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Morbidity and Mortality Among Pediatric Congenital Heart Disease Patients on Waiting List at Cardiac Center –Ethiopia.

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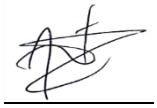
A Thesis Submitted to the Department of Cardiology/ Surgery as Partial Fulfillment of the Requirement for a Subspecialty Certificate in Cardiothoracic Surgery.

Addis Ababa.

24th July, 2025 G.C.

Declaration

I, Ashenafi Negash, do hereby declare that this thesis is a result of the works of my own making except where credit is given in a review of the previous literature in the content and by my knowledge, has never been submitted for any academic award or qualifications in this Institution.

Name: Dr. Ashenafi Negash Signature:  Date: 23rd July, 2025

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The undersigned have examined the thesis report entitled "***Morbidity and Mortality Among Pediatric Congenital Heart Disease Patients on Waiting List at Cardiac Center -Ethiopia***." presented by Dr. Ashenafi Negash with registration number **GSR/5751/15**, a candidate for Sub-specialty Certificate in Cardiothoracic Surgery and hereby certify that it is worthy of acceptance.

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Assurance of Principal Investigator and Advisor

We the undersigned hereby affirm that the research thesis entitled: "***Morbidity and Mortality Among Pediatric Congenital Heart Disease Patients on Waiting List at Cardiac Center - Ethiopia***." is an original work conducted by the principal investigator. The thesis is being submitted to the Department of Cardiology/ Surgery, Tikur Anbessa Specialized Hospital, College of Health Science, Addis Ababa University, as partial fulfillment for the requirement of Cardiothoracic Surgery Sub-specialty Certificate Training.

The undersigned principal investigator takes full responsibility for scientific, ethical and technical integrity of the study.

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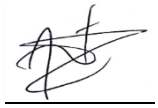
Name: Ashenafi Negash (MD) **Signature**:  **Date**: 24th July, 2025

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Abbreviation and acronyms

ASD: Atrial Septal Defect

AVCDs: Atrioventricular Canal Defects

AVSDs: Atriventricular Septal Defects

BFA: BMI-for-Age

CCE: Cardiac Center Ethiopia

CHD: Congenital Heart Disease(s)

CHF-CCE: Children Heart Fund, Cardiac Center-Ethiopia

CICU: Cardiac Intensive Care Unit

CS: Cesarean Section (implied from Mode of Birth alongside SVD)

DALYs: Disability-Adjusted Life-Years

HR: Hazard Ratio

ICU: Intensive Care Unit

IQR: Interquartile Range

IRB: Institutional Review Board

LHA: Length/Height-for-Age

LMICs: Low-to-Middle Income Countries

ND: Neurodevelopmental

NYHA: New York Heart Association

OPD: Outpatient Department

PDA: Patent Ductus Arteriosus

SD: Standard Deviation

SPSS: Statistical Package for Social Sciences

STATA: Statistical Analysis Software

SVD: Spontaneous Vaginal Delivery

TOF: Tetralogy of Fallot

VSD: Ventricular Septal Defect

WFA: Weight-for-Age

WFL/H: Weight-for-Length/Height

WHO: World Health Organization

Abstract

Introduction: Congenital heart diseases are prevalent globally, causing significant morbidity and mortality, particularly in low-to-middle income countries where limited cardiac care infrastructure, like in Ethiopia, leads to protracted surgical waiting lists exceeding 15,000 patients. Despite these known challenges, there is a scarcity of local data on the specific burden of morbidity and mortality, and their predictors among paediatric CHD patients on the surgical waiting lists in Ethiopia.

Objective: Assessed the morbidity and mortality patterns, and their predictors, among paediatric CHD patients waiting open-heart surgery at the Children's Heart Fund Cardiac Center-Ethiopia.

Methods: A retrospective cohort study was conducted at the Children's Heart Fund Cardiac Center-Ethiopia, analyzing data from pediatric congenital heart disease patients registered for open-heart surgery between September 1st, 2019, and August 31st, 2021. Patients under 15 years old who were candidates for open-heart surgery constituted the study population. Follow-up was conducted retrospectively until December 31st, 2024. Data on patient demographics, clinical status, nutritional status, and outcomes (survival, date/cause of death, morbidity events) were primarily abstracted from medical records, with phone contact used to ascertain missing information. Statistical analysis involved descriptive statistics, Kaplan-Meier survival curves with log-rank tests, and multivariable Cox proportional hazards models to identify mortality predictors. All analyses were performed using STATA version 15.0 and SPSS version 26.

Result: In this retrospective cohort study of 297 paediatric CHD patients on a waiting list for open-heart surgery, 11.8% underwent surgery, 22.6% died, and 65.7% remained waiting. The overall incidence death rate was 614.4 per 100 person-years of observation, with 67 deaths occurring over 4,000 person-days of follow-up. The median time from enrolment to death was 517 days (17 months), while the median time to surgery was 721 days (24 months). Significant predictors of mortality were weight at enrolment (HR=0.78; 95% CI: 0.66, 0.93), number of OPD visits (HR=0.92; 95% CI: 0.86, 0.99), complication (HR=4.58; 95% CI: 2.53, 8.28), and Cyanotic CHD (HR=2.60; 95% CI: 1.45, 4.66).

Conclusion: This study revealed a high waitlist mortality, a prolonged waiting period, low surgery rate, and high morbidity. Lower weight, fewer outpatient visits, the occurrence of complications, and having cyanotic heart disease are determinants of mortality.

1. Introduction

1.1 Background

Congenital heart diseases (CHDs) encompass structural abnormalities of the heart or great vessels present from birth, leading to disrupted blood flow and significant physiological impairments (1). These conditions represent the most prevalent birth defects globally, with an estimated incidence ranging from 8 to 10 per 1,000 (0.8%–1%) live-born, full-term infants, a figure that can increase tenfold in preterm infants, reaching approximately 8.3% (2). Without timely intervention, one in three babies with CHD in low-to-middle income countries (LMICs) tragically die within their first month of life (2,3). In Ethiopia, Africa's second most populous nation with an estimated 120 million people, CHD is a leading cause of morbidity and mortality, particularly among neonates (4,5).

Beyond early mortality, CHD significantly compromises the daily lives and long-term health of affected individuals, imposing immense physical, emotional, and financial burdens on families (6,7). In resource-limited settings like Ethiopia, patients with CHD frequently experience compounding challenges such as poor somatic growth, recurrent infections, and progressive pulmonary hypertension, all of which can exacerbate their cardiac conditions and worsen prognoses (2,3,6,8). The natural history of untreated or delayed-treatment of CHD in children often involves a relentless progression of symptoms, including growth failure, recurrent respiratory infections, heart failure, and irreversible pulmonary vascular disease, further complicating future surgical interventions and outcomes (3,6). Even for those who eventually undergo surgery, the magnitude of postoperative complications can be substantial; a study at the Cardiac Center of Ethiopia reported a postoperative complication rate of 30.5% (9).

The provision of comprehensive cardiac surgical care in Ethiopia remains critically limited. Currently, surgical services are available at only five local centers: a single charity organization (the Cardiac Center Ethiopia), one tertiary public hospital, and three for-profit facilities (5). This meager infrastructure is further strained by an alarmingly low number of only five cardiac surgeons and 12 pediatric cardiologists serving the entire population (5). Consequently, more than 15,000 patients are on a protracted waiting list for cardiac surgery nationwide, with some reported to have waited durations exceeding five years (5). This substantial accumulation is primarily driven by systemic challenges, including chronic shortages of essential consumables,

insufficient infrastructure, a severely limited number of specialized centers and trained healthcare professionals, and significant financial barriers to access (5,7,10).

The prolonged waiting period for life-saving cardiac surgery carries dire implications, particularly for pediatric patients whose cardiovascular systems are still developing and whose conditions can rapidly deteriorate. During this waiting time, children are highly susceptible to increased morbidity (e.g., hospital admissions for decompensated heart failure, severe cyanotic spells, arrhythmias, or end-organ damage) and a heightened risk of mortality before ever reaching the operating table (3,11). A study focusing on critical CHD infants in a developing country reported that 17% died before surgery or intervention, underscoring the horrible consequences of delayed care (11). Despite this critical public health challenge, there is a significant scarcity of localized data specifically detailing the burden of morbidity and mortality among pediatric CHD patients on surgical waiting lists in Ethiopia (5). Understanding the specific patterns of adverse events and the factors predicting these outcomes is crucial for informing policy, optimizing resource allocation, and developing targeted interventions to improve patient management and reduce the suffering and loss associated with delayed care.

This study, therefore, aims to bridge this critical knowledge gap by comprehensively assessing the morbidity and mortality patterns, and their associated predictors, among pediatric CHD patients waiting open-heart surgery at the Cardiac Center Ethiopia.

1.2 Statement of the Problem

Congenital heart disease (CHD) stands as the most common birth defect. The enduring burden of unrepaired CHD is evident even in school-aged children, where its global prevalence remains notably high at 4.7 per 1,000 children (1). A substantial proportion of these cases will eventually necessitate surgical correction, with a critical subset presenting as life-threatening and contributing significantly to infant mortality, particularly in LMICs where one in three babies tragically die within their first month of life (1,3)**.**

The prognosis for children with CHD-encompassing their survival rates, the extensive costs of medical care, and the potential for developmental disabilities—is profoundly influenced by several key factors: the timeliness of diagnosis, the duration of treatment delay, and the inherent severity of their cardiac condition (2,6,7). Notably, the probability of cardiac death from CHD is highest during infancy, underscoring the urgency of early intervention. Delayed diagnosis, for instance, has been identified as a significant risk factor for mortality in infants with critical CHD (11).

In Ethiopia, despite the compelling need for surgical correction, the severe limitations in cardiac care infrastructure have resulted in a staggering backlog of over 15,000 patients awaiting surgery (5). This dire situation means that a significant number of pediatric CHD patients face prolonged waiting times, exposing them to increased risks of disease progression and adverse outcomes. During this often-extended period, children on the waiting list are vulnerable to a spectrum of complications, including worsening heart failure, irreversible pulmonary hypertension, recurrent infections, malnutrition, and even premature death, without ever receiving the definitive surgical intervention they desperately need (3,6,8,9,11).

Crucially, while the existence of this immense waiting list is recognized and its mean duration unknown, there's a significant gap in our understanding of the specific morbidity and mortality experiences of these pediatric patients while they are awaiting surgery in the Ethiopian context (5). Comprehensive data on the demographic, disease-specific, and associated factors contributing to adverse outcomes during this critical waiting period are scarce. This lack of detailed evidence hinders the ability to identify high-risk individuals, prioritize interventions, allocate resources effectively, and advocate for improved cardiac care infrastructure.

