Addis Ababa University, College of Health Sciences, School of Medicine, Department of Pediatrics and Child Health

Delayed diagnosis of Congenital Heart Diseases and associated factors in Tikur Anbessa Specialized Hospital: cross-sectional study; Addis Ababa, Ethiopia

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APPROVAL SHEET

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I, the undersigned Pediatric Cardiology fellow, declare that I have submitted my original work on a title delayed diagnosis of congenital heart diseases and associated factors in Tikur Anbessa Specialized Hospital: a cross sectional study; Addis Ababa, Ethiopia.

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ACRONYMS/ ABBREVIATIONS

CHD	***Congenital heart disease***
CCHD	***Critical Congenital heart disease***
TASH	Tikur Anbessa Specialized Hospital
PCH	Department of Pediatrics and Child Health
ASD	Atrial Septal Defect
PDA	Patent Ductus Arteriosus
AVSD	Atrioventricular Septal Defect
ToF	Tetralogy of Fallot
TGA	Transposition of Great Arteries
VSD	Ventricular Septal Defect
DORV	Double Outlet Right Ventricle
PS	Pulmonary Stenosis
PHTN	Pulmonary Hypertension
ICU	Intensive Care Unit
NICU	Neonatal Intensive Care Unit
AS	Aortic Stenosis
HLHS	Hypoplastic Left Heart Syndrome
CoA	Coarctation of Aorta
TA	Tricuspid Atresia
TAPVC	Total Anomalous Pulmonary Venous Connection
PAPVC	Partial Anomalous Pulmonary Venous Connection

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ABSTRACT

Background: Congenital heart disease (CHD) is the most common malformation in newborns. In Africa alone, 500,000 live newborns are born each year with CHD. Sub-Saharan Africa contributes a larger portion of these numbers. Nearly one fourth of these CHDs are critical CHDs and thus need to be diagnosed and managed timely. Time to first diagnosis of these defects varies across countries. Delayed diagnosis is common in third world countries. The prevalence of delayed diagnosis in Ethiopia is unknown. Knowing the magnitude of late diagnosis would help in designing the mechanisms for early detection and possible intervention. With appropriate and timely interventions, more than 85% of all children with CHD can survive to adulthood.

Objective: The aim of this study was to determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors in TASH, 2023.

Methods and materials: The study was conducted in TASH at department of Pediatrics and Child Health. A cross-sectional design was employed. The data was collected using kobotoolbox tool and was exported to SPSS version 29 for analysis. Descriptive statistics was used to examine participants' socio-demographic, socioeconomic and clinical characteristics. Binary and multivariate logistic regression analysis was utilized to assess association between variables.

Results: Over half (53.1%) of the study participants had delayed diagnosed of CHD. The majority of patients (84.4%) with cyanotic HDs were diagnosed late. The proportion of delayed diagnosis among acyanotic CHDs was 45.4%. The median age at diagnosis for acyanotc CHD was 6 months IQR [1.5-24] whereas the median age at diagnosis for cyanotic was **9** months IQR [1.5-29]. The probability of delayed diagnosis of CHD was 2.34 times higher in children whose mother did not have optimal ANC visit during pregnancy (AOR 2.34 95% CI 1.05-5.25 P=0.0.039)

Conclusions: The magnitude of delayed diagnosis of CHD was unacceptably high (53.1%). The factors associated with delayed diagnosis were ANC visits, obstetric ultrasound, place of birth, type of birth attendants and type of CHD. To avert delayed diagnosis of CHDs, improving antenatal care, increasing health care workers awareness and perinatal screening are recommended.

Key Words: Congenital Heart Defects; Pediatrics; delayed diagnosis; Ethiopia

1. Introduction

1.1 Background

Congenital heart disease (CHD***)***, as proposed by Mitchell et al., is "a gross structural abnormality of the heart or intra-thoracic great vessels that is actually or potentially of functional significance"(1). Globally, congenital heart disease accounts for nearly one-third of all congenital birth defects(2). Twenty-eight percent of all major congenital anomalies consist of heart defects(3). Of all congenital heart diseases, nearly 25% of cases have critical congenital heart defects (CCHDs)(4). There are different schemes of classification of CHDs. Some classify as simple defects, moderate complexity and complex lesions(5). Others classify depending on hemodynamic significance as significant or insignificant(6). Emphasis to earlier detection and management of congenital heart disease is integral to eliminating preventable child deaths and to attain sustainable development goals(7).

In Africa, 500,000 live newborns are born each year with CHDs(8). Sub-Saharan African countries contribute a larger portion of these numbers. The vast majority of these children receive sub-optimal or no care at all(9). 90 percent of these CHD-affected children reportedly lack access to quality healthcare(8). A third of newborns with moderate to severe CHD will not survive past the neonatal period if they are not given the appropriate treatment. Without interventions, nearly half of them would die in early infancy(7). Without comprehensive care, survivors beyond infancy will suffer from different complications(10).

Approximately 50 % of all CHDs do not warrant intervention other than follow-up or simple medications. The remaining 50 % require timely surgical or trans-catheter intervention to cure or achieve palliation(11). Delayed diagnosis of CHDs is common in low and medium income countries(12). A study by Rashid et al. demonstrated that delayed diagnosis in CHDs in a low- and middle-income country is 85.1%(13). Late presentation of CHD is norm than exception in Africa (8,14). In contrast, the proportion of delayed diagnosis in a high-income countries was reported to be as low as 8.9%(15).

CHD treatment has been one of modern medicine's greatest success stories in centers with comprehensive cardiac treatment facilities(16). In high income countries (HICs), 85% of all

children with CHD survive to adulthood. With appropriate care, 90 % of children with complex CHD, such as tetralogy of Fallot or neonatal coarctation, and nearly 95 % of children with simple CHD lesions, such as ventricular septal defect, survive to adulthood. Currently, about 80% of children with complex CHD such as transposition of the great arteries or truncus arteriosus survive to adulthood in high income countries(17).

Despite the 34.5% reduction in global CHD mortality during the past decade, Africa's CHD deaths have rather increased. This is attributed to poverty and limited care centers with appropriate treatment(8). In sub-Saharan African countries, there has been an increase in childhood mortality attributable to CHD except the southern sub-Saharan Africa region(18).

1.2. Statement of the problems

Prenatal CHD diagnosis has been made possible by technological advancements in diagnostic images. In a retrospective study conducted in Beijing China, the majority (91.41%) of CHDs were identified through prenatal diagnosis. The rest were diagnosed either before obstetric discharge/transfer (5.62%) or later through delayed diagnosis(2.97%)(19). In a study done in Kenya, prevalence of late diagnosis was reported to be 60%, but they used different definition to define late diagnosis of a CHDs(20). Screening using bedside pulse oximetry before discharge from birth clinic is currently recommended. Despite increasing prenatal diagnosis of critical CHDs, delayed diagnosis still occurs in over 10% of cases even in high income countries(15).
Delayed diagnosis of cyanotic CHD is defined when newborns with the defect are sent home without diagnosis at birth place (clinic, health center or hospital). In cases of acyanotic CHDs, delayed diagnosis is defined when the child is diagnosed at a later time when cardiac surgery or intervention should have already been performed (15,21).

Delayed diagnosis of CHD results in significant morbidity and mortality(22). It is associated with cardiovascular compromise and organ dysfunction that precludes definitive management with subsequent risk of mortality(12,23).

Congenital heart diseases that require surgical or device closure in the first year of age are termed as critical CHDs(24). Missed diagnosis of critical congenital heart diseases (CCHDs) is associated with serious complications, including seizure, cardiac arrest, and death(23,25,26). Prevalence reports of late-detected CCHDs differ widely in case definition and study methodology, but prevalence rates as high as 10% to 30% were reported(4,24,26,27). Factors that have been associated with late diagnosis of CCHDs include hospital nursery level, types of CCHD and absence of extra-cardiac defects(27–30).

