MAGNITUDE AND PATTERNS OF CONGENITAL MALFORMATION AND ASSOCIATED FACTORS AMONG NEONATES ADMITTED TO JIMMA MEDICAL CENTER NEONATAL AND PEDIATRICS WARDS, SOUTH WEST ETHIOPIA

BY: KASSAHUN BERHANU (MD, Pediatrics resident)

A THESIS TO BE SUBMITTED TO THE DEPARTMENT OF PEDIATRICS AND CHILD HEALTH, FACULTY OF MEDICAL SCIENCES, JIMMA UNIVERSITY FOR THE PARTIAL FULFILMENT OF THE REQUIREMENT OF SPECIALITY CERTIFICATE IN PEDIATRICS AND CHILD HEALTH

OCTOBER 2020
JIMMA, OROMIA, ETHIOPIA

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ADVISERS: Workineh Tesfaye (MD, assistant professor of pediatrics and child Health)

Melkamu Berhane (MD, associate professor of pediatrics and child Health)

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Declaration

Assurance of principal investigator

I, agree to accept the responsibility for the scientific, ethical and technical conduct of the research project & for provision of required progress report as per terms and condition of the faculty of medical sciences in effect at the time grant is forwarded as the result of this application.

Name of principal investigator	Signature	Date
Dr. Kassahun Berhanu	_____	_____

Approval of the advisors

This thesis has been submitted with my approval as university advisor

Name of the advisors	Signature	Date
Dr. Workineh Tesfaye	_____	_____
Dr. Melkamu Berhane	_____	_____

Abstract

Background: *According to World Health Organization, the word congenital anomaly include any morphological, functional, biochemical or molecular defects that may develop in the embryo and fetus from conception until birth, and present at birth, whether detected at the time of birth or later. There are several known factors that are associated with congenital malformations, which can relate to genetics, environment, or maternal health/well-being. There is paucity of data on prevalence and risk factors of congenital malformation in newborns in Ethiopia in general and Jimma Medical Center in particular.*

Objectives: *To assess the magnitude, pattern and factors associated to congenital malformation in neonates admitted to neonatal and pediatrics wards of Jimma Medical Center.*

Methods: *Institution based prospective cross-sectional study was conducted in the neonatology and pediatrics wards, Department of pediatrics and child health, Jimma Medical Center from March to July 2020. Structured questionnaire was used to capture the relevant data. EpiData version 4.0 and SPSS version 20.0 were used for data entry and analysis respectively. Descriptive statistics was carried out to see the patterns of congenital malformation whereas bivariate and multivariate logistic regression analyses were performed to identify the factors associated with congenital malformations at p-value of 0.05 and confidence interval of 95%.*

Results: *422 neonates admitted to neonatology and pediatrics wards were enrolled in the study, yielding 100% response rate. Closer to one in five admitted neonates (78, 18.5%, 95% CI 14.7-22.3) in the study had congenital malformation. Central nerves system is the most commonly involved (29, 6.87%) followed by the gastrointestinal system (24, 5.68%). In multi-variable logistic regression analysis, having less than four antenatal care follow up (AOR 2.05, 95% CI 1.21, 3.48, p=0.008), lack of periconceptional folic acid supplementation (AOR 2.38, 95% CI, 1.13, 5.03, p=0.023), and maternal under nutrition (AOR 7.73, 95% CI, 1.60, 34.61, p=0.008), are significantly associated with congenital malformation.*

Conclusion and recommendation: *Congenital malformation is one of the commonest reasons of admission to the neonatology and pediatrics wards of Jimma Medical Center. The most commonly affected system is the central nerves system. There is significant association between congenital malformation and poor antenatal attendance, lack of periconceptional folic acid supplementation, and maternal under nutrition. Large scale, multicenter center study is*

recommended in collaboration with different stakeholders to understand the real burden of congenital malformation and associated factors so that possible preventive and curative interventions can be designed.

Key words: *Congenital malformation, neonates, Jimma University Medical Center, Ethiopia*

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Contents

List of tables

ACRONYMS AND ABBREVIATIONS

ANC=Antenatal Care

CVS=Cardiovascular System

CNS=Central Nervous System

CM= congenital malformation

DC= Data Collector

GIS=Gastrointestinal System

GUS=Genitourinary System

GA=Gestational Age

IRB= Institutional Review Board

ICD=International Classification of Disease

JMC= Jimma Medical Center

MSS=Musculoskeletal System

NICU=Neonatal Intensive Care Unit

PI=Principal Investigator

U/S=Ultrasound

WHO= World Health Organization

CHAPTER 1: INTRODUCTION

1.1 Background

The World Health Organization (WHO) defines the term congenital malformation (CM) as structural defect at birth. According to the WHO, the term congenital anomaly includes any morphological, functional, biochemical or molecular defects that may develop in the embryo and fetus from conception until birth, and present at birth, whether it is detected at that time of birth or not (1). The human reproduction is a complicated process and is prone to be adversely affected by various factors related to the host and environment (2). The first trimester especially between the 3rd and 8th weeks of gestation, is crucial period for morphogenesis of organs. Any insult in any form during this period can cause congenital abnormalities (1-3).

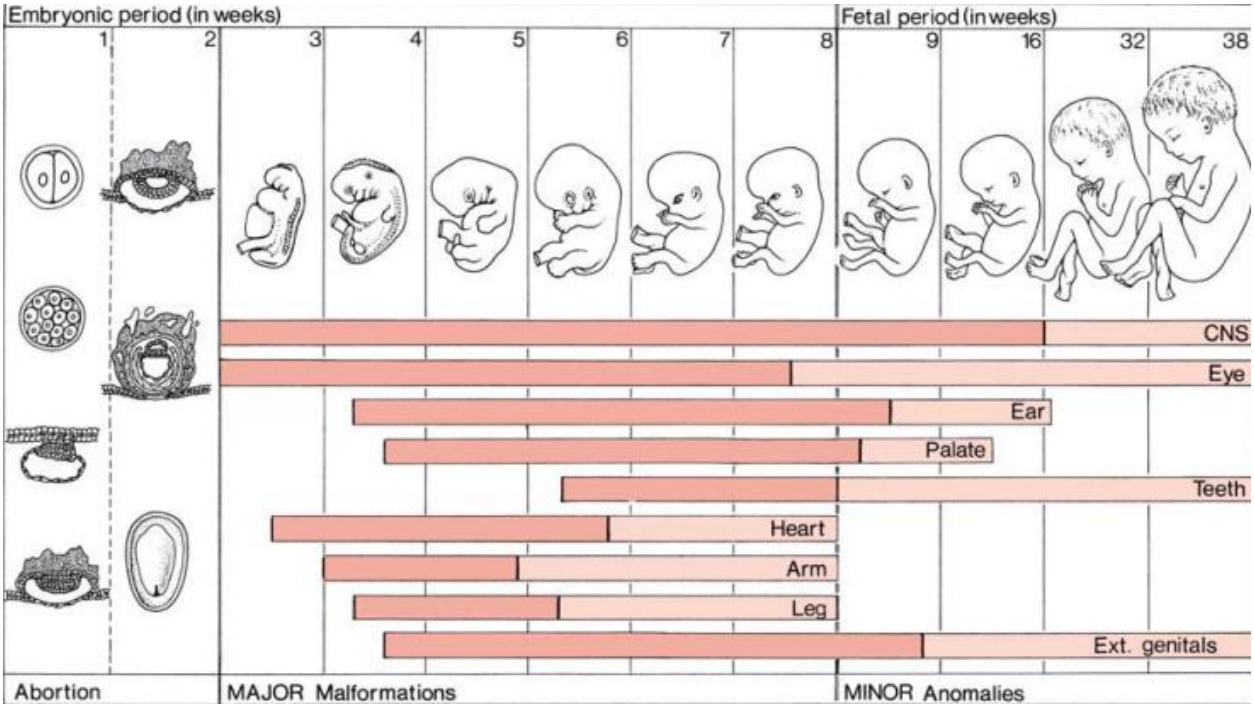

Figure 1: Critical periods in human development and the site of action of teratogens

