AN EVALUATION OF THE MANAGEMENT OF CONGESTIVE HEART FAILURE IN CHILDREN AT KENYATTA NATIONAL HOSPITAL

CYNTHIA NDUTA MUREGI (B. PHARM)
U56/87725/2016

A dissertation submitted in partial fulfillment of the requirements for the award of the degree of Master of Pharmacy in Clinical Pharmacy in the School of Pharmacy of the University of Nairobi.

November 2018

DECLARATION OF ORIGINALITY

Name of Student:	Cynthia Nduta Muregi
Registration No:	U56/87725/2016
College:	College of Health Sciences
School:	School of Pharmacy
Department:	Pharmaceutics and Pharmacy Practice
Course Name:	Master of Pharmacy in Clinical Pharmacy
Title of Work:	An Evaluation of the Management of Congestive Heart Failure in Children in Kenyatta National Hospital.

DECLARATION

I, Cynthia Nduta Muregi, declare that:

1. I understand what Plagiarism is and I am aware of the University's policy in this regard.

2. I declare that this dissertation is my original work and has not been submitted elsewhere for examination, an award of a degree or publication. Where other people's work or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements.

3. I have not sought or used the services of any professional agencies to produce this work.

4. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work.

5. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with the University Plagiarism Policy.

Signed…… Date……..

SUPERVISORS

This is to certify that this dissertation has been submitted for review with our approval as the University supervisors.

1. Dr. Peter N Karimi (Ph.D.)

Lecturer, Department of Pharmaceutics and Pharmacy Practice

Signature…….. Date…….

2. Dr. George Mugendi (B.Pharm, M. Pharm)

Lecturer, Department of Pharmaceutics and Pharmacy Practice

Signature…….. Date…….

DEDICATION

This dissertation is dedicated to my family, my greatest support team in the process of this work. Above all this dissertation is in debt to the Almighty God who has made all this possible by his great mercy and grace.

ACKNOWLEDGMENTS

My deepest gratitude and appreciation goes to my family and especially Jeremiah for the immense support during this journey. Thank you for supporting and encouraging me to pursue my dreams.

I would like to highly appreciate my supervisors Dr. Peter N. Karimi and Dr. George Mugendi for the immense support you offered me in the frequent perusal of this document. I am grateful for pushing me to complete this dissertation.

Special thanks go to Nett Consultants for the short course you offered me on research. It went a long way in making my work easier in this journey as well as increasing my intrinsic motivation for research.

Much appreciation to my colleagues and classmates for the journey we have made together. We have been a great team.

Finally, all thanksgiving goes to God for making the completion of this work possible.

ABBREVIATIONS AND ACRONYMS

ACEIs	Angiotensin Converting Enzyme Inhibitors
AV	Atrioventricular
CHF	Congestive Heart Failure
ICD	Implantable Cardioverter Defibrillator
KNH	Kenyatta National Hospital
RAAS	Renin Angiotensin Aldosterone System
SPSS	Statistical Package for Social Sciences
TB	Tuberculosis
UON	University of Nairobi
URTIs	Upper Respiratory Tract Infections
UTIs	Urinary Tract Infections
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Etiology: The cause, origin or manner of causation of a condition or disease. In this study expected causes of heart failure include, infections, rheumatic heart disease, cardiomyopathies and nutritional deficiencies among others.

Congestive heart failure: A medical condition in which the heart is progressively unable to pump blood at a rate commensurate with the body metabolic needs.

Prevalence: The number of cases of a disease existing in a given population at a specific period of time (period prevalence) or at a particular moment in time (point prevalence)

Cardiomyopathies: Diseases of the heart muscle affecting the heart's structure, shape, and size.

Rheumatic heart disease: A complication of rheumatic fever that involves the destruction of one or more heart valves especially due to group A beta-hemolytic streptococcal pharyngitis in children.

LIST OF FIGURES

LIST OF TABLES

TABLE OF CONTENTS

ABSTRACT

Background

Congestive heart failure in the pediatric population is a significant cause of morbidity and mortality. It has a wide variety of etiologies. These causes vary widely among different geographical regions globally, ages and social classes(1). There is a paucity of data on the epidemiology, etiology, and management of congestive heart failure in children as compared to major advances in research in adult heart failure(2). Primary caregivers of children with congestive heart failure face various challenges when caring for their children.

Objectives

This study sought to identify the etiology of congestive heart failure as well as the types of drugs used in its management among children in Kenyatta National Hospital. It also sought to investigate the challenges faced by parents and guardians in the care of these children.

Methods

A cross-sectional study was done involving pediatric patients with heart failure whose medical records were reviewed. This was done to determine the etiologies and types of drugs used in the management of heart failure among children. Challenges facing parents and guardians of children with heart failure were also explored. Fifty three records of the patients were selected from the KNH records department and thirty parents and guardians of the children recruited from the pediatric wards. The data was entered into Excel 2013 and analyzed using STATA version 13.0. It was then summarized and presented in pie charts, bar graphs, and tables.

Results

The major etiology for heart failure among the 53 patients whose records were reviewed was infections (58.5%), this included respiratory tract and urinary tract infections. Other etiologies included; congenital heart disease (34%,) pulmonary hypertension (26%), cardiomyopathies (15.1%) and rheumatic heart disease (13.2 %.)

The most commonly prescribed drugs were furosemide (98.1%), digoxin (67.9%). Only 22.6% of the patients were on the prescribed drug combination for heart failure in children according to the Kenya national clinical guidelines. The major challenges faced by the 30 parents and guardians recruited were; financial constraint (90%), disruption of their work or business (73.3%), frequent readmissions (70%) and discrimination (53.3%).

Conclusions

The etiology of congestive heart failure in the pediatric patients was multifaceted and there was poor adherence to the Kenya National guidelines for the management of heart failure in children. This is in regard to the choice of drugs for heart failure as well as the dosing. Numerous challenges face parents and guardians of children with heart failure.

Recommendations

Prompt treatment of infections in children with underlying heart disease to prevent the development of heart failure is recommended. Further research on the lack of prescriber preference for Enalapril in the management of pediatric heart failure should be done. Strengthening of prescriber capacity in the management of congestive heart failure in children should be done.

CHAPTER ONE: INTRODUCTION

1.1 Study background

Congestive heart failure is a medical condition in which the heart is progressively unable to pump blood at a rate commensurate with the body's metabolic needs. The pumping action of the heart grows weaker over time resulting in heart failure(1). In most cases, both sides of the heart are affected but either side right or left can be affected. Among young children and infants, the condition commonly manifests as respiratory distress, tachycardia, feeding difficulties, tender hepatomegaly, profuse sweating, gallop rhythm and arrested growth and development. In older children, it presents as orthopnea, dependent edema, crepitations, fatigue, and exercise intolerance together with raised jugular venous pressure (3).

The prevalence of heart failure has increased with time making it a global epidemic affecting at least 26 million people worldwide (4). There exists little data on the prevalence and incidence of heart failure among the pediatric population. This is due to changes in patterns, etiologies, geographical areas, ages and social classes that make it difficult to come up with formidable research data (1). It is also quite challenging to diagnose heart failure in young infants and children due to its overlap with other pathological conditions. Early mortality also contributes to the under-reporting of the cases (5).

A few studies have attempted to describe the prevalence of heart failure in the pediatric population amidst the above-mentioned challenges. Pediatric hospitalizations due to heart failure in the United States occur in about 11,000 to 14,000 children annually with a mortality of about 7% (6). A 10-year hospital-based study done in a tertiary hospital in Belgium indicated a 10.4% prevalence of heart failure among children with various forms of heart disease (7). Regionally, reported prevalence data for the period 2012 to 2015 from Ethiopia at a tertiary health center was about 2.9% of all pediatric admissions (5). A Kenyan study in a tertiary hospital indicated that heart failure consists of about 1:1000 hospital admissions in the pediatrics department(8).

Heart failure morbidity and mortality in the pediatric population carries with it a high socio-economic burden. This is especially due to reduced economic productivity by the parents as well as the magnified economic impact due to the loss of potentially productive years per death. The costs of hospitalization due to heart failure in children are also inevitably higher than those of adults because of the frequent requirement for catheter-based and surgical interventions (1).

A wide range of etiologies for pediatric heart failure exists ranging from simple myocarditis to complex structural heart disease. These etiologies vary widely across different countries and also different parts of large countries such as India. In developing countries, these mainly include rheumatic heart disease, tropical diseases, and nutritional deficiencies. Other conditions resulting in heart failure include congenital heart disease, cardiomyopathies, and myocarditis affecting children both in the western world and in developing countries (9).

Management of heart failure in children generally includes supportive, pharmacological and surgical measures. Supportive measures include bed rest in cardiac position, restriction of salt and fluid intake, oxygen by nasal prongs or catheter in severe heart failure. Pharmacological measures involve the use of anti-failure medications which include among others: Diuretics, digoxin and angiotensin-converting enzyme inhibitors (3). Surgical measures are also many times indicated for structural heart problems.

1.2 Problem Statement

It has been found that developing countries face a different pattern of etiologies for heart failure due to tropical diseases as well as a low socio-economic status. This predisposes the children to nutritional deficiencies that are a major cause of anemia and cardiac cachexia resulting in the development of heart failure. Causes of heart failure also vary with geographical locations globally and different age groups among children. It is therefore important to study the etiology of heart failure in different settings. There is a paucity of data in Kenya in the area of congestive heart failure in the pediatric population.

The management of congestive heart failure in children often requires the use of several medications, more so in a case where there is a co-morbid condition. This increases the cost as well as the possibility for drug-drug interactions and challenges with adherence.
The relatively small numbers of children with heart failure are not reflective of the overall economic and social impact of congestive heart failure. This is because the average cost of management of this condition in children is higher. Children frequently need surgical and catheter-based procedures and interventions that are quite costly. They also have frequent hospitalizations resulting in high hospital costs as well as negatively affecting the economic productivity of parents.

Many of the existing formulations for drugs used in heart failure in the market are unsuitable for use by the pediatric population, consequently, adult formulations are used. This, therefore, creates a loophole for medication errors including inaccurate dose administration that complicates the management of the condition. Due to the high rates of recurrence of heart failure and frequent readmissions, parents and guardians of these children face various challenges in the care of these children.

1.3 Study justification

Many studies have been carried out on heart failure in the adult population, however, few studies exist on heart failure among pediatric patients especially in sub-Saharan Africa. The causes of pediatric heart failure vary widely across geographical regions(1). It is important to identify the causes of pediatric heart failure in KNH. Drug use in pediatric heart failure management varies due to lack of current evidence-based solutions. This study evaluated the types of drugs used in KNH in comparison to the recommendations in the Kenya National Guidelines(3). No study has been carried out locally about the unique challenges faced by parents and guardians of children with congestive heart failure. This study provides an insight on these challenges.

1.4 Purpose of the study

This study sought to add to the scarce body of literature available on heart failure among pediatric patients in developing countries as well as to point to the need to improve the

pharmacological management of pediatric patients suffering from the disease by improving compliance to guidelines

The study also forms a basis for understanding the major challenges faced by caregivers of children with heart failure and encourage clinicians to counsel them accordingly.

1.5 Study objectives

1.5.1 Broad objective

To evaluate the etiology and management of heart failure in children below 12 years and the challenges faced by their parents or guardians at Kenyatta National Hospital.

1.5.2 Specific objectives

1. To determine the etiologies of congestive heart failure among children below 12 years at Kenyatta National Hospital.
2. To evaluate the types of drugs used in the management of congestive heart failure among children below 12 years at Kenyatta National Hospital and the conformity to the Kenya national guidelines recommendations.
3. To determine the challenges faced by the parents or guardians of children with congestive heart failure at Kenyatta National Hospital.

1.6 Research Questions

1. What are the etiologies of congestive heart failure among children below 12 years at Kenyatta National Hospital?
2. What types of drugs are used in the management of congestive heart failure among children at Kenyatta National Hospital and how does the treatment of these patients conform to the Kenya National guidelines for the management of this condition?
3. What are the challenges faced by parents or guardians of children with congestive heart failure care at Kenyatta National Hospital?

1.7 Significance and anticipated output

The findings of this study are useful to clinicians to increase their vigilance on the major causative factors of pediatric heart failure and therefore optimizing management of these risk factors before pediatric heart failure sets in.

