PREVALENCE AND FACTORS ASSOCIATED WITH DELAYED DIAGNOSIS OF CONGENITAL HEART DISEASE AT KENYATTA NATIONAL HOSPITAL.

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DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other university.

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SUPERVISORS' APPROVAL

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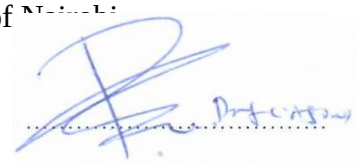
Signature:  **Date:** 30th June, 2023

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LIST OF ABBREVIATIONS

ASD- Atrial Septal Defect

AVSD- Atrio-Ventricular Septal Defect

CCHD- Critical Congenital Heart Disease

CHD- Congenital Heart Disease

KES- Kenyan shillings

LMIC- Low- and Middle-income countries

NHIF- National Hospital Insurance Fund

PDA-Patent Ductus Arteriosus

PV- Pulmonary Valve

UHC- Universal Health Coverage

VSD- Ventricular Septal Defect

WHO- World Health Organization

DEFINITION OF TERMS

Critical congenital heart disease- these are severe and life-threatening heart defects that require surgical intervention or catheterization within the first year of life.

Cyanosis- pathological condition in which the skin and mucus membranes have a bluish discoloration.

Acyanosis- Lack of the bluish discoloration of mucus membranes.

Case definitions:

I. Delayed diagnosis will be defined as a cyanotic congenital heart disease diagnosed after one week of life and acyanotic congenital heart disease diagnosed after 3 months.

II. Delayed referral will be defined as no execution of referral 2 days after referral recommendation

III. Socioeconomic status-Poverty will be defined as household income below minimum wage in Kenya which is Ksh 13,500(1).

IV. Parental literacy level- Illiteracy will be defined as inability to read or write or understand simple written text in any language (2). We will also evaluate the level of education, which will be described as none, primary school level, secondary school level and tertiary level.

V. Cultural and spiritual beliefs- This will be defined as any values shared amongst a group of people that may hinder seeking medical advice first including: seeking spiritual guidance, giving traditional medication or performing rituals, waiting for consent to go to hospital or for medical or surgical intervention(3).

ABSTRACT

Congenital heart diseases are malformations of the heart and cardiovascular system that are present from birth and are associated with or without cyanosis. They are the most common congenital abnormality with an incidence of 8:1000. Without timely diagnosis and intervention, Critical congenital heart disease (CCHD) has an associated overall 30% mortality, with 50% occurring within the first year of life in LMIC. Delayed diagnosis is defined as cyanotic heart disease diagnosed after the first week of life and acyanotic heart disease diagnosed after 3 months. Late diagnosis leads to late intervention resulting in a high morbidity and mortality.

The purpose of study: To assess the prevalence and factors associated with delayed diagnosis of CHD at Kenyatta National hospital.

Methodology: This was a cross-sectional study carried out in KNH in the children with CHD. Consecutive sampling was done until the desired sample size of 257 was attained. Relevant demographic information was obtained via a structured and detailed questionnaire. Binary logistic regression was conducted to investigate factors associated with delayed diagnosis. Further analysis was done using both descriptive and inferential analysis.

Results: In the total population of 257 children with CHD, 222 had delayed diagnosis giving a prevalence 86.4%. 65.9% were under 5 years, 55.6% were female and 75.3% were referred. On multivariable analysis monthly income of less than Ksh.13, 500, no murmurs and referrals were independently associated with delayed diagnosis.

Conclusion and recommendations

86.4% of patients with CHD were diagnosed late. Factors associated with delayed diagnosis were female gender, birth weight of >1.8kgs, children of multiparous mothers. A monthly income of less than Ksh.13, 500, no murmurs and referrals were independently associated with delayed diagnosis.

Community screening and awareness of CHD, early referrals would reduce the delay in diagnosis of CHD.

SECTION ONE

1.0.INTRODUCTION AND LITERATURE REVIEW

Background

Congenital heart diseases are malformations of the heart and cardiovascular system that are present from birth. They are the most common congenital abnormalities, with an incidence of 1% and a prevalence of 5-11 %(4). CHD is the second leading cause of mortality within the first year of life and accounts for approximately 20% of prenatal deaths (5). 28% of all major congenital anomalies are heart defects (6). Majority of congenital heart defects diagnosed late are located in low- and middle-income countries (7). Without intervention, CCHD has an associated 30% mortality and a further 50% within the first year of life in developing countries (8). The prevalence of CHD in the developing world is inferred from data from other countries. There is deficiency of local data highlighting the burden of CHD and delayed diagnosis of CHD in Kenya, leading to a lack of prioritization of specialized cardiac services(9).

CHD can be broadly classified as cyanotic and acyanotic lesions. Cardiac causes of cyanosis can be classified as either ductal- dependent or ductal-independent lesions. Ductal-dependent lesions are those that depend on the ductus arteriosus for adequate pulmonary circulation. Ductal-independent lesions are those that result in pulmonary and systemic blood mixing. Mixing of oxygenated and deoxygenated blood occurs through a shunt (10).

25% of all cyanotic CHD are categorized as Critical Congenital heart diseases and these are severe, life-threatening heart defects that require surgical intervention or cardiac catheterization within the first year of life (11), failure to which it results in mortality or significant morbidity.

Table 1: Classification of CHD (12)

CYANOTIC HEART DISEASE	**ACYANOTIC HEART DISEASE**
Decreased pulmonary flow Tetralogy of Fallot Tricuspid Atresia	Left-Right shunt lesions VSD ASD AVSD, PDA
Increased Pulmonary flow	**Obstructive lesions**
Transposition of great arteries Total anomalous pulmonary venous return	Aortic stenosis Coarctation of the aorta, PV stenosis

Identifying congenital cardiac lesions may pose a challenge if keen examination isn't carried out. Less than 50% of congenital heart diseases are identified during neonatal screening; 69% being identified with pulse-oximetry and only 31% by clinical examination (13). Pulse oximetry has a high specificity and a low rate of false positive hence should be incorporated in screening CHD. Once a congenital heart disease is suspected, the preferred diagnostic tool is an echocardiogram done by a highly skilled medical practitioner and in our setting these are paediatric cardiologists. An echocardiogram is a highly specific and sensitive tool in diagnosing CHD(14).

Delayed diagnosis is when a cyanotic CHD is diagnosed after discharge from the delivery hospital or acyanotic CHD diagnosed when cardiac surgery should have already been carried

out (15) (16). This is a significant problem in that delayed diagnosis is associated with significant morbidity and mortality (17) (18). For the purpose of this study, delayed diagnosis will be defined as cyanotic heart disease diagnosed after the first week of life and acyanotic heart disease diagnosed after 3 months.

Kenya being a developing country, basic healthcare isn't accessible to all (19). According to WHO, 90% of children in LMIC have suboptimal or no access to care (20). Specialized cardiac care is therefore not a privilege that many can afford. Majority of Kenyans do not have medical insurance (21). However, with the commencement of NHIF (22) and UHC, specialized care is now becoming more within reach of some of the population (19).

Kenyatta National hospital is the largest referral hospital in Kenya and is the only government hospital where majority of the paediatric cardiac interventions are being done at the moment. There is a gap of specialists in the country, with few Paediatric cardiologists and paediatric cardiothoracic surgeons expected to serve the whole country (23). As a measure not to overwhelm and strain the already scarce resources, there is a referral chain whereby patients start from clinics and are referred upwards. These health facilities lack the necessary equipment, adequate health workers or sufficient training required for diagnosing CHD, and as a result this could lead to delayed diagnosis (24).

In addition, Kenya has many communities and each has their own cultural practices, which could cause hindrances to access medical services, resulting in delayed diagnosis of CHD (25). This study will give us the much needed data on the prevalence and factors associated with delayed diagnosis of CHD at KNH.

SECTION TWO

2.0 LITERATURE REVIEW

Delayed diagnosis of CHD is a significant problem that is faced worldwide. However, in the developed world, countries have done their due diligence and implemented certain measures to ensure that the prevalence of congenital heart disease has had a substantial downward trend over the years.