The prevalence of CMs ranges between 2% and 3% and varies in different geographical, racial, and ethnic parts of the world (1, 2). As far as the involvement of different system of the body is concerned, the central nervous system has the highest incidence of CMs, i.e., 10/1000 followed

by heart 8/1000, kidney 4/1000, limb 1/1000, and miscellaneous 6/1000 live births (2). Though CM affects every system, Central nervous system (CNS) and cardiovascular system (CVS) are the two most commonly affected one. For instance, when we see the embryogenesis of these two systems, CNS malformations are grouped into neural tube defects (NTDs) and associated spinal cord malformations (4). NTDs account for the largest proportion of congenital anomalies of the CNS and result from failure of the neural tube to close spontaneously between the 3rd and 4th week of in utero development (2, 4).

Cardiogenesis involves a precisely orchestrated series of molecular and morphogenetic events that combines cell types from multiple lineages (2, 4). Development of the heart begins in the third week. Development of a vascular system is an early necessity in the embryonic life. It develops from the splanchnic mesoderm in the cardiogenic area in front of the buccopharyngeal membrane (2, 4). Two extraembryonic sources exist (vessels of the yolk sac and vessels of the chorion) which form the vitelline and umbilical systems, and the third, completely intraembryonic cardinal system, produced close to the developing central nervous system, eventually giving rise to the heart and vasculature (4). Formation of the heart tube takes place from the horseshoe-shaped group of cells called cardiogenic crescent in the mesoderm between the yolk sac and the confluence of the left and right coelomic cavities from which all of the body cavities are later derived on the 20th day of life (2, 4).

The heartbeat probably begins at the straight tube stage or at the early loop stage (4). Cardiac loop formation (normally to the right) begins by 21 days of age breaking the symmetry of embryo, and forms four cardiac chambers (4). From 22-28 days of embryogenesis of cardiovascular development, it undergoes formation of the cardiac loop, beginning of the development of left and right ventricles, cardiovascular septation, evolution of the aortic arches, and commencement of the circulation (4). From 29-35 days the right and left ventricles and ventricular septum continue to grow and develop, approximation of the aorta to the interventricular foramen, mitral valve and left ventricle, separation of the ascending aorta and main pulmonary artery, right ventricle enlarges and muscular ventricular septum moves from

right to left leading to the opening of the tricuspid valve into the right ventricle, ostium primum is closed, ventricular apex swings leftward and the main features of the cardiovascular development between the 36th and 49th days of life (weeks 6–7 of the embryonic development are closure of the infundibular septum and closure of the membranous part of the ventricular septum which can be delayed until after birth (4). Ventricular septal defects (VSD) result from failure of the closure of the interventricular septum beyond the first 7 weeks of gestation and atrial septal defect (ASD) after 9weeks (2, 4).

1.2 Classification of CM

Morphologically, the congenital abnormalities may be classified as primary or secondary CM or as minor and major malformation (1, 2). Minor malformation is defined as structural abnormalities present at birth that has minimal effect on clinical function but may have a cosmetic effect, like, a pre-auricular tag. Major malformation has a significant effect on function or on social acceptability, like, ventricular septal defect (VSD) and cleft lip (1, 2, 4). The primary congenital defects arise from genetic (intrinsic) defects resulting in basic alteration of the structure <10 week of gestation (2). Primary CMs are further subdivided into isolated (single) defects or multiple congenital anomalies (multiple defects) in one individual (4). An isolated primary defect can be classified, according to the nature of the presumed cause of the defect, as a malformation, dysplasia, deformation, or disruption (4). A malformation is a structural defect arising from a localized error in morphogenesis that results in the abnormal formation of a tissue or organ. Dysplasia refers to the abnormal organization of cells into tissues. In contrast, a deformation is an alteration in shape or structure of a structure or organ that has developed, or differentiated, normally. A disruption is a defect resulting from the destruction of a structure that had formed normally before the insult (2, 4). Multiple primary defects can be classified, as syndrome, sequences and association. Syndrome is a pattern of multiple abnormalities that are related by pathophysiology, resulting from a single, defined etiology. Sequences consist of multiple malformations that are caused by a single event, although the sequence itself can have different etiologies. An association refers to a nonrandom grouping of malformations in which there is an unclear, or unknown, relationship among the malformations, such that they do not fit the criteria for a syndrome or sequence (2, 4).

Secondary congenital defects arise from non-genetic (extrinsic) defects. These include disruption, where there is a morphological defect arising from the external breakdown of or an interference with an originally normal developmental process (e.g. amniotic band disruption sequence), and deformation, where a variation in structure (shape, size or position) occurs in a normal tissue in response to external mechanical forces (talipes equinovarus defect in anhydramnios) (4).

1.3 Statement of the problem

Worldwide, from various studies, approximately 1 in 40 or 2-3% of the newborns is reported to have congenital malformation (4). WHO estimates that some 270 000 deaths worldwide (about 7% of all neonatal deaths) were caused by congenital anomalies in 2010 (1). They are most prominent causes of death in settings where overall mortality rates are lower, for example in the European Region, where as many as 25% of neonatal deaths are due to congenital anomalies (1). In 2013, birth defects accounted for 1 in 5 infant deaths in the United States, with a rate of 137.6 deaths per 100,000 live births, which was higher than other causes of mortality, such as preterm/low birth weight (109.5/100,000), sudden infant death syndrome (55.5/100,000), maternal complications of pregnancy (37.3/100,000), and respiratory distress syndrome (25.3/100,000)(2). In Ethiopia though CM is commonly seen in our clinical practice, the exact burden of CM is not known. But one study done in north Ethiopia found that the prevalence of CM is about 1.61% (5). In both developed and developing countries, although CMs are the most serious causes of infant mortality and disability, about 94% of CMs, 95% of deaths and 15-30% of hospital admissions of infants and children due to CMs are in low- and middle-income countries (7).

