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A retrospective study of factors associated with intrauterine fetal death in antenatal and labour wards in Princess Marina Hospital in Gaborone, Botswana

By

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Approval page

The research proposal has been examined by my supervisor, approval by an external examiner and submitted to the school of Graduate studies in the University of Botswana in partial fulfillment as for the award of degree of Masters Nursing Science.

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Statement of originality

I declare that "A retrospective study of factors associated with intrauterine fetal death in antenatal ward in Princess Marina Hospital in Gaborone, Botswana" is my own work and all the sources used have been acknowledged through means of complete references. This work also has not been submitted for any other academic purposes.

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Sign: …… Date: ……

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Abstract

Introduction

Intrauterine fetal death (IUFD) or stillbirth is stillbirth as fetal death deliveries after 24 completed weeks of gestation with weight of > 500g and does not show any sign of life at any time after delivery. Around 3.2 million of fetal deaths occur per year worldwide, and 98% of these deaths are reported in low and middle income countries. Botswana had stillbirth rate of 16.1 in 1000 births and 6.9 per 1000 births in 2009 and 2014 respectfully.

Underreporting of IUFD cases, improper identification of etiological factors, and lack of uniformity in data collection and classification of causes of fetal death lead to the difficulty in preventing fetal death worldwide. Botswana seems to be amongst the countries that do not have studies that indicate the magnitude of IUFDs. It also seems like the country does not have the health policies, guidelines or protocols that embrace the causes and prevention of IUFDs.

Identifying the cause of death enables comparison of national and international health care, and also assists in identifying prevention measures. It is therefore important that countries like Botswana conduct studies and research on contributing factors towards IUFD in order to generate data about preventable causes, and strategies that can be formed to reduce new incidences in the future.

Purpose of the study

The purpose of this study is to conduct a retrospective analysis of data on patients' files in order to identify antepartum and intrapartum factors contributing towards IUFD at antenatal and labour wards in PMH.

Method

A quantitative retrospective descriptive institution based study will be conducted by reviewing all records of mothers who had IUFDs/stillbirths in antenatal ward and labour ward in Princess Marina Hospital (PMH) from January 2013 to December 2018. Around 1518 patient records of mothers who had intrauterine fetal death/stillbirth will be reviewed. Data collection form will be used to extract information on possible factors contributing to IUFD such as maternal factors, socioeconomic factors, management factors, socioeconomic factors, management factors, labour and delivery factors, demographic factors, fetal factors, placental and umbilical factors.

Sample size

All records of mothers who had IUFDs/stillbirths (around 1518) from 2013 to 2018 will be reviewed in this study.

Selection

Convenience sampling will be used to select all the records of mothers who had IUFD/stillbirth from antenatal and labour wards for in PMH.

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LIST OF ABBREVIATIONS

ANC: Antenatal care

APH: Antepartum haemorrhage

IUFD: Intrauterine fetal death

PPH: Postpartum haemorrhage

PROM: Premature rapture of membranes

PIH: Pregnancy Induced Hypertension

SPSS: Statical Package for Social Sciences

UNICEF: United Nations International Children's Emergency Fund

WHO: World Health Organisation

CHAPTER 1

1.1 Introduction and background

This chapter provides an overview of the study. The reader is introduced to the background, problem statement, purpose of the study, objectives of the study, research questions, significance of the study, operational definitions, conceptual framework, literature review, and study methods.

Fetal death at any point during gestation is a traumatic event not only to the family but also to the caregiver. Intrauterine fetal death (IUFD) occurs either before onset of labour (antepartum death) or during labour (intrapartum death) and this fetus when delivered is referred to as stillbirth (Safarzadeh et al, 2014). The gestational age at which intrauterine demise is considered as stillbirth is different in various studies and countries. .

World Health Organisation (WHO) (2006) defined intrauterine fetal death or stillbirth as death before expulsion or removal of a product of conception from its mother, regardless of the duration of pregnancy; the death is indicated by absence of signs of life of a newborn after delivery, such as absence of: heartbeat, pulsation of the umbilical cord or definite movement of voluntary muscles.

Bano, Asif, Qmar & Asif (2016) on the other hand defined stillbirth as fetal death deliveries after 24 completed weeks of gestation with weight of > 500g and does not show any sign of life at any time after delivery. Choudhary & Gupta (2014) defined IUFD as death of fetus in the uterus at or after 24 weeks of gestation. These are the definitions adopted for this study, and so the terms IUFD and stillbirth will be used interchangeably throughout.

According to Korteweg, Gordijn and Timmer (2010), intrauterine fetal death (IUFD) can be divided into two: i) Antepartum Intrauterine Death (IUD), whereby fetal death occurs in the antenatal period and ii) Intrapartum fetal death, whereby fetal death occurs during labour. It is estimated that about two thirds of the IUFDs occur during the antepartum period (Choudhary & Gupta, 2014), while one third of the IUFDs take place during the intrapartum period (McNamara, O'Donoghue, & Greene, 2018)

Bano et al (2016) have identified that improper identification of etiological factors, lack of uniformity in data collection and classification of causes of fetal death have led to the difficulty in preventing fetal death worldwide. Nevertheless, some researchers revealed that there are risks and causative factors associated with fetal death. Dave, Patidar, Goyal and Dave (2016) shared that several maternal demographic factors such as weight, age, education level, socioeconomic status, social habits, are associated with increased risk of intrauterine fetal death.

Garg and Kumar (2017) on the other hand suggested that antepartum intrauterine death is caused by anaemia, hypertensive disorders of pregnancy, and accidental hemorrhage, while prematurity, birth asphyxia, congenital malformation and cord prolapse may result in intrapartum stillbirths. However, most of these causes are preventable and fetal outcome can be improved by provision of good health care services during antepartum and intrapartum period (McNamara et al, 2018).

Stillbirth is absent from the Millennium Development Goals (MDG), remains missing in the Sustainable Development Goals (SDG), and persists to be a neglected issue, invisible in policies and programmes, underfinanced and in urgent need of attention (Heazell, Siassakos, Blencowe, Burden, Bhutta, Cacciatore… et al, 2016). The End Preventable Stillbirth (EPS)

series launched in January 2016 in London exposed the neglected issue of stillbirths that has not received the necessary focus at global and country levels. The main aim of the launch was to call at attention of stillbirths as a global public health issue. During the launch, the team provided updated estimates, assessed the impact of stillbirths on women and societies, and presented evidence for action to end preventable stillbirths by 2030 (Lawn, Blencowe, Pattinson, Cousens, Kumar, Ibiebele…et al, 2016). As a strategy to address the issue of preventable stillbirths, the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) established a goal to be achieved by 2030 for fetal mortality rate of 12 or less stillbirths per 1000 births (Lima, Junior & Takano, 2016). This should be achieved by all UNICEF member countries including Botswana.

The prevalence of IUFD has decreased in developed countries. However, it remains very high in underdeveloped and developing countries and the incidence rate varies in different parts of the world (Garg & Kumar, 2017). Kurse & Baruash, (2016) stated that stillbirth on its own, not under perinatal mortality has been accounted by only 2% of the world's vital registration. Perinatal mortality is the number of stillbirths in the first week of life per 1000 births (Singh, Pandey, Gupta, Arya, Pratap, Naik (2013). According to WHO (2006) perinatal mortality indicator plays a vital role in providing the information needed to improve the health status of pregnant women, new mothers and newborns. This is a main marker to assess the quality of health care (Singh et al, 2013) and the information could also be used to identify the contributing or causative factors of IUFD.

It is estimated that around 3.2 million of fetal deaths occur per year in the world and 98% of these deaths occur in low and middle income countries (Bano et al, 2016). According to

Neogi, Negandhi, Chopra, Das, Zodpey, Gupta et al (2016) 70% of the 98% are contributed by the developing countries in Asia and Sub Saharan Africa.

The above statement is supported by Dave et al (2016), who estimated that globally, the number of stillbirths in 2009 was 2.64 million with the highest stillbirth rates found in South Asia and Sub-Saharan Africa. On the other hand, Neogi et al (2016) also shared similar sentiments when they estimated a stillbirth rate of 25.5 per 1000 total births for developing countries, with Sub-Saharan Africa representing the highest rate of 32.2 per 1000 total births, followed by South Asia with a stillbirth rate of 31.9 per 1000 total births. At a national level, the lowest stillbirth rates were in Finland and Singapore (both 2.0 per 1000 births) and in Denmark and Norway (both 2.2 per 1000 births). The five countries with the highest rates were Pakistan (47 per 1000 births), Nigeria (42 per 1000 births), Bangladesh (36 per 1000 births), Djibouti (34 per 1000 births), and Senegal (34 per 1000 births) (Safarzadeh et al, 2014). Statistics Botswana (2014) revealed that stillbirth rate for Botswana in 2009 was 16.1 per 1000 births while in 2014 it was recorded as 6.9 per 1000 births.