Identification of the challenges in the management of congestive heart failure among children is helpful in preparing the caregivers of the children as well as informing economic decisions on availing some of the necessary requirements such as drugs lacking in the management of this condition. The study is also useful for researchers wishing to do further research on pediatric heart failure given the scarcity of data in this area.

1.8 Limitations

Finding out the etiology and the types of drugs used for the management of pediatric heart failure involved a retrospective study that relied entirely on the accuracy of the patient records available. The study involved the collection of data from the caregivers of children with congestive heart failure and therefore the likelihood of information bias.

1.9 Conceptual framework.

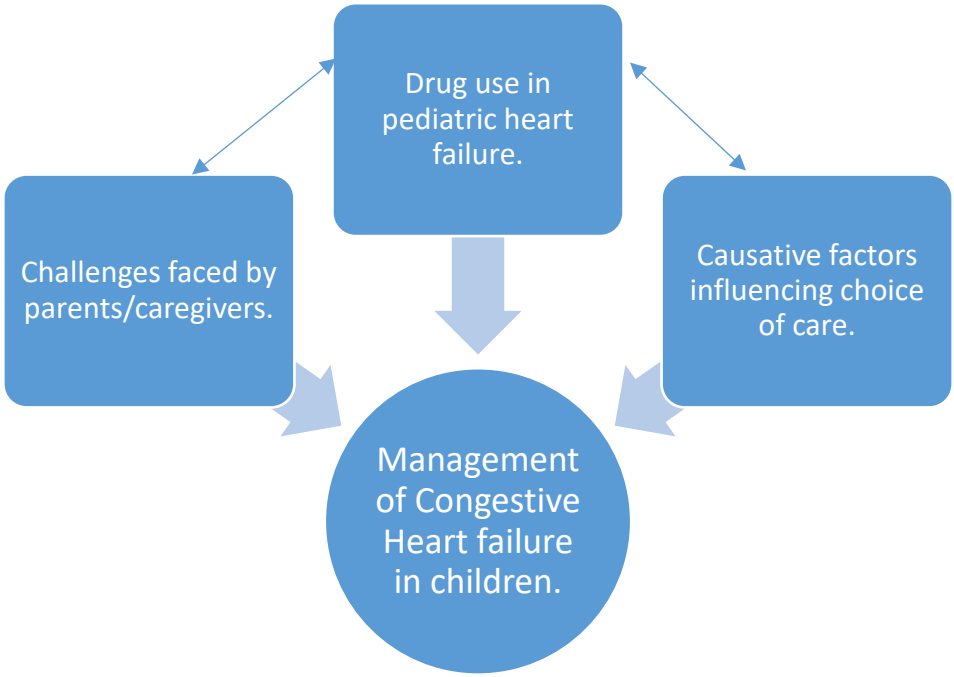


Figure 1: The conceptual framework

Various etiologies of pediatric heart failure require different therapeutic approaches in order to eliminate the factors triggering heart failure. These involve the management of infections, anemia, malnutrition, rheumatic heart disease and surgical approaches to congenital heart diseases. These, therefore, affect the choice of drug types used among different patients with heart failure.

The parents or guardians of these children face several challenges that directly affect the children's relapse into heart failure and therefore requiring re-hospitalization. Low socioeconomic status is associated with an increased risk of infections and malnutrition and therefore increasing the risk of heart failure. They also face the challenge of reduced economic productivity due to frequent hospitalizations and therefore may not always afford the drugs required in the long term to manage the different conditions.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter discusses the common known causes of pediatric congestive heart failure in various studies as well as aspects of drug use in heart failure. It also reviews the challenges faced by parents and guardians of children diagnosed with congestive heart failure that has been studied previously.

2.2 Etiology of heart failure in the pediatric population

There are potentially many causative and precipitating factors of congestive heart failure in the pediatric population. These factors differ greatly from those in the adults. They are usually either of cardiac or non-cardiac origin (1). Generally, pediatric heart failure in children can be divided into two groups. The first group involves pump failure caused by either congenital or acquired conditions and the second group is over-circulation that is caused by conditions that precipitate volume overload of the heart chambers.

The major key to the diagnosis of the causative factors of heart failure is the time of its onset. Different etiologies are likely especially in different ages: at the fetal stage, after birth, at infancy and in children older than two years (10).

Variations for heart failure etiology in children exist across different regions. A systematic literature review carried out using 83 unique studies found out that severe anemia and lower respiratory tract infections are the predominant causes in low-income countries while congenital heart diseases and cardiomyopathies predominate in the developed countries. This study was however limited by heterogeneity in diagnostic criteria and study design, therefore, comparison of regional data was limited. The study recommended standardized definitions of heart failure in children to enable more reliable cross-regional comparisons of data (11)

A study done in Belgium in a tertiary pediatric center showed that among the children selected with heart disease, 10.4% developed heart failure. The study observed that congenital heart disease was the most common cause of heart failure in infants. Other causes were more likely in older children and these included: arrhythmias, cardiomyopathies and acquired heart diseases (7).

Infections such as pneumonia, throat, and upper airway infections as well as urinary tract infections are significant causative factors of heart failure.(8). A retrospective review of predictors of mortality associated with pediatric heart failure in Nigeria identified lower respiratory tract infections as the leading cause of heart failure(41.9%)(12). There is a significant burden of perioperative infections among children with congenital heart diseases. These infections are associated with progressive heart failure and poor growth. Among the risk factors for infection include malnutrition, inadequate management of heart failure and delayed presentation (13). Immunocompromised children are at high risk of TB infections including TB pericarditis that leads to constrictive pericarditis due to pericardial effusions. Steroid therapy with caution can be considered in preventing the progression to constrictive pericarditis (14).

Anemia is associated with adverse outcomes and worse prognosis in heart failure. Anemia has been shown to occur with or without iron deficiency (15). It is not yet clear whether management of anemia can improve outcomes however proposed therapeutic approaches include iron supplementation and erythropoiesis stimulators especially in cardio-renal syndrome (16). A study done in a pediatric Kenyan population indicated anemia as the second leading cause of heart failure at 17.1% after infections at 22.8%. The most common causes of anemia as found in the study included malaria, malnutrition, helminth infestations and sickle cell disease (8).

Heart failure due to structural malformations in the heart in children is commonly due to the significant left to right shunting such as in ventricular septal defects. Symptoms usually occur during the transition from fetal to neonatal circulation. These include tachypnea as a result of pulmonary edema. Tachypnea interrupts breathing and therefore affecting the child’s nutrition. Valve regurgitations including atrioventricular and semilunar valves are also important causes of heart failure.

Complex heart malformations may also combine pressure and volume overload affecting both pulmonary and systemic malformations. Early surgical interventions are the best treatment options for congenital heart diseases if viable and available (1). Cardiomyopathies such as dilated and hypertrophic cardiomyopathies may occur. Rarely does hypertrophic cardiomyopathy progress to heart failure in children.

Studies have shown that children with dilated cardiomyopathy have the greatest risk of developing heart failure. Dilated cardiomyopathy in children has many causes, among them being a genetic impairment where the myocardium is unable to generate adequate force due to alterations in the structure of the heart muscle (1). Dilated cardiomyopathy is the most common cause of cardiac transplantation in children. Its outcomes depend on heart failure status, age at presentation and the cause of the cardiomyopathy. However, most causes of dilated cardiomyopathy are unknown. This limits disease-specific therapies from being applied (17). An implantable cardioverter-defibrillator (ICD) placement is the major therapy recommended for patients at risk of sudden cardiac death in dilated cardiomyopathy. This however only functions as a bridge before transplantation is done (18).

Rheumatic heart disease results from an autoimmune response to group A *Streptococcus* infection. This results in Acute Rheumatic fever that precedes rheumatic heart disease as it results in irreversible valve damage and consequently heart failure (19). This valve damage includes mitral and aortic valve stenosis. Rheumatic heart disease causes about 250,000 deaths per year worldwide(20) Penicillin prophylaxis is essential in preventing recurrent episodes of acute rheumatic fever.

A study was done in Uganda among subjects with Rheumatic heart disease to determine the predictors of morbidity and mortality after presentation showed that 35% developed decompensated heart failure (21). The study concluded that heart failure among these patients was associated with poor compliance with penicillin prophylaxis. An Ethiopian study indicated that 53.7 % of acute heart failure among children aged 2 months to 14 years was due to rheumatic heart disease (5).

2.3 Drug use in heart failure in the pediatric population

Developmental considerations are of concern in the use of drugs in heart failure in the pediatric population. Various animal models have demonstrated that maturity of myocardial contractility occurs during the postnatal period and is mediated by changes in calcium homeostasis and signal transduction. Contractile responses to stimulation by beta-agonists and phosphodiesterase inhibitors are less robust than in the adult myocardium. If these findings correlate with the human myocardium, then there are implications for the therapeutic management of heart failure in the pediatric population (1).

A practical guide to the diagnosis and management of pediatric heart failure emphasizes that in the clinical setting, an accurate diagnosis and an understanding of the possible etiology are critical in optimizing therapy. Heart transplantation is the most effective treatment of choice in end-stage heart failure or a left ventricular assistive device before transplantation, recovery or determination of destination therapy in systemic disease. Meanwhile, diuretics and angiotensin-converting enzyme inhibitors are the first line of choice (22). Digoxin, beta blockers, and aldosterone antagonists are also of use in the management of pediatric heart failure though with limited studies on their efficacy.

Research in the therapeutic management of congestive heart failure in children lags behind as compared to major advances attained and documented in the adult population. The general use of drugs has been based on pharmacological knowledge and therefore the use of ACEIs, mineralocorticoid antagonists and beta blockers have been recommended in the face of a paucity of evidence-based studies. An analysis that focused on the prevailing nihilism of therapy of congestive heart failure in children aimed to encourage physicians to manage pediatric heart failure with a rationally designed therapy using available drugs showing benefits in adults but using surrogate variables such as weight gain, respiratory rate, heart rate, biomarkers and image-derived data for monitoring of condition (2). In 2006, a review of reports of ACEI use in pediatric heart failure indicates the benefits of ACEIs in children as lowering aortic pressure and systemic vascular resistance as well as lowering right and left atrial pressures in heart failure.

ACEIs are also useful in infants with pulmonary hypertension and children with large ventricular-septal defects by decreasing left to right shunt in systemic vascular resistance. These beneficial effects were experienced in the long term without tolerance development. However smaller doses have to be administered initially to avoid hypotension and then a gradual increase in dose to the target dose (23).

Some researchers have opposed the use of vasodilators to reduce vascular resistance in circulatory failure in children with congenital heart defects and therefore proposing that they do not offer an acceptable therapeutic option. This is due to induction of hypotension when systemic output fails to rise with a significant limitation in maximum cardiac output not exceeding 141/min/m^2. This is according to a study that used the pressure-flow resistance diagram to elucidate the effect of vasodilators established in previous studies. The vasodilators here were hydralazine, sodium nitroprusside and angiotensin-converting enzyme inhibitors (24).

A systematic analysis done on children with heart failure showed that renal failure, hypotension, and hyperkalemia were the most significant side effects in children being managed for heart failure with renin-angiotensin system inhibitors. Renal failure was identified in 11%, hypotension in 4.5% and hyperkalemia in 0.7% of the patients. Low weight and young age were found to increase the risk of renal failure (25).

Digoxin is useful in maintaining clinical stability and exercise capacity in clinical heart failure with particular benefit in cardiomegaly and severe heart failure(26). Digoxin has also been found to be beneficial in decreasing sympathetic tone and improving growth in infants.

Digoxin is associated with an increased risk of the development of arrhythmias among children. According to a study done in a national referral hospital in Uganda, digoxin use in children with Congenital heart defects showed an increased risk of arrhythmias with the most common being first degree AV block among those aged above 5 years. The prevalence of arrhythmias was 27.3%. Other risk factors for arrhythmias were electrolyte imbalances and child's age (27).

Assessment of digoxin toxicity is necessary, however, according to a study done to determine the association between serum digoxin concentrations with signs and symptoms of digoxin toxicity in children, it was shown that serum digoxin concentrations were not strongly associated with signs and symptoms of toxicity which mainly included nausea, vomiting, and tachycardia (28). This implies therefore that clinical assessment for digoxin toxicity as well as monitoring for arrhythmias remains the major basis for determination of digoxin toxicity.

