BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GESTATIONAL DIABETES MELLITUS IN ADDIS ABABA, ETHIOPIA.

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DEDICATION

In the memory of my dear mother, Mamit Tsegay N/Mariam, I wish you could have been here. I owe my beginnings, foundation and accomplishments to you. Thank you for your unconditional love and support, but above all for believing in me.

Even though you are not with me right now, I know you are proudly smiling from heaven.

DECLARATION

Student number: 61958379

I declare that the thesis entitled **"BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GESTATIONAL DIABETES MELLITUS IN ADDIS ABABA, ETHIOPIA",** is my own work and the sources that were used or quoted have been indicated and acknowledged by means of complete referencing and that this work has not been submitted before for any other degree at any other institution.

October, 2020

SIGNATURE DATE

(Getahun Sinetsehay Alemayehu, Mrs)

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ABSTRACT

Aim: The purpose of the research was to determine the magnitude and factors associated with gestational diabetes mellitus (GDM), and to explore the experiences of gynaecologists/obstetricians and midwives in the monitoring and prevention of GDM- related adverse maternal outcomes in order to propose best practice guidelines which may be implemented to overcome the problem.

Methods: A concurrent mixed methods design was used. Participants for the quantitative study were selected using systematic random sampling, with purposive sampling being used for the qualitative part of the study. A total of 2000 medical records were reviewed using a checklist, in addition to which 7 gynaecologists/obstetricians and 12 midwives were interviewed using an in-depth interview guide. Descriptive and inferential statistics were used for the quantitative part, while Colaizzi's manual qualitative data analysis method was used for the qualitative part of the study.

Findings: The magnitude of GDM was found to be 2.2%. Age and family history of diabetes mellitus were found to be factors associated with GDM (at $p \leq 0.001$). Other factors such as obesity, previous GDM, previous history of fetal macrosomia and multiple gestations were identified by respondents as factors related with GDM. In addition, the study explored the experiences of health professionals (HPs) in the monitoring and prevention of adverse

maternal outcomes related to GDM, with the results showing some differences in screening and diagnostic techniques. It was also shown that lifestyle modification (physical exercise, diet management) and medication were utilised for managing women with GDM. In this regard, all the HPs agreed that creating awareness is the best intervention for preventing GDM as well as its adverse maternal outcomes.

Conclusions: The magnitude of GDM is increasing, and much needs to be done to draw attention to the burden that GDM places on the health of pregnant women and the public. Since GDM is not considered a public health problem, little is being done to monitor the condition and its adverse maternal outcomes. It is hoped that the best practice guidelines developed from this research study may assist in reducing the adverse maternal outcomes of GDM in Ethiopia.

KEY TERMS:

Antenatal care, best practice, gestational diabetes mellitus, guideline, health professionals, maternal morbidity, maternal mortality, mixed method, monitoring, Neumann's system model, prevention.

Abstract in Setswana

DINTLHAKAELO TSA TIRISO E E GAISANG YA GO TLHOKOMELA LE GO THIBELA DITSHWAETSEGO TSA BOMME LE DINTSHO TSE DI GOLAGANENG LE BOLWETSI JWA SUKIRI (*DIABETIS MELLITUS*) JWA BAIMANA KWA ADDIS ABABA, ETHIOPIA.

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LEFAPHA: DITHUTO TSA BOITEKANELO

MOTLHOKOMEDI: MOP TG LUMADI

TSHOBOKANYO

Maikaelelo: Lebaka la patlisiso e ne e le go tlhotlhomisa go nna teng le mabaka a a golaganeng le bolwetsi jwa sukiri jwa baimana (GDM), le go tlhotlhomisa maitemogelo a dingaka tsa malwetsi a basadi (gynaeologists/ obstetricians) le babelegisi mo go tlhokomeleng le go thibeleng ditlamorago tse di maswe mo baimaneng tse di amanang le GDM gore go tshitshinngwe dintlhakaelo tse di gaisang tse di ka diragadiwang go fenya bothata.