1.2 Problem Statement

Stillbirth has far-reaching consequences for parents, caregivers, communities, and society that are frequently overlooked and underappreciated (Leisher, Lawn, Kinney, Kuo, & Bernis 2016). Literature review from different countries revealed that different factors such as maternal factors, socio-economic factors, labour and delivery factors, umbilical cord factors, placental factors, fetal factors and demographic factors may contribute significantly towards IUFDs. Fetal deaths bring about the experience of guilt, anger, blame, anxiety, sadness, or fear of litigation and disciplinary action which may affect the caregivers both personally and professionally (Heazell et al., 2016.

Botswana seems to be amongst the countries that do not have health policies, guidelines or protocols that embrace the causes and prevention of IUFDs. Literature search also did not yield any studies that indicate the magnitude of IUFD in Botswana.

Botswana statistics (2014) revealed that the country had stillbirth rate of 16.1 in 1000 births in 2009 while in 2014 the stillbirth rate was 6.9 per 1000 births. Approximated numbers from Princess Marina Hospital (PMH) labour ward for 2014 and 2016 showed stillbirth rate of 38 (stillbirth-248, births- 6540) and 38.5 (stillbirths-258, births-6704) per 1000 births respectively. Although the numbers exist, it seems like they are not used in any way to appreciate the costs they bring to families and the government or at least be used to prevent new cases of stillbirth in the country.

Bano et al (2016) indicated that underreporting of stillbirths is common in developing countries and there is the likelihood that an additional 1-2 million stillbirths are not reported. If countries like Botswana continue to ignore the occurrence of stillbirth, the perinatal mortality will remain high indicating poor health quality. The financial and psychological costs to the women, families and health caregivers will also remain high.

According to Korteweg et al (2008), identifying the cause of death helps parents in their mourning process and to find closure to determine the recurrence risks, assists in counseling for future pregnancies, enables comparison of national and international health care, and also assists in identifying prevention measures. Therefore, there is need for detailed studies and research on contributing factors towards IUFD in order to generate data about preventable causes, and strategies that can be formed to reduce new incidences in the future. The results of the study will inform and guide the policy makers to be able to address the problem.

1.3 Purpose of the study

The purpose of this study is to conduct a retrospective analysis of data on patients' files in order to identify antepartum and intrapartum factors contributing towards IUFD at antenatal and labour wards in PMH.

1.4 Objectives of the study

1. To determine the prevalence of stillbirths in antenatal and labour wards in PMH for the years 2013 to 2018
2. To identify maternal, demographic and socioeconomic factors associated with antepartum and intrapartum fetal death.
3. To establish fetal, placental, umbilical, labour and delivery factors contributing towards IUFD
4. To determine management factors contributing towards antepartum and intrapartum fetal death.

1.5 Research questions

1. What is the prevalence of stillbirth in antenatal ward for the years 2013 to 2018?
2. What are the maternal, demographic and socioeconomic factors associated with antepartum and intrauterine fetal death?
3. What are the fetal, placental, umbilical, labour and delivery factors associated with IUFD?
4. What are the management factors contributing towards antepartum and intrauterine fetal death?

1.6 Significance of the study

1.6.1 Significance of the study to midwifery curricula

The information would be used to contribute towards midwifery nursing and medical teaching curricula by adding necessary content for sensitization of students on factors contributing towards fetal mortality and prevention measures in Botswana.

1.6.2 Significance of the study to nursing and midwifery practice

Critical use of information obtained from this study may be included in the guidelines and protocols for easy reference on daily work activities.

1.6.3 Significance of the study to policy formulation

The research information may be used as a foundation to develop or review policies, guidelines and health programs for prevention of IUFDs in Botswana.

1.6.4 Significance of the study to future research

Due to lack of prior research on fetal death issues in Botswana, the information may be used to form the basis of research knowledge for future researchers on the topic in the country.

1.7 Operational definitions

For the purpose of this study the terms used in this study will be defined as:

Antepartum fetal death: fetal death occurring during the antenatal period (Korteweg, Gordijn & Timmer, 2010)

Intrauterine Fetal Death (IUFD): Death of fetus in utero after 24 weeks of gestation (Patel, Thaker, Shah, Majumder, 2014).

Intrapartum stillbirth: Death of a fetus after 24 weeks of gestation during the intrapartum period (Korteweg, Gordijn & Timmer, 2010).

Stillbirth: A newborn delivered after 24 completed weeks of gestation and does not show any sign of life at any time after delivery and weighing > 500g (Bano et al, 2016).

Stillbirth rate: Number of stillbirths per 1,000 births (live births and stillbirths from 24 weeks gestation and/or weighing ≥500g) (World Health Organisation, 2006).

Perinatal mortality: Death of the child during the period between the 24th week of gestation and the end of the first week (7 days) of life including stillbirths (Singh, Pandey, Gupta, Arya, Pratap, & Naik, 2013)

Perinatal mortality rate: Number of stillbirths and neonatal deaths per 1000 total births (Singh, Pandey, Gupta, Arya, Pratap, & Naik, 2013)

Antenatal care: This is the care a pregnant woman receives from the onset of pregnancy till onset of labour (Kanavi, Shobha, & Kavita, 2017).

Intrapartum care: This is the care woman receives while in labour, during delivery and immediate postpartum period i.e. first one hour after delivery (Jamal & Agarwal, 2017).

1.8 Conceptual Framework

A conceptual framework is a structure which the researcher believes can best explain the natural progression of the phenomenon to be studied. It is the researcher's explanation of how the research problem would be explored. The conceptual framework presents an integrated way of looking at a problem under study. It assists the researcher in identifying and constructing his/her worldview on the phenomenon to be investigated (Adom, Adu-Gyamfi, Agyekum, Ayarkwa, Dwumah, Abass et al, 2018). A Fishbone conceptual framework from Kaoru Ishikawa in the 1960s will be adopted and used as a guide in this study to elaborate on different factors contributing towards intra uterine fetal death. This conceptual framework was used because it

applies the use of the cause and effect analysis aimed at identifying all the possible causes of a problem. This is applicable to this study because it may assist in identifying the possible causes or contributing factors of IUFD/stillbirth.