Beta-blockers have been used in children with heart failure though in limited studies. Propranolol was found to be useful in the management of heart failure in infants in a prospective randomized trial. It has been found to have beneficial effects on heart rate variability, cardiac remodeling, neuro-hormonal activation and on the clinical heart failure score. Propranolol is especially useful in the management of heart failure prior to surgery or after palliative procedures (29). Caution should be exercised in the use of beta blockers by starting with low doses and increasing gradually to the desired doses while monitoring heart rate and blood pressure (30). Therapy with beta-blockers can interfere with glucose metabolism and also aggravate ketotic hypoglycemia (31).

Diuretics are used in the management of heart failure to relieve symptoms but are not necessary for all children(32). They result in a decrease in the net absorption of sodium and water and therefore decreasing systemic venous return and congestion. They are however known to cause electrolyte disturbances with progressive hypokalemia, hypomagnesemia, and hyponatremia (33). However, their doses should be maintained as low as possible to prevent the activation of the renin-angiotensin-aldosterone system that has a negative effect in cardiac remodeling (29).

Aldosterone antagonists have been found to be useful in reducing symptoms and mortality in adults with severe heart failure. They also form part of the renin-angiotensin-aldosterone blockade and therefore aid in reducing resistance to diuretics. These benefits remain unproven in children even though they are commonly used.

The only aldosterone antagonist that has been studied in a randomized controlled trial for the management of heart failure in children is milrinone. Milrinone to a large extent reduces the incidences of low cardiac output syndrome following cardiac surgery by reducing ventricular filling pressures as well as increasing cardiac output (33)**.**

The National clinical guidelines for the management of heart failure in children recommend the use of diuretics (furosemide), digoxin, potassium supplements, and ACE inhibitors. (3)

2.4 Challenges faced by parents and guardians in pediatric heart failure

2.4.1 Frequent re-admissions

Fewer hospital admissions are associated with decreased health-care costs, patient and family satisfaction and decreased healthcare costs. The drivers of readmission rates include the resources of the community and family as well as the composition of the patient population in a hospital. Readmissions, therefore, vary by hospital. Re-admission is commonly associated with poor discharge planning and handing over to the community primary caregivers (34).

In the United-States, a nationwide analysis of emergency department visits showed that although there were few pediatric emergency department visits related to heart failure, they were associated with increased hospital readmissions and resource use. Heart failure-related patients were significantly more likely to be admitted (35). A study done on a pediatric health information system database showed that patients with cardiomyopathy and heart failure had a high frequency of 30-day readmission that was heart failure related. Out of the children selected, the prevalence of 30-day readmission was 12.9% (36). Studies are lacking in developing countries on the rates of readmission of pediatric heart failure patients.

2.4.2 Communication to parents/guardians

The regular follow-up, compliance with medication and management of symptoms depend on the state of parent’s empowerment, action, and engagement. It is important that they ask questions and discuss their deep concerns. They also require information that is useful in self-care and in making decisions (36).

2.4.3 Socio-economic challenges

An assessment of health-related quality of life and functional status among children with cardiomyopathy revealed that lower quality of life was associated with lower socioeconomic status(37). Frequent readmissions are also associated with reduced parental economic productivity therefore further affecting the family's economic status (1).

2.4.4 Adherence to medications.

Management of chronic conditions such as Rheumatic heart disease and cardiomyopathies to prevent the occurrence of heart failure requires optimum compliance with medication (21). This compliance is affected by many factors including, availability and accessibility of medications. This requires parents and caregivers to be willing and able to have an expenditure on drugs. Availability of pediatric formulations is also a challenge, therefore, requiring manipulation of adult formulations which further complicates the problem of adherence. The prevalence of drug manipulation to obtain the prescribed dose in Kenyatta National Hospital is about 6.4% (38).

CHAPTER THREE: METHODOLOGY

3.1 Introduction.

This chapter contains the methodological aspects of the study to determine the etiologies of congestive heart failure in children, the types of drugs used as well as the challenges faced by the parents and caregivers of children with congestive heart failure. It includes the design of the study, location, the target population, research instruments, their validity and reliability, data collection and management, ethical considerations as well as the budget and work- plan.

3.2 Research design

A cross-sectional study involving pediatric patients' hospital records was carried out to determine the etiologies and types of drugs used in the management of heart failure among children from 1st January 2017 to 31st December 2017. The challenges faced by the parents or guardians of the children were also investigated. The duration stipulated was suitable due to the relatively small numbers of pediatric patients who develop congestive heart failure in a population. The design was also likely to be cost-effective and provided reliable findings. The study will provide a basis for analytical studies in the future.

3.3 Study site

The study was carried out at Kenyatta National Hospital which is a teaching and referral hospital in Eastern Africa. It is located in Nairobi, Kenya's capital city. The hospital has about 50 wards with a bed capacity of 1800 and 22 out-patient clinics. It hosts teaching institutions such as the College of Health Sciences- University of Nairobi as well as the Kenya Medical Training College. The hospital caters for about 30,000 pediatric in-patients each year. Pediatric patients with congestive heart failure are managed at the pediatric wards. The children are usually admitted together with their parents or guardians. They are then discharged through the pediatric out-patient cardiology clinic.

In this study, records of children with congestive heart failure were obtained from the respective department of Kenyatta National Hospital while parents and guardians of children with congestive heart failure were sought from the pediatric wards, 3A, 3B, 3C and 3D. The simple random sampling method was used to select records as well as to recruit parents and guardians.

3.4 Target population

Two sets of populations were used for the study, they included all infants and children aged 12 years and below diagnosed with congestive heart failure between 1st January 2017 and 31st December 2017. The other population was parents and caregivers of children admitted in the various pediatric units with congestive heart failure.

3.4.1 Inclusion criteria

The subjects only included those that met the following criteria:

- Infants and children aged 12 years and below with a confirmed diagnosis of congestive heart failure admitted at Kenyatta National Hospital whose records were complete.
- Parents and guardians of children who are the primary caretakers of the children and understand the full child's health history.
- Parents and guardians of children who are willing to provide written consent.

3.4.2 Exclusion criteria

Eligible participants that were excluded from the study included:

- Parents and guardians who decline to give informed consent.
- Patients with incomplete records that do not indicate the cause and drugs used in managing congestive heart failure.
- Parents and guardians who are psychosocially challenged and unable to give the required information.

3.5 Sampling

3.5.1 Sample size

3.5.1.1 Sample size for the records

The Cochran formula (39) for calculation of sample size was used to determine the sample size for the study.

$$n = \frac{z^2_{1-\alpha/2}\, p\,(1-p)}{d^2}$$

Where: *n* = the minimum sample size required for the study

p = Prevalence of one of the variables of interest. In a previous study on etiology of heart failure at KNH, the main causative factor was found to be infections at 22.8% (8). This prevalence was used to determine the sample size.

$z_{1-\alpha/2}$ = the standard normal deviate value at 95% confidence interval which is 1.96.

d = the desired precision for this study was 0.05.

$$n = \frac{1.96^2 * 0.228(1-0.228)}{0.05^2}$$

n = 270 participants

The formula above is applicable when the target population is 10,000 and above. According to the records at KNH, the number of pediatric patients with heart failure from 1st January to May 2018 was sixty. An adjustment of the sample size for a finite population was therefore done as shown below;

S (adjusted sample size) = N*n / n+N

S = 270*60/ 60+270 =49

An additional 15% was added to cater for incomplete records.

= 49 X (1+0.15) = 57 participants

However, for the year 2017, it was only possible to get 53 records.

3.5.1.2 The sample size for the parents/guardians

Since the exact number that would be available during the study period was unknown, a representative sample was estimated. According to the law of central theorem, a sample size of 30 and above is adequate to generalize the results of a study to a population. In this study, therefore, 30 parents or guardians were involved.

3.6 Research instruments

3.6.1 Eligibility screening forms

These forms were used to guide the selection of records of infants and children who met the inclusion criteria in the retrospective arm of the study (Appendix I) as well as parents and guardians of children with congestive heart failure who met the inclusion criteria. (Appendix II).

3.6.2 Informed consent form

Obtaining a voluntary consent was done using this form (Appendix III) for parents or guardians of children who met the inclusion criteria. This consent was obtained after explaining the purpose of the study to the individuals. There was a Kiswahili version for those who did not understand English (Appendix IV).

3.6.3 Data collection forms

a) All information relevant to the study from the patients' records of infants and children who met the inclusion criteria was collected and entered into the data collection form (Appendix V). The data collection form included Socio-demographic data such as age, weight, height and gender, the cause of heart failure, types of drugs used in the management of heart failureand adherence to the national clinical guidelines.

b) A structured questionnaire (Appendix VI) was used to collect information from parents and guardians after obtaining their consent as well as signing the consent declaration form. This questionnaire included:

c. An assessment of the parents' or guardians' understanding of the child's condition, the pharmacological management required.

d. A structured assessment of adherence to medications and the challenges that affect adherence to medication such as availability of medicines.

e. An assessment of some of the main challenges including financial strain, lack of financial and social support among others.

3.7 Pilot study or Pre-testing

A pilot study was carried out with 5 records of patients as well as 3 parents/guardians (10% of estimated sample size) to test the ease of data collection, completeness, and relevance of the information collected.

This activity was done at the hospital's registry for the records while the parents and guardians were interviewed at the different pediatric units of Kenyatta National Hospital. Only records and individuals who met the inclusion criteria were pre-tested.

3.8 Validity

The external validity of this study was ensured by using adequate sample size of 53 children and 30 parents and guardians. The internal validity was maintained by ensuring that the data collection forms and the questionnaires were well laid out to meet the objectives of the study. The arrangement of the questions was done sequentially using clear, concise and simple language.

3.9 Reliability

To ensure the consistency of the research study findings, the data collection forms and questionnaires were pre-tested for reproducibility as mentioned in the pilot study. There was a systematic approach to data collection from the records as well as from the parents/guardians as indicated in the study procedures outlined in section **3.10**

3.10 Study procedures

The principal investigator obtained patient IP numbers based on the ICD-10 classification with 150 being for heart failure. The patient numbers obtained were used in file retrieval from the main records department of KNH. These hospital inpatient numbers were recorded on a sheet of paper and each record assigned a unique study identification number.

Medical records, treatment charts and prescription records obtained from the files were reviewed by the principal investigator and data on patient's demographics, the cause of heart failure, treatment and adherence to guidelines was systematically collected using the data collection form. (Appendix V).

The hospital file records were only used by the principal investigator and did not leave the registry premises for safety purposes. The sheet containing the patient numbers was securely stored under lock and key. Confidentiality of the medical information therein was ensured. After data collection, they were refilled by the principal investigator.

The principal investigator identified the children with congestive heart failure in the pediatric wards from the ward records and then proceeded to recruit the parents or guardians of these children using an eligibility assessment form (Appendix II). Consent explanation was given to each of the participants at the ward by the primary investigator after which they were asked to sign the informed consent form if they agreed to take part in the study. Those who declined to sign informed consent were excluded from the study. The principal investigator with the help of the parent/guardian then identified an appropriate space and place for carrying out the interview to ensure privacy.

An interview was then done by the primary investigator to the parents/guardians guided by a structured questionnaire. The interview was geared towards identifying the challenges faced by parents of children with heart failure receiving care at Kenyatta National Hospital.

3.11 Data management

Raw data was entered into Microsoft-Excel worksheet 2013 using the data collection form and questionnaire number identifiers to link them to the database of participant's details. This was done by the principal investigator after each day of data collection.

Patient identifier information was securely stored separately from the rest of the data. There were key data checks by the research assistant after each day of data collection and entry to check for inconsistencies, missing information and to compare sampled data entry forms with original source instruments.

Corrections required were noted and done. On completion of the data entry process, the data was exported onto SPSS version 20.0 for analysis.

Descriptive analysis was done to determine the frequencies and variable proportions. These included the frequency and percentages of each of the causes of heart failure, drug combination patterns and adherence to clinical guidelines on choice and drug dosage. Frequencies and percentages were also used to measure the challenges faced by parents and guardians including the general knowledge of the child's condition, drug availability, financial strain, adequacy of time with a health care provider, the rate of readmissions and lack of financial and social support. These were presented in frequency distribution tables, graphs, and percentages as appropriate.