Therefore, this study aims to systematically explore and quantify the morbidity and mortality among pediatric CHD patients on the surgical waiting list at the Cardiac Center Ethiopia, identifying the demographic, disease-specific, and associated factors that contribute to these outcomes. By shedding light on these critical aspects, this research seeks to provide evidence crucial for improving the management and prognosis of children awaiting life-saving cardiac surgery in resource-limited settings.

1.3 Significance of the study

This study is vital for providing crucial morbidity and mortality data for pediatric CHD patients on surgical waiting lists in Ethiopia, a critical gap in current knowledge. The findings will directly inform policymakers and healthcare administrators, enabling better resource allocation, more effective priority setting, and optimized follow-up strategies for these vulnerable patients.

By detailing the challenges faced by children awaiting surgery in a resource-limited setting, this research will enhance scholarly understanding of CHD progression and outcomes under conditions of delayed care. It will offer practical insights to improve clinical practice and shape public health policy, contributing to better management and advocacy for children with CHD in Ethiopia and other similar contexts.

2. Literature review

Global burden and challenges of congenital heart disease

Congenital heart disease (CHD) represents the most prevalent birth defect globally and poses a significant challenge to pediatric healthcare, with a profound impact on infant morbidity and mortality worldwide (1). A meta-analysis and systematic review of global prevalence in school-age children reported an overall prevalence of unrepaired CHD at 4.7 per 1,000 children (1). The estimated incidence of CHD ranges from 8 to 10 per 1,000 (0.8%–1%) live-born, full-term infants, a figure that can increase tenfold in preterm infants, reaching approximately 8.3% (2) (2). While advancements in fetal diagnosis and postnatal cardiac interventions have modified the spectrum of CHD and subsequent medical needs in high-income settings, access to such specialized care remains highly disparate across geographic regions. The importance of prenatal diagnosis for CHD is well-known, as it allows for better planning of delivery and perinatal care in specialized centers, significantly improving the survival of infants with critical CHD (2). A global study on cardiac surgery access reveals that approximately 75% of the world lacks access to cardiac surgery when needed due to insufficient infrastructure, human resources, and financial coverage (3). In developed countries, effective treatment for CHD can lead to an expected survival rate of 85% into adulthood (1,3).

The dire landscape in low-to-middle income countries

The burden of CHD is particularly acute in low-to-middle income countries (LMICs), where these conditions are the most common cardiovascular diseases requiring surgical intervention (3). A global study on cardiac surgery access highlights that an estimated one million babies, or one in every 125 live births annually, are affected by CHD in LMICs (3). This same study underscores that approximately 70% of these affected infants will require medical or surgical treatment within their first year of life (3). Alarmingly, a systematic review on barriers to accessing congenital heart surgery in LMICs reports that about 90% of children with CHD are born in LMICs, and over 90% of patients lack access to necessary treatments (10). This contributes to the finding that around 90% of children with CHD in LMICs are denied treatment or receive suboptimal care, with up to 80% of cases not diagnosed until the disease has progressed to advanced or irreversible stages of heart failure (3). Furthermore, a global meta-analysis on school-age CHD prevalence noted that a significant number of diagnoses occur for

the first time at school-age, with a prevalence of 1.5 per 1,000 children for such late diagnoses (1), highlighting persistent challenges in early detection. However, without timely intervention, one in three babies with CHD in LMICs tragically succumbs within their first month of life (1,3) In Ethiopia, specifically among neonates, CHD is a leading cause of morbidity and mortality (4).

Morbidity and consequences of delayed care

Patients who survive beyond infancy without definitive treatment or those facing prolonged delays in surgical intervention are subjected to a cascade of severe and often irreversible complications (3). These include frequent pulmonary infections, a heightened risk of bacterial endocarditis, the development of irreversible pulmonary vascular changes (pulmonary hypertension), myocardial fibrosis, and neurological events. Such morbidities not only impair the child's functional status and quality of life but also significantly increase operative risks should surgery eventually become available (3). A review emphasizes that despite improved survival, many CHD survivors need long-term medical care and face substantial functional deficits. These include permanent neurodevelopmental (ND) deficits impacting cognition, behavior, attention, and exercise performance, which can limit educational and employment opportunities and significantly reduce their quality of life. Poor somatic growth, identified as a major and potentially modifiable comorbidity for children with CHD, frequently originates in utero. Furthermore, sustained and progressive deficits in ventricular function can interfere with exercise performance, diminish quality of life, and ultimately predispose patients to intractable heart failure (6). The probability of cardiac death from CHD is highest during infancy (11). Indeed, in LMICs, congenital heart defects account for 66% of preventable deaths and 58% of disability-adjusted life-years (DALYs) due to congenital malformations, underscoring the critical impact of scaling up surgical care (3). Alarmingly, a study from a developing country focusing on critical CHD infants found that 17% died before surgery or intervention, further emphasizing the dire consequences of delayed care (11). Even for those who undergo surgery, the magnitude of postoperative complications can be substantial; a study at the Cardiac Center of Ethiopia reported a postoperative complication rate of 30.5% (9).

The challenge of surgical waiting lists in Ethiopia

The profound disparities in access to cardiac care in LMICs contribute substantially to the growing problem of surgical waiting lists. Ethiopia, the second most populous nation in Africa

with a population of 120 million people (5), faces a severe challenge where cardiovascular disease is a leading cause of morbidity and mortality among its young population (5). Annually, it is estimated that between 20,000 to 25,000 children are born with CHD in Ethiopia (5).

A comprehensive review on the state of cardiac surgery in Ethiopia revealed that currently, there are only five cardiac surgical centers in the country, with merely five trained adult and pediatric cardiac surgeons for the entire population (5). Further analysis from this review indicates that only two of these five centers perform regular open-heart surgeries, with most cardiac surgical cases historically performed by visiting international cardiac surgeons, highlighting a significant reliance on external support (5). The local specialized workforce is also critically limited, comprising only 12 pediatric cardiologists, 2 adult cardiologists, and 1 interventional cardiologist nationwide (5). This dire situation, coupled with chronic shortages of essential consumables, trained manpower, infrastructure, and funding, has resulted in a staggering national backlog of over 15,000 patients awaiting cardiac surgery, with a reported backlog duration of more than five years for some cases. The mean waiting time for these patients is currently unknown (5).

A systematic review on barriers to accessing congenital heart surgery in LMICs identifies key factors that exacerbate these waiting lists and delay care. These barriers encompass preoperative challenges such as geographical access (distance, travel costs, limited transport), significant financial burdens (out-of-pocket expenses, lack of insurance), and limited awareness or late diagnosis among patients, families, and even general practitioners (10). A qualitative study examining the experiences of caregivers in Ethiopia further corroborates these challenges, highlighting that many patients are diagnosed late or after hospital discharge, with diagnosis often dependent on proximity to health facilities and healthcare worker awareness (7). Caregivers frequently face long journeys and high transportation costs, and the financial burden of care, including fees for diagnosis, travel, food, accommodation, and drugs, often forces them to borrow money or sell assets, deeming lack of financial resources as the biggest barrier (7). Perioperative barriers include the severe lack of trained cardiac surgeons and specialized staff (e.g., anesthesiologists, perfusionists, nurses), insufficient infrastructure (e.g., ICU beds, operating rooms, specialized equipment), and consistent shortages of essential consumables and blood products (7,10). Lastly, postoperative barriers involve inadequate follow-up care and the ongoing financial strain of post-surgical recovery (7,10). The cumulative effect of these delays is severe; some studies indicate mortality rates as high as 25% in children referred from LMICs to

high-income countries due to prolonged waits (10). Caregivers also experience significant psychological distress, anxiety, and depression due to these long waits and the substantial financial burden (7).

For pediatric CHD patients, being on such a prolonged waiting list exposes them to a heightened risk of disease progression, increased severity of complications, and potentially irreversible damage before surgical intervention can be performed. This period is associated with a greater likelihood of morbidity and mortality directly attributable to the delay in definitive treatment. Indeed, in LMICs, congenital heart defects account for 66% of preventable deaths and 58% of disability-adjusted life-years (DALYs) due to congenital malformations, underscoring the critical impact of scaling up surgical care (3).

Factors influencing morbidity and mortality on waiting lists

Research has begun to elucidate various factors associated with morbidity and mortality among CHD patients, with particular relevance to those awaiting surgery. A systematic review and meta-analysis on social determinants of disparities in mortality outcomes in congenital heart disease identified that socio-demographic characteristics play a role; for instance, a study indicated that Black patients with non-critical CHD in their first year of life and those with critical CHD as neonates experienced increased mortality. Similarly, patients from deprived backgrounds, those born from multiple pregnancies, and those born to mothers under 18 years of age or with less than 12 years of education, exhibited a greater likelihood of death after the neonatal period (12).

Beyond socio-demographic aspects, clinical and disease-specific factors are paramount. As previously noted, growth failure is a significant and modifiable comorbidity (6). An extensive retrospective cohort study on cardiac patients' surgery outcomes in Ethiopia, involving 1520 individuals between 2012 and 2023, reported an overall post-surgical mortality rate of 12.6% (8). This study identified several critical factors associated with increased mortality following cardiac surgery that are highly relevant to patients on a waiting list, as their conditions may progress: being 15 years or older at the time of surgery, having a congenital heart disease diagnosis (compared to rheumatic heart disease), and having a body mass index (BMI) less than 18.5 (indicating underweight) (8). The finding regarding low BMI strongly reinforces the importance of addressing poor somatic growth as a modifiable comorbidity (6,8). The presence of

comorbidities also significantly increased mortality risk (8). An Ethiopian study on the incidence and predictors of mortality among neonates with congenital heart disease highlighted that the place of delivery is an independent predictor, with neonates born at home facing a significantly higher risk of mortality (4). Furthermore, prematurity and severe comorbidities also exhibited a higher hazard of mortality (5,11). Studies have also identified low birth weight, delayed diagnosis, and the presence of extracardiac anomalies as significant risk factors for mortality in infants with critical CHD (11). Specific types of CHD, such as pulmonary atresia, hypoplastic left heart syndrome, transposition of the great arteries (4), and single ventricle physiology (11), were associated with particularly high mortality rates.

Crucially, a study at the Cardiac Center of Ethiopia identified several factors that significantly increase the risk of postoperative complications, which in turn are associated with prolonged ICU and hospital stays, and increased mortality. These factors include: age less than one year at the time of surgery, higher New York Heart Association (NYHA) functional class (III/IV), low weight-for-age Z-score (< -2), and the presence of chromosomal anomalies. The type and severity of the CHD, the presence of complications like pulmonary hypertension or heart failure, and the development of neurodevelopmental deficits also critically influence outcomes (6). The duration of the waiting time itself is a crucial determinant, as delayed access to surgery allows for disease progression and the accumulation of irreversible complications, which can worsen existing risk factors and increase the complexity and risk of eventual surgical intervention (3).

