# ADHERENCE TO CLINICAL GUIDELINES IN THE MANAGEMENT OF DIARRHOEA DISEASES IN CHILDREN AGED BELOW FIVE YEARS ADMITTED AT MAMA LUCY HOSPITAL, NAIROBI

BY

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A Thesis Submitted in Partial Fulfilment for the Award of the Degree of Post Graduate Diploma in Bio-Medical Research Methodology at the University of Nairobi.

# DECLARATION

I declare that this thesis is my original work and has not been presented for award of a degree in any other University.

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# DEDICATION

To my grandmothers, Clara and Grace.

#### ABSTRACT

**Introduction**: Globally, diarrheal diseases exert significant burden of childhood morbidity and mortality. Developing countries of Southern Asia and Sub-Saharan African bear the greatest impact accounting for over 83% of the global burden of diarrheal disease. Despite the availability of evidence-based diarrhea management protocols, it has remained the second leading cause of mortality among children below 5 years and is responsible for an estimated 1.5 million children deaths annually. However, adherence to the clinical guidelines has remained suboptimal impacting on treatment outcomes negatively. The aim of this study, therefore, was to evaluate levels of adherence to clinical guidelines and assess associated health outcomes among children aged 5 years and below admitted with diarrhea at Mama Lucy Kibaki hospital in Nairobi.

**Methodology:** A retrospective Medical Record Review (MRR) study was conducted at Mama Lucy hospital to evaluate levels of adherence to WHO clinical guidelines in the treatment of diarrhea disease among children aged 5 years and below. Patient's medical data was abstracted using a specially designed screening tool and a questionnaire developed from the clinical guidelines. Data collected was imported into SPSS version 21 for analysis and reporting. Descriptive statistics were computed and presented for continuous and categorical variables in tables, graphs and charts. Mean with corresponding standard deviations and percentages were reported. Simple logistic analysis was used to evaluate the association of different levels of adherence to clinical outcomes (status on exit from hospital and length of hospital stay).

**Results:** Diarrhea continues to rank among the top burden of disease at Mama Lucy hospital accounting for 21% among children aged below 5 years and is secondary only to pneumonia 31%. Adherence to clinical guidelines remains relatively low at 47% and a child who had not been assessed on admission for signs and symptoms of dehydration had an increased risk of dying by 16 times (OR 16.25, 95% CI 3.09-89.6, *p*-value 0.001) compared to a child who had been appropriately assessed. Excessive use of intravenous fluids, antidiarrheal drugs and over prescription of antibiotics are main impediments to adherence. The study recommends harmonized training to all cadres of staff on implementation of clinical guidelines, reinforced protocols and guidelines in clinical areas and close monitoring of implementation processes. In addition, a public

health approach embracing multiple strategies such as health education and nutrition is recommended.

**Conclusion:** Diarrhea continue to impact on morbidity and mortality despite being preventable. A multi-prong strategy is required to enhance management and control of diarrhea in children

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# ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
AVPU	Coma scale denoting alert, response to Voice, an appropriate response to Pain and Unresponsive
ETAT <sup>+</sup>	Emergency Traige and Treatment Plus
GOK	Government of Kenya
HIV	Human Immunodeficiency Syndrome
МОН	Ministry of Health
ORS	Oral Rehydration Salts
PI	Principle Investigator
RCT	Randomized Controlled Trail
SPSS	Statistical Package for Social Scientists
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organization

#### **DEFINITION OF TERMS**

Adherence-The clinical guidelines define adherence as the process of strictly doing what is required by the rules. To follow a plan of action.

**Diarrheal disease case definition-** WHO describes diarrhea as passage of 3 or more loose stools in 24 hours or more frequent stools than normal for a person. This does not include formed stool or "pasty"stools passed by an infant. The stool may be speckled by blood in cases of dysentery

**Standard treatment guidelines**- Systematically developed statements using evidence-based processes, consensus and experienced experts' opinion to assist health care decision making regarding a health problem

#### **CHAPTER ONE**

#### **INTRODUCTION**

#### **1.1 Background information**

Despite the existence of proven clinical guidelines for the treatment of diarrheal diseases, it remains a significant public health problem worldwide and a leading cause of morbidity and mortality (Sarker et al., 2016). Globally, an estimated 2.5 billion cases of diarrhea occurs annually and about 1.5 million children under five years of age die of diarrhea annually (Bhutta & Das, 2013). This figure has been described as being greater than the mortality in young people as a result of Acquired Immunodeficiency syndrome (AIDS), malaria and measles combined (UNICEF/WHO, 2009). Developing countries of Africa and South Asia bear the greatest impact with over 83% of diarrheal disease burden (Diouf et al, 2014). Sub-Saharan Africa remains the region in the world with highest under-five mortality with a ratio of 1 out of every 12 children dying before their fifth birthday as compared to 1 in every 147 children from developed countries of the world (UNICEF & WHO, 2015). Clinical guidelines are developed through rigorous processes and their implemented have proven effective (Sierra et al., 2012). However, adherence to the guidelines has remained suboptimal with glaring gap impacting on treatment outcomes. This thesis, therefore, aimed to assess how well clinical guidelines are adhered to during management of children below the age of 5 years with diarrheal disease admitted at Mama Lucy hospital in Nairobi.

Diarrhea is described as the passage of 3 or more loose or watery stools in 24 hours and is categorized as acute if lasting for less than 14 days, chronic or persistent if it occurs for more than two weeks and acute bloody diarrhea or dysentery if stool is speckled with blood (Frank-briggs, 2012).

Acute diarrhea refers to sudden onset of watery loose stool lasting for less than 14 days. In children, pathogens such as rotavirus, exterotoxigenic Escherichia Coli, Shigella, Compylabacteria Jejuni, Cryptosporidium, Vibrio cholera and Salmonella have been associated with acute watery diarrhea (Arvelo et al., 2010). The greatest risk associated with acute diarrhea is dehydration due to excessive loss of fluids and electrolytes often leading to severe dehydration with shock preceding death (Canavan & Arant, 2009).

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Acute bloody diarrhea typically, presents with visible blood stains in the watery stool (Liza & Gonzales, 2016) and is a sign of invasion by microorganisms leading to enteric infection. This form of diarrhea occurs in nearly 10% of all diarrhea disease and is associated with over 15% mortality among children aged <5 years (Shikur&Tamiru, 2014). Shigella and Entamoeba histolytica are the most common micro-organisms associated with bloody diarrhea (Mota et al., 2010).

Chronic or persistent diarrheal disease on the other hand refers to an increase in stool consistency that lasts for over 4 weeks. Globally chronic diarrhea accounts for 3.5% of all diarrhea and is associated with 30-50% mortality (Bahartha & Alezzi, 2015). Chronic diarrhea is classified as watery, fatty (malabsorption) and inflammatory depending on the causes (Shikur & Tamiru, 2014). Management of chronic diarrhea is intensive requiring detailed assessment , investigation, appropriate antimicrobial and nutrition (Juckett & Trivedi, 2011).

Diarrheal diseases remain major causes of morbidity and mortality especially among children aged below five years and is responsible for 1.5 to 2 million deaths annually (Tambe et al., 2015). In developing countries, children experience a median of 5 diarrheal episodes every year which can affect over 15% of their days (Mansour et al., 2014). Dehydration is the greatest risk in children presenting with diarrhea and predictor of poor outcomes (Brandt et al., 2015). Dehydration occurs when the child continuous to lose fluids and electrolyte from the body through copious stool output, most often with little input due to anorexia, poor absorption of nutrients and increased catabolism from the body reserves to generate energy (Sarker et al., 2016). Severe dehydration alone studies have shown heighten the risk of death with almost 0.5% (Lamberti et al., 2015). In addition, continued reduced intake during diarrhea episodes which has been observed as common practice especially in most developing countries is associated with increased incidences of malnutrition with the subsequent cyclic relationship (Beck, 2010, Godana&Mengistie, 2013, Gupta, 2014).

