PATTERNS AND RISK FACTORS OF CONGENITAL HEART DISEASE AND TREATMENT OUTCOMES DURING ACUTE PHASE HOSPITALIZATION AMONG CHILDREN AGED UNDER 5 YEARS AT KENYATTA NATIONAL HOSPITAL

By

SHEILA NYABISI AIKO

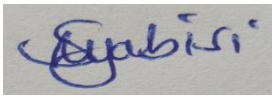
H56/37717/2020

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING (PEDIATRICS) OF THE UNIVERSITY OF NAIROBI

NOVEMBER, 2022

DECLARATION

This thesis is my own personal work and has not been offered in any other institution for examination purposes.

Signature  Date: 28/11/2022

Sheila Nyabisi Aiko

Reg. no: H56/37717/2020

APPROVALS

SUPERVISORS' APPROVAL

The dissertation presented herein is offered for examination with our authority as the University supervisors.

Signature ..... Date 28/11/2022

Dr. Angeline Kirui PhD, MSc. BScN

Lecturer

Department of Nursing Sciences

University of Nairobi

Signature : Date:25/11/2022

Ms. Hannah Inyama MScN, BScN

Lecturer

Department of Nursing Sciences

University of Nairobi

CHAIRMAN, DEPARTMENT OF NURSING SCIENCES

Sign ..... Date: 28-11-2022

Dr. Emmah Kanini Matheka

PhD, MSc, BSN

Chairman, Department of Nursing Science.

University of Nairobi

DEPARTMENT OF NURSING SCIENCES
CHAIRMAN
28 NOV 2022
UNIVERSITY OF NAIROBI
P.O. Box 30197, NAIROBI

DEDICATION

This thesis is dedicated to all paediatric clients who have had to endure the ordeal of congenital heart disease. I also dedicate this work to my beloved family.

ACKNOWLEDGEMENT

To my supervisors, Dr. Angeline Kirui and Ms. Hannah Inyama, I am most grateful for your great support, effective supervision, timely feedback and valuable insights that led to the successful completion of this thesis. I am also thankful to the management of Kenyatta National Hospital for allowing me to carry out the study in the facility. I also acknowledge and sincerely thank my study respondents for their role in making this study a success. My regards also go to my family, friends and colleagues for standing with me throughout this journey in prayers and moral support.

Above all, I am most thankful to the Almighty God for every blessing in my life.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS AND ACRONYMS

ASD	Atrial Septal Defects
CHD	Congenital heart disease
GBD	Global Burden of Diseases
HICs	High income countries
KNH	Kenyatta National Hospital
LBW	Low Birth Weight
LMICs	Low- and Middle-Income Countries
MRI	Magnetic Resonance Imaging
NCDs	Non-Communicable Diseases
NICVD	National Institute of Cardiovascular Diseases
ORs	Odds Ratios
PDA	Patent Ductus Arteriosus
PFO	Patent Foramen Ovale
RTIs	Respiratory Tract Infections
SDGs	Sustainable Development Goals
SSA	Sub-Saharan Africa

SPSS	Statistical Package for Social Sciences
TGA	Transposition of Great Arteries
TOF	Tetralogy of Fallot
UN	United Nations
US	United States
VSD	Ventricular Septal Defect
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Congenital anomalies	Refers to structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or in infancy.
Congenital heart disease	Refers to a structural abnormality or defect of the heart or great vessels present at birth.
Acute phase	Refers to a period of an illness or infection characterised by immediate or rapidly developing symptoms that last for a short or limited duration to which urgent medical intervention may be needed.
Treatment outcomes	Denotes the result of a medical intervention on a patient's health status which can be measured.
Patterns	Refers to the types of CHD diagnosed among the study population.
Risk factors	Refers to various variables that may lead to congenital heart disease among children aged below 5 years.
Patient recovered	It denotes that a patient was discharged from the hospital after successful treatment.

ABSTRACT

Background: Congenital heart diseases (CHD) are common congenital anomalies that account for a significant proportion of mortality and morbidity in children. Presentation of CHD varies from asymptomatic discovered accidentally to severe and debilitating complications and death. Early diagnosis and treatment have great effects on prognosis. Inadequate knowledge on the patterns of CHD, associated risk factors and its treatment outcomes impede the development of appropriate interventions.

Objective: This study evaluated the patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital (KNH).

Methods: This was a retrospective case-control study, involving children aged below 5 years admitted to KNH's Pediatric Unit between 1st January, 2017 and 31st December, 2021 who had CHD. A total of 2,450 medical records of pediatric patients were reviewed. A similar number of health records (matched for age) without CHD was used as a control group. The researcher used census method whereby all pediatric patients' health records with documented CHD case and their matched controls, under the specified period, were reviewed. The data was extracted from the pediatric patients' medical records, kept at the hospital's Records department, using a data abstraction form. The outcome of interest included mortality and recovery rates. The study data was analyzed descriptively using SPSS version 25 and presented in form of frequencies and percentages. In addition, chi-square test statistic and odds ratios were utilized to analyze the study variables' association at 5% significance level. Findings of the study were summarized in tables and figures.

Results: Over the period 2017 to 2021, ventricular septal defect cases rose from 74 to 116 (a 56.8% rise); atrial septal defect cases rose from 45 to 74 (a 64.4% rise); patent ductus arteriosus cases rose from 61 to 85 (a 39.3% rise) while pulmonary valve stenosis cases rose from 31 to 47 (a 51.6% rise). Ventricular septal defect (27.4%), was the most prevalent CHD. Risk factors of CHD included multiple pregnancy (Chi square $p = 0.002$); lack of access to prenatal care during pregnancy (Chi square $p = 0.000$); maternal diabetes mellitus (Chi square $p = 0.000$); maternal medications use during pregnancy (Chi square $p = 0.019$) and prematurity (Chi square $p = 0.000$). The risk factors of CHD established to have a statistically significant association with poor treatment outcomes among the children included; infants' down syndrome (Chi square $p = .000$; OR = 4.52) and prematurity (Chi square $p = .007$; OR = 2.21). Recovery rate in the CHD group was 87.3% while the mortality was 12.7%.

Conclusion: There was an increasing trend of prevalence of the CHD defects in children in KNH over the five-year period. Children with cyanotic CHD, on average, had 3 times higher odds of dying from CHD compared to those with acyanotic CHD. Infants' down syndrome and prematurity were the risk factors related to poor treatment outcomes of CHD among children admitted at KNH.

Recommendations: The increasing trend of CHD needs further evaluation. Staff sensitization on diagnosis of CHD, since the most common CHDs are acyanotic which are not easy to identify. Infants' down syndrome and prematurity require more attention and specialized care.

CHAPTER ONE: INTRODUCTION

1.1 Background

Congenital heart disease (CHD) refers to birth defects that affect the normal development and functioning of the heart caused by malformations of the heart structure from birth.CHD is thus a structural abnormality of the heart and (or) great vessels that is present at birth (Hoffman, 2013). CHD may involve the heart walls, the heart valves, or the blood vessels that lead to and from the heart. Congenital heart defects are of numerous kinds and can range from simple conditions that do not cause symptoms to complex conditions that cause severe, life-threatening symptoms (Cucu & Chifiriuc, 2018). CHD can either be cyanotic - one that causes low levels of oxygen in the blood or acyanotic - one that does not cause low levels of oxygen in the blood (Kshirsagar, Mohite & Erram, 2020).

General symptoms of CHD in infants include; cyanosis - a blue tinge to the skin, nails or lips; rapid breathing; rapid heartbeat; swelling of the legs, tummy and/or around the eyes; shortness of breath during feeding leading to poor weight gain; extreme tiredness and fatigue during exercise; fainting during exercise and swelling in the hands, ankles or feet (Rossouw, 2021). These symptoms may develop shortly after birth or later such as during teenage or early adulthood. The symptoms may also vary depending on the type of heart defect (Wu, He & Shao, 2020). Though the exact cause of CHD, in most cases, is unknown, possible risk factors for CHD include genetic conditions such as Down’s syndrome, maternal diabetes, maternal smoking or drinking alcohol during pregnancy, rubella infection, flu (influenza) during the first trimester, use of certain

medications during pregnancy, and exposure to organic solvents (Zheleva& Atwood, 2017; Saxena, 2019).

Congenital heart disease is diagnosed through use of a wide range of tests including echocardiogram, electrocardiogram, chest x-ray, pulse oximetry, cardiac catheterization and heart MRI (Oster et al., 2013). Treatment of CHD depends on the type of defect and its severity with some congenital heart defects resolving without treatment as the infant grows or having no major effects on the child's life. However, more severe heart defects are managed via medications, heart procedures or a heart transplant with regular specialist review throughout one's life (Rossano, 2020). Common complications of CHD include growth and development impairments, repeated respiratory tract infections (RTIs), heart infection (endocarditis), pulmonary hypertension, heart rhythm problems, heart failure and blood clots inside the heart which can lead to pulmonary embolism or stroke if they block blood supply to lungs and the brain respectively (Bouma, & Mulder, 2017).

Statistics from the 2017 Global Burden of Diseases (GBD) Congenital Heart Disease Collaborators' study indicated that about 12 million people are living with CHD worldwide, an 18.7% increase from cases in 1990. The global prevalence of CHD, according to the study, is estimated at 1.8 per 100 live births, with a 4.2% global increase in birth prevalence of CHD between 1990 and 2017 (Zimmerman et al., 2020). The annual global mortality of CHD in 2017 was estimated to be 261,247 with 69% of these deaths occurring in infants younger than 1 year. CHD deaths were highest in the low and low-middle income countries with the burden of CHD in sub-Saharan Africa

(SSA) noted as being on the rise (Zühlke et al., 2019). An estimated 500,000 children are born with CHD in Africa each year with a major proportion of this in SSA. The incidence of CHD in SSA ranges from 19 to 75 per 1,000 live births (Hewitson & Zilla, 2019). CHD is the leading cause of birth defects and the second leading cause of death in infants in sub-Saharan Africa, after infectious diseases. Unfortunately, the vast majority of these children receive sub-optimal or no care at all (Zimmerman & Sable, 2020).

There are marked differences in decline of CHD mortalities in infants between high income countries (HICs) of more than 50% in the period 1990 - 2017 compared to a decline of only 6% in LMICs over the same period denoting significantly lesser success rate in curbing the burden of CHD among developing countries. However, in HICs and LMICs, long-term morbidity and mortality is higher among CHD patients than in the general population (Zühlke et al., 2019). World Health Organization's reports indicate that during the past decade, CHD mortality increased in the central, eastern and western sub-Saharan regions by 38.1%, 4.6% and 40.3%, respectively with the southern SSA being the only region that saw a decline in CHD deaths of 20.1%. The increased mortality in much of the SSA region is linked to poverty and limited access to appropriate treatment (Zimmerman & Sable, 2020).

Part of the aims of UN's Sustainable Development Goals (SDGs) is to reduce the mortality of neonates to less than 12 deaths per 1000 live births, the mortality of children to less than 25 deaths per 1000 live births and to reduce premature mortality due to non-communicable diseases (NCDs) by one-third by 2030. Congenital heart

disease accounts for nearly one-third of all congenital birth defects and, therefore, the focus on congenital heart disease is integral to eliminating preventable child deaths and NCDs in the SDG era (Musa et al., 2017; Liu et al., 2019).

In Sub-Saharan Africa, Kenya included, CHD is a leading cause of infant mortality, and as leading causes of mortality continue to shift from communicable diseases to non-communicable diseases in LMICs, the importance of CHD as a cause of global infant mortality is likely to continue to increase in years ahead (Tankeu et al., 2017). An understanding of the patterns of treatment outcomes for the diverse kinds of congenital heart defects is of great value in low resource settings such as Kenya to guide policy and strategy interventions and resource allocation for effective management of this pertinent health condition (Jivanji et al., 2019).

Although there has been tremendous advancement in the diagnosis and management of CHD over the past several decades, much of what is known about congenital heart disease care and management comes from the developed countries and not from LMICs where the burden of CHD is on an upward trajectory (Bouma& Mulder, 2017).

1.2 Problem Statement

Congenital heart disease is among the leading cause of infant mortality in Kenya and imposes a heavy disease burden on the country's healthcare system and on the patients' families (Jivanji et al., 2019). At KNH, between 120 and 150 congenital open-heart operations, with a similar number of congenital catheter interventions were performed on an annual basis. Health records at KNH's Pediatric Unit showed the burden of CHD

as a cause of infant mortality was rising and hence CHD had been noted as a health condition in need of greater attention (KNH Cardiac Care Unit, 2021).

Locally, there was paucity of data on patterns and risk factors of CHD and their treatment outcomes among the pediatric population. To bridge this gap, this study evaluated the patterns and risk factors of CHD and treatment outcomes during acute phase hospitalization among children aged below 5 years at KNH.

1.3 Study Justification

Understanding the patterns and risk factors of CHD and acute phase treatment outcomes among the pediatric population admitted at KNH constituted a critical first step for developing a clear roadmap for optimal resource allocation, clinical care and development of cost-effective treatment strategies at the facility. This in turn would facilitate increased access to high-quality CHD care for all children in need at KNH.

Increased focus on congenital heart disease burden in developing countries such as Kenya is vital, not only for improving access to high-quality pediatric cardiac diagnosis and treatment, but also for the realization of the SDGs and specifically SDG No. 3, which aims to end preventable deaths of neonates and children under-5. This would also positively contribute to realization of Kenya's Vision 2030 health goals of a health population served by an equitable and affordable health care system of the highest possible standards for all.

Data from this study may also be utilized by clinicians and policy makers at KNH in identifying priority areas for urgent intervention in their efforts of improving clinical

care and management of pediatric CHD patients at KNH. In addition, other scholars and researchers may utilize this study as reference in their further investigation of the study subject.

1.4 Research Questions

1. What are the patterns of congenital heart disease for children aged less than 5 years admitted at Kenyatta National Hospital?

2. What are the risk factors associated with congenital heart disease among children aged less than 5 years at Kenyatta National Hospital?

3. What are the treatment outcomes of children aged under 5 years with CHD during acute phase hospitalization at Kenyatta National Hospital?

1.5 Objectives

1.5.1 Broad Objective

To evaluate patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital.

1.5.2 Specific Objectives

1. To establish the patterns of congenital heart disease during acute phase hospitalization among children aged less than 5 years at Kenyatta National Hospital.

2. To establish risk factors associated with congenital heart disease among children aged less than 5 years at Kenyatta National Hospital.

3. To determine the treatment outcomes of children aged under 5 years with CHD during acute phase hospitalization at Kenyatta National Hospital.

1.6 Research Hypothesis

The study tested the null hypothesis that there was no significant association between the type and risk factors of CHD and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital.

1.7 Significance of the Study

The findings from this study may inform policy reforms on institution of appropriate interventions aimed at improving treatment outcomes of congenital heart disease among under five years olds at Kenyatta National Hospital. The findings from this study may also inform patient care practices among pediatric nurses at KNH with greater emphasis on timely detection and management of CHD among children aged below 5 years admitted at the hospital. The findings may also be used to inform nursing education with insights generated from this study acting as a basis for formulation of nurses' training tools and guides on how to effectively care for pediatric CHD patients admitted at KNH. Lastly, the findings from this study may also inform research by acting as a reference point and a basis for further research on the study subject among other scholars.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of literature as guided by the study objectives. The chapter begins with an overview of congenital heart disease. The chapter also contains a review of empirical literature on patterns of congenital heart disease in pediatric patients during acute phase hospitalization, factors associated with congenital heart disease among pediatric patients and treatment outcomes of pediatric patients with congenital heart disease. The chapter also contains a summary of the reviewed empirical literature as well as the study's theoretical and conceptual frameworks.

2.2 An Overview of Congenital Heart Disease

Congenital heart disease is a large and rapidly growing global problem in child health. It is the most common birth defect and is a major cause of infant morbidity and mortality across the globe (Rossano, 2020). In the last few decades, there have been major breakthroughs in cardiovascular care such as improvements in diagnosis and surgical treatment leading to considerable increases in the survival of newborns with CHD in high-income countries. This, however, has not been the case in many LMICs where the burden of CHD is heaviest and rates of death and disability continue to rise (Tankeu et al., 2017). Unfortunately, most of the data about CHD globally are extrapolated from HICs, and quality regional data from LMICs are lacking. Adequate documentation of the burden of CHD in LMICs is essential to drive a policy shift towards increasing access to high quality care for children with CHD (Zimmerman & Sable, 2020). More research on CHD in LMICs is therefore required to bridge existing information gaps.

Part of the UN's Sustainable Development Goals is the reduction of neonatal deaths to less than 12 deaths per 1000 live births and mortality of under-five children to less than 25 deaths per 1000 live births. They also aim to reduce premature mortality due to non-communicable diseases (NCDs) by one-third by 2030 (Mandalenakis et al., 2020). Given that CHD accounts for nearly one-third of all congenital defects, it is apparent that focus on CHD is integral to eliminating preventable child deaths and NCDs in the SDG era (Zühlke et al., 2019). As countries and international agencies implement, monitor, and evaluate the UN's SDGs, refined and updated estimates of congenital heart disease burden are crucially important to identify areas in need. It is also clear that sustainable CHD treatment should be prioritized as a major focus towards reaching the SDGs in LMICs. Failing to build this capacity, CHD may become a major contributor to missing the 2030 SDG target (Rossouw, 2021). Increased attention on CHD is thus warranted as part of efforts for the realization of SDGs in developing countries.