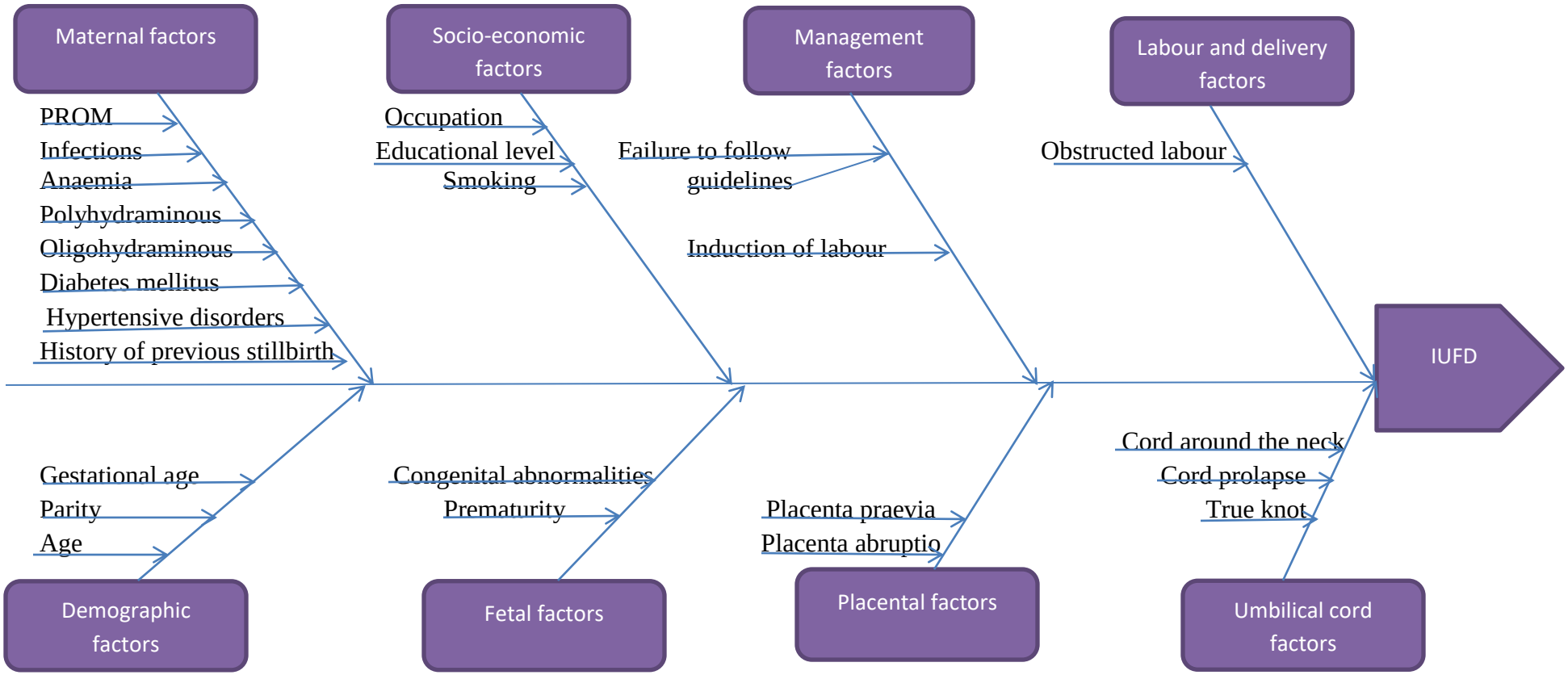
1.9 Description of the fishbone model

The Fishbone diagram/model (also called the Ishikawa diagram) is a tool for identifying the root causes of quality problems. It was named after Kaoru Ishikawa, a Japanese quality control statistician, the man who invented and pioneered the use of this chart in the 1960's (Juran & Godfrey, 1999). The Fishbone diagram is an analysis tool that assists in examining the effects and the causes that create or contribute to the problem. Fishbone diagram may also be referred to as a cause-and-effect diagram because of its function (Ilie & Ciocoiu, 2010). According to Liliana (2016), construction of a Fishbone diagram is a structured approach that helps to determine the root causes or characteristic of a problem. The studied effect is the fish head, and the horizontal line represents the spine of the fish while the bone structure is represented by the categories of the causes and the possible causes (within the categories).

Ilie and Ciocoiu (2010) were applying the fishbone diagram to determine the risk of an event with multiple causes.

Figure 1.1

The Fishbone diagram



Adopted from: Ilie & Ciocoiu (2010

1.10 Application of the fishbone model to the study

In conceptualization, this study seeks to use the fishbone model since it is applicable in studying factors contributing towards IUFDs. There is a correlation between event (IUFD/stillbirth) and its multiple causes or contributing factors

In the above diagram the head of the fish is the problem status which is the IUFD, and from the head is the straight horizontal line representing the spine of the fish. The spine carries the message from the different parts of the fish e.g. from the ribs through the spine to the head. The ribs of the fish are represented by the 8 arrows pointing from the spine. The arrows represent brainstormed categories of possible causes of IUFD which are the maternal factors, socioeconomic factors, management factors, labour and delivery factors, demographic factors, fetal factors, placental factors and umbilical factors. Emerging from the lines of categories are the lines representing brainstormed possible causes within the categories which could contribute to the IUFD, e.g. a possible cause of IUFD within placental factors category could be placenta abruptio. The possible causes under different categories in the diagram are: Maternal factors category (PROM, infections, anaemia, polyhydraminous, oligohydraminous, diabetes mellitus, hypertensive disorders, history of previous stillbirth), socio-economic factor category (occupation, educational level, smoking), management factor category (failure to follow guidelines, induction of labour), Labour and delivery factor category (obstructed labour), demographic factor (gestational age, marital status, parity, age), fetal factor category (congenital abnormality, prematurity), placental factor category (placenta praevia, placenta abruptio), umbilical cord category (cord around the neck, cord prolapse, true knot). These are the same factors which will be used to guide the data collection form.

1.11 Conclusion

Literature revealed that around 3.2 million stillbirths occur globally every year. In Botswana 16.1 and 6.9 stillbirth rate was reported in 2014 and 2016 respectively, while in PMH for the same years the stillbirth rate was at 38 and 38.5. Despite this, there is lack of recognition of stillbirth in the global health policies and programs. This is therefore a call for urgent attention for countries to record, report and come up with strategies to reduce the rate of stillbirths. If not attended, stillbirth can result in depression amongst mothers and their families. Health care providers also experience some guilt, anger, anxiety and sadness and also live in fear of litigation and disciplinary action. It is through analysis of IUFDs and stillbirth cases that good health care strategies to improve the services could be identified and implemented.

CHAPTER 2

2.0 LITERATURE REVIEW

2.1 Introduction

Literature review involves compiling, classifying and evaluating the research that has already been written by other researchers on a topic of interest. These have the benefits of enriching the researcher with the history about the topic and so enabling her/him to gain an understanding of the relationships between the subject of study and other subject areas (Hart, 2018). This chapter presents literature review on factors associated with intrauterine fetal death in antenatal ward in Princess Marina Hospital in Gaborone, Botswana. A systematic search of published articles will be conducted from different online databases such as; Google scholar, Ebscohost, Proquest Central, PubMed and HINARI to identify sources for this literature review. Key terms used for the search of literature were: IUFD, fetal death, intrauterine death, stillbirth and fetal demise.

2.2 Unexplained fetal deaths

Unexplained stillbirth is said to account for about 25-60% of stillbirths (Korteweg et al, 2008). A substantial body of research revealed that causes of IUFD/stillbirth could not be identified in some cases; Singh et al (2013) 33.4%, Patel, Thaker, Shah, & Majumder (2014) 38.4%, Dave et al (2016) 12.5%, Liu, Wang, Yu, & Su (2014) 25-60%. According to the articles, it is evident that a significant that some stillbirths are due to unknown cause.

2.3 Demographic factors

2.3.1 Maternal age

Fetal mortality rate vary considerably by maternal age. Studies conducted by Bano et al (2016) revealed that and Safarzadeh, Ghaedniajahromi, Ghaedniajahromi, Rigi, and Massori, (2014) revealed that majority of women who had IUFDs were between 21-30 years (51.33%) and (41.5) followed by 31-40 (28.67%) and (29.40%) respectfully. Garg and Kumar (2017) also indicated that IUFD was common amongst age group 20-30 (61%). Results found in the study by Singh et al (2013) showed that IUFD rate was high among age groups 26-30 (27%), followed by 21-25 (25.67%) while Choudhary and Gupta (2014) revealed that IUFD was common amongst age group 21-25 (45.71%) and 26-30 (36.91%).

In contrary, results from the study done by Ahmad (2014) and Amuni, Unkels, Mdegela, Utz, Adaji, and den Broek (2014) revealed that high maternal age at childbearing is consistently associated with an increased risk of fetal death and the risk increases more with advancing age above 35 years.

Different studies have different views concerning the association between age and IUFD/stillbirth. Therefore, more studies need to be done in Botswana so that it can be easy to link the age groups with IUFDs/stillbirth.

2.3.2 Parity

Some studies indicated that primiparity and grand parity equally affected IUFDs. The study conducted by Singh et al (2013) revealed that 25% of the IUFDs occurred in primigravidas while 24 % occurred in multiparas. Bano et al (2016) also observed that primiparity and multiparity contributed 49.33% and 50.6% of IUFDs respectfully. As they were systematically reviewing different studies which were reporting on factors associated with and cause(s) of

stillbirth in low- and middle-income countries, Amuni, et al (2014) shared that developing countries such as Palestine, Nigeria, Vietnam, Ghana, Pakistan, Nepal and Uganda indicated that both primiparity and grandmultiparity have been associated with IUFD.

Garg and Kumar (2017) on the other hand reported that the incidence of IUFD was higher in multigravida (72.5%) as compared to primigravida (27.5%) and similar observations were made by Patel et al (2014) where they revealed that multigravidas contributed (60%) while primigravida contributed (40%) of the fetal death cases. Another study by Divya, Nayak and Swarup (2015) also substantiated the view by indicating that 60.8% of stillbirths occurred in multiparas while 39.1% in occurred in primigravidas.

Dissimilar observations were made through the studies which revealed that primigravidas had more IUFDs than multiparas, Dave et al (2016) 44.5%, Patel et al (2016) 47.05%, and Ghumare & Morey (2016) 54.3%. It is evident from the literature above that studies need to be done locally to try and identify if parity has any link with IUFDs/stillbirth because different studies share different findings.

