REPUBLIC OF CAMEROON
PEACE-WORK-FATHERLAND

MINISTRY OF HIGHER EDUCATION

THE UNIVERSITY OF YAOUNDE I

FACULTY OF MEDICINE AND BIOMEDICAL SCIENCES

REPUBLIQUE DU CAMEROUN
PAIX-TRAVAIL-PATRIE

MINISTERE DE L'ENSEIGNEMENT SUPERIEUR

UNIVERSITE DE YAOUNDE I

FACULTE DE MEDECINE ET DES SCIENCES BIOMEDICALES

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

RISK FACTORS FOR CONGENITAL MALFORMATIONS IN TWO HOSPITALS IN YAOUNDE: A CASE-CONTROL STUDY

Thesis submitted and publicly defended in partial fulfilment of the requirements for the award of Medicinae Doctor (MD) degree

By

EFETI EWONGO NJOMBE EWUSI

17M035

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Academic Year 2023-2024

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Date of public defense:

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DEDICATION

To my lovely parents,

Mr Bruno Njombe Ewusi
&
Mrs Njombe Ewusi née Lucy Enanga Ewoh

Walking down the memory lane, I can only remember how present you have been from the start. You have loved me unconditionally, supported and encouraged me through my dreams and aspirations. I am immensely grateful for everything and I will continue to make you proud.

ACKNOWLEDGMENTS

I will forever be grateful to God Almighty, for seeing me through the highs and lows of this seven-year journey.

I equally wish to express my profound gratitude to everyone who contributed to this milestone. Special notes to:

- The main supervisor of this work, **Pr. Mbu Robinson**. It was a rewarding experience to work with an illustrious personality like you. Your simplicity, rigor and commitment made it easy and reassuring. My heartfelt appreciation cannot be overemphasised.
- My co-supervisors, **Dr. Ebong Cliford** and **Dr Batoum Veronique** for accepting to co-supervise this work. Your contributions and commitment were essential for the completion of this work. I cannot thank you enough for being integral parts of the team.
- **The Dean and the entire staff** of the Faculty of Medicine and Biomedical Sciences-University of Yaoundé I, for the guidance and virtues imparted upon me throughout this journey.
- **The honourable jury members**, for accepting to read through and scrutinise our work. Thank you for your comments and corrections, which were aimed at improving this work.
- **The Directors and the entire medical and nursing staff** of the Yaoundé Central Hospital and the Yaounde Gynaecology, Obstetrics and Paediatric Hospital, for granting authorisations to carry out this study in your institutions.
- **Dr Elong Jules**, for providing excellent statistical input for this study.
- My siblings: **Mbella Njombe Ewusi, Mafany Njombe Ewusi** and **Kale Njombe Ewusi**, for being present and rendering services when needed.
- My grandparents: **Mbamba Dora**, who was a midwife and who constantly prayed for one of her children to become a medical doctor. I am privileged to be the answer of that prayer. Not forgetting **Mbamba Ewoh** and **Mbamba Ewune** for their prayers and support.
- **My entire extended family**, thank you for your endless love and support.
- **Dr Lyonga Kharim**,and **Dr Sule Ibrahim** for guiding me from preparatory classes till date.
- **Dr Mouthe Jimmy** for always being ready and available to show his support.
- My seniors: **Dr Nsoh Fofang, Dr Atabe Neri, Dr Akelekeh Ndah, Dr Obolo Ines**, for their constant support from my freshman year till my final year.

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- **My juniors**: Nkwelle Vanelle and Akat Pride Arrah
- **My classmates**: Mbange Likowo, Regina Batebe, Chelsea Ngomo, Makwet Chirifa, Ranibelsoft Ejedepang, Fru Candide, Njonyu Tarlishi, Leyuga Senka, Nako Suzie, Doungabe Tobio, Ekassi Arnold, Fotso Ingride, Lynn Ewane, Etoundi Louise for making this journey a memorable one.
- **Sakerrettes10** and **CAMESA** for their support from the very beginning.
- And to all whose names were not mentioned above, your contributions did not go unnoticed.

THE ADMINISTRATIVE AND TEACHING STAFF FOR 2023/2024 OF THE FACULTY OF MEDICINE AND BIOMEDICAL SCIENCES

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KWEDI Karl Guy Grégoire	L	Dental Surgery
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KEY:

- **HD**= Head of Department
- **P**= Professor
- **AP**= Associate Professor
- **SL**= Senior Lecturer
- **L**= Lecturer

THE PHYSICIAN'S OATH

Declaration of Geneva adopted by the Geneva Assembly of the World Medical Association in Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia (August 1968)

On admission to the medical profession:

I will solemnly pledge myself to consecrate my life to the service of humanity

I will give my teachers the respect and gratitude which is their due

I will practice my profession with conscience and dignity The health of my patients will be my first consideration

I will respect secrets confided in me, even after the patient has died

I will maintain by all the means in my power the honour and noble traditions of the medical profession

My colleagues will be my brothers

I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient

I will maintain the utmost respect for human life from the time of conception, even under threat

I will not use my medical knowledge contrary to the laws of humanity

I make these promises solemnly, freely and upon my honour.

SUMMARY

Background: Congenital malformations (CMs) are structural or functional errors in foetal development occurring during intrauterine life and are present at birth. About 6% of babies are born with congenital malformations globally. Studies in Cameroon report a prevalence of 9 per 1000 births. Superstitious beliefs are thought to be the cause of these malformations in our context. Having a child with this condition can be physically and psychologically traumatic hence, the need to carry out this study in order to throw more light in the situation in our context.

Objective: The main objective was to **s**tudy the risk factors associated with the occurrence of congenital malformations in two hospitals in Yaoundé.

Methods: We carried out a retrospective case control study in the Yaoundé Gynaecology, Obstetric Paediatric Hospital and the Yaoundé Central hospital. All the files of women who delivered in the chosen hospitals from January 2018 to December 2022, were included in our study. Cases were files of women who delivered babies with CMs and controls were files of women who had babies without CMs. They were matched for maternal age and parity.

Results: We had a total of 118 cases and 118 controls. The musculoskeletal system (42.4%), central nervous system (36.4%) and digestive system (28.8%) were the most affected. The risk factors identified in our study were: paternal age from 42-50 years (OR 2.38, CI 1.27-4.45, $p = 0.004$), family history of CMs (OR 83.08, CI 11.22-615.21, $p < 0.001$), less than three antenatal consultation]]s (OR 3.73, CI 2.04-6.81, $p < 0.001$), first ANC contact from 20 weeks of gestation (OR 7.2, CI 3.58-14.48, $p < 0.001$), no periconceptional folic acid intake (OR 38.39, CI 9.04-162.95, $p < 0.001$), use of traditional drugs (OR 10.40, CI 2.36-46.09, $p < 0.001$), smoking (OR 13.24, CI 1.69-103.59, $p < 0.001$), alcohol intake (OR 13.69, CI 6.66-28.15, $p < 0.001$) and pesticides exposure (OR 5.79, CI 3.02-11.11, $p < 0.001$). Amniotic fluid abnormalities (OR 5.17, CI 1.88-14.19, $p < 0.001$) and polyhydramnios (OR 15.75, CI 2.03-121.84, $p < 0.001$ were found in the presence of an underlying CM.

Conclusion: The main systems involved were the musculoskeletal, central nervous and digestive systems. Family history of CMs, first ANC from 20 weeks of gestation, less than 3 ANC contacts, lack of folic acid supplementation, paternal age from 42-50 years, alcohol intake, smoking, traditional drug use and exposure to pesticides all had higher odds of CMs.

Key words: congenital, malformation, risk, factor.

RESUME

Introduction : Les malformations congénitales sont des erreurs structurelles ou fonctionnelles dans le développement du fœtus qui se produisent pendant la vie intra-utérine et sont présentes à la naissance. Environ 6 % des bébés naissent avec des malformations congénitales dans le monde. Des études menées au Cameroun font état d'une prévalence de 9 pour 1000 naissances. Les croyances superstitieuses sont considérées comme la cause de ces malformations dans notre contexte. Avoir un enfant atteint de cette maladie peut être physiquement et psychologiquement traumatisant, d'où la nécessité de mener cette étude.

Objectif : L'objectif principal était d'étudier les facteurs de risque associés à la survenue de malformations congénitales dans deux hôpitaux de Yaoundé.

Méthodes : Nous avons réalisé une étude cas-témoins à l'Hôpital Gynéco-Obstétrique et Pédiatrique de Yaoundé et à l'Hôpital Central de Yaoundé. Tous les dossiers des femmes ayant accouché dans les hôpitaux choisis de Janvier 2018 à Décembre 2022, ont été inclus dans notre étude. Les cas étaient des dossiers de femmes ayant accouché de bébés atteints de malformations congénitales et les témoins étaient des dossiers de femmes ayant accouché de bébés sans malformations congénitales. Ils ont été appariés pour l'âge maternel et de la parité.

Résultats : Nous avons eu un total de 118 cas et 118 témoins. Le système musculo-squelettique (42,4 %), le système nerveux central (36,4 %) et le système digestif (28,8 %) étaient principalement touchés. Les facteurs de risque identifiés dans notre étude étaient : âge paternel de 42-50 ans (OR 2.38, IC 1.27-4.45, p = 0.004), antécédents familiaux de MC (OR 83.08, CI 11.22-615.21, p < 0.001), moins de trois contacts prénatales (OR 3.73, CI 2.04-6.81, p < 0.001), première contact prénatale à partir de 20 semaines d'aménorrhée (OR 7.2, CI 3.58-14.48, p < 0.001), pas de prise d'acide folique en période périconceptionnelle (OR 38. 39, IC 9.04-162.95, p < 0.001), utilisation de médicaments traditionnels (OR 10.40, IC 2.36-46.09, p < 0. 001), le tabagisme (OR 13.24, CI 1.69-103.59, p < 0.001), la consommation d'alcool (OR 13.69, CI 6.66-28.15, p < 0.001) et l'exposition aux pesticides (OR 5.79, CI 3.02-11.11, p < 0.001).). Des anomalies du liquide amniotique (OR 5.17, CI 1.88-14.19, p < 0.001) et un polyhydramnios (OR 15.75, CI 2.03-121.84, p < 0.001) ont été constatés en présence d'une MC sous-jacente.

Conclusion : Les principaux systèmes concernés sont le système musculo-squelettique, le système nerveux central et le système digestif. L'âge paternel de 42 à 50 ans, les antécédents familiaux de MC, la première consultation prénatale après 20 semaines d'aménorrhée, moins de 3 contacts prénatales, l'absence de supplémentation en acide folique, la consommation

d'alcool, le tabagisme, l'utilisation de médicaments traditionnels et l'exposition aux pesticides sont autant de facteurs qui augmentent le risque de MC.

Mots clés : malformation, congénitale, facteur, risque.

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LIST OF ABBREVIATIONS

CM: Congenital Malformation

CMV: Cytomegalovirus

β-hCG: beta-human Chorionic Gonadotropin

WHO: World Health Organisation

YCH: Yaoundé Central Hospital

YGOPH: Yaoundé Gynaecology, Obstetrics and Paediatrics Hospital.

CHAPTER 1 : INTRODUCTION

1.1 BACKGROUND

Congenital malformations (CM), also termed birth defects, are errors in foetal development occurring during intrauterine life and are present at birth [1]. They can be structural or functional abnormalities with varying implications on the lives of the affected babies [2]. About 6% of babies globally, are born with a congenital disorder each year [3]. Approximately 94% of the children born with these malformations are found in low-and middle-income countries, including those in Africa [3,4]. In Cameroon, one of the studies done found a prevalence of 9 per 1000 births in 2017 [5]. The main visible congenital malformations reported at birth concerned skeletal, neurological, and gastrointestinal systems. In about 18.5% of cases, diagnosis is confirmed following a therapeutic termination of pregnancy, after suggestive findings on antenatal ultrasound scan [6]. These malformations constitute one of the major causes of neonatal admissions and demise in Cameroon [5,7].

Risk factors associated with congenital malformations are by far more common in the developing countries compared to the developed ones. Inadequate pregnancy follow up, uncontrolled exposure to teratogenic agents, infections, alcohol consumption during pregnancy, tobacco use, inadequate folate supplementation, and diabetes mellitus are some of the reported risk factors [8]. For most cases, the exact cause(s) have not yet been clearly identified and the aetiology is considered multifactorial [9,10].

However, superstitious beliefs dominate as the cause of these anomalies in an African setting [9]. This implies that there is little or no understanding of the risk factors associated with congenital malformations in our context. This prompted us to try to shed more light on this topic by identifying the risk factors associated with congenital malformations in our setting, in order for us to propose preventive measures thereby, promoting better outcomes of pregnancies.

1.2 RATIONALE

Congenital malformations, as stated in the background, is a public health problem that accounts for one of the major causes of neonatal admissions and neonatal demise in Cameroon [7,11]. These malformations are more common in low-and middle-income countries compared to high-income countries, owing to the fact that there is little maternal knowledge of the risk factors associated with this condition. The occurrence of these malformations can be a traumatic experience, both physically and emotionally, for the families and for the children who grow up with this condition.

In our setting, few studies have been done concerning the risk factors of these malformations and the frequency of occurrence is probably underestimated owing to the fact that stillbirths and new-borns who die at home are not usually taken in to consideration. In order to prevent this tragic phenomenon, we carried out this study to identify the risk factors of congenital malformations in our setting.

1.3 RESEARCH QUESTION

- What are the risk factors associated with congenital malformations at the Yaoundé Gynaecology, Obstetrics and Paediatrics Hospital and the Yaoundé Central Hospital?

1.4 RESEARCH HYPOTHESIS

- There may be socio-demographic, medical and environmental factors associated with the occurrence of congenital malformations in Yaoundé.

1.5 RESEARCH OBJECTIVES

1.5.1 Main objective

The main objective of our work was to study the risk factors associated with the occurrence of congenital malformations in two hospitals in Yaoundé.

1.5.2 Specific objectives

From the main objective, we had as specific objectives;

1) Describe the socio-demographic and clinical profiles of women who delivered children with congenital malformations.
2) Identify the types of congenital malformations that occur in our context.
3) Identify factors that are associated with the occurrence of congenital malformations.

1.6 DEFINITION OF OPERATIONAL TERMS

- Congenital malformation; it is the existence of a structural or functional defect at or before birth.
- Neonates: they are new-borns aged from 0-28 days.
- Term neonate: this is a new-born delivered from 37 weeks of gestation to 42 completed weeks of gestation.
- Preterm neonate: this is a new-born delivered before 37 weeks of gestation.
- Stillbirth; this is the delivery of a dead foetus from the 28^{th} week of pregnancy or with a weight greater than 1000g.
- Teratogen: it is an agent or factor which causes malformations to the embryo.
- Embryo: early developmental stage, from fertilisation to eight weeks of gestation.
- Antenatal consultation: it can be defined as the care given to pregnant women by skilled health-care professionals in order to ensure the best health conditions for both mother and child during pregnancy.