2.3 Patterns of Congenital Heart Disease in Paediatric Patients during Acute Phase Hospitalization

This section contains a review of empirical studies on patterns of congenital heart disease in pediatric patients during acute phase hospitalization. It reviews forms of CHD reported among the pediatric patient population and their patterns in various settings.

In Sudan, Abdurrahman and Diab (2022) performed a cross-sectional observation study to determine patterns of CHD in pediatric patients. They reviewed medical records of 596 CHD patients from selected pediatric hospitals in Khartoum State seen over a two-

year period using a checklist. Results indicated that ventricular septal defect (VSD) was the most commonly occurring lesion (26.6%), followed by tetralogy of fallot (TOF; 14.1%) and then patent ductus arteriosus (PDA; 10.6%). The most common combined anomalies were transposition of great arteries (TGA) and patent foramen ovale (PFO) at 9.1%. The study called for institution of appropriate long-term strategies to prevent a further rise in CHD prevalence.

Similarly, a retrospective study was conducted at the Ugandan Heart Institute in Mulago Hospital to examine the patterns of CHD among admitted pediatric patients between 2007 and 2014. Results showed that of 4,621 children seen at the hospital during the study period, 76.3% had CHD with 55% of these being females. From the findings, isolated ventricular septal defect was the most common CHD diagnosed -27.2% followed by patent ductus arteriosus - 22% and atrial septal defects (ASD) - 9.4%). Tetralogy of fallot (TOF) and Truncus arteriosus were the most common diagnosed cyanotic heart defects at 7% and 5%, respectively (Namuyonga et al., 2020).

A retrospective study carried out in Ghana also assessed the patterns of diagnosed CHD in a local tertiary health facility. Electronic health records from the hospital's pediatric unit for the period January 2018 to October 2019 were reviewed and analysed. Results showed that from the over 10,000 records reviewed, 79 CHD cases were recorded with a male to female ratio of approximately 1:1. Most (77.2%) of the diagnoses were in children aged below 5 years. Ventricular septal defects (VSD) and patent ductus arteriosus (PDA) were the most common acyanotic CHD diagnosed while Tetralogy of Fallot was the most common cyanotic CHD lesion seen (Thomford et al., 2020).

In a study conducted in Nigeria, Abah et al. (2018) evaluated the spectrum of cardiac diseases among paediatric patients in one of the local tertiary hospitals. They undertook a retrospective review of all pediatric patients seen in the paediatric unit of Benue State University Teaching Hospital from June 2012 to December 2015. Data were analyzed using descriptive statistics using Microsoft Excel. Results showed that of the 8,590 patients seen, 39 had cardiac diseases, with 28(71.8%) of the 39 having CHD. The most prevalent type of CHD was acyanotic CHD (53.8%). Ventricular septal defect (VSD) accounted for most of the cases at 72%.

An empirical study performed in India assessed the pattern of CHD among pediatric patients using echocardiography. Four hundred and thirty CHD cases with a male to female ratio of 1.3:1 were analyzed. Results showed that about 67% of the patients had acyanotic CHD while 33% had cyanotic CHD lesions. The most common acyanotic CHD was ventricular septal defect followed by atrial septal defect and patent ductus arteriosus. The most common cyanotic CHD was TOF followed by transposition of great vessels, total anomalous pulmonary venous connection and single ventricle. The study concluded that VSD and TOF were the most common acyanotic and cyanotic CHD, respectively (Meshram & Gajimwar, 2018).

A prospective descriptive study performed in Iraq sought to establish patterns of CHD in children in the city of Karbala. Children, aged below 5 years, with a confirmed diagnosis of CHD seen in the Pediatric echo-cardiac clinic in Karbala Pediatric Teaching Hospital between October 2011 and October 2012 were enrolled. Data were analyzed using SPSS v.10. A total of 110 children were included. The male to female

ratio was 1:1.6. Most of the patients had acyanotic CHD - 78.2%while 21.8% had cyanotic CHD. Ventricular septal defect followed by atrial septal defect (ASD), patent ductus arteriosus (PDA) and pulmonary valve stenosis were the most common acyanotic congenital heart lesions while, Tetralogy of Fallot (TOF) followed by transposition of the great arteries(TGA) were the commonest cyanotic congenital heart lesions. Female gender was more dominant in less complex CHD lesions while the male gender had more complex CHD (Jasim, Hussein & Abbas, 2017).

A prospective descriptive study conducted in Pakistan evaluated the pattern of congenital heart defects at the National Institute of Cardiovascular Diseases (NICVD) pediatric outpatient department. It included all pediatric patients, aged under-5, diagnosed with CHD using echocardiography with data analyzed using SPSS v 20.0. Results showed that 60.6% of the CHD cases were simple acyanotic lesions while 38.6% were complex cyanotic lesions. TOF was the commonest CHD and the most common cyanotic lesion and accounted for 24.4% of the total cases. It was followed by ventricular septal defect (VSD) - 21.5%; atrial septal defect (ASD) - 9.3% and patent ductus arteriosus (PDA) - 8.6%. Pulmonary valve stenosis was the most common obstructive lesion accounting for 3.1% of the CHDs. The commonest combination of CHD cases noted was ASD with VSD (Pate et al., 2016).

It is evident from the reviewed studies that acyanotic CHD were more commonly diagnosed among the surveyed children than acyanotic CHD. Ventricular septal defect, patent ductus arteriosus, atrial septal defect and pulmonary valve stenosis were the most

common acyanotic CHDs diagnosed while tetralogy of fallot, transposition of great arteries and truncus arteriosus were the most common diagnosed cyanotic heart defects.

2.4 Risk Factors Associated with Congenital Heart Disease among Paediatric Patients

This section contains a review of empirical studies on risk factors associated with congenital heart disease among pediatric patients. It reviews various maternal and child related factors associated with CHD among children as reported in various studies.

In Pakistan, Faheem et al. (2021) did a study on risk factors for CHD among pediatric patients attending a local tertiary care hospital. A total of 500 patients, 250 cases and 250 controls, were enrolled for the study. Results of the study showed that parental consanguinity, family history of CHD, maternal co-morbidities, first born child and low birth weight were independent risk factors for development of congenital heart disease. On the other hand, medications used by the mother during the index pregnancy, maternal age and gender of the child did not significantly increase the risk of developing CHD.

A cross-sectional study conducted in Uganda evaluated the factors associated with CHD among 179 cases aged below 5 years at Mulago National Referral Hospital. Multivariate logistic regression was applied in analysis of the data. Results suggested low birth weight, high birth order, and maternal febrile illness during pregnancy, parental alcohol use and paternal socioeconomic status were dominant risk factors for CHD among children. Rigorous implementation of public health policies and

interventions targeted at these particular factors could be important in reducing the burden of CHD among children in Uganda (Kapakasi et al., 2021).

Similarly, a cross-sectional case-control study conducted in Iran explored the factors associated with occurrence of CHD in pediatric patients. A total of 1,338 known cases of CHD, diagnosed by echocardiography or angiography and 1,201 healthy controls were included in the study, with the assessment done using a questionnaire. From the findings, the factors found to be statistically associated with CHD among the study population included positive parents' consanguinity, previous maternal history of abortion, maternal age of above 30 years and positive history of CHD among siblings of the cases and underlying maternal chronic diseases including diabetes, hypertension during pregnancy. The study concluded that more frequent prenatal screening and effective management of any diagnosed health conditions was recommended for all pregnant women (Asbagh et al., 2020).

A cross-sectional study carried out in Ethiopia investigated the factors associated with occurrence of CHD among children with congenital defects admitted in 4 public hospitals in Addis Ababa. Data were collected using a structured questionnaire and were analyzed using logistic regression analysis. A high burden of congenital heart defects among congenital anomalies was established in the study population. The study also established that maternal previous history of abortion, maternal diabetes and past history of drug intake during pregnancy were significantly associated with congenital heart defects. The study concluded that maternal behavioural factors were critical predictors of CHD (Talargia, Seyoum & Moges, 2018).

A population-based case-control study was done in China to examine the risk factors for CHDs in Guangdong region. The study included 4,034 pairs of case and control infants enrolled from the Guangdong Registry of CHD, 2004-2013. Data were analyzed using multivariate logistic regression and reported using adjusted odds ratios (ORs). According to the study, multiple maternal environmental exposures, including living in newly renovated rooms, residential proximity to main traffic, paternal smoking, and maternal occupation as manual worker were significantly associated with CHDs. Maternal perinatal diseases including maternal fever, diabetes, influenza, and threatened abortion, maternal medication use during pregnancy, advanced maternal age, low socioeconomic status, and paternal alcohol intake were also significantly associated with CHDs (Ou et al., 2016).

Abqari et al. (2016) undertook a case-control study to determine the risk factors associated with congenital heart defects. The study was carried out at a pediatrics department of a tertiary medical hospital in Uttar Prdesh between February 2014 and August 2015. Participants were CHD cases and age-matched controls, and data were analyzed suing logistic regression analysis. According to the study, paternal age, bad obstetric history, antenatal febrile illness and advanced maternal age were found to increase the risk of CHD whereas intake of multivitamins was found to be protective. The study concluded that there was need to prioritize antenatal care and counseling to pregnant mothers along with good maternal nutrition and folic acid supplementation.

Similarly, a case control study was undertaken in India to determine risk factors of CHDs in children. A total of 75 cases of CHDs and equal number of matched controls,

drawn from a local tertiary hospital in Maharashtra, were enrolled for the study. The study found that maternal factors like consanguinity, family history of congenital heart diseases, maternal co-morbidities like gestational diabetes and hypertension and drug intake during pregnancy as well as fetal factors including prematurity, LBW and chromosomal abnormality were significant underlying risk factors for development of CHDs in children (Kumar et al.,2015).

It was thus evident from the reviewed empirical studies that a wide range of maternal and neonatal related factors were associated with CHD among the pediatric patient population.

2.5 Treatment Outcomes of Paediatric Patients with Congenital Heart Disease

This section contains a review of empirical studies on treatment outcomes in pediatric patients with congenital heart disease. It reviews mortality rates occasioned by CHD in the pediatric patient population in various settings. It also highlights forms of CHD contributing the most to poor treatment outcomes among the pediatric patient population.

Zheng et al. (2021) undertook a retrospective study to ascertain in-hospital treatment outcomes for pediatric patients with CHD following CHD surgery between 2005 and 2017. Results indicated that out of a total of 19,114 children with CHD who underwent surgical intervention, 444 died, giving an in-hospital mortality of 2.3%. The results also showed that complex mixed CHDs had the highest fatality rate. Isolated cyanotic heart defects had the second highest fatality rate while simple acyanotic heart defects had the lowest mortality rate. The study also established that neonatal period had the highest

mortality rate, followed by infant mortality, while toddler age and preschool age mortalities were significantly lower. In addition, the fatality rate in boys was significantly higher than that in girls. The study concluded that mortality rates of CHD surgery in children decreased year by year, and that the younger the age and the more complicated the cyanotic heart disease, the higher the mortality rate was likely to be.

An evaluation of treatment outcomes among children with CHD was undertaken in Sweden. The study investigated the mortality risk in patients with CHD compared with matched controls without CHD using Cox proportional regression models and Kaplan-Meier survival analysis. Results showed that mortality among the cases at 6% was significantly higher than among the controls at 0.3%. The mortality risk was 17.7 times higher in children with CHD compared with controls. Odds of mortality were also significantly higher among cases with mixed complex cyanotic heart defects compared with those diagnosed with simple isolated acyanotic heart defects. The highest mortality risk was also found during the first 4 years of life in patients with CHD (Mandalenakis et al., 2020).

Similarly, a study conducted in US also examined the treatment outcomes in infants diagnosed with CHD over the past few years. It was a retrospective analysis of infant treatment outcomes following CHD diagnosis and treatment over the period 1999-2015. Results showed that, over the study period, 5.7% of the total infant deaths were due to CHD. The incidence of infant CHD mortality decreased from 0.45 in 1999 to 0.33 in 2015 per 1000 births and from 64 to 56 per 1000 infant deaths. However, mortality rates were higher in infants born to African American mothers compared to

those born to white mothers. Thus, despite the decline in CHD mortality, significant racial disparities still exist (Mubayed & Al-Kindi, 2019).

A prospective registry-based study was performed in Sweden to assess treatment outcomes among children diagnosed with CHD compared to their matched controls. Data was extracted from hospital-based patient records from 1970 to2011 and were analyzed using various inferential statistics. Results showed significant difference in mortality rates between the cases and the controls with higher mortality rates among pediatric patients with CHD. Within the cases, mortality was also higher among the neonates and infants compared to older pediatric patients. In addition, pediatric patients with the most severe complex defects such as common arterial trunk, transposition of the great vessels, double inlet ventricle, hypoplastic left heart syndrome, tetralogy of fallot and atrioventricular septal defect had the highest risk for death. The study concluded that the mortality risk in CHD cohort remained high compared with the risk in matched controls and hence pediatric patients with CHD were a vulnerable group (Rosengren et al., 2017).

Similarly, a retrospective study was undertaken to evaluate treatment outcomes for infants with CHD from 2003 to 2012 in Spain. Poisson regression was used to estimate the mortality rate and relative risk of mortality. The study found that there were 2,970 (4.58%) infant deaths in a population of 64,831 patients with CHD. Most (73.8%) of the deaths occurred during the first week of life. Infant mortality rate in patients with CHD was 6.23 per 10,000 live births and did not change over the period. The congenital heart diseases with highest mortality rates, among the infants, were hypoplastic left

heart syndrome -41.4%, interruption of aortic arch -20% and total anomalous pulmonary drainage -16.8%. Pulmonary stenosis (1.1%) and atrial septal defect (1%) showed the lowest mortality rate (Picarzo et al., 2018).

Faraoni et al. (2016) did a study to evaluate treatment outcomes among pediatric patients with CHD compared to those without CHD. Source of the analyzed data was the pediatric database of the American College of Surgeons National Surgical Quality Improvement Program. The study included children with minor, major and severe CHD, each of whom was matched with controls without CHD and who underwent similar non-cardiac surgery of comparable complexity. Results showed that the incidence of overall mortality was significantly higher in children with major and severe CHD compared with their controls, whereas no difference was observed between children with minor CHD and their matched controls. The study called for further research aimed at identifying optimal care strategies for this vulnerable population.

It was evident from the reviewed empirical studies that CHD contributed to poor treatment outcomes in the pediatric patient population across various settings. Most of the mortality was attributable to complex acyanotic and cyanotic CHD forms. It was also evident that mortality was higher among children with CHD compared to their non-CHD counterparts.

2.6 Literature Gaps

The reviewed empirical studies pointed to a general agreement that congenital heart disease remained a major public health problem in children's health across the world and particularly in LMICs. And though there had been significant decline in mortality

rates from CHD in high income countries due to advancements in diagnosis and treatment in cardiac related health conditions, the same could not be said of the situation in LMICs where the burden of CHD was rising. The empirical literature also pointed to consensus that in all settings, complex cyanotic heart defects contributed more to poor treatment outcomes compared to single uncomplicated acyanotic heart defects. The empirical literature review also suggested that a wide range of maternal and neonatal related factors were associated with the occurrence of CHD and that mortality rates were significantly higher in CHD patients compared to those without CHD.

However, most of the studies reviewed in the literature were largely done in other countries whose healthcare settings and systems differed from that of Kenya. From the empirical literature, it was clear that there was paucity of local empirical literature on patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years in the country and hence the need for the current study. The findings from this study offer valuable insights that may inform interventions to enhance care of pediatric patients with CHD at Kenyatta National Hospital with a view of improving patient treatment outcomes.

2.7 Conceptual Framework

The independent variables of the study included type of CHD, the child's age, type of intervention/surgery done and underlying comorbidities among the children, if any. The dependent variable of the study was patient treatment outcome, denoted by whether the patient recovered or died from CHD. The study's intervening variables included

approved guidelines on pediatric CHD management, expertise/experience of HCPs and stage of CHD. This was as illustrated in Figure 2.1.