2.3.3 Gestational age

In their study conducted in 2013, Singh et al indicated that majority of IUFDs (64.2%) were from 37 to 40 weeks of gestation whereas preterm IUFDs accounted for 31, 07% of total IUFDs. This seemed to align with the study by Yagnik and Gokle (2016) which shared that maximum stillbirths were seen in women at 36-39 weeks of gestation (43%) followed by 32-35 weeks (38%) then 28-31 weeks (10%).

In contrast, several studies pointed out that the rate of IUFD was high with low gestational age. Safarzadeh et al (2014) in their study highlighted that the rate of IUFD tended to decrease with increasing gestational age. The results of the study showed that 62.7% IUFDs

occurred between 22-32 weeks while 37.3% occurred between 33-42 weeks. This view seemed to be supported by Garg and Kumar (2017) who shared that 57.5% of IUFDs occurred between 24-35 weeks of gestation while 36.25% occurred between 36-40 weeks and 6.25 of them happened at 41 weeks and above. Divya et al (2014) also revealed that 55% of IUFDs occurred between 28-36 weeks of gestation, 11.7% between 37-42 weeks while 33.3% occurred below 28 weeks. Different studies associated IUFD with different gestational age i.e. second and third trimester or postdates. This implies that fetal demise can occur anytime during pregnancy, and so health care givers should be alert throughout to prevent IUFDs.

2.4 Maternal conditions

Underlying maternal morbidity is stated to be increasing the risk of stillbirth in a number of developing countries (Amuni et al, 2014).

2.4.1 Hypertensive disorders in pregnancy

Liu et al (2014) during their system review of major factors for stillbirth in different trimesters of pregnancy established that about 10% of all stillbirths related to maternal medical illnesses, were associated with hypertension. Different studies revealed that hypertensive disorders contributed to IUFD, Patel, Sirpurkar and Patel (2016) 27.3%, Garg and Kumar (2017) 28.7%, Choudhary and Gupta (2014) 28.7%, Dave et al (2016) 21.5% and Jamal and Agarwal (2017) 41%.

Some authors singled out forms of hypertensive disorders as major contributing factors to IUFD. Safarzadeh et al (2014) shared a common sentiment that pre-eclampsia contributed towards IUFDs at 24.39%. Patel et al (2014) on the other hand associated Pregnancy Induced Hypertension (PIH) with 33.7% of the cases, while Divya et al (2015) associated pre-eclampsia (25%), gestational hypertension (2.5%) and chronic hypertension (2.5%) with IUFDs.

Generally all the articles studied above indicated that hypertensive disorders contributed significantly to IUFDs. The hypertensive disorders noted from the articles were pre-eclampsia, PIH and chronic hypertension.

2.4.2 Diabetes mellitus

According to Ahmad (2014), pregnancy in women with diabetes is associated with an increased risk of fetal death, and the incidence of this disorder is increasing. Studies included in the review reported a three to four-fold increased risk of fetal death in women with diabetes type 1 and a two to three fold increased risk among women with diabetes type 2. Different articles in the same review indicated that the increased risk among women with diabetes may pertain to higher prevalence of other risk factors such as high maternal age, hypertensive disorders, congenital anomalies (especially cardiac anomalies), and fetal macrosomia.

Liu et al (2014) in their study revealed that diabetic pregnancy was responsible for about 3% of all IUFDs and the stillbirth rate for pregnancies complicated by diabetes mellitus ranged between 5-35 in1000 births. Divya et al (2015) and Choudhary and Gupta (2014) indicated that diabetes contributed 4.2% of the IUFDs. The findings were similar to those found by Bano et al (2016) which indicated that diabetes was seen in 4.6% of the cases. Some variations were reported in the study by Singh et al (2013) in which they indicated that diabetes was associated with as little as 1.35% of the cases. The reviewed articles reveal that diabetes is graded low in relation to its association with IUFD.

2.4.3 Anaemia

Several authors share similar sentiments that anaemia is associated with high incidence of IUFD. A substantial literature attributed anaemia to IUFD, Sharma, Sidhu and Kaur (2016) 74.4%, Choudhary et al (2014) 41.6%, Jamal and Agarwal (2017) 25%, Singh et al (2016) 16.55%, Garg and Kumar (2017) 15%, Patel et al (2014) 11.2%, Bano et al (2014) 4.66%, and Dave et al (2016) 4.5%. According to the articles above anaemia seems to be contributing towards IUFD and so it needs to be corrected throughout the stages of pregnancy.

2.4.4 Infections

Only a few investigations from the studied articles seemed to have evaluated the association of infections and IUFD. According to Ahmad (2014) maternal bacterial or viral infections during pregnancy have been reported to account for approximately 12% of fetal deaths in high-income countries. The microorganisms most frequently isolated in fetal death were group B streptococcus, Escherichia coli and Enterococcus fecalis. Results in the study by Jamal & Agarwal (2017) indicated that 16.7% of IUFD cases were associated with maternal infections. Patel et al (2016) on the other hand linked 10% of the cases to infections. Garg & Kumar (2017) shared that infection was noted in 5% of the cases, while Divya et al (2015) and Aminu et al (2014) indicated that infections were found in 2.5% and 1.3% cases respectfully. The articles showed that a variety of maternal infections contributed to IUFDs.

2.4.5 History of previous stillbirths

Singh et al (2016) pointed out that a past history of intrauterine fetal death indicates some subclinical genetic or chromosomal problem which can recur in future pregnancies. In their study, the authors pointed out that history of previous IUFD was seen in 4.05% cases. This was similar to a study by Divya et al (2015) in which IUFD was noted in 3.3% cases. Sharma et al

(2016) also revealed that there was a history of previous stillbirth in 9.2% of the women with stillbirth, while Yagnik & Gokhle (2016) shared that 8% of the cases had past history of stillbirths. This then shows that women who had stillbirth are at high risk of having another stillbirth.

2.4.6 Oligohydraminous and polyhydraminous

Dave et al (2016) shared that oligohydraminous contributed to 7.5% while polyhydraminous caused 2% of the IUFDs while Divya, Nayak and Swarup (2015) mentioned that oligohydraminous was associated with 7.6 % of the cases. Patel et al (2014) in their study had the impression that oligohydraminous caused 6.2% of IUFDs. It is evident from the articles that both oligohydraminous and polyhydraminous can equally contribute towards IUFD.

2.4.7 Premature Rapture of Membranes (PROM)

Several researchers indicated that PROM contributed to IUFD. Dave et al (2016), Safarzadeh et al (2014), Garg and Kumar (2017), and Choudhary and Gupta (2014) linked PROM with 2%, 22%, 3.2%, and 2.86% of the cases respectively.

2.5 Socioeconomic factors

2.5.1 Occupation and education level

Review of literature revealed that some researchers noted that socio-economic factors can affect fetal outcome. Patel et al (2016) indicated that majority of cases belonged to low socioeconomic status (58.8%) while Sharma et al (2016) revealed that 71.2% of women with IUD were from low-income group. In their study, Kumar et al (2016) claimed that illiteracy, poor socioeconomic condition and social status of women were important contributory factors responsible for higher fetal mortality rate, since these prevent women from going to the hospital for health check-up. They further indicated that 82% of the women with IUFDs belonged to

lower middle class. However, the study conducted by Neogi et al (2015) on the factors associated with stillbirth in India, revealed that there was no link between socio-economic status and IUFD. The study discussed that in both cases (stillbirths) and controls (live births) more than 90% of the women with IUFDs were house helpers.

It is evident from the literature above that low socioeconomic status has a link with IUFD. However studies are still needed to be done in Botswana to identify if there is any similar link.

2.5.2 Smoking

During pregnancy, chemicals such as nicotine and carbon monoxide narrow placental blood vessels. This leads to reduced nutrients and oxygen availability to the fetus hence compromised fetal development or death (NICE, 2010). Liu et al (2014) in their study shared that smoking during pregnancy or exposure to environmental smoke causes an increased risk of stillbirth. They further indicated that smoking carried into the third trimester was found to have more significant influence on the risk of stillbirth than smoking during the second trimester. The authors attributed this to the longer duration of cigarette exposure and the greater impact of the feto placental circulation.

2.6 Fetal factors

2.6.1 Congenital abnormalities

Choudhary and Gupta (2014) and Patel et al (2014) indicated that 11.5% and 9.8% fetal deaths respectively were linked to congenital anomalies. Major fetal anomalies (anencephaly and Neural tube defect) were found in 38% cases of fetal death in a study by Safarzadeh et al (2014). Singh et al (2013) in their study also found that among the fetal causes, major congenital anomalies accounted for 9.45% cases, out of which 9 had hydrocephalous, 8 had neural tube

defects, 7 had anencephaly, 2 cases were gastroschisis, one case of bilateral renal agenesis and one had congenital cardiac disease.

