,(MoH, 2015) were clear indicators of poor immunization coverage.

In some districts of Uganda, immunization coverage is still less than 80% \, for example Kisoro is one of the districts whose measles immunization coverage in 2014 was between 50%-78%, (Measles vaccine and Human Papilloma Virus vaccine guide, 2015 Uganda). This puts the entire country at a risk new outbreak of Vaccine Preventable Diseases.

Immunization programs have been emphasized at lowest Health Facilities in Uganda, Health providers like village Health Team mobilize mothers at village levels to take their children for immunization however this was not seen fully achieved,(MoH, 2013).This report also found out that only 30% of Ugandan children were fully immunized. One may ask why immunization performance remains poor in the country despite the interventions.

Mugwata is one of the Ugandan villages where mothers still fall victims and defaulters in taking their children for immunization despite the different strategies implemented by the ministry of health such as mass immunization. Unfortunately there is no clear report whether enough researches have been done to assess factors for such a trend of immunization performance in certain areas like Mugwata village. Hence this study aimed at assessing mother's knowledge attitudes and practices of immunization of children aged 0-5 years of age in Mugwata village.

1.3 Justification of the study.

The study findings are to help local health service providers to make necessary interventions aimed at improving mothers' knowledge, attitude and practices hence improve on immunization coverage in Kisoro district.

The findings will be used by MoH to design policies and guidelines for improving immunization in entire country.

The research is to enable the researcher to achieve a diploma in clinical medicine and community health.

1.4. Study objectives.

1.4.1. General objectives.

To determine the knowledge, attitudes and practices of rural mothers in Mugwata village Gisozi parish in Kisoro district towards immunization of children of age 0-5 years.

1.4.2. Specific objectives.

i) To assess knowledge of the rural mothers about immunization of children 0-5 years

ii) To study the attitudes of rural mothers towards immunization of children aged 0-5 years.

iii) To determine the practices of mothers on immunization of children under five years.

1.5 Research questions

i) What is the knowledge of mothers about immunization in Mugwata village in Gisozi Parish in Kisoro District?

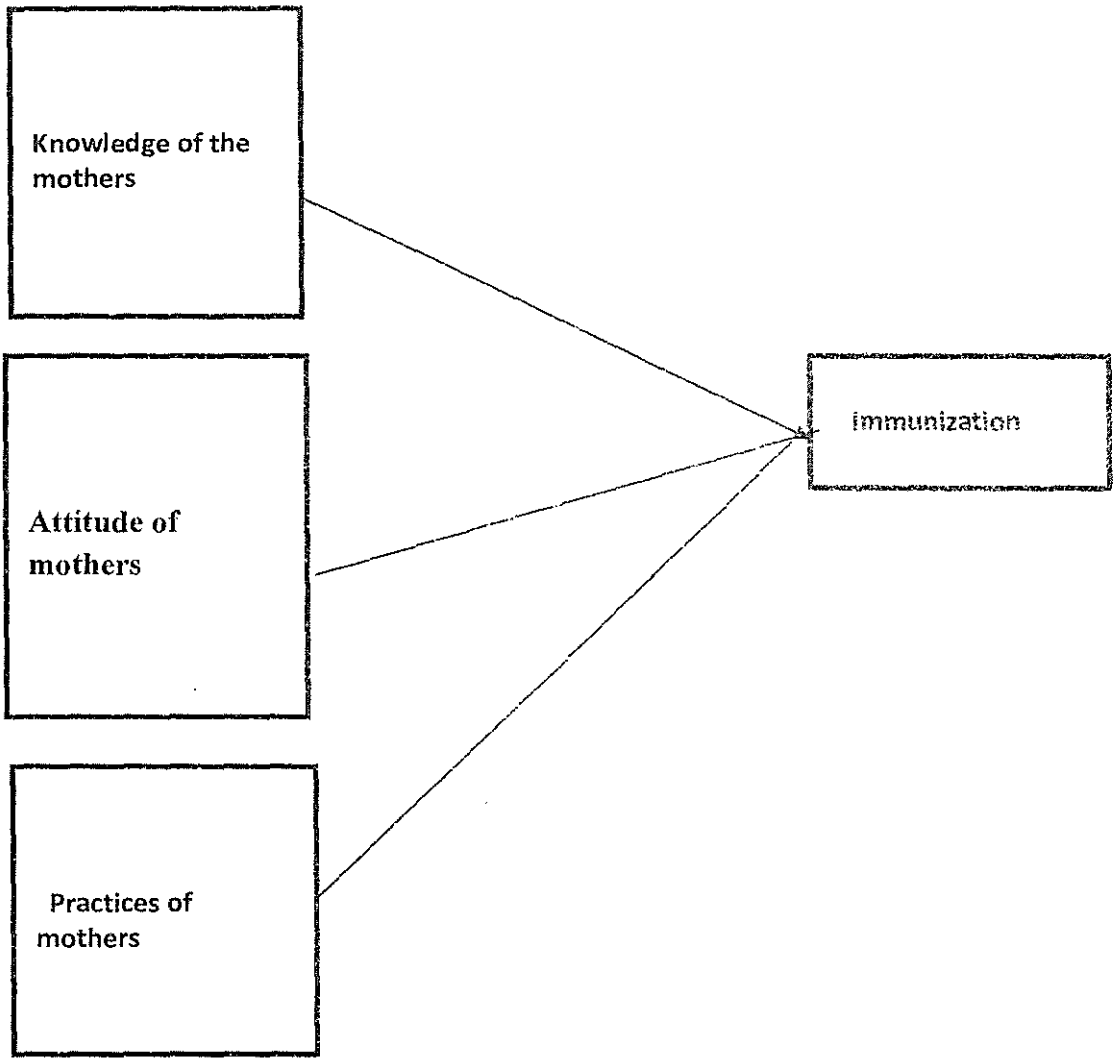
ii) What are the attitudes of mothers about immunization in Mugwata village?

iii) What are the practices of mother towards immunization of children aged 0-5 years in Mugwata village?

1.6 Scope of the study.

The scope was limited to mothers of children less than five years in Gisozi Parish. The study was conducted in Mugwata village, Gisozi Parish one of the 4 parishes in Muramba sub county, Gisozi is geographically located at border of Uganda and DRC, Part of Mgahinga gorilla national park covers part of Gisozi Parish. Data about immunization was collected in April 2017.

1.7 Conceptual flame work.



CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

This chapter analyzes and presents the findings of other researchers about the study under investigation.

2.1 Knowledge of rural mothers about immunization.

According to Okol Winnie,(2014) on a study about knowledge attitude and practices among parents on immunization in Rwot village, Alebtong district: majority of respondents 19(63.8%) defined immunization as injection given to make a body strong and prevent diseases and 9(30%) respondents said immunization is a way of protecting the body against killer diseases like polio, tetanus, whooping cough and 2(6.7%) respondents understood immunization as administration of vaccines to boost body's immunity.

According to Siddigi et al. (2010), in a study about mothers' knowledge on EPI and its relation with age-appropriate vaccination for children in peri-urban Karachi India, the percentage proportion of mothers correctly identifying the 7 EPI diseases were as follows; TB 57%, diphtheria 52.2%, tetanus 33.3%, measles 40.5%, polio 43.5%, and hepatitis B 31%; hence mothers' knowledge about EPI diseases were quite low and not associated with their children's EPI coverage.

Yousif M.A et al, (2013) mentioned that in their study about KAP of parents towards immunization in Taif Saudi Arabia, findings showed that there was increased knowledge on child immunization among parents with high level of education than those with low level of education.

According to Baberturiji A O et al, (2012) assessment of Knowledge Attitude Practices of stakeholders towards immunization in Bomo state Nigeria, all stakeholders were aware of immunization. However there was lack of adequate information about logistics and time of immunization programs.