Management and control of diarrheal diseases is based on evidence-based clinical guidelines that are developed through rigorous processes and have proven easy to administer and are cost effective to use (Isanaka et al., 2012, Ganguly et al., 2015). In 2004, WHO and UNICEF issued a joint statement recommending the use of low osmolality oral rehydration salts (ORS) and zinc supplements in the treatment of diarrhea, continued feeding during diarrheal episodes and after to

allow for catch up time (UNICEF/WHO, 2013). The evidence based guidelines have been tested through randomized control trials (RCT), expert opinions and have proven efficacious in the treatment of diarrheal diseases worldwide (Brandt et al., 2015). The new low osmolality solution is a combination of 75mEq/l of sodium, 75 mmol/l of glucose and 245 mOsmol/l osmolality. Compared to the earlier solution (90mEq/l of sodium and total osmolality of 311mOgm/l), is the single most effective solution against all types of diarrheal diseases (Wardlaw et al., 2010). The low osmolality solutions evidence has shown reduces the need for supplemental intravenous fluids by 33% after initial hydration for severe cases, lowers incidence of vomiting by 30% and shorten stool volume by 20% and has also been found effective in the treatment for cholera in children (Telmesani, 2010). The additional zinc supplementation at a dose of 20 mg for children six months and above and 10 mg for those below six months given for 10-14 days is associated with reduced incidences, frequency, severity and persistence of diarrhea (Sarker et al, 2016). The physiology of zinc in treatment of diarrhea is thought to impact on the immune function enhancing the intestinal epithelial recovery during diarrheal episodes (De Queiroz et al., 2014). In most developing countries, children are found to be deficient of zinc increasing the need for supplementation during diarrheal episodes (Wieringa et al., 2015). In addition, intravenous fluids are recommended when assessment indicates that the child has severe dehydration and the guideline outlines the protocol for intravenous infusion as well as the tailing off procedure (KNBS, 2014). Antibiotics are only recommended where a child has bloody stool or confirmed cases of cholera or dysentery or incases of co-existence of diseases that require antibiotic therapy (Carvajal-Vélez et al., 2016). Nutritional maintenance through exclusive breastfeeding for children below six months and continued breastfeeding with additional foods during the course of diarrhea are recommended to counteract nutritional loses (UNICEF/WHO 2013).

Adherence to evidence-based guidelines remains critical to quality treatment and care (Brandt et al, 2016). However, adherence to clinical treatment guidelines in the management of diarrhea studies have shown is still inadequate (Vecchio et al., 2016). Appropriate adherence to treatment guideline in diarrhea management demand an initial assessment and classification of dehydration levels to guide treatment regimen (Pathak et al, 2016). For example, immediately a child arrives at the front line, a rapid assessment of diarrhea status and classification should be initiated. Diarrhea should be classified as mild based on weight loss of <5%, moderate when weight loss is between 5-10% and severe if >10%. Assessment of weight however poses a challenge as it requires

comparison with previous weight rating which may not be available. Therefore a more rapid assessment recommendation includes evaluation of cardinal signs; capillary refill which should be not more than 2 seconds, decreased skin turgor, the status of breathing and level of consciousness and categorized according to degree of dehydration (Lulu, 2010). Figure 1 presents a simplified dehydration assessment format.

Symptoms	Minimal or no	Mild to moderate	Severe dehydration
	dehydration (<3% loss	dehydration (3% -9%	(>9% loss of body
	of body weight	loss of body weight)	weight)
Mental status	Well, alert	Normal, fatigued or	Apathetic, lethargic,
		restless, irritable	unconscious
Thirst	Drinks normally, might	Thirsty, eager to drink	Drinks poorly, unable
	refuse liquids		to drink
Heart rate	Normal	Normal to increased	Tachycardia, with
			bradycardia in most
			severe cases
Quality of pulses	Normal	Normal to decreased	Weak, thready or
			implalpable
Breathing	Normal	Normal, fast	Deep
Eyes	Normal	Slightly sunken	Deeply sunken
Tears	Present	Decreased	Absent
Mouth and Tongue	Moist	Dry	Parched
Skin fold	Instant recoil	Recoil in <2 seconds	Recoil >2 seconds
Capillary refill	Normal	Prolonged	Prolonged, minimal
Extrimities	Warm	Cool	Cold, molted, cyanotic
Urine output	Normal to decreased		Minimal

Table 1. Symptomatic assessment and classification of dehydration

Adapted from: Kenya Basic Pediatric Protocol (2016)

Once initial assessment is done, appropriate diagnosis is made, degree of dehydration classified and appropriate treatment commenced according to stipulated guidelines where rehydration using intravenous therapy for the severe cases, oral rehydration using the new ORS and continued appropriate dosage of zinc sulphate with antibiotics only given to children presenting with bloody diarrhea or in cases of comorbidities requiring use of antibiotics (GOK, 2014). Close monitoring of the child and change of treatment should be followed and decision implemented based on findings (WHO/ UNICEF, 2013). Exclusive breastfeeding for children below 6 months should be encouraged and feeding for children aged above 6 months intensified to compensate for nutritional loss. At the time of discharge from the hospital, the child should continue with Zinc sulphate tablets for 10-14 days. Figure 2 outlines the syndromic management of diarrhea in children 5 years and below.

History of diarrhea/vomiting child <5 years				
$\checkmark$				
Check for shock, cold	N/saline 20mls/kg/bwt 15 min. Boluses 60 mls up			
hands plus weak/absent	to 4 times or until return of pulse, treat			
pulse, either capillary	hypoglacemia			
refill>3sec.	IV step 1. 30mls/kg/bwt ringers lactate over 30min			
	If age $\geq 12$ months or 60 mis if age $< 12$ months.			
Severe dehydration, Plan	IV step 11. 70mls/kg/bwt ringer over 2.5hours if			
C, unable to drink AVPU	age $\geq$ 12months or over 5 hours is age <12months.			
<a eyes,<="" plus="" sunken="" td=""><td></td></a>				
slow skin recoil >2sec.				
	NGT rehydration 100ml/kg ORS 6 hours			
Re-assess at least hourly, after 3-6 h	ours reassess as severe, some or no dehydration			
and manage according to plan C,B or	r A respectively			
Some				
(moderate)dehydration,	Plan D ODS by month 75 mls/kg over 4 hours plus			
able to drink adequately	aontinued broastfooding <6 months or			
but 2 or more signs of	breastfeeding and appropriate putrition >6 months			
sunken eyes skin recoil 1-	reassess at 4 hours, treat according to classification			
2 sec, restlessness or	reassess at + nours, near according to classification			
irritable				
$\downarrow$				
No dehydration	Plan A 10mls/kg ORS after each loose stool			

Fig 1: Syndromic management of childhood diarrhea (Adapted from: Kenya Basic Pediatric Protocol 2016)

Practice treatment guidelines provide the best available evidence for clinical management and evaluation of quality of care (Puddy & Wilkins, 2011). The aim of this study is to establish levels of adherence to treatment guidelines as stipulated in the WHO clinical guidelines which has been adapted and implemented in Kenyan health care system through the Ministry of Health (Ministry of Health, 2010). An excellent adherence demands that every step outlined in the protocol is followed and implemented. Therefore, to assess levels of adherence, a questionnaire with 31 variables was used to extract the data from medical records on demographic characteristic of the patient, history of diarrhea, physical examination and assessment of presenting symptoms, diagnosis and classification of degree of dehydration on admission, syndromic management based on severity of dehydration, fluids administration, monitoring medical reviews, duration of inpatient hospital stay and status on discharge. To measure levels of adherence, the investigator evaluated critical steps that were adhered to in the management of diarrhea against total variables to establish the degree of adherence. A binary yes/no outcome was established where either all steps were followed or not followed during general assessment, classification of dehydration, treatment and rehydration therapy ordered and if medical review was conducted after 6 hours to reassess and reclassify levels of dehydration to guide treatment.

#### **1.2 Statement of the problem**

Following the global recommendation on treatment guideline for diarrhea, Kenya embraced strategies aimed at scaling up the recommended treatment and reduce the mortality from diarrhea in children aged <5 years. Treatment of diarrhea has been included as an output in the Ministry of Health Strategic Plans, elaborated in the National Policy Guidelines on Diarrheal diseases and envisaged in the National Diarrhea and Pneumonia Scale-up Plan. As well, the re-classification of zinc sulphate from prescription only to over the counter product, the development of a locally produced ORS/Zinc co-pack and the introduction of the Rotavirus vaccine to routine immunization schedule all aimed at curtailing the prevalence of diarrhea diseases. Notwithstanding the strategic plans, the Maternal and Child Health Report (KDHS 2009) indicates that diarrheal disease alone accounts for over 19% of post neonatal death in Kenya and the 4<sup>th</sup> cause of premature death of children aged <5 years. However, studies conducted in Kenya to evaluate the uptake of guidelines showed poor results. For example, a review of 2008-09 Demographic and Health Survey pointed that almost a third (29.89%) of children who reported having diarrhea two weeks to study never received any form of treatment and only 4% of the children received zinc supplements (Njeri &

Muriithi, 2013). Furthermore, none of the studies conducted have interrogated the association between adherence to guidelines and treatment outcomes. The study at Mama Lucy hospital therefore aimed to assess variations in diarrheal disease according to seasonal patterns, evaluate levels of adherence and the relationship to treatment outcomes.