Relationships between variables were analyzed using chi-square and regression analysis at 0.05 level of significance. These included relationships between the baseline characteristics of parents/guardians and adherence to medication.

3.12 Ethical considerations.

Ethical approval was sought from Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee prior to carrying out the study (ERC No p158/03/2018). Institutional authorization was obtained from the KNH administration. Study participants were requested to sign declaration forms after being taken through the consenting process.

Confidentiality of patient data was ensured by the use of study serial numbers instead of patient names. Data collection materials were also kept under lock and key. The study participants benefitted from free counseling of their child's condition as well as addressing any concerns the patient had concerning their child's condition and management. There was little or no risk to the participants since no invasive procedures were carried out.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents the analysis and findings of the study as in the research methodology. The results presented are on the causes of pediatric heart failure, its management and the challenges faced by parents and guardians of children with Congestive Heart failure at Kenyatta National Hospital. The study data was collected from the hospital records of children aged below 12 years diagnosed with Congestive Heart failure between 1st January 2017 and 31st December 2017 from Kenyatta based on the study variables. The rest of the data was collected by interviewing the parents and guardians about the challenges that they face in the care of their children.

4.2 Data analysis for selected records of children managed for heart failure.

In this section, frequency tabulations and sample statistics are presented in order to give a description of the individual variables.

4.2.1 Patient demographics

From the hospital records, data on age and sex of 53 pediatric patients were obtained and analyzed.

Table 1: Socio-demographic characteristics of the children

Variable	Categories	Frequency	Percent
Age	<1 year	16	30.2
	1-<5 years	26	49.1
	5 -12 years	11	20.8
Gender	Male	26	49.1
	Female	27	51

From Table 1, majority of the children (49.1%) were aged between 1 and 5 years, with minority of the children 20.8% aged between 5 and 12 years. Gender was equally distributed with half of the patients being male and the other half female.

4.2.2 Etiology of heart failure

The following were the main causes of heart failure as represented in **Table 2**.

Table 2: Etiology of pediatric heart failure

Etiology	Frequency	Percent
Infections	31	58.5
Congenital heart disease	18	34.0
Anemia	11	20.7
Cardiomyopathies	8	15.1
Rheumatic heart disease	7	13.2
Pulmonary hypertension	17	32.1
Malnutrition	6	11.3

n = 53

In the majority of the cases (n=31, 58.5%), infections including pneumonia, upper respiratory tract infections or urinary tract infections were present. Eighteen (34%) participants had congenital heart disease while 14 (26%) of them had pulmonary hypertension. Other subjects had cardiomyopathies (n=8, 15.1%) rheumatic heart disease (n=7, 13.2%) and malnutrition (n=6, 11.3%) respectively.

Some of the cases of heart failure had only one etiology. These include congenital heart disease (n=3, 5%), infections (n= 4, 7%), anemia (n= 2, 1.9%), rheumatic heart disease (n=7, 13.2%). Majority of the heart failure cases had several causes including congenital heart disease plus infections (n= 6, 11.3%), cardiomyopathies plus infections (n= 6, 11.3%) and congenital heart disease plus infections plus pulmonary hypertension (n= 7, 13.2%).

4.2.3 Types of drugs used in the management of heart failure

Various drugs were utilized in the management of heart failure. As indicated in **Figure 2,** nearly all the patients were on furosemide (n= 52, 98.1%). Digoxin was utilized in 36 (67.9%), spironolactone in 18 (34.0%), sildenafil in 14 (26.4%) while Enalapril was used in 14(26.4%) and Carvedilol in 6 (11.3%) of the 53 cases.

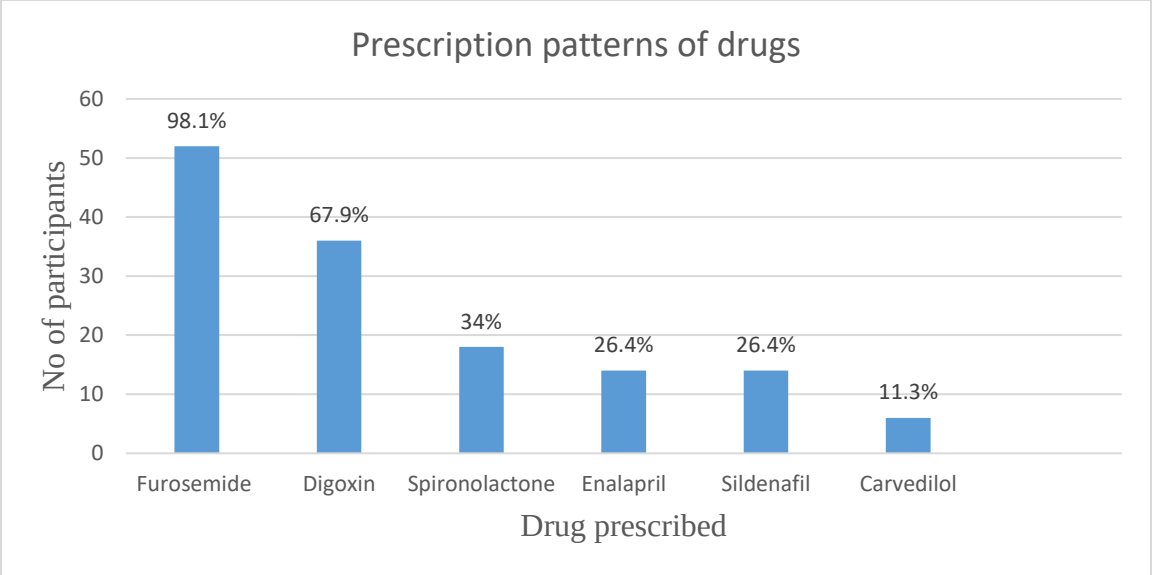


Figure 2: A bar graph showing prescription patterns of drugs used in heart failure

4.2.4 Dose appropriateness with reference to the national clinical guidelines

The doses administered to the children were compared with the doses recommended in the Kenya national guidelines for the management of heart failure in children and are represented in the table below.

Table 3: Dose appropriateness of the drugs used in pediatric heart failure

Drug	Dose	Frequency	Percentage
Furosemide	Under dose	19	35.9
	Normal dose	26	49.1
	High dose	1	1.9
	N/A	8	15.1
Digoxin	Under dose	23	43.4
	Normal dose	5	9.4
	High dose	5	9.4
	N/A	20	37.7
Spironolactone	Under dose	5	9.4
	Normal dose	9	17.0
	High dose	1	1.9
	N/A	38	71.7
Sildenafil	Under dose	4	7.5
	Normal dose	7	13.2
	High dose	2	3.8
	N/A	40	75.5
Enalapril	Under dose	5	9.4
	Normal dose	6	11.3
	High dose	1	1.9
	N/A	41	77.4

4.2.5 Types of drug combination used

Various drug combinations were used to manage heart failure in the children from the 53 records. This is shown in **Table 4** below. Contrary to the guidelines, only 12 (22.6%) cases were on the recommended combination of furosemide, digoxin and Enalapril/captopril.

Table 4: Table showing drug combinations used in pediatric heart failure

Drug combination	Frequency(Percent)
Furosemide +Digoxin +Enalapril/captopril	12(22.6%)
Furosemide + Digoxin	7 (13.2%)
Furosemide + Digoxin + Spironolactone	7 (13.2%)
Furosemide +Digoxin +Sildenafil	6 (11.3%)
Furosemide alone	9 (17%)
Other drug combinations	22.9%

4.2.6 Mortality

Heart failure in children is associated with a high mortality rate. Of the 53 records evaluated, 13 (24.5%) of the cases were deceased.

4.3 Challenges faced by parents and guardians of children with heart failure

Information was sought through an interview on the socio-demographic characteristics as well as the various challenges faced by parents and guardians in the care of their children with heart failure.

4.3.1 Socio-demographic characteristics of the parents and guardians

As **Table 5** shows, most of the caregivers were females (n=29, 96.7%) and the majority (n=25, 83.3%) were married. A significant proportion of the caregivers (n= 26, 86.7%) attained the secondary level of education and below. Their income level was between Ksh 0 -5000.

Table 5: Baseline characteristics of the parents and guardians

Variable	Category	Frequency	Percent
Gender	Male	1	3.3
	Female	29	96.7
Marital status	Single	4	13.3
	Married	25	83.3
	Others	1	3.3
Education level	Secondary and below	26	86.7
	Above secondary	4	13.3
Income level	0-5000	23	76.7
	5000-20000	6	20
	20000-50000	1	0.3

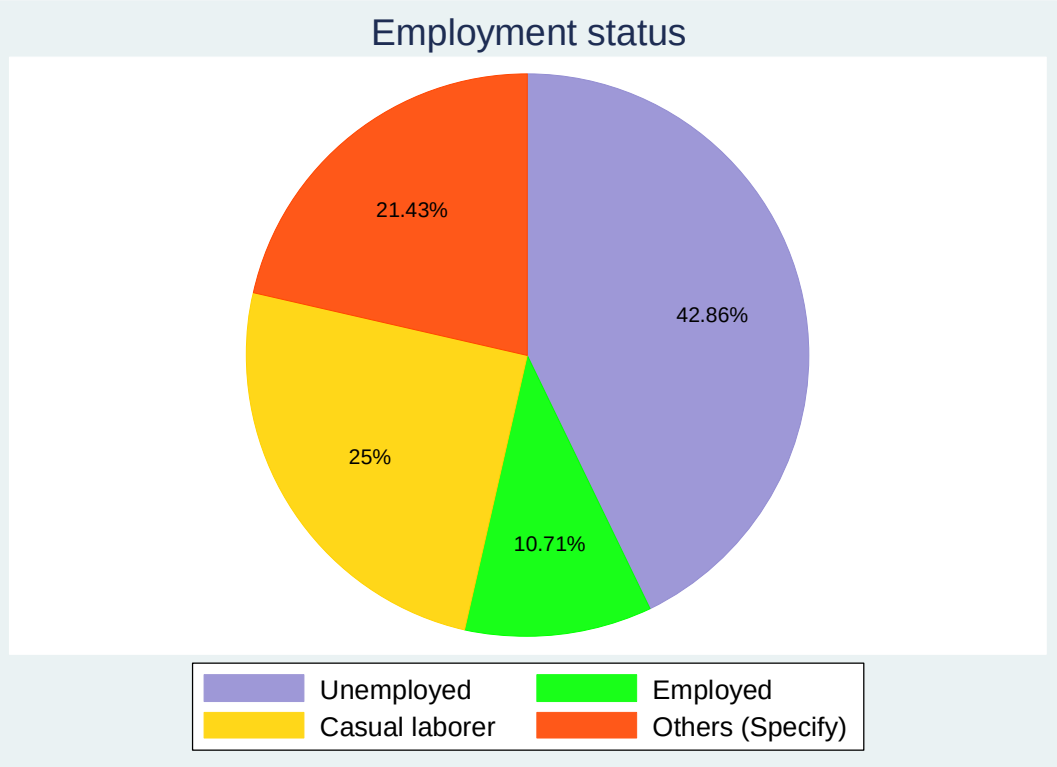


Figure 3: Employment status of the parents and guardians

The majority (42.9%) of the parents and guardians were unemployed while 21.4% were casual laborers in the low-income level of Ksh 0-5000.

4.3.2 General knowledge of the child's condition.

Twenty-five (83.3%) parents/guardians knew that their child has heart failure while 5(16.7%) were not aware. Fourteen (46.7%) of them did not know if the disease was curable and one (3.3%) intimated that there was no cure while 13(43.3%) said otherwise. Most parents/ guardians (n= 25, 83.3%) did not know for how long the treatment would last while 4(13.3%) said the treatment would last until the cause is controlled.

Nineteen (63.3%) parents/guardians knew what drugs their child uses for heart failure and were able to mention the names of these drugs while 10 (33.3%) did not know what drugs the child was on.

4.4 Challenges faced by parents and guardians

Respondents intimated that they faced various challenges during the treatment of their children. Twelve (40%) of them said that they were not able to get all the prescribed medicines from KNH while 18(60%) obtained them. Twenty (96.7%) respondents were satisfied with the time they spent with the healthcare providers while only one (3.3%) felt otherwise.