CHAPTER 2 : LITERATURE REVIEW

2.1 INTRODUCTION

2.1.1 Definition

According to WHO, congenital malformations are defined as functional (like metabolic disorders) or structural disorders which occur in utero and can be detected prenatally, at birth or later during infancy (like hearing defects) [3]. They enclose of a wide range of disorders, which could have mild (minor malformations) or severe implications (major malformations) on the lives of the concerned children and families [12].

2.1.2 Epidemiology

Each year, approximately 6% of babies are born with congenital malformations worldwide [3,8]. It has been expected that these malformations occur in 2.76% of new-borns in the United States [1]. They are more common in low and middle income countries, with Abidjan (Ivory Coast) accounting for an average frequency 172.5 Cas/year [13]. In Cameroon, there have been some studies done, one of which found a prevalence of 9 per 1000 births in 2017 [5]. According to WHO in 2020, congenital malformations account for 5,258 or 2.94% of total deaths. The age adjusted Death Rate is 10.13 per 100,000 of population ranking Cameroon 7th in the world [14].

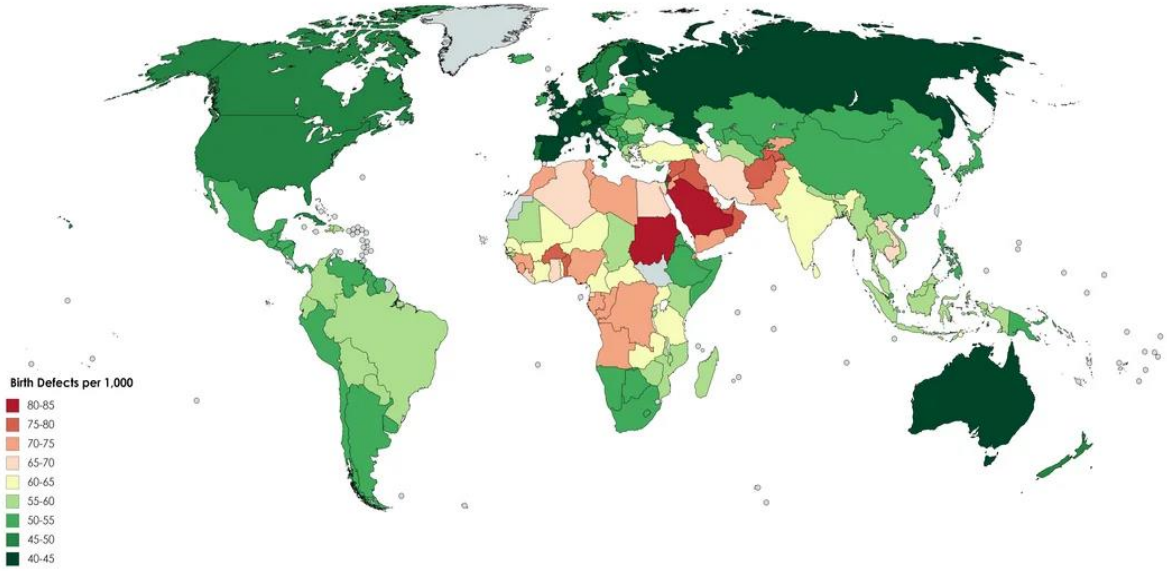

Figure 1: Congenital malformations per country in 2018.
Moving from the brown to the green areas, there is a decrease in numbers of congenital malformations in the corresponding countries [15].

2.2 RECALL

2.2.1 Anatomy

2.2.1.1 The uterus

The non-gravid uterus is a pear-shaped, muscular thick-walled organ located in the pelvic cavity. It is found between the bladder anteriorly and the rectum posteriorly. It communicates superiorly with the uterine tubes and inferiorly with the vagina and is covered on each side by the broad ligament (two layers). It is divided into two major but unequal parts; the larger portion (body) and the smaller cervix below which projects into the vagina. The transverse constriction which connects these two parts is called the isthmus. The body's side-to-side dimension is greater than the antero-posterior dimension and the fallopian tubes join the uterus at the superior lateral angles. In the nulligravid woman, the uterus is approximately 7-8 cm long, 4-5 cm at its widest diameter, and weighs 30-40 g. In multiparous women, it is larger. In the pregnant state, the characteristics vary depending on the gestational stage [16].

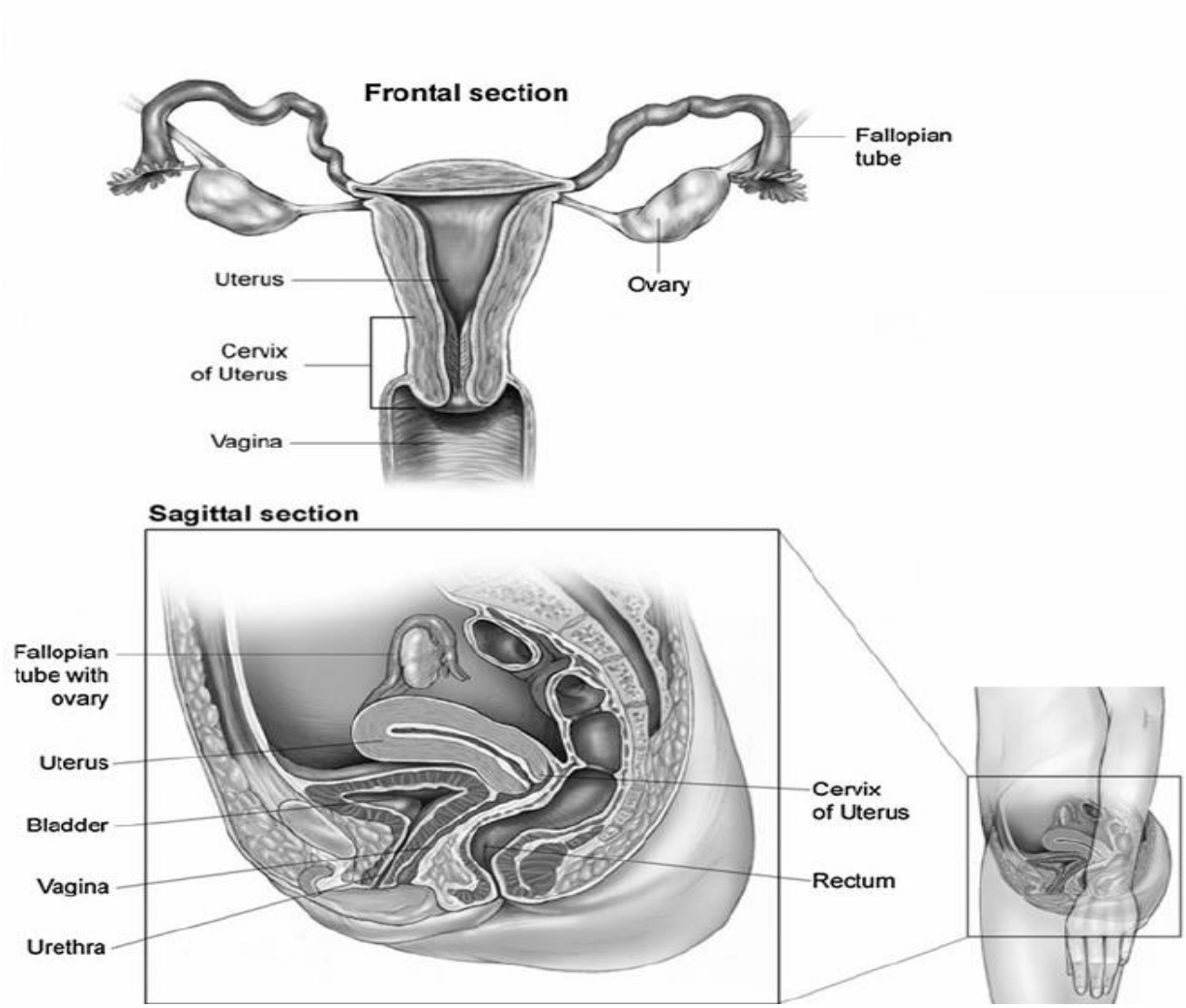

Figure 2: Anatomy and location of the uterus[17].

The very thick wall of the uterus is made up of three layers: mucous, muscular and serous. The mucous layer, also the endometrium, is soft and spongy and it is made up of tissue resembling embryonic connective tissue. Its surface consists of a single ciliated columnar epithelium. Its tissue contains many tubular glands which open into the cavity of the uterus and it is friable and delicate. The muscular layer (myometrium) is continuous with the tubes and the vagina and is very thick, at about 1.5-2.5 cm. Equally, it extends into the cardinal ligaments at the cervix, the ovaries and round ligaments, and minimally into the uterosacral ligaments. The muscular coat has two main layers: the stronger inner layer, of which its fibres are interlaced and run in various directions and the weaker outer layer composed of longitudinal fibres. The muscle layer hypertrophies with the internal os to form a sphincter. The serous layer (perimetrium) is a thin peritoneal covering. It is strongly adherent over most of the body and the fundus and thickens posteriorly and it is separated from the muscle by the parametrium [16].

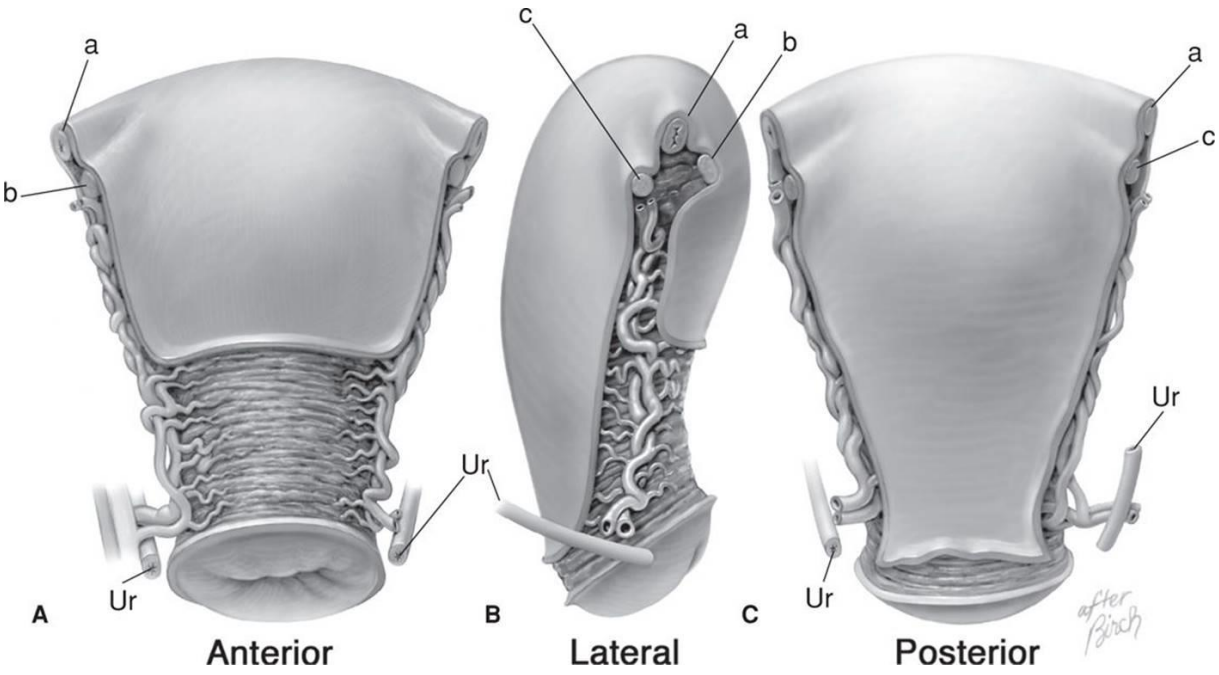

Figure 3: Outer view of the uterus.
A=anterior, B=right lateral, C=posterior views, a=fallopian tube, b=round ligament, c=utero-ovarian ligament, Ur=ureter [18].

2.2.2 Physiology

2.2.2.1 Normal pregnancy

Pregnancy or gestation, is the physiological process of a developing foetus which takes place in the maternal body. The time elapsed since the first day of the last normal menstrual period (LNMP), which precedes the time of oocyte fertilisation, is called the gestational age. Considering a 28-day regular menstrual cycle, the start of gestation which is based on the LNMP is two weeks prior to ovulation. The gestational or menstrual age is expressed in completed weeks. The foetal or developmental age of the conception is gotten from the time of implantation, which is four to six days after complete ovulation. The pregnancy duration is calculated at 40 completed weeks or 280 days gestation. The estimated due date (EDD) can be estimated using the Naegele's rule: 7 plus the first day of the LNMP and subtracting 3 months, plus 1 year.

The period of gestation is divided into 3 trimesters made up of 3 calendar months each. The first trimester is subdivided into the embryonic and foetal periods. The embryonic period is the stage at which the foetus' organs develop and it is the period during which the embryo is very sensitive to teratogens. This period begins from the time of fertilisation or at 2 through 10

weeks' gestational age and ends at the start of the foetal period, which is 8 weeks after fertilisation or 10 weeks following the onset of the LNMP [16].

Pregnancy is confirmed by the presence of amenorrhea and a positive pregnancy test. However, there are other signs and symptoms of pregnancy which include [19];

- Amenorrhea: cessation of menses
- Breast changes like increase in size, tenderness, larger and more pigmented nipples, broader and darker areolae
- Skin changes like striae gravidarum, linea nigra, palmar erythema, chloasma and angiomas
- Nausea and/or vomiting (morning sickness) which occurs in about 70-85% of pregnancies
- Hair growth changes
- Increase in urinary frequency, nocturia and bladder irritability due to the pressure from the enlarging uterus
- The cervix becomes softer
- Cervical mucus changes
- Vaginal appears dark bluish or purple-red due to increase blood flow.
- Uterine changes: increase in size throughout the pregnancy.

The diagnostic methods of pregnancy include:

- Measurement of human chorionic gonadotropin (hCG): sensitive early pregnancy tests detect changes in hCG levels. The β subunit of hCG is produced upon implantation and can be detected in the maternal serum 6-12 days following conception, or early as 20-22 days after the LNMP. β-hCG reaches its peak at 10-12 weeks of gestation and decreases later. Serum and urine levels of β-hCG generally return to normal (<5mlU/ML) 21-24 days following delivery or foetal loss [16].
- Imaging studies: the most useful technical aid in diagnosing and monitoring pregnancy is an ultrasound. From 6 weeks of gestation, cardiac activity can be discerned via transvaginal sonogram. The embryo has a human appearance by the end of the embryonic period (10 weeks by the LNMP). Between 6-13 weeks of gestation, the gestational age can be determined by the crown rump length, with a margin of error of about 8% or 5 days [16].

- Foetal palpation/uterine size: secondary to uterine enlargement, uterine size can be used to diagnose pregnancy. The foetus can be palpated through the maternal abdominal wall after 22 weeks of gestation and the position can be gotten by Leopold's manoeuvres [16].
- Foetal heart tones: with the aid of a handheld Doppler (after 10 weeks of gestation) or by foetoscope (after 18-20 weeks of gestational age), foetal heart tones can be detected. The normal heart rate ranges from 110-160 beats per minute, with a higher rate seen in early pregnancy [16].