Different authors had varied views about congenital abnormalities and IUFD. Among the congenital abnormalities, they cited hydrocephalus, anencephaly and neural tube defects to be leading contributing factors towards fetal deaths.

2.6.2 Prematurity

Prematurity has shown to be a risk factor for fetal death (Garg and Kumar, 2017). In their study on "review of socio-economic factors and obstetric causes of stillbirths at tertiary care hospital" Vidyadhar, Chandaliya, & Pandit (2012) highlighted that prematurity was associated with 23.66% of stillbirth cases while Ghumare and Morey (2016) and Sharma et al (2016) linked prematurity with 18.8% and 28% of stillbirths respectfully. The studies above indicated that prematurity is one of the contributory factors towards IUFD. There is therefore, need for quality care of mothers before and during pregnancy, labour and delivery to prevent preterm stillbirths.

2.7 Umbilical cord factors

Divya et al (2015) evaluated the etiological factors and determinants of intrauterine fetal death in a tertiary care hospital and established that one (1) fetus was born with a true knot of the umbilical cord and 4.2% had tight cord around neck.

Another study conducted by Singh et al (2013) shared that cord prolapse contributed to 2.7% of the IUFD cases while Jamal and Agarwal (2017) linked umbilical cord prolapse with 1.7% of the cases. The annual cumulative incidence of fetal death was 23/1000 live umbilical cord prolapse cases delivery per year in the study done by Wasswa, Nakubulwa and Mutyaba (2014). The articles studied above indicated that tight cord around the neck, cord prolapse and umbilical true knot have an association with IUFD. The authors indicated in their studies that in

most cases, it is not easy to identify the umbilical factors until after delivery of a stillbirth e.g. true knot. So it is difficult to prevent the occurrence of such fetal deaths.

2.8 Placental factors

2.8.1. Placenta praevia and placenta abruptio

Most of the literature on Antepartum Haemorrhage (APH) suggests that there is a strong correlation between IUD, placenta praevia and placenta abruptio. This is evidenced by literature form a study done by Sharma et al (2016) who shared that APH contributed to 12 % of IUDs. In their study, Safarzadeh et al (2014) on the other hand revealed that 13.8% of the IUDs were due to placenta praevia while Bano et al (2016) and Jamal & Agarwal (2017) indicated that 3.33%, and 30.3% of the IUD cases were accompanied by placenta abruptio respectively. Garg and Kumar (2017) revealed that placenta praevia contributed 5% of IUDs and placenta abruptio contributed 11.25%. Similar results were noted from the study done by Choudhary and Gupta (2014) where it was indicated that placenta praevia and placenta abruptio contributed 3.9% and 11.7% of IUDs respectfully. Sharma et al (2016) also highlighted that from the mothers who had IUDs 3.2% had placenta praevia while 15.6% had placenta abruptio. Most of the studies showed that placenta abruptio contributed to most of the IUFDs as compared to placenta praevia.

2.9 Labour and delivery

2.9.1 Obstructed labour

In their study of evaluation of etiological factors associated with IUFD, Patel et al (2016) indicated that obstructed labour contributed to 5.88% of the IUFDs. Garg and Kumar (2017) and Singh et al (2013) in their studies indicated that obstructed labour brought about 3.75% and 6.08% of IUFD cases respectfully, while Kavani et al (2017) reported that obstructed labour caused 55.7% of the stillbirths. Three out of four studies above showed that obstructed labour

contributed to IUFD at a lower rate (3.75%-6.08%) while one study showed a significant percentage of 55.7 %. The difference could be attributed to different factors.

2.10 Management factors

According to Choudhary & Gupta (2014), factors such as lack of prenatal care, inaccessible or limited health care facilities are said to be highly contributing to perinatal deaths in developing countries. Misuse of oxytocin was implicated to have contributed to 28% of 735 stillbirths in a teaching hospital in Bangladesh (Aminu et al, 2014). This gives the impression that failure to follow protocols and guidelines during care of mothers at time of pregnancy, labour and delivery compromises their care.

2.11 Conclusion

The findings from the literature review revealed that a number of factors contributed to IUFDs and stillbirth. All the articles reviewed indicated that demographic factors, maternal factors, socio-economic factors, placental factors, fetal factors, umbilical cord factors, and management factors contribute towards IUFDs. Most of the articles reviewed were from India and it seemed as if little has been done on factors contributing to IUFDs in Africa, Botswana being inclusive where no articles were identified during literature search. This information may be used to prevent IUFDs/stillbirth in Botswana.

CHAPTER 3

3.0 THE STUDY METHODS

3.1 Introduction

This chapter will cover the tools and techniques for doing research such as study settings, study design, study population, sampling and sample size, ethical considerations data collection and data analysis.

3.2 Study design

In this study, a quantitative retrospective descriptive institution based study will be conducted by reviewing records of mothers who had IUFDs/stillbirths in antenatal ward and labour ward in PMH. According to Wyse (2011) quantitative research helps in the testing theories, establishing facts, showing relationships between variables, and anticipating outcomes. The quantitative research method will be used to collect numerical data that will be used to answer the study question and also to determine the correlation between event (IUFD/stillbirth) and its multiple causes or contributing factors.

In retrospective research, data that was originally not collected for research purposes is analysed (Gearing, Mian, Barber, & Ickowicz, 2006). "A variety of data sources can be utilized to collect information for a record review. These sources could be in the form of hard copies of case notes and case files, manually entered registers, and computerized databases. Data sources can include case notes, inpatient case files, attendance registers, nursing and doctors' records, pharmacy records, disease registries, laboratory records, adverse event monitoring systems, clinical trial information, and national demographic records, etc" (Sarkar & Seshadri, 2014. p1).

In this study, a retrospective study will be conducted by manually reviewing all obstetric records for mothers who had IUFDs/stillbirth from January 2013 to December 2018 to capture data on possible causes of IUFDs/stillbirths.

Descriptive research gives the accurate portrayal of the characteristics of individuals, situations, or groups and the frequency at which certain phenomena take place using statistics to describe and summarise the data. Data in this type of research is commonly gathered through observation and survey tools (Nassaji, 2015). In this study a data collection tool will be used to capture information on the characteristics of groups such as demographic factors (maternal age, gestational age, parity, and marital status), fetal factors (congenital abnormalities and prematurity) etc. The data collected will then be summarised by getting the frequency at which these characteristics occurred during the study period (2013 to 2018) i.e. how many IUFDs were associated with demographic characteristics within the period of study.

3.3 Study setting

Study setting describes the location where the study will be conducted. The proposed study will be conducted at Princess Marina Hospital (PMH), a referral centre located in the capital city of Botswana. PMH is chosen because it is a referral centre for all the health facilities in the Southern side of Botswana, so almost all the complicated cases including anticipated or diagnosed IUFDs.

Botswana is a landlocked country located in Southern Africa, sharing boarders with Namibia, Zimbabwe, Zambia and South Africa. It is a middle income country with a total population of 2.02 million inhabitants with a total fertility rate of 2.9 children per woman (Botswana statistics, 2011).

Princess Marina Hospital has existed in Gaborone, Botswana for close to five decades. The hospital was established in 1966 when the country gained independence and began operating on April 4, 1967. PMH offers a wide variety of services both preventive and curative and also serves as a primary, district and tertiary hospital. The hospital offers different services such as surgery, dietetics, pharmacy, obstetrics and gynaecology, to mention but a few (Ngidi, 2016).

The obstetrics department comprises of three units; antenatal ward, labour ward and post natal ward. Antenatal ward is a 30 bedded unit, but since PMH is a referral hospital there is a high influx of patients from different hospitals in the Southern part of Botswana and clinics from Gaborone and neighboring villages. The ward is overcrowded most of the times, with an average patient population of 40-60 per day. This results in some of the patients being accommodated on floor mattresses.

Pregnant mothers who are not in active phase of labour but having different types of pregnancy associated conditions such as latent phase of labour (i.e. those with cervical dilatation of 3cm and below), hypertensive disorders of pregnancy, PROM, diabetes mellitus, anaemia, polyhydraminous, oligohydraminous, infections, postdates, mothers with IUFDs but not in labour, previous cesarean section at 38 weeks of gestation, etc. are admitted to antenatal ward every day. But since antenatal ward is not a delivery unit, mothers who get into labour are transferred to labour ward for delivery. This means some of the information will be followed in labour ward registers. Antenatal ward is staffed with 18 midwives who cover three shifts per day (morning, evening and night duties). This clearly shows that there is gross understaffing of the unit due to shortage of midwives in Botswana.