1.4 Causes of CM

The causes of congenital malformations may be divided into five broad groups as single gene defects (mutant genes); chromosome abnormalities; multifactorial disorders which are the result of interaction between genetic predisposition and presumed environmental factors; teratogenic factors; and those of unknown cause (3). In general causes of CM can be monogenic (like X-linked hydrocephalus, Achondroplasia, Ectodermal dysplasia, Apert syndrome, and Treacher Collins syndrome); chromosomal aberrations and copy number variants (like Trisomy 21, 18, 13

XO, XXY, Deletions 4p−, 5p−, 7q−, 13q−, 18p−, 18q−, 22q−, Prader-Willi syndrome); maternal intrauterine infections like herpes simplex virus, cytomegalovirus, varicella-zoster virus, rubella virus, Zika virus, toxoplasmosis; maternal illness like diabetes mellitus, phenylketonuria, hyperthermia; uterine environment like deformation uterine pressure, oligohydramnios, clubfoot, torticollis, congenital hip dislocation, pulmonary hypoplasia, 7th nerve palsy, disruption, amniotic bands, congenital amputations, gastroschisis, porencephaly, intestinal atresia, twinning; environmental agents like Polychlorinated biphenyls, herbicides, mercury, alcohol; medications like Thalidomide, Diethylstilbestrol, Phenytoin, Warfarin, Cytotoxic drugs, Paroxetine, Angiotensin-converting enzyme inhibitors, Isotretinoin (vitamin A), D-Penicillamine, Valproic acid, Mycophenolate mofetil; unknown etiologies like neural tube defects, such as anencephaly and spina bifida cleft lip/palate, pyloric stenosis; sporadic sequence complexes like VATER/VACTERL sequence (vertebral defects, anal atresia, cardiac defects, tracheoesophageal fistula with esophageal atresia, radial and renal anomalies), Pierre Robin sequence), and nutritional like neural tube defects due to low folic acid) (4). Despite the tremendous advances in genetics over the last decade, the etiology of more than 50% of malformations is still unknown (3). Mutant genes, chromosome abnormalities and known teratogens are each identified in about 7–8% of malformations, and a further 20–25% of malformations fall into the group of multifactorial disorders (3).

1.5 Early Diagnosis and Prevention of CM

Different prenatal, antenatal and postnatal screening methods are used for early identification of CM (2). Suspicion of a congenital malformation may arise on clinical grounds or because of an abnormal result from a routine prenatal investigation (2). A pregnancy may be at high risk of abnormality because of a particular family history or the advanced age of the mother. Higher-risk groups for chromosome abnormalities include older mothers, those with a previous chromosomally abnormal child, and when one parent is a translocation carrier (1-4). Maternal serum markers, chorionic villus sampling, amniocentesis, cordocentesis, and ultrasonography can be used to detect anomalies. For instance, measuring the level of AFP in amniotic fluid was first carried out for the prenatal diagnosis of neural tube defects. An increasing number of single gene disorders and chromosome abnormalities can now be identified at the molecular level (4). In utero intervention for some CMs such as hydrocephalus, posterior urethral valve, cleft lip, and hydronephrosis is gaining popularity (2, 3).

1.6 Significance of the study

There is paucity of data on magnitude, pattern and associated factors of congenital malformation in Ethiopia in general and JMC in particular. Hence this study will be an input for providing base line data for the institution and contribute data to improve the paucity of data at a national level.

CHAPTER 2: LITERATURE REVIEW

2.1 Magnitude and pattern of CM

A cross sectional study was undertaken from May 2010 through Feb 2013 for estimation of gross congenital malformations among live birth and stillbirth children born in Assam Medical College, a tertiary referral hospital in northeast India, in which a total of 18,192 births including live births and still births were examined and 206 cases of structural malformations were observed making the prevalence of CM among the live births 1.2%. CM was predominant among males and musculoskeletal system was the most commonly involved system (8).

A retrospective study was conducted on the prevalence of congenital malformations in Cross River and Akwa Ibom states of Nigeria from 1980–2003. A total of 127 929 births were recorded, of which 452(0.35%) cases of malformations were recorded. The anomalies recorded in the skeletal system were the highest detected followed by that of the central nervous system (24.6%) and the urogenital system (18.4%) (9).

Cross-sectional hospital-based study involving young infants below 2 months of age admitted at Bugando Medical Centre, Tanzania between October 2012 and January 2013, which demonstrated 131 infants among the 445 examined to have congenital anomalies, giving a prevalence of 29%. The most commonly affected body system was the central nervous system (29.8%), followed by the musculoskeletal and gastrointestinal systems accounting for 22.9% and 9.2% cases respectively (10).

The prospective hospital-based study conducted over a period of 18 months in the neonatal unit of Combined Military Hospital, Kharian, Pakistan from September 2011 to February 2013, has shown that 7% of the neonates had congenital malformation. Among different body systems affected, anomalies related to the central nervous system accounted for 20.35%, musculoskeletal for 18.58%, genitourinary system for 15.04%, cardiovascular system for 13.27%, ear, eye, face, neck for 11.94%, digestive system for 8.40%, whereas syndromes and skin malformations accounted for 6.19% each (11).

In Ethiopia, there are only very few studies done on CM. A retrospective cross-sectional study was conducted in two referral hospitals, Debre Markos Referral Hospital and Felege Hiwot Referral Hospital where 19,650 infants were born between 2015 and 2017. Among these, 1.61% of the infants had birth defects. The most frequent type of birth defects seen were neural tube defects (32.5%), followed by oro-facial clefts (27.1%), cardiovascular system defects (12%) and upper and lower limb defects (8.8%) (6).

2.2 Risk factors of congenital malformation

In 1996, it was thought that malformations were caused by monogenic defects in 7.5% of patients; chromosomal anomalies in 6%; multigenic defects in 20%; and known environmental factors, such as maternal diseases, infections, and teratogens, in 6–7%. In the remaining 60–70% of patients, malformations were classified as caused by unknown etiologies (4). In early human history, birth defects in both animals and humans were often attributed to a curse from God or because of evil. Even today, some cultures think that mothers who give birth to infants with BDs have had communication with a devil or evil spirits (2).

A prospective hospital-based study was conducted over a period of 18 months in the neonatal unit of Combined Military Hospital, Kharian, Pakistan from September 2011 to February 2013, which has found the causes of CM to be genetic, environmental or unknown. Among genetic causes, 6% were due to chromosomal abnormality, 25% single-gene disorders, and 20-30% multifactorial, whereas in 50% of the cases, the cause is unknown (11).

A cross-sectional study was conducted involving young infants below 2 months of age, admitted at a university teaching hospital in Tanzania, between October 2012 and January 2013 and showed that, maternal factors that were significantly associated with congenital anomalies included the lack of periconceptional use of folic acid, a maternal age of above 35 years and an inadequate attendance to antenatal clinic. Infant factors that were significantly associated with congenital anomalies were female sex, a birth weight of 2.5 kg or more, singleton pregnancy and a birth order above 4 (10).

A prospective study was undertaken at Zagazig University Hospital, Zagazig Governorate, Egypt on all babies born from January 2011 to December 2011, which has found that, maternal age

(<20 years or >35 years) was associated with increased incidence of CMs although this was not significant. There were significantly more CMs among neonates with parental consanguinity than among babies without parental consanguinity. Both maternal under nutrition and obesity were significantly associated with an increase in CMs among neonates. There were significantly more cases with a story of an anomaly in another child or in the family among mothers of neonates with CMs. The incidence of CMs was significantly higher amongst the LBW (<2500 g) babies than among normal birth weight babies and in preterm babies than full term (12).