Data in Ethiopia concerning children with delayed diagnosis of CHDs is lacking. Specifically the magnitude of CHDs among cardiovascular diseases was also not studied. But there is a high burden of CHD in TASH; likely with delayed presentation and late diagnosis. Accordingly, this study was aimed to determine the magnitude of delayed diagnosis of CHD and its associated factors.

1.3. Significance of the study

Globally, the annual mortality rate of CHDs among children has declined(18). Despite the better survival and quality of life of children with CHD, these defects still represent a major health problem worldwide(31). African countries, given higher fertility rate, continue to contribute greater proportion of children with CHDs. In contrary, timely diagnosis and comprehensive care continues to lag behind especially in sub-Saharan African Regions.

Data in Ethiopia concerning children with delayed diagnosis of CHD are lacking. Given the expected burden of CHD in low-income countries, it is necessary to identify the magnitude of delayed diagnosis and the associated factors. Accordingly, this study will help to determine the magnitude of delayed diagnosis and associated factors in children with CHDs in TASH, Addis Ababa, Ethiopia. The research outcome from this study will help health care workers and policy makers to understand the magnitude of the problem and act accordingly.

2. LITERATURE REVIEW

2.1. Prevalence of CHDs

CHD is the most common birth defect, and is associated with higher mortality and morbidity than any other congenital abnormalities. About 6/1000 live births are thought to be affected by the moderate-to-severe form of congenital heart disease (CHD). If the bicuspid aortic valve is taken into account, this incidence rises to 19/1,000 live births. If tiny muscular VSDs and other trivial lesions are taken into account, the rate of CHDs is predicted to increase further to 75/1,000 live births(32). But these numbers vary greatly depending on geographic location, genetic background and the study methodologies implemented. Generally 8 per 1,000 live births is accepted as the best estimate of the incidence of CHDs(33).

The implementation of a widespread neonatal Pulse Oximetry screening program, enabled only a slight decline in the rate of late diagnosis of cyanotic CHD; while the overall rate of late diagnosis of CHD remained constant at 10%(34). In one study, more than half of all babies with CHD have a normal routine newborn examination and are discharged home without diagnosis(35). Most of these heart defects are not immediately life threatening. Some of them, however, are critical defects, usually with duct-dependent systemic or pulmonary circulation.

Cardiovascular malformations account for about 12% of infant deaths and nearly half of all deaths from malformations(36). Newborn screening for CCHD through Pulse Oximetry can detect some CCHD conditions thereby averting late detection(37).

2.2. Delayed diagnosis of CHDs

Delayed diagnosis of CHD results in significant morbidity and mortality(22). Even after cardiac surgery, it might be associated with organ dysfunction and cardiovascular compromise(23). Worldwide, both in high-income and low- and middle-income nations, there is a high rate of delayed diagnosis of CHDs. Delay in diagnosis can occur in as many as 10% of cases of all CHDs and in 29.5 % of cases of CCHDs, even in high-income countries(15,27).

The majority of relevant CHDs are identified during neonatal screening or even in utero during fetal echocardiographic screening. Despite this, a significant portion of CHDs are missed in the early clinical screening and are discovered after being discharged from a health facility. In

underdeveloped countries, where antenatal care and institutional deliveries are limited, CHDs continue to be detected for the first time during childhood or even after.

Fetal screening can detect structural heart diseases, but it varies greatly depending on operator skill, gestational age, fetal position, and type of cardiac defects. Some CHDs and a few critical ones may be missed(38). Prenatal ultrasound detects 25–50% of CHD; the same percentage can be detected by newborn physical examinations(39). According to Saxena et al., the sensitivity and specificity of postnatal CHD detection can be increased by combining a physical examination with Pulse Oximetry(40). A clinical score along with Pulse Oximetry, according to some authors, can improve the sensitivity of CHD detection(41).

2.3. Factors affecting delayed diagnosis of CHDs

In a study published by Murni et al., a number of factors were independently associated with a delay in CHD diagnosis, including cyanotic CHDs, residence outside of the city, non-syndromic patients, low family income, normal labor, and term gestation at birth(12). Other contributing factors are inadequately trained health system and socioeconomic constraints among those in low- and middle-income country settings(13). Most studies conducted in developing countries concluded that social and financial factors also play a significant role in delayed diagnosis of CHDs (12,22,42).

According to some studies(13,34), acyanotic CHDs were found to be delayed in diagnosis more frequently than cyanotic CHDs. But other studies reported an equal (21) or even lower proportion(12,15). Theoretically, clinical findings in cyanotic CHD should be more obvious than acyanotic CHD because of the bluish discoloration of children with cyanotic CHD (43).

2.4. Complications associated with delayed diagnosis of CHDs

Children with CHD who presented later or whose diagnoses were delayed frequently experienced multiple complications. The prevalence of these complications can exceed 70%(12). Congestive heart failure is the most common complication followed by pulmonary hypertension. Severe polycythemia is the predominant complication in cyanotic heart diseases(5,12). Adolescents and adults with CHDs continue to suffer from the same complications(44–46). Apart from the cardiovascular effects, some CHDs can significantly affect the physical growth and neurodevelopment of the child(47). Children with CHD are at increased risk of

neurodevelopmental disorders, disabilities or developmental delay(48,49). Late surgical intervention by itself will endure several morbidity and mortality(50).

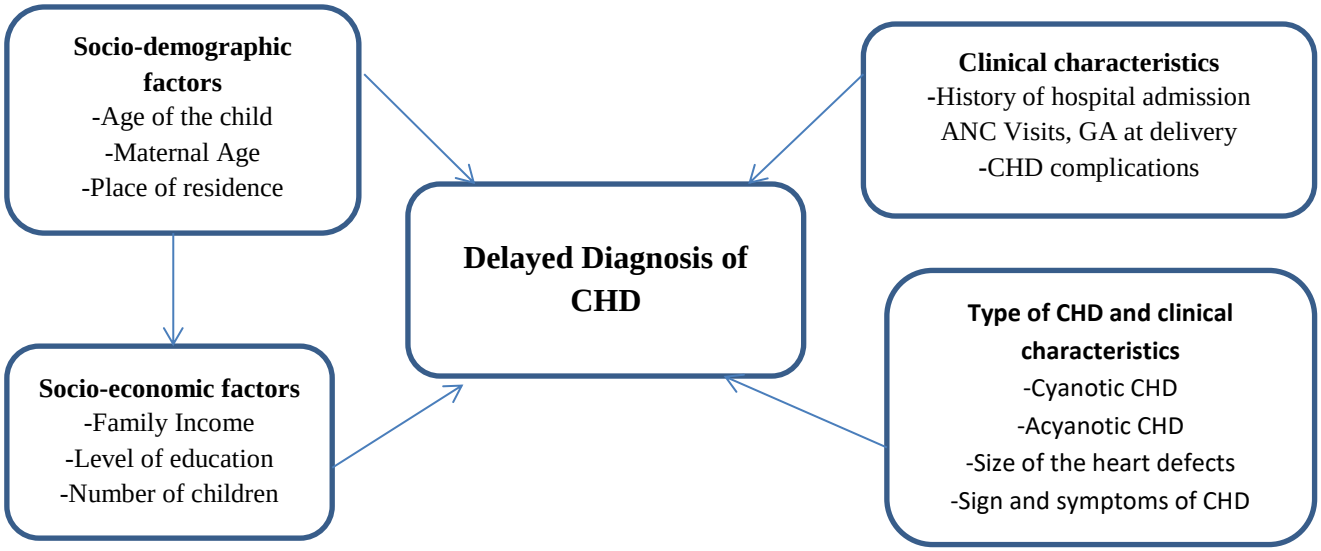

Fig.1. Conceptual frame work showing the relationship between delayed diagnosis of CHD and associated factors developed by the principal investigator after literature review

3. OBJECTIVE OF THE STUDY

3.1. General Objective: To determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors in TASH, Addis Ababa, Ethiopia, 2023

3.2. Specific Objectives:

- To assess the magnitude of delayed diagnosis of congenital heart diseases
- To assess the factors associated with delayed diagnosis of Congenital Heart Diseases

4. METHOD

4.1. Study area

The study was conducted at Tikur Anbessa Specialized Hospital (TASH), department of pediatrics and child health (PCH). The department has EOPD, regular OPDs, follow up clinics, wards and intensive care units. TASH is the largest referral teaching hospital located in the capital city of the country, Ethiopia. Pediatric cardiac patients are referred from all corners of the country. TASH is the only government owned hospital where pediatric cardiac surgery is being done. Pediatric cardiology unit is staffed with consultant pediatric cardiologists, pediatric cardiology fellows and trained nurses. Pediatric residents and medical interns are assigned on rotation bases. The unit offers inpatient and outpatient care, diagnostic tests and mission based interventional and cardiac surgeries.