2.2.2.2 Foetal development

Foetal development takes place in an orderly and intricate way. It begins before knowledge of the actual pregnancy and ends with the birth of the baby. Between conception and delivery, there are many detailed steps that have to occur [20]. Within the first 8 weeks, the conceptus grows from a single-celled zygote to a multi-layered, multi-dimensional foetus [21]. Foetal development is described in three stages: germinal, embryonic and foetal stages [20].

1. Germinal stage: this is the shortest stage of foetal development. It begins when a sperm cell fertilises an egg in the fallopian tube, creating a zygote. Over the course of one week, the zygote begins its journey to the uterus, during which it divides numerous times giving rise to two separate structures. Eventually, one structure becomes the embryo (and later on, the foetus) and the other, the placenta. The cell division continues at a fast rate. The zygote becomes the blastocyst and it implants itself in the uterus by the 6-7th day. The body immediately starts producing pregnancy hormones and inhibits menstruation if implantation is successful [20].

2. Embryonic stage: next, is the development of the embryo which occurs within the amniotic sac, under the lining of the uterus on one side. Most internal and external organs are formed during this stage from about 3 weeks after fertilisation (5 weeks of gestation). The embryo elongates forming a human shape [22].
   From the third week of development, the two-layered disc of cells transitions to a three-layered disc through the process of gastrulation. The embryo forms an indentation called the primitive streak along the dorsal surface of the epiblast. A node at the caudal or "tail" end of the primitive streak emits growth factors that direct cells to multiply and

migrate. The cells travel toward and through the primitive streak and then spread laterally to create two new layers of cells. The three germ layers are now the endoderm, mesoderm and the the ectoderm.

Each of these germ layers will eventually develop into specific structures in the embryo. The ectoderm gives rise to the central and peripheral nervous systems, sensory organs, epidermis, hair, and nails. The mesoderm ultimately becomes the skeleton, muscles, connective tissue, heart, blood vessels, and kidneys. The endoderm forms the epithelial lining of the gastrointestinal tract, liver, and pancreas, and the the lungs [23,24].

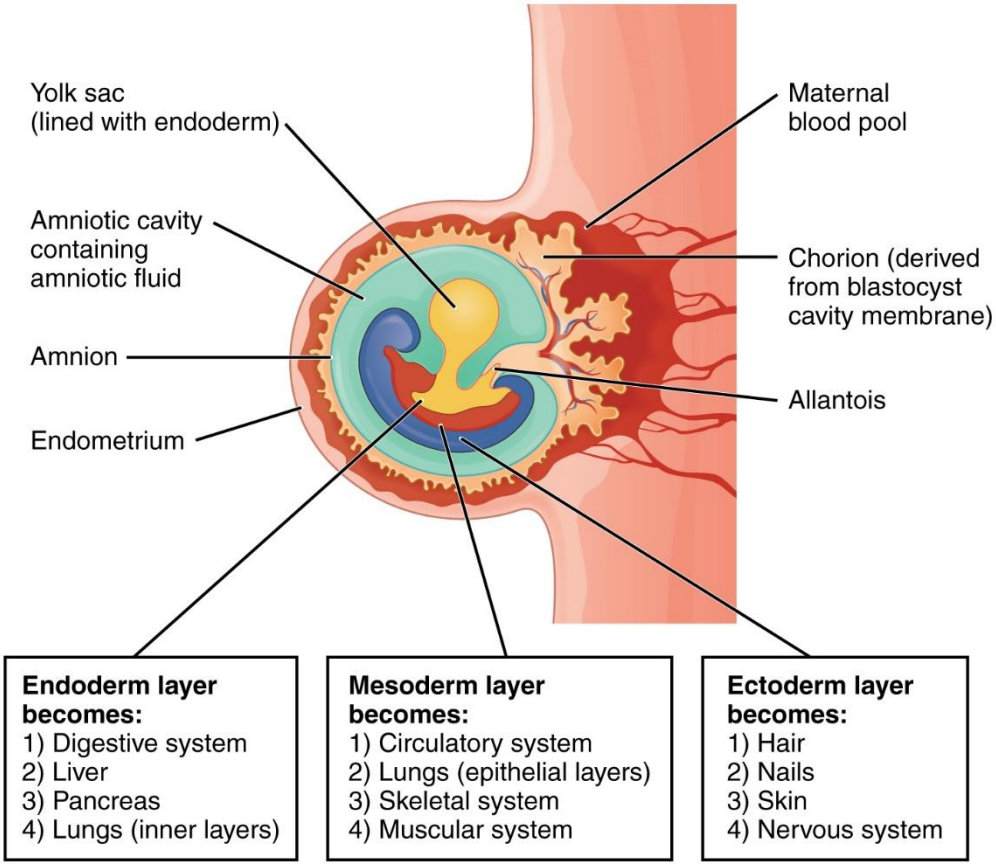

Figure 4: Fate of the embryo's germ layers [23].

At week 4, the embryo is about 1/6-inch long and has developed a head and a trunk. The structures that will become arms and legs, called limb buds, begin to appear. The brain develops from the neural tube and some cranial nerves are visible. The eyes, ears, tissue that develops into the vertebra, and some other bones form [25,26]. The major blood vessels and the heart begin to develop earlier (by the 16th day) by the 20th day, the heart

starts pumping fluid through the major blood vessels and the first red blood cells are formed the following day and continue to develop in the embryo and placenta.

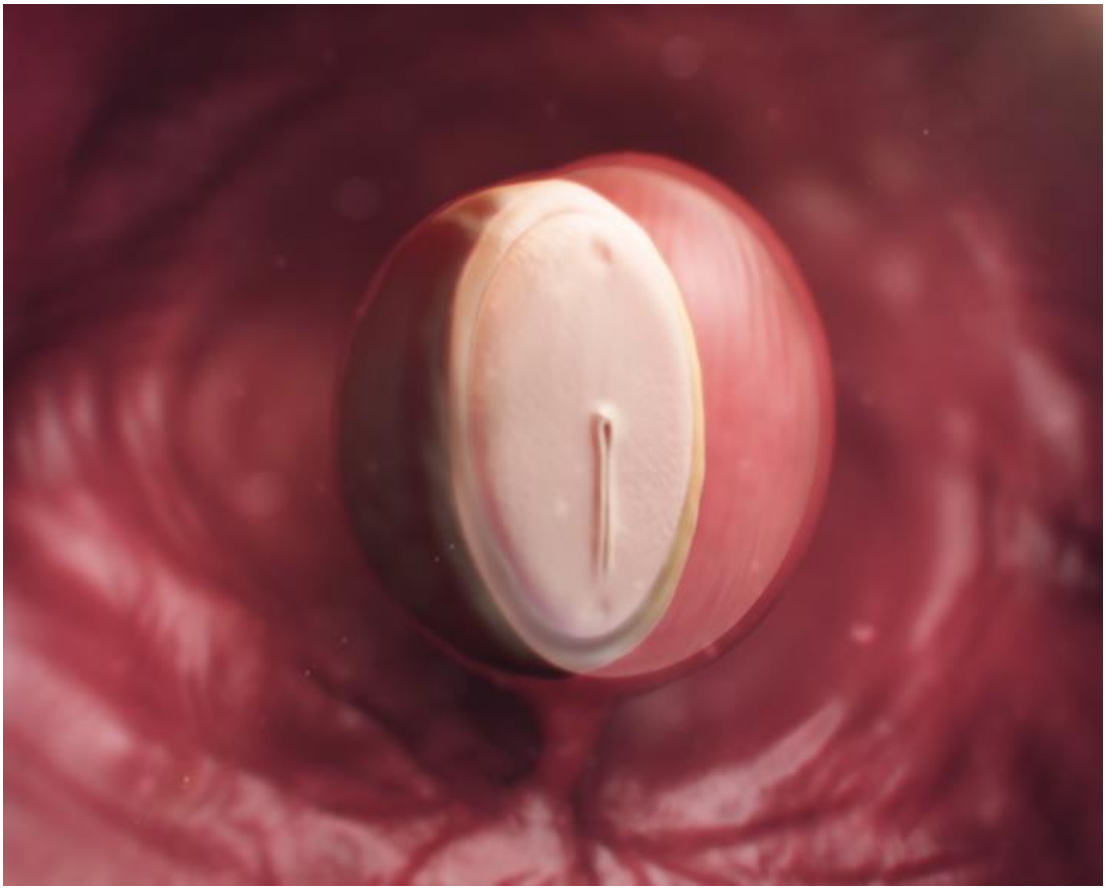

Figure 5: Embryo at week 5 [27].

At week 6, the embryo is about 1/2-inch and has a four-chambered heart and nostrils. Electrical activity begins in the developing nervous system and brain. The lungs, fingers, toes and ears begin to form and the eyes become visible. The hands and feet can be distinguished and have webbed fingers and toes. The trunk of the body begins to straighten.

Figure 6: Embryo at week 6 [27].

At week 8, the embryo is about 11/4-inches long, with the head making up about half this size. The beginnings of all key body parts are present but they are not completely at their final locations. The ears, eyes, arms and legs are identifiable. The eye lids begin to close in order to protect the developing eyes and the neck begins to develop

Figure 7: Embryo at week 8 [27].

Nearly all organs are formed completely by 10 weeks after fertilisation (12 weeks of gestation) except the brain and the spinal cord which continue to develop throughout the pregnancy. During this period of organogenesis, most congenital malformations occur. The embryo is very vulnerable to the effects of environmental factors like drugs, viruses and radiation. Hence, pregnant women should not be given teratogenic drugs and any live-virus vaccinations [22].

3. Foetal stage: at 10 weeks of gestation, the embryo is considered a foetus. The structures which have already been formed, grow and develop till birth and the foetus gets its assigned sex [22]. Most of the growth process occurs in this stage (both in weight and length) [20]. Between the ninth and twelfth week of gestation, the reflexes start to emerge. The foetus begins to make reflexive motions with its legs and arms [26]. As the placenta develops, it sends tiny hair-like projections (villi) uterine wall. The projections branch complicated treelike pattern. This arrangement greatly permits the exchange of

more nutrients and waste materials due to an increased surface area between the uterine wall and the placenta. By 18-20 weeks, the placenta is formed and continues to grow throughout the pregnancy and weighs about 1 pound at delivery [22,28].

Figure 8: Foetus at 11 weeks of gestation [27].

2.2.3 Antenatal consultations

According to the WHO, antenatal consultation/care (ANC) is defined as the care given to pregnant women and adolescent girls by skilled health-care professionals in order to ensure the best health conditions for both mother and child during pregnancy. The components of ANC are: risk identification; prevention and management of pregnancy-related or concurrent diseases; and health education and health promotion. Through ANC, some congenital malformations can be prevented with adequate intake of folic acid, and appropriate management of pathologies with pregnancy. The figure below shows how often ANC visits should be done and what should be done at each visit.

First Visit	11–13 Weeks	16–20 Weeks	26–28 Weeks
1. History and physical (H&P) 2. Labs: ▪ Hct/Hgb ▪ Rh factor ▪ Blood type ▪ Antibody screen ▪ Pap smear ▪ *Gonorrhea* and *Chlamydia* cultures ▪ Urine analysis (protein, glucose, ketones) ▪ Urine culture ▪ Infection screen: Rubella, syphilis, hepatitis B, human immunodeficiency virus (HIV), tuberculosis (TB) ▪ Cystic fibrosis screen ▪ Urine drug screen ▪ Hemoglobin electrophoresis	1. H&P 2. Fetal exam: ▪ Fetal heart tones 3. Urine dip: Protein, glucose, leukocytes 4. First-trimester screen	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height 3. Urine dip: Protein, glucose, leukocytes 4. Fetal ultrasound: Anatomy, dating 5. Quad screen 6. Genetic amniocentesis (if indicated)	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height 3. Labs: ▪ Complete blood count ▪ Ab screen ▪ *Gonorrhea* and *Chlamydia* cultures (optional) ▪ Diabetes screen ▪ Urine dip: Protein, glucose, leukocytes ▪ Syphilis screen (optional) 4. Give anti D immunoglobulin if indicated (28 weeks)

Week 32	Week 36	Week 38	Week 39	Week 40
1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height 3. Urine dip: protein, glucose, leukocytes	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height ▪ Fetal presentation 3. Urine dip: Protein, glucose, leukocytes 4. Group B strep culture 5. HIV—required in some states	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height ▪ Fetal presentation 3. Urine dip: Protein, glucose, leukocytes 4. Cervical exam (frequency is controversial)	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height ▪ Fetal presentation 3. Urine dip: Protein, glucose, leukocytes	1. H&P 2. Fetal exam: ▪ Fetal heart ▪ Fundal height ▪ Fetal presentation 3. Urine dip: Protein, glucose, leukocytes

Figure 9: Antenatal visits [19].

2.2.4 At-risk pregnancy

At-risk pregnancy is defined as one in which the foetus, new-born or the mother may possibly be at a high risk of morbidity and mortality before, during and after birth. Certain disorders that may complicate pregnancies are:

- Hypertensive disorders in pregnancy
- Infections
- Gestational diabetes
- Foetal growth disorders
- Congenital malformations
- Intrauterine foetal deaths
- Etc

For our study, we will focus on congenital malformations.

2.3 CONGENITAL MALFORMATIONS

2.3.1 Risk factors of congenital malformations

There are certain factors that predispose foetuses or babies of being victims of congenital malformations. They are grossly divided into three: pre-conception, post-conception and others.

1. Pre-conception factors: they are factors that exist before conception and are of genetic origin. The most common example of this is Down syndrome (trisomy 21). Other examples include Edward's syndrome and patau syndrome.
2. Post-conception factors: they occur after conception but before parturition. They consist of socio-demographic, environmental and medical factors like infections, drugs, exposure to pesticides, chronic diseases [29].
3. Others: these include maternal socio-demographic data like low socio-economic status and low level of education.

2.3.1.1 Socio-demographic factors [29].

Women with low socio-economic status are more likely to be malnourished before and during pregnancy, and are at greater risk of exposure to environmental teratogens such as alcohol and

maternal infections leading to congenital anomalies in their foetuses. Also, women at extreme ages are more likely to have children with these malformations.

2.3.1.2 Medical factors

2.3.1.2.1 Infections:

- Bacterial infections: in the first 3 months, patients present with features of the disease which include; Vesiculobullous eruptions or macular copper-colored rash on the soles and palms and papular lesions surrounding the nose and mouth as well as petechial lesions.
- Protozoan infection: Congenital toxoplasmosis occurs following maternal vertical transmission to the foetus. It may manifest in the early neonatal period or later in life causing severe life-long complications. Diagnosis is made through laboratory tests. The classical triad is: chorioretinitis, hydrocephalus and intracranial calcifications.
- Viral infections: numerous viral infections are implicated as cause of several birth defects. Some present with non-specific clinical features. Some viral infections include:

  Cytomegalovirus (CMV): Not all babies present with disease or its complications after being exposed. Ultrasound features detectable during prenatal screening include; intracranial calcifications, microcephaly, periventricular or hepatic echo densities and foetal hydrops. The presence of one or more of these may suggest congenital CMV.