A cross sectional study was conducted from 1995-2009 on 660280 children at Ain Shams University Hospital, North East region of Cairo which showed an increased CMs with a maternal risk factors for CMs of multiparity, age of the mother above 35 years at conception, maternal illness especially diabetes, fever and common cold and exposure to pollutants. Mothers of children with CMs were more significantly affected than controls with polyhydramnios, oligohydramnios, early vaginal bleeding and preeclampsia. Twin pregnancy was recorded in 2.94% and breech presentation in 11.32% in this study. Past history of abortion or stillbirth was detected in 32.39% of mothers of patients with CMs. Fathers above 50 years at time of conception was detected in 29.99% of patients with CMs, and 85.28% of them were nonprofessionals (drivers, peasants, and laborers in factories). Consanguineous marriage was present in 45.8% of parents of patients and family history of CMs was detected in 16.69% of affected families (13).

In a retrospective cross-sectional study conducted in Debre Markos and Felege Hiwot Referral Hospitals, lack of folic acid supplementation, presence of chronic disease, intake of drugs and consumption of alcohol during pregnancy were significantly associated with congenital malformations (6).

Though the exact number is not known, there are many neonates with congenital malformations admitted to JMC neonatology and pediatrics wards. This number is large enough to be a concern for us clinicians observing this and searching a solution if any. However, there has never been a study on magnitude, pattern and associated factors for this problem in Jimma as a whole and specifically in our hospital.

CHAPTER 3: OBJECTIVE OF THE STUDY

3.1 General objective:

- ✓ To assess the magnitude, pattern and factors associated with congenital malformation in JMC, southwest, Ethiopia.

3.2 Specific objectives:

- ✓ To determine the magnitude of congenital malformation among neonates admitted to JUMC.
- ✓ To identify pattern of congenital malformations among neonates admitted to JUMC
- ✓ To determine the factors associated with congenital malformations among neonates admitted to JUMC.

CHAPTER 4: MATERIALS AND METHODS

4.1 Study area and period

4.1.1 Study area

The study was conducted at JMC, which is a referral hospital found in Jimma Town, southwest Ethiopia. The town is around 350km from the capital city, Addis-Ababa. It serves as a referral and specialized medical center for over 15 million populations in the catchment areas of south western Oromia, Gambella and some parts of Southern Nations and Nationalities Regional State. Currently, it is assumed to be serving even a higher population because of the influx of displaced people and new visitors from neighboring South Sudan. It provides a broad range of medical services to both in and out patients of all age groups. It also serves as a teaching hospital to several medical specialties, dental medicine, nursing, midwifery, public health, pharmacy, anesthesia and medical laboratory students in both undergraduate and post- graduate programs.

Department of pediatrics and child health is one of the major specialties which has 7 pediatricians, one pediatric oncologist and one pediatric intensivist. It has about 130 beds capacity, with PICU and NICU facilities. The neonatology ward has 32 bed capacity including NICU. The NICU is staffed with 21 nurses, two senior and four junior residents, which rotate each month and two pediatricians and often attended by additional trainees.

4.1.2 Study period

The study was conducted from March 1 to July 30, 2020.

4.2 Study design

Institution based Cross-sectional study design was used.

4.3 Source population

All neonates admitted to JMC neonatology and pediatrics wards.

4.4 Study population:

All neonates admitted to JMC neonatology and pediatrics wards during the study period that fulfill the inclusion criteria.

4.5 Inclusion and exclusion criteria

4.5.1 Inclusion criteria:

Neonates who were admitted to neonatology and pediatrics wards of JMC during the study period, whose parents or caretakers gave consent to take part in the study.

4.5.2 Exclusion criteria:

Neonates who are admitted to neonatology and pediatrics wards of JMC during the study period, whose mothers had mental illness, critically ill or died or parents refused to give consent.

4.6 Sampling and Sample size determination

All neonates who are admitted to neonatology and pediatrics wards of JMC during the study period were included consecutively. Sample size was calculated by using a single population proportion formula with the assumption of 95% level of confidence, 5% marginal error, taking the proportion of CM at rate of 50%, because there is no similar study done in our setup.

$$n = \frac{(Z\ 1-\alpha/2)\ 2\ p\ (1-p)}{d2}$$

Sample size was calculated with the following assumption:

n = minimum sample size,

Z 1-α/2= significance level at α =0.05

d= margin of error (5%)

P= prevalence of CM at 50 %

n = 384

10% non-response rate = 38

Total number = 422

4.7 Study variables

4.7.1 Dependent variable

- ✓ Congenital malformations

4.7.2 Independent variables

- ✓ Maternal Age, ANC follow up, maternal history of drug intake, gravidity, consanguinity, maternal acute or chronic illness, previous history of CM, neonates sex, birth weight, GA,

maternal educational status, socioeconomic status, maternal nutritional status, singleton or twin, address and folate supplementation.

4.8 Data collection method and procedures

4.8.1 Data collection method

Interviewer administered structured questionnaire and patient chart abstraction was used to collect data. The questionnaire was developed in English and then translated in to local languages (Amharic and Afan Oromo), and then back translated in to English by a third person to check for consistency. Two General practitioners (GP) trained for one day on data collection procedure were used for data collection and ward senior resident who was given orientation was used for supervision. The principal investigator checked for completeness of the questionnaire on daily basis.

4.8.2 Data quality assurance

To assure the quality of data, the following measures were undertaken. Structured data collection instrument was used. The questionnaire was pretested and clarity of language was checked.

The principal investigator closely supervised the activity on a daily basis. At the end of each data collection days, the principal investigator checked the completeness of filled questionnaires and whether recorded information makes sense to ensure the quality of the data collected. Meeting was also conducted whenever necessary, with the data collectors so that any ambiguity was cleared by discussion.

4.8.3 Data processing and analysis

Data coding, cleaning and verification were done before entering into EpiData manager version 4.0 and exported to the Statistical Package for Social Sciences (SPSS) version 20.0 for analysis. Descriptive statistics was carried out to see the pattern of CM and univariate and multivariate logistic regression analysis were performed to determine factors associated with congenital malformation. P-value of less than 0.25 at a CI of 95% was considered as a candidate variable for multi variate logistics regression. P value of less than 0.05 at a CI of 95% was considered as significant.

4.9 Operational definitions

- **Congenital malformation**- a structural or physical defect present in a baby at birth, which is diagnosed either by physical examination or imaging.
- **Major malformation –** are malformations which have significant medical, social or cosmetic consequences and associated with morbidity and mortality, and require medical intervention.
- **Minor malformation –** are malformations which have no significant health problem and have limited social or cosmetic consequences.
- **Neonates** - all children under the age of 28 days.
- **Still birth** - is birth of a baby born with no signs of life at or after 28 weeks of gestation.
- **Early neonatal death** – is the neonatal death occurring within the first seven days of life
- **First-degree relative** - is a close blood relative which includes the individual's parents, full siblings, or children
- **Gestational age**: Estimated by using last normal menstrual period (LNMP) or by Ballard score.
- **Preterm**: Gestational age<37 completed weeks
- **Term** -Gestational age above 37 completed weeks
- **Normal Birth weight**: Birth weight above 2500gm.
- **Low Birth weight**: Birth weight<2500gm.
- **Bad obstetric history**: a mother who have previous history of either abortion, still birth or early neonatal death
- **Substance abuse**: those who take kat (chat) and/or alcohol and/or are active or passive smokers.
- **Low-set ears**- This designation is made when the helix meets the cranium at a level below a horizontal plane that is an extension of a line through both inner canthi
- **Short palpebral fissures**- Decreased horizontal distance of the eyelid folds based on measurements from the inner canthus to the outer canthus
- **Syndactyly**- Incomplete separation of the fingers or toes.

