

Setting Up the Stillbirth Registration System and Investigating the Related Causes in Iran in Selected Hospitals: Observational Cohort Study

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Abstract

Background

One of the major causes of perinatal mortality is stillbirth. In many cases, the cause of stillbirth is difficult to identify, and the cause of many cases remain unexplained. Because of the lack of registration stillbirth system in our country we developed protocol and instructions for stillbirth and setting up a stillbirth registration system in selected hospitals around country.

Methods

Iranian Maternal and Neonatal Network (IMaN) registers information about almost all births (live & dead) around the country, but this network does not collect data about stillbirth causes. In this study, we developed the stillbirth evaluation protocol with experts' cooperation, and we designed forms for the stillbirth registration system electronically. Then we trained related individuals in 14 selected hospital from 12 provinces (14 cities) of Iran. After a year, we extracted, analyzed, and, based on the Relevant Condition of Death Classification (ReCoDe), interpreted the collected data.

Results

A total of 105,562 births and 762 stillbirths registered. In 742 registered stillbirth cases in 14 selected hospitals, the relevant causes were identified in 65.4% of cases, while 34.6% of cases remained unclassified. The most frequent relevant conditions were fetal (33.2%), maternal (9.1%), amniotic fluid (8.8%), placenta (7.7%), and umbilical cord (6.2%).

Conclusions

Our registration decreased the percentage of stillbirth with an unexplained cause from about 70–34.6%.

Background

The incidence of stillbirth varies from country to country and also depends on its definition (1). Based on a report from World Health Organization (WHO), 2.6 million stillbirths happened globally in 2015, most of which belonged to low- and middle-income countries (2). The average stillbirth rate (≥ 22 weeks' gestation) was 7.42 per 1000 total births during 2014-2016 in Iran (3).

The causes of about 25-60% of stillbirths are unknown and this rate in our country reaches up to about 70% (4). Identifiable causes can be related to maternal, placental and fetal factors. Risk factors for stillbirth in developed countries include nulliparity, advanced maternal age, overweight, and fetal growth

disorders (5, 6). In contrast, prolonged labor leading to asphyxia and trauma and multiple infections are the leading causes of stillbirth in developing countries (7).

The "Every Newborn, Action plan" (ENAP) was approved in 2014 at the 67th session of the World Health Assembly. This action plan offers knowledge-based solutions to prevent neonatal mortality and stillbirth. In collaboration with experts and stakeholders around the world, the United Nations Children's Fund (UNICEF) and WHO are leading the program. This action plan aims to put an end to preventable deaths, both infant mortality, and stillbirth. Based on ENAP, the neonatal mortality rate and the stillbirth rate should reach less than or equal to 10 per 1000 live births and 10 per 1000 births (total births) by 2035 in all countries (8).

In addition to imposing a high economic burden on the family and the country's health system, stillbirth has a devastating psychological effect on the mother and can even affect subsequent pregnancies. For this reason, and aligned with ENAP goals, this study was designed to investigate and evaluate the related causes of stillbirth. The project was conducted in two phases:

Phase 1: Exploration of stillbirth rate at the national and sub-national level

Phase 2: Development of protocol and instructions for stillbirth and setting up a stillbirth registration system in selected hospitals of the country

Methods

Phase1:

In the first phase, using Iranian Maternal and Neonatal Network data, we determined the stillbirth rate at the national and provincial levels during three years (2014-2016). Iranian Maternal and Neonatal Network (IMaN) registers almost all births (live & dead) in addition to the maternal and neonatal health information electronically across the country. In this phase, we estimated the average stillbirth rate of 7.42 per 1000 total births during 2014-2016 in Iran. The details of the first phase have been published elsewhere (3).

Phase 2:

To implement Phase 2, we performed a comprehensive review of all protocols, guidelines, and classifications addressing stillbirth in different countries. For this purpose, a committee was formed comprising the project's executive members alongside three gynecologists/obstetricians, an epidemiologist, two pediatricians, and a neonatologist. Various protocols from different countries were reviewed. After an initial internal appraisal by the project team, a summary of available approaches was presented to the scientific committee through several working sessions at the Ministry of Health and Medical Education (MoHME). Ultimately, the committee agreed upon the Wisconsin Stillbirth Service Program (WiSSP) and the Relevant Condition of Death Classification (ReCoDe) to serve as the basis for the scientific protocol.