  Rubella virus: This is one the most dangerous viral infection leading to serious complications in the fetus. About 25% of infant born to mothers who contract rubella in the first trimester of pregnancy have congenital rubella syndrome (CRS).The common birth defects from CRS are; cataract, heart defects, low birth weight, skin rash at birth, deafness, and intellectual disabilities. Others include glaucoma, brain damage.

2.3.1.2.2 Drugs: the various drugs involved are:

- Misoprostol: even though it has a low teratogenicity, it is known to cause facial nerve, with or without limb deformities.
- Anti-epileptics: Drugs such as Phenytoin and sodium valproate are known to cause birth defects.

Phenytoin: This is known to cause foetal hydantoin syndrome; IUGR, Microcephaly, Limb defects, Hypoplastic nails and distal phalanges, Heart defects and cleft lip.

- Use of Sodium valproate in pregnancy in pregnancy can cause; spina bifida, cleft palate, atrial septal defect, hypospadias and polydactyl.
- Warfarin: it is associated with foetal Warfarin syndrome, Hypoplasia of nasal bridge, Laryngomalacia, Pectus carinatus, Atrial septal defect, Patent Ductus arteriosus, Ventriculomegally, stippled epiphyses, telebrachydactyly and IUGR.
- Tradition medicine consumption: Consumption of traditional medicine is common in Africa. These medicines are prepared from different herbs and other substances whose chemical composition is unknown. These preparations may contain chemical agents with teratogenic effects and cause congenital birth defects. Some birth defect which may be considered idiopathic may perhaps be caused by these traditional medications.
- Folic acid: low supplementation in folic acid before conception and during the embryonic period has been associated with the occurrence of congenital malformations (neural tube defects).

2.3.1.2.3 Chronic diseases

- Diabetes is known to be associated with poor pregnancy outcomes. Diabetic women are at risk of recurrent miscarriages, unexplained intrauterine foetal death, intrauterine growth restriction, foetal macrosomia and congenital birth defects. Common birth defects seen infants whose mothers were diabetics include; heart defects, CNS defects, Renal, Gastrointestinal tract defects and limb malformations [29].
- Maternal overweight and obesity increases the risk of several major and organ-specific congenital malformations [30].
- Maternal preeclampsia, is associated with subtle new-born cardiac morphological and functional alteration. Equally, maternal chronic hypertension exposes new-borns to a significant risk of developing renal, limb and lip/cleft/palate congenital malformations, and the risk is further exacerbated by superimposing eclampsia [31,32].

2.3.1.3 Environmental factors

2.3.1.3.1 Smoking, alcohol intake and pesticide use: these have been thought to expose the new-borns to a high risk of developing a variety of congenital malformations like those affecting the cardiovascular, musculoskeletal and digestive systems.

2.3.2 Classification of congenital malformations

The WHO classifies congenital malformations as either structural or functional abnormalities (metabolic disorders) which occur during intrauterine development.

Structural anomalies are physical abnormalities that occur when the organs or skeletal structure are improperly formed. These can often be detected on ultrasound during the antenatal period [33].

Structural congenital malformations can be classified as two types: major anomalies or minor anomalies, both of which may be present in one individual.

- Major malformations are structural changes that have significant medical, surgical, social or cosmetic consequences for the affected individual, and typically require medical intervention. They account for the most mortality and morbidity related to congenital malformations. Examples are spina bifida, anencephaly, heart defects and orofacial clefts.
- Minor anomalies are structural changes that pose little or no significant health problems hence, having limited social or cosmetic consequences for the affected individual. Minor anomalies are more common than major anomalies and can be a useful tool for clinicians to identify syndromes. Examples of minor anomalies are single palmar crease and clinodactyly [12].

2.3.2.1 Functional congenital malformations

Functional congenital malformations are anomalies in how a body system works. This can lead to developmental disabilities which can include:

- Nervous system and brain problems: learning disabilities; intellectual impairment, behavioural disorders, seizures, speech and language disabilities, ASDs (autistic spectrum disorders) and attention disorders.

- Sensory disorders: blindness and other visual problems alongside deafness and partial hearing loss.
- Metabolic disorders involve PKU (phenyhlkentonuria) where the body can't break down the amino acid phenylalanine. Others include dysfunction of endocrine glands like the thyroid leading to hyper or hypothyroidism.
- Degenerative disorders where the child seems to be developing normally but suddenly starts to lose function and previously acquired skills. Some examples are Rett Syndrome, muscular dystrophy and X-ALD (the subject of the movie Lorenzo's Oil).
- Immune disorders, which is a newly explored area, in which the child's immune system does not function adequately to protect them from constant infections, allergic disorders, asthma, autoimmune diseases and/or cancer [34].

2.3.2.2 Structural congenital malformations

Structural congenital malformations can affect multiple body parts: central nervous system (CNS), orafacial, musculoskeletal, cardiovascular, digestive and urogenital defects.

Table I: Major structural congenital malformations [35].

External	**Internal**

• Neural tube defects
  ○ Anencephaly
  ○ Craniorachischisis
  ○ Iniencephaly
  ○ Encephalocele
  ○ Spina bifida
• Microcephaly
• Microtia/Anotia
• Orofacial clefts
  ○ Cleft lip only
  ○ Cleft palate only
  ○ Cleft lip and palate
• Exomphalos (omphalocele)
• Gastroschisis
• Hypospadias
• Reduction defects of upper and lower limbs
• Talipes equinovarus/club foot
	• Congenital heart defects
	  ○ Hypoplastic left heart syndrome
	  ○ Common truncus
	  ○ Interrupted aortic arch
	  ○ Transposition of great arteries
	  ○ Tetralogy of Fallot
	  ○ Pulmonary valve atresia
	  ○ Tricuspid valve atresia
	• Esophageal atresia/tracheoesophageal fistula
	• Large intestinal atresia/stenosis
	• Anorectal atresia/stenosis
	• Renal agenesis/hypoplasia

Chromosomal	
Trisomy 21 (Down syndrome)	

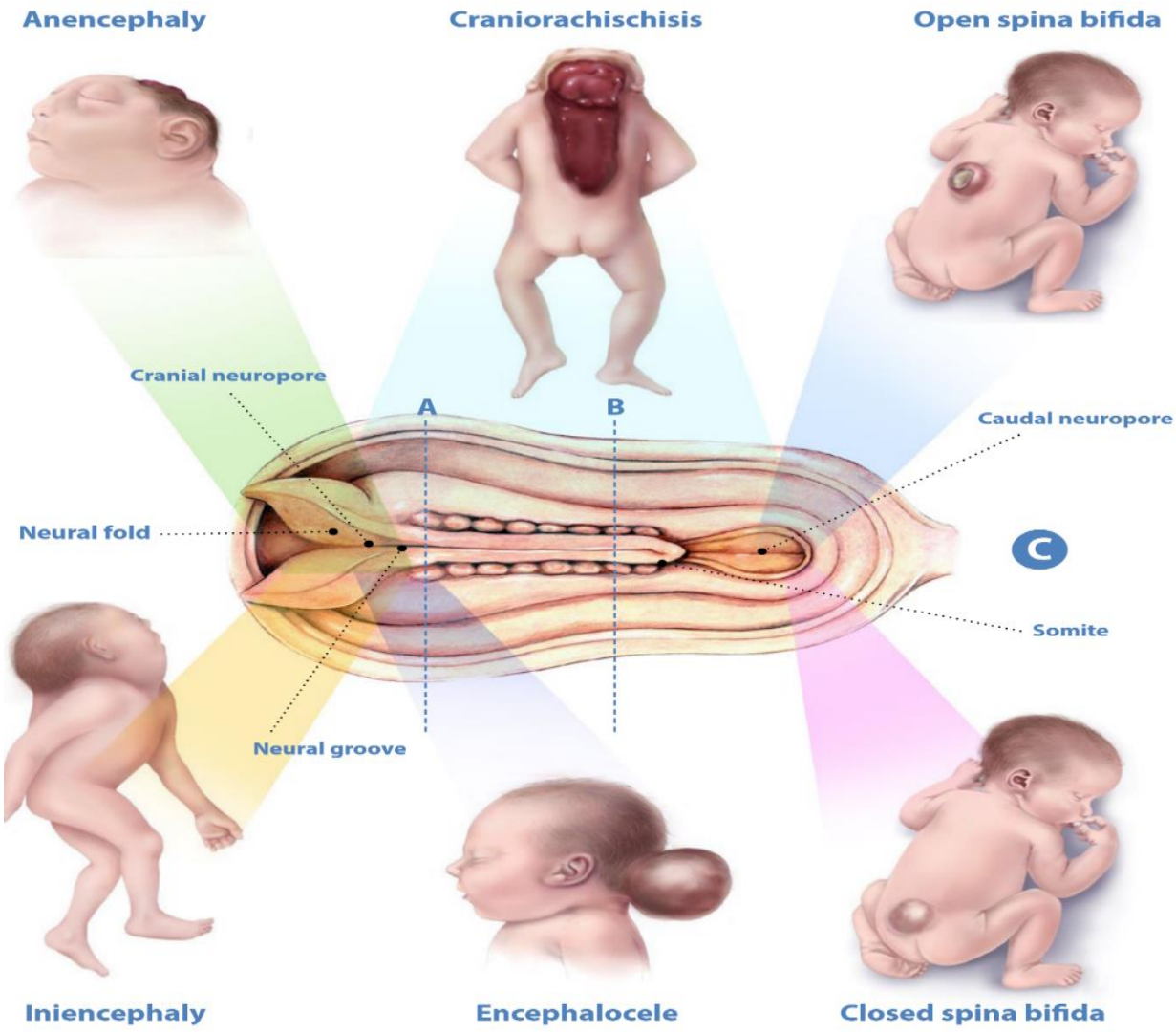

Figure 10: Illustration of a major structural congenital malformation; central nervous system involvement [36].

Table II: Minor structural congenital malformations [35].

Selected external minor congenital anomalies	
Absent nails	Lop ear
Accessory tragus	Micrognathia
Anterior anus (ectopic anus)	Natal teeth
Auricular tag or pit	Overlapping digits
Bifid uvula or cleft uvula	Plagiocephaly
Branchial tag or pit	Polydactyly type B tag, involves hand and foot
Camptodactyly	Preauricular appendage, tag or lobule
Cup ear	Redundant neck folds
Cutis aplasia (if large, this is a major anomaly)	Rocker-bottom feet
Ear lobe crease	Single crease, fifth finger
Ear lobe notch	Single transverse palmar crease
Ear pit or tag	Single umbilical artery
Extra nipples (supernumerary nipples)	Small penis (unless documented as micropenis)
Facial asymmetry	
Hydrocele	Syndactyly involving second and third toes
Hypoplastic fingernails	Tongue-tie (ankyloglossia)
Hypoplastic toenails	Umbilical hernia
Iris coloboma	Undescended testicle
	Webbed neck (pterygium colli)

Figure 11: Illustration of a minor structural congenital malformation: Bilateral postaxial polydactyly with short fingers and dysplastic fingernails [37].

2.3.3 Diagnosis of congenital malformations

The diagnosis can be made before and after birth:

Before birth: ultrasonography and sometimes magnetic resonance imaging, blood tests, amniocentesis, or chorionic villus sampling

After birth: physical examination, ultrasonography, computed tomography, magnetic resonance imaging, and blood tests [38].

2.3.4 Management of congenital malformations

2.3.4.1 Preventive measures:

- Ensuring adolescent girls and mothers have a healthy diet including a wide variety of vegetables and fruit, and maintain a healthy weight;
- Ensuring an adequate dietary intake of vitamins and minerals, particularly folic acid in adolescent girls and mothers;
- Ensuring mothers avoid harmful substances, particularly alcohol and tobacco;
- Avoidance of travel by pregnant women (and sometimes women of child-bearing age) to regions experiencing outbreaks of infections known to be associated with congenital disorders;
- Reducing or eliminating environmental exposure to hazardous substances (such as heavy metals or pesticides) during pregnancy;
- Controlling diabetes prior to and during pregnancy through counselling, weight management, diet and administration of insulin when required;
- Ensuring that any exposure of pregnant women to medications or medical radiation (such as imaging rays) is justified and based on careful health risk–benefit analysis;
- Vaccination, especially against the rubella virus, for children and women;
- Increasing and strengthening education of health staff and others involved in promoting prevention of congenital disorders; and screening for infections, especially rubella, varicella and syphilis, and consideration of treatment [38].

2.3.4.2 Management and care

Some congenital disorders can be treated with medical or surgical interventions.

Surgery with good follow up care can often mitigate the potential lethality (as in the case of congenital heart defects) or the morbidity (e.g., congenital talipes, cleft lip/palate) associated with structural congenital disorders

Medical treatment for certain metabolic, endocrine and hematological conditions can improve quality of life

Children with some types of congenital disorders may require long term support including physical therapy, speech therapy, occupational therapy and support from families and community [3,36].