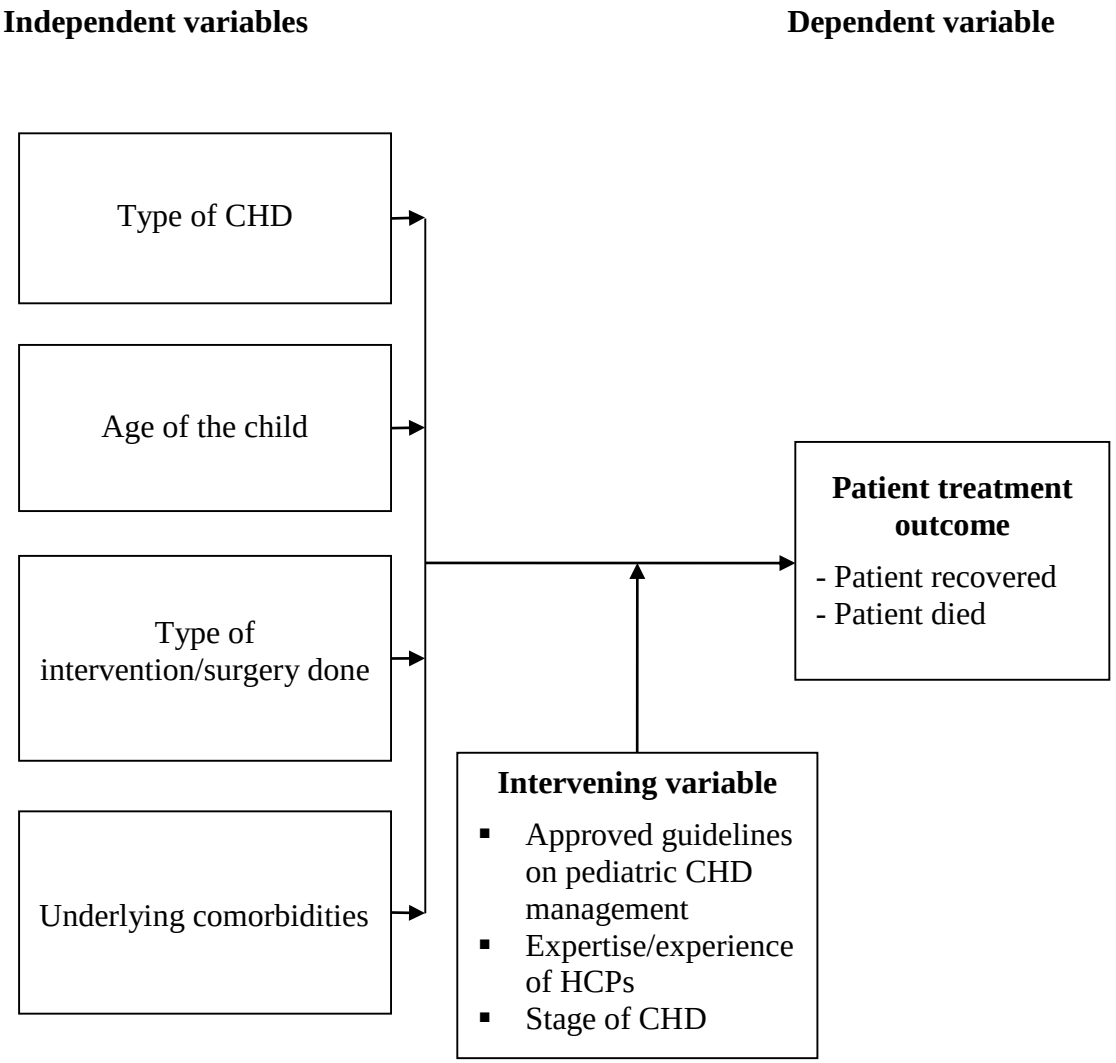


Figure 2.1: Conceptual framework

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter thus covers the following aspects: the study design, study area, study population, inclusion and exclusion criteria, sample size and sampling method, data collection tools and procedures, pretesting of tools, data analysis, ethical considerations, study limitations as well as the study findings dissemination plan.

3.2 Study Design

This study adopted a retrospective case-control study design. This is a type of an observational study in which two existing groups differing in outcome are identified and compared on the basis of some supposed/suspected attribute (Newtonraj et al., 2017). This study design was considered appropriate for this study as it allowed the researcher to compare data on the research subject between CHD cases and a control group (that was, cases without CHD) in order to establish association between the various maternal and neonatal factors and incidence of CHD among the study group.

In addition, a retrospective chart review of the medical records of children aged below 5 years treated with CHD at Kenyatta National Hospital was carried out. This enabled the researcher to identify the patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among this cohort.

3.3 Study Area

This empirical research study was carried out in the Records Department of Kenyatta National Hospital. Kenyatta National Hospital (KNH) is Kenya's largest public referral hospital, located about four kilometers from the Nairobi city centre, off Ngong road along Hospital Road. The current bed capacity of the hospital is about 2,000. The facility offers a wide range of specialized in and out-patient health care services. The specialized health-care services provided at KNH include radiotherapy, heart surgery, neurosurgery, oncology, diabetic, renal dialysis and kidney transplant operations, plastic and reconstructive surgery, orthopedic surgery and burns management among others. The hospital also facilitates medical training and research and participates in national healthcare planning.

In KNH, pediatric patients presenting with various health conditions were cared for in the Pediatric Unit. Thus, pediatric patients with CHD, during acute phase of hospitalization, were managed within the hospital's Pediatric Unit and thereafter their records were transferred to the Records Department upon their discharge, referral back to another hospital for continued care or upon their demise. The Records Department at KNH thus provided a good platform for evaluating the health records of pediatric patients with CHD treated in the hospital from a retrospective basis.

3.4 Study Variables

A summary of the variables of the study was as presented in Table 3.1.

Table 3.1: Study variables

Study objective	List of variables	Measurable outcome	Statistical analysis
1 -patterns of CHD	- Type of CHD - Child's age - Type of intervention done - Underlying comorbidities	- Kinds of CHD diagnosed - Kinds of surgical interventions used - Any comorbidities noted	Descriptive statistics Frequencies Percentages Inferential statistics Chi-square test Odds ratios
2 - risk factors of CHD	- Mother related factors - Child related factors	- maternal age - maternal BMI - pregnancy type - maternal substance use - maternal health status - family history of CHD - prematurity	Descriptive statistics Frequencies Percentages Inferential statistics Chi-square test Odds ratios
3 -treatment outcomes of CHD	- Patient recovered - Patient developed complications - Patient died	- Patient mortality rates - Patient recovery rates	Descriptive statistics Frequencies Percentages Inferential statistics Chi-square test Odds ratios

*Consideration period - acute phase hospitalization

3.5 Study Population

The study population constituted of two groups as follows;

3.5.1 Study Group

Population of the study comprised of children aged below 5 years admitted to the Pediatric Unit of Kenyatta National Hospital between 1st January, 2017 and 31st

December, 2021 who had CHD. Existing hospital records indicated that the hospital handled 2,450CHD cases over this 5-year period.

3.5.2 Control Group

A similar number of health records of pediatric patients (matched for age) without CHD was used as a control group.

3.6 Inclusion and Exclusion Criteria

3.6.1 Inclusion Criteria

The study included all health records of pediatric patients aged below 5 years, with CHD and without CHD, seen in KNH's Pediatric Unit between 1st January, 2017 and 31st December, 2021.

3.6.2 Exclusion Criteria

The study excluded patients' health records that missed crucial data required for the success of this research work.

3.7 Sample Size and Sampling Method

The researcher used census method whereby all pediatric patients' health records with documented CHD case and their matched controls, under the specified period, were utilized for the study. As such, the study sample size comprised of 2,450 health records of children aged below 5 years admitted to the Pediatric Unit of Kenyatta National

Hospital between 1st January, 2017 and 31st December, 2021 who had CHD and an equal number of matched controls without CHD.

3.8 Data Collection Instruments and Procedures

Data on patterns of congenital heart disease, associated factors and treatment outcomes for the study population was obtained from secondary sources, which were the patients' health records, retrieved from the hospital's Registry. The data was obtained using a Data Abstraction Form (Appendix 2). This is a standard instrument used to systematically collect data from documented reports. Abstraction involves direct matching of information found in the record to the data element required for the study. The information that was collected included the patient's demographics as well as on any maternal and neonatal related factors associated with CHD and the patients' treatment outcomes. The primary outcome for this study was death or survival to hospital-discharge rate.

To ensure the safety of the patients' records, the researcher extracted the required information from the patients' health records within the confines of the hospital's registry. This ensured that the patients' records were immediately returned to their designated section after extracting the required information and hence ensuring that the records did not leave the safety of the hospital's Registry.

3.9 Pre-testing of Tools

Pretesting of the data abstraction form was carried out at Mbagathi County Referral Hospital where 245 data abstraction forms (representing 10% of the study sample size)

were used. Pretesting was carried out to refine the data collecting tool. Upon pretesting, the data collection instrument was adjusted where necessary and a final form of the tool was made.

3.10 Validity and Reliability of the Study Tool

Validity refers to the degree to which an instrument measured what it was supposed to measure (Kothari, 2010) or whether the findings obtained from the analysis of the data adequately represented the phenomena under study (Denscombe, 2014). The study tool was availed to the supervising lecturers who helped establish its content and construct validity to ensure that the items were adequately representative of the study subject.

Reliability is the ability of a research instrument to produce consistent findings on repeated trials (Nsubuga, 2006). Reliability of the study tool was evaluated using the Cronbach's Alpha Coefficient based on data from the study tool's pretesting with an acceptable reliability threshold of at least 0.7. The study tool yielded a Cronbach's Alpha Coefficient value of 0.872 which was greater that the set threshold of 0.7, hence the study tool was deemed to be reliable.

3.11 Data Management

This section outlines how the study data was analysed and stored as described in the subsequent subsections.

3.11.1 Data Analysis

At the point of collection, data was organized, examined for accuracy and completeness, coded and entered into computer software ready for analysis. The study

data was analyzed descriptively. As such, the study applied descriptive statistics that included percentages and frequencies to analyze the study data. This was done using the Statistical Package for Social Sciences (SPSS v. 25). In addition, chi-square test statistic and odds ratios were utilized to analyze the association between the study variables at 5% significance level. Results of the study were presented in tables, charts and graphs.

3.11.2 Data Storage

The raw data in form of data abstraction form was kept in a safe under lock and key and was accessible to the authorized persons only. The processed data was stored in a flash disk, in a password protected folder which was accessible to authorized persons only. The documents shall remain under safe custody for ten years before destruction according to research documents ethics.

3.12 Ethical Considerations

Ethical clearance was sought from the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee (UoN/KNH-ERC). The approval to conduct the study at Kenyatta National Hospital was also sought from relevant authorities at the hospital. In addition, appropriate authorization, to access patients' health records of targeted participants who met the inclusion criteria, was sought from the Head of the Pediatric Unit and the Officer-In-Charge of the Records Department at KNH. The study data was processed confidentially, anonymously and securely and was used for the purposes of the study only and due care was observed to safeguard the integrity of the patients' records during data extraction. To ensure the safety of the patients' records,

the researcher extracted the required information from the patients' health records within the confines of the hospital's Registry, hence ensuring that the records did not leave the safety of the hospital's Registry.

3.13 Limitations of the Study

Since the study utilized secondary data collected using a data abstraction form, some patients' health records were found to contain incomplete data. The missing data or even lack of needed information in the patients' records limited its usability. To counter this limitation, the researcher undertook data cleaning prior to the final analysis of the study data.

The study was based on results gathered from a single hospital in the country. Thus, the findings may not be generalized to all other hospitals in the country due to differences in sizes, geographical location and institution set up. To counter this limitation, the researcher has recommended for a wider study involving other hospitals in the country to allow for comparison and generalization of the findings.

3.14 Dissemination of Study Findings

The study findings shall be disseminated through forwarding a copy of the final research project report to the University of Nairobi and to Kenyatta National Hospital and through presentation in organized workshops and conferences.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents the study results as set out in the research methodology. The results were presented on the patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital. The contents of the chapter include: the study's response rate, demographic characteristics of the study participants, patterns of CHD among the study participants, risk factors associated with congenital heart disease among the study participants, treatment outcomes of the study participants during acute phase hospitalization and associations of the patterns and risk factors of CHD with the patients' treatment outcomes. This is in accordance with the study objectives. A total of 70.2% of the targeted files were accessed, information abstracted and analyzed.

4.2 Demographic Characteristics of the Study Participants

The study sought to establish the demographic profile of the under five years old children admitted to the Pediatric Unit of Kenyatta National Hospital in the period 1st January, 2017 and 31st December, 2021. The demographic attributes considered included the children's gender, age, birth weight, whether they were schooling and point at which the CHD was diagnosed (for the cases).

For the cases, most (75.4%, n = 1297) were aged 1 - 5 years; half (50.9%, n = 876) were schooling and most (82.4%, n = 1418) were diagnosed with CHD after infancy.

For the controls, most (66.8%, n = 1469) were aged 1 - 5 years and most (56.7%, n = 1248) were schooling. Those classified as 'not schooling' were the children that had not attained school-going age.

This showed that the children in the two categories (with CHD and without CHD) had similar demographic characteristics. Table 4.1 shows the results.

Table 4.1: Demographic characteristics of the study participants

		With CHD (n = 1,720)		**Without CHD (n = 2,200)**	
Demographic attributes		**Freq.**	**%**	**Freq.**	**%**
Gender	Male	891	51.8	1182	53.7
	Female	829	48.2	1018	46.3
	Total	**1,720**	**100.0**	**2,200**	**100.0**
Age	Under 1 year	423	24.6	731	33.2
	1-5 years	1297	75.4	1469	66.8
	Total	**1,720**	**100.0**	**2,200**	**100.0**
Whether schooling?	Yes	876	50.9	1248	56.7
	No	844	49.1	952	43.3
	Total	**1,720**	**100.0**	**2,200**	**100.0**
Point at which the CHD was diagnosed	During infancy	302	17.6	-	-
	After infancy	1418	82.4	-	-
	Total	**1,720**	**100.0**	**-**	**-**

4.3 Patterns of CHD among the Study Participants

The first objective of the study sought to establish the patterns of congenital heart disease during acute phase hospitalization among children aged less than 5 years at Kenyatta National Hospital. The results were as described in the subsequent subsections.

4.3.1 Types of CHD Diagnosed

The study sought to establish the kind of CHD that were diagnosed among the study participants.

From the results shown in Table 4.2, most (82.8%, n = 1424) of the cases of CHD diagnosed among the study participants were acyanotic while 15.9% (n = 274) were cyanotic CHD cases.

According to the results, the most prevalent CHD diagnosed were ventricular septal defect (27.4%, n = 471), patent ductus arteriosus (20.9%, n = 360), atrial septal defect (17.3%, n = 298) and pulmonary valve stenosis (9.7%, n = 167) - all of which were acyanotic CHDs. On the other hand, the most occurring cyanotic CHDs included tetralogy of fallot which accounted for 8.3% (n = 143) of total cases followed by transposition of the great vessels which accounted for 5.7% (n = 98) of total cases. This showed that CHDs diagnosed among the study participants were diverse, with acyanotic congenital heart disease being the most prevalent. Results are as presented in Table 4.2.

Table 4.2: Types of CHD diagnosed (n = 1,720)

CHD category	Kinds of CHD diagnosed	Frequency (n)	Percent (%)
Acyanotic CHDs	Ventricular septal defect	471	27.4
	Atrial septal defect	298	17.3
	Patent ductus arteriosus	360	20.9
	Pulmonary valve stenosis	167	9.7
	Aortic stenosis	38	2.2
	Coarctation of the aorta	74	4.3
	Atrioventricular septal defect	11	.6
	Bicuspid aortic valve	5	.3
	Sub-total	**1424**	**82.8**
Cyanotic CHDs	Tetralogy of fallot	143	8.3
	Transposition of the great vessels	98	5.7
	Truncus arteriosus	2	.1
	Total anomalous pulmonary venous return	9	.5
	Tricuspid valve abnormalities (Tricuspid atresia)	4	.2
	Pulmonary atresia with ventricular septal defect	12	.7
	Hypoplastic left heart syndrome	1	.06
	Ebstein anomaly	5	.3
	Sub-total	**274**	**15.9**
	Unknown/not indicated	22	1.3
Total		**1,720**	**100.0**

4.3.2 Patterns of CHD among the Children

The study also explored the patterns of the most prevalent CHDs among the children over the 5-year period (2017 - 2021).

The most prevalent acyanotic CHDs had a general upward trend over the 5-year study period, 2017 to 2021. According to the results, ventricular septal defect cases rose from

74 in 2017 to 116 in 2021 marking a 56.8% rise in number of reported cases over the period. Atrial septal defect cases rose from 45 in 2017 to 74 in 2021 marking a 64.4% rise in number of reported cases over the period. Patent ductus arteriosus cases rose from 61 in 2017 to 85 in 2021 marking a 39.3% rise in number of reported cases. Pulmonary valve stenosis cases rose from 31 in 2017 to 47 in 2021 marking a 51.6% rise in number of reported cases over the period. This showed that, during the study period, the highest increase in acyanotic CHDs was seen in atrial septal defect while the least increase was seen in patent ductus arteriosus. Figure 4.1 illustrates the results.