Once a draft of the protocol was developed, the executive committee reviewed it in terms of scientific and executive merits eventually leading to the final protocol. The elements of ReCoDe were kept unchanged. Furthermore, the protocol was also reviewed by experts from different disciplines and organizations (pathologists, internal medicine specialists, members of the Bureau of Maternal Health at MoHME, and their opinions were considered for finalizing the protocol. In Iran, the chancellors of medical universities are the steward of the health system in their catchment area; in addition to being involved in providing a spectrum of health care from primary health care to advanced hospital care, the universities are involved in accreditation, monitoring, and evaluation of the public non-MoHME and private health care providers. So, we involved some of the medical universities' relevant members in the process of finalizing the protocols. We defined stillbirth as a baby's birth with 22 or more completed weeks of gestation who died before or during labor (9).

Our electronic form included items for physical evaluation of stillborn fetuses and the umbilical cord and placenta evaluation.

Based on the experts' opinions and data analysis from previous years, 14 hospitals from 12 provinces and 14 cities with the highest numbers of deliveries were selected. All selected hospitals were from the public sector, affiliated with one of the medical universities.

In each hospital, relevant individuals were trained about protocol and filling forms. It was a web-based database, and the representatives of the selected hospitals had access to enter data and upload necessary files. Also, three photos of the dead fetus in whole body frontal view, frontal and lateral view of the face, and if possible, an AP babygram X-ray were uploaded in the network. Screenshots of lab results and ultrasounds were also uploaded to the system by relevant and trained staff.

The research team performed regular monitoring through phone and online applications as well as physical field visits. A reminder training workshop and a videoconference were held for relevant staff of the selected hospitals.

As of June 25, 2019, a total of 762 stillbirth cases in 2018 and 2019 were registered in the Stillbirth Registry System. The data were exported in the format of an Excel spreadsheet. The stillbirth forms and photographs were sent to a gynecologist/obstetrician (**S.S**) to classify the cases according to the ReCoDe classification. She was registered as First Observer. A second researcher (**N.Kh.**) reviewed the cases and coded them independently under the ReCoDe classification, which was registered as Second Observer. The first and second observers encoded each case after evaluating the forms, photos, radiographs, tests, and ultrasounds. The discrepancies of cases between two observers were resolved by a third observer (**M.ML**), who carefully evaluated all the documents.

It must be noted that some cases were excluded as they reflected neonatal death. Also, as the system was not designed for twin pregnancies, data from the second twin were added when both twins were stillborn. The data were analyzed using IBM SPSS Statistics v24.0.

Results

Between June 25, 2018, and June 25, 2019, 762 stillbirth cases were registered in the 14 study hospitals; at the same time, 1319 cases were registered by the IMaN system; i.e., 11.7% of stillbirth cases were not captured by IMaN. The number of total births registered by IMaN was 105,562. Among all cases (762 stillbirths), 363 cases (47.6%) were male, 321 cases (42.1%) were female, and 18 cases (2.4%) had ambiguous sex. Also, 120 mothers (15.7%) had a history of stillbirth, and 60 stillbirth cases (7.9%) were twins (30 twins). The nationality of 728 mothers (99.5%) was Iranian, and 34 (4.5%) had other nationalities. Table 1 presents the demographic characteristics of the registered stillbirth (based on the new registration system) and live -birth cases (based on IMaN).

Cohen's Kappa coefficient was used to measure the agreement between the observers in the case of group classification, which was equal to 0.658 (P -value <0.001).

We were able to determine cause of stillbirth in 65.4% of cases, and 34.6% remained unclassified. There is a variable in IMaN called "IUFD cause" that records the causes of intrauterine death based on the available evidence without careful investigation. Based on this variable, the rate of unclassified IUFD cases was 72.1%.

In this study, the most frequent known conditions (primary category) were fetus-related (33.2%), mother-related (9.1%), amniotic fluid (8.8%) placenta (7.7%), and umbilical cord (6.2% each). (Figure 1)

Among fetal causes, lethal congenital anomalies were the most frequent primary category. Details are illustrated in Table 2. Four leading "first relevant categories" were: lethal congenital anomaly (19.3%), non-immune hydrops (5%), fetal growth restriction (4.7%), and abruptio placenta (4.7%).