# **1.3 Justification of the study**

Diarrheal diseases have consistently ranked among the top morbidities affecting children admitted at Mama Lucy Hospital. A record review of the registers showed that between 300 -500 children aged below 5 years are admitted at the hospital with diarrhea annually (drawn from average of past 3 years). Globally, good diarrheal management remains relative low especially in high burden countries of Sub-Sahara Africa (Carvajal-Vélez et al., 2016). The study at Mama Lucy hospital sort to establish baseline information on diarrhea management among admitted children which will provide evidence for strategic interventions to improve quality of care and increase efficiency in service delivery.

# **1.4 Research questions**

- What is the seasonal distribution and temporal trends of diarrhea in children aged <5 years admitted at Mama Lucy hospital from January to December 2016?
- What is the level of adherence to WHO clinical guidelines in the management of diarrhea in children aged <5 years admitted at Mama Lucy Hospital from January to December 2016?
- What is the relationship between levels of adherence to clinical guidelines and treatment outcomes of children admitted with diarrhea at Mama Lucy Hospital from January to December 2016?

# **1.5 Broad objective**

To illustrate seasonal distribution and temporal pattern of diarrheal disease, evaluate levels of adherence to WHO clinical guidelines in the management of diarrheal diseases and determine associated treatment outcomes in children aged<5 years admitted from January to December 2016 at Mama Lucy Hospital in Nairobi.

# **1.5.1** Specific objectives

- To illustrate seasonal distribution and temporal trends of diarrheal disease in children aged
   <5 years admitted at Mama Lucy hospital from January to December 2016.</li>
- To evaluate levels of adherence to WHO treatment guidelines in the management of diarrhea in children aged <5 years admitted at Mama Lucy hospital from January to December 2016.
- 3. To compare adherence to clinical guidelines on treatment outcomes (length of hospital stay and status of child on exit from the hospital dichotomized alive or dead).

# 1.6 Theoretical framework for the study

The relationship of variables identified for this study have been demonstrated in figure 2.

# **Exposure (independent) variables**



Key: H/W Health worker

# Fig 2: Theoretical framework for the study exposure and outcome Variables

#### **CHAPTER TWO**

#### LITERATURE REVIEW

#### **2.1 Introduction**

Diarrheal diseases remain of public health concerns in most developing countries like Kenya (Bhutta & Das, 2013). Yet for over four decades there has been existence of evidence-based guidelines to support clinical practice providing systematic approach to the management of diarrhea in children. However, despite the gains that can be accrued from strict adherence to treatment guidelines, their use in most countries has remained sub-optimal. This chapter presents an overview of studies evaluating adherence to clinical guidelines in children aged <5 years presenting a compelling case for their role in diarrhea management.

#### 2.2 Reviewed literature on adherence to clinical guidelines

Adherence to treatment guidelines remains the hallmark of good clinical practice in management of diarrhea and an extensive body of knowledge exist in support (Brandt et al, 2016, Shikur and Tamiru, 2014). However, very few studies have been conducted assessing levels of adherence to clinical guidelines in the treatment of diarrhea in children below five years. In India, Pathak, et al. (2011) analyzed 883 treatment prescriptions from pharmacies and major hospitals to assess levels of adherence to clinical guidelines for acute diarrhea. The study found that only 6% of prescriptions had provided the recommended treatment of low osmolality salts and zinc sulphates, 58% prescribed ORS alone while 22% had ORS, zinc sulphate and other drugs not included in the guidelines, antibiotics were found in 71% of the prescriptions.

The study demonstrated low adherence to treatment guidelines and inappropriate use of antibiotics for the treatment of diarrhea. Similar results were reported by Carvajal-Velez *et al* (2016) in their study involving 12 countries with high burden of childhood diarrhea in Sub-Sahara Africa using Demographic and Health surveys, there was low prevalence of good clinical management of diarrheal ranging from 17% in Cote d'Ivoire, 38% in Niger and slightly higher (67%) in Sierra Leone. A further comparison made between communities based treatment of diarrheal diseases and health facilities did not yield better results. The study concluded that too many children were

not receiving the appropriate treatment as per the guidelines and called for increased efforts to improve the quality of care as a top priority. A study by Stephen and colleagues to evaluate management of acute diarrhea among children admitted at Juba Teaching Hospital found poo assessment of children with diarrhea and there was inappropriate use of rehydration fluids to 43% of children who had no dehydration (Stephen, Murila, &Wamalwa, 2017). The guidelines require that children are properly assessed, classified according to degree of severity and syndromic management with appropriate rehydration, zinc sulphate and continued feeding (Telmesani, 2010). As well, the guidelines stipulate opportunities when antibiotic must be used. For example, only children presenting with bloody diarrhea or suspected infective diarrhea should be treated with antibiotics (Carvajal-Vélez et al., 2016).

Boonstra et al (2005) cross sectional study to assess adherence to management guidelines in treatment of acute respiratory infections and diarrhea in children below five years in primary health care in Botswana observed that sub-optimal adherence to clinical guidelines in history taking and physical examination and over use of antibiotics prescriptions. The study recommended improving the scope of diagnostic and therapeutic management of major illness. In contrast, Lumbert and colleagues (Lamberti, Walker, Taneja, Mazumder, & Black, 2015) study to assess adherence to clinical guidelines to zinc supplementation among children below 5 years through follow-up after discharge found good to moderate adherence with givers administering zinc for an average of 10.7 days and with 47.8% completing the stipulated 14 day. The study concluded that proper instructions on discharge were instrumental to adherence.

In Kenya, Weru (unpublished) conducted a clinical audit to evaluate adherence to clinical guidelines in the treatment of acute watery diarrhea in children aged 5 years and below admitted at Garissa hospital using clinical record review of 376 patient's files. The study found inadequate assessment and classification of children presenting with diarrhea, inappropriate use of rehydration fluids where 9.1% of children without dehydration were put on intravenous therapy while 19.7% of children categorized severely dehydration were not put on intravenous fluids. In addition, the study found that only 1.9% of children received the recommended medical reviews and adjustment of treatment after 6 hours.

Despite the low adherence to clinical guidelines in treatment of diarrhea being common, no study has explored how the levels of adherence associate with clinical outcomes of the treatment. In this study, the researcher will analyse the relationship of adherence to treatment guidelines on syndromic management of diarrhea and treatment outcomes defined as length of hospital stay (number of days a patient remains in the hospital) and status on discharge (alive/dead).

#### **CHAPTER THREE**

#### METHODOLOGY

#### 3.1 Study design:

A hospital based retrospective Medical Record Review (MRR) study was conducted to illustrate temporal pattern of diarrheal disease, evaluate levels of adherence and determine treatment outcomes associated with different levels of adherence to WHO clinical guidelines in the treatment of diarrheal disease in children aged <5 years.

#### 3.2 Study site

Mama Lucy Hospital is situated in the Eastern part of Nairobi County. Nairobi County has a diverse population ranging from the upper socio-economically able to the lowest living in the informal settlements. Mama Lucy hospital serves mostly the population from the surrounding informal settlements and referral from the neighboring health facilities and clinics. Being a County hospital, it provides most of health care services; out-patient services including emergency care, maternal and child health, radiology, pharmaceutical services and in-patient including medical, surgical and reproductive health services, therefore ideal to undertake the study.

#### 3.3 Study population

The study population included medical records of children aged <5 years admitted at Mama Lucy hospital with initial diagnosis of diarrhoea as per case definition. Mama Lucy hospital admits an estimated 300 to 500 children < 5 years of age with diarrhea disease every year (calculated from the mean of past 3 years). Therefore, all files of children with diarrhea according to case definition were enrolled into study.

#### 3.3.1 Inclusion criteria

Patient's medical records of children aged <5 years admitted at Mama Lucy hospital with history of diarrhea as defined in the case definition.

# 3.3.2 Exclusion criteria

Patient's medical records of children aged <5 years admitted at the hospital with diarrhea but having an initial diagnosis of surgical condition or any other where treatment was unlikely to follow the classic guideline protocols for diarrhea diseases.