Since monitoring is required for these patients, it was noted that 23 (76.7%) children were regularly followed up at the cardiology clinic while 3 (10%) were not. Four (13.3%) were newly diagnosed with heart failure. The parents and guardians were asked about the major challenge they face in visiting the clinic for follow-up. Nine (30%) respondents claimed they did not go for regular follow-ups at the clinic since they were already readmitted at the day they were supposed to attend the clinic. Eight (26.7%) of the participants mentioned lack of finances as their major challenge for lack of clinic attendance while 2 (6.7%) mentioned unavailability of services in the cardiology clinic as their main problem. Seven (23.3%) did not cite any challenge with going to and attending the clinic.

Majority of the parents and guardians 27 (90%) experienced financial strain as a significant challenge in the care of their children. Only 3 (10%) did not experience financial strain. Nineteen (63.3%) respondents reported that they did not receive any form of financial/social support from their families while 10 (33.3%).Twenty-two (73.3%) respondents reported that the child's medical condition affected their work/business while 8 (26.7%) did not have their work or business affected by the demand of caring for their child.

Discrimination is common among parents of children who constantly require medical care. Sixteen (53.3%) respondents reported that they faced discrimination based on child's medical condition, 12 (40%) of the respondents reported that they did not face discrimination based on child's medical condition, while 2 (6.7%) of the respondents did not give a response.

Children with heart failure are likely to be admitted severally especially if the cause of heart failure is not controlled. Eight (26.7%) respondents reported that their child was hospitalized at least two times while 21 (70%) had more than two.

4.5 Adherence to medication

The modified Morisky question tool was used to assess adherence of drugs from the parent/guardian perspective**.** Seven (36.8%) had low adherence, 9 (47.4%) had medium adherence and three (15.8%) parents/guardians had a high adherence A Fisher's test was carried out to determine if there exists any relationship between adherence to medication and the baseline characteristics of the parents and guardians as well as some of the challenges faced by parents and guardians. Multivariate analysis using linear regression was also done to determine the most important predictors of adherence. The results are presented in **Table 6**. Of significance was the association between the income category and adherence to medication with a P-value of 0.012 which is less than $\alpha = 0.05$.

Table 6: Associations between adherence and various characteristics of caregivers

Variable		Adherence level			P-value Univariate	P-value Multivariate
		0	1	2		
Income category						
	<5000	7(100%)	6(75%)	1(25%)	**0.025***	**0.012***
	>5000	0	2(25%)	3(75%)		
Education level	Secondary and below	6(85.7%)	8(100%)	2(50%)	0.084	0.673
	Above secondary	1(14.3%	0	2(50%)		
Awareness of medications	Yes	2(28.6%)	2(25%)	1(25%)	1.000	0.380
	No	5(71.4%)	6(75%)	3(75%)		
	>2	5(83.3%)	5(62.5%)	4(100%)		
Medication availability	Yes	4(57.1%)	2(25%)	1(25%)	0.471	0.461
	No	3(42.9%	6(75%)	3(75%)		
Time with a health provider	Yes	0	1(12.5%	0	1.000	0.527
	No	7(100%)	7(87.5%)	4(100%)		
Financial strain	Yes	0	1(12.5%)	1(25%)		
	No	7(100%)	7(87.5%)	3(75%)	0.673	0.463
	No	2(28.6%)	2(25%)	1(25%)		

- *statistically significant p-value

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS.

5.1 Introduction

This chapter includes the discussion of the results and findings of this study and their relationship to other similar studies. It also includes the conclusion of the study and recommendations.

5.2 Discussion

Pediatric heart failure has several possible causative factors that differ with age groups and geographical location (1). According to the findings of the study, the main etiology of heart failure was infections. Other significant etiologies include congenital heart disease, pulmonary hypertension, cardiomyopathies, and rheumatic heart disease among others. These results differ slightly from another one done on a Kenyan pediatric population (8). However, the main causative factor in both studies was infections.

Different age groups among the children have different causative factors of heart failure. In this study, the majority of the children were aged between 1 and 5 years. For this group of patients, infections were the predominant causative factor of heart failure. For the older children aged 5 to 12 years, the most important causative factor was rheumatic heart disease. This is in line with the general epidemiology of rheumatic heart disease that usually has its peak incidence from about 5 to 14 years (20).

Congenital heart disease predominated as the main cause of heart failure among the infants. This is a common finding in other studies that support that heart failure in children above 1 year and heart failure in infants has clear differences in etiology. A study done in a tertiary pediatric center showed that congestive heart failure is the most common causative factor of heart failure during infancy (5).

For some of the cases, there was only one single causative factor of heart failure. Rheumatic heart disease was the most common single factor causing heart failure. Most of the heart failure seemed to occur due to a combination of factors and not due to one particular factor only.

The most common combination of causative factors was congenital heart disease and infections followed by cardiomyopathies and infections. This seemed to indicate that infections were more likely to cause heart failure in the setting of an underlying heart condition.

Fifty-eight percent of pediatric heart failure in this study had infections as a causative factor occurring either alone or in combination with other factors. This is in tandem with a review on mortality predictors associated with pediatric heart failure in Nigeria that showed a prevalence of 41.5% of heart failure caused by lower respiratory tract infections (12). However, a previous study done in a Kenyan population showed a prevalence of 22.8% infections as the cause of heart failure (8). Congenital heart disease was present in 34% of the cases in this study as compared to 13.3% in the above study.

Pulmonary hypertension was also a major factor causing right heart failure. Pulmonary hypertension in most of these cases is likely due to hypoxia as a result of obstruction due to hypertrophied adenoids which were present in 14 of the 17 cases. A case report documented almost instantaneous relief of pulmonary hypertension after surgical removal of the adenoids and the return of almost normal hemodynamics 3 months after the surgery (40).

Malnutrition is common in children with heart failure (40) This is usually due to malabsorption, inefficient use of nutrients and decreased intake among others. The state of malnutrition may cause weakening of the heart muscle and cardiac cachexia, therefore, further compromising the heart function. In this study, 11.3% of the cases had malnutrition. Children with heart failure, therefore, require constant assessment of their nutritional status as well as nutritional support using enteral and parenteral nutrition.

Furosemide is necessary as a diuretic in fluid mobilization from the body as a result of fluid overload due to pump failure and most of the patients were using it. Digoxin is useful in inotropic support and was given to 67.9% of patients; enalapril, on the other hand, was only prescribed in 14% of the patients. This is contrary to the Kenya National guidelines that recommend the use of a combination of furosemide, digoxin, and enalapril.

This is because it is also recommended in other guidelines such as the International Society for Heart and Lung Transplantation guidelines for the management of pediatric heart failure (41) as well as the Canadian Cardiovascular Society guidelines for the management of heart failure in children (42). However, some studies have documented acute kidney failure that is enalapril-induced during the management of heart failure (43).

Other drugs used in the management of heart failure included spironolactone that was present in 34% of the cases. Spironolactone is a common drug in regimens of heart failure in pediatric patients (44). It is effective for aldosterone blockade that plays a significant role in the pathophysiology of heart failure (45). It is, however not included in the Kenya National clinical guidelines. Sildenafil was used in 39% of the cases mainly for the management of pulmonary hypertension.

The dose appropriateness of the drugs used for managing heart failure was also assessed with reference to the Kenya National guidelines. Digoxin had a high frequency of under dosing at 43.4% and a 9.4% frequency of over dosing. Dosing errors in digoxin are common due to the lack of ideal preparations as well as different patient to patient requirements (46). The narrow therapeutic range is also a cause of digoxin dose errors. Digoxin intoxication can be fatal and therefore care should be exercised while dosing the drug. Furosemide was also highly underdosed at 35.9% of the patients. This was especially common in the oral dosing most of which was less than 2-3mg/kg.

Congestive heart failure is associated with high rates of mortality. A study at a specialized tertiary hospital ranked it among the top three causes of deaths in the pediatric emergency unit (47). In this study, 13 (24.5%) of the cases were documented deceased.

Communication to parents and guardians about the child's condition, treatment, and investigations being performed is essential in allaying their fear and anxiety. A study showed that 69% of patients showed some level of dissatisfaction in the lack of communication and preferred to know why some investigations were being done and the results thereafter (48).

Awareness of disease and treatment is also helpful to the parents in increasing adherence among cardiac patients as well as being prepared for any possible eventualities such as readmissions (49). This study showed a relatively high level of awareness of the caregivers that their children had heart failure. However many of them did not know whether the condition has a cure and subsequently did not know for how long the treatment would last. All these point to lack of communication to the parents on the child's treatment process by the caregivers.

Various challenges affect the parents and guardians of children with congestive heart failure. Among them included lack of availability of the prescribed medications for heart failure. Drug unavailability and shortages significantly affect drug therapy and patient outcomes. Managing product supplies in resource deficient settings is in itself complex (50). It may result in prolonged periods of lack of essential drug products. In heart failure, strict adherence to medications is required for patient stability.

Parents and guardians were highly satisfied with the level of care they got from the healthcare providers especially the doctors and nurses at KNH. 96.7% of the patients mentioned that they had enough time with the healthcare providers. A study carried out in the United Kingdom showed that a significant population of health workers often feel overworked and therefore lack time to do essential tasks (51). Contrary to expectation, many of the caregivers expressed that they had quality time with the caregivers to handle their children and respond to their queries.

The pediatric cardiology clinic offers follow up services to patients with heart conditions and especially those discharged with cardiovascular issues. The parents cited that due to the high frequency of readmission, by the time the date to attend clinic arrived, they were already readmitted and therefore rarely attended the clinic.

Seventy percent of the parents said the child had been admitted for more than two times due to the same condition indicating the high frequency of readmissions. One study showed a frequency of 30-day readmission for heart failure in children as 12.9% (36). Another study showed that the median time to readmission for children with congenital heart disease was 12 days (52).

Several parents mentioned unavailability of service in the clinic as a major reason for not attending the clinic. Financial strain was also a significant challenge in both meeting the cost of travelling to the clinic as well as paying consultation fees. They also mentioned that they were frequently asked to purchase extra drugs and carry out expensive medical tests during the clinic visits.

Higher levels of distress and hopelessness are experienced by parents and guardians of children with congestive heart failure and especially due to congenital heart disease (53). Financial and social support is essential in encouraging these parents. In this study, however, 63.3% of the parents claimed they did not receive support from their family in the illness of their child especially due to the prolonged time of illness.

Lastly, discrimination and stigma are common among parents of children who are chronically ill (54). About half of the parents who took part in this study said they faced discrimination based on their child's condition.

5.3 Conclusions

The major causative factors for heart failure in this study were infections, congenital heart disease and rheumatic heart disease in children above 5 years. Most of the causative factors occurred in combination with infections being present in most combinations of causative factors. There was poor adherence to the Kenya National guidelines in the choice of drugs for heart failure as well as the dosing. Enalapril was not used commonly used in heart failure in this study. Furosemide and digoxin were highly under dosed among these patients. Parents lacked awareness on significant aspects of their children's condition such as whether the condition is curable, and for how long the treatment would last. Among the major challenges faced by parents and guardians of children with heart failure include: unavailability of medicines for heart failure, frequent readmission rates, financial strain, lack of financial and social support as well as discrimination.

5.4 Recommendations

5.4.1 Recommendations for practice

- Prompt treatment of infections in children and especially those with underlying heart disease to prevent the development of heart failure should be done by physicians.
- Adenoidectomy for recurrent and un-resolving adenoid hypertrophy to prevent the occurrence of pulmonary hypertension resulting in right heart failure is essential.
- Early surgical interventions for congenital heart disease that can be corrected.
- Ensure good prescribing practice in treatment sheets to avoid dosing errors.
- Use of guidelines by prescribers in the management of heart failure in children to ensure accuracy in drug choice and minimize dosing errors.
- Enhanced follow-up of patients in the hospital clinics who develop Acute Rheumatic Fever for monthly antibiotic prophylaxis to prevent further valve damage due to streptococcal infections as well as early surgical intervention for valve repair to reduce the risk of heart failure.
- Review of guidelines by the relevant stakeholders through research to include drugs such as spironolactone that are commonly prescribed.

5.4.2 Recommendations for future research

- Further research on reasons for prescriber preferences in the use of medicines for the management of heart failure and why they did not adhere to the recommendations for management of the condition in the Kenya National Guidelines.