Table1: Demographic characteristics of stillborn and live birth registered in the selected hospitals (June 25, 2018 - June 24, 2019)

Factors	Stillbirth, N (%)	Live births, N (%)
Child sex		
Male	360 (47.2)	54202 (52.0)
Female	321(42.1)	49989 (48.0)
Ambiguity	18 (2.4)	52 (0.0)
Missing data	63 (8.3)	-
Mother's age		
Less than 18 years	41 (5.4)	4935 (4.7)
18-35	566 (74.3)	82999 (79.6)
More than 35 years	150 (19.7)	16309 (15.6)
Missing data	5 (0.7)	-
Gestational age		
Preterm (22-36 weeks)	557 (73.1)	14899 (14.3)
Term (37-41 weeks)	129 (16.9)	89119 (85.5)
Post term (\geq 42weeks)	0 (0.0)	225 (0.2)
Missing data	76 (16.9)	-
Fetus weight		
ELBW (Less than 999gr)	265 (34.8)	1192 (1.1)
VLBW (1000-1499gr)	100 (13.1)	1450 (1.4)
LBW (1500-2499gr)	133 (17.5)	10092 (9.7)
Normal (2500-4000gr)	149 (19.6)	88362 (84.8)
Macrosomia (More than 4000gr)	13 (1.7)	3147 (3.0)
Missing data	102 (13.4)	-
Fetal stage		
Early (22-28 weeks)	296 (38.8)	979 (0.9)
Late (\geq 28 weeks)	390 (51.2)	103264 (99.1)
Missing data	76 (10.0)	-
Gravidity		
1 gravida	249 (32.7)	32656 (31.3)

Factors	Stillbirth, N (%)	Live births, N (%)
2-4 gravida	347 (45.5)	62601 (60.1)
more than 4 gravida	67 (8.8)	8986 (8.6)
Missing data	99 (13.0)	-
Parity		
0-1	493 (64.7)	72446 (69.5)
2-4	151 (19.8)	29583 (28.4)
≥5	20 (2.6)	2214 (2.1)
Missing data	98 (12.9)	-
Total	762 (100)	105562 (100)

Table2: First and second relevant categories of causes of stillbirth based on ReCoDe classification (14 selected hospitals, Iran, 2018-2019)

Group	Category	First relevant category N (%)	Second relevant category N (%)
Group A: Fetus	Total	253 (33.2)	32 (4.2)
	Lethal congenital anomaly	147 (19.3)	0 (0.0)
	Infection	8 (1.0)	0 (0.0)
	Non-immune hydrops	38 (5.0)	12 (1.6)
	Iso-immunisation	4 (0.5)	1 (0.1)
	Fetomaternal haemorrhage	1 (0.1)	0 (0.0)
	Twin-twin transfusion	5 (0.7)	1 (0.1)
	Fetal growth restriction	36 (4.7)	18 (2.4)
	Other	14 (1.8)	0 (0.0)
Group B: Umbilical cord	Total	47 (6.2)	13 (1.7)
	Prolapse	2 (0.3)	2 (0.3)
	Constricting loop or knot	18 (2.4)	2 (0.3)
	Velamentous insertion	3 (0.4)	3 (0.4)
	Other	24 (3.1)	6 (0.8)
Group C: Placenta	Total	55 (7.7)	26 (3.4)
	Abruptio Placenta	36 (4.7)	12 (1.6)
	Placenta Praevia	1 (0.1)	3 (0.4)
	Vasa Praevia	0 (0.0)	0 (0.0)
	Placental insufficiency /infarction	2 (0.3)	1 (0.1)
	Other	20 (2.6)	10 (1.3)
Group D: Amniotic fluid	Total	67 (8.8)	43 (5.6)
	Chorioamnionitis	1 (0.1)	0 (0.0)
	Oligohydramnios	28 (3.7)	29 (3.8)
	Polyhydramnios	6 (0.8)	4 (0.5)
	Other	32 (4.2)	10 (1.3)
Group E: Uterus	Total	2 (0.3)	1 (0.1)
	Rupture	0 (0.0)	0 (0.0)