2.4 REVIEW OF STUDIES

2.4.1 In the world

Title of place of study	Authors and year of study	Setting and sampling	Results
Prevalence and Pattern of Congenital Malformations among Neonates in a Medical College Hospital - A Retrospective Study. India	R Padmanabhan, R Venkatasubramanian, A Heber. 2023	The retrospective study of live neonates from new-born to 28 days of age both inborn and outborn admitted to the unit irrespective of their general condition with CMs comprised the study population Details of investigations like ultrasonography, radiology, echocardiography, laboratory studies have done were noted from the case record. Their outcome in the form of morbidity, hospital stay, and mortality was analysed.	In 2132 babies, with malformations were 87 (4.08%). Of which inborn babies were 3.9% and outborn babies were 4.8%. Of the malformed babies were 54% of male and 45% of female, 1% was DSD. Cesarean delivery was 63.2%, other modes were 36.8%. The cardiovascular system was involved in 35.6% of babies, followed by the musculoskeletal system (26.4%), then the genitourinary system 13.8%, gastrointestinal (9.2%), and central nervous system (10.3%). Maternal risk factors associated with malformations were

			maternal diabetes in 2.3%, age between 21 and 30 in 87.4%, and consanguinity in 8%. Maximum mortality occurred in babies with cardiovascular system malformations (76.5%). Majority of babies with malformations discharged (65.5%) only 19.5% of babies expired and 15% of babies were referred for intervention at a higher centre.
Neural tube defects: Prevalence, mortality, and maternal characteristics in two departmental hospitals in the northwestern region of Nicaragua, 2006–2018	Dania Maria Pastora Bucardo, Fredman Gonzalez, Maria Montes Pastora, Paula Andrea Pimienta Ramirez, Indian Lopez Bonilla, Nadja A Vielot, Richard H. Finnel	A cross-sectional study was carried out in northwestern Nicaragua from January 2006 to December 2018. All cases of NTDs (anencephaly, spina bifida, and encephalocele) were registered in hospital surveillance systems, and the medical histories of the mothers and new-borns were reviewed. Prevalence was calculated by considering the number of live births and	Two hundred fifty cases of NTDs were identified from 178,498 deliveries (177,316 live births and 1,182 stillbirths). The prevalence of NTDs during this time period was 14.01 (95% CI: 12.27–15.74) per 10,000 births. The prevalence of spina bifida ($n = 140$), anencephaly ($n = 97$), and encephalocele ($n = 13$) was 7.84, (95% CI: 6.54–9.14), 5.43 (95% CI: 4.30–6.45), and 0.73 (95% CI: 0.33–1.12) per 10,000 births,

		stillbirths older than 20 weeks of gestation with NTDs, divided by the total number of live births and stillbirths in each study year. Neonatal mortality rate (NMR) for NTD, and case fatality for spina bifida was calculated.	respectively. Mothers with foetus or new-borns affected with NTDs did not use folic acid prior to conception, and 11% experienced periods of hyperthermia during the first trimester of pregnancy. NMR for NTDs was 0.55 per 1.000 livebirths. Case fatality for all NTDs and for spina bifida were 55% and 18%, respectively.
Effect of Race on the Prevalence of Congenital Malformations among New-borns in the United States	Alexander Egbe, Simon Lee, Deborah Ho and Santosh Uppu. 2015	This is a population-based cross-sectional study to analyse racial differences in prevalence of CM diagnoses. We reviewed all live births in the 2008 Nationwide Inpatient Sample (NIS) database and determined birth prevalence of 55 selected CM diagnoses in Caucasians. We then calculated the relative risk of these CM diagnoses in African American, Hispanics	Overall CM prevalence was 29.2 per 1,000 in a cohort of 1,048,252 live births of which 51% were Caucasians. Compared to Caucasian, risk of overall CM was lower in African Americans (RR=.9, CI. 8–. 9) and Hispanics (RR=.9, CI. 8–.9). Risk of overall CM was similar in Caucasians and Asians. Relative to the Caucasians, African Americans had lower risk of cardiac, genitourinary, and craniofacial

		and Asians relative to Caucasians.	malformations but higher risk of musculoskeletal malformations. Hispanics had lower risk of genitourinary and gastrointestinal malformation. Asians had higher risk of craniofacial and musculoskeletal malformation.
Burden and consequence of birth defects in Nepal-evidence from prospective cohort study.	Prajwal Paudel1, Avinash K. Sunny 2 , Rejina Gurung2,Abhishek Gurung2, Honey Malla2, Netra B. Rana3, Nawaraj KC4, Ram Narayan Chaudhary5 and Ashish KC6*	This is a prospective cohort study conducted in 12 hospitals of Nepal for 18 months. All the women who delivered in the hospitals during the study period was enrolled. Independent researchers collected data on the social and demographic information using semi-structured questionnaire at the time of discharge and clinical events and birth outcome information from the clinical case note. Data were analysed on the prevalence and type of birth defect. Logistic regression was done to	Among the total 87,242 livebirths, the prevalence of birth defects was found to be 5.8 per 1000 live births. The commonly occurring birth defects were anencephaly (3.95%), cleft lip (2.77%), cleft lip and palate (6.13%), clubfeet (3.95%), eye abnormalities (3.95%) and meningomyelocele (3.36%). The odds of birth defect was higher among mothers with age < 20 years (adjusted Odds ratio (aOR) 1.64; 95% CI, 1.18–2.28) and disadvantaged ethnicity (aOR 1.78; 95% CI, 1.46–2.18). The odds of

		assess the risk factor and consequences for birth defect.	birth asphyxia was twice fold higher among babies with birth defect (aOR 1.88; 95% CI, 1.41–2.51) in reference with babies without birth defect. The odds of neonatal infection was twice fold higher among babies with birth defect (aOR 1.82; 95% CI, 1.12–2.96) in reference with babies without birth defect. Babies with birth defect had three-fold risk of pre-discharge mortality (aOR 3.00; 95% CI, 1.93–4.69).

2.4.2 In Africa

Title and place of study	Authors and year of study	Setting and sampling	Results
Risk factors associated with congenital anomalies among new-borns in southwestern Ethiopia: A case-control study	Soressa AbebeI, Girmai Gebru1, Demisew Amenu , Zeleke Mekonnen, Lemessa Dube	Case—control study was conducted on newborns and their mothers in six purposively selected hospitals in southwestern Ethiopia from May 2016 to May 2018. Data was collected	Risk factors such as unidentified medicinal usage in the first three months of pregnancy (AOR =3.435; 99% CI: 2.012–5.863), exposure to pesticide (AOR =3.926; 99% CI: 1.26612.176), passive smoking

		after evaluation of the neonates for the presence of congenital anomalies using the standard pretested checklist. The data was analysed using SPSS version 25.0. P <0.01 was set as statistically significant.	(AOR =4.104; 99% CI: 1.892–8.901), surface water as sources of drinking (AOR =2.073; 99% CI: 1.221–3.519), folic acid supplementation during the early pregnancy (AOR =0.428; 99% CI: 0.247–0.740) were significantly associated with the congenital anomalies.
Prevalence of overt congenital anomalies and associated factors among new-borns delivered at Jimma university medical center, southwest Ethiopia, 2018: A cross-sectional study	Bekalu Getachew, Tilahun Alemayehu, Soressa Abebe, Niguse Hambo, Solomon Tesfaye, Tesema Etefa, Ruth Tilahun	An institutional based cross-sectional study was conducted from May 1 to June 30, 2018. Data was collected from 754 delivered neonates with their respective mothers using structured and interviewer-administered questionnaire. All data were cleaned, coded and entered into EPI data 3.1 and exported to SPSS software version	A total of 754 neonates were delivered from 754 mothers. The study finding showed that the prevalence of overt congenital anomalies among live and still births neonates was 4.1 % (411 per 10,000 births). Majority of anomalies were isolated and major in 93.5 % and 96.7 % of cases respectively. Central nervous system anomalies had

		20:0 for analysis. Analysis included descriptive statistics and logistic regression. Multivariate logistic regression model was fitted to assess the association between the independent and dependent variables. Adjusted Odds ratios were calculated with 95 % CIs and considered significant with a p-value < 0.05.	the highest prevalence (45.1 %) and followed by orofacial clefts (25.8 %) and musculoskeletal system defects (13 %).Unknown medication uses during early pregnancy (AOR = 15.18; 95 % CI: 5.51–40.27, p-value=<0.00), history of maternal khat chewing in early pregnancy (AOR = 3.41; 95 % CI: 1.46–7.95, p-value = 0.004), and maternal chronic illness before conception (AOR = 4.3; 95 % CI = 1.65–11.37, p-value = 0.031), were the factors associated with overt congenital anomalies. Folic acid use (AOR = 0.18; 95 % CI: 0.02–0.92, p-value = 0.003) during periconception had a protective effect

			from overt congenital anomaly.
Pattern and risk factors of congenital anomalies in a paediatric university hospital, Alexandria, Egypt	Marwa Shawky Mohammed Abdou1* , Aida Ali Reda Sherif, Iman Mohamed Helmy Wahdan1 and Khaled Saad El din Ashour. 2019	A retrospective case series and a case-control study were conducted. Patients' records for the years 2010–2015 were reviewed, and a sample of 200 infants (100 cases and 100 controls) was taken from infants presented to Paediatrics, Paediatric Surgery, and Genetics Clinics of the hospital. Data were collected using a record review checklist and a predesigned interviewing questionnaire.	The study revealed that congenital anomalies of the digestive system (38.0%), musculoskeletal system (32.9%), and circulatory system (11.0%) were the most common types of CAs. Males were more affected with CAs than females (63% versus 37%). The major risk factors for CAs were old-aged parents, complications during pregnancy, unprescribed medications and excessive vitamin A intake during pregnancy, exposure to chemicals and pesticides during pregnancy, and living near mobile strengthening stations.
Prevalence and pattern of birth defects in a tertiary	Mkpe abbey1 Olufemi a Oloyede2 goddy Bassey1	This is a descriptive retrospective cross-sectional study. It	Out of the 7,670 deliveries that occurred, 159

health facility in the Niger Delta area of Nigeria	Benjamin M Kejeh3 Barbara e Otaigbe4 Peace I Opara4 austa U eneh4 chris I akani1	involved data from the labour ward and neonatal birth registers of the University of Port Harcourt Teaching Hospital on the total number of births and the babies that were delivered with major birth defects between August 2011 and December 2014. We also conducted a statistical comparison of the prevalence of congenital abnormalities in the Niger Delta with that in other regions of Nigeria and the developed world of Europe.	maternities had babies with major birth defects giving a prevalence of 20.73 cases per 1,000 live births. This figure is far more than that which was obtained in other regions of Nigeria -4.15: cases per 1,000 live births in the South East (P,0.001), 15.84:1,000 in the South West (P,0.01), and 5.51:1,000 in the North East (P,0.001). Eighty-five (53.46%) of the defects occurred in 1,681 unbooked patients, while 74 (46.54%) happened in 5,989 booked maternities (P,0.001). The predominant abnormalities were those of the central nervous system at 27.0%, gastrointestinal system 11.95%, cardiovascular system 10.69%, anterior

			abdominal wall 8.18%, skeleton 6.29%, and chromosomal abnormalities at 5.66%.

2.4.3 In Cameroon

Title and place of study	Authors and year of study	Setting and sampling	Results
Epidemiology of congenital malformations visible at birth in Yaoundé	Kamla Joël Igor1, Kamgaing Nelly1, 2, Nguifo Fongang EJ3, Fondop Joseph4, Billong Serge1, Djientcheu Vincent de Paul1,3	This was a cross sectional descriptive prospective study. We studied all new-borns presenting one or more malformations detectable at birth in 10 selected and representative maternities for one year. Data of interest were type of malformation, new-born anthropometric parameters, socio-demographic records of parents, obstetrical data, past medical history of the mother, history of previous malformations,	The prevalence was 9 per 1000 births. The most common types of malformations were (per 1.000 births) polydactyly 2.1; clubfeet 1.1, Neural tube defects 1.4; Hydrocephalus 1.1; oro-facial clefts 0.9; and abdominal parietal defects 0.7. The pair myelomeningocele and hydrocephalus was common polymalformation. The sex ratio was 1.1. Mothers of malformed babies were mostly found in the age group 26 to 35 years (49.6%), single, housewives with a secondary education level. Suspected risk

		abortion or still birth, irradiation, foetal toxic drugs including folic acid around the conception.	factors were maternal fever during the first trimester (31.4 %), past history of spontaneous abortions (23.4 %), primiparous mothers (36.6 %), and absence folic acid supplementation in periconceptional period (100 %).
Congenital Malformations: Report of 5 Rare Cases Seen in 20 Years (1994-2014) in Cameroon and Review of Literature	Enow Orock GE. 2016	We report 5 rare congenital malformations found in 20 years of practice (1994-2014) in our service amongst 3 females and 2 males. Multisystem malformations involve more than one system and are rare. We found a case of amelia (lower limb) associated with gastroschisis, congenital bilateral polycystic kidneys, unilateral uterine adnexal agenesis fortuitously	There is no birth defect registry in Cameroon and data on such defects is largely inexistent. However congenital anomalies are seen but often unreported from various obstetric and paediatric services across the country. In the case where such cases are reported, the family is usually uncollaborative and detail investigations to identify potential risk factors are unavailable. Knowledge on CMs and their risk factors in our environment is essential for prevention, early detection and long and

		discovered in an adult and a congenital huge haemangioma of the nasal tip and dorsum giving a 'clown nose deformity'.	short term management. It is in order to raise awareness that we decided to publish these rare congenital defects that we found in the course of 20 years of practice in our community. REF
Prenatal Diagnosis of Congenital Malformations in Douala General Hospital	Tchente Nguefack Charlotte1,2*, Nzesseu Djomo Aurore2,3, Brulet Charlotte4, Barla Esther5, Belley Priso Eugene2. 2015	It was a cross-sectional study carried out at the Douala General Hospital in the obstetric and neonatal units over a period of 42 months, from January 2008 to June 2012. The procedure consisted of; firstly an explanation of the study purpose with consent of parents obtained, thereafter, the parents were interviewed and data extracted from their files. The new born had a complete clinical exam. Morphological and biological	During this period, 6048 neonates were examined, 99 of whom had a malformation giving a prevalence of 1.64%. Musculoskeletal defects were the most common (36.4%), followed by digestive tract defects (22.2%). Ultrasounds were carried out mainly in the second term. Among the malformed babies, only 16.2% were diagnosed during the prenatal period. The obstetricians did better than radiologist in the prenatal diagnosis of congenital malformations. All the urinary tract malformations and 33.3% of the

		assessment were done to ascertain diagnosis if needed. They were then followed up for 48 hours. Data were analysed using SPSS. Statistical analyses were mainly descriptive: mean, median, mode and frequency were calculated.	polymalformations were diagnosed by prenatal echography. Among the malformed babies, 33% died within the first 48 hours of life and polymalformed babies were more concerned (66.7%).

CHAPTER 3: METHODOLOGY

3.1 TYPE OF STUDY

This was a retrospective case-control study.

3.2 SITE OF STUDY

We carried out this study in two hospitals in the city of Yaoundé. We worked at the obstetrics/gynaecology units of the Central Hospital (YCH) and the Gynaecology, Obstetrics and Paediatrics Hospital (YGOPH). These hospitals were chosen for this study because of their great patient turnover, adequate follow up and anticipated clear records.

The Yaoundé Gynaecology, Obstetrics and Paediatric Hospital:

It is a reference health facility created in 2002 and specialises in mother and child health care. Its gynaecology/obstetrics department has a capacity of 3 delivery tables, 34 inpatient beds and 4 operating rooms with two laparoscopy columns. The service carries out an average of 3015 deliveries per year with a staff of 14 specialists.

The Yaoundé Central Hospital:

This reference hospital located in the heart of Yaoundé has one of the biggest specialised maternity unit with over 72 inpatient beds, 6 delivery tables, 2 service operating rooms and a large highly trained staff. It records about 219 deliveries per month.

3.3 DURATION OF STUDY

This study was carried out over a duration of 8 months, from November 2023 to June 2024 and it covered a period of 5 years, from 2018 to 2022 inclusive.

3.4 POPULATION SAMPLE

The sample population consisted of files of women who gave birth in the chosen hospitals.

3.4.1 Inclusion criteria

A. Cases; files of women who gave birth during the study period who had:

- Live neonates and stillbirths at term or preterm with congenital malformations.

B. Controls:

- Files of women who had children without malformations during the study period.

3.4.2 Exclusion criteria

- For both cases and controls, files with incomplete information.

3.4.3 Sampling method

This was done in a consecutive manner.