Despite the evident and severe impact of prolonged surgical waiting times on pediatric CHD patients in LMICs, comprehensive, localized data on the specific patterns and predictors of morbidity and mortality during this critical waiting period remain scarce in Ethiopia (5). The study on the state of cardiac surgery in Ethiopia explicitly states that mortality data for patients on the waiting list are unknown, and the mean waiting time is not known (5). A global meta-analysis on school-age CHD prevalence further highlights this data by noting the complete absence of studies from Africa in its analysis, underscoring a significant regional knowledge gap regarding the overall burden and late diagnoses (1). While studies in Ethiopia have provided valuable insights into post-surgical outcomes and associated risk factors (8,9,13), and systematic reviews highlight global barriers to access (10), detailed evidence tailored to the unique socio-economic, healthcare, and disease burden contexts of the region, specifically concerning the waiting period, is lacking. A qualitative study on caregivers' experiences in Ethiopia further

underscores gaps in communication with healthcare providers, which can impede effective patient management during the waiting period and post-operative care (7). Understanding the specific demographic, maternal, neonatal, and clinical factors that contribute to adverse outcomes for children on the waiting list is essential for developing targeted interventions, improving risk stratification, and optimizing the allocation of limited resources. This study aims to fill these crucial knowledge gaps by systematically investigating the morbidity and mortality experienced by pediatric CHD patients on the waiting list at the Cardiac Center Ethiopia.

Conceptual framework

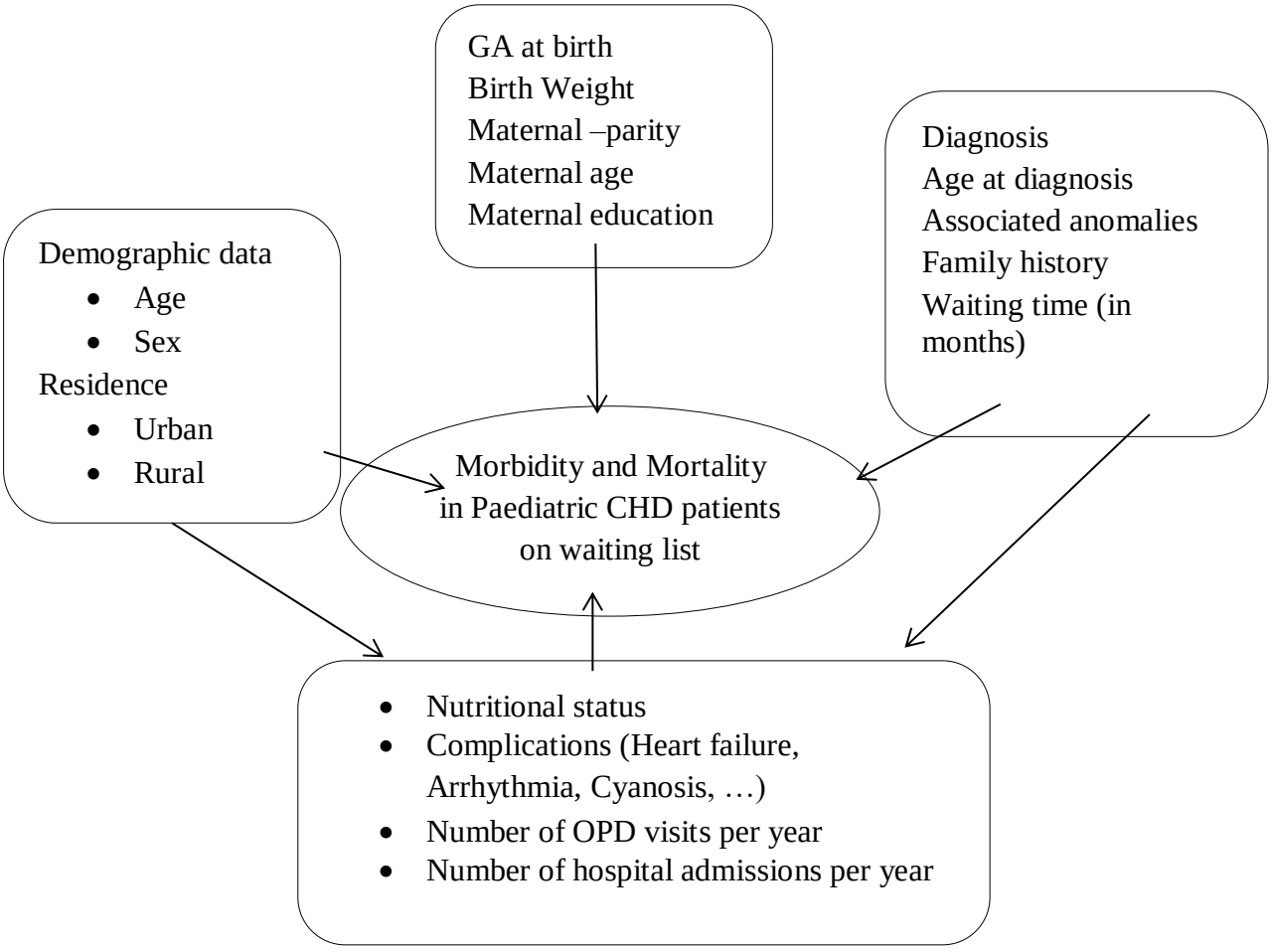

Figure 1: A conceptual framework that shows the relation between dependent and independent variables

3. Objectives

3.1 General objective

To assess the morbidity and mortality of paediatric congenital heart disease patients on waiting list at CHF-CCE.

3.2 Specific objective

1. To determine the survival status and mortality rate of pediatric CHD patients while on the waiting list for open heart surgery at the CCE.
2. To identify the morbidity patterns and complications experienced by pediatric CHD patients while on the waiting list for open heart surgery at the CCE.
3. To determine the cumulative incidence of surgery and death among pediatric CHD patients while on the waiting list at the CCE.
4. To identify predictors of morbidity among pediatric CHD patients while on the waiting list for open heart surgery.
5. To identify predictors of mortality among pediatric CHD patients while on the waiting list for open heart surgery.
6. To evaluate the impact of waiting time on the morbidity and mortality outcomes of pediatric CHD patients while on the waiting list for open heart surgery.

4. Methods and Materials

4.1 Study area and period

The study was conducted at the Cardiac Center Ethiopia (CCE), a charity organization established in 2009 that provides comprehensive cardiac care. CCE is equipped with two operating tables, four surgeons, and ten Cardiac Intensive Care Unit (CICU) beds. The study focused on patients awaiting cardiac surgery at CCE between September 1st, 2019, and August 31st, 2021.

4.2 Study design

A hospital based retrospective cohort study design will be employed.

4.3 Population

Source population

All patients registered with a diagnosis of CHD below the age of 15 years and are candidates for open heart surgery.

Study population

The study population comprised all pediatric patients diagnosed with Congenital Heart Disease (CHD) who were below the age of 15 years and registered as candidates for open-heart surgery at the Cardiac Center Ethiopia (CCE) between September 1st, 2019, and August 31st, 2021. This period was chosen to establish a well-defined cohort for retrospective follow-up and to ensure a sufficient duration for observing relevant clinical outcomes. Patients who were registered for interventional cardiac catheterization procedures without the intent of open-heart surgery were excluded.

4.4 Data sources and collection procedures

Patient demographic, clinical, and outcome data were primarily extracted from existing medical records at the Cardiac Center Ethiopia (CCE). Data collection was performed using a structured questionnaire, which was prepared in English. This questionnaire guided the systematic abstraction of information from various sources, including patient charts, registration logs, surgical waiting lists, initial and follow-up anthropometry records, and echocardiography reports. Maternal medical history and behavioral characteristics were also abstracted from available medical records. To gather additional information on patient wellbeing and to address any

missing data points from medical records, patients or their primary caregivers were contacted by telephone. Data collection was carried out by the principal investigator and at least three general practitioners. These data collectors underwent comprehensive training on the study's purpose and detailed data collection procedures to ensure consistency and accuracy in data abstraction.

4.5 Follow-up period and outcome ascertainment

Patients in the cohort were followed retrospectively from their date of registration on the waiting list for open-heart surgery (defined as the 'entry date') up to **December 31st, 2024**. This fixed cut-off date ensured a consistent and standardized follow-up period for all patients within the defined cohort, allowing for approximately 3.3 to 5.3 years of observation depending on their registration date.

For each patient, the following outcomes were ascertained:

- **Survival status:** Patients were classified as either 'Censored' (survived up to the follow-up end date or were lost to follow-up) or 'Death'.
- **Date of event:** For patients who underwent surgery, the date of surgery was recorded. For patients who died, the date of death was meticulously abstracted from medical records.
- **Morbidity events:** Relevant morbidity data, including but not limited to, hospital admissions for CHD-related complications, outpatient department (OPD) visits, nutritional status, and documented complications (e.g., heart failure, cyanosis, arrhythmia), were collected up to the follow-up end date or the date of death/surgery.

4.6 Handling of censoring and loss to follow-up

Patients who were alive at the end of the follow-up period (December 31st, 2024) or who were lost to follow-up before this date without a documented death were considered 'censored' at their last known contact date or the follow-up end date, whichever came first. Efforts were made to minimize loss to follow-up by thoroughly reviewing all available medical records and administrative databases for any updated contact information or outcome data. Additionally, for patients with no documented follow-up record since their registration date up to the study follow-up end date, attempts were made to ascertain their survival status through direct phone contact with the patient or their primary caregiver, utilizing the contact information available in their medical records.

Standard survival analysis methods were employed to appropriately account for censored observations in the statistical analysis.

4.7 Sample size determination

The sample size for this retrospective cohort study was primarily determined by the total number of eligible pediatric CHD patients registered at the CCE within the defined recruitment period. This approach aimed to conduct a census of the available cohort, thereby maximizing the statistical power for detecting associations and providing a comprehensive assessment of morbidity and mortality of CHD. The exact number of eligible patients was ascertained during the initial data abstraction phase by reviewing the cardiac center's registration logs and patient medical records for the specified period.