4.2. Study design

A cross-sectional study design was employed.

4.3. Study Period

The study was conducted from June 30 to October 30, 2023.

4.4. Study Population

The study populations were pediatric cases diagnosed with congenital heart disease. Direct caregivers to the children were approached. In case the age of the child is 12 years or above assent was taken.

Inclusion criteria

All children aged less than or equal to 18 years of age who were diagnosed with structural congenital heart disease and visiting cardiac follow up clinic were included.

Exclusion criteria

- Secundum ASD less than 5 mm (51)
- Patent ductus arteriosus (PDA) <2 mm size (6)
- PDA diagnosed in infants less than 3 months of age

4.5. Sample size

The sample size was determined using the following assumptions (table 1).

Table 1: Sample size determination for Delayed diagnosis of Congenital Heart Diseases and associated factors in TASH

Objectives	Assumptions	Formula used	Sample size
To determine magnitude of delayed diagnosis	Confidence interval 95% ($z_2^{\alpha 2} = 1.96$), margin of error 5% and Proportion of delay to first diagnosis, 85% (13)	$n = \frac{z_2^{\alpha 2}\, pq}{d^2}$	195
To assess the factors associated with delayed diagnosis	Residence (OR=2.08)(12). 50.3% in unexposed 69.8% in exposed Power 80%	Double population formula using epicalc	218
	Cyanotic heart disease (OR=4.16). 7% in unexposed 26.9% in exposed Power 80%(12)	Double population formula using epicalc	130
Remark	The largest sample was taken (218) and 5% for non-response rate was added		
Total sample size	228		

4.6. Sampling technique

A consecutive sampling method was employed to recruit study participants.

4.7. Data collection method and procedure

Data collection was done at pediatrics cardiac follow up clinic by trained health care workers. Study participants fulfilling inclusion criteria were included consecutively till the required sample size was attained. Data was collected online using http://www.kobotoolbox.org/ software tool using data collection form https://kf.kobotoolbox.org/#/forms/aQx4nzeMYou3oEL9SqoyVf. Both the online and hard copy records of study participants were reviewed.

4.8. Operational definitions

- Age at first diagnosis: Postnatal age at which CHD was diagnosed through appropriate echocardiography.
- Delayed Diagnosis: Definition for delay in diagnosis for cyanotic and acyanotic CHDs will be as follows.

- ***Cyanotic heart diagnosis:*** newborns discharged from their birth clinic or hospital without a CHD diagnosis(21)
- ***Acyanotic heart diagnosis:*** delayed diagnosis is defined when the child was diagnosed when immediate treatment, intervention or cardiac surgery should have already been performed according to contemporary standards of pediatric cardiology(13,15,52,53).

- Cases with more than one cardiovascular abnormalities were assessed for delayed diagnosis according to the dominant lesion which would precipitate presentation so that earliest intervention required(54)
- Home births in cases of cyanotic CHDs were classified as delayed unless diagnosed prenatally(24).
- Direct Care givers: Direct care givers were either one of the families or guardians of the child.

4.9. Variables of the study

Dependent variable

- Delayed diagnosis of CHDs

Independent variable

- Socio-demographic and socio-economic characteristics (age, sex, residency, family's occupational status, educational status and income)
- Perinatal history and clinical characteristics
- Types of CHDs (Acyanotic CHDs, Cyanotic CHDs)

4.10. Data management, statistical analysis and Data Quality Assurance

Data Analysis

The data from kobotoolbox software tool was exported to SPSS version 29 for analysis. Initially, data exploration was done for:

- ✓ Data clearing
- ✓ Ensuring that underlying assumptions of statistical analyses were satisfied and
- ✓ Identifying potential outliers that might require further investigation

Descriptive statistics was used to examine participants' socio-demographic, socioeconomic and clinical characteristics. Chi-square test was used to assess the relationship of independent and dependent variables. Binary and multivariate logistic regression analysis was utilized to assess association between variables. Confidence levels at 95% CI was used and statistical significance was considered at $P<0.05$. Tables and figures were employed for presenting the results.

5. Ethical considerations

This study was conducted after obtaining ethical clearance from the Pediatric and Child Health Department Ethical committee. Only study participants who gave consent were included. Eligible participants were verbally informed by trained data collector about the purposes and benefits of the study. Study participants were encouraged to ask questions and clarification was provided. Study Participants were included if they show their willingness to participate in the study, including participation in the interview and use of their medical records. The participants were notified that they had the right to refuse or withdraw from the study at any time with no effect on their routine care. Privacy and confidentiality were maintained by avoiding the use of identifiers and restriction of data access. Unique codes that cannot be traced back were created. The principal investigator will make sure that the collected raw data will be kept safe and confidential.

6. Results

6.1. Sociodemographic Characteristics

A total of 228 study participants were recruited. From these, 63.6% were female. Most of the study participants (62.3%) were from Addis Ababa. Maternal age at delivery was less than 35 years in 56.6% of the cases. More than three fourth of the parents had at least formal school (Table2).

Table 2: Sociodemographic Characteristics

Variables	n	%	Delayed Diagnosis		X^2 (P-value)
			Yes	No	
Sex					
Female	145	63.6	75	70	
Male	83	36.4	46	37	0.29(0.59)
Region					
Addis Ababa	142	62.3	67	75	
Oromia	51	22.4	33	18	
Amhara	18	7.9	12	6	
Others	17	7.4	9	8	6.09(0.11)
Family Monthly Income					
500 – 5000 ETB	137	60.1	74	63	
>5001 ETB	91	39.9	47	44	0.12(0.79)
Maternal Educational status					
College/University	63	27.6	29	34	
Primary/High school_	119	52.2	68	51	
No Formal Education	46	20.2	24	22	2.06(0.36)
Maternal age					
18-34 Years	129	56.6	68	61	
35-55 Years	99	43.4	53	46	0.02(0.90)
Paternal Educational status					
College/University	144	63.2	73	71	
Primary/High school	64	28.1	37	27	
No Formal Education	20	8.8	11	9	0.93(0.63)
Paternal age					
18-34 Years	63	27.6	31	32	
35-55 Years	165	72.4	90	75	0.52(0.47)
Maternal Occupational status					
Self Employeed	179	78.5	96	83	
Gov/NGO Employee	49	21.5	25	24	0.11(0.75)
Paternal Occupational status					
Self Employeed	139	61	73	66	
Gov/NGO Employee	89	39	48	41	0.04(0.84)

6.2. ANC and Delivery Characteristics

Nearly all the mothers reported at least one ANC follow up visit with majority having more than four visits. Obstetric ultrasound was done for most of them. The larger proportions of deliveries were at government hospitals attended largely by nurses, midwives or health officers (Table 3).