Neiderhouse V.P et al, (2007) in a study on barriers to immunization stated that the parent's insufficient knowledge about vaccines and their importance's also led to failure to immunize their children.

According to the study by Arinaitwe Pius, (2011), factors contributing to low immunization coverage of children under five years in Kayonza sub-county in Ntungamo district, most of the mothers failed to identify the right age to start (21%) and stop (23%) immunization for their children.

2.2 Attitudes of rural mothers about immunization.

Oria P.A et al, (2013) mentioned in their study on assessing parents knowledge towards seasonal vaccination before and after seasonal influenza vaccination effectiveness, findings showed that some parents thought it was not necessary to seek hospital care for influenza instead they used home based remedies like hot water and hot lemon.

Rogalaska J et al, (2010) in their study in Poland on attitudes of parents towards HPV vaccine stated that some parents thought that the vaccines were harmful and they lacked confidence in it.

Sanford R.K et al, (200) in their research on addressing immunization benefits and risks stated that most parents support immunization for their children but misconceptions exist , some parents believed immunization would weaken their children's immune system.

According to Awodele O et al, (2013) knowledge and attitude of mothers attending antenatal clinic in Lagos university teaching hospital in Nigeria towards immunization; 66.5% of respondents believed that immunization was necessary for their children, 64.2% were ready to ensure that children are immunized irrespective of the cost, 65.4% mothers believed they can advise their fellow women to receive immunization for their children and only a few (1.5%) of mothers thought giving immunization to a children can cause HIV/AIDS.

According to Mapatono MA et al, (2008) Attitudes and practices of mothers of children between 0-4 years; 98% of mothers had a positive attitude towards immunization unlike that the coverage was low, 37%.

According to Babaturiji AO et al, (2012) assessment of KAP of stakeholders towards immunization in Bomo state, Nigeria; majority of respondents indicated that they accept

immunization and allow their children to receive immunization hence had good attitudes except that some mothers had traditional alternatives for immunization.

According to international journal of academic research in progressive education and development by Christopher N. N et al, (2014) knowledge of infant nutrition among mothers in Enugu state, southeastern Nigeria, many mothers believe that immunization no longer prevents diseases that it instead exposes children to illnesses and death.

2.3 Practices of mothers towards immunization.

Basil Tibanyenda et al, (2010) in a study on assessment of activities and impact of community own resource persons on families and communities in healthy child Uganda in Bwizibwera project area documented that there were increased numbers of immunized children and that in case of disease outbreak ,there is quick response to take children for immunization.

According to Ayebazibwe N, (2009), on a study of immunization coverage and risk factors for high dropout rates in Rakai district Uganda, out of 528 children in the study, 38.3% were drop outs, 56.6% were fully immunized, 4.16% were not immunized at all while 0.75% were on schedule. Immunization coverage was fairly high but dropout rates were higher than what is considered acceptable. And the factors for drop out are late age of immunization, occurrence of missed opportunity for immunization and misconception that sick children should not be immunized.

According to Juliet N.et al (2013), about childhood vaccinations in Kampala-Uganda, about a half of 821 children received all vaccines with in recommended time ranges. Time receipt was lowest for measles, highest for BCG vaccine.

Mapatano MA et al, (2008) in their study on their KAP of mothers in Kinshasa, DRC towards childhood immunization, findings showed that if mothers were able to produce their immunization cards it was most likely that their children were fully immunized.

According to Tagbo BN et al, (2012) on a study of mothers' knowledge, perception and practices of childhood in Enugu-Nigeria; most of the mothers (95.2%) took their children to health facilities for immunization. Therefore most of the children were immunized.

According to Saddigi et al (2010) study on mothers' knowledge about age-appropriate vaccination of infants in peri-urban Karachi, only 44.8% of children were appropriately vaccinated for their age.

According to the report by UDHS, 2011; 52% of the children aged 12-13 months were fully vaccinated in Uganda. 4% had not received any vaccine. Dropped rate for DPT was 23%, oral polio vaccine dropout was 33%. Only 4 in 10 children were fully vaccinated by 12 months while 6 children in 10 children were not.

According to UNICEF report (2012) national coverage for immunization in Nigeria for measles in children was 71% hence the coverage was still small.

CHAPTER THREE

METHODOLOGY

3.0. Introduction

This chapter presents the study area, study period, study population, sample size determination, sampling techniques, sampling strategy, study design, definition of variables, data quality control, data collection, data analysis, data presentation, ethical consideration, study limitations and their remedies and dissemination of results.

3.1. Study area

The study area was Mugwata village, one of the 9 villages in Gisozi Parish, Muramba sub county Kisoro District. Gisozi Parish is at the slopes of Mufumbiro ranges.
Kisoro is one of the districts in Kigezi sub region in south western Uganda. Its borders are DRC from the west, Republic of Rwanda to the south, Kanungu District to the north and Rubanda District to the East. Kisoro is inhabited by primarily the Bafumbira; Fumbira dialect which is similar to Kinyarwanda is spoken in the district. A section of Kisoro is inhabited by Kiga whose dialect is intermediate between Kiga and Fumbira.

The district has 14 sub-counties and Muramba sub-county inclusive. The people in Gisozi seek immunization services from Muramba Health Center III, Gisozi Health center II and immunization outreaches conducted within the community and sometimes house to house mass immunization.

The major occupation of people of Gisozi parish is subsistence farming.

3.2. Study design

The study design was an observational descriptive and cross-sectional study .Cluster sampling method was used since it reduces the costs of preparing sampling frame and reduces the cost of travel between selected units.

3.3. Study period

Data was collected in June 2017.

3.4. Study population.

The study population comprised of mothers with children aged 0-5 years selected from Mugwata village in Gisozi parish. A sample of 65 mothers with children aged below the age of five was selected and participated in the study. This category of mothers was chosen because they are the caregivers of children 0-5 years of age as well as they are responsible for taking children for immunization.

3.5. Sample size determination

The following formula was be used to determine sample size, (Keish Leslie 1967)

$$N = \frac{Z^2 Pq}{d^2}$$

Where N = sample size required.

p = proportion of the study population without characteristic under study taken as 50% (mothers with poor knowledge attitudes and practices about immunization)

z = standard deviation at 95% confidence level taken to be 1.96

d=error allowed by the researcher taken as 10% at confidence level of 1.96

q=1-p

1-p=100-50

$$N = \frac{z^2 p (1-p)}{d^2}$$

$$N = \frac{(1.96)^2 50(100-50)}{10^2}$$

=96 respondents

Due to financial and time limitations 65 mothers were interviewed instead of 100, this is because every mother had equal chances of being included.

3.6. Sample techniques

The sample of mothers with children aged 0-5 years were selected using cluster sampling techniques.

3.7. Sampling strategy

Inclusion and exclusion criteria were used.

3.7.1 Inclusion criteria

Mothers with children 0-5 years, who were willing to participate in the study and were residents of Mugwata village, were included in the study

3.7.2 Exclusion criteria

Mothers who were nonresidents of Mugwata were excluded.
Mothers who were not willing to participate in the study were excluded.

3.8. Definition of variables

3.8.1. The independent variables

Mother's knowledge and attitudes on immunization

3.8.2. The dependent variables

Practices of mothers on immunization of children depend on mothers' knowledge and attitudes.

3.9. Data quality control

In order to ensure quality the following was done: A questionnaire was designed and pretested by doing a pilot study among 4 mothers from Mugwata village to assess its strength and relevancy and later adjusted to improve its strength, relevance, reliability and validity. After piloting the study, It was discovered that 3 mothers could not easily interpret the questions, those who managed took long hence interpretation to every mother was emphasized to obtain quality information.