Mekgwa: Go dirisitswe thadiso ya mekgwa e e tlhakantsweng. Banni-le-seabe ba thutopatlisiso e e lebelelang dipalopalo ba ne ba tlhophiwa go diriswa go tlhopha sampole ka go se latele thulaganyo, mme go tlhopha sampole ka maikaelelo go ne ga diriswa mo karolong ya thutopatlisiso e e lebelelang mabaka. Go sekasekilwe palogotlhe ya direkoto tsa kalafi tse 2 000 go diriswa lenanetshekatsheko, mme mo godimo ga moo, go ne ga nna le dipotsolotso le dingaka tsa malwetsi a basadi di le supa le babelegisi ba le 12 go diriswa kaedi ya dipotsolotso tse di tseneletseng. Dipalopalo tse di tlhalosang le tse go sweditsweng ka tsona di ne tsa diriswa mo karolong ya dipalopalo ya thutopatlisiso, fa go dirisitswe mokgwa wa ga Colaizi wa tokololo ya *data* ya mabaka mo karolong e e lebelelang mabaka.

Diphitlhelelo: Go nna teng ga GDM go ne ga fitlhelwa e le 2.2%. Dingwaga le hisetori ya

bolwetsi jwa sukiri ya baimana mo lelapeng di fitlhetswe e le dintlha tse di golaganeng le GDM (ka $p \leq 0.001$). Dintlha dingwe, jaaka go nona phetelela, GDM mo nakong e e fetileng, go nna teng ga *macrosomia* ya masea mo nakong e e fetileng le boimana jwa masea a feta bongwe di ne tsa supiwa ke batsibogi jaaka dintlha tse di golaganeng le GDM. Go tlaleletsa foo, thuto e ne ya sekaseka maitemogelo a baporofešenale ba boitekanelo (HPs) mo tlhokomelong le thibelo ya ditlamorago tse di sa siamang mo baimaneng tse di golaganeng le GDM, mme dipholo di bontshitse dipharologano dingwe mo dithekeniking tsa go sekirina le go phekola. Go bonagetse gape gore phetolo ya mokgwa wa botshelo (katiso ya mmele, tsamaiso ya mokgwa wa go ja) le kalafi di ne tsa diriswa go laola bolwetsi jwa basadi ba ba nang le GDM. Mo lebakeng le, baporofešenale botlhe ba boitekanelo ba ne ba dumelana gore go dira temoso ke tsereganyo e e gaisang ya go thibela GDM ga mmogo le ditlamorago tsa yona tse di sa siamang mo baimaneng.

Ditshwetso: Go nna teng ga GDM go a oketsega, mme go tshwanetse go dirwa go le gontsi go lemosa ka mokgweleo o bolwetse jono bo o bayang mo boitekanelong jwa baimana le setšhaba. Ka ntlha ya gore GDM ga e kaiwe jaaka bothata jwa boitekanelo jwa setšhaba, ga go dirwe go le kalo go tlhokomela bolwetsi le ditlamorago tsa jona tse di sa siamang mo baimaneng. Go solofelwa gore dintlhakaelo tsa tiriso e e gaisang tse di dirilweng mo thutopatlisisong eno di ka thusa go fokotsa ditlamorago tse di sa siamang tsa GDM mo baimaneng kwa Ethiopia.

MAREO A BOTLHOKWA:

Tlhokomelo ya pele ga pelego, tiragatso e e gaisang, bolwetsi jwa sukiri jwa baimana, dintlhakaelo/kaedi, baporofešenale ba boitekanelo, malwetsi a boimana, dintsho tsa baimana, mokgwa o o kopantsweng, tlhokomelo, Sekao sa thulaganyo sa Neumannn, thibelo.