	Uterine anomalies	0 (0.0)	0 (0.0)
	Other	2 (0.3)	1 (0.1)
Group F: Mother	Total	69 (9.1)	90 (11.8)
	GDM	26 (3.4)	25 (3.3)
	Diabetes	2 (0.3)	7 (0.9)
	Thyroid diseases	6 (0.8)	22 (2.9)
	Essential Hypertension	6 (0.8)	8 (1.0)
	Hypertensive diseases in pregnancy	16 (2.1)	18 (2.4)
	Lupus/Antiphospholipid Syndrome	0 (0.0)	0 (0.0)
	Cholestasis	0 (0.0)	0 (0.0)
	Drug abuse	1 (0.1)	3 (0.4)
	Infection	0 (0.0)	0 (0.0)
	Cardiac disease	1 (0.1)	3 (0.4)
	smoking	0 (0.0)	0 (0.0)
	HBV	0 (0.0)	0 (0.0)
	HCV	0 (0.0)	0 (0.0)
	VDRL+	1 (0.1)	1 (0.1)
	Other	10 (1.3)	3 (0.4)
Group G: Intrapartum	Total	1 (0.1)	0 (0.0)
	Asphyxia	1 (0.1)	0 (0.0)
	Birth Trauma	0 (0.0)	0 (0.0)
Group H: Trauma	Total	0 (0.0)	0 (0.0)
	External	0 (0.0)	0 (0.0)
	Iatrogenic	0 (0.0)	0 (0.0)
Group I: Unclassified	Total	264 (34.6)	0 (0.0)
	No relevant condition identified	256 (33.6)	0 (0.0)
	No information available	8 (1.0)	0 (0.0)

Discussion

In the present study, we reported stillbirth cases over a 12-month period of the pilot implementation of a new registration system in 14 hospitals. According to the ReCoDe classification, in 742 cases of stillbirth in 14 selected hospitals, the relevant causes were identified in 65.4% of cases, while 34.6% of cases remained unclassified. The most frequent relevant conditions were fetal (33.2%), maternal (9.1%), amniotic fluid (8.8%), placenta (7.7%), and umbilical cord (6.2%). Our registration decreased the percentage of stillbirth with an unknown cause from about 70% in the nationwide IMAN to 34.6%.

Based on other studies, 15% to 20% of stillbirths are associated with congenital anomalies (10). Our results indicated a frequency of 19.3% for congenital anomalies. Such cases may be reduced through preconception consultation and tests, antenatal care, prenatal diagnostic testing, and pregnancy termination (10). A retrospective cohort study of 65,308 singleton pregnancies showed that isolated critical congenital anomalies increase stillbirth risk up to 15 times (11). Close and regular monitoring are recommended for mothers at higher risk due to special medical conditions. According to proclamation number 302/25013, dated November 8, 2011, issued by the Iranian Ministry of Health and Medical Education, screening tests for fetal disorders (including chromosome abnormalities and neural tube defects) must be recommended to pregnant women (12). Due to the high prevalence of congenital anomalies in our study, we recommend programs to provide optimal prenatal care for all mothers, especially those with low socioeconomic status and lower education levels. We recommend free-of-charge or subsidized screening services as the most effective prenatal measures to identify congenital anomalies and chromosome abnormalities.

As intrauterine growth retardation is a common cause of stillbirth, it may be considered a suitable target for reducing the frequency of stillbirths (13, 14). This study defined it as estimated fetal weight (EFW) below the 10th percentile (15).

Sonographic assessment of intrauterine growth must be considered for at-risk patients. Fetal growth charts may help identify intrauterine growth retardation cases and distinguish them from constitutional cases (15). Therefore, serial sonographies are recommended in these cases (16-18).

Unexplained Stillbirth:

Our study found about 34.6% of stillbirths to be unexplained. Based on other studies, this is incredibly challenging, as it hinders the development of effective strategies for preventing stillbirths (19). According to our findings, 51.2% of stillbirths occurred after week 28, among which about 32% were unexplained stillbirths. Unexplained stillbirths constitute the largest category of relevant conditions among stillbirths after week 28, followed by malnutrition and placental abruption. One cohort study investigated the risk factors associated with unexplained stillbirths from 1978 to 1996. The risk factors included higher maternal age (40 years or more; OR=3.7, 95%CI: 1.06 to 1.3), a lower maternal education level (OR=2.5, 95%CI: 1.1 to 5.5), the birth weight ratio between the 2.4th and 10th percentile (OR=2.8, 95%CI: 1.5 to 5.2), and birth weight ratio over the 87th percentile (OR=2.4, 95%CI: 1.3 to 4.4) (20).

Considering all influential factors of stillbirth, developing an interactive model may be beneficial for estimating the risk of stillbirth, similar to models used for estimating the risk of myocardial infarction and mortality due to cardiovascular risk factors. Risk analysis must guide management policies and provide an evidence-based approach to choose the accurate antepartum tests and induction of labor (21). It must be noted that autopsy, placental examination, and genetic tests may reveal the etiology of stillbirth in many of the unexplained cases (22).