4.10. Ethical considerations

Ethical clearance was obtained from the Institutional Review Board (IRB) of Jimma University Institute of Health with Reference number IRB000217/20. Additionally, permission letter was obtained from JMC clinical director office and the department of pediatrics and child health before the commencement of the study.

4.11. Plan for dissemination of results

The finding of this study will be submitted to Jimma University Faculty of Medical Sciences, Department of Pediatrics and Child Health, and other relevant stake holders. Attempts will also be made to publish it on peer reviewed scientific journal.

CHAPTER 5: RESULTS

5.1 Characteristics of neonates admitted to NICU and pediatrics ward, JMC, 2020

In this study, parents of 422 neonates admitted to the NICU and pediatrics ward were approached and all of them gave their consent, yielding 100% response rate. About 264 (62.6%) of the study subjects were male. The median age at presentation is 13.5 hours with the minimum and maximum age at presentation of 5 minutes and 14 days respectively. Two third of the study subjects (280, 66.4%) were born after ≥37 completed weeks. Majority (396, 93.8%) of the study subjects were born at health institution, mainly hospital (Table 1).

Table 1: Characteristics of Neonates admitted to NICU and pediatrics ward JMC, 2020 (N=422)

Variables	Category	Frequency	Percent
Sex	Male	264	62.6
	Female	158	37.4
Age at presentation	<24hr	238	56.4
	24-72hr	98	23.2
	≥72hr	86	20.4
	<37wk	142	33.6
GA at birth	≥37wk	280	66.4
Birth weight	<2500gm	150	39.2
	≥2500gm	233	60.8
	Unknown birth weight	39	9.2
Type of gestation	Singleton	356	84.4
	Multiple gestation*	66	15.6
Place of birth	Home	22	
	Institutional delivery	396	
	Others**	4	
Mode of delivery	SVD	293	
	Assisted	13	
	C/S	116	

*Four of the multiple gestations are triplets, ** on the way (in Ambulance)

SVD-Spontaneous Vaginal Delivery and C/S-Caesarian Section

5.2 Sociodemographic Characteristics of mothers of neonates admitted to the NICU and pediatrics ward, JMC, 2020

Most of the mothers (377, 89.3%) of the neonates were in the age range of 19-35 years. Regarding the educational status of the mothers, about a third (153, 36.3%) of them attended primary school whereas most of them (257, 60.9%) live in rural area. (Table 2)

Table 2 Socio-demographic Characteristics of mothers of neonates admitted to NICU and pediatrics ward, JMC, 2020 (N=422)

Variables	Category	Frequency	Percent
Age	<19yr	19	4.5
	19-35	377	89.3
	>35	26	6.2
Ethnicity	Oromo	321	76.1
	Amhara	40	9.5
	Gurage	7	1.7
	Kaffa	29	6.9
	Dawro	7	1.7
	Yem	8	1.9
	Other*	10	2.4
Religion	Orthodox	94	22.3
	Muslim	277	65.6
	Protestant	50	11.8
	Catholic	1	0.2
Educational status	Can't read & write	132	31.3
	Primary school (1-8)	153	36.3
	Secondary school (9-10)	73	17.3
	>10	64	15.2
Occupation	Housewife	274	64.9
	Merchant	27	6.4
	Daily laborer	6	1.4
	Farmer	67	15.9
	Employee	48	11.4
Residency	Rural	257	60.9
	Urban	165	39.1

*Indicates Silte, Benchi, Agnuak, and Nuer

5.3. Obstetric Characteristics of mothers of neonates admitted to NICU and pediatrics ward, JMC, 2020(N=422)

Over half of the mothers (229, 54.3%) were multiparous and 68 (16.1%) had bad obstetrics history. Almost all the mothers (405, 96%) had ANC visit, half of them (211, 50%) having ≥4 antenatal visits. Nearly two third of the mothers (267, 65.9%) were having ANC follow up at HC. (Table 3)

Table 3 : Obstetric Characteristics of mothers of neonates admitted to NICU and pediatrics ward, JMC, 2020 (N=422)

Variables	Category	Frequency	Percent
Gravidity	1	176	41.7
	2-4	177	41.9
	≥5	69	16.4
Parity	1	193	45.7
	2-4	169	40.0
	≥5	60	14.2
Previous history of abortion	Yes	44	10.4
	No	378	89.6
Previous history of still birth	Yes	14	3.3
	No	408	96.7
Previous history of early neonatal death	Yes	22	5.2
	No	400	94.8
Bad obstetric history*	Yes	68	16.1
	No	354	83.9
No of ANC visit	0	17	4
	<4	194	46
	≥4	211	50
Place of ANC follow up (n=405)	Health center	267	65.9
	Hospital	107	26.4
	Private clinic	31	7.7

*indicates, the sum of the values for abortion, early neonatal death and still birth, ** on the way (Ambulance)

5.4 Medical characteristics of mothers of neonates admitted to NICU and pediatrics ward, JMC, 2020(N=422)

About a quarter of the mothers (100, 23.7%) have received folic acid during the current pregnancy, whereas two third (275, 65.2%) of them were well nourished with a MUAC of >23cm. Only few (56, 13.3%) of the mothers had reported different degree of substance abuse. Only very few (7, 1.7%) of the mothers had previous history of a child with CM, and only (1, 0.2%) mother had first degree relative with CM, which was cleft lip. (Table 4)

Table 4 : Medical characteristics of mothers of neonates admitted to NICU and pediatrics ward, JMC, 2020 (N=422)

Variables	Classification	Frequency	Percent
Mother received folic acid during pregnancy	No	322	76.3
	1st trimester	34	8.1
	2nd trimester	51	12.1
	3rd trimester	15	3.5
Maternal chronic diseases	No	390	92.4
	DM	2	0.47
	HIV/AIDS	5	1.2
	HTN	20	4.7
	Epilepsy	1	0.24
	Other *	4	0.95
Drug intake other than folate during current pregnancy	Yes	212	50.2
	No	210	49.8
Maternal history of any febrile illness during current pregnancy	Yes	25	5.9
	No	397	94.1
Maternal chat chewing habit	Yes	47	11.1
	No	375	88.9
Frequency of chewing chat	Daily	7	1.6
	>Once/week but <daily	35	8.3
	>Once/month but <weekly	5	1.2
Exposure to cigarette smoke in the household	Yes	4	0.9
	No	418	99.1
Frequency of exposure to cigarette smoke	Daily	3	0.7
	> Once/week but < daily	1	0.2
	> Once/month but<weekly	0	0
Maternal alcohol drinking habit	Yes	9	2.1
	No	413	97.9
Frequency of alcohol intake	Daily	0	0
	> Once/week but < daily	4	0.95
	> Once/month but<weekly	5	1.2
Substance abuse*	Yes	56	13.3
	No	366	86.7
Maternal (MUAC)	<19cm	8	1.9
	≥19-<23cm	139	32.9
	≥23cm	275	65.2
Mother has 1st degree relative with CM	Yes	1	0.2
	No	421	99.8

* The sum of values for alcohol drinking, chat chewing and exposure to cigarette smoke.