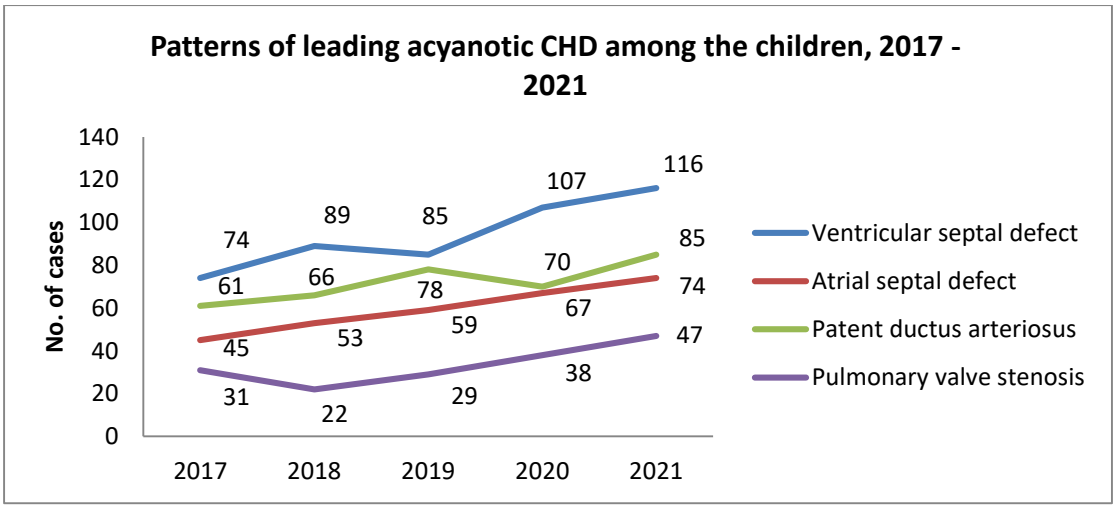


Figure 4.1: Patterns of leading acyanotic CHD among the children

Similarly, the most prevalent cyanotic CHDs had a general upward trend over the 5-year study period, 2017 to 2021. According to the results, tetralogy of fallot cases rose from 21 in 2017 to 36 in 2021 marking a 71.4% rise in number of reported cases over the period. Transposition of the great vessels cases rose from 16 in 2017 to 23 in 2021 marking a 43.8% rise in number of reported cases over the period. This showed that,

during the study period, tetralogy of fallot recorded the highest increase among the two leading cyanotic CHDs. The results are as shown in Figure 4.2.

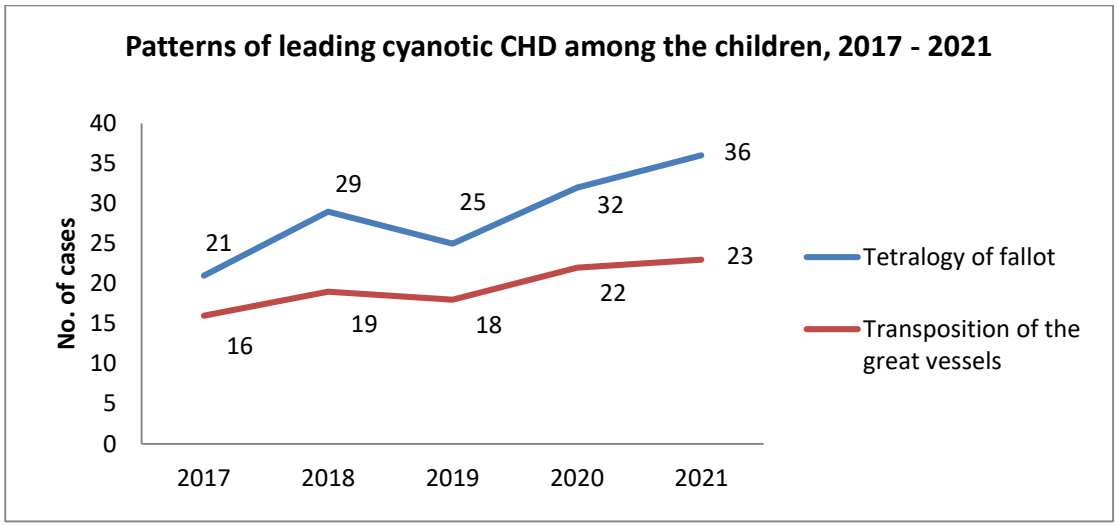


Figure 4.2: Patterns of leading cyanotic CHD among the children

Further, on aggregate, acyanotic CHD cases rose from 261 in 2017 to 326 in 2021 marking a 24.9% rise in number of reported cases over the period. Cyanotic CHD cases rose from 53 in 2017 to 61 in 2021 marking a 15.1% rise in number of reported cases over the period, denoting that, during the study period, acyanotic CHD increased with a slightly larger margin compared to the cyanotic CHD.

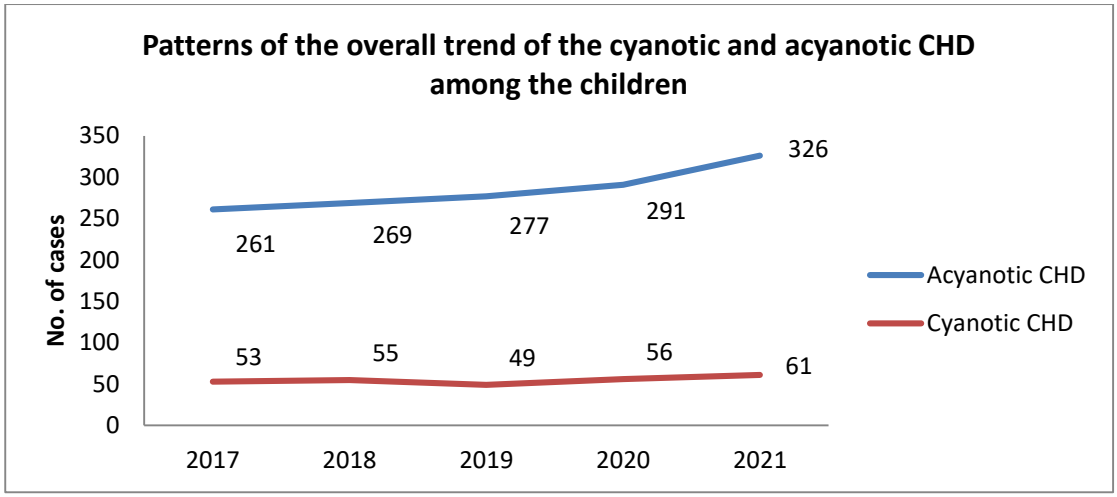


Figure 4.3: Overall trend of the cyanotic and acyanotic CHD, 2017 - 2021

4.3.3 Other Related Attributes

The study also sought to establish other attributes related to the patterns of congenital heart disease during acute phase hospitalization among the study participants. These attributes included types of interventions performed, kinds of supportive care offered to the patients, nature or kinds of complications experienced and any documented challenges observed during patient care.

Regarding the kinds of treatment interventions performed for the CHD cases, all (100%, n = 1720) of the CHD patients received medications (Antibiotics, anti-heart failure drugs and non-steroid anti-inflammatory drugs); most (77.3%, n = 1329) were treated through surgery or surgical interventions (PDA ligation, VSD closure, TGA/TOF correction and open-heart surgery); a third (33.6%, n = 578) underwent catheter procedures while 24.2% (n = 417) received oxygen therapy. This denoted that various treatment interventions were used in the care of the CHD patients, with surgical

interventions and use of medications being the most prevalent. The results are as depicted in Figure 4.4.

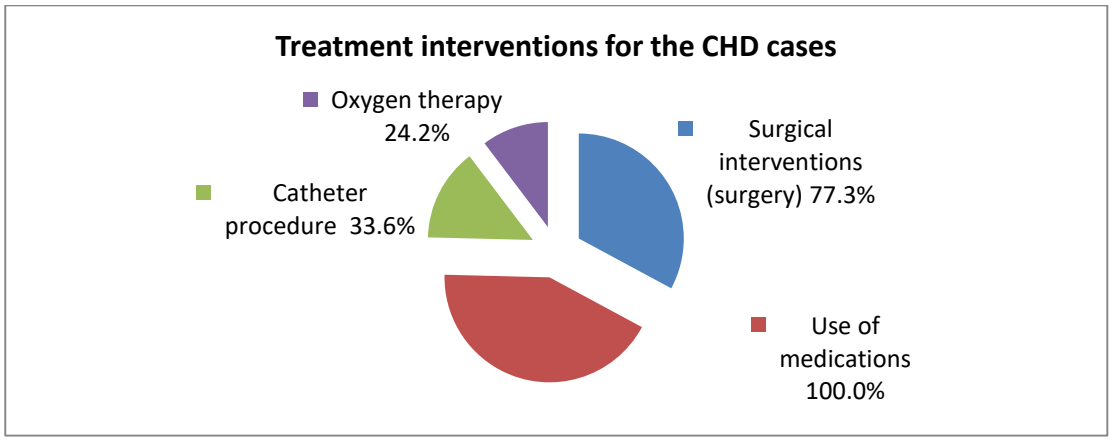


Figure 4.4: Treatment interventions for the CHD cases (n = 1,720)

Regarding the kinds of supportive care offered to the CHD patients, all (100%, n = 1720) of the CHD patients received regular medical care follow-ups; most (88.3%, n = 1519) also benefited from nutrition support, psychosocial support (76.1%, n = 1309) as well as physical activity therapy (61.8%, n = 1063) while 18.2% (n = 313) received ventilatory support. This showed that the CHD patients were offered several supportive care services. The results are as depicted in Table 4.3.

Table 4.3: Kinds of supportive care offered to the CHD cases (n = 1,720)

Supportive care services	Frequency (n)	Percent (%)
Ventilatory support	313	18.2
Nutrition support	1519	88.3
Physical activity therapy	1063	61.8
Psychosocial support	1309	76.1
Regular medical care follow-ups	1720	100.0

Regarding the kinds of complications reported among the CHD cases, the study established that the most prevalent included pulmonary hypertension at 43.7% (n = 752); respiratory tract infections at 36% (n = 619); pulmonary embolism at 24.8% (n = 427); pulmonary edema at 22.3% (n = 384) and developmental delays at 19.5% (n = 335). Other complications reported among the CHD cases, albeit in lower incidences, included endocarditis (heart infections), irregular heart rhythms (arrhythmias), heart failure and stroke. This denoted that a significant proportion of the children diagnosed with congenital heart disease at KNH experienced a wide array of serious health complications during the acute hospitalization phase. Table 4.4 illustrates the results.

Table 4.4: Kinds of complications reported among the CHD cases (n = 1,720)

Kinds of complications reported	Frequency (n)	Percent (%)
Pulmonary hypertension	752	43.7
Pulmonary edema	384	22.3
Pulmonary embolism	427	24.8
Respiratory tract infections	619	36.0
Endocarditis (heart infections)	126	7.3
Irregular heart rhythms	161	9.4
Heart failure	23	1.3
Stroke	49	2.8
Developmental delays	335	19.5

Regarding documented challenges observed in the care of children with CHD, the most prevalent challenges included high cost of treatment noted in 77.2% (n = 1327) of the cases, long hospital stays noted in 66% (n = 1136) of the cases and CHD related health complications noted in 61.3% (n = 1054) of the cases. Other documented challenges reported in the care of the children with CHD included complex medical and surgical

care procedures noted in 21.5% (n = 370) of the cases; medication side effects noted in 41.2% (n = 709) of the cases and low number of multidisciplinary cardiac care specialists as observed in 25.1% (n = 432) of the cases. It was thus evident that a wide range of challenges were experienced during care of the CHD patients with high cost of treatment, long duration of hospitalization and CHD related complications being leading challenges. Table 4.5 outlines the results.

Table 4.5: Documented challenges in care of the CHD cases (n = 1,720)

Documented challenges	Frequency (n)	Percent (%)
Complex medical and surgical care procedures	370	21.5
CHD related health complications	1054	61.3
Medication side effects	709	41.2
Low number of multidisciplinary cardiac care specialists	432	25.1
Long hospital stays	1136	66.0
High cost of treatment	1327	77.2

4.4 Risk Factors Associated with CHD among the Study Participants

The second objective of the study sought to establish the risk factors associated with congenital heart disease among children aged less than 5 years at Kenyatta National Hospital. The results are as presented in the subsequent subsections.

4.4.1 Maternal Age and Congenital Heart Disease in Children

Results on maternal age indicated that most (61.5%, n = 1057) of the mothers of the children with CHD were aged 30 - 39 years, 26.4% (n = 454) were aged 18 - 30 years while 12.2% (n = 209) were aged 40 - 49 years.

Similarly, most (56.5%, n = 1244) of the mothers of the children without CHD were aged 30 - 39 years, 30.5% (n = 670) were aged 18 - 30 years while 13% (n = 286) were aged 40 - 49 years.

The results illustrate that the age distribution of the mothers of children with and without CHD were similar, with most in both categories being relatively young mothers. The results are as shown in Figure 4.5.

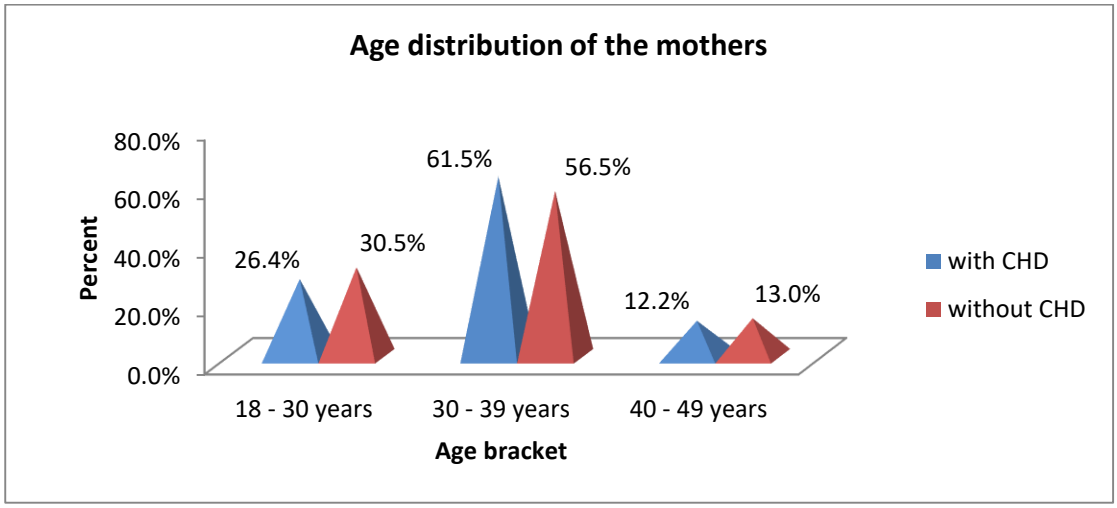


Figure 4.5: Age distribution of the mothers

Further, no statistically significant association was established between the mothers' age and CHD among the children (X^2 = .630, df = 1 and p = 0.427). However, the odds of CHD among the children were found to be 1.06 times higher among mothers aged

40 years and above compared to those aged 39 years and below. This implied that maternal age did not significantly contribute to CHD among children at Kenyatta National Hospital. Table 4.6 illustrates the results.

Table 4.6: Association of maternal age with CHD in children

	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
Age	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**[at 95% CI]**
≤ 39 years	1511	1914			1.06
≥ 40 years	209	286	.630	.427	[0.78 - 1.32]

4.4.2 Maternal BMI and Congenital Heart Disease in Children

From the results, most (70.1%, n = 1206) of the mothers of children with CHD had normal BMI with the remaining being either overweight or obese. Similarly, most (73.9%, n = 1626) of the mothers of children without CHD had normal BMI with the rest being either overweight or obese. The results denoted that the CHD group had more mothers who were overweight and obese compared to the non-CHD group. The results are as shown in Figure 4.6.

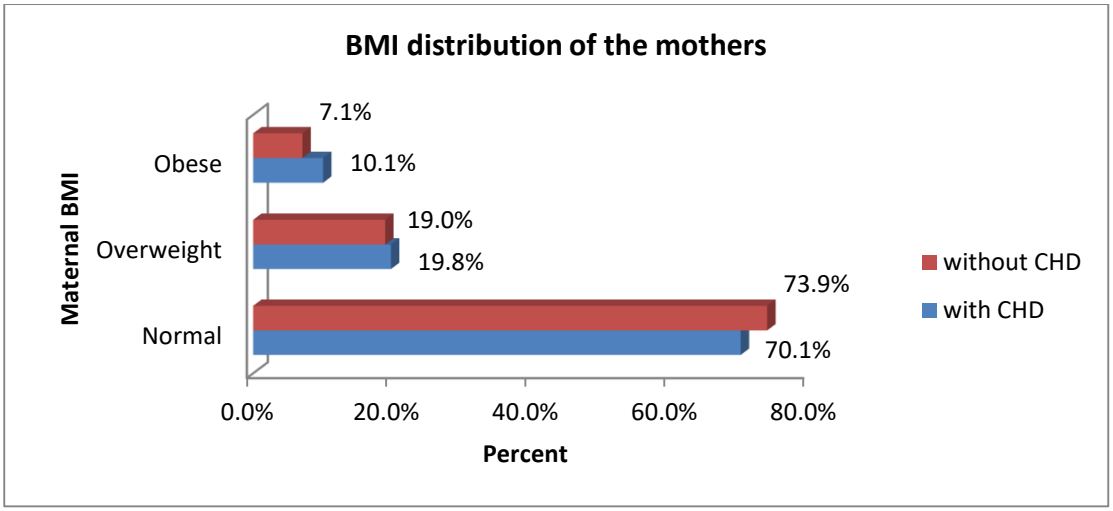


Figure 4.6: BMI distribution of the mothers

Further, a statistically significant association was established between high maternal BMI and CHD among the children ($X^2 = 6.925$, df = 1 and p = 0.008) as shown in Table 4.7. In addition, the odds of CHD among the children were found to be 1.49 times higher among mothers who had a high BMI (overweight or obese) compared to those that had a normal BMI. This implied that maternal BMI was significantly associated with CHD among children at Kenyatta National Hospital.