Maternal Risk Factors:

Maternal risk factors were the relevant causes of about 9% in this research. Gestational diabetes and hypertensive disease in pregnancy were the most common conditions. Hypertension and diabetes are two common risk factors that impose higher risk to pregnancy (7%-10% and 3%-5%, respectively) (21). Placental insufficiency and abruption are among the most critical causes of stillbirth in mothers with hypertensive disease. Adequate control of blood pressure, eclampsia, and pre-eclampsia may lower stillbirth risk, although premature delivery frequently occurs (23). Historically, these two factors account for a large number of stillbirths, but ideal management incorporating preconception care and consultation has reduced stillbirth in these cases (24). Nevertheless, such patients are often challenging as they are more susceptible to placental abruption, intrauterine growth restriction, and pre-eclampsia. There is limited data on the cost-effectiveness of interventions targeting stillbirth. As discussed before, medical risk factors have a considerable impact on mothers' and children's health; therefore, appropriate medical care and preconception consultation may profoundly affect pregnancy outcome. Care providers are recommended to perform a risk assessment on an individual basis. Screening for hypertension and diabetes is necessary to prevent unfavorable pregnancy outcomes; furthermore, other factors such as advanced maternal age, prepregnancy obesity, infertility, and low education level (as an indicator of low socioeconomic status) must be incorporated in all risk assessments (21).

Advanced maternal age is an independent risk factor for stillbirth. Even after adjusting for risk factors such as multiple pregnancies, hypertension, diabetes, previous miscarriage, and placental abruption, which are more common in older women, maternal age remains an independent risk factor. Advanced maternal age is associated with preterm delivery, fetal abnormalities, and fetal growth restriction (25).

In addition, women aged 35 years or more are at higher risk for stillbirth associated with congenital anomalies (26). With the advent of prenatal diagnostic tests and the possibility of deliberate abortion, these rates have been declining. Longitudinal studies indicate that fetal death with anomalies after week 20 has been gradually replaced by deliberate termination of pregnancy before 20 weeks of gestation (10, 27).

Placental disorders:

Placental abruption was the relevant cause of 4.7% of stillbirths in our study. Placental abruption occurs in almost 1% of pregnancies, but it accounts for some 10% to 20% of stillbirths (28). The risk of fetal

demise amounts to over 50% when the placenta disintegrates or when the placenta's central part is involved. Therefore, the placenta's gross and microscopic examination should be considered an integral part of stillbirth assessments (29).

Umbilical Cord:

Umbilical cord abnormalities accounted for 10% of fetal deaths in a population-based study (28). Almost like our study, umbilical cord abnormalities were responsible for 6% of stillbirths. An umbilical cord knot may provide an immediate, potential explanation of fetal death for the physician and the patient; nonetheless, death should be attributed to the umbilical cord knot only after a comprehensive search for other causes and when other findings corroborate this diagnosis (28).

In our study, we benefited from a large sample size from different geographical part of Iran. This study was one of the first study that registered related causes of stillbirth in our country. But we have some limitations for example missing data on some variables and our data base for registering stillbirth had limitation for uploading photos of dead fetus add screenshots of lab data. Only 6 photos could be uploaded. In cases where more photos were needed, the photos were sent to the research team via WhatsApp.

Conclusions

Expanding the stillbirth registration system in the country can reduce the number of unexplained cases. Identifying the causes of stillbirth based on registration information will improve the quality of data. Also, we can improve the quality and access to perinatal care for vulnerable women and enhance diagnostic and management strategies for high -risk fetuses.

Abbreviations

ReCoDe: Relevant Condition at Death

IMaN: Iranian Maternal and Neonatal Network

WHO: Word Health Organization

Declarations

Ethical approval and consent to practice:

Our study have been performed in accordance with the Declaration of Helsinki. It was reviewed and approved by the Ethics of Research Committee at the School of Medicine, Iran University of Medical Science at 4/22/2107. All experimental protocols were approved by the medical research ethics committee of Iran University of Medical Science. The ethics committee's code is IR.IUMS.REC 1395.95-03-221-29716. All methods were performed in accordance with the relevant guidelines and regulations.

The members trained by our team were in fact birth registrars at selected hospitals, and that was part of their duty. The members we trained for the study were not directly involved in the study.