# 3.4 Sample size

A visit to the hospital revealed that approximately 300 to 500 children with diarhea are admitted in the children's ward at Mama Lucy hospital each year (approximated from averaging past 3 years). Therefore, in this study, all cases admitted at Mama Lucy hospital during the study period and meeting the criteria (inclusion/exclusion) were enrolled.

# 3.5 Sampling procedure

Using patient's admission registers, all files of children who had been admitted at the hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016 were retrieved using a screening tool designed to capture medical information of children aged below 5 years. Data on child date of birth, gender, weight on admission, reason for hospitalization, date of admission and date of discharge. A second tool designed to collect history on diarrhea was then used to extract study related information. Medical records that were found eligible as per case definition were included in the study and stratification according to degree of severity of dehydration categorized as in shock, severe dehydration, some dehydration and those with diarrhea and not dehydrated (Lamberti, Fischer Walker, & Black, 2012).

# 3.6 Study variables

# 3.6.1 Dependent (outcome) variables

The main focus of the study was to assess the degree of adherence to clinical guidelines and how it affects management of diarrhea among children aged below 5 years admitted at Mama Lucy. Adherence was dichotomized into adherence or non-adherence.

# 3.6.2 Independent (exposure) variables

In this study, the main exposure variables we the status of the child on discharge from ward (alive/dead) and length of hospital stay ( $\leq 3$  days/>3days).

#### 3.7 Data collection

The principle investigator was in-charge of the data collection process with the aid of two research assistants. To quantify the burden of diarrhea disease among children admitted at Mama Lucy hospital, a screening tool was used to gather medical history of children below 5 years who had been admitted at the hospital during the study period. A second tool was used to extract diarrhea related information from cases of diarrhea who qualified to be included into the study

Systematically, the researchers using an online platform for data collection entered relevant information from the patients file to the questionnaire which is designed to collect data for the study according to the research question. A total of 31 variables were extracted describing demographic characteristics of study children, history of diarrhea, general physical assessment, classification of diarrhea on admission, syndromic management, monitoring within 48 hours and adjustment of treatment according to WHO protocol and status at discharge from hospital including length of stay. To enhance internal validity, the researchers conducted a number of tests. An intra-rater validity test was performed where each of the rater performed a reassessment of previously extracted data and evaluate the degree of agreement, this was repeated until an agreement of >95% was reached. In addition, an inter-rater validity tests between the two raters were performed whereby the two raters evaluated a sample data and assess how well they are in agreement. The aim was to have over 95% agreement. The principle investigator who was responsible of overall quality of extracted data reassessed an extra sample of extracted data to determine pattern and extent of consistency. Each day, all medical records retrieved for purposes of the study were archived back for secure storage. A data flow diagram is provide in figure 3





# Fig 3: Data collection information flow

# 3.8 Data Analysis

Extracted data from medical files collected using an online platform generated a Microsoft Excel spreadsheets which was adapted for analysis. Data cleaning was done by checking and correcting inconsistencies in data entries, improperly entered observations and to correct spelling mistakes. Cleaned data was imported into SPSS version 21 for processing. Descriptive statistics on demographic characteristics, diarrhea distribution and temporal patterns were calculated and presented in forms of percentages, tables, graphs and charts. Critical steps of diarrhea management (physical assessment, diagnosis and treatment) and an overall adherence were calculated and present as adherence to clinical guidelines when all critical steps were accomplished or not adhered when one or more of critical steps were missed. To evaluate the effect of levels of adherence to treatment outcomes, a simple logistic regression analysis was computed for categorical variables and presented. Odds ratio, 95% confidence interval and *p*-value <0.05 were considered statistically significant.

#### **3.9 Ethical considerations**

#### 3.9.1 Training of research assistant

To achieve quality data collection, two research assistants were recruited to join the PI. Training of the research assistants on all aspects of data collection, safety of research materials, confidentiality of medical records, storage and back-up of data collected as well as appropriate working relationship with the hospital staff was addressed. The data collection tool was comprehensively tested and demonstrated before the actual data collection process.

# 3.9.2 Waiver of consent

The study was a retrospective review of medical records of children aged 5 years and below admitted from 1<sup>st</sup> January to 31<sup>st</sup> December 2016 with history of diarrhea. As such, a request for waiver of consent was applied and granted by the ERC at Kenyatta National Hospital.

#### 3.9.3 Confidentiality of study materials

Medical records of files sampled for the study were held with utmost level of confidentiality and reviewed within the hospital premises. All information gathered were kept protected from unauthorized access and all soft copies of the study materials were password protected. All back up materials remained in the custody of principle investigator and accessed only by the research team. In addition, to maintain confidentiality of every medical record reviewed, a unique identifier number was used and no identifying names entered into the questionnaire during the document review. This process guaranteed the anonymous of study participants.

# 3.9.4 Risk associated with study

As there was no direct contact with the study patients whose medical records were reviewed, there was no direct threat, however, measures were implemented to ensure the security of all documents involved in the study from damage as well as unauthorized access. No identifying features were entered into the questionnaire minimizing bleach to confidentiality.

## **3.9.5** Benefits to study population

There are no direct benefits to patients whose medical files were reviewed; however, the results of the study will be used to inform clinical practice especially management of children admitted with diarrhea, subsequently improving quality of care.

#### **3.9.6** Ethical clearance

Ethical approval to conduct the study at Mama Lucy hospital was obtained from Kenyatta National Hospital Ethical and Scientific Review Unit reference (KNH-ERC/Mod&SAE/289). Permission to access the medical records at the hospital was given by the hospital management. The principle investigator had a letter of introduction as student at University of Nairobi Institute of Tropical and Infectious Diseases.

#### 3.10 Study limitation

The study being a hospital-based is limited in generalization to the study population, however, all efforts were made to generate a report that address gaps in the utilization of clinical guidelines that are applicable to similar settings.

As well, the study relied on past medical records of patients admitted with diarrhea, since the records were not taken for the purposes of the study; there were existence of incomplete data. To ensure quality data was generated, the study tool had been designed to comprehensively extract information on management of children with diarrhea.

#### **CHAPTER FOUR**

#### RESULTS

#### 4.1 Demographic characteristics of children admitted at Mama Lucy hospital

A total of 1303 medical files of children admitted from 1<sup>st</sup> January to 31<sup>st</sup> December at Mama Lucy Kibaki hospital were reviewed using a screening tool designed to capture demographic characteristics as presented in Table 2. Among the study children 55% were male and 45% were female. The mean age in months was  $10.5(\pm 13.5)$  with a minimum of less than 1 month and maximum of 59 months. Over half of the children (68%) were below 1 year of age and almost all children 1262(97%) were weighed on admission as opposed to only 384 (30%) weighed at the time of discharge. Diarrhea and respiratory conditions were the most common cause of admission at 21% and 31%, respectively. The mean duration of hospital stay was 6.8 ( $\pm 5.3$ ) with a minimum of 1 day and maximum of 107 days. Three days were the most common number of days a child stayed in the ward accounting for 16% of the admissions.

Variable	n	Percentage (%)	Mean
Age in months (N=1303)			
< 12	879	67.5	10.5(±13.5)
12-23	234	17.9	
24-35	82	6.3	
36-47	68	5.2	
48-59	40	3.1	
Reason for admission			
Diarrhea	271	20.7	
Respiratory	408	31.3	
Neonatal sepsis/jaundice	229	17.6	
Prematurity/LBWT	82	6.3	
Malaria	54	4.1	
SAM	33	2.5	
Conclusions	45	3.5	
Meningitis	29	2.2	
Anaemia	21	1.6	
Others	131	10.1	
Duration of hospital stay			
≤3	365	28.0	6.8 (±5.9)
4-7	540	41,4	
>7	398	30.6	
Measurement of weight			
On admission	1262	96.8	
On discharge	384	29.5	

Table 2: Demographic characteristics of children aged below 5 years admitted at MamaLucy hospital from 1<sup>St</sup> January to 31<sup>St</sup> December 2016

#### 4.2 Most common diseases among children admitted at Mama Lucy

The distribution of the top ten diseases mirrors the national prevalence with respiratory, diarrhea diseases leading at 31% and 21%, respectively, (Figure 4). Neonatal illnesses were the 3<sup>rd</sup> and 4<sup>th</sup> with neonatal sepsis (18%) and prematurity (6%). The hospital admitted new-borns referred from neighbouring health units or after home delivery. Malaria accounted for 4%, convulsions 4%, severe acute malnutrition 3% while meningitis and anaemia accounted for 2% and 2%, respectively. Other illness (10%) were mostly surgical conditions such as burns, intestinal obstruction and adenohypertrophy.