Labour ward is a 13 bedded unit, 8 delivery rooms, four admission beds, and 1 room for patients with hypertensive disorders such as preeclampsia and eclampsia. The information of all

delivered mothers including those who had stillbirth is documented in labour ward registers i.e. patient's name and PM number, diagnosis, delivery outcome (which requires nurses to indicate whether it was a life birth or stillbirth). The ward is staffed with 23 midwives for the three shifts, which means on average 3 nurses are on duty per shift. Labour ward reports revealed that there were 6024, 6158 & 6289 deliveries in 2016, 2017 and 2018 respectfully. The stillbirths will be picked from deliveries in these years including those from 2013, 2014 and 2015.

After delivery patients are sent from labour ward to postnatal ward where they are finally discharged and their records are sent back to records department. This is where most of the patients' records will be followed, with their PM numbers retrieved from antenatal ward and labour ward registers.

3.4 Study population

All study records of women who had IUFDs/ stillbirths from January 2013 to December 2018 will be included in the study.

3.5 Sampling

When conducting a retrospective chart review study, sampling is described as a method by which study cases or records are selected from the target population or database. Convenience sampling is one of the commonest sampling methods used in retrospective review of literature (Taherdoost, 2017). A common method of convenience sampling involves selecting all of the consecutive cases within a given time frame. The convenience method is cited to be a suitable approach as long as the period is long enough to include seasonal variations or other changes over time that are relevant to the research question (Sarkar & Seshadri, 2014). Based on the descriptions, convenience sampling method is noted to be suitable for this study and hence

will be used to identify the cases. Therefore, records of all mothers who had IUFDs/stillbirths between January 2013 and December 2018 which meet the criteria will be included in the study.

3.5.1 Sample size

A hypothesis testing usually involves comparing the characteristics of two or more groups, while a descriptive survey may be concerned specifically with describing the characteristics of a single group. The aim of this type of survey is often to obtain an accurate estimate of a particular figure, such as a mean or a proportion (Fox, Hunn, & Mathers, 2009). For example, we may want to know how many IUFDs are there on average in a year, then how many of these IUFDs came as result of causative factors such as maternal, socioeconomic, management etc. In this case, the aim is not to compare the figures within the causative factors, but rather, to accurately reflect the real figures in the wider population. So basing on this explanation, all the records of mothers who had IUFDs/stillbirths will be included and evaluated in this study. The aim is to get the real figure of IUFDs from the total deliveries from 2013 to 2018, then study the possible causes for all the individual deaths. Basing on the estimated number of stillbirths from PMH for 2014 (248) and 2016 (258), the average number of stillbirths per year is 253. This therefore means the estimated average number of IUFDs to be studied from 2013 to 2018 (6 years) is around 1518.

3.5.2 Inclusion criteria

The inclusion criteria for the study will be:

- Records of all mothers who had antepartum fetal deaths with gestational age > 24 weeks diagnosed by absent heart sound and further confirmed by ultrasonography from January 2013 to December 2018.

- Records of all mothers who had intrapartum stillbirths with gestational age > 24 weeks and or weighing > 500g from January 2013 to December 2018.

3.5.3 Exclusion criteria

The exclusion criteria for the study will be:

- All IUFD and stillbirth cases with gestational age less than 24 weeks
- Cases delivered outside PMH
- Records of women with molar pregnancy
- Records with missing data

3.6 Ethical and confidentiality considerations

Permission to conduct the study will be sought from the University of Botswana Institutional Review Board (IRB), Ministry of Health and Wellness Research and Development Committee and Princess Marina Research and Ethical Committee (**Appendices: A, B,& C**). Since the study is retrospective, at the time of data collection patients will not be in the hospital, so permission to waive patient consent will be sought from the PMH institutional review board to access patients' records. To ensure confidentiality of data, patients' identifying information will not be included in the data extraction records but instead codes will be used to record identifying information. A separate document that links the study code to subjects' identifying information will be locked in a separate location and access to this document will be restricted, i.e. the principal researcher will be the only one who keeps the key. Also the data/ documents that are no longer in use will be properly disposed, destroyed or deleted. Where there is need, security codes will be assigned to access computerized records.

3.7 Procedure for data collection

3.7.1 Data collection instrument

A data collection tool needs to be well designed to ensure fastidious searching of records (Matt & Mathew, 2013). Organization, simplicity and clarity are essential criteria for the development of a uniform data abstraction instrument. Data collection should be organized in a logical order and when possible should parallel the flow of the information in the health record (Gearing et al, 2006). Data collection tool from Melese, Habte, Tsima, Mogobe, Chabaesele, Rankgoane… Motana (2017) will be adopted for use during data collection in this study. The tool is organized in a logical order with the Botswana antenatal record and made simple, clear and user friendly. The authors used a tool to evaluate the high levels of post-abortion complication in a setting where abortion service is not legalized. The tool was pretested and standardization was done to ensure validity and reliability before use.

3.7.2 Description of the data collection form (Appendix E)

The tool for this study will comprise of two columns, one with characteristics and the other one with "tick where appropriate". The characteristics column comprises of different variables which are hypothesized to be the causative or contributing factors to IUFD/stillbirth.

Characteristics (i) entails demographic factors which are age, marital status, parity, and gestational age. Age: is categorized into ranges of 14 and below, 15-19, 20-24, 25-29, 30-34, 35-39, and 40 and above. Marital status: is categorized into single, married, divorced, widowed or separated. Parity: is categorized into zero, one, two, three, or 4 and above. Gestational age: is categorized into 24-28, 29-33, 34-38, 39-42 and 42 and above. The data collectors will be

expected to indicate where the mother falls within the categories by placing only one tick against one relevant variable.

Characteristics (ii) comprises of socioeconomic factors, which are occupation, educational level and smoking. Occupational factors - the data collectors will be expected to indicate if the mother is unemployed, a domestic worker or permanently employed by placing a tick against only one of these. Educational level- the data collector will have to indicate if the mother has never been to school or went as far as primary level, secondary level or tertiary level by placing only one tick against only one of these.

Characteristics (iii) comprises of maternal factors which are PROM, oligohydraminous, polyhydraminous, diabetes mellitus, History of previous stillbirths, infections, hypertensive disorders (PIH, chronic hypertension, preeclampsia, eclampsia). The data collectors will be expected to indicate if the mother had any of the factors by placing a tick against any of the factors. In this case more than one variable can be ticked at a time.

Characteristics (iv) comprises placental factors which are placenta praevia and placenta abruptio. The data collectors will have to indicate if the mother had any of the two factors.

Characteristics (V) comprises of fetal factors which are prematurity and congenital malformations. The data collectors will indicate if the stillborn was a preterm and or had congenital malformation by placing a tick against one or both factors.

Characteristics (vi) comprise of umbilical cord factors which are cord around the neck, cord prolapse and true knot. The data collectors will be expected to indicate if there was cord around the neck, cord prolapse or true knot. More than one variable may be ticked.

Characteristics (vii) comprise of obstructed labour and so the data collectors will be expected to indicate if the mother had an obstruction during labour.

Characteristics (viii) comprises of management factor which expects the data collectors to indicate if there was failure to use guidelines and or indicate if the mother's labour was induced.

The users of the instrument will be expected to place only one tick against variables under demographic factors, socioeconomic factors, maternal factors, placental factors and labour and delivery. An option of more than one tick will be allowed to be used against variables under fetal factors, umbilical cord factors, and management factors because more than one of these variables can affect the fetus at a time.

3.7.3 Recruitment of study research assistants

Investigators may optimize data collection from the medical record by selecting data abstractors who are experienced clinically, interested in research, and eager to learn. These attributes and abstractor qualifications may contribute towards minimized data collection error (Gregory & Radovinsky, 2012). Recruitment advertisements for research assistants will be done through University of Botswana Website and Administrator email. More recruitment advertisement will be placed at different departments such as Registry department, Labour ward and Antenatal ward. Preferably nurses and midwives will be recruited as research assistants.

All research team members will be trained by the primary researcher, supervisor and the co-supervisor. Contents of the training will include detailed outlines of the study, ethical conduct, professional conduct and data extraction skills.