Table 4.7: Association of maternal BMI with CHD in children

	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
BMI	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**[at 95% CI]**
Normal	1206	1626			1.49
Overweight & Obese	514	574	6.925	.008	[1.28 -1.67]

4.4.3 Nature of Pregnancy and Congenital Heart Disease in Children

Results in Figure 4.7 indicate that majority of the mothers in the CHD group (94.8%, n = 1631) and those in the non-CHD group (96.8%, n = 2129) had singleton pregnancies. However, the number of the mothers with multiple pregnancies was higher in the CHD group (5.2%, n = 89) compared to the non-CHD group (3.2%, n = 71), denoting more prevalence of multifetal pregnancies in the CHD group compared to the non-CHD group.

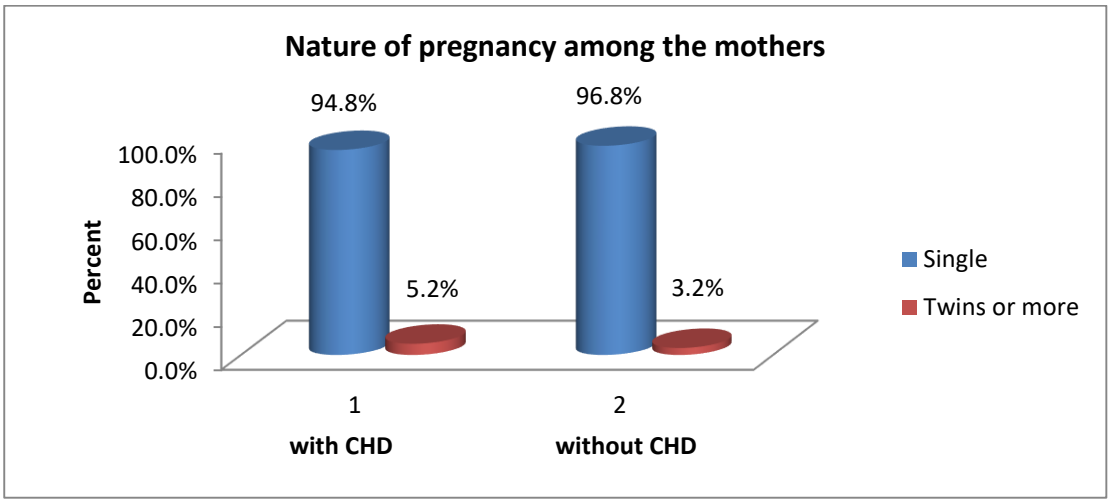


Figure 4.7: Nature of pregnancy among the mothers

In addition, the study established that there was a statistically significant association between multiple pregnancy among the mothers and CHD among the children (X^2 = 9.348, df = 1 and p = 0.002). In addition, the odds of CHD in children were 3.71 times higher among mothers with multiple pregnancies compared to mothers with singleton pregnancy. This implied that multifetal pregnancy among mothers was associated with CHD in children at Kenyatta National Hospital. The results were as shown in Table 4.8.

Table 4.8: Association of nature of pregnancy with CHD in children

	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
Nature of pregnancy	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**[at 95% CI]**
Single	1631	2129			3.71
Multiple	89	71	9.348	.002	[2.98 - 5.16]

4.4.4 Maternal Smoking Status and Congenital Heart Disease in Children

Results indicated that majority (98.7%, n = 1697) of the mothers of children with CHD and majority (98.8%, n = 2174) of the mothers of children without CHD at KNH did not smoke during their pregnancy, denoting low prevalence of smoking among the mothers. This was as shown in Table 4.9.

Table 4.9: Whether the mothers smoked during pregnancy

	Whether the mothers smoked during pregnancy				
	Yes		**No**		
Groups	**Freq.**	**%**	**Freq.**	**%**	**Total (n)**
With CHD	23	1.3	1697	98.7	**1720**
Without CHD	26	1.2	2174	98.8	**2200**

However, the study found no statistically significant association between the mothers' smoking status and CHD among the children (X^2 = .189, df = 1 and p = 0.664). Further, the odds of CHD among the children were 0.76 times lower among mothers who did not smoke during pregnancy compared to those who smoked during their pregnancy.

This implied that maternal smoking status was not significantly associated with CHD among children at Kenyatta National Hospital. The results were as shown in Table 4.10.

Table 4.10: Association of maternal smoking status with CHD in children

Whether the mother smoked during pregnancy	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
	Yes [N = 1720]	No [N = 2200]	X^2	Sig. (p)	[at 95% CI]
Yes	23	26			.76
No	1697	2174	.189	.664	[.68 - .91]

4.4.5 Maternal Alcohol and Substance Use and Congenital Heart Disease in Children

From results, most (88.9%, n = 1529) of the mothers of children with CHD and most (92.1%, n = 2027) of the mothers of children without CHD did not engage in alcohol and substance abuse during their pregnancy. However, it was evident from the results that more of the mothers in the CHD group engaged in alcohol and substance use during pregnancy compared to those in the non-CHD group. This was as depicted in Figure 4.8.

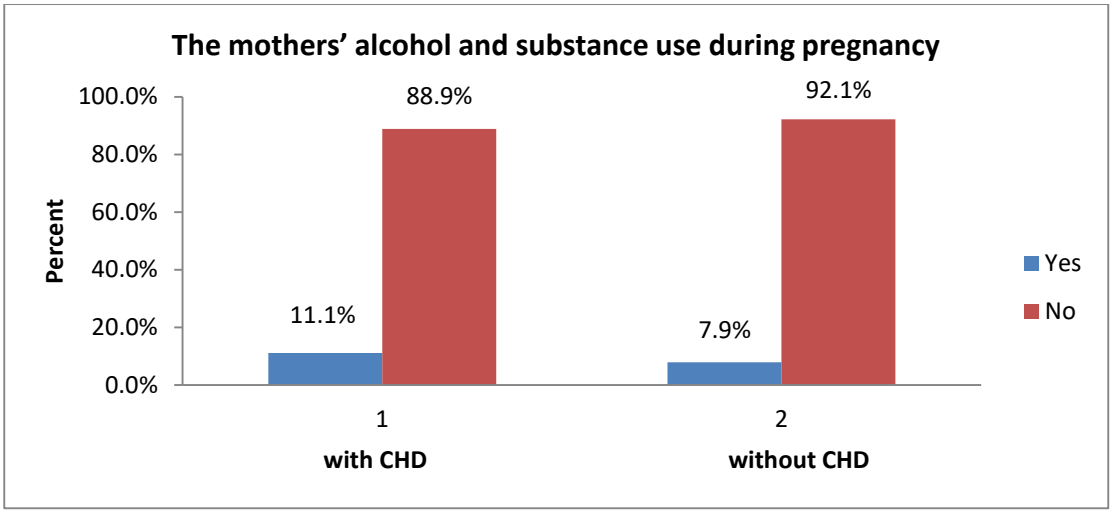


Figure 4.8: The mothers' alcohol and substance use during pregnancy

Further, a statistically significant association was established between the mothers' alcohol and substance use during pregnancy and CHD in children (X^2 = 12.038, df = 1 and p = 0.001). In addition, the odds of CHD in children were 1.94 times higher among mothers who engaged in alcohol and substance use during their pregnancy compared to those who did not. This implied that mothers' alcohol and substance abuse during pregnancy was significantly associated with CHD among children at Kenyatta National Hospital. Table 4.11 contains the results.

Table 4.11: Association of maternal alcohol and substance use during pregnancy with CHD in children

Engaged in alcohol and/or substance use during pregnancy	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
	Yes [N = 1720]	No [N = 2200]	X^2	Sig. (p)	[at 95% CI]
Yes	191	173			1.94
No	1529	2027	12.038	.001	[1.62-3.30]

4.4.6 Access to Prenatal Care and Congenital Heart Disease in Children

Most (93.4%, n = 1607) of the mothers of children with CHD and most (96.2%, n = 2116) of the mothers of children without CHD had access to prenatal care during their pregnancy, denoting that most of the mothers in both groups had access to prenatal care during their pregnancy. Figure 4.9 shows the results.

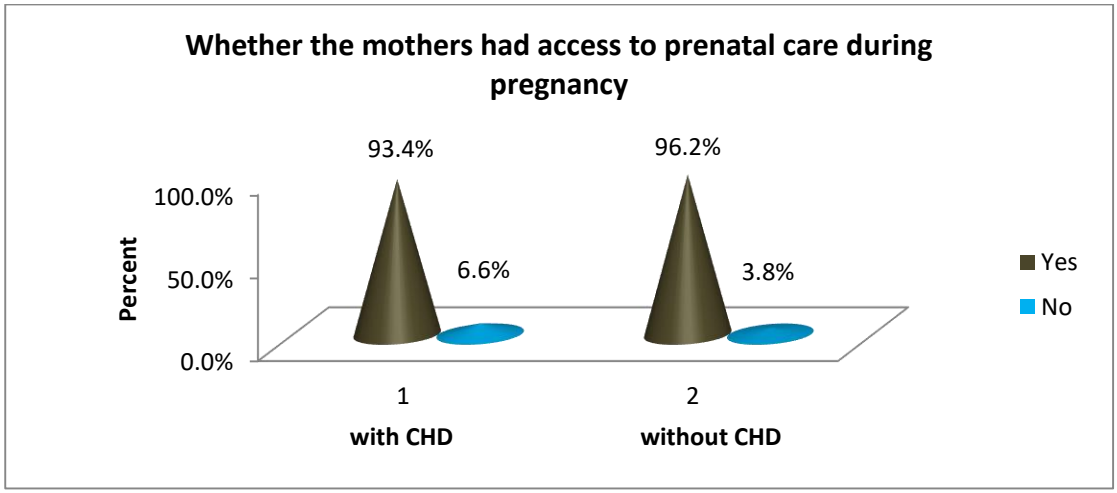


Figure 4.9: Whether the mothers had access to prenatal care during pregnancy

Further, a statistically significant association was established between the mothers' access to prenatal care during pregnancy and CHD in children (X^2 = 15.312, df = 1 and p = 0.000). In addition, the odds of CHD in children were 2.72 times higher among mothers who had no access to prenatal care during their pregnancy compared to those who had access to prenatal care during their pregnancy. This implied that mothers' lack of access to prenatal care during pregnancy was significantly associated with CHD among children at Kenyatta National Hospital. Table 4.12 illustrates the results.

Table 4.12: Association of mothers' access to prenatal care with CHD in children

Had access to prenatal care during pregnancy	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
	Yes [N = 1720]	No [N = 2200]	X^2	Sig. (p)	[at 95% CI]
Yes	1607	2116			2.72
No	113	84	15.312	.000	[1.89 - 4.25]

4.4.7 Maternal Health Conditions during Pregnancy and CHD in children

From the results, 79.6% (n = 1369) of the mothers of children with CHD had no pre-existing health conditions during pregnancy while 93.5% (n = 2056) of the mothers of children with no CHD had no pre-existing health conditions during pregnancy. The results, however, illustrate that the proportion of mothers that had pre-existing health conditions during pregnancy was higher in the CHD group (20.4%, n = 351) compared to the non-CHD group (6.5%, n = 144).

Results also showed that in both groups, the most common pre-existing health conditions that the mothers had during pregnancy included diabetes mellitus, hypertension, urinary tract infections and influenza. Rubella infection was largely less common though it was seen among few mothers in the CHD group. The results were as presented in Table 4.13.

Table 4.13: Whether the mothers had any health conditions during pregnancy

	Whether the mothers had any health conditions during pregnancy				
	Yes		**No**		
Groups	**Freq.**	**%**	**Freq.**	**%**	**Total (n)**
With CHD	351	20.4	1369	79.6	**1720**
Without CHD	144	6.5	2056	93.5	**2200**
Common maternal health conditions documented					
	with CHD (n =351)		**without CHD (n = 144)**		
Health conditions	**Freq.**	**%**	**Freq.**	**%**	
Diabetes mellitus	137	39.0	36	25.0	
Hypertension	79	22.5	31	21.5	
UTIs	50	14.2	46	31.9	
Rubella infection	12	3.4	0	0.0	
Flu (influenza)	64	18.2	24	16.7	
Others	9	2.6	7	4.9	

Further, several of the maternal health conditions were established to have a statistically significant association with CHD among the children at KNH. These included diabetes mellitus (X^2 = 8.706, df = 1 and p = 0.000); hypertension (X^2 = 3.914, df = 1 and p = 0.021) and flu (influenza) (X^2 = 4.173, df = 1 and p = 0.014). However, no statistically significant association was established between urinary tract and rubella infections with CHD among the children.

Further, the odds of CHD in children were 4.18 times higher among mothers that had diabetes mellitus during pregnancy compared to those without the condition. Similarly, the odds of CHD in children were 1.77 times higher among mothers that had hypertension during pregnancy compared to those without the condition. Further, the

odds of CHD in children were 2.09 times higher among mothers that had influenza during pregnancy compared to those without the condition. In addition, the odds of CHD in children were 1.09 and 1.46 times higher among mothers with urinary tract infections and Rubella infection respectively during pregnancy compared to those without these health conditions.

This implied that maternal health conditions of diabetes mellitus, hypertension and influenza during pregnancy were significantly associated with CHD among children at Kenyatta National Hospital. The results were as outlined in Table 4.14.

Table 4.14: Association of maternal health conditions with CHD in children

Maternal health conditions	Chi-sq. p value (95% CI)		Odds ratio value [at 95% CI]
	X^2	Sig. (p)	
Diabetes mellitus	8.706	.000	4.18 [3.35 - 4.67]
Hypertension	3.914	.021	1.77 [1.43 - 2.16]
UTIs	1.019	.218	1.09 [.74 - 1.32]
Rubella infection	.737	.165	1.46 [1.19– 1.71]
Flu (influenza)	4.173	.014	2.09 [1.36 – 3.18]

4.4.8 Maternal Medications Use during Pregnancy and CHD in children

The results indicated that most (66.7%, n = 1147) of the mothers of children with CHD and 70.2% (n = 1544) of the mothers of children with no CHD made no use of medications during pregnancy. The results, however, illustrate that the proportion of mothers that made use of medications during pregnancy was higher in the CHD group

(33.3%, n = 573) compared to the non-CHD group (29.8%, n = 656). Most of the medications used, according to the study results, included antibiotics (amoxicillin, erythromycin), antihypertensive drugs (aldomet, nifedipine) and antidiabetics (insulin injections, metformin). Figure 4.10 illustrates the results.

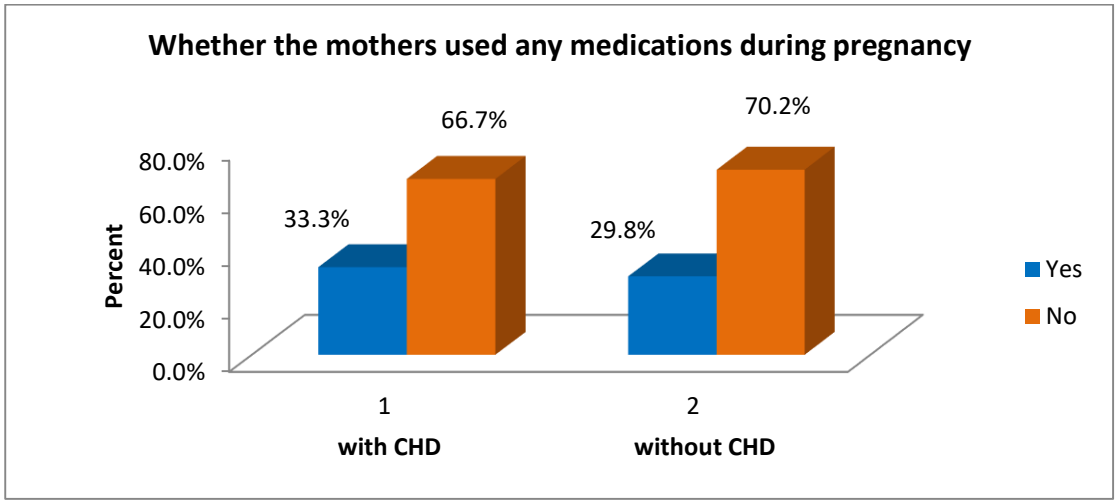


Figure 4.10: Whether the mothers used any medications during pregnancy

Further, maternal use of medications during pregnancy was found to have a statistically significant association with CHD among the children at KNH (X^2 = 5.481, df = 1 and p = 0.019). Further, the odds of CHD in children were 1.66 times higher among mothers that used mediations during pregnancy compared to those that did not use medications during their pregnancy. In respect of the types of drugs used, highest odds of CHD were noted among children whose mothers used antihypertensive drugs (OR = 2.13) and antidiabetics drugs (OR = 1.85) as is shown in Table 4.15. This implied that maternal use of medications during pregnancy was significantly associated with CHD among children at Kenyatta National Hospital.