A population based retrospective study done in a high-income country by Lieberman RF et al., between 2004- 2009, revealed a rapid decline in delayed diagnosis from 17.1% to 10.6%. This was largely attributed to an increase of prenatal ultrasounds by skilled sonographers being incorporated into the management of pregnant women (26). During this period there was an increase in prenatal CCHD diagnosis from 44.9 to 63.8%. It was also noted that delayed diagnosis of CHD was associated with deliveries not done in tertiary hospitals (27). This study was significant in creating guidelines for early detection of congenital heart diseases by thorough prenatal screening and postnatal screening, including the use of pulse oximetry in screening CHD in the first hours of life, enabling prompt specialized care, early intervention and better outcomes (28).

Murni et al., carried out a prospective study in Indonesia, a resource limited country. This study demonstrated that 86.2% children were diagnosed late and at the time of presentation had severe complications. Of these, 49.4% patients presented with heart failure and 16% with pulmonary congestion and pulmonary hypertension (29) (30). This further predisposes these patients to diseases such as pneumonia which are still a challenge to manage in LMIC (30). Malnutrition is also another common complication in children with delayed diagnosis of

CHD (31). Poor nutrition in children with congenital heart diseases is associated with need for ICU admission, prolonged ventilation and poor recovery (32) (33). This study concluded that the most common reason for delay was delayed diagnosis by the physician, other factors like delayed referral, financial constraints and illiteracy level of guardians also played a major role in contributing to the delayed diagnosis of CHD in these children (29).

An observational study carried out in Pakistan found that the main factor for delay was delayed first consultation to doctor at 37.2%. Other factors were financial constraints, cultural beliefs amongst others (33).

Another retrospective study done in a middle income setting by Mat Bah MN et al., revealed that even with the increase in prenatal ultrasounds being carried out as routine management during pregnancy, the majority of CCHD were still being detected late at 74%(34).

In Kenya, a study done by Awori et al., demonstrated that the mean age of referral of children to a paediatric cardiologist was 16.9 months; hence a large number missed the ideal window for surgical intervention. From this we can therefore postulate that the majority of the patients with congenital heart disease present with delayed diagnosis (35). This strongly highlights the huge gap in timely diagnosis of CHD and the need to further investigate the contributing factors.

Once a diagnosis of CHD is delayed, it poses a huge challenge in terms of surgical intervention. A retrospective study carried out by Brown KL, et al., investigated surgical outcomes of children with CHD, at different times of diagnosis. It concluded that those who were diagnosed late, frequently had severe cardiopulmonary disease at presentation and this was associated with prolonged vent stay when admitted to the Intensive care unit and are associated with a high morbidity and mortality (36).

2.1.Summary of literature review

Study Title/ author/ year/ country	Type of study and study population	Findings
Factors and Morbidities Associated with the Delayed Diagnosis of Congenital Heart Disease in Children Under 5 Zahid Z, Khan HS, Mazhar Z and Anam M. Pakistan 2022.	Retrospective study 500 patients	The delayed diagnosis of CHD is associated with life-threatening complications and comorbidities, which can be prevented with early diagnosis.
T.Hurisa, H.Megersa, T.Tsegaye, Ethiopia, 2021.	Retrospective cross-sectional study 216 children	Delayed diagnosis of CHD was noticed in 95.4% of children
Delayed diagnosis in children with congenital heart disease. Murni, I.K., Wirawan, M.T., Patmasari, L et al. Indonesia, 2021.	Mixed method study 838 patients	60% of children with CHD were diagnosed with significant delay. The most common cause was delayed diagnosis by the doctor. Delayed diagnosis is associated with complications.
Birth prevalence and delayed diagnosis of critical congenital heart disease: A population-based study from a middle-income country. Mat Bah MN, Sapian MH et al. Malaysia, 2020.	Retrospective cohort study 3557 patients	Due to limited resources in the MIC, the delayed diagnosis of CCHD is high

Factors Contributing to Delayed Diagnosis of Congenital Heart Disease in Paediatric Population. Iqbal S,1 , Saidullah S , Ahmed R et al Pakistan, 2020.	Cross-sectional study 265 patients	Delayed diagnosis of CHD was noted among 79.6% cases. Acyanotic CHD was the commonest type of CHD in the present study. Most common factors contributing to delayed diagnosis of CHD were delayed 1st consultation, delayed diagnosis by the doctor and delayed referrals
Pattern of congenital heart disease in a developing country tertiary care centre: Factors associated with delayed diagnosis Usman Rashid, Ahmad U Qureshi et al. Pakistan, 2016.	Cross-sectional Observational study 354 patients	Diagnosis of congenital heart defect was delayed in the majority of patients. Multiple factors such as lack of adequately trained health system and socioeconomic constraints were responsible for the delay.
Delayed diagnosis of critical congenital heart defects: trends and associated factors. Liberman RF, Getz KD, Lin AE et al. USA. 2014.	Retrospective cohort 916 patients	Even with prenatal diagnosis of CCHDs, delayed diagnosis still occurs in over 10% of cases.
Delayed diagnosis of congenital heart disease worsens preoperative condition and outcome of surgery in neonates Brown KL, Ridout DA, Hoskote A et al. UK, 2006.	Retrospective study 286 patients.	Delayed diagnosis of CHD is associated with a worse perioperative outcome.

Delayed recognition of congenital heart disease. Massin MM, Dessy H. Belgium, 2006.	Prospective study 744 patients	In all cases of late diagnosis, clinical cardiac findings were present that should have alerted the physician on the possible presence of underlying CHD.

2.2.Justification and utility

Previous studies have shown that there is a high rate of delay in diagnosis of CHD in LMIC. Much of this data has been informed by research carried out in other countries and continents. The factors associated with these delays were specific to those countries. The aim of this study was to seek the prevalence of delayed diagnosis of CHD in Kenyatta National hospital, specifically a tertiary public hospital that sees a majority of Kenyans of whom majority are low income earners. And to describe factors that were associated with this delay. This is of importance because delayed diagnosis makes children with CHD at high risk for intervention, and even with intervention, there is a higher incidence of significant morbidity and mortality.

This study will add to the existing research on delayed diagnosis of CHD and associated factors in Africa. Data obtained from this study may inform policies and guidelines on CHD, educating the public on CHD and improving the resources at Kenyatta national hospital and thereby improving survival rates by decreasing childhood morbidity and mortality.

2.3.Research questions

1. What is the prevalence of delayed diagnosis of congenital heart disease in children under 12 years at KNH?

2. What are the factors associated with delayed diagnosis of congenital heart disease in children less than 12 years at KNH?

2.4.Study objectives

2.4.1. Primary objective:

1. To determine the prevalence of patients aged below 12 years with CHD at Kenyatta National hospital who are diagnosed late.

2.4.2. Specific objectives

1. To describe the characteristics of children with delayed diagnosis of CHD at Kenyatta National Hospital.
2. To determine the factors associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

SECTION THREE

3.0. RESEARCH METHODOLOGY

3.1. Study design

This was a cross-sectional study. This was an appropriate design for this study because the researcher sought to investigate the prevalence of delayed diagnosis of CHD among children diagnosed with CHD at Kenyatta National hospital. The study data collected at one point in time. The denominator was children below 12 years with congenital heart disease receiving services at KNH during the study period while the numerator was the number of children with delayed diagnosis of CHD.

3.2.Study setting

This study was conducted at Kenyatta National Hospital, the main national tertiary referral centre in Kenya. It was conducted specifically at the Paediatric wards and Paediatric cardiology clinic.

KNH has 6 specialist cardiologists and runs a weekly cardiac clinic, which sees approximately 60 patients each week. Majority of the patients are referred to Kenyatta National hospital from peripheral facilities for diagnosis or confirmation of diagnosis by echocardiogram.

The diagnostics capability available at KNH includes electrocardiogram, echocardiogram and cardiac catheterization.

Kenyatta has four paediatric wards and runs a Paediatric Cardiology clinic every Friday.