Table 3: Obstetrics and Delivery Characteristics

Variables	N	%	Delayed Dx		P-value
			Yes (n)	No (n)	
Maternal number of ANC visits					
Less than or equal to 4	39	17.1	28	11	**0.010**
More than 4	189	82.9	93	96	
Obstetrics Ultrasound (N= 222)					
Yes	208	91.2	104	104	**0.003**
No	14	6.1	14	3	
Repeat Obstetric US Done (N= 208)					
Yes	185	81.1	90	95	**0.006**
No	23	10.1	14	9	
Mode of Delivery					
Vaginal	168	73.7	101	67	**<0.001**
Caesarian Section	60	26.3	20	40	
Gestational age at Delivery					
Term	217	95.2	116	101	0.604
Pre-term	11	4.8	5	6	
Place of Delivery					
Government Hospital	113	49.6	58		**0.004**
Health center	73	32	47	55	
Private health care	30	13.2	8	26	
Home	12	5.3	8	22	
Birth Attendant				4	
Midwife/Nurse/Health officer	155	68	93	62	**0.002**
Physician	62	27.2	21	41	
Traditional Birth attendant	11	4.8	7	4	

Note: P-value by chi-square, significant values are put in bold numbers

6.3. Clinical characteristics

Most of the patients referred to the cardiac clinic were from public hospitals. Nearly a third of patients have clinical syndromes mainly down syndrome. By the time of diagnosis, 67.5% (N= 154) had at least one symptom that might suggest cardiac illness. Fast breathing, breast feeding interruption and poor growth were the most common symptoms. Almost half the study participants had history of admission to a health care facility. Pneumonia was the most common reason for hospital admission. First degree family with history of CHD was reported to be 6.6% (Table 4).

Table 4: Clinical Characteristics

Variables	N	%
Source of referral		
Government Hospital	140	61.4
Private Facility	56	24.6
Health Center	32	14
History of CHD in family (First Degree)		
Yes	15	6.6
No	213	93.4
Any associated clinical Syndrome		
Yes: Down Syndrome	62	27.2
Yes: Other syndrome	4	1.8
No	162	71.1
Was the child ever symptomatic		
Yes	154	67.5
No	74	32.5
What were the symptoms		
Fast Breathing	109	47.8
BF Interruption	79	34.6
Poor Growth	78	34.2
Easy fatigability	63	27.6
Head ache	43	18.9
Prolonged feeding	33	14.5
Diaphoresis	32	14
Body swelling	6	2.6
Other Symptoms	37	16.2
History of Admission		
Yes	104	45.6
No	124	54.4
Reason for Admission		
Pneumonia	83	36.4
Polycythemia	18	7.9
Heart Failure	17	7.5
Infective Endocarditis	13	5.7
Tet Spell	11	4.8
Other	9	3.9
Shunt lesions by size (N= 159)		
Severe	114	71.7
Moderate	29	18.2
Mild	16	10.1
Pulmonary Blood Flow in Cyanotic CHDs (N= 42)		
Increased	19	45.2
Decreased	23	54.8
Is there Pulmonary HTN (N= 228)		
Yes	95	41.7
No	133	58.3
Degree of PHTN (N= 95)		
Severe	81	85.3
Moderate	4	4.2
Mild	10	10.5
Any Intervention Done		
Yes	26	11.4
No	202	88.6
Intervention Type (N= 26)		
Surgical	21	80.8
Device	5	19.2

6.4. Distribution by specific congenital heart diseases

Nearly 80% of study participants had acyanotic heart diseases (Fig 2). Isolated VSD is the most common CHD with the frequency of 26% and further 10% in combination with other shunt lesions. Nearly half of cyanotic CHDs are TOF cases. It constitutes 9.6% of overall CHDs. Other complex lesions combined form 11% of all CHDs. The prevalence of obstructive congenital heart diseases is 8.8%. Generally, septal defects constitute about 70% of all CHDs (Table 5).

The median age at diagnosis for all CHD was 7 months with interquartile range of 1.5 to 24 months. The median age at diagnosis for acyanotc CHD was 6 months IQR [1.5-24] whereas the median age at diagnosis for cyanotic was **9** months IQR [1.5-29] (Table 5).

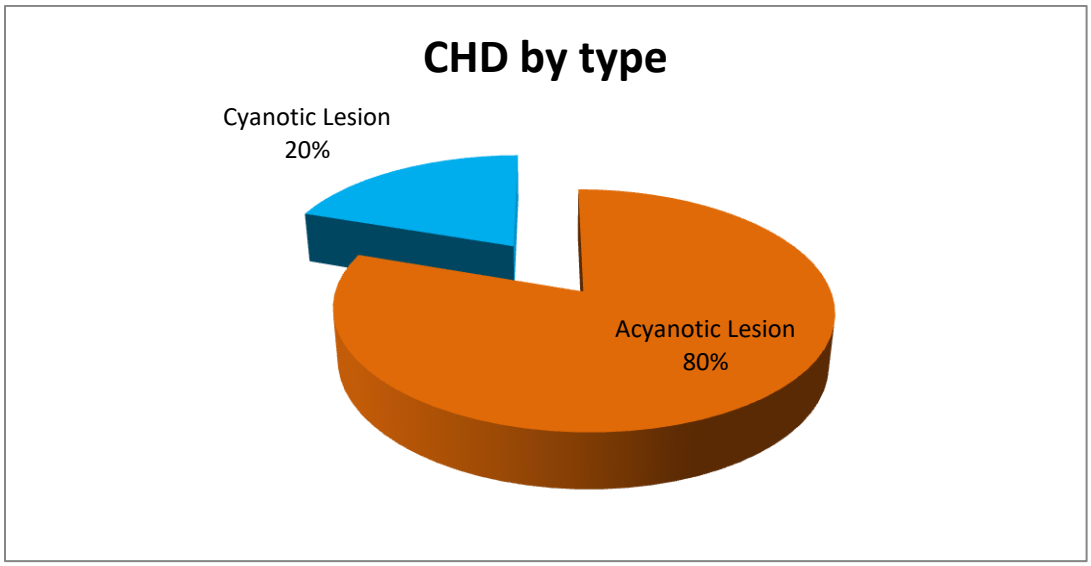

Figure 2 Congenital Heart Disease by lesion type

Table 5: Distribution by specific congenital heart diseases and age at diagnosis

Variables	n	%	Time to diagnosis in months Median (IQR)
Acyanotic CHD			
Isolated VSD	59	25.8	8 [3-34]
ASD	13	5.7	12 [6-48]
PDA	37	16.2	12 [3-48]
AVSD	28	12.3	5.5[1.25-13.5]
VSD + ASD/PDA	24	10.5	3.5 [0.23-9.5]
Obstructive L (PS or CoA)	20	8.8	3.5 [0.65-15]
Sub-total (Acyanotic CHDs)	183	80.3	6 [1.5-24]
Cyanotics CHD			
ToF	22	9.6	18 [4-36]
Complex Lesions	25	11	6 [1-24]
Sub-total (Cyanotic CHDs)	45	19.7	9 [1.5-29]
Overall	228	100	**7** [1.5-24]

6.5. Proportion of delayed diagnosis

Overall, more than half of study participants (53.1%) had delayed diagnosed. The proportion of delayed diagnosis among acyanotic CHDs is 45.4%. The majority of patients (84.4%) with cyanotic HDs had delayed diagnosis (Figure 3). Among shunt lesions, AVSD is the most common (60.7%) heart defect with delayed diagnosis followed by PDA (54.1%). From cyanotic CHDs, 90.9% of TOF patients were diagnosed late. For the rest of cyanotic CHDs combined, the prevalence of delayed diagnosis is 76% .