A formal sample size calculation was performed to ensure adequate power for identifying factors associated with mortality. The calculation was based on a two-sided significance level of $\alpha=0.05$ and 80% statistical power ($1-\beta=0.80$). Drawing from an Ethiopian study on mortality in neonates with CHD, a Hazard Ratio (HR) of 1.9 was utilized, representing the effect of "Place of delivery" as a predictor of mortality (Ayfokru et al., 2024). Using a Cox proportional hazards model in STATA version 15, the minimum required sample size to detect this effect was determined to be 240 patients. To account for potential loss to follow-up and incomplete data inherent in retrospective medical record reviews, an additional 15% of the calculated sample size was added. Therefore, the final estimated sample size for this study was approximately 276 patients.

4.8 Study variables

Dependent variables

- Survival condition of the child, Time to surgery, Time to death

Independent variables

- **Socio-demographic characteristics of the child and mother**: Sex of the child, Age of the child (at diagnosis, enrolment for surgery, and end of study), Age of the mother at child's birth, Residence, Marital status of the mother, Educational status of the mother, and Birth order of the child.
- **Anthropometric measurements of the child**: nutritional status of the child at (at diagnosis, enrolment for surgery, and end of study)

- **Clinical characteristics**: Number of hospital admissions, number of OPD visits, complication, primary CHD diagnosis, types of CHD, and associated anomaly.

4.9 Operational definition

Congenital Heart Diseases (CHDs): Structural abnormalities of the heart or great vessels present from birth, diagnosed by a pediatric cardiologist, typically through echocardiography.

Morbidity: The incidence of disease or complications observed in pediatric CHD patients during the study period, including but not limited to occurrences of recurrent infections, heart failure, progressive pulmonary hypertension, and poor somatic growth.

Mortality: The death of a pediatric CHD patient during the waiting period for surgical intervention at the specified cardiac center (CHF-CCE), recorded from the time of placement on the waiting list until surgical intervention or death.

Nutritional Status: Assessed using anthropometric measurements such as Weight-for-Length/Height (WFL/H), Length/Height-for-Age (LHA), Weight-for-Age (WFA), and BMI-for-Age (BFA), compared against WHO growth standards, indicating categories like wasting, stunting, or underweight.

Heart Failure: Clinical diagnosis based on signs and symptoms of impaired cardiac function (tachypnea, tachycardia, hepatomegaly, poor feeding, exercise intolerance), potentially supported by imaging findings (cardiomegaly on chest X-ray, ventricular dysfunction on echocardiography).

Pulmonary Hypertension: Elevated blood pressure in the pulmonary arteries, diagnosed through echocardiography or cardiac catheterization, often classified by severity.

Waiting List: The registry of pediatric CHD patients eligible and awaiting surgical intervention at the Cardiac Center Ethiopia (CCE), with the waiting period commencing from the date of listing and ending with surgery, death, or loss to follow up from the list.

Surgical Intervention: Any corrective or palliative cardiac surgical procedure performed on a CHD patient, requiring admission to the Cardiac Intensive Care Unit (CICU) post-operatively.

4.10 Statistical analysis

Descriptive statistics were employed to summarize the baseline characteristics of the study population. Continuous variables were expressed as the mean ± standard deviation (SD) for normally distributed data, and as the median with interquartile range (IQR) for non-normally distributed data. Categorical variables were presented as frequencies and percentages.

On univariable analysis, Kaplan–Meier curves were generated to visualize the survival experience of the cohort, with time zero defined as the date of registration on the waiting list for surgery. The significance of differences between survival curves was assessed using the log-rank test. A multivariable Cox proportional hazards model was constructed to identify independent predictors of mortality. Covariates were included in the model if they demonstrated a P-value of ≤0.25 during the univariable prescreening. The proportionality assumption of the Cox regression model was assessed using Schoenfeld residuals (global test). Furthermore, model fitness was evaluated using the Cox-Snell residual test.

To calculate the cumulative incidence of events (e.g., surgery, death) during the waiting period, a competing risks data analysis was utilized, acknowledging that other events may preclude the primary outcome of interest. The $\chi 2$ test for trend in proportions was used to evaluate the association between waiting time and the occurrence of events on the waiting list. A P-value of less than 0.05 was considered statistically significant for all analyses. Missing data in regression models were handled by case-complete analysis. All statistical analysis was performed using STATA version 15.0.

4.11 Data quality control and management

To ensure data quality, the structured questionnaire was thoroughly checked for completeness and consistency prior to data collection. The questionnaire also benefited from comments and feedback from the study advisors. Data collectors received comprehensive orientation on the study's objectives, the importance of confidentiality, and detailed procedures for extracting data from medical records.

During the data collection phase, the principal investigator conducted daily supervision, meticulously checking the completeness and consistency of the collected data. Upon completion of data collection, all questionnaires were again checked for completeness and consistency before data entry. The data were then coded and entered into Statistical Package for Social Sciences (SPSS) version 25 for management and analysis.

4.12 Ethical Considerations

The study commenced after obtaining ethical approval from the Research Ethical Committee of the Surgery Department/IRB of Addis Ababa University, College of Health Sciences. Given the retrospective nature of the data collection from existing medical records, a waiver of individual informed consent was granted for chart review. However, if direct phone contact was made with patients or caregivers for additional information, verbal informed consent was secured for the use of their data for academic and research purposes, and only those who agreed participated.

Patient confidentiality was maintained throughout the study. Medical record numbers were used for data abstraction, and no personal identifiers were included in the research report. Access to the collected information was limited to the principal investigator and trained data collectors.

4.13 Data presentation and dissemination

Descriptive analyses were used to summarize the study population's characteristics. Continuous variables were presented as mean and standard deviation (SD), while categorical variables were expressed using frequencies and percentages. Data were displayed, described, and summarized using text, tables, and figures.

The study findings will be submitted to the Department of Surgery as part of the requirements for the Fellowship Certificate in Cardiothoracic Surgery. Further efforts will be made to present the results at professional conferences and publish them in peer-reviewed journals.

5. Result

A total of 346 CHD patients were found recorded between September 1st, 2019, and August 31st, 2021 for cardiac surgery at the center. Of these, 14 charts were excluded from analysis because of incomplete record. An additional 35 patients were excluded from the analysis because of refusal and unreachable phone of care givers. Finally, 297 CHD patients were included in this retrospective cohort study. Of the 297 CHD patients included in the study, 35 (11.8%) were operated, 67 (22.6%) were dead and 195 (65.7%) were waiting.

5.1 Socio-demographic characteristics

Among the 297 pediatric CHD patients included in the study, 154 (51.9%) were male and 143 (48.1%) were female. The mothers of the majority (278 (93.6%)) of CHD patients were married. The majority of the children, 258 (86.9%), resided in urban areas (Table 1).

Table 1: Socio-demographic characteristics of pediatric CHD patients on the waiting list (N=297)

Characteristic		**Frequency**	**Percent (%)**
Sex of the Child	Male	154	51.9
	Female	143	48.1
Maternal Marital Status	Married	278	93.6
	Single	5	1.7
	Separated/Divorced/Widowed	14	4.7
Maternal Education Level	Unable to read and write	37	12.5
	Primary (1-8)	95	32.0
	Secondary (9-12)	85	28.6
	College/University and above	80	26.9
Residence	Rural	39	13.1
	Urban	258	86.9

The majority of CHD patients were from urban centers and densely populated regions. Addis Ababa accounted for the largest proportion of patients (40.4%), followed by Oromia (32.7%) and Amhara (14.5%), collectively representing over 87% of the study population. Conversely, regions such as Afar, Benishangul Gumuz, Dire Dawa, Gambela, Southwest Ethiopia, and Tigray each contributed a very small percentage of patients (0.7% each) (Figure 2).

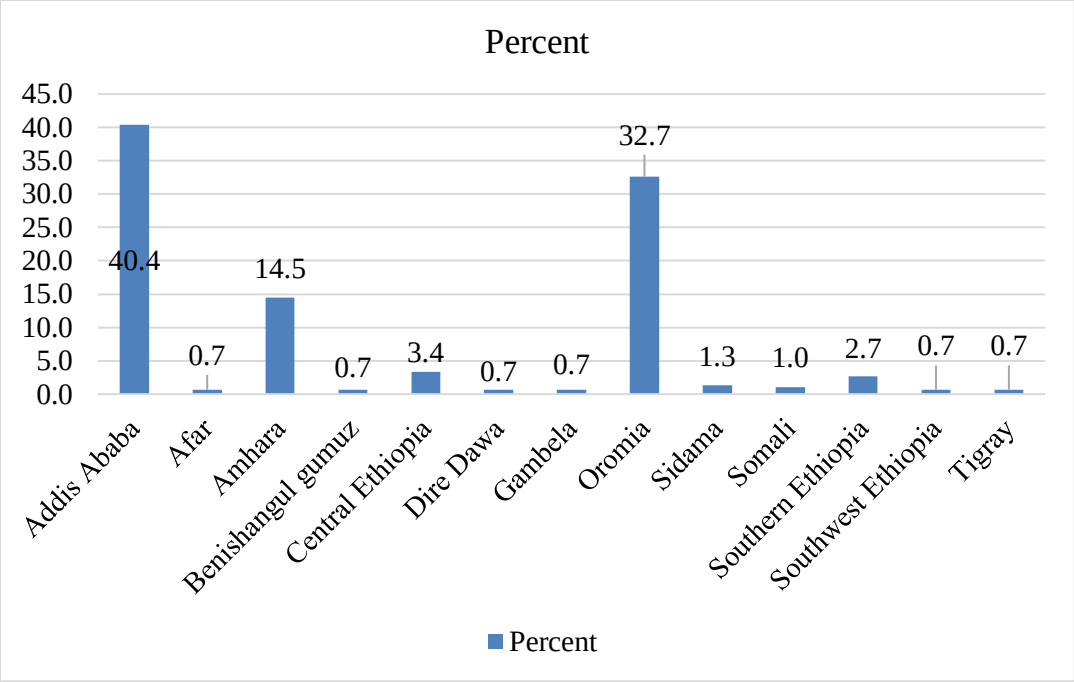

Figure 2: Regional distribution of CHD patients waiting for cardiac surgery at the Cardiac Center-Ethiopia, 2025

5.2 Clinical and Anthropometric Characteristics at Diagnosis/Enrollment

Patients were diagnosed with CHD at a median age of 10.00 months (IQR: 29.00). The median age at enrollment for open-heart surgery planning was 14.00 months (IQR: 31.00). The median maternal age at the time of the child's birth was 28.00 years (IQR: 9.00). The median child's birth order was 2.00 (IQR: 2.00), and the median maternal parity for this child was 2.00 (IQR: 2.00).

At the time of diagnosis, the median weight was 7.50 kg (IQR: 7.00) and median height was 70.00 cm (IQR: 31.00). At enrollment for surgery, these values slightly increased to a median weight of 8.50 kg (IQR: 7.00) and a median height of 77.00 cm (IQR: 29.00). The median gestational age at birth was 39.00 weeks (IQR: 4.00) (Table 2).