3.3.Study population

All children below 12 years with congenital heart disease receiving services at KNH

3.3.1. Inclusion criteria

All children admitted to the Paediatric wards and at the paediatric cardiology clinic with:

I. A diagnosis of CHD confirmed by echocardiogram

II. All children under 12 years with a diagnosis of CHD

III. Has an informed parental consent

IV. Those with other congenital anomalies in addition to CHD.

3.3.2. Exclusion criteria

I. Those without informed consent

3.4.Sample size calculation

As per Fischer's formula for calculating one sample size using precision around a proportion.

$$n = \frac{Z^2 P (1-P)}{d^2}$$

n= minimum sample size required for study

z= 1.96 (normal deviate for 95% confidence interval)

d= 0.05 (degree of precision around the mean)

P= 60% (the proportion of children with delayed diagnosis of CHD)

N=256.1

Thus, a sample size of 257 was included in the study.

3.4.Sampling procedure

Consecutive sampling was used. The researcher with the help of two research assistants approached guardians of children who meet the inclusion criteria and recruited them into the study. Recruitment was done consecutively until the sample size was attained. Consecutive sampling technique provides an equal opportunity for all those who meet the inclusion criteria equal chance of being recruited within the study duration period.

3.5.Recruitment procedure

Recruitment of the study subjects was done by the principal investigator with the help of research assistants. The research assistants were trained beforehand and the exercise included identification of new diagnosis of CHD, filling the data collection tool and obtaining informed consents. The researcher approached guardians at each respective study area and explained the purpose of the study and administered consent. Those who met the inclusion criteria were recruited to the study. Relevant data was obtained from the guardian and input into the data collection tool.

3.6.Research instruments

The study research instrument was a structured questionnaire. The questionnaire included three major sections where Section A included demographic characteristics of the patient, Section B included CHD diagnosis characteristics and Section C included information on guardian demographic factors.

3.7.Validity and reliability

A pre-test was conducted at the Kenyatta National hospital paediatric cardiology clinic. The purpose of the pretest was to emphasize on ensuring that the research instrument selected contains all the necessary questions that can help in attaining better outcomes in improving research validity. In enhancing the reliability, a highly skilled and experienced paediatric cardiologist reviewed the study data collection instrument in relation to the study objectives. An expert statistician was also contacted to review the data collection tool.

3.8.Data collection procedure

Data collection process began after KNH-UoN Ethics review committee approval and permission to collect data from KNH administration. The researcher with the two research assistants approached guardians of children at the New-born Unit, Paediatric wards and Paediatric cardiology clinic. They explained the purpose of the study and administered consent. The consent also allowed access to the patients' medical records to obtain past medical information. Once the consent was granted, the guardian was required to provide their demographic details. They also provided demographic details of the child, which were cross-checked in the medical files. All children with a diagnosis of CHD were screened. There was a review of the echocardiogram and diagnosis of CHD confirmed. The time of echocardiogram diagnosis was confirmed. The reasons for delay were evaluated in a data-collecting tool, which was filled by the guardians or through interviews carried out by the research assistants or the principal investigator.

3.9.Variables in the study

Independent variables

Child characteristics (Gender, age, referral status, presence of other malformation)

Guardian characteristics (age, parity, prenatal ultrasound, occupation, insurance, income, place of delivery)

Dependent variable

Delayed diagnosis of CHD

3.10. Quality assurance

The data collection tool was completed by a research assistants who had be trained prior to the exercise. This was done under the supervision of the principal investigator. The data collection tool aided to obtain the demographic and clinical data. The research assistants enlisted had a minimum of diploma in nursing qualification, therefore knowledgeable. In addition, the research assistants underwent training for two days to ensure that they are well conversant with the research tool and ethical research practices. The first day of training was used to explain the research tool and the data required to be recorded. The second day of training focused on interacting with the respondents and testing the data collection tool. The principal investigator supervised the data collection procedure and continuously monitored research assistants in ensuring that they collected quality data. To prevent repeat findings, the questionnaires were assigned serial numbers. Following collection, the data was reviewed on a weekly basis to ensure completeness. Continuous data entry was made into a password-protected Epi data database. The Principal Investigator recruited a qualified statistician who was in charge of assessing, cleaning, and analyzing the data to achieve the intended goals.

3.11. Data cleaning and entry

The raw data was cleaned and coded for ease of analysis into Epi-data 3.1. Each of the responses were serialized to ensure that it was accurately entered and could be traced as well. The collected data will be entered into STATA version 17 and analyzed using its statistical data.

3.12. Data storage and archival

Filled questionnaires were stored in a lockable cabinet only accessible to the Principal Investigator. Backup of soft data was stored in a flash disk and protected under passwords. The researcher, statistician and study supervisors had access to the data. The researcher had had the rights to share the study data set with any other interested party for the purpose of learning and knowledge management.

The data will be stored for a period of five years after which the hardcopy papers will be shredded into pieces, and the soft copy data will be stored in the repository.

3.13. Data analysis

Data was analyzed using both descriptive and inferential analysis. Categorical data was grouped and analyzed in terms of frequencies and percentages while continuous variables were assessed using mean and standard deviation.

The prevalence of delayed diagnosis of CHD was calculated as a proportion of the total sample. The prevalence was determined and compared as follows:

$$\%\text{prevalence} = \frac{Number\ of\ patients\ with\ delayed\ diagnosis\ of\ CHD}{Total\ no.\ of\ patients\ diagnosed\ with\ CHD} * 100$$

Binary logistic regression was used to compare patient characteristics, associated factors and occurrence of cardiac complications.

3.14. Ethical consideration

Permission

The study was approved by the KNH-UoN Ethics committee which reviewed the ethical aspects of the study. Permission was granted by the KNH administration to access patient health information in the files.

Consenting

In addition, only those who agree to consent to the study were recruited. Consent obtained to help in accessing patient medical files and registers. Thus, only health information of those who agree to consent were accessed.

Assent

For those children who were 6 to 12 years, an assent form was provided since there was an interaction with them.

Confidentiality and privacy

Confidentiality, anonymity and privacy was fully guaranteed throughout the study. The data obtained was used for the purpose of this research only and was not shared with any platform. Confidentiality and anonymity was observed when collecting, storing, processing data, and handling the results.

Risks and benefits

There were no risks involved in participating in this study considering that it is non-invasive. During the research period the guardian was advised on the progress of the child's condition. Overall results were used by healthcare workers to help improve care for babies with congenital heart defects.

Cost of treatment

The likelihood of injuries during this study were low hence the researcher ensured that data collection was done without any issues. In case of severity of CHD during the study, the researcher directed the guardian to appropriate care within the study area. This study participation was fully voluntary.

3.15. Study strengths

KNH being a major referral centre and receives a high number of referrals hence has good generalizability in Kenya.

3.16. Study limitation and delimitation

Some guardians declined consent.

Time constraints.

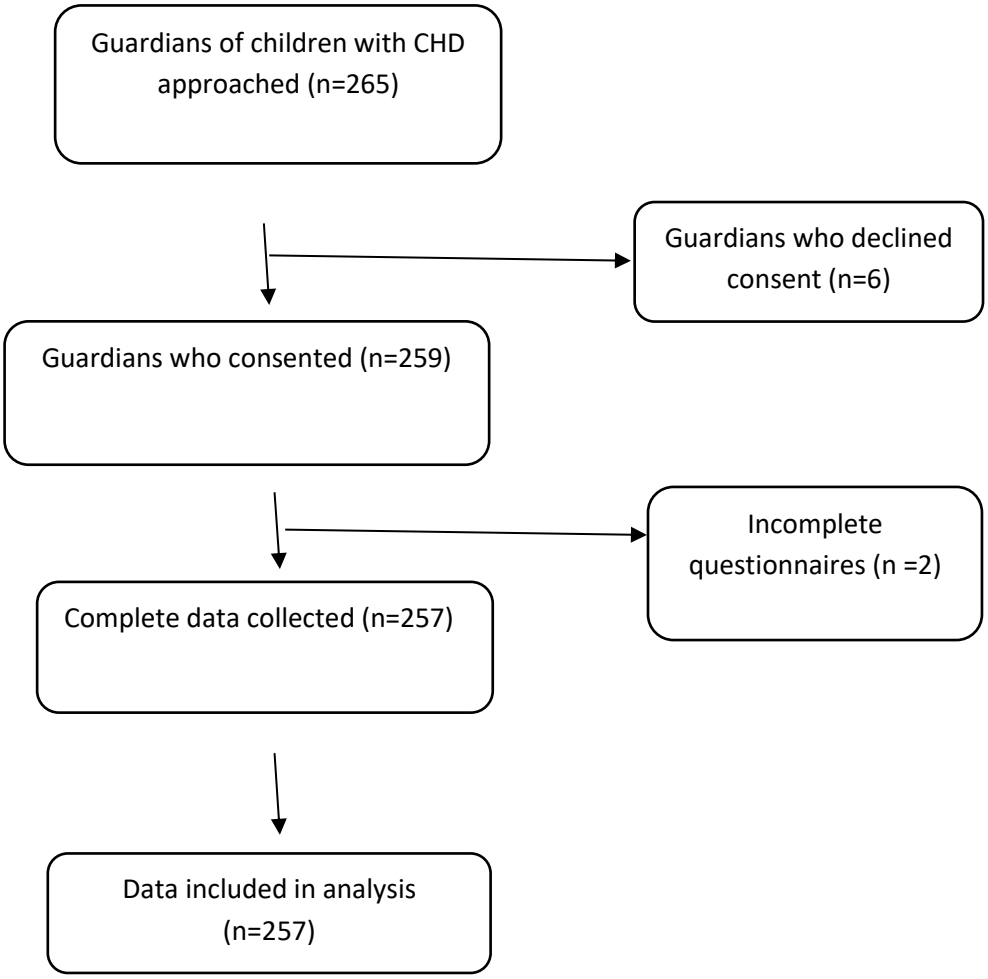
SECTION FOUR:

4.0 RESULTS

4.0. Introduction

A total of 257 children with congenital heart diseases were enrolled into the study. In this study, 265 mothers/guardians of children with CHD were approached, six of them declined consent while 3 of the questionnaires returned were incomplete hence were excluded from the study.

Figure 1: Study flowchart



4.1.Demographic characteristics of guardians of children with congenital heart disease at KNH

Majority, 82.9% (n =213) of the respondents were mothers of the children with CHD, 55.3% (n =142) reside outside Nairobi. More than half, 54.1% (n =139) were aged between 25 and 34 years, 77.4% (n =199) of the respondents were married and 55.3% (n =142) had a household monthly income of Ksh. 13,500 or more. Majority of the mothers have primary and secondary education, 73.5% (n=189) as shown in Table 1.

Table 1: Demographic characteristics of guardians of children with congenital heart disease at KNH

Demographic factors	**Frequency n=257**	**Percent %**
Relationship with the child		
Mother	213	82.9
Guardian	44	17.1
Residence		
Within Nairobi	115	44.7
Outside Nairobi	142	55.3
Maternal age		
<=24 years	51	19.8
25 - 34 years	139	54.1
>=35 years	67	26.1
Marital status		
Single	58	22.6

Married	199	77.4
Mother education level		
Primary	64	24.9
Secondary	125	48.6
Tertiary	68	26.5
Occupation		
Unemployed	76	29.6
Self employed	100	38.9
Informal employment	64	24.9
Formal employment	17	6.6
Monthly household income (Ksh).		
<13500	115	44.7
>=13500	142	55.3
Paternal characteristics		
Paternal education level		
Primary	43	19.8
Secondary	60	27.6
Tertiary	114	52.5
Age (Mean ±SD)	35.89±8.1	

4.2. Maternal obstetric and neonatal medical characteristics

The total number of study participants was 257. In investigating parity, 69.3% (n =178) were multiparous. Most of the respondents, 91.4% (n =235) had attended antenatal care, 69.6% (n =179) had obstetric ultrasound during ANC visit. Among those who had ANC visits, only 9.4% (n =17) had CHD diagnosis during the ANC ultrasound conducted. 71.6% (n =184) of the children were term, 23.7% (n =61) were admitted into the newborn unit as shown in Table 2.

Table 2: Obstetric and neonatal medical characteristics

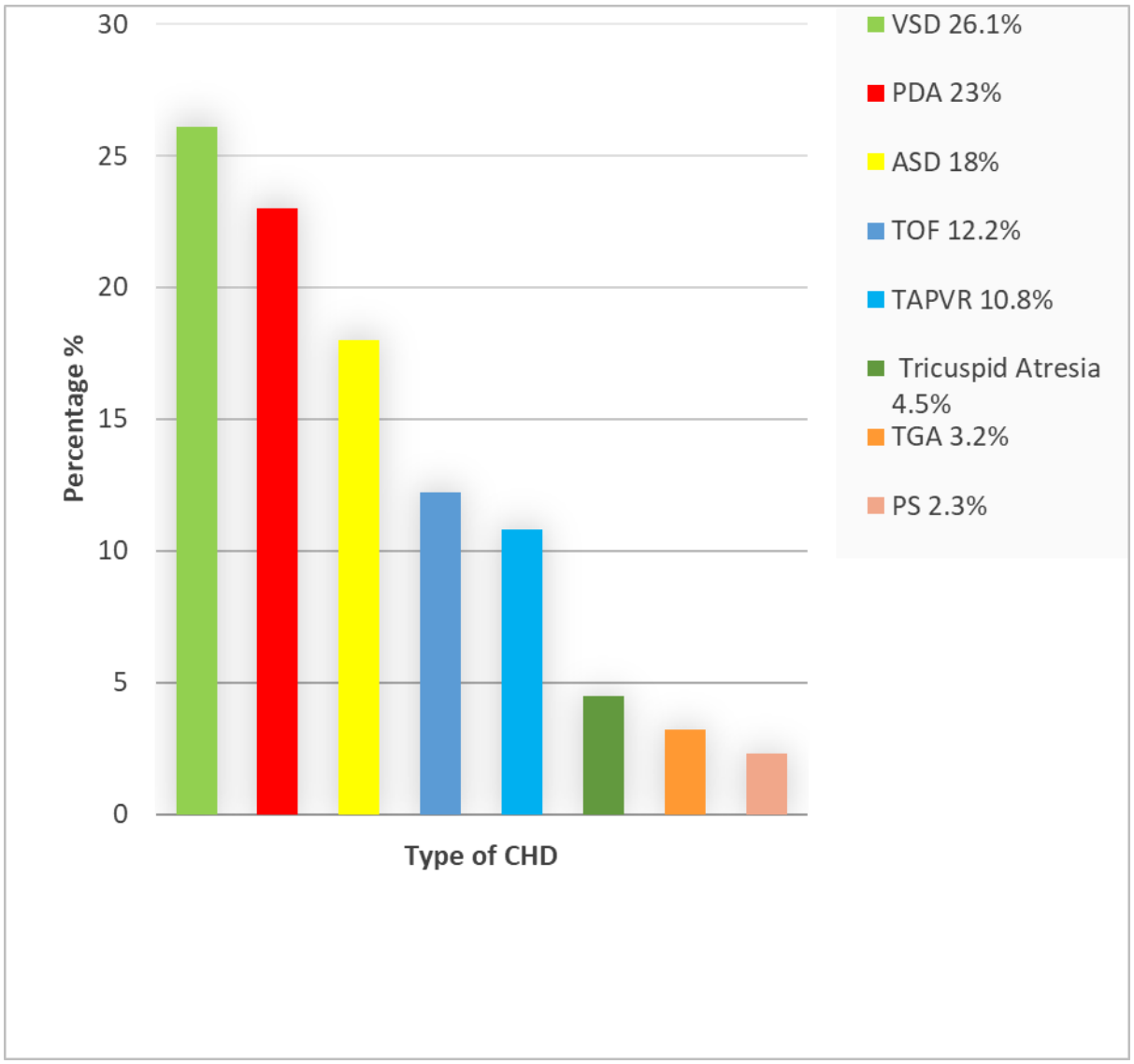
	Frequency n=257	**Percent %**
Parity		
Primiparous	79	30.7
Multiparous	178	69.3
ANC attendance		
Yes	235	91.4
No	22	8.6
ANC ultrasound		
Yes	179	69.6
No	78	30.4
CHD diagnosis during ANC ultrasound (n =179)		
Yes	17	9.4
No	162	90.6
Gestational age delivery		
Preterm	30	11.7

Term	184	71.6
Post-datism	43	16.7
Admission to NBU		
Yes	61	23.7
No	195	75.9
Require oxygen supplementation		
Yes	66	25.7
No	191	74.3

4.3.Types of congenital heart diseases among children seeking care at KNH

Among the study participants, 28.8 %(n =74) had VSD, 24.1 %(n =62) had PDA, 18.3 %(n =47) had ASD while 10.5 %(n =27) had tetralogy of fallot as shown in Figure 2.