3.4.4 Sample size estimation

The minimum sample size was determined using the formula below:

$$n = \left[\frac{2 * \left(Z_{\alpha} + Z_{\beta}\right)^2 * p * (1-p)}{(p_0 - p_1)^2} \right]$$

Where;

P_0 = Proportion of women in the control group who did not have children with congenital malformations.

P_1 = Proportion of women in the cases who had children with congenital malformations.

$P = \frac{P_0 + P_1}{2}$

$\alpha = 0.05$

$Z_{\alpha} = 1.96$

$\beta = 0.1$

$Z_{\beta} = 1.28$

Therefore, **n = 79 participants**

With ratio 1:1 with 79 cases and 79 controls.

3.5 PROCEDURE

3.5.1 Administrative formalities

To carry out this study, we did the following:

- Developed the research proposal and had it validated by supervisors.
- Submitted a request for ethical clearance from the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences, University of Yaoundé I and research authorisation from YGOPH and YCH.

3.5.2 Recruitment and data collection

After we obtained study authorisations and ethical clearance, we recruited cases and controls from the registers and extracted data from their files with the aid of an adapted and validated data collection sheet. Cases were files of women who gave birth to neonates with congenital malformations and controls were files of women who gave birth to neonates without malformations, matched for age and parity.

3.5.3 Study variables

During our study, we searched for the following:

- Socio-demographic data: this included maternal and paternal age, profession, level of education, marital status, religion, region of origin.
- Maternal clinical history: we checked for parity, infections, chronic diseases like diabetes, hypertensive disorders, alcohol consumption, smoking, traditional drug consumption, personal and family history of congenital malformations, paternal age, folic acid supplementation, number of antenatal care contacts, number of ultrasound scans done.
- Types of congenital malformations: this included information on the sex of the baby, systems affected, specific malformation per system, gestational age at delivery and if it was a stillbirth or not.

3.6 DATA ANALYSIS

Data from completed and validated questionnaires was entered into and analysed using IBM SPSS 26.0 (Statistical Package for Social Sciences).

Chi square was used for comparison between categorical data and Student's T-test for numerical data. Case and control group characteristics was compared by calculating the odds ratio and the corresponding 95% confidence intervals and p values. All p values less than 0.05 were considered statistically significant.

We represented our results with tables. Qualitative variables were presented as absolute numbers, frequencies and percentages while quantitative variables were presented as means, standard deviations and ranges.

3.7 HUMAN RESOURCES

- Main investigator
- Supervisor and co-supervisors
- Statistician.

3.8 MATERIALS USED

- A4 reams of paper
- Writing material (pencils, pens, erasers)
- Patient medical records
- A pre-established data collection sheet (see appendix)
- A laptop
- A smart phone
- Internet connection
- USB flash drives.

3.9 ETHICAL CONSIDERATIONS

Before we commenced data collection, ethical clearance was requested and obtained from the ethical committee of the Faculty of Medicine and Biomedical Sciences. Equally, we requested for administrative authorisations from the hospitals of interest; YGOPH and YCH.

Data collection was performed in utmost discretion and anonymity for every individual. All data collected was used for research only.

CHAPTER 4 : RESULTS

4.1 DIAGRAMMATIC REPRESENTATION OF RECRUITMENT

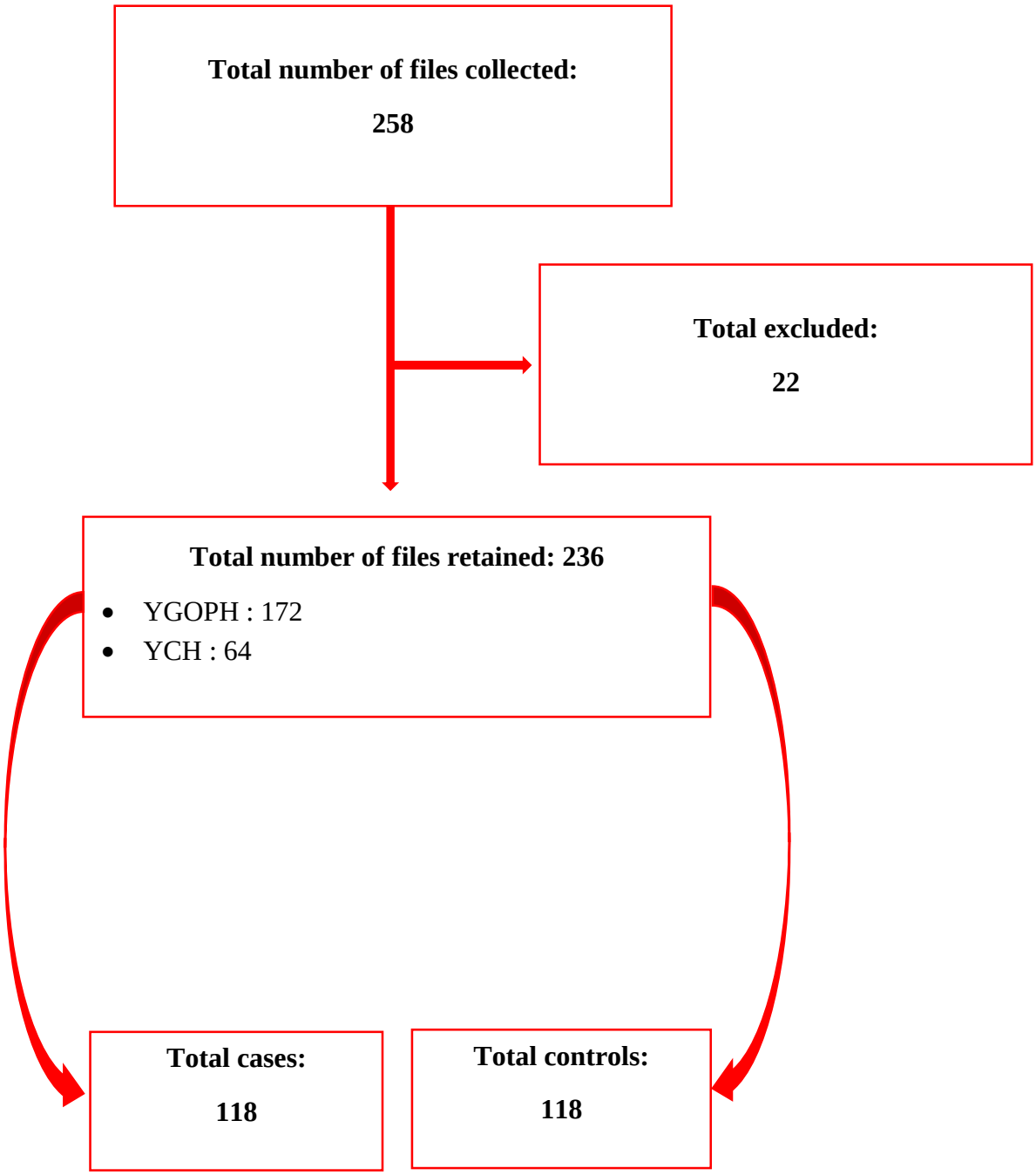

Figure 12: Participant flow diagram

For this study, we reviewed 258 patient file records from January 2018 through December 2022. The files were evaluated over a four-month period (January to April 2024), of which 22 were missing or had incomplete information and were found to be ineligible. Thus, a total of 236 files were retained in our study. We had 118 cases and 118 controls, giving a ratio of 1:1.

4.2 CHARACTERISTICS OF NEW-BORNS WITH CONGENITAL MALFORMATIONS

The tables below show the distribution of new-borns with congenital malformations according to defined variables and their distribution according to the systems affected.

Table III: Distribution of cases according to defined variables.

Variables	Frequency (N=118)	Percentage (%)
Gestational age at delivery (Weeks of gestation)		
28-30	25	21.1
31-33	17	14.4
34-36	18	15.3
≥37	58	49.2
Baby's sex		
Female	45	38.1
Male	68	57.6
Undefined	5	4.2
Malformation seen on ultrasound scan or at birth		
Yes	116	98.3
No	2	1.7
Stillbirth		
Yes	26	22.0
No	92	78.0

Most deliveries occurred from 37 weeks of gestation (49.2%), with the extremes being 29 and 41 weeks of gestation. The majority were males (57.6%), at a sex ratio of 1.51. At birth, 22.0% were stillborn. Visible malformations on obstetric ultrasound scans or at birth accounted for 98.3%, and the main systems involved were the musculoskeletal system (42.4%), the central nervous system (36.4%) and the digestive system (28.8%).

Table IV: Repartition of new-borns according to the number of systems affected and location of congenital malformations.

Variables	Frequency (N=118)	Percentage (%)
Number of systems affected		
1 system	94	79.7
2 systems	16	13.6
3 systems	5	4.2
4 systems	1	0.8
5 systems	2	1.7
Location of congenital malformations		
Musculoskeletal system	50	42.4
Central nervous system	43	36.4
Digestive system	34	28.8
Genitourinary system	14	11.9
Cardivascular system	10	8.5
Pulmonary system	4	3.4

Most of the new-borns (79.7%) had a congenital malformation affecting a system. Polyformation accounted for 20.3% of cases and involved up to 5 systems at the same time. The main systems concerned were the musculoskeletal system (42.4%), the central nervous system (36.4%) and the digestive system (28.8%).

4.3 MALFORMATIONS OF THE MUSCULOSKELETAL SYSTEM

The table below shows the types of congenital malformations of the musculoskeletal system found in this study.

Table V: Types of congenital malformations of the musculoskeletal system

Congenital malformations of musculoskeletal system	**Frequency (n=50)**	**Percentage (%)**
Club feet	20	40.0
Polydactily	17	34.0
Club hands	4	8.0
Cleft lip/palate	4	8.0
Genu varum	2	4.0
Syndactily	2	4.0
Sirenomelia	1	2.0

Congenital malformations of the musculoskeletal system were dominated by clubfeet and polydactyly, accounting for 40.0% and 34.0% of cases respectively.

4.4 CONGENITAL MALFORMATIONS OF THE CENTRAL NERVOUS SYSTEM

Table VI shows the distribution of congenital malformations of the central nervous system found in this study.

Table VI: Types of congenital malformations of the central nervous system

Congenital malformations of central nervous system	**Frequency (n=43)**	**Percentage (%)**
Hydrocephalus	21	48.8
Anencephaly	9	20.9
Dandy walker syndrome	3	7.0
Microcephaly	3	7.0
Cerebellar agenesis	2	4.7
Ventriculomegaly	2	4.7
Spina bifida	2	4.7
Holoprosencephaly with single ventricule	1	2.3

Hydrocephalus was the main congenital malformation of the central nervous system, accounting for 48.8% of cases.

4.5 CONGENITAL MALFORMATIONS OF THE DIGESTIVE SYSTEM

The types of congenital malformations of the digestive system are found in this study are shown in table VII below

Table VII: Types of congenital malformations of the digestive system

Congenital malformations of digestive system	**Frequency (n=34)**	**Percentage (%)**
Omphalocele	18	52.9
Duodenal atresia	5	14.7
Gastroschisis	4	11.8
Tongue tie	3	8.8
Segmental dilatation of the colon	2	5.9
Esophageal atresia	1	2.9
Diaphragmatic hernia	1	2.9

Omphalocele was the most frequent congenital malformation of the digestive system, accounting for 52.9% of cases.

4.6 OTHER CONGENITAL MALFORMATIONS

Congenital malformations seen in the other systems are enumerated table VIII below

Table VIII: Other congenital malformations.

Other congenital malformations	Frequency	Percentage (%)
Genitourinary system (n=14)		
Hydronephrosis	5	35.7
Genital ambiguity	5	35.7
Polycystic kidneys	2	14.3
Unilateral renal agenesis	1	7.1
Vaginal prolapse	1	7.1
Cardiovascular sytem (n=10)		
Ventricular septal defect	3	30.0
Cardiomegaly	3	30.0
Ebstein anomaly	1	10.0
Single ventricle defect	1	10.0
Transposition of great vessels	1	10.0
Atrial septal defect	1	10.0
Pulmonary system (n=4)		
Pulmonary hypoplasia	4	100.0
Others	0	0.0

Concerning the genitourinary system, hydronephrosis (35.7%) and genital ambiguity (35.7%) were the most frequent. Cardiovascular anomalies were dominated by ventricular septal defects (30%) and cardiomegaly (30%). Congenital malformations of the pulmonary system were essentially represented by pulmonary hypoplasia, accounting for 100% of cases.

4.7 SOCIODEMOGRAPHIC CHARACTERISTICS OF THE STUDY POPULATION

Tables IX and X enumerate the socio-demographic characteristics of our study population

Table IX: Population distribution by age and marital status.

Variables	Case	Control	OR	P
	N=118; n(%)	N=118; n(%)	(CI at 95%)	
Maternal age groups (years)				
15-19	12 (10.2)	9 (7.6)	1.37 (0.55-3.38)	0.324
20-24	32 (27.1)	31 (26.3)	1.04 (0.58-1.85)	0.500
25-29	26 (22.0)	26 (22.0)	1.00 (0.54-1.85)	0.562
30-34	24 (20.3)	29 (24.6)	0.78 (0.42-1.44)	0.266
35-39	18 (15.3)	15 (12.7)	1.23 (0.59-2.58)	0.354
40-44	4 (3.4)	6 (5.1)	0.65 (0.18-2.38)	0.374
≥45	2 (1,7)	2 (1,7)	1.00 (0.13-7.22)	0.689
Marital status				
Married	34 (28.8)	41 (34.7)	1	
Single	84 (71.2)	77 (65.3)	1.31 (0.75-2.28)	0.201
Paternal age groups (years)				
15-23	5 (4.2)	1 (0.8)	5.17 (0.59-45.00)	0.106
24-32	14 (11.9)	32 (27.1)	**0.36 (0.18-0.72)**	**0.002**
33-41	53 (44.9)	62 (52.5)	0.73 (0.44-1.22)	0.149
42-50	37 (31.4)	19 (16.1)	**2.38 (1.27-4.45)**	**0.004**
51-59	4 (3.4)	4 (3.4)	1.00 (0.24-4.09)	0.639
≥ 60	5 (4.2)	0 (0.0)	/	0.030

The mean age of the cases (28.31 ± 7.03 years) was comparable to that of the control group (28.19 ± 6.69 years) with extreme ages being from 17 to 47 years in both groups (p = 0.894). No association was found between maternal age or marital status and the occurrence of congenital malformations (p ⩾ 0.05). However, men aged between 42 and 50 were 2.3 times more likely to have children with congenital malformations (p = 0.004).

Table X: Population distribution by educational level and occupation.