3.7.4 Data collection process

Patients' obstetric records from January 2013 to December 2018 will be reviewed and IUFDs above 24 weeks of gestation and or stillbirth weighing 500 grams or above will be included. Detailed history of the patients who had IUFDs/stillbirth will be collected from the patients' obstetric records such as maternal factors (PROM, infections, anaemia, polyhydraminous, oligohydraminous, diabetes mellitus, hypertensive disorders, history of previous stillbirth), socio-economic factors (occupation, educational level, smoking), demographic factors (maternal age, parity, marital status and gestational age), management factors (failure to follow guidelines and induction of labour), labour and delivery factors (obstructed labour), umbilical cord factors (cord around the neck, cord prolapse and true knot), placental factors (placenta praevia and placenta abruptio) and fetal factors (congenital abnormalities and prematurity).

The researcher and the four midwives recruited as research attendants will be extracting data from the patient records. The researchers will manually search for the delivery registers which have all the IUFDs and deliveries for the years 2013 to 2018 from antenatal and labour ward registers. From the registers in antenatal and labour wards, the research team (principal researcher and research assistants) will then search for names and Princess Marina (PM) for all the mothers who had IUFDs. Using the names and the PM numbers the patients obstetric records will be followed at records department. Patients' obstetric records will then be retrieved from records department and will be taken to a room specially prepared for data collection. The researcher and the research assistants will sit together and each member will take a record to start collecting data. Using the designed data extraction tool, the research team will fill all the variables as needed. For the sake of confidentiality, patients' names will not be used, but instead

the coding system will be used. Simple coding with numbers will be used, i.e. number one (1, 2, 3, 4 etc.) until the last document.

3.8 Management of data

During the process of data collection, the principal researcher will be in charge of all the proceedings, documents and other materials used throughout the study. The principal researcher will use a password to access the computerized data. No unauthorized personnel will be allowed to access the data, and every time after use the records will be kept in a lockable cupboard to protect the privacy and confidentiality of the patient's records. Data will be captured as it is and not manipulated or changed during the data collection process. This will ensure that the information is not distorted or compromised in any way.

At the end of data collection process, only the collected data will be processed and shared with the research team and the PMH staff. Copyright protection policy will be used to ensure that those who need to use the data could do so following the right channels. Immediately after finishing with the files, they will be returned to records department. The compiled study data may be stored for five years after which it could be disposed or destroyed safely.

3.9 Testing of the instrument for data collection

The instrument for this study will be tested through the use of a pilot study. Pilot studies are small scale forms of a research investigation which cannot fully represent the sample size to answer the research question. The pilot study can be conducted to assess the design of the study, its feasibility, and evaluate the methodology and procedures of the investigation (Matt & Mathew, 2013).

Following approval by relevant authorities, the study will be piloted at PMH antenatal and labour wards on patient records from January 2012 to April 2012 (**Appendix: D**). The same

inclusion and exclusion criteria will be used and the same data collection form which is going to be used for the study will be used. For this pilot study, 30 patient records of mothers who had IUFDs/stillbirths will be reviewed. The number suggested will be based on a flat rule of thumb by Machin, Campbell, Tan and Tan (2018). The authors indicated that flat rule of thumb is a single number (30) that is suggested for every situation in determining a pilot study size. The four midwives who have been recruited to be the research assistants will be used to conduct the pilot study. The piloting team will be using the same data extraction form which will be used for the main research study. The form will be labeled "pilot testing instrument" and the individual research assistants will be expected to complete data extraction from one record within 30 minutes. After all the 30 records have been completed, the information will be analysed to assess for any omissions or irregularities. After analysis the necessary corrections and the final approval of the form may be made. The final version of the data collection form will then be used for the research study.

This pilot study will be used to assess the feasibility of the planned study, determine the adequacy of the instrumentation, and evaluate any potential methodological pitfalls such as data collection strategies. It will also provide the opportunity to evaluate the reliability of the data collection tool, clarify the data abstraction protocols, and highlight the frequency that operationalized variables are missing from patient records.

3.9.1 Reliability

Reliability refers to the consistency of the instrument or the consistency displayed by the instrument when exposed to similar situations on repeated occasions. The reliability coefficient is obtained by repetition of the same measure on a second time, and it is called the test reliability.

If the coefficients yield above 0.7, they will be considered to be acceptable, and coefficients yield above 0.8, will be considered to be very good (Heale & Twycross, 2015).

To test the reliability of the data extraction tool for this study, two forms will be used to capture data from the same patient record by different research assistants. If the coefficient yield falls at 0.7 or above, the tool will be regarded as reliable but if the coefficient falls below 0.7, the data collection form will be corrected and later be retested until the coefficient yield is improved to 0.7 or above.

3.9.2 Validity

According to Taherdoost (2016) validity refers to how the actual area of investigation has been well covered by the collected data, or what is measured is basically what was intended to be measured by the researcher.

3.9.2.1 Construct validity

"This type of validity is a judgment based on the accumulation of evidence from numerous studies using a specific measuring instrument. Evaluation of construct validity requires examining the relationship of the measure being evaluated with variables known to be related or theoretically related to the construct measured by the instrument" (Kimberlin & Winterstein, 2008, p. 2279). The information captured from the tool in this study will be compared with the information from literature review in order to measure the validity of the instrument.

3.9.2.2 Content validity

This category checks whether the instrument adequately includes all the content that it should with regard to the variables (Heale & Twycross, 2015). The data collection tool formulated for this study will be used to capture all the variables desired to aid in identifying the

factors contributing to IUFD. The variables such as socioeconomic factors (occupation, educational status, smoking), maternal factors (PROM, infections, anaemia, polyhydraminous, oligohydraminous, diabetes mellitus, hypertensive disorders, history of previous c/section), demographic data (age, parity, gestational age, marital status), fetal factors (congenital abnormalities, prematurity), placental factors (placenta praevia and placenta abruptio), Labour and delivery (Obstructed labour) and umbilical cord factors (cord around the neck, cord prolapse and true knot). This type of validity can be ensured by working with other nurses and supervisor to cross check if all the variables intended to be covered are included.

3.10 Data analysis

Statical Package for Social Sciences (SPSS) 22 software will be used to capture collected data, its cleaning and analysis. This is a suitable software because once the data has been loaded, it can then complete data set to produce suitable output, and it can also accommodate a large set of variables. Frequency, percentage, means, standard deviation will be computed to present the findings. For nominal data Chi-square analysis will be used to assess the association between the independent variables (causes or contributing factors) and the dependent variable (IUFD/stillbirth), and $P<0.05$ will be used as the point of significance.

Through descriptive statistics the researcher is going to calculate the frequencies and percentages median and mode for socioeconomic (occupation, educational level and smoking), umbilical cord factors (placenta praevia and placenta abruptio), placental factors, maternal factors, labour and delivery factors and fetal factors while demographic factors (marital status, and age) will be computed using the mean and standard deviation.

3.11 Data dissemination

The research findings will be disseminated through briefings at antenatal and labour wards in PMH, training institutions, and other government health facilities which provide labour and delivery care to patients. There will also be poster presentations at the University of Botswana to share the findings. The information will also be shared at local, regional and international research conferences. Proper procedures will also be followed to publish the findings in a journal that addresses IUFDs/stillbirth issues.

3.12 Study Limitations

Limitations of using data obtained from the medical record via retrospective review include incomplete or missing data within the medical record, records lacking specific patient information, difficulty in interpreting or verifying documented information, and variability in the quality of documentation among health care personnel (Gregory & Radovinsky, 2012). The medical records may lack complete information or some information may be incorrectly documented or missing from the medical records. Some of the records may be completely missing from the facility. Studying from one facility in the country may also be a limitation since it is not representative enough of all the health facilities in the country.

3.13 Conclusion

The study will be a retrospective (descriptive) i.e. patients' records will be reviewed. The records will be followed from PMH antenatal and labour wards as well as records department. A convenience sampling method will be used and records for women who had IUFDs/stillbirths and meet the criteria will be reviewed. An ethical permission will be sort from the relevant authorities and confidentiality will be maintained throughout the process. A data collection form

which will be piloted before the actual study will be used. The chapter also covers statistical analysis study limitations, and a timeline for activities.

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Appendix A: Letter of permission to conduct a study (UB ethics committee)

P.O.Box 1642 AAD
Poso House
Gaborone
21 April 2019

Institutional Review Board (IRB**)**
Ethics Committee
Office of research and development
University of Botswana
Gaborone
Ufs: Head, School of Nursing, University of Botswana
Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO CONDUCT A STUDY

I am a final year Masters of Nursing Science (MNSc) student specializing in midwifery at the University of Botswana. In partial fulfillment of this program, I have to conduct a research study entitled "A retrospective study of factors associated with intrauterine fetal death in antenatal and labour wards in Princess Marina Hospital in Gaborone, Botswana". The study aims at reviewing factors associated with intrauterine fetal death in antenatal ward, and some records will be followed in labour ward and records department in Princess Marina Hospital in Gaborone. It is hoped that the study will assist in generating data about common preventable causes of IUFDs and planning strategies to reduce their incidence in the local population.