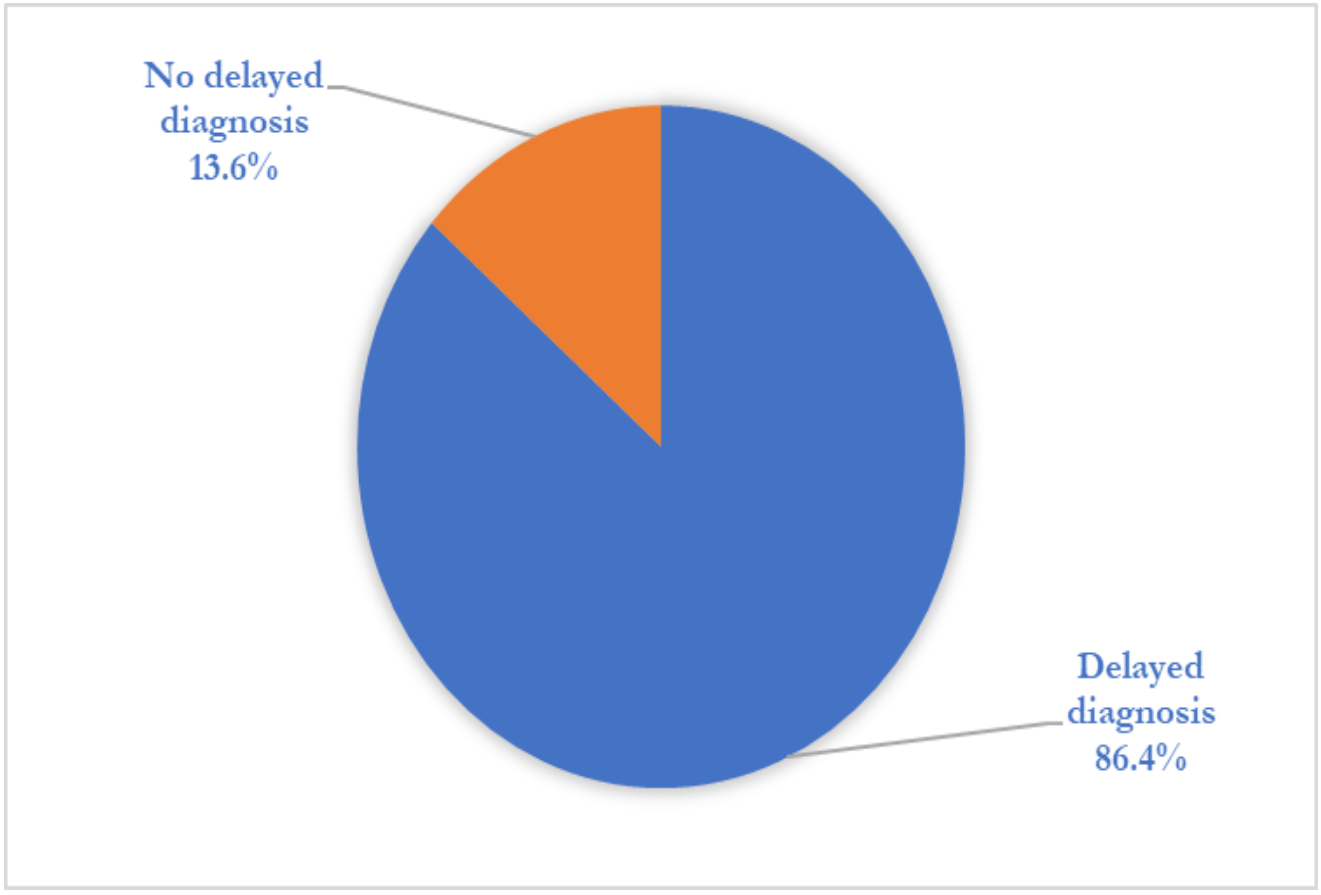
Figure 2: Types of congenital heart diseases among children seeking care at KNH



4.4.The prevalence of delayed diagnosis in patients aged below 12 years with CHD at Kenyatta National hospital.

The prevalence of delayed diagnosis was 86.4% (n =222), 95%CI: 81.6% - 90.3% as shown in Figure 3.

Figure 3: Prevalence of delayed diagnosis



4.5.The characteristics and clinical presentation of children with delayed diagnosis of CHD at Kenyatta National Hospital.

Characteristics of children who had delayed diagnosis of CHD were investigated as shown in Table 3. One hundred and forty-seven (65.9%) were below 5 years of age, 55.6 %(n =124) were female, 75.3 %(n =168) had >=2500g birth weight. Further, 43.5 %(n =97) had fast breathing, 34.5 %(n =77) had difficulty in breathing, 55.6 %(n =123) had a murmur, 10.3% (n =23) had dysmorphic features of which the majority was attributed to Down's syndrome. Referral status assessment showed that 73.1 %(n =163) were referred. Among those who were referred, 42.3 %(n =69) arrived at the referred facility more than 48 hours later. The main reasons for the delay in echocardiogram included delayed booking of echocardiogram due to long waiting list, lack of transportation from referring facilities and financial constraints.

Table 3: The characteristics of children with delayed diagnosis of CHD at Kenyatta National Hospital. (n =222)

	Frequency n=257	**Percent %**
Age		
<=3 months	25	11.2
4 months - 60 months	147	65.9
>60 months	50	22.9
Gender		
Male	98	44.4
Female	124	55.6
Birthweight		

<2500g	55		24.7
>=2500g	168		75.3
Fast breathing	97		43.5
Bluish discoloration	33		14.8
Fatigue	30		13.5
Difficulty breathing	77		34.5
Cough	44		19.7
Swelling of the body	4		1.8
Chest pain	26		11.7
Poor weight gain	32		14.3
Lethargy	18		8.1
Presenting SPO2			
<90%	87		38.9
>90%	61		23.7
Unrecorded	109		42.4
Murmurs			
Present		60	23.3
Absent	197		76.7
Requiring SPO2			
Yes	30		30.9
No	67		68.0
Edema	6		2.7
Hepatomegaly	3		1.3
Chest x-ray findings			

Enlarged shadow	53	23.8
Abnormal shape	30	13.5
Unclear margins	32	3.1
Presence of congenital malformation	18	8.1
Presence of dysmorphic features	23	10.3
Presence of chronic illness	24	10.8
Referral status		
Referred	163	73.1
Non-referral	60	26.9
Time of arrival at facility (n =163)		
0 - 24 hours	46	28.2
25 - 48 hours	27	16.6
>48 hours	69	42.3

4.6.The factors associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

4.6.1. Maternal characteristics associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

The findings from binary logistic regression revealed that the odds of delayed diagnosis in children of multiparous mothers were 4.9 times higher than in primiparous women and this was statistically significant (COR =4.90, 95%CI:2.32 – 10.36, p <0.001). Children of guardians with an income of >=Ksh. 13,500 did not have a significant less delay in diagnosis in comparison to those whose guardians who earned a monthly income of <Ksh.13, 500, COR =0.49, 95%CI: 0.24 – 0.89, p =0.006 as shown in Table 4

Table 4: Maternal characteristics associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

Factors	Delayed diagnosis N=222	No delayed diagnosis N=35	COR(95%CI)	P-value
Relationship with child				
Mother	181(85.0)	32(15.0)	0.41(0.12 - 1.42)	0.225
Guardian	41(93.2)	3(6.8)	Ref	
Residence				
Within Nairobi	96(83.5)	19(16.5)	0.64(0.31 - 1.31)	0.273
Outside Nairobi	126(88.7)	16(11.3)	Ref	
Maternal age				
<=24 years	40(78.4)	11(21.6)	2.34(0.84 - 6.69)	0.102
25 - 34 years	122(87.8)	17(12.2)	1.19(0.47 - 3.04)	0.709
>=35 years	60(89.6)	7(10.4)	Ref	
Marital status				
Single	49(84.5)	9(15.5)	0.82(0.36 - 1.86)	0.665
Married	173(86.9)	26(13.1)	Ref	
Parity				
Primiparous	57(72.2)	22(27.8)	Ref	
Multiparous	165(92.7)	13(7.3)	4.90(2.32 - 10.36)	<0.001
Maternal level of education				
Primary	59(92.2)	5(7.8)	Ref	
Secondary	111(88.8)	14(11.2)	0.28(0.09 - 0.80)	0.018