Table 2: Clinical and anthropometric characteristics of pediatric CHD patients on the waiting list (N=297)

Variable	Mean	SD	Median	IQR
Age at diagnosis (months)	26.58	35.999	10	29
Age at enrollment for surgery (months)	30.6	36.161	14	31

Maternal age at child's birth (years)	28.67	6.029	28	9
Child's birth order	2.35	1.314	2	2
Maternal parity for this child	2.76	1.502	2	2
Weight at diagnosis (kg)	9.56	6.321	7.5	7
Height at diagnosis (cm)	78.18	24.106	70	31
Weight at enrollment for surgery (kg)	10.47	6.166	8.5	7
Height at enrollment for surgery (cm)	82.36	22.848	77	29
Gestational age at birth (weeks)	38.02	2.88	39	4

5.3 Clinical and Birth-Related Characteristics of Pediatric CHD Patients on Waiting List

A large majority, 267 (89.9%), of the children were born in a health facility, while 30 (10.1%) were home deliveries. Most deliveries were singletons, accounting for 293 (98.7%) of cases. Regarding mode of birth, 227 (76.4%) were through SVD, and 70 (23.6%) were by CS. Family history of CHD was reported in 15 (5.1%) of the cases. Furthermore, 188 (63.3%) children were born at term gestation, while 99 (33.3%) were preterm and 10 (3.4%) were post-term. About 58 (19.5%) of the patients had associated anomalies other than CHD (Table 3).

Table 3: Clinical and birth-related characteristics of pediatric CHD patients on the waiting list (N=297)

Characteristic		**Frequency**	**Percent (%)**
Place of Delivery	Health facility	267	89.9
	Home	30	10.1
Type of Delivery	Singleton	293	98.7
	Twins	4	1.3
Mode of Birth	SVD	227	76.4
	CS	70	23.6
Family History of CHD	No	282	94.9
	Yes	15	5.1
Gestational Age Category	Preterm	99	33.3
	Term	188	63.3
	Post-term	10	3.4
Associated Anomaly Other Than CHD	No	239	80.5
	Yes	58	19.5

Note: Associated anomaly other than CHD include Down syndrome, cleft lip & palate, congenial hypothyroidism, imperforate anus, anorectal anomaly, and omphalocele.

5.4 Primary Congenital Heart Disease Diagnoses

Ventricular Septal Defect (VSD) was the most frequent diagnosis with 136 (45.8%) of the cases, followed by Atrial Septal Defect (ASD) at 53 (17.8%) and Patent Ductus Arteriosus (PDA) at 43 (14.5%). Tetralogy of Fallot (TOF) was present in 29 (9.8%) of the patients. The least common were Atrioventricular Canal Defects (AVCDs), which presented in 7 (2.4%) of the patients (Figure 3). Overall, acyanotic CHD types prevailed, representing 241 (81.1%) of patients, while cyanotic CHD types presented in 56 (18.9%) of the diagnoses (Figure 4).

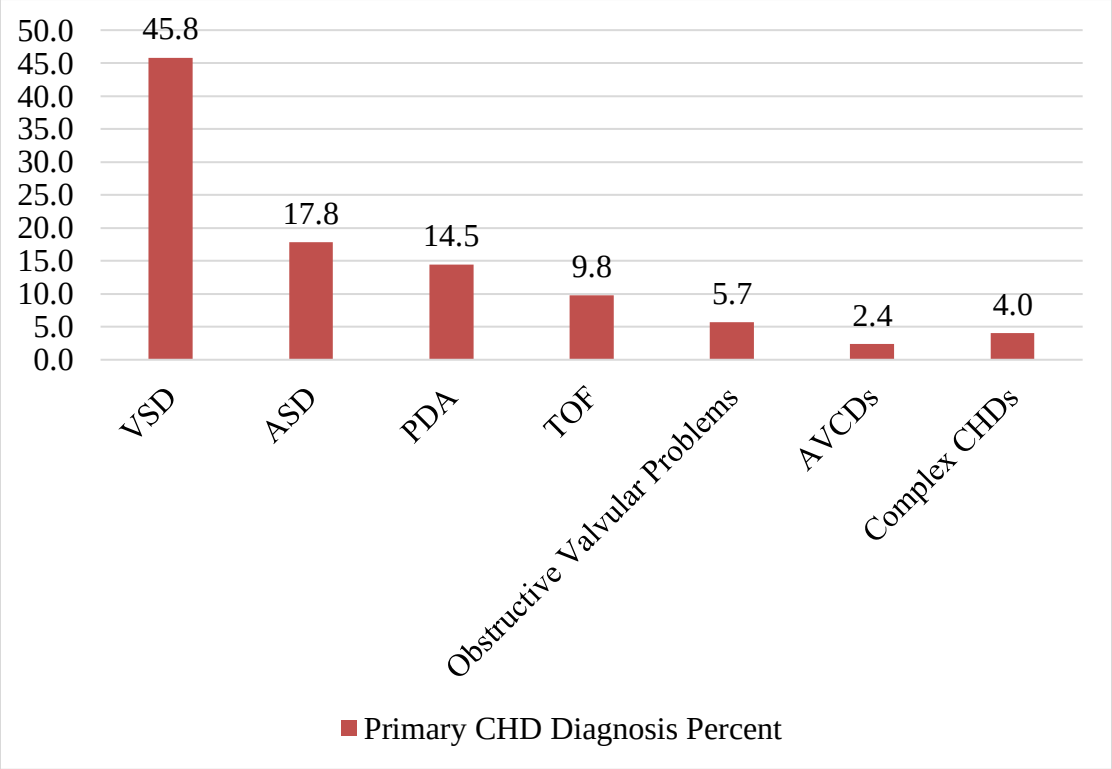

Figure 3: Primary congenital heart disease diagnoses types among CHD patients waiting for surgery at the Cardiac Center-Ethiopia

Note: **AVCDs** include balanced AV canal defect, common AV canal defect, complete balanced AVSD, and transitional AVSD; **Obstructive and Regurgitant Valvular/Vascular Lesions** include circumferential sub-aortic Membrane with left ventricular out flow obstruction (LVOTO), MVP, Sever Mitral Regurgitation, Aortic coarctation, and Valvular pulmonary stenosis; **Other Complex CHDs** include Ebstein anomaly of TV with moderate TR, Tricuspid atresia Type 1B, and Tricuspid atresia type C.

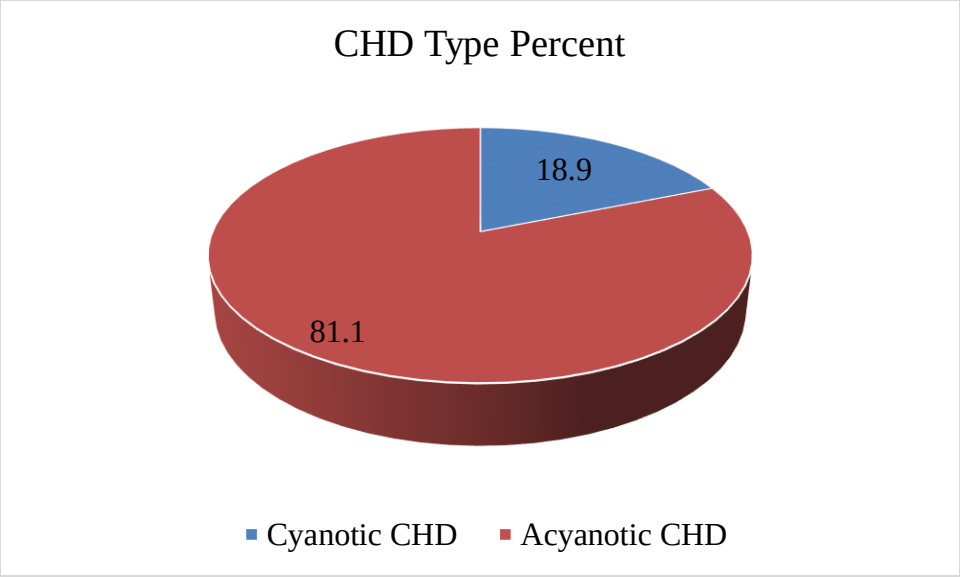

Figure 4: Types of CHD among pediatric patients waiting for surgery at the Cardiac Center-Ethiopia, 2025

5.5 Morbidity Patterns During the Waiting Period

About 103 (35%) of the patients have ever been hospitalized at least once during their waiting time for the surgery. Half of the patients, 149 (50.2%), have ever visited OPD during their waiting time. During the follow-up period, patients had a mean of 3.84±5.50 OPD visits.

Majority (66%) of the patients visited OPD for routine follow-up for CHD. Pneumonia was the second most frequent, observed in 27 (14.4%) of cases (Table 4).

Table 4: Diagnoses recorded during morbidity events/complications (N=188 events/patients)

Diagnosis	**Frequency**	**Percent (%)**
Pneumonia	27	14.4
Routine follow-up for CHD	124	66.0
Pulmonary hypertension	17	9.0
Congestive Heart Failure	9	4.8
Difficulty breathing / desaturation / cyanosis	7	3.7
Total	**188**	**100.0**

The most common reason for admission was CHF, accounting for 61 (46.9%) of cases, followed by pneumonia at 31 (23.8%), and difficulty breathing / desaturation / cyanosis at 16 (12.3%).

Admissions directly related to CHD and its complications (including CHF, CHF and Pulmonary Hypertension, Difficulty Breathing/Desaturation/Cyanosis, and Other general systemic complications of CHD such as renal failure, anemia, and sever acute malnutrition) collectively accounted for 84 (64.6%) of all hospital admissions during the waiting period (Table 5). For those admitted, the mean length of hospital stay was 12.96±14.25 days, with a median stay of 7.00 days, ranging from 1 to 90 days.

Table 5: Reasons for hospital admissions during the waiting period among pediatric CHD patients waiting for surgery at the Cardiac Center-Ethiopia.

Diagnosis for Hospital Admission	**Frequency**	**Percent (%)**
Pneumonia	31	23.8
CHF	61	46.9
Difficulty Breathing / Desaturation / Cyanosis	16	12.3
Other general systemic complications of CHD	7	5.4
Gastrointestinal & Abdominal Issues	5	3.8
Malaria	5	3.8
URTI	5	3.8
Total	**130**	**100.0**

Note: Other general systemic complications of CHD include renal failure, anemia, and malnutrition.

5.6 Complications

Pulmonary hypertension was the most prevalent complication, observed in 38 (48.7%) of the cases. CHF was the second most common, reported in 30 (38.5%) of cases (Table 6).