3.10. Data collection

Data was collected by a questionnaire. Because most of the mothers had low levels of education and could not easily interpret and fill in the questionnaires by themselves, it was seen necessary to interpret question by question in order to obtain quality information.

Two research assistants with good knowledge of local language "Rufumbira" and English were trained on research methodology and studied objectives before data collection to assist in data collection.

3.11. Data analysis and management

The data collected was analyzed manually using tally sheets. Both qualitative and quantities methods where applied. Observations were made according to the study while conclusions were drawn basing on the findings.

Fully manipulated data was locked in a cupboard and only accessed by the researcher to ensure data safety and confidentiality.

3.12. Data presentations

Results were displayed in tables, pie-charts, bar graphs relevant to variables measured, and statistical packages were Microsoft Excel.

3.13 Ethical considerations

Adherence to ethical standards was observed. Ethical and scientific clearance to carry out the study was obtained from Research and Ethics committee of Kampala International University, Western Campus. Then permission to conduct the study was sought from the Chairpersons LC1 and III of Mugwata village and Muramba Sub County respectively. Participation in the study was strictly voluntary and only mothers who gave informed consent were interviewed. Confidentiality was maintained throughout the study. In addition access to data collection was restricted to only those involved in the study. Mothers with poor knowledge, attitudes and practices about immunization who were encountered were health educated and advised accordingly.

3.14 Study limitations and remedies.

An element of bias could be introduced since interviews were conducted in the local language "Rufumbira" yet the tools were printed in English .This could also result in some degree of non-differential miss clarification. To mitigate effects of possible bias, adequate training of research assistants was done with particular emphasis on how questions were to be posed to the study participants.

The study was based at village level, therefore it may not represent the entire district hence results should be interpreted limited to the area of study.

The researcher faced financial constraints in transport and other expenses.

Remedy; the researcher drafted a budget which was strictly followed.

Some mothers declined decline participation.

Remedy; the researcher followed ethical considerations for successful community entry and participation was strictly voluntary.

3.15. Dissemination of results

Copies of research reports were distributed to Kampala International University Research Committee, and another copy to the office of LC III Chairperson, Muramba sub-county.

CHAPTER FOUR

RESULTS

4.0 Introduction.

This chapter consists of findings from the study about knowledge attitudes and practices of mothers on immunization. The results are presented in Tables and Figures

4.1.0. Demographic Characteristics.

Demographic information was collected of age, education level, occupation and marital status from the respondents.

4.1. 1: Distribution of respondents according to their demographic chacteristics.

Variables	Frequency (n=65)	Percentage (%)
Age group		
15-24	28	43.1
25-34	26	40
35-44	10	15.4
45 and above	01	1.5
Education level		
Never went to school	06	9.2
Primary	37	56.9
Secondary	10	32.6
Tertiary	01	1.5
Occupation		

Peasants	57	87.7
Civil servants	04	6.1
Small scale business	02	3.1
Muslims	02	3.1
Marital status		
Married	54	83.1
Single	02	3.1
Cohabiting	01	1.5
Divorced	05	7.7
Widows	03	4.6
Number of children aged 0-5 per household	Number households n=65	Total number of children n=121
1	23	23
2	30	60
3	10	30
4	02	08

Majority of the mothers 28 (43.1%) were aged 15-24 years and only 01 (1.5%) of the mothers was 45 years and above.

Most of the mothers 59(90.8%) had attained formal education; 6(9.2%) had never gone to school.

Most of the mothers 57 (87.7%) were peasants, 4(6.2%) were government civil servants, 2(3.1%) were small scale business holders and others were 2(3.1%).

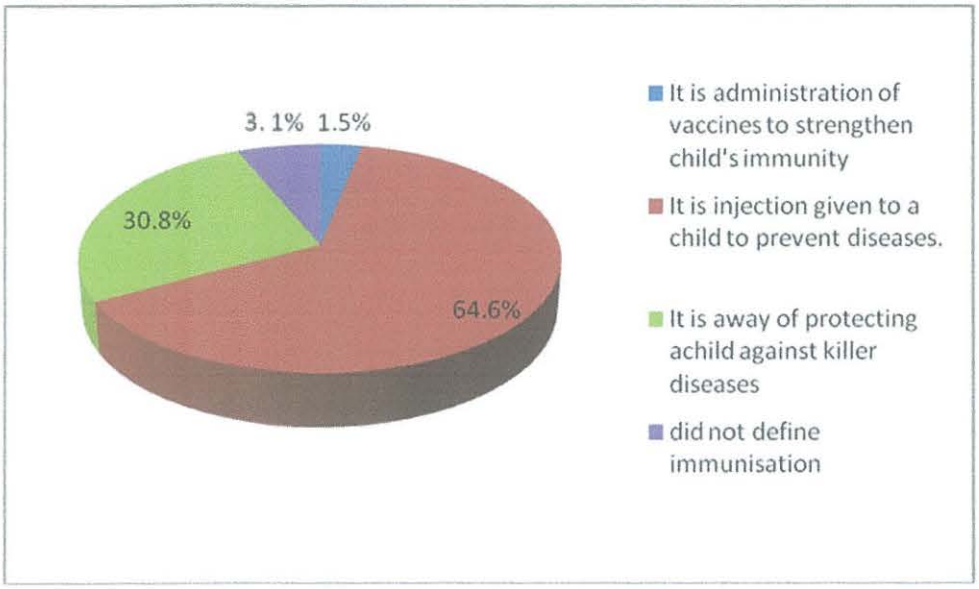
Most of the mothers 54(83.1%) were married, 5(7.7%) were divorced, 3(4.6%) were widows, 2(3.1%) were single mothers and only 1(1.5%) were cohabiting.

On average each household had 2 children of age 0-5 years.

4.1.2 Knowledge of Mother's on Immunization

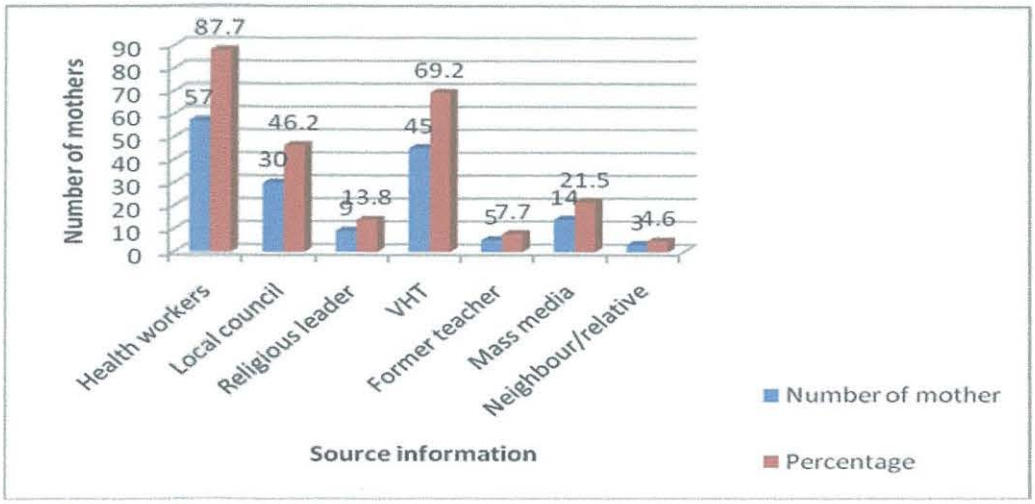
The study explored the mother's knowledge through asking them to define immunization. The collected data was analyzed by use of a pie chart

4. 1.3 Distribution of mothers according to knowledge about the definition of immunization