Tertiary	52(76.5)	16(23.5)	0.41(0.19 - 0.90)	0.027
Occupation				
Unemployed	66(86.8)	10(13.2)	2.42(0.29 - 20.34)	0.415
Self employed	88(88.0)	12(12.0)	2.18(0.27 - 17.97)	0.468
Informal employment	52(81.3)	12(18.8)	3.70(0.45 - 30.62)	0.226
Formal employment	16(94.1)	1(5.9)	Ref	
Insurance cover (NHIF)				
Yes	141(87.6)	20(12.4)	1.31(0.63 - 2.69)	0.46
No	81(84.4)	15(15.6)	Ref	
Monthly household income				
<13500	94(81.7)	21(18.3)	Ref	
>=13500	128(90.1)	14(9.9)	0.49(0.24 - 0.89)	0.006
ANC attendance				
Yes	202(86.0)	33(14.0)	0.61(0.14 - 2.74)	0.748
No	20(90.9)	2(9.1)	Ref	

4.6.2. Child related factors associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

The findings established that the odds of delayed diagnosis were three times higher in female children as compared to male children, COR =3.16, 95%CI:1.45 – 6.90, p =0.004. Those who had normal weight at birth were five times more likely to have delayed diagnosis, COR =5.43, 95%CI: 1.26 – 23.39, p =0.009. Patients who had no murmurs were two times more likely to have delayed diagnosis compared to those with murmurs, COR =2.38, 95%CI: 1.13 – 5.02, p =0.028. Patients who were referred were three times more likely to have a delayed diagnosis of CHD, COR =3.28, 95%CI: 1.58 – 6.80, p=0.001 as shown in Table 5.

Table 5: Child related factors associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

Factors	Delayed diagnosis N=222	No delayed diagnosis N=35	COR(95%CI)	P-value
Gender				
Male	98(79.7)	25(20.3)	Ref	
Female	124(92.5)	10(7.5)	3.16(1.45 – 6.90)	**0.004**
Birth weight				
<2500g	55(96.5)	2(3.5)	Ref	
>=2500g	167(83.5)	33(16.5)	5.43(1.26 - 23.39)	**0.009**
Fast breathing				
Yes	96(85.7)	16(14.3)	0.91(0.44 - 1.85)	**0.855**
No	126(86.9)	19(13.1)	Ref	
Bluish discoloration				
Yes	33(62.3)	20(37.7)	0.64(0.55 - 6.41)	**0.126**
No	189(92.6)	15(7.4)	Ref	
Fatigue				
Yes	30(62.5)	18(37.5)	1.78(0.15 - 4.58)	**0.084**
No	192(91.9)	17(8.1)	Ref	
Difficult breathing				
Yes	76(84.4)	14(15.6)	0.78(0.38 - 1.62)	**0.568**
No	146(87.4)	21(12.6)	Ref	
Cough				

Yes	44(95.7)	2(4.3)	4.08(0.94 - 17.63)	**0.076**
No	178(84.4)	33(15.6)		
Murmur				
Absent	123(91.1)	12(8.9)	Ref	
Present	99(81.1)	23(18.9)	2.38(1.13 - 5.02)	**0.028**
Presence of congenital malformation				
Yes	18(94.7)	1(5.3)	3.0(0.39 - 23.21)	**0.485**
No	204(85.7)	34(14.3)	Ref	
Presence of dysmorphic features				
Yes	23(82.1)	5(17.9)	0.69(0.25 - 1.96)	**0.557**
No	199(86.9)	30(13.1)	Ref	
Presence of chronic illness				
Yes	24(88.9)	3(11.1)	1.29(0.39 - 4.54)	**0.482**
No	198(86.1)	32(13.9)		
Referral status				
Referred	163(91.1)	16(8.9)	3.28(1.58 - 6.80)	**0.001**
Non-referral	59(75.6)	19(24.4)	Ref	

4.7.Multivariable analysis of factors associated with delayed diagnosis of CHD.

Binary logistic regression analysis revealed that monthly household income of less than Ksh.13, 500 AOR =1.36, 95%CI: 1.06 – 4.02, p =0.002, children without murmurs, AOR =2.34, 95%CI: 1.83 – 6.54, p =0.016 and those who were referred, AOR =3.53, 95%CI: 1.21 – 10.26, p =0.021 were independently associated with delayed diagnosis as shown in Table 6.

Table 6: Multivariable analysis of factors associated with delayed diagnosis of CHD

Factors	AOR(95%CI)	P-value
Maternal level of education		
Primary	Ref	
Secondary	0.33(0.05 - 1.98)	0.223
Tertiary	0.46(0.16 - 1.37)	0.162
Monthly household income		
<13500	1.36(1.06 - 4.02)	0.002
>=13500	Ref	
Birth weight		
<2500g	3.68(0.70 - 19.39)	0.124
>=2500g	Ref	
Murmurs		
Present	Ref	
Absent	2.34(1.83 - 6.54)	0.016
Referral status		
Referred	3.53(1.21 - 10.26)	0.021
Non-referral	Ref	

SECTION 5: DISCUSSION

5.0. To determine the prevalence of patients aged below 12 years with CHD at Kenyatta National hospital who are diagnosed late.

In this study, it was shown that 86.4% of children had delayed diagnosis of CHD. This is a relatively high figure and compared to a study done in Ethiopia which revealed delayed diagnosis at 95.4%, this shows that the level of delayed diagnosis of CHD in LMIC is very high. While a study done in Indonesia, a Middle income country, revealed 60% delay in diagnosis of congenital heart disease. This could be as a result of better infrastructure, hence early diagnosis of CHD. In comparison to a study done in a higher income country, USA, the incidence was much lower at 13.8% and was largely attributed to antenatal diagnosis of CHD through ultrasounds and thorough newborn CHD screening. In this study, it was also noted that despite 91.4% of the mothers attending ANC, 64.6% of mothers had antenatal ultrasound scans, and only 9.4% of CHD were diagnosed prenatally. Ultrasound scans are user dependent and require skilled sonographers to pick up CHD prenatally.

5.1. To describe the characteristics of children with delayed diagnosis of CHD at Kenyatta National Hospital.

In this study it was noted that the majority of the children with delayed diagnosis of CHD were referrals with the majority of them residing outside Nairobi. Majority of the paediatric cardiologists are based in Nairobi, hence the patients need to be referred for cardiac evaluation thereby leading to a delay in diagnosis.

In this study it was noted that those with a birth weight of more than 1.8kgs, were found to have delayed diagnosis. This could be because stable newborns weighing over 1.8kgs are discharged home after a few hours. This is not enough time for CHD to be apparent. Majority of these children are not admitted to the newborn unit where there is specialized care.

Majority of the children without cyanosis were diagnosed late. Cyanosis is a clinical feature that is easily noticeable by most clinicians including midwives and community health workers. Children with cyanosis as a presenting feature were referred on time and diagnosis of CHD made promptly.

In this study, it was noted that children with murmurs had timely diagnosis in comparison to those that did not present with a murmur. This is because a murmur is a universally known characteristic of CHD and can be easily picked up by a skilled health care worker and referred for a timely echocardiogram or cardiologist review. However, this could pose a challenge in that children do have innocent murmurs, and referral of all murmurs could further congest the already strained resources.

It was noted that the majority of the children with delayed diagnosis were of the female gender and this was statistically significant. This could be attributed to the fact that we reside in a patriarchal society where the male gender is still seen as the more superior gender hence healthcare is prioritized in the male gender.

5.2. To determine the factors associated with delayed diagnosis of CHD in children aged below 12 years at Kenyatta National hospital.

In this study it was revealed that the odds of multiparous mothers having delayed diagnosis was 4.9 in comparison to primiparous mothers and this was statistically significant. This could be because multiparous mothers are less anxious and may wait for a period of time before seeking medical care.