Table 6: Specific types of complications experienced by pediatric CHD patients on the waiting list (N=78 complications)

Complication Type	**Frequency**	**Percent (%)**
Pulmonary hypertension	38	48.7
Congestive Heart Failure	30	38.5
Anemia	3	3.8

Failure to thrive	3	3.8
Renal failure	2	2.6
Arrhythmia	1	1.3
Coma due to ?embolic event	1	1.3
Total	**78**	**100.0**

5.7 Nutritional assessment of Pediatric CHD patients

The nutritional status of pediatric CHD patients at the time of enrollment for open heart surgery was assessed using WHO growth standards. This analysis covered two primary age groups.

Children Aged 0-59 Months

Among the 0-59 month age group, a significant burden of undernutrition was prevalent at enrollment. Overall, for Weight-for-Length/Height (WFL/H), 33.5% of children were wasted, with 14.2% severely wasted. Length/Height-for-Age (LHA), indicating chronic undernutrition, revealed 14.2% were stunted, with 4.1% severely stunted. For Weight-for-Age (WFA), 30.9% were underweight, including 11.4% severely so. BMI-for-Age (BFA) showed 33.1% below -2 standard deviations, and 13.6% severely thin. Conversely, smaller proportions exhibited excess weight, with 6.7% at risk of overweight (WFL/H) and 6.8% at risk of overweight (BFA).

Disaggregating by sex in this age group, male patients generally presented with higher rates of undernutrition across most indicators. For WFL/H, 34.9% of males were wasted (vs. 31.8% of females); for LHA, 18.7% of males were stunted (vs. 8.9% of females); for WFA, 33.6% of males were underweight (vs. 28.6% of females); and for BFA, 35.9% of males were thin (vs. 29.6% of females).

Children Aged 5-14 Years (60-179 Months)

In the 5-14 year age group, undernutrition remained a considerable concern at enrollment. For Length/Height-for-Age (LHA), 14.0% were stunted, including 2.3% severely stunted. BMI-for-Age (BFA) showed 23.3% were thin (below -2 SD), with 7.0% severely so. For the 5-9 year subset, Weight-for-Age (WFA) indicated 24.3% were underweight, with 8.1% severely underweight. Excess weight was also noted, with 11.6% at risk of overweight and 9.4% overweight or obese based on BFA.

Sex-specific analysis within the 5-14 year group revealed certain patterns. Male patients showed a higher prevalence of thinness (BFA) at 28.6% (vs. 18.2% in females) and underweight (WFA, 5-9 years) at 25.0% (vs. 23.5% in females). Stunting (LHA) was similar between sexes, with 14.3% in males and 13.6% in females.

5.8 Mortality rate

The overall incidence death rate in the study cohort was 614.4 per 100 person-years of observation (95% CI: 483.7 – 780.8). A total of 67 deaths occurred over 4,000 person-days of follow-up among 297 included records.

5.9 Time to death and surgery

As previously stated, of the 297 pediatric CHD patients, 67 (22.6%) died while on the waiting list. For these 67 patients, the median time from enrollment to death was 517 days, (IQR: 750 days). In months, the median time to death was 17 months (IQR: 25 months).

Only 35 (11.8%) of the 297 patients underwent open-heart surgery by the end of the follow-up period. The median time from enrollment to surgery was 721 (IQR: 832) days, for the 35 operated patients. In months, the median time to surgery was 24 (IQR: 28) months.

5.10 Association Between Primary CHD Diagnosis and Mortality

To investigate the association between the primary CHD diagnosis and patient mortality during the waiting period, a Chi-square test of independence was performed. The analysis indicated that there was no statistically significant association between the type of primary CHD diagnosis and the survival condition of the patient (χ^2 (6) = 12.246, p = 0.057).

Among the specific diagnoses, AVCDs showed the highest mortality rate, with 4 (51.7%) of 7 patients dying while on the waiting list. This was followed by Complex CHDs, with 5 (41.7%) of 12 patients dying (Table 7).

Table 7: Survival condition by primary CHD diagnosis (N=297)

Primary CHD Diagnosis	**Alive**	**Dead**	**Total**	P-value
VSD	107 (78.7%)	29 (21.3%)	136	0.057
ASD	39 (73.6%)	12 (26.4%)	50	
PDA	39 (90.7%)	8 (9.3%)	43	
TOF	22 (75.9%)	7 (24.1%)	29	

Obstructive Valvular Problems	13 (76.5%)	4 (23.5%)	17	
AVCDs	3 (42.9%)	4 (57.1%)	7	
Complex CHDs	7 (58.3%)	5 (41.7%)	12	
Total	**230 (77.4%)**	**67 (22.6%)**	**297**	

5.11 Kaplan-Meier and Survival Analysis (Log-Rank Tests)

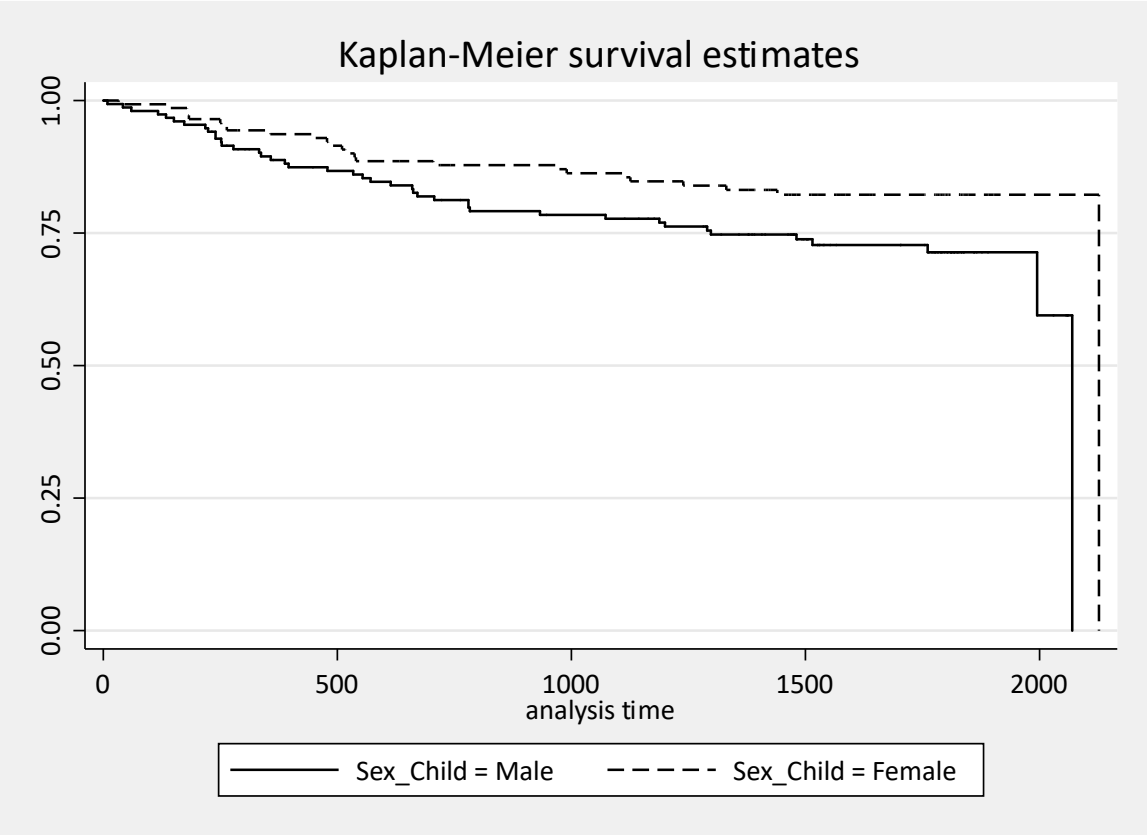

Figure 5: Kaplan Meir curve of sex of the child versus survival status among pediatric CHD patients, CCE, 2025

Log-Rank tests were performed to compare the survival functions of pediatric CHD patients on the surgical waiting list across various demographic, clinical, and disease-specific characteristics. The Log-Rank test results revealed statistically significant differences in survival distributions for several key characteristics. Sex was significantly associated with survival ($p = 0.0338$), with male patients experiencing a higher observed mortality than expected. Weight at Diagnosis (kg) showed a highly significant association with survival ($p < 0.001$), indicating that patient weight at diagnosis significantly impacts time on the waiting list. Similarly, the Number of Hospital

Admissions from enrollment to December 31, 2024 was found to be a highly significant predictor of survival ($p < 0.001$), with a higher number of admissions correlating with poorer survival outcomes. Furthermore, whether a child faced complication was highly significant ($p < 0.001$), with children experiencing complications having substantially higher observed mortality. Finally, Types of CHD also demonstrated a highly significant difference in survival ($p < 0.001$), indicating that Cyanotic CHD is associated with poorer survival.

Conversely, maternal marital status ($p = 0.0849$), child's birth order ($p = 0.6247$), number of OPD Visits ($p = 0.7787$), maternal education level ($p = 0.5873$), maternal parity ($p = 0.8826$), and primary CHD Diagnosis ($p = 0.0754$) did not show statistically significant differences in survival distributions (Table 8).

Table 8: Log-Rank test results for factors associated with survival on waiting list

Characteristic	**Chi-square (df)**	**p-value**
Sex	4.51 (1)	0.0338
Maternal Marital Status	4.93 (2)	0.0849
Child's Birth Order	6.20 (8)	0.6247
Weight at Diagnosis (kg)	15.369 (86)	< 0.001
Number Hospital Admissions	52.07 (9)	< 0.001
Number of OPD Visits	11.48 (16)	0.7787
Complication	43.73 (1)	< 0.001
Maternal Education Level	1.93 (3)	0.5873
Maternal Parity	3.71 (8)	0.8826
Primary CHD Diagnosis	11.45 (6)	0.0754
Types of CHD (Cyanotic/Acyanotic)	22.24 (1)	< 0.001

5.12 Analysis of waitlist mortality and its risk factors in CHD patients

Bivariable Cox proportional hazards regression analysis identified several factors as candidates for inclusion in the multivariate model (p-value cutoff of ≤0.25). Among the demographic and clinical characteristics, sex of child, age at enrollment, maternal age at child birth, weight at enrollment, number of hospital admissions, number of OPD visits, and complication were identified as candidates. Types of CHD and primary CHD diagnosis types also met the selection

criteria. However, variables such as residence, maternal education level, associated anomaly, and child's birth order were not considered for the multivariate model (Table 9).