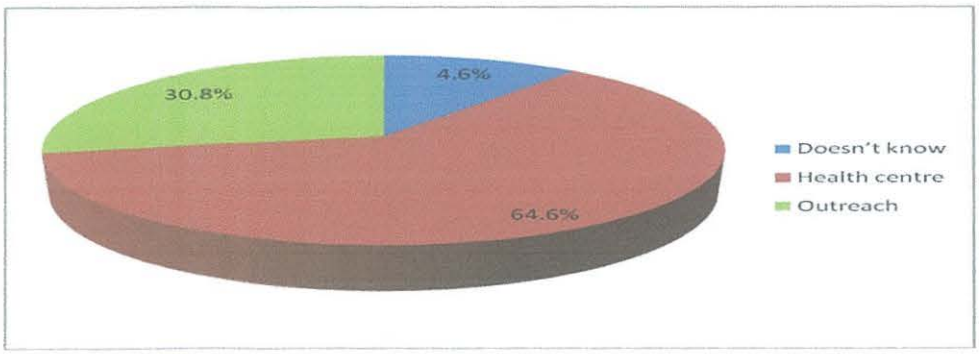
Most of the mothers 63(96.9%) were able to define immunization; 42(64.6%) defined immunization as injection given to a child to prevent diseases, 20(30.8) % of mothers understood it as a way of protecting a child against killer diseases, 1(1.5%) knew immunization as administration of vaccines to strengthen a child's immunity while 2(3.1%) of the mother did not define immunization.

4.2.2 Distribution of mothers according to the source of knowledge on immunization



The most common source of information was through health workers 57(87.7%) followed by village health team 45(69.2%), then local council 30(46.2%), mass media 14(21.5%), religious leader 9 (13.8%), former teacher 5(7.7%) and a few mothers 3(4.6%) received information from neighbors/relatives.

4.2.3 Distribution of mothers according to knowledge about where mothers take their children for immunization



Most of mothers 42(64.6%) take their children to health centers for immunization, 20(30.8%) take their children for immunization at routine outreaches while 3(4.6%) didn't know where to take their children for immunization.

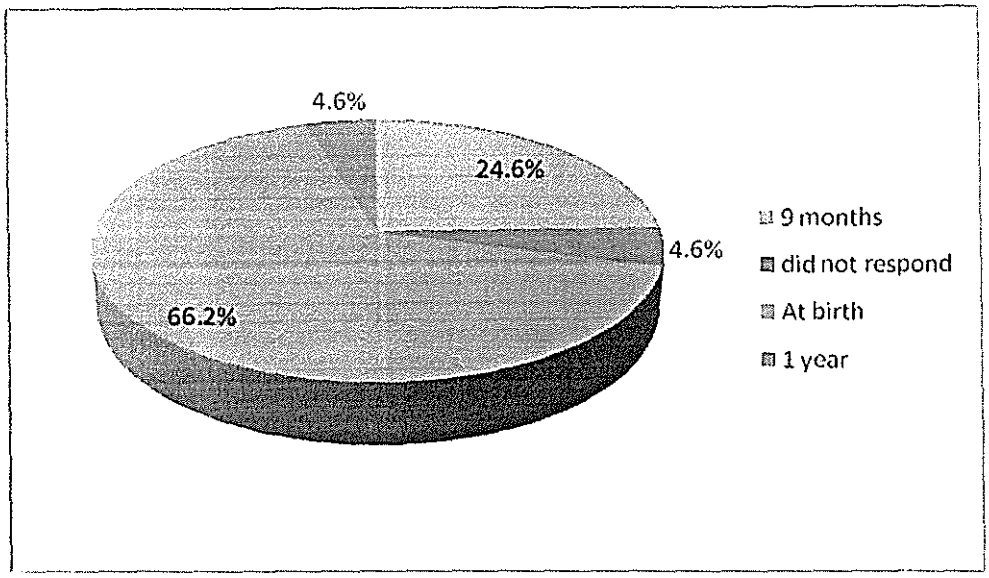
4.2.4 Distribution of mothers according to knowledge of different immunizable diseases in children of 0-5 years of age. n=65

Disease	Mothers	
	Frequency	Percentage (%)
Poliomyelitis	65	100
Measles	50	76.9
Tuberculosis	47	72.3
Whooping cough	31	47.7
Diphtheria	13	20.0
Tetanus	33	50.8
Heamophilus influenza b	04	6.2
Pneumonia	03	4.6
Diarrhea	02	3.1
Hepatitis B	01	1.5
Others like; scabies, otitis media and vomiting.	03	4.6

All respondents mentioned poliomyelitis among the diseases they knew, 50(76.9%) mentioned measles, 47(72.3%) mentioned TB, whooping cough 31(47.7%), Tetanus 33(50.8%), diphtheria 13 (20%), Heamophilus influenza b 4(6.2%), pneumonia 3(4.6%), diarrhea 2(3.1%), Hepatitis B 1(1.5%) and 3(4.6%) mothers out of total respondents mentioned other diseases like; Otitis media, vomiting, and scabies as immunizable diseases.

1(1.5%) and 3(4.6%) mothers out of total respondents mentioned other diseases like; Otitis media, vomiting, and scabies as immunizable diseases.

4.2.5 Distribution of mothers according to knowledge about correct earliest age of immunization



Most of the mothers 43(66.2%) said that the first earliest age for immunization is at birth, 16(24.6%) said at 9 months, 3(4.6%) said at 1 year and 3(4.6%) did not respond

4.2. 6 Distribution of mothers according knowledge on last age for immunization.

Age(years) of children	Number of mothers.	Percentage (%)
2	39	60.0
1	05	7.7
5	14	21.5
6	03	4.6
No response	04	6.2
Total	65	100.0

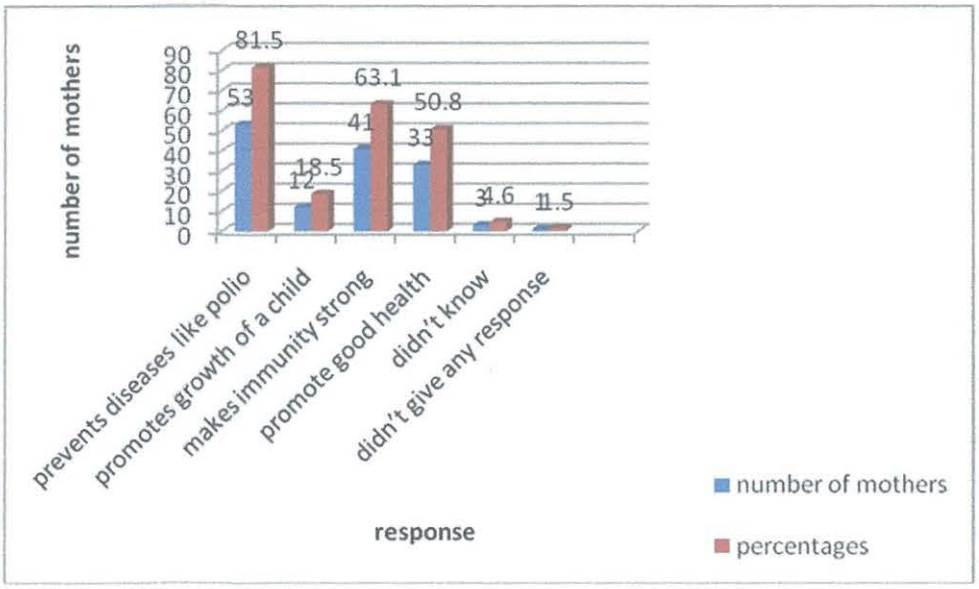
4.3. ATTITUDE OF MOTHERS ABOUT IMMUNIZATION

4.3.1: Distribution of mothers according to belief about importance of immunization.