5.5 Magnitude and pattern of congenital malformation in neonates admitted to NICU and pediatrics ward, JMC, 2020(N=422)

In this study, closer to one in five neonates (78, 18.5%, 95% CI 14.7-22.3) had congenital malformations, majority (59, 13.98%) of them having only one type of malformation. The most frequently identified CM is malformation of the CNS (29, 6.87%) followed by the GI system (24, 5.68%). (Table 5)

Table 5: Magnitude and Pattern of CM in neonates admitted to NICU and pediatrics ward, JMC, 2020(n=78)

Variable	Category	Frequency	Percent
Does the neonate have CM?	Yes	78	18.50
	No	344	81.50
Number of defects	1	59	13.98
	2	8	1.89
	>2	11	2.60
Type of congenital malformation	CNS	29	6.87
	CVS	12	2.84
	Orofacial anomalies	18	4.26
	GI	24	5.68
	Genital organ	2	0.47
	MSK	19	4.50
	RS	3	0.7
	Syndrome	7	1.66

5.5.1 Distribution of CM by body system with type of CM in neonates admitted to NICU and pediatrics ward, JMC, 2020

Out of 78 neonates with CM, two third (53, 67.96%) is localized to two systems (CNS and GI). Out of 29 babies having CNS malformations, 19 (4.5%) had NTD, whereas out of 12 neonates with CVS malformation, half (6, 50%) of them had Ventricular Septal Defect (VSD). (Table 6)

Table 6 : Distribution of CM by body system with type of CM in neonates admitted to NICU and pediatrics ward, JMC, 2020 (N=422)

Body system	Type of defect	Frequency	Percent
CNS	Neural tube defect	19	4.50
	Hydrocephalus	7	1.66
	Microcephaly	2	0.47
	Neuroectodermal anomaly	1	0.24
CVS	Ventricular septal defect(VSD)	6	1.42
	Patent ductus arteriosus(PDA)	2	0.47
	Vascular anomaly	2	0.47
	Atrial septal defect(ASD)	1	0.24
	TGA	1	0.24
Orofacial	Cleft lip & palate	9	2.13
	Cleft lip	1	0.24
	Microphthalmia	1	0.24
	Other	7	1.66
GIT	ARM	8	1.89
	TEF	4	0.94
	HSD	3	0.71
	Duodenal atresia	3	0.71
	Ilial atresia	3	0.71
	Omphalocele	3	0.71
Genital	Hypospadias	2	0.47
MSS	Club foot	7	1.66
	Polydactyl	6	1.42
	Other*	6	1.42
RS	Stridor disorder	3	0.71
Syndrome	Down syndrome	3	0.71
	Edwards syndrome	1	0.24
	Charge syndrome	1	0.24
	Pierre Robin syndrome	1	0.24
	VACTREL	1	0.24

* The sum of congenital knee hyperextension, sublaxation, syndactyly, Locur button foot, single palmar crease and Sandle toe

5.6 Factors associated with congenital malformation in neonates admitted to NICU and pediatrics ward, JMC, 2020

In order to identify the factors associated with CM among neonates admitted to NICU and pediatrics ward, JMC, bivariate and multivariate logistic regression analyses were conducted. The variables with p-value ≤0.25 on bivariate analysis which included maternal age, ANC follow up, residency, folate supplementation; substance abuse and nutritional status of the mother were subjected for multivariate logistic regression. Out of these variables, ANC follow up, folate supplementation, and nutritional status of the mother had statically significant association with CM on multivariate logistic regression.

The odds of having CM is 2 times higher among mothers having less than 4 ANC visits compared to those having ≥4 ANC visits (AOR 2.05, 95% CI 1.21,3.48, p=0.008). Similarly, neonates whose mothers didn't take folic acid supplementation during current pregnancy were 2.4 times more likely to develop CM compared to those who had taken folate supplementation (AOR 2.38, 95% CI, 1.13,5.03, p=0.023). Additionally, neonates born to mothers who are under nourished (MUAC<19cm) were found to be 7.73 times more likely to develop CM compared to well-nourished mothers (AOR 7.73, 95% CI 1.6, 34.61, p=0.008) (Table 7).

Table 7: Bivariate and Multivariate logistic regression model to identify factors associated with congenital malformation among neonates admitted to NICU and pediatrics ward, JMC, South West Ethiopia, 2020.

Variables		Congenital malformation		COR, 95%CI	p-value	AOR, 95%CI	P- value
		Yes (%)	No (%)				
Maternal age	<19	2(10.5)	17(89.5)	1	1	1	
	19-35	68(18.0)	309(82.0)	1.87(0.42,8.28)	0.41	2.12(0.48,9.85)	0.30
	>35	8(30.8)	18(69.2)	3.78(0.70,20.38)	0.12*	5.45(0.96,30.81)	0.055
ANC	<4	47(24.2)	147(75.8)	2.09(1.25,3.50)	0.005*	2.05(1.21,3.48)	0.008
	≥4	28(13.3)	183(86.7)	1	1	1	1
Maternal Residence	Rural	57(22.2)	200(77.8)	1.95 (1.13,3.37)	0.016*	1.40(0.77,2.52)	0.26
	Urban	21(12.7)	144(87.3)	1	1	1	1
Folate supplementation	Yes	9(9.0)	91(90.0)	1	1	1	1
	No	69(21.4)	253(78.6)	2.78(1.32,5.73)	0.007	2.38(1.13,5.03)	0.023
Substance use	Yes	15(26,8)	41(73.2)	1.76(0.92,3.37)	0.089	1.66(0.84,3.31)	0.14
	No	63(17.2)	303(82.8)	1		1	1
Maternal (MUAC)(cm)	<19	5(62.5)	3(37.5)	8.99(2.07,39.07)	0.003	7.73(1.6,34.61)	0.008
	19-23	30(21.6)	109(78.4)	1.48(0.88,2.49)	0.135	1.38(0.86,2.38)	0.24
	>23	43(15.6)	232(84.4)	1	1	1	1

[1]**MUAC- mid upper arm circumference**

CHAPTER 6: DISCUSSION

Congenital malformations or birth defects may be detected soon after birth or later, depending upon the nature of the defect (1, 2). Though, being preterm and neonatal sepsis are the common cause of neonatal death in Ethiopia and other developing countries, CM are significantly contributing to infant mortality and morbidity in developed countries (14,15). Because of this, developed countries have established accurate surveillance systems to find out the birth prevalence of congenital anomalies for effective preventive strategies.

In this study, we have found that around one in five neonates admitted to NICU and pediatrics wards of JMC during the study period have different forms of congenital malformations. This finding is comparable with the finding of disease control priorities project for LMICs which estimated that 15-30% of admissions are due CM (7). However, it is high compared to magnitude of CM reported in other studies from Niger delta state of Nigeria and Indonesia in which magnitude of 11.1% and 13.1% respectively were reported (16, 17). But it is lower compared to study done in Tanzania, which reported magnitude of CM of about 28.5% (10).