Fig 4: Most common illnesses among children admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016.

#### 4.3 Diarrhea among study children

Diarrhea disease occurred in 271 of all children admitted at Mama Lucy from  $1^{st}$  January to  $31^{st}$  December 2016. 150 (55%) were males and 121 (45%) were females. The mean age in months was 11.69 (±8.4) with a minimum of 2 and maximum of 50 months (Table 4.2). All children 271(100%) were weighed on admission with a mean weight of 7.03(±2.137) compared to 195 (72%) weighed at the time of discharge with a mean of 7.31 (±1.99) reflecting an inconsistence or lapse in management.

 Table 3: Demographic characteristics of children aged below 5 years admitted with diarrhea

 at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

Variable	n	Percentage%	Mean
Age in months (N=271)			
2-11	157	57.9	11.69(±8.4)
12-23	94	34.7	
24-35	12	4.4	
36-47	4	1.5	
48-59	4	1.5	
Weight measurement			
On admission	271	100.0	7.03(±2.137)
On discharge	195	72.0	7.31(±1.99)

#### 4.4 Classification of diarrhea among children admitted at Mama Lucy hospital

Acute watery diarrhea was the most prevalent diarrheal disease with 249(92%) of the total number of children with diarrhea, bloody diarrhea had 18(7%) while chronic/persistent diarrhea with 4(2%). Duration of diarrhea before treatment had a minimum of one day to a maximum of 30 days with a mean of  $4.67(\pm 4.83)$  and a mode of 3 days. Diarrhea accompanied by vomiting occurred in 209(77%) of the cases and duration of vomiting before treatment had mean of  $4.21(\pm 4.28)$ , a mode of 3 days and minimum of one and maximum of 33 days.

Variable	n	Percentage%	Mean	
Types of diarrhea (N=271)				
Acute watery diarrhea	249	91.9		
Acute bloody diarrhea	18	6.6		
Chronic/persistent diarrhea	4	1.5		
Duration of diarrhea before treatment (l	N=271)			
<4	162	59.8	4.67 (±4.83)	
4-7	84	31.0		
>7	25	9.2		
Diarrhea and Vomiting (N=271)				
Yes	209	77.1		
No	62	22.9		
Duration of vomiting before treatment (	N=209)			
<4	125	59.8	4.21(±4.28)	
4-7	69	33.0		
>7	15	7.2		
Child vomit everything (N=209)				
Yes	125	59.8		
No	84	40.2		

Table 4: Categories of diarrheal disease among children aged below 5 years admitted atMama Lucy hospital from 1st January to 31st December 2016



Fig 5: Categories of diarrhea among aged below 5 years admitted at Mama Lucy hospital, from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

# 4.5 Temporal pattern and distribution of diarrhea during the year

A temporal pattern of diarrheal disease among children admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December was generated (Figure 6). Despite the reduction of statistics from September to December during health workers industrial action that paralyzed operations in most hospital, there is a distinct increase in diarrheal cases in the month of March 53 (20%), April 33 (12%) and July 33(12). This period concedes with the onset of long rains in Kenya (March-July). The result highlight the importance of having a steady presence of health workers at the clinical areas to maintain consistence in services delivery especially of infectious diseases such as diarrhea.



# Fig 6: Temporal pattern of diarrhea incidences among children aged below 5 years admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

**4.6 Physical assessment on severity of diarrhea in children admitted at Mama Lucy hospital** On admission, physical assessment was performed on 264 (97%) of children and only 7 (3%) had no documented evidence of assessment. Peripheral pulse 245 (90%), and level of consciousness 243(90 %%) were the most assessed signs while sunken eyes despite its importance in classifying degree of dehydration was the least assessed 119(44%). Other signs assessed were capillary 229(85%), skin turgor 228(84%) and if the child was able to feed 210(78%).

Variable	n	Percentage%		
Peripheral pulse (N=271)				
Normal	245	90.4		
Weak	19	7.0		
Status not documented	7	2.6		
Capillary refill (N=271)				
<2 seconds	229	84.5		
>2 seconds	36	13.3		
Status not documented	6	2.2		
Sunken eye (N=271)				
Yes	119	42.8		
No	126	46.5		
Not documented	29	10.7		
Skin turgor (N=271)				
Immediate 1-seconds	228	84.1		
Prolonged >2 seconds	35	12.9		
Not documented	8	3.0		
Level of consciousness (N=271)				
Alert	243	89.7		
Altered	24	8.9		
Not documented	4	1.5		
Child able to feed (N=271)				
Yes	210	77.5		
No	56	20.7		
Not documented	5	1.8		

Table 5: Syndromic assessment of children with diarrhea admitted at Mama Lucy hospitalfrom 1st January to 31st December 2016

# **4.7** Classification of diarrhea according to severity of dehydration among children admitted at Mama Lucy hospital

Classification of diarrhea according to degree of severity was correctly done for 234(86%) of cases while 43(14%) were not classified appropriately according to WHO clinical guidelines. Children who presented with diarrhea and categorized as in shock were 11(4%), severe dehydration were 36(13.3%), some dehydration were 67(25%) while majority 157(58%) had diarrhea with no dehydration. Diarrhea with comorbidities occurred in 189 (69.9%) of cases and most prevalent comorbidities were pneumonias 103(54%), severe acute malnutrition 30(16%) and a combination of pneumonia and severe acute malnutrition accounted for 13(6.9%) (Table 6).

Variable	n	Percentage %		
Classification diarrhea according to degree of severity (N=271)				
In shock	11	4.1		
Severe dehydration	36	13.3		
Some dehydration	67	24.7		
No dehydration	157	57.9		
Diagnosis according to WHO clinical guidelines (N=271)				
Yes	234	86.3		
No	43	13.7		
Diarrhea with comorbidities (N=271)				
Yes	190	70.1		
No	82	29.9		
Co-morbidities (N=190)				
Severe pneumonia/pneumonia	103	54.2		
Severe acute malnutrition	30	16.0		
Severe malaria	9	4.7		
Pneumonia/ Sam	13	6.8		
Others	34	17.9		

 Table 6: Classification of diarrhea according to severity among children admitted at Mama

 Lucy from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

# 4.8 Syndromic management of diarrhea diseases

Syndromic management of diarrhea recommends a systematic approach that follows the degree of severity of dehydration to guide treatment of patient who have severe dehydration and classified as in shock, severe dehydration, some dehydration and diarrhea with no dehydration.

# 4.8.1 Treatment of shock in children with diarrhea

The WHO clinical guidelines for children presenting with diarrhea and in shock recommend an initial bolus infusion of 20mls/kg body weight administered within 15 minutes and can be repeated to correct the dehydration to stabilize the child. Once stable, the child should proceed to plan C for management of severe dehydration. Among 11 children admitted with diarrhea and classified in shock, 3(28%) were prescribed the ringers lactate bolus 20ml/kgs body weight, 3(28%) were started on treatment for severe dehydration without initial rapid influsion, 4(37%) were give intravenous ringers lactate in 5% dextrose, while 1(9.1%) was put on maintenance fluid with hourly monitoring. In addition hydrasec, an antidiarrheal medication was prescribed to one child (Figure 7).



# Fig 7: Management children with diarrhea and in shock admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

#### 4.8.2 Management of children with severe dehydration

Management of severe dehydration follows plan C of WHO clinical guidelines. At step 1, an infusion with ringers lacate 30mls/kg body weight is administered over 30 minutes if child above one year and over 60 minutes if under 1 year. This is followed by 70ml/kg body weight for two and half hours if child above 1 year or over 5 hours if child below 1 year. A total of 36 children were classified under severe dehydration (Figure 8). A third 11(31%) were administered the correct amount of intravenous fluids infusion, 14(39%) were administered intravenous fluids and oral rehydration salts, 7(19%) were given ringers lactate in 5% dextrose and 4(11%) were treated with resonal plus intravenous fluids. Resonal is recommended for children with severe acute malnutrition. In addition, 9(25%) were given hydrasec an anti-diarrhea therapy for 3 days.