Table 9: Bivariable Cox proportional hazards regression analysis of CHD pediatric patients waiting open heart surgery from Sep 2019 to Dec 2024

Characteristic	**Category**	**Hazard Ratio (HR)**	**95% Confidence Interval**	**p-value**	**Reference**
Sex of the Child	Male	1.71	[1.04, 2.83]	**0.036**	Female
Age at Enrollment (Months)	Per 1-month increase	0.98	[0.97, 0.99]	**0.002**	
Weight at Enrollment (Kg)	Per 1-kg increase	0.87	[0.81, 0.93]	**<0.001**	
Number of Hospital Admissions	Per 1-admission increase	1.12	[1.02, 1.23]	**0.016**	
No of OPD Visits	Per 1-visit increase	0.9	[0.88, 1.00]	**0.054**	
Complication	Yes	4.56	[2.78, 7.46]	**<0.001**	No
Residence	Rural	0.63	[0.27, 1.45]	0.276	Urban
Maternal Education Level	Unable to read and write	0.56	[0.21, 1.52]	0.255	College/university and above
	Primary (1-8)	1.04	[0.55, 1.93]	0.912	
	Secondary (9-12)	1.10	[0.58, 2.08]	0.770	
Primary CHD Diagnosis	ASD	1.34	[0.70, 2.55]	0.377	VSD
	PDA	0.49	[0.17, 1.40]	**0.181**	
	TOF	1.18	[0.52, 2.72]	0.690	
	Obstructive Valvular Problems	1.34	[0.47, 3.83]	0.586	
	AVCDs	3.10	[1.08, 8.88]	**0.035**	
	Complex CHDs	2.42	[0.93, 6.29]	0.070	
Types of CHD	Cyanotic CHD	3.13	[1.90, 5.16]	**<0.001**	Acyanotic CHD
Associated Anomaly	Yes	0.99	[0.55, 1.80]	0.979	No
Maternal Age at Child Birth	Per 1-year increase	1.03	[0.99, 1.07]	**0.117**	
Birth Order	Per 1-unit increase	1.03	[0.86, 1.24]	0.722	

In the multivariate cox regression analysis, weight at enrollment (Kg), number of OPD visits, complication, and type of CHD were significant predictors of mortality during the waiting time for CHD open heart surgery. Conversely, sex of child, age at enrollment, maternal age at child birth, number of hospital admissions, and primary CHD diagnosis did not demonstrate a statistically significant association with mortality in this revised multivariate model.

For every one-kilogram increase in weight at enrollment, the hazard of mortality decreased by 22% (HR=0.78, 95% CI: 0.66–0.93, p=0.005). Each additional outpatient department (OPD) visit was associated with an 8% reduction in the hazard of mortality (HR=0.92, 95% CI: 0.86–0.99, p=0.017). Children who faced complications had a substantially higher hazard of mortality, approximately 4.58 times that of those without complications (HR=4.58, 95% CI: 2.53–8.28, p<0.001). Furthermore, patients with cyanotic CHD exhibited a 2.60 times higher hazard of mortality compared to those with acyanotic CHD (HR=2.60, 95% CI: 1.45–4.66, p=0.001) (Table 10).

Table 10: Multivariate cox regression analysis of factors associated with time to death of CHD pediatric patients waiting open heart surgery from Sep 2019 to Dec 2024

Characteristic	**Category**	**Hazard Ratio (HR)**	**95% Confidence Interval**	**p-value**	**Reference**
Sex of the Child	Male	1.31	[0.77, 2.21]	0.317	Female
Age at Enrollment (Months)	Per 1-month increase	1.02	[0.99, 1.05]	0.143	
Maternal Age at Child Birth	Per 1-year increase	1.02	[0.98, 1.07]	0.328	
Weight at Enrollment (Kg)	Per 1-kg increase	0.78	[0.66, 0.93]	**0.005***	
Number of Hospital Admissions	Per 1-admission increase	0.92	[0.80, 1.05]	0.228	
Number of OPD Visits	Per 1-visit increase	0.92	[0.86, 0.99]	**0.017***	
Complication	Yes	4.58	[2.53, 8.28]	**<0.001***	No
Primary CHD Diagnosis	ASD	1.20	[0.62, 2.31]	0.586	VSD
	PDA	0.56	[0.19, 1.61]	0.280	
	TOF	0.67	[0.27, 1.63]	0.375	
	Obstructive Valvular Problems	1.92	[0.64, 5.73]	0.243	
	AVCDs	1.63	[0.54, 4.93]	0.387	
	Complex CHDs	1.09	[0.39, 3.05]	0.869	
Types of CHD	Cyanotic CHD	2.60	[1.45, 4.66]	**0.001***	Acyanotic

6. Discussion

This study assessed morbidity and mortality outcomes among pediatric CHD patients awaiting open-heart surgery at Children Heart Fund Cardiac Center-Ethiopia, with a particular focus on

identifying key determinants of these outcomes. The time to death, time to surgery, and nutritional status of pediatric CHD patients was also assessed.

The current study found that patients were diagnosed with CHD at a median age of 10.00 months (IQR: 29.00), with the median age at enrollment for open-heart surgery planning being 14.00 months (IQR: 31.00). In stark contrast, diagnosis and referral for CHD often occur much earlier in high-income settings, primarily due to the widespread implementation of advanced diagnostic capabilities and newborn screening programs. For instance, a study in Texas, USA, on critical CHD reported a median age at referral to a cardiac center of just 1 day (IQR: 0-6 days) (14). Furthermore, in Europe, children with severe CHDs undergo their first surgical intervention at a median age of 3.6 weeks (15). Delayed diagnosis and enrolment to surgery was also noted in other studies such as in Brazil (16) and Thailand (17). The delayed diagnosis and referral to surgery to the center could be attributed to the lack of trained Physicians (only five cardiac surgeons and 12 pediatric cardiologists serving the entire population) in Ethiopia (5). This delay can lead to the progression of disease, development of severe complications such as heart failure, or irreversible organ damage, which can increase perioperative risks and contribute to poorer long-term outcomes.

In this retrospective cohort study of 297 pediatric CHD patients on a waiting list for open-heart surgery, 11.8% underwent surgery, 22.6% died, and 65.7% remained waiting. The current study reported an overall incidence death rate of 614.4 per 100 person-years of observation (approximately 16.83 deaths per 1000 person-days of observation) with 67 deaths occurring over 4,000 person-days of follow-up among pediatric CHD patients awaiting open-heart surgery. This incidence density is higher when compared to another study in Ethiopia which reported an incidence density of 11.9 per 1000 person-days of observation and a mortality rate of 9.9% (4).

The median time from enrollment to death was 517 days (17 months), while the median time to surgery was 721 days (24 months). This prolonged waiting period aligns with the significant delays reported in the Brazilian study, which identified a median waiting time of 19 months for elective surgical or percutaneous cardiac treatment (16). However, the prolonged waiting period for open-heart surgery for pediatric congenital heart disease patients is considerably longer when compared to findings from other settings. For instance, a study on pediatric heart surgery waiting time in Thailand reported a significantly shorter median waiting time of 195 days (17). This

marked disparity underscores the severe challenges faced by patients in Ethiopia, indicating potentially greater unmet needs in cardiac services, more limited surgical capacity, or other systemic barriers that lead to extended waiting lists. Such prolonged delays heighten the risk of morbidity and mortality for pediatric CHD patients who often require timely interventions to prevent irreversible complications and improve their long-term outcomes.

This disparity highlights the prolonged nature of the waiting period, indicating that many patients face a significant risk of adverse outcomes, including death, before they even have the opportunity for surgical correction. These findings collectively emphasize the urgent need for strategic interventions to mitigate risks and improve survival rates for pediatric CHD patients navigating lengthy surgical waiting lists in resource-constrained settings.

The mortality while waiting for open-heart surgery for pediatric CHD patients in the current study was substantial, with 22.6% of patients dying during the waiting period. In comparison, the study on pediatric heart surgery waiting time in Thailand reported a considerably lower mortality while waiting (only 5% of patients waiting for surgery for up to 2 years died) (17). This stark difference underscores the more severe consequences of surgical delays in the current study's setting, emphasizing the urgent need for interventions to reduce the high mortality burden among pediatric CHD patients awaiting life-saving procedures.

The prevalence of specific CHD types in this cohort revealed that VSD was the most frequent primary diagnosis (45.8%), followed by ASD (17.8%) and Patent Ductus Arteriosus (PDA) (14.5%). This distribution aligns with a study done in Brazil that revealed VSD (28.98%), PDA (18.42%), and ASD (11.05%) as the most frequent types (16). The current finding is also in agreement with a study conducted in Hawassa Referral Hospital that revealed VSD (39%) as the leading type of CHD (18). This finding was supported by another study done in the cardiac referral clinic of TASH that reported the most prevalent types of CHDs to be ASD (41.2%), VSD (26.6%), and PDA (9.5%) although the ASD was higher than VSD (19). Overall, acyanotic CHD types were predominant, representing 81.1% of patients, while cyanotic CHD types accounted for 18.9%. The high prevalence of acyanotic defects, while often amenable to repair, still contributes significantly to the surgical burden and the patient volume on waiting lists. This understanding of the disease profile is crucial for healthcare planning and resource allocation in centers managing pediatric CHD patients, enabling a more targeted approach to care for the most

common defects while also acknowledging the complexities presented by the less frequent but often more severe cyanotic conditions.

The nutritional assessment at enrollment revealed a substantial burden of undernutrition across both pediatric age groups awaiting open-heart surgery. A high prevalence of wasting, stunting, and underweight was observed in children aged 0-59 months, with similar patterns of stunting and thinness persisting in the 5-14 year age group. These findings are in agreement with a study conducted in Indonesia that reported a significant prevalence of undernutrition, with 49% being underweight, 47.8% stunting, and 31.4% wasting (20). This widespread undernutrition among children with CHD is concerning, as it reflects the heightened metabolic demands, feeding difficulties, and recurrent infections commonly associated with their condition, which can further compromise their physiological reserve. Furthermore, male patients tended to exhibit higher rates of undernutrition across several indicators, suggesting potential sex-specific vulnerabilities. These findings underscore the pressing need for routine nutritional screening and the implementation of targeted nutritional interventions for pediatric CHD patients on surgical waiting lists, aimed at optimizing their pre-operative status and potentially improving their overall prognosis and surgical outcomes.