We have demonstrated that malformations of the central nervous system (CNS) were the most common malformations, followed by malformations of gastrointestinal system. This is similar to finding from Tanzania, where CNS was the most commonly affected system (10). Other studies have reported pattern of congenital malformation different from our finding, a study done in Indonesia and Nigeria showed that anomalies of the gastrointestinal system (GIT) were the most common, followed by malformation of the CNS (16, 17). These differences are expected as pattern of congenital malformation can vary in different parts of the world or in the same area at different time due to differences in genetic and environmental factors (18).

Folic acid is known to be necessary for growth and function of human cells and is crucial for normal brain and spinal cord development during the first 4 weeks of gestation (2, 4, 10). Several studies have shown that folic acid reduces occurrence of some congenital anomalies e.g. neural tube defects, orofacial clefts, limb reduction defects, congenital heart defects, urinary system defects and omphalocele (10,19 and 20). Significant association has been seen between congenital malformation and lack of periconceptional use of folic acid in this study. Similar findings have been reported from study done in Tanzania (10).

Maternal malnutrition is associated with macro and micro nutrient deficiencies which are important for organogenesis (3). Maternal under nutrition (SAM) was significantly associated with an increase in CMs among admitted neonates in this study, similar to studies done in Egypt which have shown association between congenital malformation and maternal under nutrition (12, 13).

Antenatal care visit is an important part of prenatal care during which health education is usually given on various issues including adequate nutrition, avoidance of exposure to teratogens and different preventive and curative measures regarding maternal infections can be implemented. Supplementation of different nutrients will also be given during the ANC visit. In this study, congenital anomalies were significantly associated with poor attendance to antenatal clinic (not attending or attending less than 4 times). Similar results have been observed in studies done in Tanzania, and Indonesia where few or no ANC clinic visits were significantly associated with congenital anomalies (10, 17).

Limitation

Diagnosis of congenital malformation needs combination of physical examination, imaging, surgery and biomedical and genetic testing. But in this study physical examination is mainly used to diagnose and sometimes surgical and imaging findings are also used. Internal organ malformations and other malformations that cannot be identified with clinical examination were not considered in this study. Due to limited investigative ability, it was not possible to assess infectious factors like rubella, cytomegalovirus, varicella and toxoplasmosis that might be associated with congenital anomalies. Furthermore, it was not possible to do genetic/chromosomal studies. As the study was conducted among neonates admitted to NICU and pediatrics wards in a tertiary teaching hospital where most referral cases from catchment area is admitted, this may possibly raise prevalence of CM than the real community or total delivery estimate of CM in the catchment area.

CHAPTER 7: CONCLUSION AND RECOMMENDATION

7.1 Conclusion

A significant number of neonates admitted at Jimma Medical Center have congenital malformation. The most commonly affected system is the central nervous system, followed by gastro intestinal tract and musculoskeletal system. There is significant association between neonatal congenital malformation and poor antenatal attendance, periconceptional folic acid supplementation, and maternal under nutrition.

7.2 Recommendations

As the burden of congenital malformation among neonates admitted at JMC is found to be high, and JMC is the only tertiary hospital in the south west of Ethiopia with more than 15 million catchment populations, additional attention should be given to this problem, so that the facility and health workers working in the facility are well prepared to appropriately handle these neonates.

Large, multicenter, facility as well as community based researches should be done by involving all the stakeholders in order to understand the real burden of the problem and possible associated risk factors. This will enable policy makers to design the necessary preventive, curative as well as rehabilitative strategies in order to reduce the burden of the problem and improve the quality of life of children affected by CMs.

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ANNEX I: Participant's information sheet and consent form

Hello, my name is Dr. Kassahun Berhanu and I am pediatrics and child health postgraduate student in Jimma University, Faculty of medical Sciences, department of pediatrics and child health. I am conducting survey on the magnitude and pattern of congenital malformations & associated factors in neonates in this hospital. The result that will come out of this study will be helpful to understand the burden of the problem. The questionnaire requires a maximum of 15-20 minutes to complete. Your participation is entirely voluntarily, and you can quit from the study any time you want. Your name and other personal identity will not be used, and hence the personal information we collect from you will completely be kept confidential and will not be disclosed to any third person other than the people conducting this study and the interview will be conducted privately.

May I now begin the interview?

If yes, continue interviewing

If no, thank and stop interviewing

Participant signature_____.

Name of the interviewer_____ Sign. _____Date _____

Name of the supervisor. _____Sign. _____Date_____

የፈቃደኝነት መጠየቂያና የመረጃ ገጽ

የመረጃ ገጽ

ሰላም ስሜ ካሳሁን ብርሃኑ ይባላል፣በጅማ ዩኒቨርሲቲ የህፃናት ህክምና እና ጤና የሁለተኛ ድግሪ (ስፔሻለቲ) ተማሪ ነኝ ። እኔ በተፈጥሮ የአፈጣጠር ችግር ያለባቸው ጨቅላ ህፃናት መጠን፣ ስርጭት እና ለዚህ የሚያጋልጡ ችግሮች ላይ ጥናት እያካሄድኩ ነው ። የዚህ ጥናት ውጤት የበሽታውን መጠን ለማወቅ ያስችላል ። መጠይቁ ከ15-20 ደቂቃ በላይ አይወስድም ። የአንቺ በጥናቱ ላይ ተሳትፎ በፈቃደኝነት ላይ የተመሰረተ ነው። መሳተፍ ካልፈለግሽ መተው ይቻላል። የአንቺ ስምና ግለሰባዊ መርጃ ሚስጥራዊነቱ የተጠበቀ ነው። ስላንቺ መረጃ ጥናቱን ከሚያካሂደው ሰው ውጭ ሌላ ሰው አያውቅም፣ መጠይቁም የሚሞላው ብቻሽን ሆነሽ ነው።

ጥያቄ አሎት?

የፈቃደኝነት ቅጽ

በጥናቱ ለመሳተፍ ተስማምተዋል?

☐ አዎ ተስማምቻለው ☐ አይ አልተስማማሁም

በመጥይቁ ሞይው የሚፈረም፡ ከላይ በመረጃ ገጽ ላይ ያለውን ለጥናቱ ተሳታፊ በተገቢ ሁኔታ አንብቤ ማስረዳቴን በፊርማዬ አረጋግጣላሁ።

የተጠያቂው ፊርማ_____ቀን_____.

የጤያቂው ስም_____ፊርማ_____ቀን_____

.

የተቆጣጣሪው ስም_____ፊርማ _____ቀን_____

Fullaa oddefannoo fi fedhii Haadholii

Fullaa oddefannoo

Akkam, Maqaan koo Dr. Kaasaahun Birhaanuu jedhama. Ani Yuuniversiitii Jimmaatti rizidentii pedaatiriksii fi fayyaa da'immaaniiti. Ammaa ani bal'ina, akkaataa fi wantoota hir'ina qaamaa dhalotaan dhufaniif nama saaxilan irratti qorannoo gochaan jira. Bu'aan qorannoo kanarraa argannu bal'ina rakkoo kanaa bekuuf nuu gargaara. Gaffiilee armaan gadii debisuuf daqiiqaa 15-20 fudhata. Hirmaannaan keessan fedhii keessan irratti kan hundaaye dha. Yoo hirmaachuu hin barbaanne dhaabuu dandessa. Maqaafi enyummaan kee qorannoo kana kessattii hin eeramu. Odeefannoon ati nuuf kennitu, nama qorannoo kana hojjetuun ala kan beeku hin jiraatu, gaffiis kan gafatamtu qobaake taateti.