Response	Mothers	
	Frequency	Percentage (%)
Important	62	95.4
Not important	03	4.6
TOTAL	65	100.0

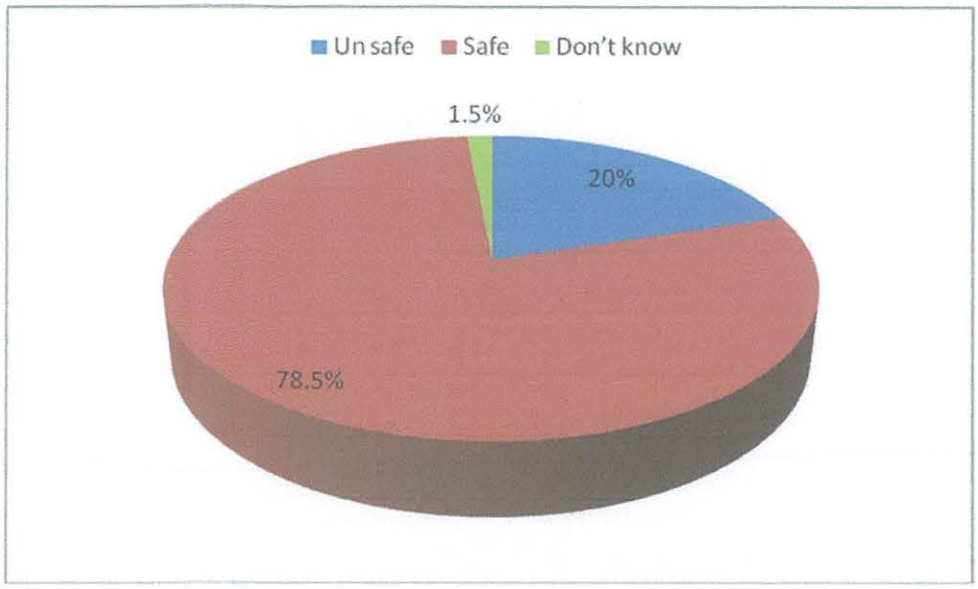
Most of respondents 62(95.4%) believed that immunization is important, 3(4.6%) mothers did not believe that immunization is important.

4.3.2: Distribution of mothers according to benefits of immunization n=65



Most of the mothers 61(93.8%) said immunization is beneficial and gave different benefits, 3(4.6%) said they didn't know benefits of immunization and 1(1.5%) did not give any response.

4.3.3: Distribution of mothers according to belief about Safety of vaccines n=65



Most of the mothers (51) 78.5% said that vaccines are safe, (13) 20% said that vaccines are not safe while (1) 1.5% didn't know whether vaccines are safe or not.

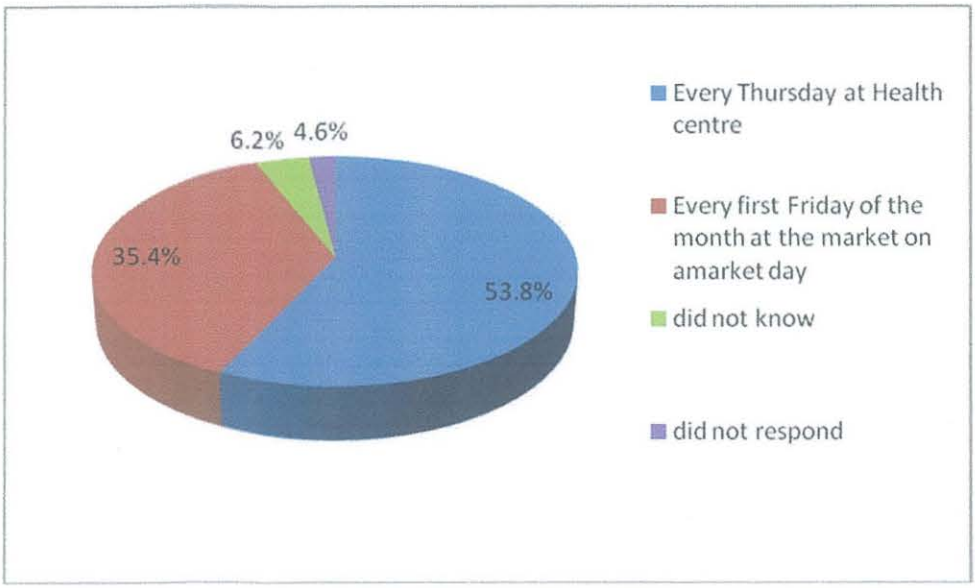
4.3.4: Distribution of mothers according to reasons for vaccines being unsafe.

Response	Frequency	Percentages (%)
Gives baby fever	05	38.5
Make baby cry	02	15.4
Cause active disease	01	7.7
Can causes swelling at site	04	30.8
Weaken immunity if many	01	7.7
Total	13	100.0

Out of 13 mothers who said that vaccines are unsafe, 5(38.5%) of them said that vaccines give fever to the child, 4(30.8%) said they cause swelling at injection site, 2(15.4%) said that they

make the baby cry, 1(7.7%) said they cause active disease to the child and 1(17.7%) said that many vaccines weaken a child's immunity.

4.3.5 Distribution of mothers according to days when immunization is done. n=65



Most of the mothers 35(53.8%) mentioned every Thursday at the health centre, 23(35.4%) said every first Friday of the month as days immunization is done, 4(6.2%) did not know day of immunization and 3(4.6%) did not answer.

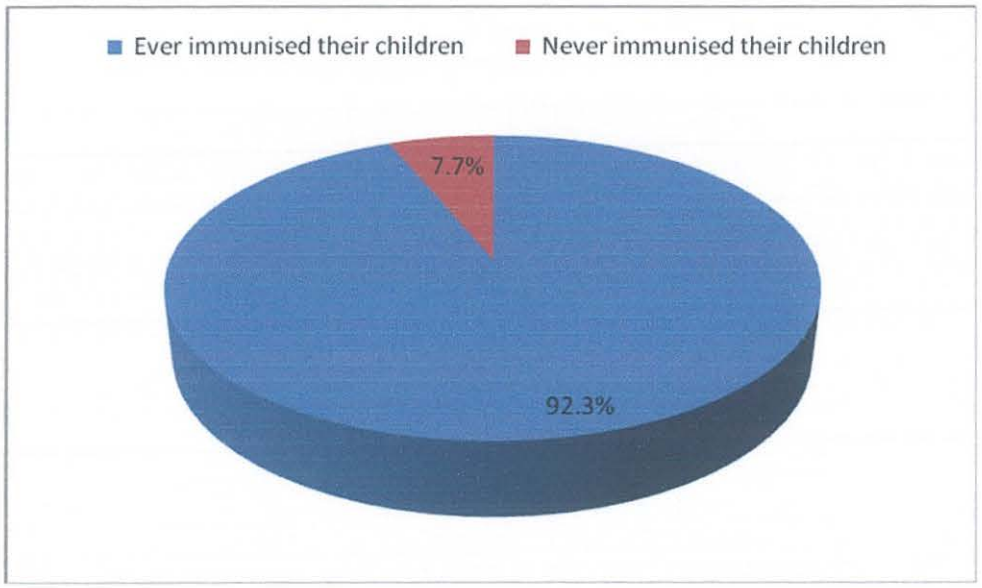
4.3.6. Distribution of mothers according to convenience of date and place for immunization. n=61

Response	Frequency	Percentage (%)
Date convenient	53	88.3
Date not convenient	7	11.7
Place convenient	49	81.7
Place not convenient	11	18.3

53(88.3%) mothers said that the date for immunization was convenient, 7(11.7%) mothers said that date is not convenient, 49(81.7%) said that place of immunization was convenient and 11 (18.3%) said place was not convenient.