# Fig 8: Management of children with severe dehydration admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

#### 4.8.3 Diarrhea with some dehydration

Diarrhea with some dehydration was present in almost a quarter 67(25%) of children admitted at the hospital (Figure 9). One quarter 17(25%) of the children were rehydrated according to plan B of the WHO clinical guidelines that recommends oral rehydration salts (ORS) 75mls/kg body

weight and the child should be reassessed and reclassify after 4 hours. Though rehydration was documented, there was almost no documentation of reassessment after 4 hours. Oral rehydration salts (ORS) together with intravenous fluids 14(21%), intravenous fluids 15(22%), resomal to children with malnutrition 6(9.0%) and 15(22%) were given others forms of treatment such as expressed breast milk or ORS exceeding the stipulated amount and time. In addition, 17(25%) of children were give hydrasec alongside the rehydration therapy for the control of diarrhea. It was also observed that children were correctly classified on initial assessment at the emergency department but upon admission in the ward, management of diarrhea included addition intravenous fluids which had not been ordered before while Hydrasec was among the first treatment to be prescribed.



# Fig 9: Management of children with some dehydration admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

#### 4.8.4 Management of diarrhea with no dehydration

Majority of children 157(58%) had diarrhea with no dehydration (Figure 10). The WHO clinical guidelines recommend treatment for children with no dehydration at the community level or outpatient where rehydration and assessment is done and the child can be allowed to go home. Almost a half 70(45%) of the children were treated according plan A of WHO clinical guidelines, 34 (22) were give intravenous fluids in addition to treatment plan A, 21(13%) intravenous fluids, 22(14%) resonal and 5(3%) only received expressed breast milk. At least 5(3%) of children with

diarrhea and no dehydration had no evidence of documented rehydration fluids ordered. An antidiarrheal drug (hydrasec) was given to 30 (19%) of children.



Fig 10: Management of diarrhea with no dehydration among children admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

# 4.9 Administration of rehydration fluids according to prescription.

To ascertain whether hydration fluids were administered per the prescription, a review of nursing documents was conducted. Majority of children 256(94%) had fluids administered according to prescription and 15 (6%) of children had no documented evidence of rehydration (Figure 11).



Fig 11: Administration of fluids according to prescription among children admitted with diarrhea at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

# 4.10 Administration of Zinc sulphate

Administration of zinc sulphate in addition to rehydration fluids has the benefits of shortening both the episodes and duration of diarrhea. Approximately three quarters 206(76%) of children received zinc sulphate in addition to rehydration (Table 7). According to the guidelines, children below 6 months should receive 10mgs daily for 10 to 14 days. Nevertheless, the study found that out of total number of children receiving zinc sulphate, 193(94%) of children received the correct dosage according to age of child while 13(6%) of children received zinc sulphate that was way above the age of child. Children aged 6 months received dosage that was equivalent to that give to children above 6 months raising the risk of over dosing the children.

# Table 7: Administration of zinc sulphate among children with diarrhea admitted at MamaLucy hospital from 1st January to 31st December 2016

Variable	n	Percentage (%)
Administration of zinc sulphate (N=271)		
Yes	206	76.0
No	65	24.0
Dosage of zinc sulphate (N=206)		
10 mg	21	10.2
20mg	185	89.8
Dosage of zinc sulphate according to age of	child (N=206)	
Yes	193	93.7
No	13	6.3

#### 4.11 Antibiotics in diarrhea management

Antibiotics in diarrhea management are recommended for bloody diarrhea, cholera or where there are comorbidities requiring antibiotics treatment. Out of the 271 children admitted at the hospital with diarrhea, 235 were put on antibiotics yet only 190(70%) had comorbidities including 4(2%) with bloody diarrhea (Table 8). Among the 36 children who were not put on antibiotics, 8(22%) had comorbidities requiring antibiotics while 45(19%) of the 235 were prescribed antibiotics did

not require antibiotics treatment because they had no comorbidities nor bloody diarrhea. A combination of two antibiotics was the most common with over a half of children 124(53%) put on two different types of antibiotics, 65(28%) had one type of antibiotic while 46(20%) of children were given three or more types of antibiotics. A combination of crystalline penicillin and gentamycin was the most frequently prescribed antibiotics 142(44.3%), ceftriaxone was second most prescribed antibiotic 42(18%), ceftriaxone and one other antibiotic 16(7%) and 73(31%), were varied.

Table	8:	Antibiotics	prescription	among	children	with	diarrhea	admitted	at	Mama	Lucy
hospit	tal f	rom 1 <sup>st</sup> Jan	uary to 31 <sup>st</sup> D	ecembe	er 2016						

Variable	n	Percentage (%)
Administration of antibiotics (N=271)		
Yes	235	87.5
No	36	22.5
Number of antibiotics per prescription	n (N=235)	
One	64	27.2
Two	126	53.6
Three	45	19.2
Types of antibiotics prescribed (N+23)	5)	
Christapen/gentamycin	104	44.3
Ceftriaxone	42	17.9
Ceftriaxone plus one other antibiotic	16	6.8
Others	73	31.0

# 4.12 Medical review within first 6 hours

Medical reviews for children with diarrhea is recommended to aid in reassessment and reclassification of levels of dehydration to guide treatment modification especially those classified in shock and those severely dehydrated. Out of the 271 cases with diarrhea, only 34 (13%) had documented evidence of medical review within first 6 hours (Figure 12). Reviews for the most deserving patients were 6(55%) and 19(53%) for those in shock and severely dehydrated,

respectively. For patient classified some dehydration, reassessment after 4 hours was almost never documented.



Fig 12: Medical review within 6 hours of commencing treatment among children admitted with diarrhea at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016

# 4.13 Duration of hospital stay and child status on exit from hospital

Duration of hospital stay calculated from the date of admission to the date of discharge had a mean duration of  $6.49(\pm 5.402)$ , mode of 3 days, a minimum of 1 day and maximum of 52 days. Status on exit from the ward was documented as either alive or dead. Children who were discharged from the hospital alive were 253(93%) compared to 18(7%) who left the hospital when they were dead.





#### 4.8 Adherence to clinical guidelines

Adherence to clinical guidelines was assessed following stipulated steps on Basic Pediatric Protocol that has been adapted from WHO clinical guidelines. Adherence was assessed on how well guidelines were followed when conducting physical assessment, classifying degree of dehydration and syndromic management. An overall adherence was calculated when all the three steps had been completely followed to guide treatment goals. The study found an overall adherence of 126(47%) with over half 145(53%) of the cases missing one or more critical steps of clinical guidelines (Figure 14). Besides, a declining trend was observed where physical assessment (97%) and classification of dehydration (86%) were more adherence to guidelines as opposed to implementation of syndromic manage (52%).



Fig 14: Adherence to clinical guidelines in management of diarrhea among children aged below 5 years admitted at Mama Lucy hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016.

#### 4.9 Simple logistic regression analysis

A simple logistic regression was applied to evaluate the association of different levels of adherence to WHO clinical guidelines to treatment outcomes which were defined as status on exit from the ward (alive/dead) and length of hospital stay was computed (table 9). Adherence to physical assessment was significantly associated with status on exit. A child who was not assessed on admission was 16 times more likely to exit from the hospital a dead compared to those who were assessed (OR 16.25, 95% CI 3.09-89.6, *p*-value 0.001). There was no significant association between adherence to classification of degree of dehydration and syndromic treatment on status on exit and length of hospital stay (P-value >0.05). Emphasizing the importance of effective assessment of signs and symptoms of dehydration and thus forming the basis for subsequent management which is likely to impact on treatment outcomes.