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LISTS OF ABBREVIATIONS

2Hpg	2 hours postprandial glucose
ACOG	American College of Obstetrician and Gynaecologists
ADIPS	Australian Diabetes in pregnancy Society
AIDS	Acquired Immunodeficiency Syndrome
ANC	Ante Natal Care
BMI	Body Mass Index
BP	Blood Pressure
CI	Confidence Interval
CS	Caesarean Section
CSA	Central Statistical Agency
DIP	Diabetes in Pregnancy
EDHS	Ethiopian Demographic Health Survey
FBS	Fasting Blood Sugar
FG	Fasting Glucose
GDM	Gestational Diabetes Mellitus
GWG	Gestational Weight Gain
HBsAg	Hepatitis B surface Antigen
HgA1C	Haemoglobin A1C
HIP	Hyperglycaemia in Pregnancy
HIV	Human Immunodeficiency Virus

HLA	Human Leukocyte Antigen
HPM	Health Promotion Model
HPs	Health Professionals
HTN	Hypertension
IADPSG	International Association of Diabetes and Pregnancy Study Groups
IUGR	Intrauterine Growth Retardation
MODY	Maturity Onset Diabetes of the Young
MOI	Ministry of Information
NCDs	Non-Communicable Diseases
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NSM	Neuman Systems Model
OGTT	Oral Glucose Tolerance Test
OR	Odds Ratio
PA	Physical Activity
RBS	Random Blood Sugar
RH	Rhesus factor
SB	Sedentary Behaviour
SPSS	Statistical Package for Social Sciences
SVD	Spontaneous Vaginal Delivery
T2DM	Type II Diabetes Mellitus
VDRL	Venereal Disease Research Laboratory

WDF	Worlds Diabetes Foundation
WINGS	Women in India with GDM Strategy
WMA	World Medical Association

CHAPTER 1

ORIENTATION TO THE STUDY

"Although the world is full of suffering, it is also full of overcoming it."

Helen Keller

1.1 INTRODUCTION

This chapter emphases on the description of the research problem which is Gestational Diabetes Mellitus (GDM), the research objectives, the relevant methodological approaches and ethical considerations. All in all, it offers the foundation for the research question and the extent of the study.

GDM refers to glucose intolerance that begins or is first recognized in pregnancy which is not clearly overt diabetes (American Diabetes Association, 2014:85-86). It usually begins midway through the pregnancy between the 24th and 28th week of pregnancy. It is a high-level blood sugar condition that some women acquire in the course of pregnancy and it differs from the other type of diabetes because it is initially identified during pregnancy in previously undiagnosed women and it usually solves after pregnancy (American Diabetes Association, 2014:83-84).

GDM is a public health problem that has short- and long-term consequences both for the fetus and the mother and it is currently affecting the female population at large (Erem, Kuzu, Deger, & Can, 2015:724). According to International Diabetes Federation Report of 2017 (i.e. report on global estimates for diabetes prevalence for 2017 and projections for 2045) 21.3 million or 16.2% of live births had some form of hyperglycaemia in pregnancy. Out of this, an estimated 85.1% were due to GDM making 1 in 7 births to be affected by it. Besides, the huge cases of GDM were in low- and middle-incomecountries, where access to maternal care is often inadequate (International Diabetes Federation, 2017).

1.2 BACKGROUND INFORMATION OF THE RESEARCH PROBLEM

A research problem produces pertinent evidence and is recognized within a wide- ranging issue of concern by researchers with the objective to answer it or to contributeto its solution, (Polit & Beck 2012:73).

1.2.1 The source of the research problem

Ethiopia is a historic country. Paleontological studies identify Ethiopia as one of the cradles of mankind (Haile 2004). Ethiopia has been a melting pot of diverse customs and cultures. Today, the country embraces a dense range of nationalities, peoples, and linguistic groups. There are over 80 different languages, constituting of 12 Semitic, 22 Cushitic, 18 Omotic, and 18 Nilo-Saharan languages (Haile 2004:46). Ethiopia has a total population of about 94,352,000 (CSA fact sheet 2017:1). The capital city of Ethiopia is called Addis Ababa and the total population of Addis Ababa is 3,435,028 (CSA report 2013:132).