REFERENCES

1. Hsu DT, Pearson GD. Heart Failure in Children: Part I: History, Etiology, and Pathophysiology. Circ Hear Fail [Internet]. 2009 Jan 1;2(1):63–70. Available from: http://circheartfailure.ahajournals.org/cgi/doi/10.1161/CIRCHEARTFAILURE.108.820217

2. Schranz D, Voelkel NF. "Nihilism" of chronic heart failure therapy in children and why effective therapy is withheld. Eur J Pediatr [Internet]. 2016 Apr;175(4):445–55. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26895877

3. Crouch M. Clinical guidelines for management and referral of common conditions. [Internet]. 2009. Available from: http://apps.who.int/medicinedocs/documents/s21000en/s21000en.pdf

4. Savarese G, Lund LH. Global Public Health Burden of Heart Failure. Card Fail Rev [Internet]. 2017;03(01):7. Available from: https://www.cfrjournal.com/articles/global-public-health-burden-heart-failure

5. Gebremariam S, Moges T. Pediatric Heart Failure, Lagging, and Sagging of Care in Low Income Settings: A Hospital Based Review of Cases in Ethiopia. Cardiol Res Pract [Internet]. 2016;2016:1–7. Available from: https://www.hindawi.com/journals/crp/2016/7147234/

6. Rossano JW, Kim JJ, Decker JA, Price JF, Zafar F, Graves DE, et al. Prevalence, morbidity, and mortality of heart failure-related hospitalizations in children in the United States: a population-based study. J Card Fail [Internet]. 2012 Jun;18(6):459–70. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22633303

7. Massin MM, Astadicko I, Dessy H. Epidemiology of heart failure in a tertiary pediatric center. Clin Cardiol [Internet]. 2008 Aug;31(8):388–91. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18727063

8. Ogeng'o JA, Gatonga PM, Olabu BO, Nyamweya DK, Ong'era D. Pattern of congestive heart failure in a Kenyan paediatric population : cardiovascular topics.

Cardiovasc J Afr [Internet]. 2013 Jun 21;24(4):117–20. Available from: http://www.cvja.co.za/onlinejournal/vol24/vol24_issue4/#19/z

9. Ramakrishnan S. Pediatric Heart Failure in the Developing World. Rev Recent Clin Trials [Internet]. 2014;9(2):86–90. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25198734

10. Jayaprasad N. Heart failure in children. Hear Views [Internet]. 2016;17(3):92. Available from: http://www.heartviews.org/text.asp?2016/17/3/92/192556

11. Shaddy RE, George AT, Jaecklin T, Lochlainn EN, Thakur L, Agrawal R, et al. Systematic Literature Review on the Incidence and Prevalence of Heart Failure in Children and Adolescents. Pediatr Cardiol [Internet]. 2017 Dec 20; Available from: http://www.ncbi.nlm.nih.gov/pubmed/29260263

12. Sadoh WE, Okperi B, Ikhurionan P, Monday P, Sadoh AE. Evaluation of Predictors of Mortality Associated With Childhood Heart Failure in Nigeria: A 2-Center Study. Pediatr Emerg Care [Internet]. 2018 Feb 5; Available from: http://www.ncbi.nlm.nih.gov/pubmed/29406480

13. Murni IK, MacLaren G, Morrow D, Iyer P, Duke T. Perioperative infections in congenital heart disease. Cardiol Young [Internet]. 2017 Dec;27(S6):S14–21. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29198258

14. Aoyama R, Ishikawa J, Harada K, Tukada Y. Tuberculous pericarditis treated with steroid in a dialysis patient. BMJ Case Rep [Internet]. 2017 Aug 1;2017. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28765186

15. van Veldhuisen DJ, Anker SD, Ponikowski P, Macdougall IC. Anemia and iron deficiency in heart failure: mechanisms and therapeutic approaches. Nat Rev Cardiol [Internet]. 2011 May 31;8(9):485–93. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21629210

16. von Haehling S, Jankowska EA, Ponikowski P, Anker SD. Anemia in heart failure: an overview of current concepts. Future Cardiol [Internet]. 2011 Jan;7(1):119–29. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21174515

17. Towbin JA, Lowe AM, Colan SD, Sleeper LA, Orav EJ, Clunie S, et al. Incidence,

causes, and outcomes of dilated cardiomyopathy in children. JAMA [Internet]. 2006 Oct 18;296(15):1867–76. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17047217

18. Hamilton RM, Azevedo ER. Sudden cardiac death in dilated cardiomyopathies. Pacing Clin Electrophysiol [Internet]. 2009 Jul;32 Suppl 2:S32-40. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19602160

19. Marijon E, Mirabel M, Celermajer DS, Jouven X. Rheumatic heart disease. Lancet [Internet]. 2012 Mar;379(9819):953–64. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673611611719

20. Marijon E, Mirabel M, Celermajer DS, Jouven X. Rheumatic heart disease. Lancet [Internet]. 2012 Mar;379(9819):953–64. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673611611719

21. Okello E, Longenecker CT, Beaton A, Kamya MR, Lwabi P. Rheumatic heart disease in Uganda: predictors of morbidity and mortality one year after presentation. BMC Cardiovasc Disord [Internet]. 2017;17(1):20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28061759

22. Masarone D, Valente F, Rubino M, Vastarella R, Gravino R, Rea A, et al. Pediatric Heart Failure: A Practical Guide to Diagnosis and Management. Pediatr Neonatol [Internet]. 2017 Aug;58(4):303–12. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28279666

23. Momma K. ACE inhibitors in pediatric patients with heart failure. Paediatr Drugs [Internet]. 2006;8(1):55–69. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16494512

24. Wessel A, Buchhorn R, Bürsch J. [Circulatory failure in children with left-to-right shunt in the framework of congenital heart defects: pathophysiology and therapeutic results]. Klin Padiatr [Internet]. 212(2):53–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10812553

25. Terano C, Ishikura K, Miura M, Hamada R, Harada R, Sakai T, et al. Incidence of and risk factors for severe acute kidney injury in children with heart failure treated

with renin-angiotensin system inhibitors. Eur J Pediatr [Internet]. 2016 May;175(5):631–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26687571

26. Campbell TJ, MacDonald PS. Digoxin in heart failure and cardiac arrhythmias. Med J Aust [Internet]. 2003 Jul 21;179(2):98–102. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12864722

27. Batte A, Lwabi P, Lubega S, Kiguli S, Nabatte V, Karamagi C. Prevalence of arrhythmias among children below 15 years of age with congenital heart diseases attending Mulago National Referral Hospital, Uganda. BMC Cardiovasc Disord [Internet]. 2016 Apr 13;16:67. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27074797

28. Moffett BS, Garner A, Zapata T, Orcutt J, Niu M, Lopez KN. Serum digoxin concentrations and clinical signs and symptoms of digoxin toxicity in the paediatric population. Cardiol Young [Internet]. 2016 Mar;26(3):493–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25912244

29. Buchhorn R. Beta-Blockers in Children with Congenital Heart Disease Before a Corrective Procedure. Rev Recent Clin Trials [Internet]. 2014;9(2):61–3. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25198740

30. Ross RD. Medical management of chronic heart failure in children. Am J Cardiovasc Drugs [Internet]. 2001;1(1):37–44. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14728050

31. Pépin V, Gagné N, Rottembourg D. Recurrent hypoglycaemia in a toddler on β-blocker therapy. Cardiol Young [Internet]. 2018 Jan 8;1–3. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29306335

32. Clark BJ. Treatment of heart failure in infants and children. Heart Dis [Internet]. 2(5):354–61. Available from: http://www.ncbi.nlm.nih.gov/pubmed/11728282

33. C. Tume S, Goldberg J, Molossi S, A. Bronicki R. Pharmacologic Approach to Heart Failure in Children. Curr Cardiol Rev [Internet]. 2016 Apr 4;12(2):117–20. Available from:

http://www.eurekaselect.com/openurl/content.php?genre=article&issn=1573-403X&volume=12&issue=2&spage=117

34. Barach PR, Lipshultz SE. Readmitting Children with Heart Failure: the Importance of Communication, Coordination, and Continuity of Care. J Pediatr [Internet]. 2016 Oct;177:13–6. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0022347616305625

35. Mejia EJ, O'Connor MJ, Lin KY, Song L, Griffis H, Mascio CE, et al. Characteristics and Outcomes of Pediatric Heart Failure-Related Emergency Department Visits in the United States: A Population-Based Study. J Pediatr [Internet]. 2018 Feb;193:114–118.e3. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0022347617313501

36. Moffett BS, Humlicek TJ, Rossano JW, Price JF, Cabrera AG. Readmissions for Heart Failure in Children. J Pediatr [Internet]. 2016 Oct;177:153–158.e3. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0022347616303596

37. Sleeper LA, Towbin JA, Colan SD, Hsu D, Orav EJ, Lemler MS, et al. Health-Related Quality of Life and Functional Status Are Associated with Cardiac Status and Clinical Outcome in Children with Cardiomyopathy. J Pediatr [Internet]. 2016 Mar;170:173–180.e4. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0022347615011634

38. Nderitu H. Prevalence of drug manipulation to obtain the prescribed dose in the pediatric in-patient units in Kenyatta National Hospital. University of Nairobi; 2014.

39. Barlett J, Kotrlick J. Determining appropriate sample size in survey research. Inf Technol Learn Perform. 2001;19(1):43–50.

40. Lewis KD, Conway J, Cunningham C, Larsen BMK. Optimizing Nutrition in Pediatric Heart Failure: The Crisis Is Over and Now It's Time to Feed. Nutr Clin Pract [Internet]. 2017 Jun 28;088453361771250. Available from: http://doi.wiley.com/10.1177/0884533617712502

41. Kirk R, Dipchand AI, Rosenthal DN, Addonizio L, Burch M, Chrisant M, et al.

The International Society for Heart and Lung Transplantation Guidelines for the management of pediatric heart failure: Executive summary. J Hear Lung Transplant [Internet]. 2014 Sep;33(9):888–909. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1053249814011565

42. Kantor PF, Lougheed J, Dancea A, McGillion M, Barbosa N, Chan C, et al. Presentation, Diagnosis, and Medical Management of Heart Failure in Children: Canadian Cardiovascular Society Guidelines. Can J Cardiol [Internet]. 2013 Dec;29(12):1535–52. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0828282X13013639

43. Dutta S, Narang A. Enalapril induced acute renal failure in a newborn infant. J Int Pediatr Nephrol Assoc. 2003;18(6):570–2.

44. Buck ML. Clinical Experience with Spironolactone in Pediatrics. Ann Pharmacother [Internet]. 2005 May;39(5):823–8. Available from: http://journals.sagepub.com/doi/10.1345/aph.1E618

45. Pitt B, Zannad F, Remme WJ, Cody R, Castaigne A, Perez A, et al. The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure. N Engl J Med [Internet]. 1999 Sep 2;341(10):709–17. Available from: http://www.nejm.org/doi/abs/10.1056/NEJM199909023411001

46. Hess T. [Underdosing and overdosing with digitalis]. Schweiz Med Wochenschr [Internet]. 1981 Mar 28;111(13):455–60. Available from: http://www.ncbi.nlm.nih.gov/pubmed/7233124

47. Jofiro G, Jemal K, Beza L, Bacha Heye T. Prevalence and associated factors of pediatric emergency mortality at Tikur Anbessa specialized tertiary hospital: a 5 year retrospective case review study. BMC Pediatr [Internet]. 2018 Oct 2;18(1):316. Available from: http://www.ncbi.nlm.nih.gov/pubmed/30285667

48. Reynolds M. No news is bad news: patients' views about communication in hospital. BMJ [Internet]. 1978 Jun 24;1(6128):1673–6. Available from: http://www.bmj.com/cgi/doi/10.1136/bmj.1.6128.1673

49. Heydari A, Ziaee ES, Gazrani A. Relationship between Awareness of Disease and

Adherence to Therapeutic Regimen among Cardiac Patients. Int J community based Nurs midwifery [Internet]. 2015 Jan;3(1):23–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25553331

50. Fox ER, Birt A, James KB, Kokko H, Salverson S, Soflin DL. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems. Am J Heal Pharm [Internet]. 2009 Aug 1;66(15):1399–406. Available from: http://www.ajhp.org/cgi/doi/10.2146/ajhp090026

51. West E, Barron DN, Reeves R. Overcoming the barriers to patient-centred care: time, tools and training. J Clin Nurs [Internet]. 2005 Apr;14(4):435–43. Available from: http://doi.wiley.com/10.1111/j.1365-2702.2004.01091.x

52. Mackie AS, Ionescu-Ittu R, Pilote L, Rahme E, Marelli AJ. Hospital readmissions in children with congenital heart disease: a population-based study. Am Heart J [Internet]. 2008 Mar;155(3):577–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18294499

53. Lawoko S, Soares JJ. Distress and hopelessness among parents of children with congenital heart disease, parents of children with other diseases, and parents of healthy children. J Psychosom Res [Internet]. 2002 Apr;52(4):193–208. Available from: http://linkinghub.elsevier.com/retrieve/pii/S002239990200301X

54. Cohen MS. Families coping with childhood chronic illness: A research review. Fam Syst Heal [Internet]. 1999;17(2):149–64. Available from: http://doi.apa.org/getdoi.cfm?doi=10.1037/h0089879

55. Al-Qazaz HK, Hassali MA, Shafie AA, Sulaiman SA, Sundram S, Morisky DE. The eight-item Morisky Medication Adherence Scale MMAS: Translation and validation of the Malaysian version. Diabetes Res Clin Pract [Internet]. 2010 Nov;90(2):216–21. Available from: http://linkinghub.elsevier.com/retrieve/pii/S016882271000402X

APPENDICES

Appendix I: Eligibility screening form for records

Eligibility screening form for records of pediatric patients with heart failure.