4.4.0. Mother's Practices on Immunization

4.4.1: Distribution of mothers according to immunization status of children. n=65



Most of the mothers 60(92.3%) had ever taken their children for immunization while 5(7.7%) mothers had never attended any immunization.

4.4.2: Immunization practices in relation to distance between different households and immunization centers.

Distance(km)	Mothers who followed the Schedule/were up to date.	Number of mothers with children who were drop outs.	Number of mothers who never took children for immunization	Total(numbers)
Less than 2	34	04	00	38
Greater than 2	15	07	05	27
Total	49	11	05	65
	75.4%	16.9%	7.7%	100%

49(75.4%) of the mothers had fully immunized their children irrespective of distance, 11(16.9%) didn't complete immunization and 5(7.7%) mothers whose households were more than 2 km away from immunization centers didn't take their children for immunization.

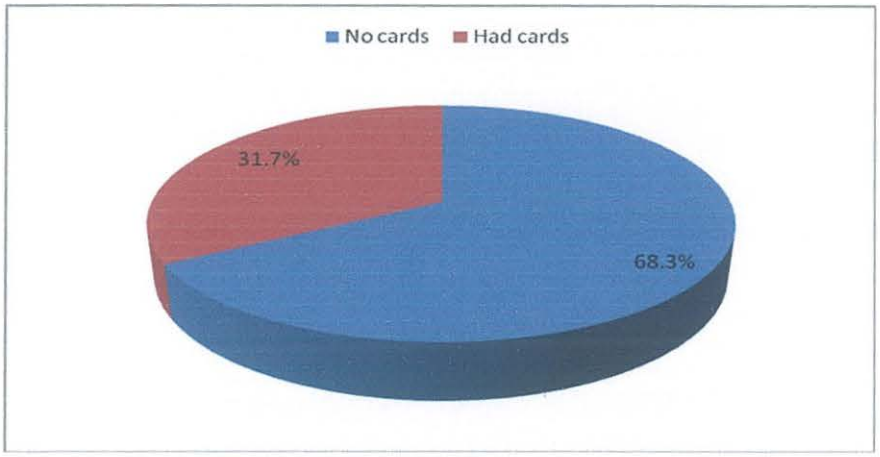
4.4.3: Distribution of mothers according to reasons for no immunization/partial immunization. n=17

;ason		Number of mothers	Percentage (%)
ck of 'ormati	Un aware of importance of immunization, immunization schedule not known	4	23.5
	Others including; Wrong ideas about contraindications of immunization, Mother un ware of need to return for 2nd or 3rd dose	2	11.8

	Total	6	35.3%
ack of notivatio	Previous worst experience including mistreatment by vaccinators	1	5.9
	No trust in immunization	1	5.9
	Total	2	11.8%
bstacles	Fear of side effects	2	11.8
	Immunization centre too far	1	5.9
	Mother too busy, child living with relatives like grandparents, family problems including mother's illness, child was sick, Sick child brought but not immunized.	2	11.8
	Waiting time too long, child still young.	2	11.8
	Lack of immunization card,	1	5.9
	Total	8	47.1%
o response given		1	5.9%

Out of the 17 mothers who did not follow the immunization schedule; 8 (47.1%) of them said it was due to obstacles, 6(35.3%) said it is because of lack of information about immunization, 2(11.8) said it was because of lack of motivation and only 1(5.9%) did not give any reason.

3.4.4: Distribution of mothers according to availability of child health card. n=60



Out of the 60 mothers who had ever taken their children for immunization, 41(68.3%) had and showed child health cards while 19(31.7%) never had child health cards.

4.4.5: Distribution mothers according to reasons for no card

Response	Number of mothers	Percentage (%)
Got lost	14	73.7
Left at immunization centre	03	15.8
Was not given	00	0.0
Others; like got burnt in house	02	10.5
Total	19	100

Out of the 19 mothers who never produced child health cards, 14(73.7%) of them said the cards got lost, 3(15.8%) said they left the cards at the immunization centre, 2(10.5%) gave other gave reasons like the card got burnt in the house and non of the mothers said that the card was not given.

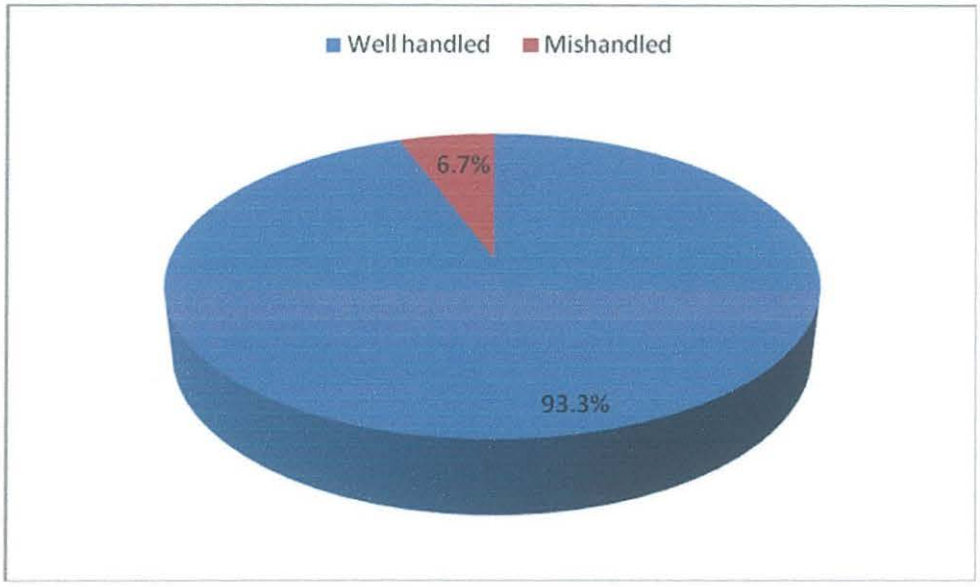
4.4.6: Participation of mothers in immunization practices in relation to their level of education.

Participation in immunization	Levels of education of mothers and their corresponding frequencies.							
	did not go to school (n=6)		primary (n=37)		Secondary and tertiary(n=22)		Total (n=65)	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Up to date	01	16.7	30	81.1	18	81.8	49	75.4
Did not follow the schedule.	01	16.7	06	16.2	04	18.2	11	16.9
Didn't participate	04	66.7	01	2.7	00	00	05	7.7
Total	06	100%	37	100%	22	100%	65	100.0%

Out of 6 mothers who did not go to school, only 1(16.7%) followed immunization schedule and 4(66.7%) did not participate at all. Out of 37 mothers who attended primary level, majority 30(81.1%) followed the immunization schedule and 1(2.7%) did not participate at all. Out of 22 who attended secondary and above, most 18(81.8%) of mothers completed immunization schedule and none of them didn't participate in immunization.

4.4.7: Distribution of mothers on how they were handled by vaccination team

n=60.



Out of the 60 mothers who have ever taken their children for immunization, 56(93.3%) of them were handled well by vaccination team and 4(6.7 %) mothers were mishandled including being verbally insulted.

4.4.8. Distribution of mothers according to charges for immunization services n=60

Response	Frequency	Percentage (%)
Charged	0	0
Not charged	60	100

Among the 60(100%) mothers who had ever taken their children for immunization, none of the mothers said she that she was charged.

CHAPTER FIVE

DISCUSSION OF FINDINGS, CONCLUSION AND RECOMMENDATIONS.

5. 1 DISCUSSION

5.1.2. Demographic characteristics of respondents.

The study targeted 65 respondents, who were mothers with children aged 0-5 years. Majority of the mothers were aged 15-24 years. These findings are attributed to early marriages and early pregnancies in Muramba sub-county and it's also in line with findings of Uganda National Population Census of 2012, (UDHS, 2016 report), which shows that Uganda's population is dominated by youth.