 Table 9 Association of different levels of adherence to clinical guidelines on status on exit and
 length of hospital stay of children aged below 5 years admitted at Mama Lucy hospital from

 1st January to 31st December 2016
 1st December 2016

	Status on exit from ward		Length of hospital stay			
Variable	OR	95% CI	P-value	OR	95% CI	P-value
Assessment	16.65	3.09-89.6	0.001	0.373	0.74-1.881	0.234
Diagnosis	0.726	0.212-1.505	0.701	0.963	0.441-2.100	0.924
Treatment	0.788	0.291-2.136	0.64	1.251	0.731-2.139	0.414

#### **CHAPTER FIVE**

#### DISCUSSION, CONCLUSION AND RECOMMENDATIONS

#### 5.1 Discussion

The main focus of the study at Mama Lucy hospital was to evaluate the implementation of WHO clinical guidelines in the management of diarrhea among children aged below 5 years. Diarrhea despite being highly preventable and the management supported by clear guidelines remain the second leading cause of morbidity in children (21%) and is only secondary to respiratory diseases (31%). These finding relate well with the report of a systematic and meta-analysis review of studies on prevalence of diarrhea among children under-five in Ethiopia where prevalence of diarrhea in children was found to be 22% (95% CI 19-25%) (Alebel et al., 2018). Children aged between 2 to 11 months presented the highest burden of diarrhea of 57.9% and gradually the prevalence tending to decrease with increasing age of the child. Similar results were found in the urban slums of Bunkura, West Bengal where children aged below 12 months had highest prevalence of 57% against an overall prevalence of 23% and 26% among children aged between 13 and 24 months (Gupta et al., 2014). These results reinforce the important role played by diarrhea in the global burden of diseases especially childhood illnesses. Boys (55%) more than girls (45%) had higher prevalence of diarrhea. Though these finding may not have rational explanation, they are in contrast with results of a study by Thiam et al in Mbour, Senegal who found a higher prevalence among girls compared to boys (Thiam et al., 2017). Acute watery diarrhea was the most frequent type of diarrhea accounting for 92%, chronic diarrhea 7% and bloody diarrhea 1%.

The highest peak of diarrheal disease conceded with onset of long rain from March to July 2016. The month of March had the highest number of children admitted with diarrhea at 20%. However, a decline in numbers of admitted children was observed from September 2016. The decline can be partly associated with health workers industrial action that paralyzed health facilities nationwide limiting numbers of patients attended. Temporal pattern of diarrheal diseases in relation to weather pattern is well studied. For example, Wangdi and Clements analysis of spatiotemporal data (2003-2013) from Health Information and Management System of Ministry of Health in Bhutan found compelling evidence linking increasing temperature and rainfall associated with spike in diarrheal incidences (Wangdi & Clements, 2017). A number of plausible explanations can be derived from

this association, first, the likelihood of contamination of drinking water by ground runoff, flooding especially occurring in overpopulated areas is likely to change the living environment which in turn provide an enabling medium of the growth of microorganisms which can lead to contamination of food sources. A 24 months follow-up using surveillance of childhood diarrheal diseases by Azage et al, in the Northwestern parts of Ethiopia investigating climatic variation and effect on diarrheal disease found a positive association of rainfall and diarrhea in children. The month of March to June had the most rate highlighting the importance of considering climatic variation variation to improve outcomes of diarrheal disease control programs (Azage et al., 2017)

The most common comorbidities were pneumonia (55%) and severe acute malnutrition (16%) while malaria was third with 5%. Diarrhea and pneumonia remains the leading cause of morbidity and mortality among young children worldwide and together accounts for 29% of annual mortality (WHO, 2013). Schlaudecker et al report on recent evidence from developing countries clearly demonstrate the interactions of diarrhea, pneumonia and malnutrition where undernutrition plays a key role in the symbiotic relationship. Malnutrition evidence support lowers the immune system allowing the growth of pathogens increasing the risk of diarrhea and pneumonia (Schlaudecker et al., 2017). The study recommends wider public health approaches including exclusive breastfeeding, micronutrients supplementation and improving access to health care.

Practice clinical guidelines are developed from exhaustive evidence and expert opinion to guide clinical practice. Management of diarrhea evidence support an initial assessment to establish degree of dehydration, classification of diarrhea according to severity of dehydration and syndromic management implemented. Adherence to guidelines has been viewed as quality assurance process to improve care and increase treatment outcomes. At Mama Lucy hospital, an overall adherence to clinical guideline was 47%. Physical assessment to identify signs of dehydration followed by a clear classification of severity of diarrhea were found to rely on the clinical guidelines for decision making 98% and 86%, respectively. However, a large gap was found in the implementation of treatment of diarrhea with only a half 52% of children receiving treated as recommended in the clinical guidelines. Syndromic management required that a child is prescribed treatment according to degree of severity of dehydration with those in shock, severe dehydration, some dehydration or no dehydration accordingly. Some of major challenges that were

associated with non-adherence to clinical guidelines included excessive use of intravenous fluids, over prescription of antibiotics and addition of anti-diarrhea drugs to slow diarrhea episodes. Besides, children requiring reassessment and reclassification of degree of dehydration (those presenting in shock and severe dehydration) to guide treatment were rarely reviewed (13%). Low adherence to clinical guidelines has been reported across the global. For example Vecchio et al assessment of adherence to clinical guidelines in industrialized countries found fairly good adherence (66%) with most violations concerning antibiotics prescription (Vecchio et al., 2016).

Appropriate assessment should be able to guide classification of severity of dehydration forming the basis for syndromic management. However, the study observed that children classified with diarrhea and no dehydration were majority (58%), some dehydration (25%), severe dehydration (13%) and only 11(4%) were in shock. Out of 157 (58%) who were admitted with no dehydration, 22% had no comorbidities. Admission to the ward for children with diarrhea and no dehydration guidelines recommend rehydration at the emergency department hence limiting number of children admitted in the ward (Granado-villar, 2015). Alternatively, these children can be managed at home with clear instructions to the care giver to return to hospital if diarrheal episodes fail to subside or the child does not retain fluids due to vomiting (Ciccarelli et al., 2013).

Conversely, the roles of appropriate general assessment prior to classification of level of dehydration and syndromic management cannot be over-emphasised in this study. The study found that a child presenting with diarrhea and who had not been assessed to evaluate degree of dehydrations on admission had increased risk of dying by 16 times (OR 16 95%CI 3.09-89.6, p=0.001) when compared to a child who had been properly assessed emphasising the importance strict adherence to clinical guidelines if the current observed trends is to be reversed.

Syndromic management underpinned by effective assessment and classification of degree of dehydration recommend the use of oral rehydration salts (ORS) and zinc sulphate alone with no additional antibiotics, antidiarrheal or antiemetic for majority of children with diarrhea (Alam et al., 2017). Intravenous fluids are only recommended in cases of severe dehydration for patient presenting in shock or severely dehydrated and should be discontinued and ORS commenced once the child is able to tolerate oral intake. However, the study found excessive use of intravenous

fluids even in mild or no dehydration. For example, intravenous fluid ringers lactate was prescribed to 42.3% of children with some dehydration and 41% of children with diarrhea and no dehydration. Children who were classified in shock or severe dehydration were often retained on intravenous fluids. A disconnect was observed that despite initial prescription of appropriate treatment plan from the emergency department, further reviews in the ward increased the use of intravenous fluids, antibiotics and antidiarrheal drugs. These findings correlate with other studies. Stephen et al study to assess management of acute diarrhea among children aged 6 to 59 months admitted to Juba Teaching Hospital found similar results. Through 75% of cases were correctly classified according to WHO clinical guidelines, 43% of children with no dehydration and 37% of children with some dehydration were prescribed intravenous fluids. The study concluded that there was inappropriate use of intravenous fluids recommending regular in-house training to improve quality of care (Stephen et al., 2017).

The administration of zinc sulphate alongside rehydration therapy has the benefit of reducing the episodes and duration of diarrhea (Alam et al., 2017). Compared to previous study conducted at Garissa County hospital which showed an adherence to zinc administration of 92%, (Weru, UON repository) the present study had lower prevalence at 76%. In addition, the study found inappropriate prescription and administration of higher dosage of zinc sulphate to children aged below 6 months where 6% of children received 20mg instead of recommended 10mg for this age group. These finding highlights the need for continued training to raise the adherence levels and also improve on dosage for effective benefits. The study also recommended duration 10-14 days.

Again, over prescription of antibiotics was apparent, out of the 235(87%) prescriptions of antibiotics, 45(19%) had no indication for antibiotic while 8(9.9%) of those who did not receive antibiotics had comorbidities that required treatment with antibiotics a combination of undue prescription with miss opportunity for antibiotics. Most commonly prescribed antibiotics was a combination of crystalline penicillin and gentamycin which accounted for 60% of all antibiotics. Other omissions observed were prescriptions with no clear treatment duration (28%) of those treated with antibiotics raising concerns of risk of over administration of antibiotics increasing

antimicrobial resistance and misappropriation of available antibiotics. Overuse of antibiotics in treatment of diarrhea is well studied. A study by Zwisler et al to assess perception and use of oral rehydration salts, antibiotics and other therapies in India and Kenya found that antibiotics were viewed superior in diarrhea treatment. In India 62% ranked antibiotics most effective compared to 23% who ranked oral rehydration salts. Similarly in Kenya, 55% ranked antibiotics ahead of oral rehydration salts at 29% (Zwisler et al., 2013). A prospective study to assess prescribing pattern and appropriateness of drug treatment of diarrhea among hospitalized children in tertiary care hospital in Western India involving 103 children and follow-up of 18 months Panchal et al found compelling evidence of 100% over-use of antibiotics with only 13% appropriate antibiotics. The study emphasized the importance of proper diagnosis and treatment of diarrhea, education and availability of local guidelines to support judicious use of antibiotics (Panchal et al., 2013).