Table 6: Proportion of delayed diagnosis by Specific CHD

Variables	Delayed Diagnosis			
	Yes		No	
Acyanotic CHD	**n**	**%**	**n**	**%**
Isolated VSD	23	38.98	36	61.02
ASD	3	23.08	10	76.92
PDA	20	54.05	17	45.95
AVSD	17	60.71	11	39.29
VSD + ASD/PDA	10	41.67	14	58.33
Obstructive L (PS or CoA)	9	45.00	11	55.00
Cyanotics CHD				
ToF	20	90.91	2	9.09
Complex Lesions	19	76	6	24
P-value by X^2 test <0.001				

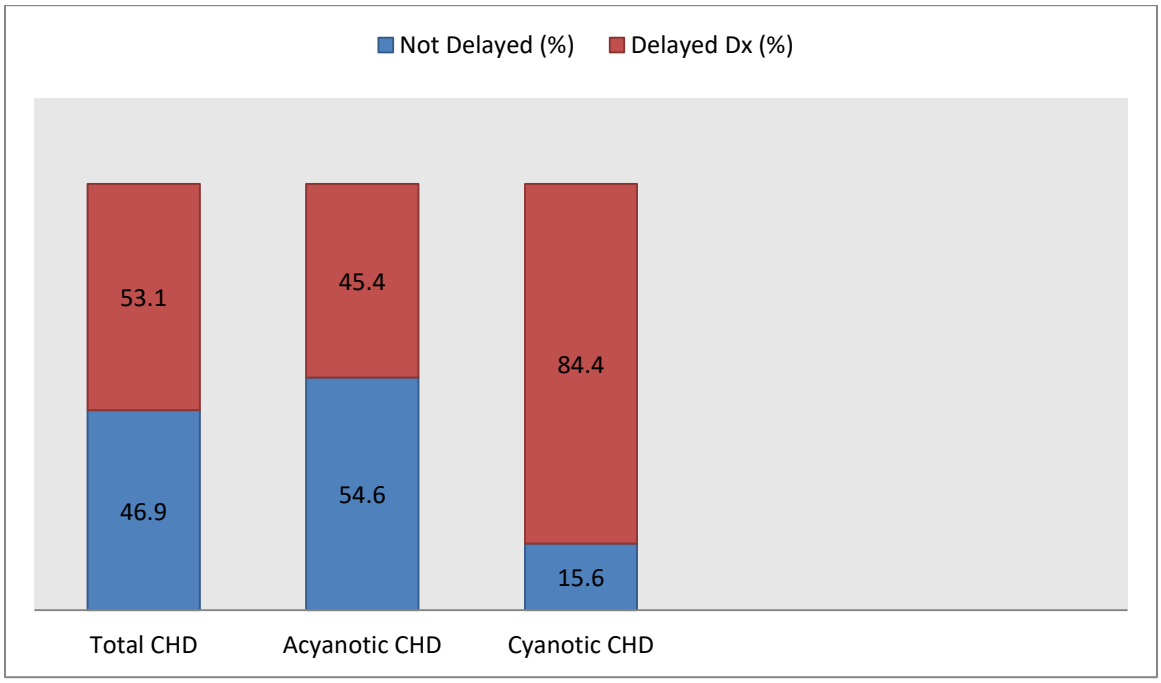

Figure 3 Proportion of delayed diagnosis by lesion type

6.6. Factors affecting delayed diagnosis

Number of ANC visits, obstetric ultrasound, mode o delivery, birth attendants, place of delivery, CHD type, size of shunt size and degree of PHTN were found to be associated with delayed diagnosis of CHDs. Less than four ANC visits increased the likelihood of delayed CHD diagnosis (AOR 2.34 95%CI 1.05,5.25 P= 0.039). The probability of delayed diagnosis of CHD was 4.47 times higher in children whose mother did not have an ultrasound ultrasound performed during pregnancy (AOR 4.47 95% CI 1.29, 17.56 P=0.019). Cases attended during delivery by non-physician were at increased risk of delayed diagnosis (AOR 2.79 95% CI 1.49, 5.19 P=0.001). There is a significant delay in diagnosis of cyanotic lesions compared to acyanotic lesions (AOR 6.84 95% CI 2.86, 16.34 P<0.001) (Table 7).

Table 7: Socio-demographic and clinical associated factors of delayed CHD diagnosis

Variables	Delayed Diagnosis		COR (CI 95%)	AOR (CI 95%)	P-value
	Yes (n)	No (n)			
Maternal educational status					
College/university	29	34	1	1	
Primary/high school	68	51	1.56 (0.85,2.89)	1.44 (0.78,2.69)	0.247
No formal education	24	22	1.28 (0.60,2.74)	1.06 (0.49,2.33)	0.880
Number of ANC visits					
> 4 visits	93	96	**1**	**1**	
≤ 4 visits	28	11	**2.63 (1.24,5.58)**	**2.34 (1.05,5.25)**	**0.039**
Obstetric ultrasound done					
Yes	104	104	**1**	**1**	
No	17	3	**5.67 (1.61,19.92**)	**4.47 (1.29,17.59)**	**0.019**
Place of Delivery					
Government hospital	58	55	1	1	
Health center	47	26	1.71 (0.94,3.14)	1.62 (0.88,2.99)	0.122
Private facility	8	22	0.35 (0.14,0.94)	0.38 (0.15,0.91)	**0.030**
Home	8	4	1.90 (0.54,6.66)	1.56 (0.44,5.69)	0.191
Mode of delivery					
Cesarean section	20	40	**1**	**1**	
Vaginal delivery	101	67	**3.02 (1.62,5.60)**	**2.84 (1.52,5.13)**	**<0.001**
Birth attendant					
Physician	21	41	1	**1**	
Nurse/Midwife/HO	93	62	2.93 (1.58,5.42)	**2.79 (1.49,5.19)**	**0.001**
Traditional birth attendant	7	4	3.42 (0.90,13.00)	2.92 (0.65,10.31)	0.175
Clinical Syndromic baby					
Yes	28	38	**1**	1	
No	93	69	**1.83 (1.03,3.25)**	1.96 (0.82,4.68)	0.063
CHD type					
Acyanotic lesion	83	100	**1**	**1**	
Cyanotic lesion	38	7	**6.54 (2.78, 15.41)**	**6.84 (2.86,16.34)**	**<0.001**
Size of shunt lesion					
Mild to Moderate	8	37	**1**		
Severe	64	50	**5.92 (2.53,13.84)**		
Degree of PHTN					
Mild to moderate	2	12	**1**	1	
Severe	48	33	**8.73 (1.83,41.58)**	9.33 (1.88,45.12)	**0.006**

Note: significant factors are put in bold

7. Discussions

The magnitude of overall delayed diagnosis in this study is 53.1%. This is higher than the report done by Massin MM and Dessy H in Belgium which was 10%(15). But it is lower than the study done in Pakistan that demonstrated delayed diagnosis in CHDs is 85.1%(13). This magnitude varied depending on socioeconomic status of a country where reports as low as 10% (15) in high-income countries and delay is a rule than an exception in Africa (14).

In our study, delayed diagnosis was more common in cyanotic heart disease (84.4%) than acyanotic ones (45.4%). This is in line with the study done by Murni et.al. and Massin MM and Dessy H (12,15). But other studies demonstrated that acyanotic heart diseases were more likely to be diagnosed late(13,34). These studies hypothesized that cyanosis could be obvious to a family and will make them seek medical advice. But the contemporary definition of delay in cyanotic heart diseases is stricter and could be the reason for the more prevalent delays in our study.

In addition to the type of congenital heart lesions, children with mothers having fewer than four ANC visits were at increased risk to be diagnosed late. Non-syndromic patients were not found to be delayed in comparison to ones with clinical syndromes in our study. This is in contrast to the study by Murni et.al. where non-syndromic patients diagnosis is delayed by 1.7 fold(12). Family income, gestational age at delivery and parental education were not found to be predictors of delayed diagnosis unlike studies in other parts of the world(12,13,22,42). In our study the prevalence of preterm delivery was less than 5% which could be the reason for the absence significant association.

Children born to mothers whose deliveries were attended by non-physicians were also diagnosed late when compared to those who were attended by physicians. Mothers who had obstetric US done were associated with decreased risk of their children being diagnosed late with CHD. During obstetric US no significant CHD was detected. The significant relationship between delayed diagnosis and having frequent ANC visits, Obstetric US examination and physician attendance may simply be explained by the better health seeking behavior of the family.

8. Limitation and strengthen of the study

This study tried to explore the magnitude, age at diagnosis and associated factors with a good sample size which will be a baseline data in Ethiopia for future researches. The main limitation of this study could be a recall bias.

9. Conclusions and recommendation

In conclusion, the magnitude of delayed diagnosis of CHD was unacceptably high (53.1%). The factors associated with delayed diagnosis were ANC visits, obstetric ultrasound, place of delivery, type of birth attendants and type of CHD. To avert delayed diagnosis of CHDs, improving antenatal care, increasing health care workers awareness and perinatal screening are recommended.