Out of the total respondents, 90.7% had ever attended formal education. However there was a high school dropout rates as evidenced by low number of mothers who reached secondary. This could be the reason for low immunization coverage due to knowledge gap among the mothers. "Educate the woman, educate the nation". Therefore the low level of education could a contributing factor to the coverage. Therefore there were low levels of education in Mugwata village.

5.1.3 Knowledge of Mothers about Immunization.

The results showed that most of the mothers were able to define immunization. This implies that the respondents knew what immunization was and understood it as a way of protecting a child against killer diseases. This is similar to the findings of Okol, (2014) whose findings showed that majority of respondents said immunization was injection given to a body and prevent diseases. Respondents said immunization is a way of protecting the body against killer diseases like polio, tetanus, whooping cough and respondents understood immunization as administration of vaccines to boost body's immunity. However, there was knowledge gap between the research findings where in Akol's research, majority of the respondents were able to mention the immunizable killer diseases, while in this research, respondents mentioned polio and measles only, hence knowledge gap and could be a contributing factor to the low immunization coverage.

More so, in a research conducted by Siddigi et al (2010), the percentage proportion of mothers correctly identified the 7 EPI diseases as; TB, diphtheria, tetanus, measles, polio, and hepatitis B, however poor knowledge was documented with some mothers mentioning other diseases like; Otitis media, vomiting and scabies as some of immunizable diseases.

Most of the mothers knew days when immunization was scheduled. This is in line with study findings by Baberturiji et al (2012) about KAP of stakeholders towards immunization in Bomo state Nigeria which revealed that all stake holders were aware of immunization, however there was lack of adequate information about logistics and time of immunization programs. More so, dates and places of immunization were convenient for most of the mothers.

Generally the knowledge about immunizable diseases was high. Most mothers identified the right age to start immunization, some mothers identified the right age to stop immunization .This implies that mothers lacked knowledge about immunization schedule leading to increased dropout rates and partial immunization of children. The findings are contradictory to that of Arinaitwe P, (2011), which stated that most mothers failed to identify the right age to start and stop immunization schedules for their children.

The commonest source of information about immunization was through health workers. This is obvious since health workers deal with immunization services which means that they are doing their job. This shows that there are other factors contributing to the low immunization coverage.

5.1.4. ATTITUDE OF MOTHERS ON IMMUNIZATION.

The results showed that the majority of the mothers believed immunization to be useful. Most of the mothers believed vaccines to be safe. This indicated a positive attitude towards vaccines and is in line with a study by Amei (2008) which stated that most of the parents believed that vaccines are safe. According to this study, attitude is not a contributing factor towards low immunization coverage in Mugwata Village, hence there could be compounding factors that could be found out.

The reasons given by some mothers who said that vaccines are unsafe included; vaccines give fever to the child, causes swelling at site of injection, make the baby cry, causes active disease to

child and that many vaccines weaken child's immunity, vaccines cause active disease to the child. This was in line with a study done by Rogalaska J et al, (2010) which stated that some parents in Poland thought that the vaccines were harmful and lacked confidence.

This was also in line with study done by Sanford R. K et al, (2007) who stated that most of the mothers supported vaccination of their children but misconceptions existed, some parents believed that administration of too many immunizations would weaken the child's immune system. Thus this could be an attributing factor to the low coverage.

Generally mothers had a good attitude towards immunization. The findings are much related to the study done by Mapatano MA in Kinshasa DRC, (2008) which showed majority of mothers had a positive attitude on immunization.

5.1.4. PRACTICES OF MOTHERS ON IMMUNIZATION.

Among the mothers who did not go to school, minority completed immunization schedule, with the most striking percentage not participating in immunization at all. Out of the mothers who attended primary level, majority were up to date in regards to the immunization schedule. Out of the respondents who attended secondary and tertiary, majorities were up to date in regards to the immunization schedule and none of them didn't participate in immunization, these findings showed good practices of immunization services which increased with levels of education. Hence education was one the factors influencing mothers' practices on immunization in Mugwata village.

Some mothers used traditional methods like bathing the child with local herbs to prevent measles. This was in line with the study done by Oria P.A et al (2013), who stated that some people thought it is not necessary to seek a hospital care for immunization instead they used home remedies like hot water and lemon juice. This is in the line with the findings in this study where majority never participated in immunization at all, which could be a contributing factor to the low immunization coverage.

Of all respondents, the minority did not follow immunization schedule. The reasons for this poor immunization practices included;

Obstacles like fear of side effects, immunization centre too far, mother too busy, child being with relatives like grandparents, family problems including mother's illness, child was sick, Sick child brought but not immunized, Waiting time too long, child still young, Lack of immunization card, Vaccines not enough.
Lack of information; like lack of awareness on importance of immunization, immunization schedule not known, Wrong ideas about contraindications of immunization, Mother unaware of need to return for subsequent doses.

Lack of motivation; like previous worst experience including mistreatment by vaccinators, No trust in immunization. Similar findings were stated by Luwagala B, (2014) while carrying out a research on immunization of children aged 0-9 months in Kyebando village. The above results show that mothers had several misconceptions and less knowledge about immunization. Thus health education on immunization either was not carried out adequately or it may have been wrongly conducted giving misinformation.

One of the factors explored was the relationship between distance from households to immunization centers and mothers' willingness to utilize immunization services which found out that most of the mothers had fully immunized their children irrespective of distance. It was anticipated that people living nearer to immunization centers would be more willing to participate in immunization than those in further distances. Basing on the assumption that the less over all costs of travelling, the more the willingness to move and attend. But this was not true.

It is believed that educated societies have a good health seeking behavior. Therefore it was assumed that one of the hindrances that perpetuated low public participation in immunization activities were low levels of education among mothers .Hence the researcher compared the mothers' level of education with their participation in immunization of their children. This factor was found contributory.

Out of the respondents who had ever taken their children for immunization, majority of them had child health cards and a few showed partially filled immunization cards .This was not in line with a study done by Mapatano M.A et al (2008) which stated that if mothers were able to

produce cards it was most likely that the child is fully immunized. The proportion of respondents who never had cards in Mugwata was much lower than that of parents in Rwot village in Albtong district according to a study by Okol, (2014) which found out that majority of the mothers never had child health cards.

Among the respondents who had taken their children for immunization, majority said that they were handled well by the vaccinators, while the minority stated that they were mishandled including being verbally insulted by vaccination team. The mishandling of mothers by vaccination team could be one of the anticipated factors for partial immunization of children, hence an indicator for low immunization coverage in Mugwata village.

5.2.0 CONCLUSIONS.

According to the study, the KAP of mothers in this study area was positive where by majority of the respondents believed vaccines to be safe. This KAP was ruled as a hindrance for immunization coverage, although the minority of the mothers believed in use of traditional medicine for immunization. This research found out that this could be a reason for low immunization coverage in the area of study, though it couldn't be taken as a sole reason for low immunization coverage.

There could have been other hidden factors leading to low immunization coverage in the study area. Therefore, this could still be an area of research to find out the real cause of low immunization coverage.

5.3.0 RECOMMENDATIONS.

The following are recommendations based on the study findings for improving the immunization services.

The MoH and its partners should involve the community in all stages of immunization programs.

MoH should improve upon the available immunization programs aimed at sensitizing people on benefits of following National Immunization Guidelines.

Health workers should improve on the attitude towards patients and clients.

Health workers should not only concentrate on giving immunization but also health educating mothers about vaccines and immunization schedule.

There is need for more research to find out the hidden factors that influence the low immunization coverage apart from KAP.