However, these participants were praised and rewarded. Informed consent was obtained from all legal guardian of participants.

Consent for publication:

Not applicable

Availability of data and materials:

The datasets generated and/or analyzed during the current study are not publicly available due to confidentiality but are available from the corresponding author on reasonable request.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:

N. KH. and M.M.L. conceptualized this paper and drafted it with contributions from M.H, A.H, M.M, S.S, M.K and F.T. All other authors participated in the analysis, and reviewed the findings, and contributed to the interpretation of the results. All authors approved the final version of the paper.

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Figures

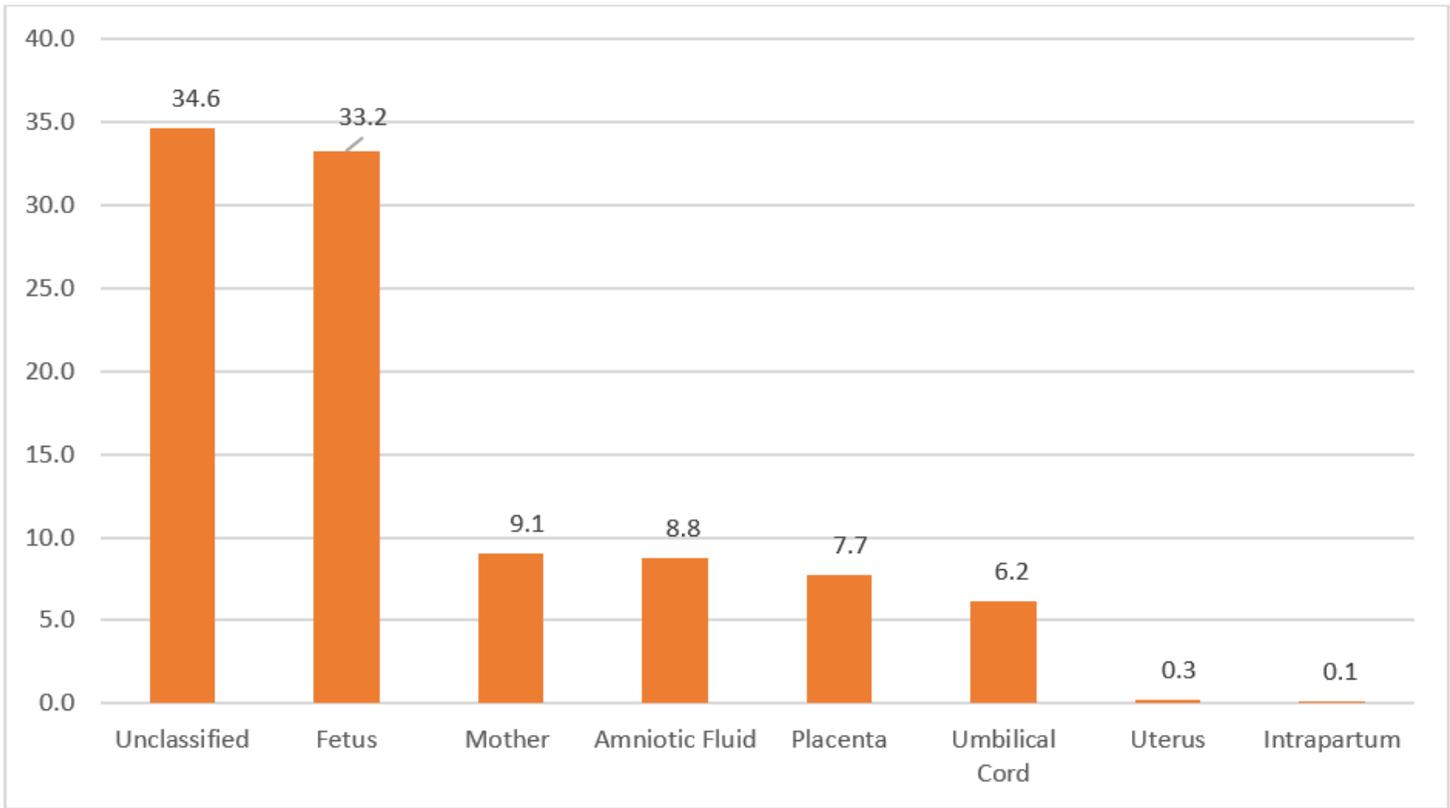


Figure 1

Frequency of first relevant groups based on ReCoDe classification (n= 762)