Table 4.15: Association of maternal use of medications during pregnancy with CHD in children

	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
Used medications during pregnancy	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**[at 95% CI]**
Yes	573	656			1.66
No	1147	1544	5.481	.019	[1.27 - 2.13]
Type of drugs used				**Odds of CHD [at 95% CI]**	
Antibiotics				1.08 [.69 - 1.45]	
Antihypertensive drugs				2.13 [1.36 - 2.70]	
Antidiabetics drugs				1.85[1.41 - 2.29]	

4.4.9 Infants' Down syndrome and Congenital Heart Disease in Children

Results showed that Down Syndrome was uncommon among the children at KNH. However, the proportion of the children with Down Syndrome was notably larger in the CHD group (1.9%, n = 32) compared to the non-CHD group (0.3%, n = 6). This was as depicted in Table 4.16.

Table 4.16: Incidence of Down syndrome among the children

	With CHD [N = 1720]		Without CHD [N = 2200]	
	Freq.	**%**	**Freq.**	**%**
Child has Down Syndrome				
Yes	32	1.9	6	0.3
No	1688	98.1	2194	99.7
Total	**1720**	**100.0**	**2200**	**100.0**

Further, infants' Down Syndrome was found to have a statistically significant association with CHD among the children at KNH (X^2 = 25.349, df = 1 and p <0.000). Further, the odds of CHD in children were 5.87 times higher among infants with Down Syndrome compared to infants that did not have this health condition. This implied that infants Down Syndrome was significantly associated with CHD among the children at Kenyatta National Hospital. Table 4.17 shows the results.

Table 4.17: Association of infants Down Syndrome with CHD in children

	With CHD		**Chi-sq. p value (95% CI)**		**Odds ratio**
Child has Down Syndrome	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**value [at 95% CI]**
Yes	32	6			5.87
No	1688	2194	25.349	< .000	[3.74-7.29]

4.4.10 Family history of CHD and Congenital Heart Disease in Children

The results indicated that of the 1,720 CHD cases, only 2.7% (n = 47) had family history of CHD, as is depicted in Figure 4.11.

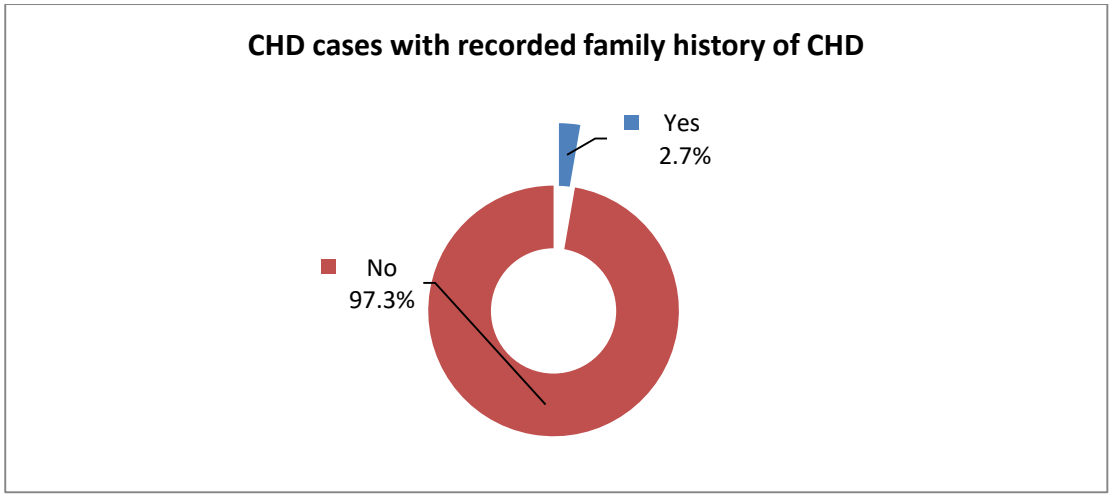


Figure 4.11: Whether there was family history of CHD

Further, a statistically significant association was established between family history of CHD and CHD among the children at KNH (X^2 = 26.08, df = 1 and p = <.000). Further, the odds of CHD in children were 3.24times higher in instances of family history of CHD compared to children where there were no instances of family history of CHD. This implied that family history of CHD was significantly associated with CHD among children at Kenyatta National Hospital. Table 4.18 illustrates the results.

Table 4.18: Association of family history of CHD with CHD in children

	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
Had a family history of CHD	**Yes [N = 1720]**	**No [N = 2200]**	**X^2**	**Sig. (p)**	**[at 95% CI]**
Yes	47	15			3.24
No	1673	2185	26.080	<.000	[2.71-3.63]

4.4.11 Gestational Age and CHD in children

The results indicated that most (84.9%, n = 1461) of the children in the CHD group and 88.8% (n = 1953) of the children in the non-CHD group were born at term.

The results, however, illustrate that the proportion of children born prematurely was higher in the CHD group (15.1%, n = 259) compared to the non-CHD group (11.2%, n = 247). Figure 4.12 illustrates the results.

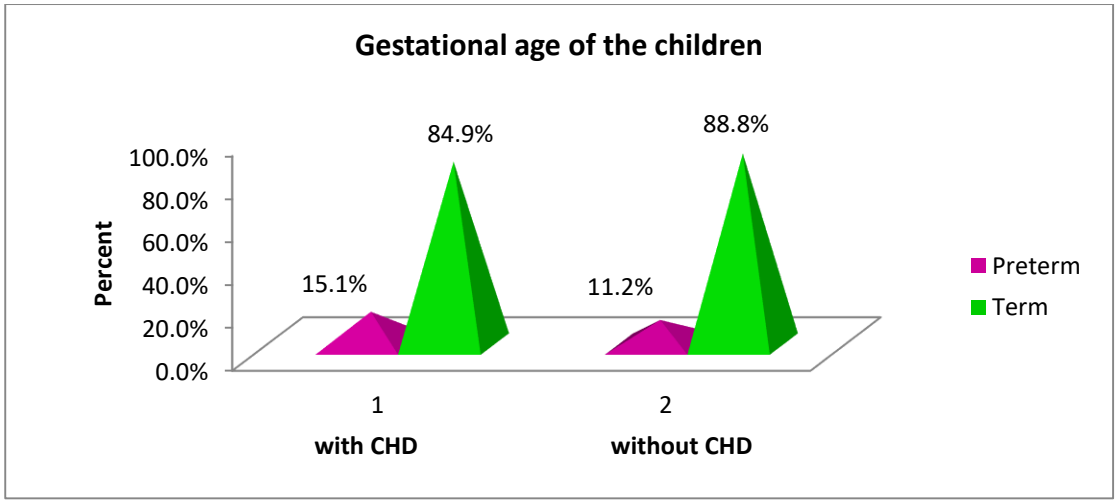


Figure 4.12: Gestational age of the children

Further, a statistically significant association was established between prematurity and CHD among the children at KNH (X^2 = 12.601, df = 1 and p = 0.000). Further, the odds of CHD in children were 2.58 times higher among those born prematurely compared to those that were born at term. This implied that prematurity (preterm births) was significantly associated with CHD among children at Kenyatta National Hospital. The results were as presented in Table 4.19.

Table 4.19: Association of gestational age with CHD in children

Child born prematurely?	With CHD		Chi-sq. p value (95% CI)		Odds ratio value
	Yes [N = 1720]	No [N = 2200]	X^2	Sig. (p)	[at 95% CI]
Yes	259	247			2.58
No	1461	1953	12.601	.000	[2.31- 2.89]

4.4 Treatment Outcomes of Children with CHD during Acute Phase Hospitalization

The third objective of the study sought to determine the treatment outcomes of children aged under 5 years with CHD during acute phase hospitalization at Kenyatta National Hospital.

According to the results, the mortality rate among children in the CHD group was 12.7% (n = 218) while the mortality rate in the non-CHD group was 7.9% (n = 173). It was further noted that mortality in both the CHD group (67.4%, n = 147) and mortality in the non-CHD group (71.7%, n = 124) were higher after infancy. Most of the mortality in the CHD group was attributable to cyanotic CHDs which contributed 70.2% (n=153) of the deaths. This denoted that poor treatment outcomes were higher in children with CHD compared to those with no CHD. The results also pointed to cyanotic CHDs causing more fatality among the under five years olds' compared to the acyanotic CHDs. Table 4.20 illustrates the results.

Table 4.20: Treatment outcomes among the children

Treatment outcomes	With CHD		Without CHD	
	Freq.	**%**	**Freq.**	**%**
Patient died	218	12.7	173	7.9
Patient recovered	1502	87.3	2027	92.1
Total	**1720**	**100.0**	**2200**	**100.0**
For patients that died, period in which they died;	**Freq.**	**%**	**Freq.**	**%**
Died after infancy	147	67.4	124	71.7
Died during infancy	71	32.6	49	28.3
Total	**218**	**100.0**	**173**	**100.0**
Mortality by category of CHD	Acyanotic CHD		65	29.8
	Cyanotic CHD		153	70.2
	Total		**218**	**100.0**

4.5 Association of the Children's Demographic Factors with CHD Type and Treatment Outcomes

The study evaluated the association of the children's demographic factors with CHD type and treatment outcomes.

According to the results, the demographic characteristics of the children found to be significantly and positively associated with cyanotic CHD were a child's age of ≤ 1 year (Chi square p = .000; OR = 2.68) and being diagnosed with CHD during infancy (Chi square p = .000; OR = 2.44). However, the child's gender and schooling status were not found to be associated with the CHD type. These results illustrated that children aged 1 year or less and those diagnosed with CHD during infancy had higher

odds of having cyanotic CHD compared to those aged over 1 year and those diagnosed after infancy. The results are as shown in Table 4.21.

Table 4.20: Association of children's demographic factors with CHD type

Children's demographics		Type of CHD: Acyanotic [N = 1424]	Type of CHD: Cyanotic [N = 274]	Chi-sq. p value (95% CI): X^2	Chi-sq. p value (95% CI): Sig. (p)	Odds ratio value [at 95% CI]
Gender	Male	745	146			1.14
	Female	679	128	2.171	.183	[.57-1.48]
Age	≤ 1 year	239	184			2.68
	> 1 year	1185	90	8.496	.000	[2.21-3.84]
In school	Yes	736	140			1.09
	No	688	134	2.285	.276	[.58-1.20]
Point at which CHD was diagnosed	During infancy	113	189			
	After infancy	1311	85			2.44
				7.047	.000	[2.08-3.72]

Further, according to the results, a statistically significant association was established between poor treatment outcomes (that is, death of a child) and a diagnosis with CHD after infancy (Chi square p = .000; OR = 3.81). However, the child's age, gender and schooling status were not found to be associated with the treatment outcomes. This is as shown in Table 4.22. Therefore, diagnosis of CHD after infancy was significantly associated with poor treatment outcomes among the under-five year olds at KNH.

Table 4.21: Association of children's demographic factors with treatment outcome

Children's demographics		Treatment outcomes: Died [N =218]	Treatment outcomes: Recovered [N = 1502]	Chi-sq. p value (95% CI): X^2	Chi-sq. p value (95% CI): Sig. (p)	Odds ratio value [at 95% CI]
Gender	Male	113	778			1.17
	Female	105	724	1.608	.457	[.85-1.39]
Age	≤ 1 year	128	285			1.04
	> 1 year	90	1217	2.093	.161	[.46-1.26]
In school	Yes	97	779			.74
	No	121	723	1.414	.593	[.39-1.45]
Point at which CHD was diagnosed	After infancy	147	155			
	During infancy	71	1347			3.81
				12.590	.000	[2.73-5.16]

4.6 Association of the Risk Factors of CHD with Treatment Outcomes among the Children at KNH

The study's null hypothesis was that there was no significant association between the type and risk factors of CHD and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital. This was evaluated using Chi-square statistic at 95% confidence level.

From the results, the risk factors of congenital heart disease in children established to have a statistically significant association with poor treatment outcomes among the children included; infants' down syndrome (Chi square p = .000; OR = 4.52) and

prematurity (Chi square p = .007; OR = 2.21). In addition, there was a statistically significant association between poor treatment outcomes among the children and cyanotic CHDs (Chi square p = .018; OR = 3.04) as well as with a CHD diagnosis made after infancy (Chi square p = .018; OR = 1.74).

This showed that various risk factors associated with CHD including infant down syndrome and prematurity, point of CHD diagnosis (in this case, after infancy) as well as the type of CHD (in this case, cyanotic CHDs) were related to poor treatment outcomes of CHD among children aged below 5 years at KNH. The results were as summarized in Table 4.23.

Table 4.23: Association of the risk factors, point of Diagnosis and CHD type with treatment outcomes among the children

	Chi-square		Odds ratio value
Risk factors	**Statistic (X^2)**	**Sig. (p)**	**[at 95% CI]**
CHD diagnosis made after infancy	6.375	.011*	1.74 [1.37 - 2.75]
Infant down syndrome	16.303	.000*	4.52 [3.38 - 5.83]
Prematurity	6.764	.007*	2.21 [1.51- 2.69]
Cyanotic CHDs	5.943	.018*	3.04 [2.44 - 3.57]

* Statistically significant at 0.05 significance level

CHAPTER FIVE: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents discussion of findings, conclusions and recommendations of the study in line with the study objectives. The study evaluated patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital.

5.2 Discussion

5.2.1 Patterns of CHD among the Study Participants

Findings of the study indicated that most of the cases of CHD diagnosed among the study participants were acyanotic while the remaining were cyanotic CHD cases. This agreed with the findings of Abqari et al. (2016), Ekure et al. (2018) and Abdelrahman and Diab (2022) who also noted that acyanotic CHD were more common than cyanotic CHD in surveyed children. Similar observations were also made by Jasim, et al. (2017) and Kshirsagar et al. (2020) where acyanotic cases reported were significantly higher than cyanotic CHD cases in examined children. This showed that the more complex congenital heart defects conditions were less prevalent compared to the less complex ones among children aged below 5 years.

According to the findings, the most prevalent CHD diagnosed were ventricular septal defect, patent ductus arteriosus, atrial septal defect and pulmonary valve stenosis - all of which were acyanotic CHDs. On the other hand, the most occurring cyanotic CHDs included tetralogy of fallot and transposition of the great vessels. This showed that

CHDs diagnosed among the study participants were diverse, with acyanotic congenital heart disease being the most prevalent. Similarly, Namuyonga et al., (2020) did also establish ventricular septal defect patent ductus arteriosus and atrial septal defects as the most commonly diagnosed CHD among children drawn from a tertiary care hospital in Uganda. Similar observations were also made by Abdurrahman and Diab (2022) and Thomford et al. (2020) who in studies conducted in Sudan and Ghana respectively also identified ventricular septal defect (VSD), patent ductus arteriosus, atrial septal defect and pulmonary valve stenosis as the most commonly diagnosed acyanotic CHDs in children while tetralogy of fallot and transposition of the great vessels were the most prevalent forms of cyanotic CHDs diagnosed in children. Similarly, studies by Abah et al. (2018) in Nigeria, Meshram and Gajimwar (2018) in India, Jasim et al. (2017) in Iraq and Pate et al. (2016) in Pakistan also cited ventricular septal defect; atrial septal defect, patent ductus arteriosus, pulmonary valve stenosis, tetralogy of fallot and transposition of the great arteries as common CHD lesions seen in children.

Findings of the study also showed a general upward trend in the patterns of acyanotic and cyanotic CHD cases reported among the under five years olds at Kenyatta National Hospital over the 5-year study period between 2017 and 2021. The increase in acyanotic CHD was higher than the increase in cyanotic CHD during the period. This implied that there was a general increase in CHD cases reported among the under five years olds at KNH over the period. The researcher attributes this to KNH being a leading referral hospital that receives major cases from all other hospitals in the country. The observed upward trend in CHD cases among children was also reported in studies by Jasim et al. (2017), Namuyonga et al. (2020) and Thomford et al. (2020). The researcher attributes

the observed pattern and trend of CHD cases to a growing burden of CHD in low resource countries noted also by Zühlke et al. (2019) and Zimmerman et al. (2020).

Findings of the study identified surgery (or surgical interventions); catheter procedures (or cardiac catheterization), use of medications and oxygen therapy as the leading treatment interventions that were performed for the CHD cases. This denoted that various treatment interventions were used in the care of the CHD patients, with surgical interventions and use of medications being the most prevalent. The findings collaborate with those of Bouma and Mulder (2017) and Jasim et al. (2017) who shared the view that surgical interventions, cardiac catheterization and use of medications remained the leading treatment interventions used in CHD patients. Similarly, Zheleva and Atwood (2017), Tankeu et al. (2017) and Rossano(2020) also noted that surgery remained the leading intervention used to treat pediatric patients with CHD, though use of medications and cardiac catheterization were also prevalent treatment interventions.