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APPENDICES

APPENDIX I: CONSENT FORM

My name is Bakunzi David a student of Kampala International University. I am conducting a study to determine the knowledge, attitudes and practices of rural mothers about immunization of children aged 0-5 years in Mugwata Village which is a requirement for the award of a Diploma in Clinical Medicine and Community Health.

The findings of the study will help to define appropriate individual, family, community level and national level of interventions to ensure optimum utilization of immunization services and vaccination coverage.
I therefore request you kindly to avail me with the required information. Information provided will be kept confidential and used purposely for this research.

The purpose of the study has been explained to me and I have understood this document so I am willing participate in the study;

Thumb print/signature.....Date.....

Respondent

Signature.....Date.....

APPENDIX II:

QUESTIONNAIRE

I am a third year student of Clinical Medicine and Community Health at Kampala International University. I am carrying out a study about knowledge attitudes and practices of mothers towards immunization of children aged 0-5 years. I am not interested in your names and you are free to decline participation. The discussion will take about 10-15 minutes.

GENERAL INSTRUCTIONS; Use a TICK√ to indicate the answer mentioned and fill in gaps provided if required.

A. RESPONDENT'S DETAILS. *(Fill in the gaps)*

i. Respondent's age.....

ii. Respondent's level of education..... vi. Village.....

iii. Respondent's occupation.....

vii. Respondent's religion.....

v. Marital status..... viii. Number of children (0-5) years.....

B. KNOWLEDGE ABOUT IMMUNIZATION.

1. What do you understand by immunization?

i. Administration of vaccines to strengthen Childs immunity.

ii. Injection given to a child to prevent diseases

iii. A way of protecting a child against killer diseases.

iv. Others

2. How did you come to know about immunization?

Health workers	☐	Local council	☐
Village Health	☐	Team/Relative/friend	☐

Religious leader ☐ Mass media ☐

Others (specify).....

3. Where do mothers of this area take their children for immunization?

   i. Health centre
   ii. Outreach
   iii. .house-house immunization
   iv. Doesn't know

4. How far is the immunization center from your home?

   i. Distance less than or equal to 2km ☐
   ii. Distance more than 2 km ☐

5. List different Vaccine Preventable Diseases (VPDs) that are immunized against in children of 0-5 years of age in Uganda.

Poliomyelitis ☐ Tetanus ☐
Diphtheria ☐ Whooping cough ☐
Haemophilus influenza ☐ Pneumonia ☐
Tuberculosis ☐ Measles ☐
Diarrhea ☐ Hepatitis B ☐

Others (specify)

6. At what age should a child starts receiving immunization?

i. At Birth ☐ iii. 9 months ☐
ii. At one month ☐ iv. At 1 year ☐

7. At what age should a child stops receiving immunization?

i. At1 year ☐ iii. At 5 years ☐

ii. At 2years ☐ iv. At 6 years ☐

C. ATTITUDE ABOUT IMMUNIZATION

8. Do you believe that immunization is of any importance?

i. Yes ☐ ii. No ☐ iii. I don't know ☐

9. What are the benefits of immunization?

i. Prevents diseases ☐ ii. Makes immunity strong ☐

ii. Promotes growth of a child ☐ iv. Promotes good health ☐

v. Others

10. Are vaccines safe?

Yes ☐ No ☐ don't know ☐

11. What are dangers of vaccines?

i..... ii.....

.ii..... iv .....

12. On which days is immunization normally scheduled?

i..... iii.....

ii..... iv.....

13. Is the date and place of immunization convenient for you?

i. Date convenient. ☐ ii. Date not convenient ☐

iii. Place convenient ☐ iv. Place not convenient ☐

Others, specify.....

D. PRACTICES OF MOTHERS ON IMMUNIZATION

14. Are all your children immunized?

i. Yes, (provides evidence of child health card(s) ☐ ii. No ☐

iii. Yes, doesn't provide evidence of child health card(s) ☐

15. If a child health card was absent, what happened to it?

Child Health Card got lost ☐

Child Health Card wasn't givens ☐

Others, specify.....

16. If the mother did not complete or children not taken for immunization at all, what are the reasons for partial immunization or not taking children for immunization?

i. Lack of motivation .....

ii. Obstacles.....

iii. Lack of motivation.....

iv. Others.....

17. If mother doesn't have a child health card, give reason for not having child health card.

i. Not given

ii. Got lost

iii. Others (specify).....

.....

18. State some of traditional ways used for preventing the following diseases.

Vaccine preventable disease	**Method of prevention**
Poliomyelitis	
Measles	
Diphtheria	
Whooping cough	
Tuberculosis	
Tetanus	
Hepatitis B	
Diarrhea	
Pneumonia	
Heamophilus influenza b	

19. How did the vaccination team handle you?

i Good ☐

ii. Bad ☐

If bad, elaborate ....

20. Did you pay for the services?

i. Yes ☐

ii. No ☐

21. How much money did you pay for the service (if yes)

i Less than 5000 /=

ii. More than 5000/=

END

THANKS FOR YOUR CO-OPERATION

KAMPALA INTERNATIONAL UNIVERSITY
TEACHING HOSPITAL

School of Allied Health Sciences (SAHS) Ishaka,
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OFFICE OF THE ADMINISTRATOR –SAHS

25th April 2017

The Chairperson Muramba Sub-county
KISORO

Approved by NZABONIMPA Stanley

CHAIRPERSON L. C. III
Muramba Local
Government Council
P. O. Box 123, Kisoro

Dear Sir/Madam,

SUBJECT: DATA COLLECTION

Academic research project is an Academic requirement of every student pursuing a 3 year Diploma in Clinical Medicine & Community Health (DCM) of Kampala International University- Western Campus (KIU-WC). DCM program is housed in the School of Allied Health Sciences (SAHS).

The students have so far obtained skills in Proposal writing especially chapter one, Three & Questionnaire design. The student's topic has been approved by SAHS Research Unit and is herefore permitted to go for data collection alongside full proposal & dissertation writing. As you nay discover the student is in the process of full proposal development. However, the student MUST present to you his questionnaire and his research specific objectives that he wishes to ddress. We as academic staff of Allied Health Sciences are extremely grateful for your support in raining the young generation of Health Professionals. I therefore humbly request you to receive nd allow the student **BAKUNZI DAVID** Reg. No. **DCM/0049/143/DU** in your area to carry ut his research. His topic is hereby attached. Again we are very grateful for your matchless support nd cooperation.

opic: **A STUDY OF KNOWLEDGE, ATTITUDE AND PRACTICES OF MOTHERS TOWARDS IMUNIZATION OF CHILDREN AGED 0-5 YEARS IN MUGWATA VILLAGE GISOZI PARISH URAMBA SUB-COUNTY KISORO DISTRICT.**

25 APR 2017

ncerely yours,

ristine Kyobuhaire, Administrator- SAHS

: Dean SAHs
: Associate Dean SAHs
: Coordinator, Research Unit- SAHS
: H.O.D Dept. Public Health
: H.O.D Laboratory Sciences
: Coordinators; TLC & DEC

Appendix IV

Budget

Item	Unit price	Amount
Stationary	10,000/=	10,000/=
Internet services	30,000/=	30,000/=
Typing and printing	40,000/=	40,000/=
Airtime	20,000/=	20,000/=
Transport	50,000/=	50,000/=
Total		150,000/=

Appendix

Work plan

ACTIVITY	JAN 2017	FEB 2017	MAR 2017	APR 2017	MAY 2017	JUN/JULY 2017
Identification of research topic and approval of it.						
Assignment of supervisor and writing the proposal						
Continuation of proposal writing, submitting to faculty for examination.						
Data collection, data analysis, report writing and submitting it to faculty and defending it.						

APPENDIX VI

MAP OF UGANDA

APPENDIX VII

MAP OF KISORO DISTRICT.