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ANNEX

English Version

Information sheet and consent Form (for direct care givers)

I. Study Information sheet I

Good morning /good afternoon; my name is _____. I am working with Dr.Tolossa Eticha who is conducting a research study for partial fulfillment of subspecialty training in Pediatric Cardiology. His research project is entitled Delayed diagnosis of Congenital Heart Diseases and associated factors in TASH: a mixed method study; Addis Ababa, Ethiopia. His supervisors are Dr. Hayat Ahmed (Assistant Professor of Pediatric Cardiology) and Dr. Henok Tadele (Associate Professor of Pediatric Cardiology)

Objective of the study: To determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors in TASH, Addis Ababa, Ethiopia, 2023

Benefits: The benefit of this study is to generate information to determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors. There will be no cost for participation and it will not affect your medical treatment at TASH. There will be no direct benefit to you for your participation in this study. However, we believe this research will have important implications for future interventions.

Risks: There are no expected risks to you for participating in this study. The study will be conducted by face-to-face interview and reviewing your medical cards. The interview will take 20-30 minutes.

Confidentiality: Your responses will be completely confidential. The information gathered during this study will be kept confidentially. Research records will be kept in a locked file, and all electronic information will be coded and secured using a password protected file; only the researcher will have access to the records. In any sort of report we make public, we will not include any information that will make it possible to identify you.

Right: Your participation is entirely voluntary. If you do not wish to participate or withdraw at any time during the study, you are free to withdraw, without giving a reason and without cost. To effectively meet the objectives of this research, we kindly request your participation.

Contact Information: You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, feel free to contact me by telephone number.

If you have any other concerns about your rights as a research participant that has not been answered by me, you may contact the principal investigator Dr. Tolossa Eticha by Email tecb2006@gmail.com or telephone number +251911413135.

II. Consent Form

I have read and understood the provided information. I understand that my participation is voluntary and I am free to withdraw at any time, without giving a reason and without cost. I do also understand that there is no risk in participating in the study, so I voluntarily agree to take part in this study.

Participant's signature _____Date _____

Data collector's Name and signature _____Date _____

Direct caregiver's Information sheet and Assent Form

For ages between 12 – 18 years) (English Version)

This assent form is prepared for a study entitled delayed diagnosis of Congenital Heart Diseases and associated factors in TASH: a mixed method study; Addis Ababa, Ethiopia. His supervisors are Dr. Hayat Ahmed (Assistant Professor of Pediatric Cardiology) and Dr. Henok Tadele (Associate Professor of Pediatric Cardiology).

Purpose of the study:

This study is being conducted to identify factors affecting the timely diagnosis of congenital heart diseases. It will also help to know the magnitude of delayed diagnosis of congenital heart diseases.

Objective of the study: Is to determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors in TASH, Addis Ababa, Ethiopia, 2023

Benefits: The benefit of this study is to generate information to determine the magnitude of delayed diagnosis of congenital heart diseases and associated factors. There will be no cost for participation and it will not affect your medical treatment at TASH. There will be no direct benefit to you for your participation in this study. However, we believe this research will have important implications for future care of children with congenital heart diseases.

Risks: There are no expected risks to you for participating in this study. The study will be conducted by face-to-face interview and reviewing your medical cards. The interview will take 20-30 minutes.

Confidentiality: The information gathered during this study will be kept confidentially. Research records will be kept in a locked file and all electronic information will be coded and secured using a password protected file. Only the researcher will have access to the records. In any sort of report we make public, we will not include any information that will make it possible to identify you.

Right to not participate or withdraw participation: You have a full right not to participate in this research and you can withdraw from the study at any time during the study. You are not forced to disclose any subjective matters which you feel uncomfortable. You will continue to receive your medical care and follow up even if you don't participate in this study.

Contact information for any queries: You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, feel free to contact me by telephone number.

If you have any other concerns about your rights as a research participant that has not been answered by me, you may contact the principal investigator Dr. Tolossa Eticha by Email tecb2006@gmail.com or telephone number +251911413135.

Direct care giver's consent form

If you assent to participate in this study, your parent or care giver will provide a signed consent. As a direct care giver, I have read and understood the information provided above. I, hereby, provide my consent for my child's participation in this study. I confirm my agreement to let my child participate in the study with my signature below.

Parent's/Direct care giver's Signature _____ Date _____

Data collector's Name and signature _____ Date _____

Questionnaire (English Version)

Code _____

MRN Number: _____

Part I. Interviewer administered questionnaire

Serial No	Item	Description
Socio-demographic Characteristics		
1	Age of the child	___ yrs _____months
2	Sex of the child	Male Female
3	Residential Area	Rural Urban
4	Maternal Educational Status	I No formal education II. Up to 12th grade III. Diploma IV. Degree and above
5	Paternal Educational Status	I No formal education II. Up to 12th grade III. Diploma IV. Degree and above
6	Family monthly Income	_____ Birr
Maternal obstetrics History		
7	Had ANC follow up	Yes No
8	Was Obstetric US done	Yes No
9	If yes to Q8 was any abnormality detected	No Yes : CHD Yes: Other non-cardiac malformation
10	Place of delivery	I Home II. Health Center III. Private facility IV. Government Hospital
11	Mode of delivery	I Vaginal II. Cesarean Section
12	Gestational age at delivery	_____-weeks _____Months
Child's clinical History		
13	Source of patient referral	I Other Hospital II. TASH Delivery Unit III. TASH NICU IV. Health Center IV. Private Facility V. Self
14	What is/was the age at first CHD	_____ years

	Diagnosis	_____ Months
15	Have you ever heard of CHD?	Yes No
16	Family history of CHD?	Yes No
17	If yes to Question #16, who was the case?	I. My other child II. My father III. My mother IV. Brother V. Sister VI. Other: Specify _____
18	Was the child symptomatic	I No II. Yes
19	What were symptoms	I Fast breathing II. Breast feeding interruption III. Prolonged feeding IV. Diaphoresis V. Generalized body swelling VI. Easy fatigability VII. Head ache VIII. Others: _____
20	Any Syndrome diagnosed?	NO Yes: Down Syndrome Yes: Other Specify: _____
21	Other non-cardiac abnormality	_____
22	Previous History of admission	No Yes: for cardiac reason Yes: for non-cardiac reason
23	If yes to question #17, how many times was he admitted/	1x 2x 3x ≥4x
24	What was/were the diagnoses made?	1. Heart Failure 2. Pneumonia 3. Severe acute malnutrition 4. Tet Spell 5. Polycythemia 6. Other: _____

Part II. Chart abstraction tools/record review

19	Diagnoses at Previous or current History of admission	1. No history of admission 2. Heart Failure 3. Pneumonia 4. Infective Endocarditis 5. Polycythemia 6. Tet Spell 7. Other: _____
Type of CHD		
20	Left to right shunts	VSD: Size ____mm / cm Rt - Lt Lt - Rt Bidirectional Type: Perimembraneous Muscular Inlet Outlet PDA: Size____mm / cm Rt - Lt Lt - Rt Bidirectional ASD: Size____mm / cm Rt - Lt Lt - Rt Bidirectional Type: Primium Secundum AVSD: Complete Intermediate Transitional Partial AVSD: Balanced Unbalanced
21	Pulmonary Hypertension	No Yes: Pressure Gradient: _____

22	Acyanotic Obstructive	PS: Valvular Sub-valvular Supravalvular PS: Mild Moderate Severe Critical AS: Valvular Sub-valvular Supravalvular AS: Mild Moderate Severe Critical Coarcitation of aorta Pressure Gradient: _____
23	Cyanotic HD	Typical ToF ToF with Pulmonary atresia ToF with ASD D-TGA with VSD D-TGA with ASD D-TGA with PDA L-TGA with VSD L-TGA with ASD L-TGA with PDA DORV – ToF type DORV – TGA type DORV with PS Other: _____ Tricuspid Atresia Type: 1A 1B 1C 2A 2B 2C Truncus arteriosus Type: I II III IV HLHS PAPVC/TAPVC Ebistein Anomaly