By this letter, I wish to request for permission to conduct a retrospective study at Princess Marina Hospital.

Your assistance will be highly appreciated

Yours faithfully

_____
Gadifele Daphne Masilo

Appendix B: Letter of Permission to conduct a study (Health Research Unit)

P.O.Box 1642 AAD
Poso House
Gaborone
21 April 2019

The Principal Research officer
Health Research Unit
Ministry of Health and Wellness
Private Bag 0038,
Gaborone
Ufs: Head, School of Nursing, University of Botswana

Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO CONDUCT A STUDY

I am a final year Masters of Nursing Science (MNSc) student specializing in midwifery at the University of Botswana. In partial fulfillment of this program, I have to conduct a research study entitled "A retrospective study of factors associated with intrauterine fetal death in antenatal and labour wards in Princess Marina Hospital in Gaborone, Botswana". The study aims at reviewing factors associated with intrauterine fetal death in antenatal ward and some records will be followed in labour ward and records department in Princess marina Hospital in Gaborone. It is hoped that the study will assist in generating data about common preventable causes of IUFDs and planning strategies to reduce their incidence in the local population.

By this letter, I wish to request for permission to conduct a retrospective study at Princess Marina Hospital.

Your assistance will be highly appreciated.

Yours faithfully

_____
Gadifele Daphne Masilo

Appendix C: Letter of Permission to conduct a study (PMH)

P.O.Box 1642 AAD
Poso House
Gaborone
21 April 2019

The chairperson
Princess Marina Hospital Ethics Committee
P.O.Box 258
Gaborone
U.F.S: Head of Department, School of nursing
Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO CONDUCT A STUDY

I am a final year Masters of Nursing Science (MNSc) student specializing in midwifery at the University of Botswana. In partial fulfillment of this program, I have to conduct a research study entitled "A retrospective study of factors associated with intrauterine fetal death in antenatal and labour wards in Princess Marina Hospital in Gaborone, Botswana". The study aims at reviewing patients' records in antenatal ward and follow up some in labour ward and records department in Princess Marina Hospital in Gaborone. It is hoped that the study will assist in generating data about common preventable causes of IUFDs and planning strategies to reduce their incidence in the local population.

By this letter, I wish to request for permission to conduct a retrospective study at Princess Marina Hospital.

Yours faithfully

_____

Gadifele Daphne Masilo

Appendix D: Letter of permission to conduct a pilot study (PMH)

P.O.Box 1642 AAD
Poso House
Gaborone
21 April 2019

The chairperson

Princess Marina Hospital Ethics Committee

P.O.Box 258

Gaborone

Ufs: Head, School of Nursing, University of Botswana

Dear Sir/Madam

RE: REQUEST FOR PERMISSION TO CONDUCT A PILOT STUDY

I am a final year Masters of Nursing Science (MNSc) student specializing in midwifery at the University of Botswana. In partial fulfillment of this program, I have to conduct a research study entitled "A retrospective study of factors associated with intrauterine fetal death in antenatal and labour wards in Princess Marina Hospital in Gaborone, Botswana". The study aims at reviewing patients' records in antenatal ward and follow up some in labour ward and records department in Princess Marina Hospital in Gaborone. It is hoped that the study will assist in generating data about common preventable causes of IUFDs and planning strategies to reduce their incidence in the local population.

By this letter, I wish to request for permission to conduct a pilot study at Princess Marina Hospital.

Your assistance will be highly appreciated

Yours faithfully

_____

Gadifele Daphne Masilo

Appendix E: Data collection form

Data extraction form

Instructions on how to use the form

a) Place a tick against the appropriate variable for the patient.
b) Place only one tick under characteristics labeled i, ii, iii, iv and vii.
c) You may place more than one tick under characteristics labeled v, vi, and viii.

Table 1.1 Data extraction form

CHARACTERISTICS (i)	**TICK WHERE APPROPRIATE**
Demographic factors	
Age in years	
• 14 and below	
• 15-19	
• 20-24	
• 25-29	
• 30-34	
• 35-39	
• 40 and above	
Marital status	
• Single	
• Married	
• Divorced	
• Widowed	
• Separated	
Parity	
• Zero	
• One	
• Two	
• Three	
• 4 and above	
Gestational age	
• 24-28	
• 29-33	
• 34-38	
• 39-42	
• 42 and above	

CHARACTERISTICS (ii)	**TICK WHERE APPROPRIATE**
Socioeconomic factors	
Occupation	
• Unemployed	
• Domestic worker	
• Smoking	
Educational level	
• Never been to school	
• Primary education	
• Secondary education	
• Tertiary education	
Smoking	

CHARACTERISTICS (iii)	**TICK WHERE APPROPRIATE**
Maternal factors	
• PROM	
• Oligohydraminous	
• Polyhydraminous	
• Diabetes mellitus	
• History of previous stillbirths	
• Infections	
• Hypertensive disorders	
PIH	
Chronic hypertension	
Preeclampsia	
Eclampsia	

CHARACTERISTICS (iv)	**TICK WHERE APPROPRIATE**
Placental factors	
• Placenta praevia	
• Placenta abruptio	

CHARACTERISTICS (v)	**TICK WHERE APPROPRIATE**
Fetal factors	
• Prematurity	
• Congenital malformations	
CHARACTERISTICS (vi)	**TICK WHERE APPROPRIATE**
Umbilical cord factors	
• Cord around the neck	
• Cord prolapse	
• True knot	

CHARACTERISTICS (vii)	**TICK WHERE APPROPRIATE**
Labour and delivery	
• Obstructed labour	

CHARACTERISTICS (viii)	**TICK WHERE APPROPRIATE**
Management factors	
• Failure to follow guidelines	
• Induction of labour	

Others:

_____

_____

_____

_____

_____

Appendix F: Research Budget

Research Budget

Table 1.2 Transport, allowance and meals for pilot study

	TRANSPORT, ALLOWANCES AND MEALS FOR PILOT STUDY			
Activity	**Number of persons**	**Number of trips**	**Cost per trip (Pula)**	**Total amount**
Transport				
Local taxis from Gaborone Block 10 to PMH	4	5	P40.00 cab x 2	P1600.00
Meals				
Lunch	4	5	89.90	1798.00
Tea	4	5	65.80	1316.00
Allowances	4 (assistants)	5	P250.00	P3750.00
TOTAL				**P8464.00**

Table 1.3 Transport, allowances and meals for research study

	TRANSPORT, ALLOWANCES AND MEALS FOR RESEARCH STUDY (DATA COLLECTION AND ANALYSIS)			
Activity	**Number of persons**	**Number of trips**	**Cost per trip (Pula)**	**Total amount**
Transport				
Local taxis from Gaborone Block 10 to PMH	4	30	P40.00 cab x 2	P9600.00
Meals				
Lunch	4	30	89.90	10,788.00
Tea	4	30	65.80	7896.00
Allowance	4 (assistants)		P30.24 per hour x 8 hours x 5 days	P4838.40
Allowance	1 (research auditor)		P5000.00 x5days	P25,000.00
Allowance	1 (research analyst)		P5000.00 x5 days	P25,000.00
TOTAL				**P83,122.40**

Table 1.4 Printing

PRINTING			
Activity	**Number of pages**	**Price each (Pula)**	**Total amount**
Permission letters (printing)	4	P2.00	P8.00
Research proposal (draft)	60	P2.000	P120.00
Final research project	60 pages x 3copies	P2.00	P360.00
Final research project binding	3	P50.00	P150.00
TOTAL			**P683.00**

Table 1.5 Stationery

STATIONERY			
Item	**Number**	**Price each (Pula)**	**Total amount**
Pens blue	10	P17.75	P177.50
Pens red	10	P22.15	P221.50
Pencils	10	P3.00	P30.00
Eraser	10	P1.50	P15.00
A4 photocopying paper	5 x Reams	P64.00	P320.00
Notepad	10	P20.70	P207.00
Memory stick	4	P150.00	P600.00
Office punch (H-20)	4	P140.00	P560.00
Stapler	4	P68.00	P272.00
Arch lever files	10	P24.00	P2400.00
TOTAL			**P4803.00**

Table 1.6 Training

TRAINING			
Item	**Number of days**	**Price each (Pula)**	**Total amount**
Conference facilities	5	P2000.00	P10,000.00
WIFI	5	P120.00	P600.00
TOTAL			**P16,000.00**
GRAND TOTAL			**P104,72.40**