Variables	**Cases**	**Controls**	**OR**	**P**
	N=118; n(%)	**N=118; n(%)**	**(CI at 95%)**	
Level of study				
Up to primary level	4 (3.4)	7 (5.9)	0.55 (0.15-1.95)	0.269
Secondary	24 (20.3)	16 (13.6)	1.62 (0.81-3.25)	0.112
High school	42 (35.6)	37 (31.4)	1.21 (0.70-2.07)	0.291
University	48 (40.7)	58 (49.2)	0.70 (0.42-1.18)	0.119
Occupation				
Informal sector	29 (24.6)	23 (19.5)	1.34 (0.72-2.49)	0.216
Student	36 (30.5)	33 (28.0)	1.13 (0.64-1.98)	0.387
Civil servant	25 (21.2)	33 (28.0)	0.69 (0.38-1.25)	0.145
Private sector	5 (4.2)	14 (11.9)	0.32 (0.11-0.1,04)	0.027
Unemployed	23 (19.5)	15 (12.7)	1.66 (0.81-3.37)	0.107

The table above shows that level of education was not associated with congenital malformations. Working in the private sector was protective (OR 0.32, CI 0.11- 0.104, p=0.27).

4.8 CLINICAL CHARACTERISTICS OF THE STUDY POPULATION

The clinical aspects of our study population are showed in tables XI, XII and XIII below

Table XI: Population distribution according to personal and family obstetrical history

Variables	**Cases**	**Controls**	**OR**	**P**
	N=118; n(%)	**N=118; n(%)**	**(CI at 95%)**	
Gravidity				
Pimigravidarum	29 (24,6)	40 (33.9)	0.63 (0.36-1.12)	0.076
Paucigravidarum	52 (44.1)	40 (33.9)	1.53 (0.90-2.60)	0.071
Multigravidarum	23 (19.5)	23 (19.5)	1.00 (0.52-1.90)	0.565
Grand muligravidarum	14 (11.9)	15 (12.7)	0.92 (0.42-2.01)	0.500
Parity				
Primiparous	40 (33.9)	50 (42.4)	0.69 (0.41-1.18)	0.114
Pauciparous	52 (44.1)	46 (39.0)	1.23 (0.73-2.07)	0.255
Multiparous	19 (16.1)	20 (16.9)	0.94 (0.47-1.87)	0.500
Grand multiparous	7 (5.9)	2 (1.7)	3.65 (0.74-17.98)	0.086
Use of assisted reproductive technologies				
Yes	2 (1.7)	2 (1.7)	1.00 (0.13-7.22)	0.689
No	116 (98.3)	116 (98.3)	1	
Personal history of mother with malformed child				
Yes	2 (1.7)	1 (0.8)	2.01 (0.18-22.55)	0.500
No	116 (98.3)	117 (99.2)	1	
Family history of mother with malformed child				
Yes	49 (41.5)	1 (0.8)	**83.08 (11.22-615.21)**	**< 0.001**
No	69 (58.5)	117 (99.2)	1	

Grande multiparous women had a 3.6-fold increased risk of having new-borns with a congenital malformation. However, the difference between the cases and controls was not statistically significant (p=0.086). Analysis of women with a family history of congenital malformations showed them to be 83 times more likely to have a new-born with a congenital malformation (p<0.001), as shown in Table XI above.

Table XII: Population distribution according to characteristics of pregnancy follow-up.

Variables	**Cases**	**Controls**	**OR**	**P**
	N=118; n(%)	**N=118; n(%)**	**(CI at 95%)**	
Number of ANCs				
0-2	51 (43.2)	20 (16.9)	**3.73 (2.04-6.81)**	**< 0.001**
3-5	25 (21.2)	25 (21.2)	1.00 (0.53-1.86)	0.563
6-8	32 (27.1)	55 (46.6)	**0.42 (0.24-0.73)**	**0.001**
> 8	10 (8.5)	18 (15.3)	0.51 (0.22-1.16)	0.079
Gestational age at first ANC (Weeks of gestation)				
< 12	16 (13.6)	25 (21.2)	0.58 (0.29-1.16)	0.084
12-15	27 (22.9)	44 (37.3)	**0.49 (0.28-0.88)**	**0.011**
16-19	22 (18.6)	37 (31.4)	**0.50 (0.27-0.91)**	**0.017**
≥ 20	53 (44.9)	12 (10.2)	**7.2 (3.58-14.48)**	**< 0.001**
Folic acid consumption				
No	47 (39.8)	2 (1.7)	**38.39 (9.04-162.95)**	**< 0.001**
Ultrasound abnormalities				
None	89 (75.4)	106 (89.8)	**0.34 (0.16-0.72)**	**0.003**
Amniotic fluid abnormalities	22 (18.6)	5 (4.2)	**5.17 (1.88-14.19)**	**< 0.001**
Polyhydramnios	14 (11.9)	1 (0.8)	**15.75 (2.03-121.84)**	**< 0.001**
Anhydramnios/Oligohydramnios	8 (6.8)	4 (3.4)	2.07 (0.60-7.08)	0.188
Nuchal cord	8 (6.8)	7 (5.9)	1.15 (0.40-3.28)	0.500

The number of ANC contacts less than 3, and the start of ANCs from the 20th week of amenorrhea multiplied the risk of having a child with congenital malformations by 3.7 and 7.2 respectively ($p < 0.001$). The number of ANC contacts ranging from 6 to 8 visits was protective (OR 0.042, CI 0.24-0.73), $p = 0.001$). The absence of periconceptional folic acid intake constituted a risk of having a child with congenital malformations (OR: 38.39; $p < 0.001$). We also found, as shown in Table XII above, that the presence of ultrasound abnormalities such as hydramnios, increased the likelihood of a child presenting with underlying congenital malformations by a factor of 15.7 ($p < 0.001$).

Table XIII: Population distribution according to infectious pathologies and comorbidities in pregnancy

Variables	**Cases N=118 n(%)**	**Controls N=118; n(%)**	**OR (CI at 95%)**	**P**
Coinfections during pregnancy				
Toxoplasmosis	2 (1.7)	1 (0.8)	2.07 (0.18-22.55)	0.500
Rubella	2 (1.7)	0 (0.0)	/	0.249
Hepatitis B	4 (3.4)	2 (1.7)	2.03 (0.36-11.33)	0.342
HIV infection	2 (1.7)	7 (5.9)	0.27 (0.05-1.34)	0.086
Comorbidities during pregnancy				
Diabetes	8 (6.8)	0 (0.0)	/	0.003
Hypertension	0 (0.0)	4 (3.4)	/	0.061
Malaria during 1st and 2nd trimester				
Yes	40 (33.9)	29 (24.6)	1.57 (0.89 (2.77)	0.076
No	78 (66.1)	89 (75.4)	1	

Table XIII above shows that about 6.8% of the women who delivered malformed babies were diabetic. Some other comorbidities were not found statistically significant. Similarly, infectious pathologies were not associated with congenital malformations ($p \geqslant 0.05$).

4.9 LIFESTYLE DURING PREGNANCY

The population distribution according to lifestyle during pregnancy is shown in the table below

Table XIV: Population distribution according to lifestyle during pregnancy

Variables	Cases N=118 n(%)	Controls N=118; n(%)	OR (CI at 95%)	P
Traditional drugs during pregnancy				
Yes	18 (15.3)	2 (1.7)	**10.40 (2.36-46.09)**	**< 0.001**
No	100 (84.7)	116 (98.3)	1	
Smoking during pregnancy				
Yes	12 (10.2)	1 (0.8)	**13.24 (1.69-103.59)**	**0.001**
No	106 (89.8)	117 (99.2)	1	
Alcohol during pregnancy				
Yes	69 (58.5)	11 (9.3)	**13.69 (6.66-28.15)**	**< 0.001**
No	49 (41.5)	107 (90.7)	1	
Exposure to pesticides during pregnancy				
Yes	54 (45.8)	15 (12.7)	**5.79 (3.02-11.11)**	**< 0.001**
No	64 (54.2)	103 (87.3)	1	

The use of toxic substances during pregnancy, such as traditional medicines (OR: 10.40; $p < 0.001$), tobacco (OR: 13.24; $p = 0.001$) and alcohol (OR: 13.69; $p < 0.001$), increased the risk of having a child with congenital malformations. In addition, exposure to pesticides during pregnancy increased the risk of having a child with congenital malformations by a factor of 5.7 ($p < 0.001$).

CHAPTER 5 : DISCUSSION

This was a case-control study, aimed at evaluating the risk factors associated with congenital malformations, describing the socio-demographic profiles and clinical histories of women who delivered children with congenital malformations, as well as identifying the types of congenital malformations that occur in our context.

To achieve this, we collected data over a period of four months (January to April 2024) from 236 files, of women who gave birth between 2018 and 2022 in YGOPH and YCH. Cases were files of women who delivered children with congenital malformations and controls were files of women who had children without congenital malformations. As observed in other studies, our results confirm that there are socio-demographic, medical and environmental factors associated with the occurrence of congenital malformations.

Characteristics of new-borns with congenital malformations in our study

In our study, the main systems affected with congenital malformations were the musculoskeletal system, the central nervous system and the digestive system, representing 42.4%, 36.4% and 28.8% respectively. This is similar to the findings published in Cameroon and the United States of America in 2019 and in 2015 respectively [6]. It was found that African Americans have a higher risk of having congenital malformations affecting the musculoskeletal system and a lower risk of it affecting the cardiovascular and genitourinary systems [39]. This is most likely due to cultural and genetic predispositions.

A bulk of the children with congenital malformations in our study were born at term, representing 49.2%, with the extremes being at 29 and 41 weeks. This is in line with the findings published in Cameroon, where the population born at term accounted for 63% [6]. This may be linked to the fact that most of the malformations concerned the musculoskeletal system, which constitute minor congenital malformations.

In the present study, there was a disparity in the gender of children born with congenital malformations, with the total percentage of males being 57.6%. This may imply that either there were more male children with congenital malformations or, the male children survive more. This gender profile closely matches that published in Tanzania in 2022, with a male dominance of 64% but contrasts the results in Nepal in 2021, with the females accounting for 52.8% [9,40].

Socio-demographic factors associated with congenital malformations in our study

The mean age of the cases (28.31 ± 7.03 years) was comparable to that of the control group (28.19 ± 6.69 years), with extreme ages being 17 as the lowest age and 47 as the highest age in both groups. However, no association was found between maternal age and the occurrence of congenital malformations. Our finding was different from other studies published in Egypt in 2019 and in Nepal in 2021. In these studies, maternal ages above 35 years and below 20 years were associated with the occurrence of these malformations [2,40]. Genetic predisposition, behavioural and developmental factors like smoking and poor diet could possibly lead to the different findings.

Paternal age was also explored in this study and we found out that men aged between 42 to 50 years were 2.3 times more likely to have children with congenital malformations. Similarly, results published in Nigeria in 2020 showed that paternal ages from 35 upwards were associated with the occurrence of orofacial clefts [41]. Likewise, results published in China in 2020 showed that paternal ages from 40 years upwards were associated with the occurrence of chromosomal, cardiovascular, urogenital and facial malformations [42]. This could be possibly due to the fact that there is more DNA replication with aging, which increases the risk of copy error mutations like insertions and deletions [43].

In our study, cases who have had the university level of education had a lower risk of having children with congenital malformations than those with secondary school level of education. This may be owing to the fact that motherhood during secondary school is usually as a result of unwanted pregnancies, leading to hidden pregnancies hence, poor pregnancy follow up. However, there was no statistical significant difference between level of education and the occurrence of congenital malformations. This closely mirrors the study carried out in Ethiopia in 2021 which revealed that there was no association between maternal educational level and congenital malformations [10].

There was no statistical significant difference between marital status and occupation and the occurrence of congenital malformations in our study. This is possibly due to the fact that the cases had other predispositions with genetic and environmental factors. This supports the findings published in Nigeria in 2022 that showed no association between socioeconomic status and the occurrence of congenital malformations [44].

Clinical characteristics of the study population

There was a 3.6-fold increased risk of the occurrence of CMs with grand multiparity. This was however not statistically significant in our study. Likewise, a similar study in Nigeria in 2019 showed no association between parity and the occurrence of CMs [45]. On the other hand, a study carried out in Qatar in 2023 showed that there was an association between parity and the occurrence of CMs [46].

Analysis of cases with a family history of CMs showed them to be 83 times more likely to have a new-born with a congenital malformation. This was consistent with the findings in Iraq in 2018 which showed an association between family history and CMs [47]. The similarities in the findings may be due to the presence of congenital malformations with genetic origin.

The number of antenatal contacts less than 3, and the start of these consultations from the 20th week of gestation multiplied the risk of having a new-born with CMs by 3.7 and 7.2 respectively. The absence of periconceptional folic acid intake also constituted a risk of having a child with CMs. These are in agreement with results published in Ethiopia in 2021 which observed that there was a significant association between the lack of folic acid supplementation and quality of antenatal care and the occurrence of CMs [48]. This is because during antenatal care consultations, education is usually given on issues like adequate nutrition, avoidance of teratogenic agents and equally various preventive, screening and curative measures which significantly reduce the risk of CMs [48].

We also found out that the presence of ultrasound abnormalities such as polyhydramnios, are associated with congenital malformations. This is due the fact that congenital malformations like oesophageal atresia and duodenal atresia may potentially impair the swallowing reflex and increase amniotic fluid and urine production resulting in polyhydramnios. This finding is supported by results published in Egypt in 2019, reporting that some ultrasound abnormalities result from an underlying CM [2].

Neither infectious pathologies nor chronic pathologies like maternal diabetes and hypertension were associated with congenital malformations in our study. On the contrary, a study in Ethiopia in 2018 found chronic and infectious pathologies like rubella, measles, syphilis and other viral infections to be associated with CMs [49]. Results published in Nicaragua in 2023 also found hyperthermia during the first trimester of pregnancy to be associated with neural tube defects [50]. This may be resulting from the fact that our data collection was carried out in two hospitals in which some of the data records were disorganised hence, some cases were not identified.

Lifestyle during pregnancy

The use of traditional drugs among the cases in our study increased the risk of having a new-born with congenital malformations. This is in line with the findings in Nigeria in 2022 that found a significant number of mothers with malformed children engaged in the consumption of traditional drugs in the antenatal period [44]. Most likely, this is because of the belief that traditional drugs strengthens the foetus and also facilitates labour.

In this study, alcohol intake was found to increase the risk of having new-borns with CMs which is dissimilar to the findings in Ethiopia in 2018 where there was no association between alcohol consumption with the occurrence of CMs [51]. The excessive intake of alcohol in our context could possibly explain this finding.

Smoking and exposure to pesticides has equally been shown to increase the risk of having a new-born with CMs in our study. Congruent with this finding, a study carried out in Ethiopia in 2021 found exposure to pesticides and smoking to increase the risk of having a new-born with CMs. A possible explanation to this is that exposure to these toxic substances during early pregnancy, which is a critical period of embryogenesis has a significant risk of disrupting the developmental process hence, leading to the occurrence of CMs [10].

Limitations of the study

A possible limitation of this study was the fact that it was carried out in 2 hospitals and in one city. Therefore, this might not be the actual picture in the general population.