It was also noted that despite the guardians having secondary and tertiary education, they still had children with delayed diagnosis of congenital heart diseases and this was statistically significant. In previous studies, delay in diagnosing CHD had been attributed to low education level. This could be due to the high unemployment rates in Kenya.

Children of guardians with a slightly higher monthly income and medical insurance were slightly more likely to present earlier to a medical facility leading to a timely diagnosis of CHD, however this was not statistically significant. This is because a higher income and medical insurance cover enables one to seek specialized care and provides a financial buffer where further investigations have to be done urgently thereby decreasing further delay.

This study adds to the pool of knowledge of CHD. It further explains factors that lead to delay of diagnosis of CHD in children under 12 years at Kenyatta National hospital. These factors are unique to this setting and further proves why we shouldn't infer data from other countries.

The limitation of this study was time constraints. A prospective study would have further enriched the study.

5.3 CONCLUSION

The aim of this study was to evaluate the proportion of children with delayed diagnosis of CHD and factors associated with this delay. 86.4% of patients with CHD were diagnosed late in our setting and this is significantly high. Delayed diagnosis of CHD was associated children of female gender, children who had a birth weight of more than 1.8kgs, those without murmurs and those who were referred.

It was also noted that the education level of guardians did not affect the time of presentation to hospital as regards CHD. In addition, multiparous mothers were 4.9 times more likely to present late in comparison to primiparous mothers. Binary logistic regression analysis revealed that monthly household income of less than Ksh.13, 500, children without murmurs and those who were referred were independently associated with delayed diagnosis.

5.4 RECOMMENDATIONS

1. Early referral of children suspected to have CHD.
2. Follow up of postnatal mothers, informing them of clinical signs of CHD
3. Continuous community awareness of CHD
4. Community screening of children for CHD including the rural areas where there is scarcity of Paediatric Cardiologists.

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APPENDICES

Appendix I: Informed consent form

Study title: Prevalence and Factors Associated with Delayed Diagnosis of Congenital Heart Disease at Kenyatta National Hospital.

Principal Investigator: Dr. Rachel Omondi (M.D)

Co-investigator : Prof. Christine Jowi

Introduction

I am a post graduate student in the paediatric department, University of Nairobi. I am conducting the above titled study and request for you and your child to take part in the study. The purpose of this consent form is to give you in depth information that will guide you to make an informed decision on whether or not you will take part in the study. Kindly read the consent form carefully. Feel free to seek clarification for any matter that arises concerning the study.

Study purpose

The purpose of this study is to evaluate the prevalence of congenital heart disease in Kenyatta National Hospital and the associated factors.

Participation in the study

Your participation in this study will be on a voluntary basis, and you may decide to withdraw from the study at any stage without any penalty. The study is purely descriptive, non-invasive, and will not attract any cost to your part.

Study Approval

This study is being conducted with the approval of the UoN Department of Paediatrics and Child Health and KNH-UoN Ethics and Review Committee. Approval No……..

Study Procedure

I, the principal investigator, together with my research assistants, will give you a full explanation of the procedure before you participate in this study. You will be required to answer the questions as asked in the questionnaire. The research assistants will help in making any clarifications regarding the questions. The completion of this questionnaire will take approximately 10 minutes of your time.

Confidentiality

Your identity will be protected with utmost confidentiality during the study. There are no identifiers that you will provide.

Risks and or discomforts

There are no major risks in the participation in the study. However, you may experience emotional distress because the questions asked are about the health and wellbeing of your child. You are encouraged to discuss any discomfort or distress with the research assistant openly.

Benefits

During the research period you will be advised on the progress of the child's condition. Information regarding your baby will be given to you and the doctor in charge of treating your baby to improve his/her management. Overall results will be used by healthcare workers

to help improve care for babies with congenital heart defects. You will not incur any cost by participating in this study.

Compensation

There will be no financial reward for participating in this study.

Communication

In case of any clarifications or queries during and after the study, you are free to contact me: Dr. Rachel Omondi. 0796-112-902 or my supervisor Prof. Dalton Wamalwa on email **dalton.wamalwa**@uonbi.ac.ke. Or phone number: +**254 708 115 132 or** you may also contact the Chair, KNH-UoN ERC email: uonknherc@uonbi.ac.ke or +254 721 257746, (020) 318262 Ext.28250.

Thank you

Signature

(Participant) ……. Date…….

I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent form in detail, and the participant has decided to participate voluntarily without any coercion or undue pressure.

Signature (Researcher)……Date……..

Kiambatisho II: Fomu ya idhini

Kichwa cha utafiti: Maambukizi na Mambo Yanayohusiana na Utambuzi uliochelewa wa Ugonjwa wa Moyo wa Kuzaliwa katika Hospitali ya Kitaifa ya Kenyatta.

Mpelelezi Mkuu: Dkt Rachel Omondi (MD)

Mchunguzi Mwenza : Prof. Christine Jowi

Utangulizi

Mimi ni mwanafunzi wa shahada ya kwanza katika idara ya watoto, Chuo Kikuu cha Nairobi. Ninafanya utafiti uliotajwa hapo juu na ombi kwako na mtoto wako kushiriki katika utafiti. Madhumuni ya fomu hii ya ridhaa ni kukupa maelezo ya kina ambayo yatakuongoza kufanya uamuzi sahihi juu ya ikiwa utashiriki katika utafiti au la. Tafadhali soma fomu ya idhini kwa makini. Jisikie huru kutafuta ufafanuzi kwa jambo lolote linalojitokeza kuhusu utafiti.

Madhumuni

Madhumuni ya utafiti huu ni kutathmini kuenea kwa ugonjwa wa moyo wa kuzaliwa nayo katika Hospitali ya Kitaifa ya Kenyatta na mambo yanayohusiana.

Ushiriki katika utafiti

Ushiriki wako katika utafiti huu utakuwa kwa hiari, na unaweza kuamua kujiondoa kwenye utafiti katika hatua yoyote bila adhabu yoyote. Utafiti huo ni wa maelezo tu, usio na uvamizi, na hautavutia gharama yoyote kwa upande wako.

Idhini ya Utafiti

Utafiti huu unafanywa kwa idhini ya Idara ya Watoto na Afya ya Watoto ya UoN na Kamati ya Maadili na Mapitio ya KNH-UoN. Idhini Na.....

Utaratibu wa Utafiti

Mimi, mchunguzi mkuu, pamoja na wasaidizi wangu wa utafiti, nitakupa ufafanuzi kamili wa utaratibu kabla ya kushiriki katika utafiti huu. Utatakiwa kujibu maswali kama yalivyoulizwa kwenye dodoso. Wasaidizi wa utafiti watasaidia katika kutoa ufafanuzi wowote kuhusu maswali. Kukamilika kwa dodoso hili kutachukua takriban dakika 10 za muda wako.

Usiri

Utambulisho wako utalindwa kwa usiri mkubwa wakati wa utafiti. Hakuna vitambulisho ambavyo utatoa.

Hatari na au usumbufu

Hakuna hatari kubwa katika ushiriki katika utafiti. Hata hivyo, unaweza kupata shida ya kihisia kwa sababu maswali yanayoulizwa ni mtu anayehusiana na afya na ustawi wa mtoto wako. Unahimizwa kujadili usumbufu wowote au dhiki na msaidizi wa utafiti kwa uwazi.

Faida

Katika kipindi cha utafiti utashauriwa juu ya maendeleo ya hali ya mtoto. Taarifa kuhusu mtoto wako utapewa wewe na daktari mwenye dhamana ya kumtibu mtoto wako ili kuboresha usimamizi wake. Matokeo ya jumla yatatumiwa na wahudumu wa afya kusaidia kuboresha huduma kwa watoto wenye matatizo ya moyo ya kuzaliwa nayo. Hutapata gharama yoyote kwa kushiriki katika utafiti huu.

Fidia

Hakutakuwa na zawadi ya kifedha kwa kushiriki katika utafiti huu.