Recent study done in southern part of Ethiopia estimated the prevalence of GDM to be 4.2% (Woticha, Deressa & Reja 2019). Another study done in public health facilities located in Gondar Town, revealed that the prevalence of GDM is 12.8% (Muche,Olayeni & Gete 2019a:73). However, old statistics show that the prevalence of GDM is 4 to 9% of pregnant women in Ethiopia (Seyoum, Kiros, Selassie, & Leole 1999:149).

1.2.2 Background to the research problem

Globally, non-communicable diseases are becoming a major public health problem of the 21st century. This ever-increasing prevalence, coupled with communicable diseasessuch as HIV/AIDS and tuberculosis, has become a significant health and economic burden on individuals, households and governments alike (Zimmet, Magliano, Herman, & Shaw 2014:58).

Diabetes mellitus (DM) is a serious, chronic disease that happens either when the pancreas produces insufficient amounts of insulin (a hormone that regulates blood sugar, or glucose), or when the body cannot efficiently utilize the insulin it produces.

Insulin is a pancreatic hormone maintaining glucose metabolism. DM is not a separate disease entity but rather a unit of metabolic conditions sharing the common underlying characteristic of hyperglycaemia, which results from deficiencies in insulin secretion, insulin action, or both (WHO 2014).

Moreover, DM is one of the leading health emergencies of the 21st century. According to WHO, Hyperglycemia is the third highest risk factor for premature mortality (Gregg, Sattar, & Ali 2016). Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. Over the past decade, diabetes prevalence has also risen faster in low- and middle-income countries than in high-income countries, (WHO 2014).

Even though there are different types of diabetes, assigning a type of diabetes to an individual often differs on the conditions present at the time of diagnosis. In addition, many diabetic individuals do not simply fall into a single class, for instance, a person who had GDM may continue to have hyperglycaemia after delivery and this may be determined as having type to DM (American Diabetes Association 2014:83-84).

Consequently, as the occurrence of diabetes continues to increase, it is highly affecting individuals of all ages, including young adults and childbearing age and they are becoming more prone to develop diabetes during pregnancy (International Diabetes Federation 2017).

GDM is a glucose intolerance that begins or first recognized in pregnancy that is not obviously diabetes (American Diabetes Association 2014:85-86). Furthermore, GDM contributes to the most common metabolic problems of pregnancy, and is associated with maternal (caesarean section, hypertension, infection, pre-eclampsia, polyhydramnios) and fetal morbidity (macrosomia, respiratory distress syndrome, birth trauma, hypocalcaemia, hypoglycaemia, hypomagnesaemia, hyperbilirubinemia,polycythaemia) (Hod 2015).

Research suggests that GDM is a potentially significant condition which is rapidly increasing and affecting many pregnancies. For instance, in the year 2013 the global prevalence of GDM in women (20-49 years) was 16.9% or 21.4 million live births (McCance 2015:690). 25% of GDM was found in the South-East Asia region which was the highest prevalence compared with 10.4% in North America and Caribbean Region. It was also estimated that more than 90% of cases of GDM occur in low- and middle-income countries (Guariguata et al. 2014:142).

According to International Diabetes Federation Report of 2017 on global estimates of diabetes prevalence for 2017 and projections for 2045, 21.3 million or 16.2% of live births had some form of hyperglycaemia in pregnancy, an estimated 85.1% were due to GDM making 1 in 7 births to be affected by GDM and the majority cases of hyperglycaemia in pregnancy were in low- and middle-income countries, where access to maternal care is often limited (International Diabetes Federation 2017).