This study revealed a child's initial weight at entry was determined to be a protective factor where an increased increment in kilograms was associated with reduced hazard of mortality. This finding is in line with a similar study done in Malaysia that reported low weight at diagnosis was a risk factors for poor survival (11). It is also in agreement with another study done in Indonesia that revealed an association between increased risk of mortality among CHD patients and malnutrition (20). Malnutrition has been a thoroughly documented comorbidity in children with CHD and is often the reason for impaired immune function, reduced cardiac reserve, and poorer outcomes. Therefore, the reported protective effect of excess weight means that well-fed children are better placed to survive the adversity of the disease process and potential morbidities until the intervention. This indicates the need for close nutritional assessment and individualized nutritional treatment as integral components of surgical waiting list children care to optimize their status and promote survival chances during this vulnerable phase.

Interestingly, a higher number of OPD visits also correlated with a decreased hazard of mortality. This finding suggests that consistent engagement with healthcare services, potentially indicating

closer medical monitoring, proactive care-seeking by families, or better access to necessary resources, contributes positively to survival by facilitating earlier intervention or better disease management. More OPD visits may be reflective of more regular medical monitoring that would lead to earlier and better detection and management of complications. This behavior is also reflective of a trend towards proactive care wherein the families are more involved in seeking early medical care, adhering to treatment protocols, and taking better care of their child's illness. Furthermore, more visits would also be reflective of more availability of basic healthcare facilities and better support systems that cumulatively work towards increasing survival rates.

The current study revealed that experiencing complications during the waiting period is an extremely significant predictor of mortality which is in line with previous studies (16,17). This indicates that managing pediatric CHD patients on surgical waiting lists is critical. Children with CHD are inherently vulnerable to a range of morbidities, including recurrent infections, heart failure exacerbations, and pulmonary hypertension, which can significantly decompensate their fragile physiological state. When these complications arise during a prolonged waiting time for definitive surgical correction, they not only increase immediate mortality risk but can also lead to irreversible organ damage, further compromise their candidacy for surgery, or necessitate its postponement. Healthcare providers need to implement robust systems for proactive identification, continuous monitoring, and aggressive, timely management of any intercurrent morbidities. Effective management of these complications is not merely about symptom control but is a vital strategy for preserving their pre-operative condition and ultimately enhancing their survival prospects while awaiting life-saving surgical intervention.

Furthermore, the type of CHD significantly impacted outcomes, with cyanotic CHD patients facing a substantially higher hazard of mortality compared to those with acyanotic forms which is also supported by a previous study in Ethiopia (4). This indicated the inherent severity and complex management challenges posed by these conditions during the waiting time.

7. Limitations of the Study

This study, being a retrospective cohort design, primarily relied on data extracted from existing medical records. This secondary data source inherently presented limitations, most notably the challenge of incomplete information for various patient parameters. A significant number of

charts were excluded due to insufficient records. To mitigate this, efforts were made to supplement missing data through telephone interviews with their primary caregivers. Despite these efforts, a notable challenge was the inconsistent and often incomplete recording of crucial nutritional assessment parameters within the medical charts, impacting the comprehensiveness of these specific data points.

8. Conclusion

This study revealed a significant burden of mortality among pediatric congenital heart disease (CHD) patients on the surgical waiting list. Only a small proportion of patients underwent surgery by the end of the follow-up period, while a considerable number died, and the majority remained on the waiting list. The median time patients spent waiting for surgery significantly exceeded the median time to death for those who succumbed, underscoring the prolonged nature of the waiting period and the substantial risk of adverse outcomes before intervention.

Ventricular Septal Defect was the most frequent primary CHD diagnosis in this cohort. Acyanotic CHD types were predominant overall, but patients with cyanotic CHD faced a substantially higher hazard of mortality during the waiting time.

Risk factors that independently determined an increased mortality during waiting period included lower weight at enrollment, fewer outpatient department visits, the occurrence of complications, and having cyanotic congenital heart disease. Conversely, sex, age at enrollment, maternal age at child birth, number of hospital admissions, and specific primary CHD diagnoses did not independently predict mortality in the multivariate model.

9. Recommendations

Based on the findings of this study, the following recommendations are given:

- **To the Cardiac Center Ethiopia (CCE) Administration and Clinical Teams:**

    - ✓ **Prioritize Nutritional Optimization:** Implement routine and rigorous nutritional screening for all pediatric CHD patients upon enrollment and throughout their waiting period. Develop and integrate tailored nutritional intervention programs to improve and maintain optimal weight, thereby enhancing patient resilience.
    - ✓ **Strengthen Outpatient Follow-up:** Establish a robust system for consistent and regular outpatient department (OPD) follow-up for all patients on the waiting list. This should include proactive scheduling, reminders, and potentially outreach efforts to encourage attendance, recognizing its association with improved survival.
    - ✓ **Intensify Complication Management:** Develop and adhere to clear protocols for the early identification, prompt diagnosis, and aggressive management of CHD-related complications during the waiting period. This includes ensuring timely access to necessary medications, supportive care, and, where appropriate, emergency interventions.
    - ✓ **Risk Stratification for Cyanotic CHD:** Implement a system for prioritizing surgical intervention for patients with cyanotic CHD, given their significantly higher mortality risk during the waiting period.
    - ✓ **Enhance Data Management:** Improve the completeness and consistency of patient medical records, particularly regarding follow-up data and outcome ascertainment, to facilitate future research and quality improvement initiatives.

- **To the Ministry of Health and Policy Makers:**

    - ✓ **Expand Cardiac Surgical Capacity:** Advocate for and invest in increasing the overall cardiac surgical infrastructure, including operating tables, intensive care unit beds, and essential consumables, to reduce the protracted waiting times for life-saving surgeries.

- ✓ **Increase Specialized Workforce:** Prioritize training and recruitment of more cardiac surgeons, pediatric cardiologists, and specialized nursing staff to address the severe shortage of skilled professionals in the country.
- ✓ **Resource Allocation:** Allocate sufficient financial and logistical resources to support comprehensive care for pediatric CHD patients on waiting lists, including nutritional support programs and enhanced outpatient services.

- **To Researchers:**

  - ✓ Conduct prospective studies to further explore the causal pathways between nutritional status, OPD visits, and survival outcomes.
  - ✓ Investigate the long-term impact of specific complications on post-surgical outcomes and quality of life.
  - ✓ Explore the effectiveness of various interventions aimed at reducing waiting list mortality in similar resource-limited settings.

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11. Annex

11.1. Data collection tool

Patient identifications		
	MRN	
	Phone number	
Part I: socio-demographic characteristics, anthropometric measurements of the child, and Maternal obstetric characteristics		
No	**Questions**	**Categories & responses**
	Date of enrollment	
101	Age of the child at enrollment	_____ years
102	Sex of the child	1. Male 2. Female
103	Residence	1. Urban 2. Rural
104	Maternal education level	1. Unable to read and write 2. Primary (1-8) 3 Secondary (9-12) 4.College/university and above
105	Maternal marital status	1. Married 2. Single 3. Separated/Divorced/Widowed
106	Weight of the child in Kg	1. at diagnosis _____ 2. at enrollment_____ 3. at surgery_____ 4. at end of study_____
107	Height of the child in CM	1. at diagnosis _____ 2. at enrollment_____ 3. at surgery_____ 4. at end of study_____
108	Maternal age (at time of this child's birth) in years	_____ years
109	GA at birth	_____ weeks
110	Birth Weight in grams	_____ grams
111	Maternal parity	_____
Part II: Maternal Behavioral Characteristics		
201	Maternal history of alcohol intake during pregnancy (for this child)	1. Yes 2. No 3. Unknown
202	Maternal history of smoking intake during pregnancy (for this child)	1. Yes 2. No 3. Unknown
203	Maternal history of chewing chat during pregnancy (for this child)	1. Yes 2. No 3. Unknown
Part III: Neonatal and Perinatal Characteristics		

301	Place of delivery	1. Health center 2. Hospital 3. Home 4. Other
302	Type of birth	1. Single 2. Multiple
303	Mode of delivery	1. SVD 2. C/S 3.Assisted VD
Part IV: Clinical Characteristics		
401	Primary CHD Diagnosis	1. VSD 2. ASD 3. PDA 4. TOF 5. Other
402	Types of CHD	1. Cyanotic CHD 2. Acyanotic CHD
403	Age at diagnosis	_____
	Date of diagnosis	
404	Is there an associated anomaly other than CHD?	0. No 1.Yes
405	What type is the associated anomaly?	_____
406	Family history of CHD	0. No 1.Yes
407	Waiting time (in months) from CHD diagnosis to surgery/death/end of study	_____ months
408	Functional status (NYHA class)	1. I 2. II 3. III 4. IV
409	Number of hospital admissions per year	_____
410	Reason for admission (Diagnosis) with duration in days	1._____ 2. _____ 3._____ 4. _____
411	Number of OPD visits per year	_____
412	Reasons (diagnosis)	1._____ 2. _____ 3._____ 4. _____
Part V: Complications		
501	Has ever the child faced any Complication?	0. No 1.Yes
502	If yes for Q.401, which complications occurred? (**Multiple responses are possible**)	1. Heart failure 2. Cyanosis 3. Arrhythmia 4. Ventricular Dysfunction 5. Other (specify) _____

Part VI: Mortality		
601	Survival condition of the patient as of December 31st, 2024?	0. Alive 1. Died
602	Cause of death	----------
	Date of death	
603	Age at the time of death in months?	---------- months

11.2. Ethical Approval

ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE
RESEARCH ETHICS COMMITTEE (REC)

Departmental Research Ethics Committee's Decision

Meeting No: - DoS/REC/150/2025/2017 Date: - 10.06.2025
Protocol number:

Protocol Title: - Morbidity and Mortality among paediatric CHD patients on waiting list at Children heart fund-Cardiac center, Ethiopia.	
Principal Investigator:	Dr. Ashenafi Negash
Department	Department of surgery
Elements Reviewed (Protocol):	☑ Attached ☐ Not Attached
Review of Revised Application ☑ Yes ☐ No	Date of Previous review: 10/06/2025
Decision of the meeting:	☑ Approved ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

I. Elements approved- 1. Protocol Version No: **2**
2. Protocol Version Date: **10.06.2025**

II. Obligations of the PI-
1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs ethics committee approval
3. End of the study, including manuscripts and thesis works should be reported to the REC

III. To CHS IRB ☐

Departmental Research Ethics Committee's Approval Period from: _____ to _____

Follow up report expected in
3 Months____ 6 Months_____ 9 Months_____ one year_____

Chairperson, Research Ethics committee's
Name: Dr. Tsegazeab Laeke
Signature:
Date: 10.06.2025

Head Department of Surgery
Name: Dr. Sevoum Kassa Merine
Signature:
Date: 10.06.2025

11.3. Plagiarism Check/ Originality Report

Submission ID: 2746821139

Morbidity and Mortality among Paediatric Congenital Heart Disease Patients on Waiting List at Cardiac Center –Ethiopia
By: Ashenafi Negash

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