24	Any Syndrome diagnosed?	NO Yes: Down Syndrome Yes: Other Specify: _____
25	Other non-cardiac abnormality	**_____**
26	LV function	**FS = _____** **EF = _____**

የመረጃና የፈቃደኝነት ማረጋገጫ(ለወላጅ/አሳዳጊ)

I. የጥናት መረጃ

እንደምን አደራችሁ? ስሜ _____ እባላለሁ። ከዶክተር ቶሎሳ ኢቲቻ ጋር እየሠራሁ ነው። ዶክተር ቶሎሳ ኢቲቻ በሕፃናት የልብ ሕክምና ክፍል ውስጥ ለመመረቅያ የምርምር ጥናት እያካሄዳ ነዉ። የእሱ የምርምር ጥናት የልጆች የልብ ሕመም በግዜ ያለመታወቅ እና ተያያዥ ምክንያቶች ነዉ። አማካሪዎቹ ዶ/ር ሃያት አህመድ (የህፃናት የልብ ህክምና ረዳት ፕሮፌሰር) እና ዶክተር ሄኖክ ታደለ (የህፃናት የልብ ህክምና ተባባሪ ፕሮፌሰር) ናቸው።

የጥናቱ ዓላማ፡- በTASH ውስጥ የልብ ታካሚ ህፃናት ምን ያህሉ ዘግይቶ እንደምታወቅ እና ተያያዥ ምክንያቶችን ለማወቅ።

ጥቅማ ጥቅሞች፡ የዚህ ጥናት ጥቅም ከተፈጥሮ የልብ በሽታዎች ጋር የሚወለዱ ህፃናት ምን ያህል ዘግይተው እንደሚታወቁ እና ተያያዥ ምክንያቶች ለማወቅ እና መረጃን ማመንጨት ነው። ለመሳተፍ ምንም ወጪ አይኖርም። በTASH ላይ ያለዎትን የህክምና አገልግሎት አይጎዳውም።. በዚህ ጥናት ላይ ለሚያደርጉት ተሳትፎ ምንም አይነት ቀጥተኛ ጥቅም አይኖርዎትም። ሆኖም ግን ይህ ጥናት ለወደፊት የልጆች የልብ ህክምና እንድሻሻል ይረዳል ብለን እናምናለን።

ስጋቶች፡ በዚህ ጥናት ውስጥ ለመሳተፍ ምንም የሚጠበቁ ስጋቶች የሉም። ጥናቱ የሚካሄደው ፊት ለፊት ቃለ መጠይቅ እና የህክምና ካርዶችን በመጠቀም ነው። ቃለ መጠይቁ ከ20-30 ደቂቃ ብቻ ይወስዳል።

ምስጢራዊነት፡ የእርስዎ ምላሾች ሙሉ በሙሉ ሚስጥራዊ ይሆናሉ። በዚህ ጥናት ወቅት የተሰበሰበው መረጃ በሚስጥር ይጠበቃል። የምርምር መዝገቦች በተቆለፈ ፋይል ውስጥ ይቀመጣሉ። ሁሉም የኤሌክትሮኒክስ መረጃ በይለፍ ቃል የተቆለፈ እና ደህንነቱ የተጠበቀ ይሆናል። መዝገቦቹን ማግኘት የሚችለው ተመራማሪው ብቻ ነው። ለለላ ሰው ይፋ በሚሆነው በማንኛውም አይነት ዘገባ እርስዎን ለመለየት የሚያስችል ማንኛውንም መረጃ አናጨምርም።

የእርስዎ ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ ነው። በጥናቱ ወቅት በማንኛውም ጊዜ ላለመሳተፍ ወይም መቀጠል ካልፈለጉ፣ ምክንያቱን ሳይገልጹ ማቆረጥ ይችላሉ። የዚህን ጥናት ዓላማዎች በብቃት ለማሳከት፣ ተሳትፎዎን በአክብሮት እንጠይቃለን።

ስለዚህ ጥናት ጥያቄዎችን የመጠየቅ እና መልስ የማግኘት መብት አልዎት። የሚችለዉን ያህል በራሴ ለመመለስ እሞክራለሁ። ስለ ጥናቱ ተጨማሪ ጥያቄዎች ካሉዎት፣ በስልክ ቁጥር +251911413135 ወይም በኢሜል tecb2006@gmail.com ዋና ተመራማሪውን ዶ/ር ቶሎሳ ኢቲቻን ሊያነጋግሩ ይችላሉ።

II. የስምምነት ሰነድ

የቀረበውን መረጃ አንብቤ ወይም ተነቦልኝ ተረድቻለሁ ። የእኔ ተሳትፎ በፈቃደኝነት እንደሆነ እና ከጥናቱ መውጣት ብፈልግ በማንኛውም ጊዜ መልቀቅ እንደምችልም ተረድቻለሁ። በተጨማሪም በጥናቱ ውስጥ መሳተፍ አደጋ እንደሌለዉ ስለተረዳሁ በዚህ ጥናት ውስጥ ለመሳተፍ ፈቃደኛ መሆኔን አረጋግጣለሁ።

የተሳታፊ ፊርማ _____ ቀን _____

የመረጃ ሰብሳቢው ስም እና ፊርማ _____ ቀን _____

የመረጃና የፈቃደኝነት ማረጋገጫ(12-18 ዓመት ለሆኑ ልጆች)

I. የጥናት መረጃ

እንደምን አደራችሁ? ስሜ _____ እባላለሁ። ከዶክተር ቶሎሳ ኢቲቻ ጋር እየሠራሁ ነው። ዶክተር ቶሎሳ ኢቲቻ በሕፃናት የልብ ሕክምና ክፍል ውስጥ ለመመረቅያ የምርምር ጥናት እያካሄደ ነው። የእሱ የምርምር ጥናት የልጆች የልብ ሕመም በጊዜ ያለመታወቅ እና ተያያዥ ምክንያቶች ላይ ነዉ። ተቆጣጣሪዎቹ ዶ/ር ሀያት አህመድ (የህፃናት የልብ ህክምና ረዳት ፕሮፌሰር) እና ዶክተር ሄኖክ ታደለ (የህፃናት የልብ ህክምና ተባባሪ ፕሮፌሰር) ናቸው።

የጥናቱ ዓላማ፡- በTASH ውስጥ የልብ ታካሚ ህፃናት ምን ያህሉ ዘግይቶ እንደምታወቅ እና ተያያዥ ምክንያቶችን ለማወቅ።

ጥቅማ ጥቅሞች፡ የዚህ ጥናት ጥቅም ከተፈጥሮ የልብ በሽታዎች ጋር የሚወለዱ ህፃናት ምን ያህል ዘግይተው እንደሚታወቁ እና ተያያዥ ምክንያቶች ለማወቅ እና መረጃን ማመንጨት ነው። ለመሳተፍ ምንም ወጪ አይኖርም። በTASH ላይ ያለዎትን የህክምና አገልግሎት አይጎዳውም።. በዚህ ጥናት ላይ ለሚያደርጉት ተሳትፎ ምንም አይነት ቀጥተኛ ጥቅም አይኖርዎትም። ሆኖም ይህ ጥናት ለወደፊት የልጆች የልብ ህክምና እንድሻሻል ይረዳል ብለን እናምናለን።

ስጋቶች፡ በዚህ ጥናት ውስጥ ለመሳተፍ ምንም የሚጠበቁ ስጋቶች የሉም። ጥናቱ የሚካሄደው ፊት ለፊት ቃለ መጠይቅ እና የህክምና ካርዶችን በመጠቀም ነው። ቃለ መጠይቁ ከ20-30 ደቂቃ ብቻ ይወስዳል።