Findings of the study also revealed that regular medical care follow-ups, nutrition support, psychosocial support as well as physical activity therapy and ventilatory support constituted the various supportive care services that were offered to the CHD patients at KNH. This showed that the CHD patients were offered several supportive care services. Similar sentiments were also shared by Talargia et al. (2018) and Pate et al. (2016) who also identified regular medical care follow-ups, nutrition support and physical exercise related support as some of the key interventions that were offered to support the treatment and care of children diagnosed with CHD. On their part, Meshram and Gajimwar (2018), Abqari et al. (2016) and Mohammad et al. (2014) did also point

to regular medical care clinics, psychosocial support, nutrition and feeding support, physical activity therapy and ventilatory support as some of the essential supportive care interventions that were offered to children diagnosed with CHD.

According to the study findings, the common kinds of complications reported among the CHD cases included pulmonary hypertension, respiratory tract infections, pulmonary embolism, pulmonary edema and developmental delays. Other complications reported among the CHD cases, albeit in lower incidences, included endocarditis (heart infections), irregular heart rhythms (arrhythmias), heart failure and stroke. This denoted that a significant proportion of the children diagnosed with congenital heart disease at KNH experienced a wide array of serious health complications during the acute hospitalization phase. Cucu and Chifiriuc (2018) and Abah et al. (2018) who also cited pulmonary hypertension, pulmonary embolism, pulmonary edema, developmental delays and arrhythmias as common complications associated with congenital heart disease in children. Similarly, Bouma and Mulder (2017), Ekure et al. (2018) and Kshirsagar et al. (2020) also averred that growth and development impairments, recurrent respiratory tract infections, endocarditis, pulmonary hypertension, heart rhythm problems, heart failure and blood clots which could lead to pulmonary embolism or stroke were common complications associated with congenital heart disease.

Based on this study, some of the documented challenges observed in the care of children with CHD included high cost of treatment, long hospital stays, CHD related health complications, complex medical and surgical care procedures; medication side effects

and low number of multidisciplinary cardiac care specialists. It was thus evident that a wide range of challenges were experienced during care of the CHD patients with high cost of treatment, long duration of hospitalization and CHD related complications being leading challenges. Similar observations were also made by Kumar et al. (2015) and Cucu and Chifiriuc (2018) who argued that the high cost of treatment for CHD, complex medical and surgical care procedures applied in CHD treatment; medication side effects and long patient hospitalization remained leading challenges in the care of patients with CHD, sentiments also echoed by Hewitson and Zilla (2019).

5.2.2 Risk Factors Associated with CHD among the Study Participants

According to the study findings, the children's demographic factors found to have a statistically significant association with more severe forms of CHD (that is, cyanotic CHD) were being aged 1 year or less and diagnosis made during infancy. This study therefore showed that infancy age related with more severe forms of CHD. Similar observations were made by Abqari et al. (2016) and Abah et al. (2018) who also reported higher incidence of more severe forms of CHD among children aged below 1 year compared to their counterparts aged above 1 year old. Similarly, Jivanji et al. (2019) and Faheem et al. (2021) also identified infancy age as a significant predictor of more severe forms of CHD among children aged below 5 years.

This study found no statistically significant association between the mothers' age and CHD among the children (Chi square $p = 0.427$), denoting that maternal age did not significantly contribute to CHD among children at Kenyatta National Hospital. Similarly, in their studies, Faheem et al. (2021), Kapakasi et al. (2021) and Talargia et

al. (2018) also reported that maternal age did not significantly increase the risk of CHD in children. However, in contrast, studies by Ou et al. (2016) and Asbagh et al. (2020) identified higher maternal age (of 35 years and above) as a significant risk factor for CHD in children.

This study established that the CHD group had more mothers who were overweight and obese compared to the non-CHD group. Further, a statistically significant association was established between high maternal BMI and CHD among the children (Chi square $p = 0.008$), denoting that high maternal BMI was significantly associated with CHD among children at Kenyatta National Hospital. The findings concurred with those of Abqari et al. (2016), Asbagh et al. (2020) and Faheem et al. (2021) who also identified high maternal BMI evidenced as either being overweight or obese among mothers as a significant risk factor for CHD in children.

This study observed that the number of the mothers with multiple pregnancies was higher in the CHD group compared to the non-CHD group, denoting more prevalence of multifetal pregnancies in the CHD group compared to the non-CHD group. The study also established that there was a statistically significant association between multiple pregnancy among the mothers and CHD among the children (Chi square $p = 0.002$), implying that multifetal pregnancy among mothers was associated with CHD in children at KNH. Other studies that also identified multifetal pregnancy as being a significant risk factor of congenital heart disease in children included those by Abah et al. (2018), Kumar et al., (2015), Namuyonga et al. (2020) and Abdelrahman and Diab

(2022). In contrast, studies by Ekure, et al. (2018) and Jasim et al. (2017) reported no significant association of multifetal pregnancies with CHD in children.

Although most of the mothers of children with and without CHD did not engage in alcohol and substance abuse during their pregnancy in the current study, it was however evident that more of the mothers in the CHD group engaged in alcohol and substance use during pregnancy compared to those in the non-CHD group. Further, a statistically significant association was established between the mothers' alcohol and substance use during pregnancy and CHD in children (Chi square p = 0.001), implying that mothers' alcohol and substance abuse during pregnancy was significantly associated with CHD among children at KNH. Other studies that also reported maternal alcohol and substance use during pregnancy as being a significant risk factor of CHD in children included those by Kumar et al. (2015), Talargia et al. (2018) and Kapakasi et al. (2021).

Based on this study, a statistically significant association was established between the mothers' access to prenatal care during pregnancy and CHD in children (Chi square p = 0.000). This implied that mothers' lack of access to prenatal care during pregnancywas significantly associated with CHD among children at Kenyatta National Hospital. Bouma and Mulder (2017) shared similar views, citing lack of or low access to prenatal care during pregnancy as one of the factors that greatly contributed to pediatric CHD cases particularly in low resource settings. Similarly, reviews by Asbagh et al. (2020) and Hewitson and Zilla (2019) also shared the viewthat low access to prenatal care services was a significant determinant of CHD incidences particularly in the sub-Saharan Africa region.

Though most of the mothers of children in the CHD and non-CHD groups had no pre-existing health conditions during pregnancy it was however observed that the proportion of mothers that had pre-existing health conditions during pregnancy was higher in the CHD group compared to the non-CHD group. Further, several of the maternal health conditions were established to have a statistically significant association with CHD among the children at KNH. These included; diabetes mellitus, hypertension and flu (influenza). This implied that maternal health conditions of diabetes mellitus, hypertension and influenza during pregnancy were significantly associated with CHD among children at Kenyatta National Hospital. Similar findings were reported by Jivanji et al. (2019), Musa et al. (2017) and Kapakasi et al. (2021) who also identified maternal diabetes mellitus, hypertension and influenza infection during pregnancy as being significant risk factors of CHD in children.

This study also observed that, though most of the mothers of children in the CHD and non-CHD groups made no use of medications during pregnancy, the proportion of mothers that made use of medications during pregnancy was higher in the CHD group compared to the non-CHD group. Further, maternal use of medications during pregnancy was found to have a statistically significant association with CHD among the children at KNH (Chi square $p = 0.019$). This implied that maternal use of medications during pregnancy was significantly associated with CHD among children at KNH. Studies by Kumar et al. (2015), Ou et al. (2016) and Meshram and Gajimwar (2018) also reported existence of a significant association between mothers' use of medications during pregnancy and increased risk of CHD in children. In contrast, Faheem et al. (2021) and Pate et al. (2016) reported that mothers' use of medications

during pregnancy did not significantly increase the risk of their children developing CHD.

Findings showed that Down Syndrome was not common among the children at KNH as only 1.9% of children in the CHD group and 0.3% of those in the non-CHD group had this health condition. However, the proportion of the children with Down Syndrome was notably larger in the CHD group compared to the non-CHD group. Further, infants' Down Syndrome was found to have a statistically significant association with CHD among the children at KNH (Chi square p <0.000), denoting that infants' Down Syndrome was significantly associated with CHD among the children at Kenyatta National Hospital. Down syndrome was also recognized to be significantly associated with CHD in children in studies by Zheleva and Atwood (2017), Rossano (2020) and Thomford et al. (2020).

This study also established a statistically significant association between family history of CHD and CHD among the children at KNH (Chi square p = <.000), implying that family history of CHD was significantly associated with CHD among children at Kenyatta National Hospital. Family history of CHD was also identified as a leading risk factor for CHD in children in studies by Tankeu et al. (2017) and Picarzo et al. (2018). Similarly, Abqari et al. (2016) and Zimmerman et al. (2020) also cited family history of CHD as being a significant predictor of CHD incidences among children.

Findings from this study also showed that, though most of the children in the CHD and non-CHD groups were born at term, the proportion of children born prematurely was higher in the CHD group compared to the non-CHD group. Further, a statistically

significant association was established between prematurity and CHD among the children at KNH (Chi square p = 0.000). This implied that prematurity (preterm births) was significantly associated with CHD among children at Kenyatta National Hospital. Studies by Liu et al. (2019), Kapakasi et al. (2021) and Zheng, G., (2021) also identified prematurity as a leading contributing factor to CHD in children, sentiments also echoed by Abah et al. (2018) and Rossano (2020).

5.2.3 Treatment Outcomes of Children with CHD during Acute Phase Hospitalization

According to the findings, the mortality rate among children in the CHD group was higher than the mortality rate in the non-CHD group. Most of the mortality in the CHD group was attributable to cyanotic CHDs which contributed 70.2% of the deaths. This denoted that poor treatment outcomes were higher in children with CHD compared to those with no CHD. It also pointed to cyanotic CHDs causing more fatality among the under five years olds compared to the acyanotic CHDs. The findings corroborate with those of Meshram and Gajimwar (2018) and Ekure et al. (2018) who also observed notably higher mortality rates among children with congenital heart disease compared to the control group (children without CHD). According to Mubayed and Al-Kindi (2019), CHD is a significant contributor to childhood mortality across the globe. Studies by Musa et al. (2017), Zühlke et al. (2020) and Namuyonga et al. (2020) also reported significantly higher mortality among children with cyanotic CHDs compared to those diagnosed with acyanotic CHDs. Zheleva and Atwood (2017) also shared the view that most of the CHD deaths in children are related to cyanotic congenital heart abnormalities as compared to acyanotic ones with Oster (2013) and Faraoni et al. (2016)

agreeing that cyanotic CHD had greater contribution to CHD childhood mortality than acyanotic CHD. This has been attributed to acyanotic CHD being much more complex and serious heart conditions as compared to the acyanotic CHD category.

Findings of the study also showed that poor treatment outcomes among the under five years olds children at KNH were significantly associated with a diagnosis of CHD being made after infancy. The results showed that mortality of the children as a result of CHD was higher among children diagnosed after infancy compared to those diagnosed during infancy implying that late or delayed diagnosis of CHD in children led to poor treatment outcomes. Studies by Talargia et al. (2018), Rossano (2020) and Wu et al. (2020) affirm these findings that CHD related mortality rates are higher among children diagnosed with CHD later in their life compared to those diagnosed immediately after birth. The researcher attributes this finding to possible late or delayed diagnosis of CHD in the children leading to higher deaths among the children. Late or delayed diagnosis of CHD in children implies that appropriate interventions to remedy the condition are equally delayed making the condition worsen and hence the poorer treatment outcomes among those children diagnosed later on in their life compared to those diagnosed early on.

From the findings, the risk factors of congenital heart disease in children established to have a statistically significant association with poor treatment outcomes among the children included infants' down syndrome and prematurity. In addition, there was also a statistically significant association between cyanotic CHDs and poor treatment outcomes among the children. This showed that various risk factors of CHD were also significant determinants of poor treatment outcomes of CHD among children at KNH.

The findings were in agreement with those of Faraoni et al. (2016) and Asbagh et al. (2020) who also established infants' down syndrome and prematurity as risk factors of CHD in children that also related to poor treatment outcomes among children diagnosed with CHD. Similarly, in studies performed by Ekure et al. (2018), Mandalenakis et al. (2020) and Zheng et al. (2021), poor treatment outcomes among children diagnosed with CHD were significantly associated with a child being born prematurely. The findings also corroborated those of Rosengren et al. (2017), Picarzo et al. (2018) and Mubayed and Al-Kindi (2019) who also identified infants' down syndrome and prematurity as significant predictors of poor treatment outcomes among children with CHD. In studies by Oster (2013), Zühlke et al. (2020) and Namuyonga et al. (2020) cyanotic type of CHD was also found to significantly correlate with higher poor treatment outcomes among children compared to acyanotic types of CHD.

5.3 Conclusions

Based on the findings of the study, the researcher drew the following conclusions:

1. There is an increasing trend of prevalence of the CHD defects in children in KNH over the five-year period. Acyanotic CHD was more prevalent among the under five years olds at KNH than cyanotic CHD. The most prevalent acyanotic CHDs among the study participants were ventricular and atrial septal defects, patent ductus arteriosus and pulmonary valve stenosis while tetralogy of fallot and transposition of the great vessels led in the category of cyanotic CHDs.
2. High maternal BMI, multifetal pregnancy, maternal alcohol and substance abuse during pregnancy, lack of access to prenatal care during pregnancy,

maternal diabetes mellitus, hypertension and/or influenza during pregnancy, maternal use of medications during pregnancy, Infants Down syndrome, family history of CHD and prematurity were the risk factors significantly associated with CHD among the under five years olds at Kenyatta National Hospital.

3. Children with cyanotic congenital heart disease, on average, had 3 times higher odds of dying from CHD compared to those with acyanotic CHD. Children with CHD had 1.5 times higher odds of dying compared to their non-CHD counterparts.
4. Infants' Down syndrome and prematurity were the risk factors related to poor treatment outcomes of CHD among children admitted at KNH. Congenital heart disease cases with infant down syndrome had 4.52 higher odds of poor treatment outcome while CHD cases born prematurely had 2.21 higher odds of poor treatment outcome.

5.4 Recommendations

1. Evaluation of factors associated with the increasing trends and patterns of CHD among children at KNH
2. Sensitization of staff to enhance diagnosis of the CHD defects, since most of them are acyanotic, which lack obvious signs and symptoms.
3. The antenatal clinic staff should carry out risk stratification to identify the most common predisposing factors, for ease of identification, monitoring and management among pregnant women.

4. Improve capacity to manage children with acyanotic CHD so as to reduce mortality with greater focus on children with infant's Down syndrome and prematurity.

5.4.2 Recommendations for Further Studies

There is need for a prospective study to evaluate both acute and long-term care and outcomes of children with CHD at Kenyatta National Hospital.

REFERENCES

Abah, R. O., Ochoga, M. O., Audu, O. P., Idoko, A., Eseigbe, E. E., &Dabit, J. O. (2018). Pattern of cardiac diseases among children in a tertiary hospital in North Central, Nigeria: A three and half year's retrospective cohort echocardiographic study. *Nigerian Journal of Paediatrics*, *45*(1), 6-9.

Abdelrahman, O., & Diab, R. (2022). Prevalence and Pattern of Congenital Heart Disease Among Children in Khartoum State, Sudan: A Reflection of the Current Cardiac Profile. *Cureus*, *14*(1), e21196.

Abqari, S., Gupta, A., Shahab, T., Rabbani, M. U., Ali, S. M., & Firdaus, U. (2016). Profile and risk factors for congenital heart defects: A study in a tertiary care hospital. *Annals of pediatric cardiology*, *9*(3), 216-221.

Asbagh, P. A., Rabbani, A., Vafaei, N., Rastegar, S. M., Moghadam, E. A., Hojati, V., ... &Mohebbi, A. (2020). Prevalence of Factors Associated with Congenital Heart Disease. *Multidisciplinary Cardiovascular Annals*, *12*(1), e106026.

Bouma, B. J., & Mulder, B. J. (2017). Changing landscape of congenital heart disease. *Circulation research*, *120*(6), 908-922.

Cucu, I. A., &Chifiriuc, M. C. (2018). Congenital Heart Disease: Global Burden and Challenges to Eliminate Health Disparities. *Ann Public Health Reports*, *2*(1), 26-9.

Ekure, E. N., Kalu, N., Sokunbi, O. J., Kruszka, P., Olusegun-Joseph, A. D., Ikebudu, D., ... & Adeyemo, A. (2018). Clinical epidemiology of congenital heart disease in Nigerian children, 2012–2017. *Birth Defects Research*, *110*(16), 1233-1240.

Faheem, H., Jalil, F., Hashmi, S., Jumani, M. I., Imdad, A., Jabeen, M., ... &Atiq, M. (2021). Risk factors predisposing to congenital heart defects. *Annals of pediatric cardiology*, *4*(2), 117-121.

Faraoni, D., Zurakowski, D., Vo, D., Goobie, S. M., Yuki, K., Brown, M. L., &DiNardo, J. A. (2016). Post-operative outcomes in children with and without congenital heart disease undergoing non cardiac surgery. *Journal of the American College of Cardiology*, *67*(7), 793-801.

Hewitson, J., &Zilla, P. (2019). Children's heart disease in sub-Saharan Africa: Challenging the burden of disease. *SA Heart*, *7*(1), 18-29.