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CONCLUSION AND RECOMMENDATIONS

CONCLUSION

At the end of this study which had as main objective to study the risk factors associated with congenital malformations in two hospitals in Yaoundé, we can conclude the following:

- The mean age of the cases was 28 ± 7.03 years with 17 as the lowest age and 47 as the highest age.They were not married and were students at university level. They were also mainly pauciparous, had family history of CMs and most did only 0-2 ANC contacts.
- The muscukoskeletal system, central nervous system and the digestive system were mainly affected with a male predominance.
- The associated risk factors for congenital malformations were: paternal age from 42-50 years, family history of congenital malformations, less than three and late onset of antenatal care consultations, lack of periconceptional folic acid supplementation, alcohol consumption, smoking, consumption of traditional drugs, exposure to pesticides.

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RECOMMENDATIONS

From our study, we humbly recommend the following:

To pregnant women

- To have early onset antenatal care
- To avoid alcohol, passive or active smoking and exposure to pesticides.
- To start supplementation of folic acid before conception.

To men

- To avoid having children at advanced ages.

To health personnel

- To educate women on the importance of early onset antenatal care contacts.
- To educate women during their antenatal care contacts on the pertinence of avoiding toxic substances in order to prevent CMs.

To the Faculty of Medicine and Biomedical Sciences, Yaoundé

- To carry out prospective cohort studies for longer periods in more hospitals and different towns on the risk factors for CMs.
- To explore more about the paternal risk factors of CMs.
- To study the risk factors of CMs per systems.

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APPENDIX

APPENDIX 1: RECRUITMENT PERMITS

UNIVERSITÉ DE YAOUNDÉ I
FACULTÉ DE MÉDECINE ET DES SCIENCES BIOMÉDICALES
COMITÉ INSTITUTIONNEL D'ÉTHIQUE DE LA RECHERCHE
Tél/ fax : 22 31 05 86 22 311224
Email: [illegible]

THE UNIVERSITY OF YAOUNDE I
FACULTY OF MEDICINE AND BIOMEDICAL SCIENCES
INSTITUTIONAL ETHICAL REVIEW BOARD

Ref : N°[illegible]/UY1/FMSB/VDRC/[illegible]/CIE

CLAIRANCE ÉTHIQUE

10 JUIN 2024

Le COMITÉ INSTITUTIONNEL D'ÉTHIQUE DE LA RECHERCHE (CIER) de la FMSB a examiné

La demande de la clairance éthique soumise par :

M.Mme : EFETI EWONGO NJOMBE EWUSI Matricule: 17M035

Travaillant sous la direction de :

- Pr MBU Enow Robinson
- Dr EBONG Clifford EBONTANE
- Dr MBOUA BATOUM Véronique Sophie

Concernant le projet de recherche intitulé : Risk factors of congenital malformations in two hospitals in Yaoundé: case-control study

Les principales observations sont les suivantes

Evaluation scientifique	
Evaluation de la convenance institutionnelle/valeur sociale	
Equilibre des risques et des bénéfices	
Respect du consentement libre et éclairé	
Respect de la vie privée et des renseignements personnels (confidentialité) :	
Respect de la justice dans le choix des sujets	
Respect des personnes vulnérables :	
Réduction des inconvénients/optimalisation des avantages	
Gestion des compensations financières des sujets	
Gestion des conflits d'intérêt impliquant le chercheur	

Pour toutes ces raisons, le CIER émet un avis favorable sous réserve des modifications recommandées dans la grille d'évaluation scientifique.

L'équipe de recherche est responsable du respect du protocole approuvé et ne devra pas y apporter d'amendement sans avis favorable du CIER. Elle devra collaborer avec le CIER lorsque nécessaire, pour le suivi de la mise en œuvre dudit protocole.

La clairance éthique peut être retirée en cas de non - respect de la réglementation ou des recommandations sus évoquées.

En foi de quoi la présente clairance éthique est délivrée pour servir et valoir ce que de droit.

LE PRESIDENT DU COMITE ETHIQUE

REPUBLIQUE DU CAMEROUN
Paix-Travail-Patrie
****
MINISTERE DE LA SANTE PUBLIQUE
****
SECRETARIAT GENERAL
****
DIRECTION DE L' HOPITAL CENTRAL DE YAOUNDE
****
SECRETARIAT MEDICAL

N° 0083/24/ AP/MINSANTE/SG/DHCY/CM/SM

REPUBLIC OF CAMEROUN
Peace-Work-Fatherland
****
MINISTRY OF PUBLIC HEALTH
****
GENERAL SECRETARY
****
DIRECTORATE OF CENTRAL HOSPITAL OF YAOUNDE
****
MEDICAL SECRETARY

Yaoundé, le 05 FEV 2024

ACCORD DE PRINCIPE

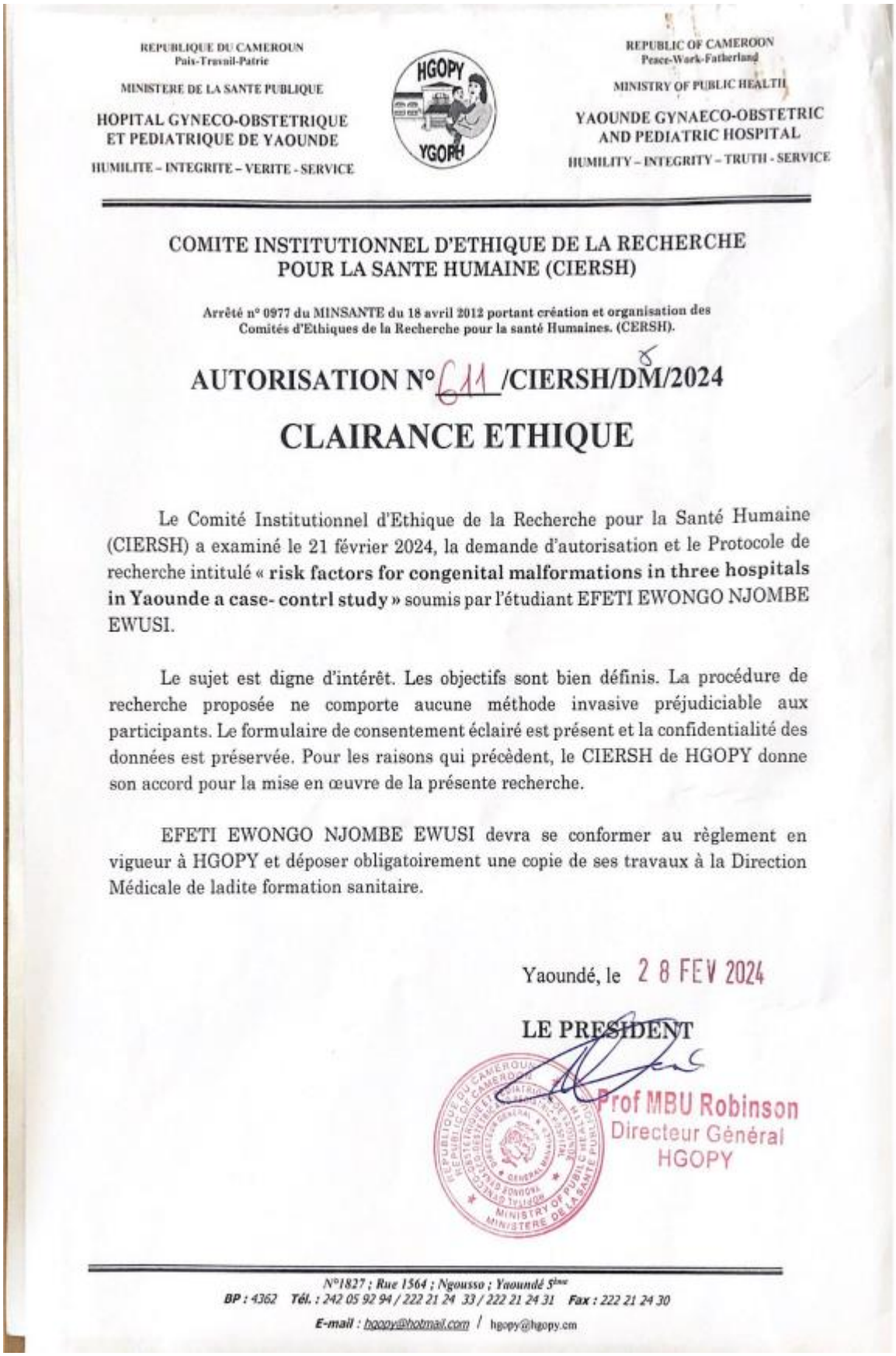
Je soussigné Professeur FOUDA Pierre Joseph, Directeur de l'Hôpital Central de Yaoundé, marque mon Accord de Principe à Madame EFETI EWONGO NJOMBE EWUSI, étudiante en 7ème année de Médecine Générale à la Faculté de Médecine et des Sciences Biomédicales de l'Université de Yaoundé I, sous le thème « RISK FACTORS FOR CONGENITAL MALFORMATIONS IN THREE HOSPITALS IN YAOUNDE: A CASE-CONTROL STUDY » dans le service de Gynécologie et Obstétrique à l'Hôpital Central de Yaoundé, sous la codirection du docteur EBONG Cliford EBONTANE.

Pour Le Directeur et par ordre
Le Conseiller Médical

Le Conseiller Médical
Pr. Mgr Pierre Engolo Zogo

Ampliations :

- Conseiller Médical ;
- Chef service concerné ;
- Intéressée;
- Chrono/Archives.



REPUBLIQUE DU CAMEROUN
Paix-Travail-Patrie

MINISTERE DE LA SANTE PUBLIQUE

HOPITAL GYNECO-OBSTETRIQUE
ET PEDIATRIQUE DE YAOUNDE

HUMILITE – INTEGRITE – VERITE - SERVICE

HGOPY
YGOPH

REPUBLIC OF CAMEROON
Peace-Work-Fatherland

MINISTRY OF PUBLIC HEALTH

YAOUNDE GYNAECO-OBSTETRIC
AND PEDIATRIC HOSPITAL

HUMILITY – INTEGRITY – TRUTH - SERVICE

COMITE INSTITUTIONNEL D'ETHIQUE DE LA RECHERCHE POUR LA SANTE HUMAINE (CIERSH)

Arrêté n° 0977 du MINSANTE du 18 avril 2012 portant création et organisation des Comités d'Ethiques de la Recherche pour la santé Humaines. (CERSH).

AUTORISATION N°611/CIERSH/DM/2024

CLAIRANCE ETHIQUE

Le Comité Institutionnel d'Ethique de la Recherche pour la Santé Humaine (CIERSH) a examiné le 21 février 2024, la demande d'autorisation et le Protocole de recherche intitulé « **risk factors for congenital malformations in three hospitals in Yaounde a case- contrl study** » soumis par l'étudiant EFETI EWONGO NJOMBE EWUSI.

Le sujet est digne d'intérêt. Les objectifs sont bien définis. La procédure de recherche proposée ne comporte aucune méthode invasive préjudiciable aux participants. Le formulaire de consentement éclairé est présent et la confidentialité des données est préservée. Pour les raisons qui précèdent, le CIERSH de HGOPY donne son accord pour la mise en œuvre de la présente recherche.

EFETI EWONGO NJOMBE EWUSI devra se conformer au règlement en vigueur à HGOPY et déposer obligatoirement une copie de ses travaux à la Direction Médicale de ladite formation sanitaire.

Yaoundé, le 28 FEV 2024

LE PRESIDENT

Prof MBU Robinson
Directeur Général
HGOPY

N°1827 ; Rue 1564 ; Ngousso ; Yaoundé 5ème
BP : 4362 Tél. : 242 05 92 94 / 222 21 24 33 / 222 21 24 31 Fax : 222 21 24 30
E-mail : hgopy@hotmail.com / hgopy@hgopy.cm

APPENDIX 2: DATA COLLECTION SHEET

Topic: RISK FACTORS OF CONGENITAL MALFORMATIONS IN TWO HOSPITALS IN YAOUNDE.

Date: ___/___/____
Questionnaire No: ___

Contact: __/__/__/__/__/__/__/__/__/

Recruitment site: YGOPH=1, YCH=2

Group: Case=1, Control=2

Number	Variable	Answer
	1. MATERNAL SOCIODEMOGRAPHIC PROFILES	
1.	Age (in years): 15-19 = 1 20-24 = 2 25-29= 3 30-34 = 4 35-39= 5 40-44= 6 ≥45= 7	
2.	Marital status: Single = 1; Married = 2; Divorced = 3; Widow = 4	
3.	Religion: Christian = 1; Muslim = 2; Atheist = 3	
4.	Level of education: None = 1; Primary = 2; Secondary = 3; High school = 4; University = 5	
5.	Occupation: Civil = 1; Private = 2; Informal = 3; Student = 4; Housewife = 5; unemployed = 6	
6.	Region of origin: Extreme North = 1; North = 2; Adamawa = 3; Centre = 4; Littoral = 5; North West = 6; South West = 7; West = 8; East = 9; South = 10; Foreigner = 11	

	2. CLINICAL HISTORY	
1	Gravidity …….	
2	Parity …….	
3	Alcohol consumption? Yes = 1; No = 2	
4.	Smoking? Yes = 1; No = 2	
6	Exposure to pesticides? Yes = 1; No = 2	
7	Traditional drug consumption during pregnancy? Yes = 1; No = 2	
8	Gestational age at first antenatal consultation <12 weeks = 1 12-15 weeks = 2 16-19 weeks = 3 ≥20 weeks = 4	
9	Number of antenatal consultations 0-2 = 1 3-5 = 2 6-8= 3 >8= 4	
10	Folic acid supplementation? Yes = 1; No = 2	
11	Number of ultrasound scans done 3 ultrasound scans = 1 < 3 ultrasound scans = 2	
12	Personal history of child with congenital malformations? Yes = 1; No = 2	
13	Family history of child with congenital malformations? Yes = 1; No = 2	
14	Paternal age (in years) 15-23=1 24-32= 2 33-41= 3 42-50= 4 51-59= 5 ≥60= 6	

15	Diabetic? Yes=1; No=2	
16	Hypertension? Yes=1; no=2	
17	Syphilis during first/second trimester? Yes = 1; No = 2	
18	Toxoplasmosis during first/second trimester? Yes = 1; No = 2	
19	Rubella during first/second trimester? Yes = 1; No = 2	
20	Hepatitis B? Yes = 1; No = 2	
21	Hepatitis C? Yes = 1; No = 2	
22	HIV? Positive = 1; Negative = 2	
23	Malaria during first/second trimester? Yes = 1; No = 2	
24	Other infections during first/second trimester. Yes = 1; No = 2	
25	If yes, which?	

	3. TYPES OF CONGENITAL MALFORMATIONS	
1.	Baby's sex. Female = 1; Male = 2; undefined= 3	
2.	Gestational age at delivery 28-30= 1 31-33= 2 34-36= 3 ≥37= 4	
3	Stillbirth? Yes = 1; No = 2	
4	Malformations seen on ultrasound scans/at birth? Yes = 1; No = 2	
5.	Systems affected and specific malformation Central nervous system = 1 Cardiovascular system = 2 Pulmonary system = 3 Digestive system = 4 Genitourinary system = 5 Musculoskeletal system = 6	