Medical review within 4 to 6 hours is critical especially for children with severe dehydration to help reclassify dehydration and modify treatment accordingly. The study at Mama Lucy hospital found that only 13% of cases were reviewed within the stipulated timeframe while 87% had no documented evidence of medical review. Medical review provides the clinician with an opportunity to evaluate child response to therapy and adjust treatment according to new status (Granado-villar, 2015).

Treatment outcomes is dependent on quality of care and degree of severity of the illness. The study found a mean average hospital stay of  $6.49(\pm 5.40)$ , a minimum of 1 day and maximum of 52 days. Three days were the most common number of days a child remained in the ward (13.7%). These finding resonate with other studies, Panchal et al study among hospitalized inpatients found a hospital stay of  $4.4(\pm 2.09)$  which is slightly lower that the hospital stay at Mama Lucy. Another outcome evaluated was status at the time of exit from the hospital. Out of the 271 patients admitted with diarrhea, 253 (87.3%) were discharged alive while 18(6.6%) dead.

#### **5.2** Conclusion

Adherence to clinical guidelines remains the mainstay of effective diarrhea management. The study at Mama Lucy hospital aimed to assess adherence to clinical guidelines in the management of diarrheal diseases among children aged below 5 years and quantify the relationship of adherence to clinical outcomes. Despite the low overall adherence to clinical guidelines (47%), there was adequate assessment of general signs and symptoms (97%) and classification of diarrhea according to severity (86%) as was observed at the time of admission in the hospital. However, there was low adherence to syndromic management with excessive use of intravenous fluids and antibiotics and some prescription of antibiotics lacking defined treatment duration (28%) raising concerns on antibiotics rational drug use and risk of antimicrobial resistance impressing the need for strict adherence to clinical guidelines.

# **5.3 Recommendations**

Diarrhea contributes a significant burden of disease at Mama Lucy hospital and implementation of clinical guidelines can play a critical roles in providing quality care and increasing efficiency in service delivery. The study recommends the following activities to bridge the gaps in diarrhea management;

- Harmonized training on evidence-based guidelines for all cadres of staff providing health care to children admitted with diarrhea and enhance continuity of care from emergency department where initial diagnosis is established and treatment commenced to the ward where bulk of care is provided.
- Strict implementation of clinical guidelines with treatment protocols to increase rational drug use and appropriate rehydration therapy to prevent unnecessary use of antibiotics and excessive use of intravenous fluids.
- The study observed that majority of patient admitted with diarrhea had no dehydration. By implementing the guidelines appropriately, such patients can be managed out-patient to reduce on bed capacity and workload.
- Monitoring and evaluating implementation process of treatment guidelines to identify bottle necks and impediments in order to increase staff motivation and improve delivery of quality care is recommended.

• The study has a policy implication. The welfare of health providers has a direct influence on quality of care and disease prevention. AS such, measures to prevent health staff industrial action is important in the fight against spread of infectious diseases like diarrhoea.

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# **APPENDIX 1: DATA COLLECTION TOOLS**

Medical Records Screening Retrieval Form
File Number
Interviewer ID (write initials) Date form completion (dd/mm/yyyy)//2018
Fill in the appropriate response in the spaces provided
2) Date of birth///
3) Calculate age in months
4) Gender: Male Female
5) Weight in kilograms on admission
6) Reason for hospitalization
7) Date of admissionDate of Discharge
2) History of diarrhea.
8) Yes
9) Eligible for enrollment
Signature of interviewer

# 

# 2) History of diarrhea.

5) Duration of diarrhea at the time of admission (in days) Not documented
6) Type of Diarrhea:
Acute watery diarrheaAcute bloody diarrheaChronic/ persistent diarrhea
Not indicated
7) Vomiting Yes No Not documented
8) Duration of vomiting (days) Not documented
9) Does the child vomit all everything given? YesNoNoNot indicated

# 3) General examination (as documented)

10) Peripheral pulse (In AVPU	<a) normal<="" th=""><th>, weakNot in</th><th>dicated</th></a)>	, weakNot in	dicated
11) Cap refill < 2 sec	>2sec	Not indicated	
12) Sunken eyes present? Yes	N0	Not indicated	
13) Skin turgor assessment perf	ormed? Yes	No	Not indicated
If yes what was the duration Im	mediate/ (1-2 sec)	, slow/prolonge	d/ >2sec
14) What was level of consciou	sness: Alert	Altered conscio	usness
Not indicated			
15) Child able to feed and drink	:: Yes N	o No	o indicated

# 4) Classification of diarrhea on admission;

Diarrhea with (Tick where applicable)	
16) Severe dehydration Shock	Some Dehydration No dehydration
17) Is diagnosis made based on clinical guid	elines recommendations (basic Pediatric protocol 2016)?
Yes	No
18.) Are there others co-morbidities on admi	ission?
Yes	No
If yes Specify	

# 5) Syndromic Management

10) D'arabas seith homena la sta ale
19) Diarrhea with hypovolemic shock
YesNo
If Yes;
-Ringers' 20mls/kg over 15 minutes,
$-70$ mls/kg Ringers over 2.5 hours if $\ge 12$ months / Over 5 hours if $< 12$ months
-Others specify
Not indicated
20) Diarrhea with severe Dehydration
Y esNo
If Yes; Plan C
- IVF 30mls/kg ringers over 30 minutes if $\geq$ 12 months or 60 minutes if <12 months
- The 70mls/kg ringers over 2.5 hours if $\geq$ 12 months or over 5 hours if $<$ 12 months
- Others specify
- Not indicated
21) Diarrhea with some dehydration
YesNo
If Yes; Plan B
- ORS 75mls/kg over 4 hours with continued breastfeeding, reassess after 4 hours and adjust
treatment
- Others specify
- Not indicated
22) Diarrhea with no dehydration
Vec No
I CSINU
II 105, Flail A ODe 10mle/lee hede weight often every lages steel, continue broostfooding and encourses food is
- Oks tomis/kg body weight after every loose stool, continue breastleeding and encourage lood is
>6 months
- Others specify
- Not indicated
23) Administration of zinc sulphate according to age of child
YesNo
If Yes; correct dosage
-20mg for children $\geq$ 6 months for 10-14 Days
-10mg for children <6 months for 10-14 Days
24) Prescription of antibiotics
YesNo.
If Yes;
Bloody diarrhea
YesNo
25) Type of antibiotics
MetronidazoleDuration
AmpicillinDuration
ErythromycinDuration
Doxycycline
Ciprofloxacin Duration
Ceftriaxine

Others specify	Duration
----------------	----------

# 6) Monitoring in the first 48 hrs.

27)	Fluid administration as per prescribed by the clinician (Review fluid chart)
Yes	NoNot documented
28)	Was there medical review within 6 hours of completion for patients with severe dehydration?
Yes	No Not documented

# 7) Outcome

30) Exit from the ward			
Alive	Dead	Date/	/
31) Duration of hospital stay to discharge			

# APPENDIX 11: BASIC PEDIATRIC PROTOCOLS FOR CHILDREN BELOW 5 YEARS

(2013)



# **APPENDIX 111: ETHICAL APPROVAL**



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Ref: KNH-ERC/ Mod&SAE/289



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September 11, 2018

Catherine Wangu Shitemi Reg. No.W61/87917/2016 Institute of Tropical and Infectious Disease (UNITID) College of Health Sciences University of Nairobi

Dear Catherine

Re: Approval of modifications – study titled 'Adherence to clinical guideline sin the management Diamhea in children aged below five years admitted at Mama Lucy Hospital, Nairobi' (P66/02/2018)

Your communication dated August 1, 2018 refers.

The KNH-UoN ERC has reviewed and <u>approved</u> your request to review medical records from January to December 2016 in order to acquire the required sample size.

These changes have been reflected in the revised proposal and are acceptable.

Yours sincerely,

PROF. M.L. CHINDIA

SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN The Director CS, KNH The Chair, KNH-UoN ERC The Director, UNITID, UoN

Protect to discover