Mawasiliano

Iwapo kutakuwa na ufafanuzi au maswali yoyote wakati na baada ya utafiti, uko huru kuwasiliana nami: Dkt. Rachel Omondi. 0796-112-902 au msimamizi wangu Prof. Dalton Wamalwa kwa barua pepe dalton.wamalwa@uonbi.ac.ke. Au nambari ya simu: +254 708 115 132 au Unaweza pia kuwasiliana na Mwenyekiti, barua pepe ya KNH-UoN ERC: uonknherc@uonbi.ac.ke au +254 721 257746, (020) 318262 Ext.28250. Asante Saini

(Mshiriki) ..... Tarehe.....

Nina Thibitisha kuwa nimemweleza wazi mshiriki asili ya utafiti na yaliyomo katika fomu hii ya ridhaa kwa undani, na mshiriki ameamua kushiriki kwa hiari bila kulazimishwa au shinikizo lisilostahili.

Saini (Mtafiti)..... Tarehe.....

Appendix III:Assent form

Study Title: Prevalence and Factors Associated with Delayed Diagnosis of Congenital Heart Disease at Kenyatta National Hospital.

Investigator: DR Rachel Omondi

I am requesting you to kindly participate in this research study. The purpose of this assent form is to provide you with information you will need to help you decide whether to participate in the study. You can ask questions at any time.

Introduction: This study seeks to have a general understanding of your diagnosis and establish whether it was done on time or it was delayed.

Study procedure: The researcher will ask you a few questions regarding the condition you have.

Risks: There will be no risks to you as a result of being recruited into this study. If you object to being recruited into it, you will not be punished or scolded.

Voluntariness: The study will be fully voluntary. You will not be paid or coerced to be in the study. It is also okay to say "Yes" and change your mind later. You can stop being in the research at any time. We will take good care of you no matter your decision.

Confidentiality: The information obtained about you will be kept in strict confidentiality.

Problems/questions: Ask us any questions you have. Take the time you need to make a choice.

If you agree or want to be in the research, please write your name below. We too will write our names to show that we discussed the research and you do not mind taking part in it.

Name of the participant …….

Name of the investigator …….

Investigator's signature …….

Date: ……/……/ 2021……

I(Name)……have explained the foregoing to the patient and answered his/her questions.

Signed……

Kiambatisho IV: Fomu ya idhini kwa watoto walio miaka 6 -12

Kichwa cha Utafiti: Maambukizi na Mambo Yanayohusiana na Utambuzi wa Kuchelewa kwa Ugonjwa wa Moyo wa Kuzaliwa katika Hospitali ya Kitaifa ya Kenyatta.

Mchunguzi: Dr Rachel Omondi

Ninakuomba ushiriki kwa huruma katika utafiti huu wa utafiti. Madhumuni ya fomu hii ya ridhaa ni kukupa taarifa ambazo utahitaji kukusaidia kuamua ikiwa utashiriki katika utafiti. Unaweza kuuliza maswali wakati wowote.

Utangulizi: Utafiti huu unataka kuwa na uelewa wa jumla juu ya utambuzi wako na kubaini kama ulifanyika kwa wakati au ulichelewa. Utaratibu wa utafiti: Mtafiti atakuuliza maswali machache kuhusu hali uliyonayo.

Hatari: Hakutakuwa na hatari kwako kutokana na kuajiriwa katika utafiti huu. Ukipinga kuajiriwa ndani yake, hutaadhibiwa au kukaripiwa.

Hiari: Utafiti utakuwa wa hiari kabisa. Hutalipwa wala kulazimishwa kuwa katika utafiti. Pia ni sawa kusema "Ndiyo"na kubadilisha mawazo yako baadaye. Unaweza kuacha kuwa katika utafiti wakati wowote. Tutakutunza vizuri wewe suala la uamuzi wako.

Usiri: Taarifa zilizopatikana kuhusu wewe zitahifadhiwa usiri mkali. Matatizo/maswali: Tuulize swali lolote ulilonalo. Chukua muda unaohitaji kufanya uchaguzi. Ikiwa unakubali au unataka kuwa katika utafiti, tafadhali andika jina lako hapa chini. Sisi pia tutaandika majina yetu kuonyesha kwamba tulijadili juu ya utafiti na hujali kushiriki katika hilo.

Jina la mshiriki .....

Jina la mpelelezi .....

Saini ya Mpelelezi .....

Tarehe: ...../..... 2021.....

I(Jina)..... wameeleza yaliyotangulia kwa mgonjwa na kujibu maswali yake. Saini.....

Appendix V: Data Collection tool

Study title: Prevalence and Factors Associated with Delayed Diagnosis of Congenital Heart Disease at Kenyatta National Hospital.

Section A:Patient Details	
Gender	Male [ ] Female [ ]
Date of birth (dd/mm/yy)	
Section B: CHD diagnosis	
Age at presentation	
Echocardiogram with a diagnosis of CHD	Yes [ ] No [ ]
Presence of any other malformation	Yes [ ] No [ ]
If yes, kindly specify	
Referral	Yes [ ] No [ ]
Reason for referral	CHD [ ] Other [ ]
If Other, please specify	
Time of arrival to referred facility	0 – 24 hours[ ] 25-48 hours [ ] >48hrs[ ]
If delayed referral, reason for delay	
Section C:Guardian/ Parents details	
Relationship	Mother [ ] Father [ ] Sibling [ ] Others (Specify)……..
Age	
Parity	
Prenatal Ultrasound	Yes [ ] No [ ]
Level of education	None [ ] Primary [ ] Secondary [ ] Tertiary [ ]

Occupation	Unemployed [ ] Self-employed [ ] Informal employment [ ] Formal employment [ ]
Insurance cover	Yes [ ] No [ ]
Monthly household Income	0 – 13, 500 [ ] >13,500 [ ]
Place of delivery	Home [ ] Clinic/ dispensary [ ] Transit to hospital [ ] Hospital [ ]
Cultural/ spiritual beliefs or rituals that resulted in delayed presentation to the hospital	Yes [ ] No [ ]

Appendix VI : Dummy Tables

Dummy table 1: Demographic characteristics

Guardian/maternal characteristics	**Frequency**	**Percentage**
Age	X	X
Leval of education	X	X
Marital status	X	X
Residence	X	X
Clinical characteristics		
Parity	X X	X
Gravidity	X	X
ANC attendance	X	X
Gestational age at delivery	X	X
Mode of delivery	X	X
Child characteristics		
Gender	**X**	**X**
Age	**X**	**X**
Birth order	**X**	**X**
Referral	x	x
Age at presentation	X	X
Other malformations	x	X

Dummy Table 5: Factors associated with delayed diagnosis of CHD

Factors	Delayed diagnosis	Non-delayed diagnosis	COR	P-value	AOR	P-value
Age	x	x	X	x	X	x
Education level	x	x	X	x	X	x
Residence	x	x	X	x	X	x
Marital status	x	x	X	x	X	X
Income						
Parity	x	x	X	x	X	X
ANC	x	x	X	x	X	X
Gestational age at delivery	x	x	X	x	X	X
Mode of delivery	x	x	X	x	X	X
Child gender	X	X	X	X	X	X
Birth order	X	X	X	X	X	X
Child age	X	X	X	X	X	X
Age at presentation	X	X	x	x	x	x

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

Ref: KNH-ERC/A/397

11th October, 2022

Dr. Rachel Aketch Omondi
Reg.No.H58386592020
Dept of Paediatrics & Child Health
Faculty of Health Sciences
University of Nairobi

APPROVED
11 OCT 2022
KNH/UoN-ERC
P. O. Box 20723 - 00202, NAIROBI

Dear Dr. Omondi,

RESEARCH PROPOSAL: PREVALENCE AND FACTORS ASSOCIATED WITH DELAYED DIAGNOSIS OF CONGENITAL HEART DISEASE AT KENYATTA NATIONAL HOSPITAL (P167/03/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P167/03/2022.** The approval period is 11th October 2022 – 10th October 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 Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept, of Paediatrics & Child Health, UoN
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Dr. Brian Maugo, Dept. of Paediatrics & Child Health, UoN
Dr. Michuki Maina KEMRI Wellcome Trust Research Programme

PREVALENCE AND FACTORS ASSOCIATED WITH DELAYED DIAGNOSIS OF CONGENITAL HEART DISEASE AT KENYATTA NATIONAL HOSPITAL.

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