Hoffman, J. I. (2013). The global burden of congenital heart disease. *Cardiovascular journal of Africa*, *24*(4), 141-145.

Jasim, A., Hussein, A., & Abbas, K.E. (2017). Patterns of congenital heart diseases in children under five years in Karbala city, Iraq. *Journal of Kerbala University*, *15*(4), 182-195.

Jivanji, S. G., Lubega, S., Reel, B., & Qureshi, S. A. (2019). Congenital heart disease in East Africa. *Frontiers in pediatrics*, *7*, 250.

Kapakasi, G. K., Mawa, R., Namuyonga, J., & Lubega, S. (2021). Factors Associated with Congenital Heart Diseases Among Children in Uganda: A Case-Control Study at Mulago National Referral Hospital (Uganda Heart Institute). *Cardiology and Cardiovascular Research*, *5*(1), 1-6.

KNH Cardiac Care Unit (2021). *CHD case reports in KNH's pediatric unit - internal reports*. KNH Publication

Kshirsagar, V. Y., Mohite, R. V., &Erram, M. (2020). Pattern and Clinical Profile of Congenital Heart Disease (CHD) in Infancy and Childhood. *Journal of Cardiovascular Disease Research*, *11*(2), 232-236.

Kumar, A., Gupta, R., Kumar, P., & Sharma, M. (2015). An assessment of risk factors for congenital heart diseases in children of age group 0-10 years: a case control study. *Journal of Evolution of Medical and Dental Sciences*, *4*(26), 4442-4448.

Liu, Y., Chen, S., Zühlke, L., Black, G. C., Choy, M. K., Li, N., &Keavney, B. D. (2019). Global birth prevalence of congenital heart defects 1970–2017: updated systematic review and meta-analysis of 260 studies. *International journal of epidemiology*, *48*(2), 455-463.

Mandalenakis, Z., Giang, K. W., Eriksson, P., Liden, H., Synnergren, M., Wåhlander, H., ... &Dellborg, M. (2020). Survival in children with congenital heart disease: have we reached a peak at 97%? *Journal of the American Heart Association*, *9*(22), e017704.

Meshram, R. M., &Gajimwar, V. S. (2018). Prevalence, profile, and pattern of congenital heart disease in Central India: A prospective, observational study. *Nigerian Journal of Cardiology*, *15*(1), 45-49.

Mohammad, N., Shaikh, S., Memon, S., & Das, H. (2014). Spectrum of heart disease in children under 5 years of age at Liaquat University Hospital, Hyderabad, Pakistan. *Indian heart journal*, *66*(1), 145-149.

Mubayed, L., & Al-Kindi, S. (2019). Recent Trends in Infant Mortality due to Congenital Heart Disease in the United States. *Pediatrics*, *144*(2), 344-350.

Musa, N. L., Hjortdal, V., Zheleva, B., Murni, I. K., Sano, S., Schwartz, S., &Staveski, S. L. (2017). The global burden of paediatric heart disease. *Cardiology in the Young*, *27*(S6), S3-S8.

Namuyonga, J., Lubega, S., Aliku, T., Omagino, J., Sable, C., &Lwabi, P. (2020). Pattern of congenital heart disease among children presenting to the Uganda Heart Institute, Mulago Hospital: a 7-year review. *African health sciences*, *20*(2), 745-752.

Oster, M. E., Lee, K. A., Honein, M. A., Riehle-Colarusso, T., Shin, M., & Correa, A. (2013). Temporal trends in survival among infants with critical congenital heart defects. *Pediatrics*, *131*(5), e1502-e1508.

Ou, Y., Mai, J., Zhuang, J., Liu, X., Wu, Y., Gao, X., ... & Lin, S. (2016). Risk factors of different congenital heart defects in Guangdong, China. *Pediatric research*, *79*(4), 549-558.

Pate, N., Jawed, S., Nigar, N., Junaid, F., Wadood, A. A., & Abdullah, F. (2016). Frequency and pattern of congenital heart defects in a tertiary care cardiac hospital of Karachi. *Pakistan Journal of Medical Sciences*, *32*(1), 79-84.

Picarzo, J. P. L., González, M. M., Zamalloa, P. L., & Marcos, D. C. (2018). Congenital heart disease mortality in Spain during a 10 year period (2003–2012). *Anales de Pediatría (English Edition)*, *88*(5), 273-279.

Rosengren, A., Mandalenakis, Z., Skoglund, K., Lappas, G., Eriksson, P., &Dellborg, M. (2017). Survivorship in children and young adults with congenital heart disease in Sweden. *JAMA internal medicine*, *177*(2), 224-230.

Rossano, J. W. (2020). Congenital heart disease: a global public health concern. *The Lancet Child & Adolescent Health*, *4*(3), 168-169.

Rossouw, B. (2021). Congenital heart disease in Africa threatens Sustainable Development Goals. *Southern African Journal of Critical Care*, *37*(1), 8-9.

Saxena, A. (2019). Status of pediatric cardiac care in developing countries. *Children*, *6*(2), 34-38.

Talargia, F., Seyoum, G., &Moges, T. (2018). Congenital heart defects and associated factors in children with congenital anomalies. *Ethiopian Medical Journal*, *56*(4), 335-42.

Tankeu, A. T., Bigna, J. J. R., Nansseu, J. R. N., Aminde, L. N., Danwang, C., Temgoua, M. N., &Noubiap, J. J. N. (2017). Prevalence and patterns of congenital heart

diseases in Africa: a systematic review and meta-analysis protocol. *BMJ open*, *7*(2), e015633.

Thomford, N. E., Biney, R. P., Okai, E., Anyanful, A., Nsiah, P., Frimpong, P. G., ... &Wonkam, A. (2020). Clinical Spectrum of congenital heart defects (CHD) detected at the child health Clinic in a Tertiary Health Facility in Ghana: a retrospective analysis. *Journal of Congenital Cardiology*, *4*(1), 1-11.

WHO (2021). *Congenital heart defects*. Geneva: WHO Reports.

WHO (2021). *Cardiovascular diseases (CVDs) - Fact sheets*. Geneva: WHO Reports.

Wu, W., He, J., & Shao, X. (2020). Incidence and mortality trend of congenital heart disease at the global, regional, and national level, 1990–2017. *Medicine*, *99*(23).

Zheleva, B., & Atwood, J. B. (2017). The invisible child: childhood heart disease in global health. *The Lancet*, *389*(10064), 16-18.

Zheng, G., Wu, J., Chen, P., Hu, Y., Zhang, H., Wang, J., ... & Zhuang, J. (2021). Characteristics of in-hospital mortality of congenital heart disease (CHD) after surgical treatment in children from 2005 to 2017: a single-center experience. *BMC pediatrics*, *21*(1), 1-8.

Zimmerman, M., & Sable, C. (2020, March). Congenital heart disease in low-and-middle-income countries: Focus on sub-Saharan Africa. In *American Journal of Medical Genetics Part C: Seminars in Medical Genetics* (Vol. 184, No. 1, pp. 36-46). Hoboken, USA: John Wiley & Sons, Inc...

Zimmerman, M. S., Smith, A. G. C., Sable, C. A., Echko, M. M., Wilner, L. B., Olsen, H. E., ... &Kassebaum, N. J. (2020). Global, regional, and national burden of congenital heart disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet Child & Adolescent Health*, *4*(3), 185-200.

Zühlke, L., Lawrenson, J., Comitis, G., De Decker, R., Brooks, A., Fourie, B., ...& Hugo-Hamman, C. (2019). Congenital heart disease in low-and lower-middle–income countries: current status and new opportunities. *Current cardiology reports*, *21*(12), 1-13.

APPENDICES

Appendix 1: Introduction Letter

Sheila Nyabisi Aiko,

P.O. Box 5856-30100,

Eldoret.

Cell: 0729 786 408

7th March 2022.

To The Director,

Kenyatta National Hospital,

Nairobi.

Dear Sir/Madam,

RE: <u>Authority To Carry Out A Research Study at KNH</u>

I am Sheila Nyabisi Aiko, a student at the Department of Nursing Sciences, Faculty of Health Sciences - University of Nairobi, Registration Number: H56/37717/2020. I am undertaking Master of Science in Nursing (Pediatrics) studies at the university. I am undertaking a research study on, "patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital", as a requirement in partial fulfillment for the award of the said degree.

I hereby request for your permission to conduct data collection within the Records Department/pediatric unit registry, from the health records of children aged below 5 years with and without CHD running from January 1, 2017to December 31, 2021.

Attached, find the copy of ERC approval letter. Thank you.

Yours faithfully,

Sheila Nyabisi Aiko.

Appendix 2: Data Abstraction Form

Patient's demographic characteristics				
Gender	Male [ ]		Female [ ]	
Age (in months or years)				
Birthweight				
Whether schooling?	Yes [ ]		No [ ]	
Point at which the CHD was diagnosed	Before Birth	At birth	Neonatal phase	Infancy phase

Patterns of CHD	
[Mark the type/kind of CHD diagnosed]	
List of CHD types	**[Tick here]**
Tetralogy of Fallot	
Transposition of the great vessels/arteries	
Truncus arteriosus	
Hypoplastic left heart syndrome	
Tricuspid valve abnormalities	
Aortic valve abnormalities	
Pulmonary atresia	
Total anomalous pulmonary venous return	
Ebstein anomaly	
Ventricular septal defect	

Atrial septal defect		
Atrioventricular septal defect		
Patent ductus arteriosus		
Pulmonary valve stenosis		
Aortic valve stenosis		
Coarctation or complete interruption of the aorta		
Any other (specify) …… ……		
Other attributes		
Type of surgical intervention performed		
Kind of supportive care received by the patient		
Nature of complications (if any)		
Documented challenges observed during patient care		
Factors associated with CHD (Mark as appropriate)		
Maternal age at conception (in years)		
Maternal BMI during pregnancy		
Whether the pregnancy was multifetal gestation?	Yes	
	No	
If yes, type of multifetal pregnancy?	Twins	
	Triplets	

	Other	
Whether the mother smoked during pregnancy?	Yes	
	No	
If yes, indicate quantity & frequency?		
Whether the mother drank/used alcohol during pregnancy?	Yes	
	No	
If yes, indicate quantity & frequency?		
Whether the mother engaged in other substance abuse during pregnancy?	Yes	
	No	
If yes, indicate quantity & frequency?		
Whether the mother had access to prenatal care during pregnancy?	Yes	
	No	
If Yes, care accessed?		
Whether the mother had any health conditions during pregnancy?	Yes	
	No	
If yes, type of health condition?	Diabetes mellitus	
	Hypertension	
	UTI	
	Rubella infection	
Others (specify) …….		
Whether the mother was using any kind of medications during pregnancy?	Yes	
	No	

If yes, which kind of medication?		
Mother has children with Down syndrome	Yes	
	No	
Family history of CHD	Yes	
	No	
Child born at term	Yes	
	No	
If preterm, indicate gestational age at birth		
Patient's treatment outcomes		
Positive outcome (patient discharged or referred back to another facility for recovery)		
Poor outcome (patient died)		

End

Appendix 3: Letter to KNH-UoN Ethics and Research Committee

Sheila Nyabisi Aiko,
Reg. No. H56/37717/2020,
Department of Nursing Sciences,
Faculty of Health Sciences,
University of Nairobi.

The Secretary,
KNH/UoN - Ethics and Research Committee,
P.O. Box 20723-00202,
Nairobi.

Dear Sir/Madam,

RE: <u>Review of my Research Protocol entitled 'patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital'</u>

My name is Sheila Nyabisi Aiko, a master's studentattheUniversityofNairobi'sDepartmentofNursingSciencesundertakingaMaster of Science in Nursing degree in Pediatrics. I am hereby requesting for your review and approval of my research protocol entitled "patterns and risk factors of congenital heart disease and treatment outcomes during acute phase hospitalization among children aged under 5 years at Kenyatta National Hospital", as a requirement in partial fulfillment of the award of the degree of Masters of Science in Nursing.

Thank you in advance

Yours faithfully,

Sheila Nyabisi Aiko.

Appendix 4: Approval Letter from KNH-UoN Ethics and Research Committee

UNIVERSITY OF NAIROBI
FACULTY 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/226

15th June, 2022

Sheila Nyabisi Aiko
Reg. No. H56/37717/2020
Dept. of Nursing Sciences
Faculty of Health Sciences
University of Nairobi

Dear Sheila,

RESEARCH PROPOSAL: PATTERNS AND RISK FACTORS OF CONGENITAL HEART DISEASE AND TREATMENT OUTCOMES DURING ACUTE PHASE HOSPITALIZATION AMONG CHILDREN AGED UNDER 5 YEARS AT KENYATTA NATIONAL HOSPITAL (P210/03/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P210/03/2022.** The approval period is 15th June 2022 – 14th June 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept., KNH
The Chair, Dept. of Nursing Sciences, UoN
Supervisors: Dr. Angeline Kirui, Dept. of Nursing Sciences, UoN
Ms. Hannah Inyama, Dept. of Nursing Sciences, UoN

Appendix 5: Approval Letter from Kenyatta National Hospital

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
   SHEILA NYABISI AIKO
2. Email address: sheilanyabisi@students.uonbi.ac.ke Tel No. 0729786408
3. Contact person (if different from PI) —
4. Email address: — Tel No. —
5. Study Title
   PATTERNS AND RISK FACTORS OF CONGENITAL HEART DISEASE AND TREATMENT OUTCOMES DURING ACUTE PHASE HOSPITALIZATION AMONG CHILDREN AGED UNDER 5 YEARS AT KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted CARDIOLOGY
   (Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR MARTIN NJUGUNA Signature ..... Date 23/06/2022
8. KNH UoN Ethics Research Committee approved study number P210/03/2022
   (Please attach copy of ERC approval)
9. I SHEILA NYABISI AIKO commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.
   Signature ..... Date 23/06/2022
10. Study Registration number (Dept/Number/Year) Cardio/[illegible]/24/2022
    (To be completed by Medical Research Department)
11. Research and Program Stamp

RECEIVED 23 JUN

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

Appendix 6: Research Permit from NACOSTI

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **950364**

Date of Issue: **27/September/2022**

RESEARCH LICENSE

This is to Certify that Miss.. Sheila Nyabisi Aiko of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: PATTERNS AND RISK FACTORS OF CONGENITAL HEART DISEASE AND TREATMENT OUTCOMES DURING ACUTE PHASE HOSPITALIZATION AMONG CHILDREN AGED UNDER 5 YEARS AT KENYATTA NATIONAL HOSPITAL for the period ending : 27/September/2023.

License No: **NACOSTI/P/22/20343**

950364

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014

CONDITIONS

1. The License is valid for the proposed research, location and specified period
2. The License any rights thereunder are non-transferable
3. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research
4. Excavation, filming and collection of specimens are subject to further necessary clearence from relevant Government Agencies
5. The License does not give authority to tranfer research materials
6. NACOSTI may monitor and evaluate the licensed research project
7. The Licensee shall submit one hard copy and upload a soft copy of their final report (thesis) within one year of completion of the research
8. NACOSTI reserves the right to modify the conditions of the License including cancellation without prior notice

National Commission for Science, Technology and Innovation
off Waiyaki Way, Upper Kabete,
P. O. Box 30623, 00100 Nairobi, KENYA
Land line: 020 4007000, 020 2241349, 020 3310571, 020 8001077
Mobile: 0713 788 787 / 0735 404 245
E-mail: dg@nacosti.go.ke / registry@nacosti.go.ke
Website: www.nacosti.go.ke

Appendix 7: Ghantt Chart

Activity	2022									
	Feb	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**
Development of the concept										
Proposal writing and presentation										
Submitting the proposal to ERC										
Pretesting the study tool										
Collecting the study data										
Data analysis, report writing and corrections										

Defense of the project										

Appendix 8: Budget

Component	Description	Item	Quantity	Unit Cost (Ksh)	Total (Ksh)
Literature Review	Literature search	Airtime Internet	6 Months 6 Months	1,000/Month 2,500/Month	6,000 15,000
	Stationery	Laptop	1	60,000	60,000
		External Hard Disc	1	7,000	7,000
		Pens, Pencils, Eraser, Folders	10	@ 100	1,000
Proposal	Related costs	Plain paper Printing Photocopying Binding	2 reams 1 Draft 2 Drafts 3 Drafts	@650 @750 @250 @100	1,300 750 500 300
Approval	KNH Data ERC		1 1	@500 @ 2,000	500 2,000
Research Phase	Pretesting of questionnaire	Printing	245	@ 20	4,900
	Study tool	Printing, photocopy	4,900	@9	44,100
	Data collection	Research Assistants	2	@ 15,000	30,000
	Data Processing and analysis	Statistician	1	@ 40,000	40,000
Report Phase	Final Report	Printing Photocopying	1 copy 4 copies	@ 1,000 @ 500	1,000 2,000

		Binding	5 copies	@ 100	500
Publishing					30,000
Sub Total					**246,850**
Contingencies	10% of sub-totals				**24,685**
Grand Total					**271,535**

Source of funding – Self

Appendix 9: Map of the Study Area