Gaaffii qabduu?

Irraati hirmaachuuf walii galtaniii?

Eeyyee_____. Lakkii_____.

Anii wanta armaan oliiti katabame irraati hirmaachuuf waliigaleera.

Mallattoo_____.

Maqaa nama gaffii gafatuu_____mallattoo_____guyyaa _____.

Maqaa nama to'atuu_____mallattoo_____guyyaa_____.

ANNEX II: Questionnaire

History part which the interviewer(data collector) is going to interview the paraent		
Neonatal characters		
No	Variables	Response
1	Sex	1. Male 2. Female 3. Ambigious
2	Age at presentation	……..mins……hr……..days unknown…….
3	GA at birth	…… weeks ……months unknown……
4	Birth weight	……..gm or ……..kg Unknown……..
5	Type of gestation	1. Singleton 2. Twin 3. Other, specify……
6	Place of birth	1. Home 2. Health Center 3. Hospital 4. Private clinic 5. Other, specify
7	Mode of delivery	1. SVD 2. Assisted (vacuum, forceps) 3. C/S
Mathernal sociodemographic characters		
8	Age	……years
9	Ethinicity	1. Oromo 2. Amhara 3. Gurage 4. Kafa 5. Dawro

		6. Yem 7. Other, specify……
10	Religion	1. Orthodox 2. Muslim 3. Protestant 4. Other, specify……
11	Educational status	1. Can't read and write 2. Primary school 3. Secondary school 4. Above high school
12	Occupation	1. Housewife 2. Merchant 3. Daily laborer 4. Farmer 5. Employee
13	Residency	1. Rural 2. Urban
Maternal obstetrics characters		
14	Gravidity	……
15	Parity	……
16	Do you have previous history of abortion?	1.Yes 2. No
16.1	If yes for question No 16, how many times?	……..
17	Do you have previous history of still birth?	1. Yes 2. No
17.1	If yes, how many times?	
18	Do you have previous history of early neonatal death?(death in <7day of birth)	1. Yes 2. No
18.1	If yes, how many times?	

19	Do you have ANC follow up?	1. Yes 2. No
19.1	If yes for question number 19 ,how many times?	…….
19.2	If question No 19 is yes, where was the follow up?	1. Health Center 2. Hospital 3. Private clinic
20	What investigations are done during ANC followup?	1. CBC/ HCT 1. Yes 2. No 2. BG/RH 1. Yes 2. No 3. VDRL 1. Yes 2. No 4. PITC 1. Yes 2. No 5. U/A 1. Yes 2. No 6. US 1. Yes 2. No 7. Other specify……. 8. Unknown
Maternal Medical Data		
21	Were you given folic acid suplimentation?	1. Yes 2. No 3. Unknown
21.1	If yes for question number 21, since when?	GA ……weeks ……. months
21.2	If yes for question 21, for how long?	……weeks …….month
22	Do you have any diagnosed chronic illness, during or before this pregnancy?	1. Yes 2. No 3. Unknown
22.1	If yes for question No 22,type of chronic illness	1. DM 2. HIV/AIDS 3. HTN 4. CKD 5. Epilepsy 6. Other, specify……
23	Did you take any drug other than folate during pregnancy?	1. Yes 2. No 3. Unkkown

23.1	If yes for question No 23, what type of drug did you take?	1. HAART 2. Insulin 3. Antihypertensive 4. Anti-epilepsy 5. Other, specify…… 6. Unknown
23.2	If yes for question No 23, when or at what GA?	GA in …… week ……month
24	Did you have any febrile illness during pregnancy?	1. Yes 2. No 3. Unknown
24.1	If yes for question No 24, which febrile illness?	Specify…….
24.2	If yes to question 24, at what GA?	……GA weeks ……GA months
25	Do you chew chat?	1. Yes 2. No
25.1	If yes for question No 25, how frequent?	1. Daily 2. More than once per week but less than daily 3. More than once month but less than once per week
26	Is there cigarette smoker in the household?	1. Yes 2. No
26.1	If yes for question No 26,how frequent you are exposed to cigarette smoke?	1. Daily 2. More than once per week but less than daily 3. More than once month but less than once per week
27	Do you drink alcohol?	1. Yes 2. No
27.1	If yes for question No 27, how frequent?	1. Daily 2. More than once per week but less than daily

		3. More than once month but less than once per week
28	Did you have any history of exposure to diagnostic/therapeutic radiation (X-ray, CT-scan or raditherapy) during current pregnancy?	1. Yes 2. No 3. unknown
28.1	If yes for question No 28, at what GA?	…….GA weeks …… GA months
29	Do you have previous history of child with CM?	1. Yes 2. No 3. Unknown
29.1	If yes for question No 29, specify?	…….
30	Do you have any first degree relative with history of CM?	1. Yes 2. No 3.. unknown
30.1	If yes for question No 30, what was the CM?	Specify……
31	Maternal MUAC	…… cm
32	Does the infant have any CM?	1. Yes 2. No 3. Unknown
32.1	If yes for question No 32, proceed to Q33	
32.2	If no for question No 32, end the interview by thanking the mother.	

Pattern of congenital malformation (according to ICD-10) More than one response is possibles		
33	Congenital malformations of the nervous system	1. Neural tube defect 2. Microcephaly 3. Hydrocephalus 4. Cranial anomalies 5. Cerebral defects 6. Neuroectodermal anomalies 7. Other, specify
34	Congenital malformations of the circulatory system	1. Ventricular septal defect(VSD) 2. Fallot's teratology(TOF) 3. Atrial septal defect(ASD) 4. Vascular anomalies 5. Patent ductus arteriosus(PDA) 6. Other, specify
35	Orofacial anomalies	1. Cleft lip & palate 2. Cleft lip 3. Cleft palate 4. Microphthalmia 5. Anophthalmia 6. Other, specify
36	CM of Digestive system	1. Anorectal malformationb 2. Hirschsprung's disease 3. Ileal atresia 4. Malrotation 5. Biliary atresia 6. Oesophageal atresia 7. Trachea-oesophageal fistula 8. Omphalocele 9. Gastroschisis 10. Other, specify
37	Congenital malformations of genital	1. Hypospadius

	organs	2. Mullerian tube defects 3. Epispadias 4. Ovarian dysgenesis
38	Congenital malformations of the urinary system	1. Renal dysplasia 2. Renal agenesis 3. Polycystis kidney 4. Ectopic kidney 5. Cysto-uretheral anomalies 6. Others, specify
39	Congenital malformations and deformations of the musculoskeletal system	1. Osteogenesis imperfecta 2. Arthrogryposis 3. Congenital talipes equinovarus 4. Genu recurvatum 5. Polydactyly 6. Other, specify
40	Congenital malformations of the respiratory system	1. Stridor 3. Congenital polycystic lung 4. Unilateral lung agenesis 5. Other, specify
41	Chromosomal abnormalities, not elsewhere classified	1. Down syndrome 2. Pataou syndrome 3. Edwards syndrome 4. Turner 5. Klinefelter syndrome 6. Others, specify

Thank you very much for your willingness to participate in my research!