General pediatric wards and ICU

Date:……..

Unique Identifier:……..____

(Tick where appropriate. All questions in this form should be responded to.)

Criteria	**Remark**	
1. Is the child 12 years and below?	YES ☐	NO ☐
2. Is the diagnosis of heart failure confirmed?	YES ☐ ☐	NO ☐ ☐
3. Is the treatment given indicated?	YES ☐	NO ☐
4. Is the causative factor of heart failure indicated?	YES	NO
If all **YES** proceed to the data collection form (Appendix V)		

Appendix II: Eligibility screening form. (Parents and guardians)

Eligibility screening form for parents and guardians General pediatric wards and ICU Date…….. Unique Identifier:_____ (Tick where appropriate. All questions of this form should be responded to.)		
Criteria	**Remark**	
1. Does the parent or guardian have a child with CHF?	YES ☐	NO ☐
2. Is the child of parent or guardian-less than 12 years?	YES ☐	NO ☐
3. Is the parent or guardian psychosocially stable?	YES ☐	NO ☐
4. Has the parent or guardian given Consent?	YES ☐	NO ☐
5. Is the parent or guardian the child's primary Caretaker?	YES ☐	NO ☐
If all **YES** proceed to the study Questionnaire (Appendix VI)		

Appendix III: Participant information form.

Title of the study: An Evaluation of the management of congestive heart failure in children at Kenyatta National Hospital.

Principal Investigator: Dr. Cynthia Muregi. Master of Pharmacy (Clinical Pharmacy) 2nd year at the University of Nairobi (UoN)

Co-Investigators Dr. P.N Karimi -Lecturer, UoN; Dr. G. Mugendi – Lecturer, UoN

Introduction:

I would like to tell you about a study being conducted by the above-listed researchers.

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'.

Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary; ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal, and iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? **YES** ☐ **NO** ☐

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.: _____

What is this study about?

The researchers listed above are interviewing individuals who are parents or guardians to children being managed for heart failure at Kenyatta National Hospital. The purpose of the interview is to find out the challenges faced by parents and guardians of children diagnosed with congestive heart failure. You will be asked questions about the challenges you may be facing in the treatment of your child's condition. There will be approximately 20 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study?

If you agree to participate in this study, you will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions.

The interview will last approximately 30 minutes. The interview will cover topics such as understanding of your child's condition, challenges affecting adherence to medication, the frequency of your child's hospitalization and accessibility to medications.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. We may need to contact you to clarify your responses when necessary.

Are there any risks, harms or discomforts associated with this study?

Although any medical research has the potential to introduce psychological, social, emotional and physical risks, efforts will be made to minimize the risks. One potential risk of being in the study is the loss of privacy. However, we will safeguard your privacy by keeping everything you tell us as confidential as possible.

We will use a code number to identify you in a protected computer file and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out that you were in this study and could access information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

Furthermore, all study staff and interviewers are professionals with special training in these interviews. In case of complications related to this study, contact the study staff right away at the number provided at the end of this document.

Benefits

Your participation in this study will allow you to benefit through free counselling of your child's condition. The findings of this research will also help us understand the challenges faced by parents and guardians of children with congestive heart failure as well as build on the existing body of knowledge on human health and science.

Will being in this study cost you anything?

This study will cost you your time. (About 30 minutes).

Will you get a refund for any money spent as part of this study?

This study will not cost you money.

What if you have questions in future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the numbers provided below.

For more information about your rights as a research participant, you may contact the Principal Investigator on Email: ndutacynthia1@gmail.com, and Telephone: **0728499884** or the Secretary/Chairperson Professor Guantai, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No.: **2726300** Ext: **44102** Email: *uonknh_erc@uonbi.ac.ke.*

What are your other choices?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Consent declaration form.

Participant's statement.

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw anytime. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **YES** ☐ **NO** ☐

I agree to provide contact information for follow-up: **YES** ☐ **NO** ☐

Participant printed name:

_____

Participant signature / Thumb stamp _____

Date _____

Witness_____Date_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above. The participant has understood and has freely given his/her consent.

Researcher's Name: _____

Signature _____

Date: _____

Role in the study: _____

For more information contact _____ at _____

from _____ to _____

Appendix IV: Maelezo kuhusu kushiriki katika utafiti

Kichwa cha Utafiti: Tathmini ya kutibu watoto walio na ugonjwa wa upungufu wa kazi za roho katika hospitali kuu ya Kenyatta.

Mtafiti Mkuu; Dkt. Cynthia Muregi -Mwanafunzi wa Mwaka wa pili (Mwanafamasia) Chuo Kikuu cha Nairobi

Watafiti Wengine

Dkt. P.N Karimi -Mhadhiri, Chuo Kikuu cha Nairobi, Dkt. G. Mugendi- Mhadhiri, Chuo Kikuu cha Nairobi

Utangulizi:

Ningependa kuzungumza nawe kuhusu utafiti huu utakaofanywa na waliotajwa hapo juu. Umuhimu wa mazungumzo haya ni kukufahamisha zaidi ili ufanye uamuzi wa busara kushiriki au kutoshiriki katika utafiti huu. Kuwa huru kuuliza maswali yoyote kuhusu kitakachofanyika utakapokubali kushiriki, madhara yanayoweza kutokea, manufaa ya utafiti huu, haki zako kama mshiriki na maswali yoyote kuhusu lolote ambalo hulielewi. Tutakapo jibu maswali yako yote, basi utaamua kushiriki au la. Utakapokubali, nitakuuliza tafadhali utie sahihi na majina yako kwa ukurasa hapa chini.

Unafaa uelewe kwa ujumla nguzo muhimu ambazo zinalinda washiriki katika ufatiti wa sayansi ya afya: i) Kushiriki kwako ni kwa hiari; ii) Unaweza kujiondoa wakati wowote bila kushurutishwa kutoa maelezo ya kufanya hivyo; na iii) Kutoshiriki kwako katika utafiti huu hakutaathiri huduma unazopaswa kuzipata kwa hosipitali hii. Tutakupa nakala yako ili ujiwekee kwa manufaa yako binafsi.

Ninaweza kuendelea? **NDIO** ☐ **LA** ☐

Utafiti huu umeidhiniswha na kitengo cha maadili na utafiti cha hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi nambari: _____

Utafiti huu unahusu nini?

Watafiti walioandikwa hapo juu wanawahoji washiriki ambao wana watoto katika hospitali ya Kenyatta walio na upungufu wa kazi za roho. Mahojiano haya yana madhumuni ya kuchunguza vikwazo vinavyowapata wazazi na waangalizi wa watoto walio na upungufu wa kazi za roho. Washiriki wataulizwa maswali kuhusu matibabu ya watoto hao na vikwazo wanavyopitia. Kutakuwa na washiriki 40 ambao wamechaguliwa kwa njia ya kisayansi ya bahati na sibu. Tunaomba idhini yako uwe mshiriki kwa utafiti huu.

Nini kitakachofanyika ukikubali kushiriki?

Yafuatayo yatafanyika: Utahojiwa na mtafiti aliyehitimu kwa sehemu ya tulivu na ya kisiri ambapo utakuwa huru kwa muda wa dakita thelathini hivi. Mahojiano yatahusu ugonjwa wa mtoto wako, matibabu yake na vikwazo unavyopitia.
Tutahitaji nambari yako ya simu ambayo tutawasiliana nawe kwa maswala yanayohusika na utafiti huu pekee. Nambari yako ya simu haitapewa watu wengine wasiohusika na utafiti huu. Tukikupigia simu, itakuwa ni kufafanua majibu ya maswali ulioulizwa.

Utafiti huu una madhara yoyote?

Ijapokuwa utafiti wa kiafya una madhara yake kama ya kisaikolojia, tutajitahidi kabisa kupunguza madhara yoyote kwako. Kwa mfano, dhara moja ni uwezekano wa kupoteza usiri wako. Hata hivyo, mambo yote utatueleza tutayaweka kwa siri. Tutakupa nambari ya siri kwa compyuta ambayo imelindwa. Stakabadhi zote zitawekwa kwenye kabati lilifungwa kwa kufuli. Lakini, kama unavyojua, bado kunao uwezekano wa kuvunjwa kabati na kuiba stakabadhi zako za siri.

Pia kuyajibu maswali katika mahojiano huenda kusikuridhishe. Kama kutakuwa na maswali ambayo hungetaka kuyajibu, utaruhusiwa kutoyajibu. Uko na haki ya kutojibu swali lolote katika mahojiano. Tutajaribu kuhakikisha mahojiano yamefanyika kwa njia ya siri. Pia, watafiti wetu wote wamehitimu kufanya mahojiano haya. Kama kutakuwa na shida zingine zozote kwa ajili ya utafiti huu, tafadhali wasiliana nasi kupitia nambari iliyo chini ya kurasa hizi. Watafiti wetu wanaweza kukuelekeza ifaavyo kwa usaidizi zaidi.

Ufatiti huu una manufaa yoyote?

Utafaidika kwa kupata wosia mwafaka kuhusu ugonjwa wa mtoto wako. Aidha, utafiti huu utatuwezesha kuelewa vikwazo ambavyo wazazi wa watoto walio na ugonjwa wa upungufu wa kazi za moyo hupitia. Pia, tutaongeza ufahamu zaidi kwa sayansi ya afya na binadamu.

Kuna gharama ya kushiriki?

Utafiti huu utahitaji dakika kidogo tu za muda wako.

Utarejeshewa pesa zako?

Utafiti huu hautakugharimu pesa.

Na kama utakuwa na maswali baadaye?

Kama una maswali zaidi au lolote ambalo hulielewi kuhusu utafiti huu, tafadhali usisite kuwasiliana nasi kupitia nambari ambazo zimeandikwa hapa chini.

Kwa maelezo zaidi kuhusu haki za mshiriki katika utafiti, wasiliana na Mtafiti Mkuu Tovuti: ndutacynthia1@gmail.com Simu: **0728499884** au Kabitu/Mwenyekiti Profesa Guantai Simu.: **2726300** ongezo: **44102** Tovuti: *uonknh_erc@uonbi.ac.ke.*

Utarudishiwa ada ya mazungumzo kupitia laini hizi kama mazungumzo yenyewe yanahusu utafiti huu.

Kuna chaguo lingine?

Kushiriki kwa utafiti huu ni kwa hiari yako. Una uhuru wa kutoshiriki au kujiondoa wakati wowote bila kupoteza haki yako ya kupata huduma zozote.

Ridhaa (kukubali kushiriki)

Taarifa ya Mshiriki

Nimesoma au nimesomewa nakala hili. Nimepata kuzungumza kuhusu utafiti huu na mtafiti mwenyewe. Maswali yangu yamejibiwa kwa lugha ninayoielewa vizuri.
Madhara na manufaa yameelezwa wazi. Ninaelewa kushiriki kwangu ni kwa hiari na kwamba ninao uhuru wa kutoshiriki wakati wowote.
Ninakubali bila kushurutishwa kushiriki katika utafiti huu. Ninaelewa kwamba bidii itatiwa kuhakikisha habari zangu zimewekwa siri. Kwa kutia sahihi kwa daftari hili, sijapeana haki zangu za kisheria ambazo ninazo kama mshiriki katika utafiti huu.