ምስጢራዊነት፡ የእርስዎ ምላሾች ሙሉ በሙሉ ሚስጥራዊ ይሆናሉ። በዚህ ጥናት ወቅት የተሰበሰበው መረጃ በሚስጥር ይጠበቃል። የምርምር መዝገቦች በተቆለፈ ፋይል ውስጥ ይቀመጣሉ። ሁሉም የኤሌክትሮኒክስ መረጃ በይለፍ ቃል የተቆለፈ እና ደህንነቱ የተጠበቀ ይሆናል። መዝገቦቹን ማግኘት የሚችለው ተመራማሪው ብቻ ነው። ለሌላ ሰው ይፋ በሚሆነው በማንኛውም አይነት ዘገባ እርስዎን ለመለየት የሚያስችል ማንኛውንም መረጃ አይኖርም።

የጥናቱ ጥቅም፥ በጥናቱ ለመሣተፍ ተስማምተው የሚፈርሙ ከሆነ የሚሰጡት መረጃ ወደፍት በተፈጥሮ የልብ ችግር ጋር ለሚወለዱ ህጻናት ህክምና እና ክትትል ለማሻሻል ይጠቅማል።

በጥናቱ ላለመሳተፍ ወይም ተሳትፎን ስለማቻረጥ፥ በጥናቱ እንዲሳተፉ አይገደዱም። እንዲሁም ተሳትፎዎን በማንኛውም ጊዜ ማቋረጥ ይችላሉ። በመሳተፎ ራስዎን ወይም ልጅዎን በተመለከተ መግለፅ የማይፈልጉት መረጃ ካለ እንዲገልፁ አይገደዱም። በጥናቱ መሳተፍ ባይፈልጉ በልጅዎ የህክምና ክትትል ላይ የሚያሳድረው ምንም አይነት ተጽእኖ አይኖርም።የዚህን ጥናት ዓላማዎች በብቃት ለማሳካት፣ ተሳትፎዎን በአክብሮት እንጠይቃለን።

ስለዚህ ጥናት ጥያቄዎችን የመጠየቅ እና መልስ የማግኘት መብት አልዎት።

እኔ የምችለዉን ያክል መልስ ለመስጠት እሞክራለሁ። ስለ ጥናቱ ተጨማሪ ጥያቄዎች ካሉዎት፣ በስልክ ቁጥር +251911413135 ወይም በኢሜል tecb2006@gmail.com ዋና ተማራማሪውን ዶ/ር ቶሎሳ ኢቲቻን ሊያነጋግሩ ይችላሉ።

II. የስምምነት ሰነድ

አንተ/ቺ በዝህ ጥናት ለመሳተፍ ከተስማማህ/ሽ ወላጅህ/አሳዳጊህ በስምምነት ሰነዱ ላይ ይፈርማሉ።
ከዚህ በታች ስምና ፊርማዬ የተገለፀው ግለሰብ ከላይ የተገለፁትን መረጃዎች በማንበብ አና በመረዳት ልጄ በጥናቱ እንድሳተፍ/እንድትሳተፍ መስማማቴን አሳዉቃለሁ።

የወላጅ/የአሳዳጊ ፊርማ _____ ቀን _____

የመረጃ ሰብሳቢው ስም እና ፊርማ _____ ቀን _____

Questionnaire (Amharic Version)

ኮድ _____

MRN ቁጥር፡- _____

ክፍል I. በቃለ መጠይቅ የተሰበሰበ መረጃ

ተራ ቁጥር	ቃለ-መጠይቅ	ገለጻ
	ማህበራዊ እና ኢኮኖሚያዊ መረጃዎች	
1	የልጁ እድሜ	___ ዓመት _____ወር
2	የልጁ ጾታ	ወንድ ሴት
3	የመኖሪያ ቦታ	ገጠር ከተማ
4	የእናት የትምህርት ደረጃ	I . መደበኛ ትምህርት አልተማርኩም II. እስከ 10/12ኛ ክፍል ጨርሻለሁ III. ድፕሎማ (Diploma) IV. ድግር እና ከዛ በላይ (Degree and above)
5	የአባት የትምህርት ደረጃ	I. መደበኛ ትምህርት አልተማርኩም II. እስከ 10/12ኛ ክፍል ጨርሻለሁ III. ድፕሎማ (Diploma) IV. ድግር እና ከዛ በላይ (Degree and above)
6	የቤተሰቡ የወር ገቢ	_____ ብር
	የእናትየዋ የእርግዝና እና የወሊድ ሁኔታ	
7	የእርግዝና ክትትል ነበራት	አዎ አይደለም
8	በእርግዝና ወቅት የአልትራሳውንድ (US) ምርመራ ተሰርቷል	አዎ አይደለም
9	በተራ ቁጥር 8 ላይ US ከተሰራ የታወቀ የተፈጥሮ ችግር ነበር?	I. አልነበረም II. አዎን : የልብ አፈጣጠር ችግር III. አዎን : ሌላ(ከልብ ውጭ) የአፈጣጠር ችግር
10	የተወለደበት ቦታ	I ቤት II. ጤና ጣብያ III. የግል ሀክም ቤት IV. የመንግስት ሆስፒታል
11	የወሊድ ሁኔታ	I በማህጸን II. በኦፕሬሽን (CS)
12	ስወለድ እርግዝናዉ የስንት ወር ነበር?	_____ወር _____ ሳምንት
	የህጻኑ የህክምና ታሪክ	
13	ወደ ሆስፒታላችን የተላኩት ከየት ነው?	I. ሌላ የመንግስት ሆስፒታል II. ከጥቁር አንበሳ ማዋለጃ ክፍል III. ከጥቁር አንበሳ ጨቅላ ክፍል IV. ጤና ጣብያ IV. የግል ህክምና ማዕከል V. በራሳችን መጥተን ንው

14	ልጅዎ ለመጀመሪያ ግዜ የልብ ችግር እንዳለበት ስታወቅ እድሜዉ ስንት ነበር?	_____ አመት _____ ወር
15	ከዝህ በፍት ስለ ተፈጥሮ ልብ ችግር ሰምተዉ ያውቃሉ?	አዎ አላዉቅም
16	በቤተሰብዎ ዉስጥ የተፈጥሮ የልብ ችግር ተከስቶ ያዉቃል?	አዎ አያዉቅም
17	ለጥያቄ ቁጥር 16 መልሱ አዎ ከሆነ ከነበረ ማን ላይ ነበረ?	የራሴ ልጅ አባቴ እናቴ ወንድም እህት ሌላ፡ ጻፍ _____
18	በልጁ ላይ የህመም ምልክት ኖሮት ያዉቃል?	I አያዉቅም II. አዎን ያዉቃል
19	ምልክቶቹ ምን ምን ነበሩ? (ከአንድ በላይ ማክበብ ይቻላል)	I ቶሎ ቶሎ መተንፈስ II. ጡት ስጠባ ማቆራረጥ III. ለረጅም ግዜ መጥባት IV. ከፍተኛ ላብ ማለብ V. የሰዉነት ማበጥ VI. ድካም ድካም ማለት VII. የራስ ህመም VIII. የእድገት መቀጨጭ IX. ሌላ: _____
20	ተያያዥነት ያለው ሌላ የተፈጥሮ ህመም አለ?	የለም አዎን፥ ዳዎን ስንድሮም (Down Syndrome) አዎን፥ ከዳዎን ስንድሮም ሌለ (Non-Down Syndrome)
21	ከልብ ዉጭ ሌላ የተፈጥሮ ችግር አለ?	የለም አዎ ፥ ጻፍ _____
22	ከአሁን በፍት ሆስፒታል ተኝቶ ያዉቃል?	አያዉቅም አዎን በልብ ምክንያት (for cardiac reason) አዎን በሌላ ምክንያት (for non-cardiac reason)
23	ተኝቶ የምያዉቅ ከሆነ ስንት ግዜ	1x 2x 3x ≥4x
24	ተኝቶ በነበረበት ግዜ የበሽታዉ አይነት ምን ነበር?	I. የልብ መድከም II. የሳንባ ምች III. የምግብ እጥረት (SAM) IV. በልብ ችግር ምክንያት ድንገት መታፈን (Tet Spell) V. የደም መወፈር (Polycythemia) VI. ሌላ፡ ግለጽ _____