Nimekubali kushiriki katika utafiti huu: NDIO ☐ **LA** ☐

Nimekubali kupeana nambari ya mawasilianao baadaye: **NDIO** ☐ **LA** ☐

Jina la Mshiriki: _____

Sahihi / Kidole _____

Tarehe _____

Taarifa ya Mtafiti

Mimi, ninayetia sahihi hapo chini, nimeelezea maswala muhimu ya utafiti huu kwa mshiriki aliyetaja hapo juu na ninaamini ya kwamba ameyaelewa vilivyo na kwamba ameamua bila kushurutishwa kukubali kushiriki.

Jina la Mtafiti: _____ **Sahihi** _____

Tarehe: _____

Kazi yangu kwa utafiti huu: _____

Kwa maelezo zaidi wasiliana na _____ kwa _____

Saa_____ hadi _____

Appendix V: Data collection form for the records.

Title: An evaluation of the management of congestive heart failure in children at Kenyatta National Hospital.

Questionnaire number……

Study identification number……...

Date of data retrieval……...

(Tick where appropriate for the questions with options.
All sections of this form should be filled from the files retrieved.)

Section 1: Patient demographics.

1) Age:…….

2) Sex: Male [0] Female [1]

3) Weight……..Height……..

Etiology of heart failure (Tick where appropriate)

Cause of heart failure	**Yes**	**No**
4.Congenital heart disease	1	0
5.Infections(Pneumonia, upper airway, urinary tract infections	1	0
6.Anemia	1	0
7.Cardiomyopathies	1	0
8.Rheumatic heart disease	1	0
9.Pulmonary hypertension	1	0
10. Adenoid hypertrophy	1	0
10a Malnutrition	1	0

6: Types of drugs used in the management of heart failure ((Tick where appropriate**)**

Drug	**Yes**	**No**
11.Enalapril	1	0
12.Furosemide	1	0
13.Propranolol	1	0
14..Digoxin	1	0
15.Spironolactone	1	0
16.Sildenafil	1	0
17.Carvedilol.	1	0

7. Type of drug combination used----------

8. Comparison of the treatment given with the national clinical guidelines on the treatment of heart failure in children.

	Appropriate	**inappropriate**
Choice of drug	1	0
Dose	1	0

9 Is the patient documented alive or deceased?

Appendix VI Questionnaire for parents and guardians.

Title: An evaluation of the management of congestive heart failure in children at Kenyatta National Hospital.

(Tick where appropriate for the questions with options.

The principal investigator should complete this form during the interview)

Questionnaire number……..

Study identification number…….

Date of interview……..

Section I: Parent/guardian bio data and demographic information.

1) What is your age in years? _____

2) What is your gender? Male [0] 2. Female[1]

3) What is your marital status? Single [0] Married [1] Divorced [2] Widowed [3] Separated [4]

4) What is your highest level of education?
   Primary [0] Secondary [1] College [2] None [3]

5) What do you do for a living?: Unemployed [0] Employed [1] Casual laborer [2] Others [3] specify…….....

6) How much do you earn on average per month? ……

Section II General Knowledge of the child's condition.

7) Are you aware that your child is having heart failure? Yes [1] No [0]

8) Does the disease have a cure? Yes [2] No [1] I don't know [0]

9) How long will the treatment last?

a) Less than one month [0]
b) Until the cause is controlled.[1]
c) Lifelong.[2]
d) I do not know.[3]

10) Do you know what drugs your child uses to manage the heart ailment?

Yes [1] No [0]

12. If yes in (12) please tell me the names of the medicines.

Section IV Adherence to medication (Modified Morisky question tool) (Answer yes= 1 or No = 0) (55)

i. Are there situations or factors that will make you fail to give medication to your child?

Yes [1] No [0]

ii. In the past two weeks are there days the child failed to take medication?

Yes [1] No [0]

iii. When you travel or leave home with your child, do you forget to bring along his/her medicine? Yes [1] No [0]

iv. When you feel like his/her symptoms are under control, do you sometimes stop him/her from taking his/her medicine? Yes [1] No [0]

v. Taking medicine every day is inconvenient to some people. Do you ever feel hassled about sticking to the treatment plan? Yes [1] No [0]

vi. How often do you have difficulty remembering giving your child his/her medicine?

A. Never/rarely [ ]

B. Once in a while [ ]

C. Sometimes [ ]

D. Usually [ ]

E. All the time [ ]

13. Adherence Score

>2 Low adherence [0]

1-2 medium adherence [1]

High adherence [2]

Section V: Major challenges facing parents and guardians

14. Do you always get all the medicines prescribed for the child from KNH?
Yes [1] No [0]

15. Do you always have enough time with the healthcare provider while receiving care at KNH?

Yes [1] No [0]

16. Is your child assigned regular follow-ups in the clinic?

Yes [1] No [0]

17. What is the main challenge you face in bringing your child for regular follow-up?

The Clinic is not helpful(child never improves) [0]

Financial strain [1]

Readmissions [2]

Unavailability of service.[3]

Distance[4]…….

18. Do you experience financial strain due to the child,?

Yes [1] No [0]

19. Do you receive support (financial or social) from your family in the care of your children

Yes [1] No [0]

20. Does the care of your child negatively affect your work/business?

Yes [1] No [0]

21. Have you encountered discrimination due to your child's condition?

Yes [1] No [0]

22. How many times has your child been admitted due to this condition?

……

Appendix VII: KNH-UON ERC authorization letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/263

July 5, 2018

KENYATTA NATIONAL HOSPITAL APPROVED 05 JUL 2018 KNH/UoN-ERC P.O. Box 20723-00202 NRB

Cynthia Nduta Muregi
Reg. No.U56/87725/2016
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Cynthia

RESEARCH PROPOSAL – AN EVALUATION O F THE MANAGEMENT OF CONGESTIVE HEART FAILURE IN CHILDREN AT KENYATTA NATIONAL HOSPITAL (P158/03/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is from 5th July 2018 – 4th July 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

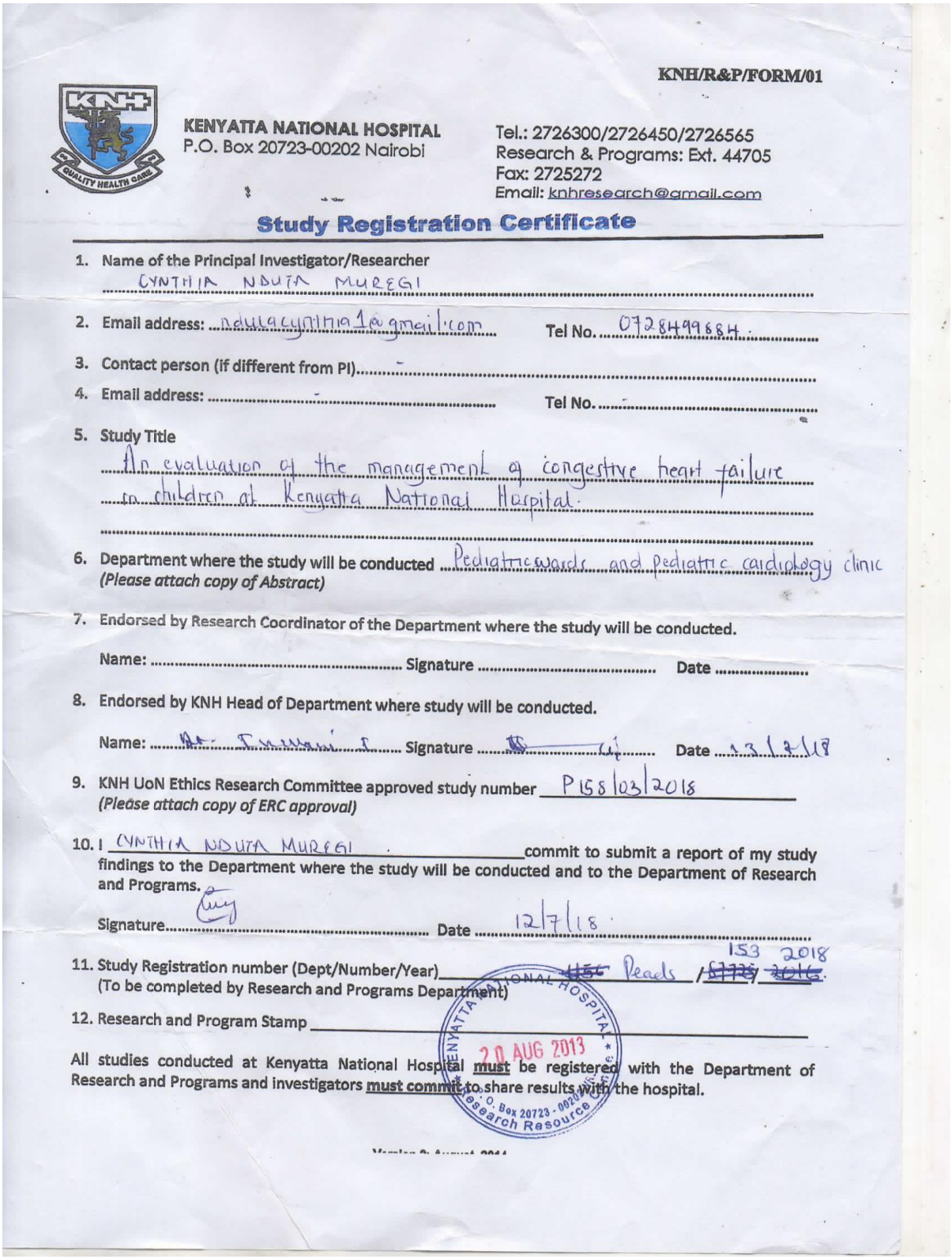
Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmaceutics and Pharmacy Practice, UON
Supervisors: Dr. Peter N. Karimi, Dr.George Mugendi

Protect to discover

Appendix VII: KNH study registration certificate.



KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   CYNTHIA NDUTA MUREGI
2. Email address: ndutacynthia1@gmail.com Tel No. 0728499884
3. Contact person (if different from PI)
4. Email address: Tel No.
5. Study Title
   An evaluation of the management of congestive heart failure in children at Kenyatta National Hospital.
6. Department where the study will be conducted Pediatric wards and pediatric cardiology clinic
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the Department where the study will be conducted.
   Name: Signature Date
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr. Twumasi I Signature Date 13/7/18
9. KNH UoN Ethics Research Committee approved study number P158/03/2018
   (Please attach copy of ERC approval)
10. I CYNTHIA NDUTA MUREGI commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
    Signature Date 12/7/18
11. Study Registration number (Dept/Number/Year) ~~H&T~~ Peads /153/2018 ~~2016~~
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL 20 AUG 2013 P.O. Box 20723 - 00202 Nairobi Research Resource

All studies conducted at Kenyatta National Hospital must be registered with the Department of Research and Programs and investigators must commit to share results with the hospital.

Appendix VIII: Pediatrics department authorization letter.

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723, 00202 Nairobi

Tel.: 2726300/2726450/2726550
Fax: 2725272
Email: knhadmin@knh.or.ke

Ref: KNH/PAEDS-HOD/48 Vol.II

Date: 16th July 2018

Cynthia Nduta Muregi
Department of Pharmaceutics & Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Cynthia

RE: AUTHORITY TO COLLECT DATA IN PAEDIATRICS DEPARTMENT

Following approval by the KNH/UON-Ethics & Research Committee for your Research Proposal, this is to inform you that authority has been granted to collect data in ***Paediatrics Department***, on your study titled ***"An evaluation of the management of congestive heart failure in children at Kenyatta National Hospital"***.

Kindly liaise with the Senior Assistant Chief Nurse, Paediatrics for facilitation.

You will also be required to submit a report of your study findings to the Department of Paediatrics after completion of your study.

DR. IRENE INWANI
HEAD OF DEPARTMENT, PAEDIATRICS

Cc. Senior Assistant Chief Nurse, Paediatrics