Besides, the magnitude of GDM ranges from 1% to 14% of all pregnancies and this depends on different situations like screening and diagnostic techniques used, genetic characteristics and setting of the population under study and prevalence of type II DM (Jang 2011:1-7).

In addition, nearly 7% of all pregnancies are complicated by GDM, resulting in more than 200,000 worldwide cases annually (Jang 2011:1-7). More important is that when compared to the general population, women with GDM have an increased risk of developing diabetes after pregnancy, with a conversion rate of up to 3% per year (International Diabetes Federation 2017). Even though the response to Oral Glucose Tolerance Test (OGTT) returns to normal after pregnancy in most cases, about 50% of women will develop Non-Insulin Dependent Diabetes Mellitus (NIDDM) within the next ten years (Herath, Herath, & Wickremasinghe 2017).

In addition, several studies done in other parts of the world suggest that GDM affects many pregnancies and its magnitude is increasing from time to time (Oostdam, van Poppel, Wouters, & van Mechelen 2011:1554-1557)**.** A closer inspection of the condition in Ethiopia exposes that there is an increasing incidence of GDM which needs

to be addressed (Seyoum et al 1999:149)**.** Every year, GDM contributes significantly to maternal morbidity and mortality in Ethiopia (Muche, Olayemi & Gete 2019a:73).

In Ethiopia, the estimated maternal mortality is 412 deaths per 100,000 live births which makes it more than three times the worldwide average (EDHS 2016). Haemorrhage, eclampsia, hypertension, and obstructed labour are the most common causes of maternal death in Ethiopia (Seyoum et al 1999:149). As a result, several of the interventions to improve maternal health have rightfully concentrated on preventing and treating these problems. GDM, however, highly increases the risk of all the causes, it is never listed as a cause of maternal death, and consequently itis not often addressed in resource-limited settings (Seyoum et al 1999:149).

Much has not been done in Ethiopia regarding the burden of GDM and its associated factors and as well its related maternal morbidity and mortality. This is quite unbecoming since a lot of research focus today is on the wellbeing ofmother and the new-born child in general.

Therefore, the present study had attempted to elicit valuable inputs to fill this void and knowing the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal morbidity and mortality related to GDM.

1.3 RESEARCH PROBLEM

The investigation of the research problem starts with becoming informed of the problem, an initial literature review to examine the problem and ultimately interpreting the research problem.

Diabetes is one of the largest health emergencies of the 21st century. According to the global estimates of WHO for risk factors for premature mortality, hyperglycaemia is the third highest risk factor, following high blood pressure and tobacco use (Gregg, Sattar, & Ali 2016).

The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. Over the past decade, diabetes prevalence has also risen faster in low- and middle-income countries than in high- income countries (WHO 2014). Consequently, as the occurrence of diabetes continues to increase, it is highly affecting individuals of all ages, including young adults and childbearing age and they are becoming more prone to develop diabetes during pregnancy (International Diabetes Federation 2017). Besides, nearly 7% of all pregnancies are complicated by GDM (Jang 2011:1-7).

In Ethiopia, the total adult population in 2020 is 53,390,400 and the prevalence of DM is 3.2% making the total cases of diabetes in adults 1,699,400 (International Diabetes Federation 2020). However, 3 years before the projected total population was estimated at 94,352,000, the estimated prevalence of diabetes was at 2% nationally (CSA fact sheet 2017: 1). Other research also suggests that the prevalence of diabetes could be greater than 5% in people older than 40 years of age (Abebe, Berhane, Worku, & Assefa 2014:1379).

As a result, pregnant mothers should be screened and diagnosed for GDM timely and they need to have a regular postpartum follow-up in order to identify and manage any complications related to GDM. But in Ethiopia, like most other developing countries, women are not often screened for GDM and in case they are screened and diagnosed, there will be very few options for managing the disease since HPs at health facilities classically follow international guidelines, which require multiple blood tests per day and this is impractical in resource limited environments (Seyoum et al 1999:149).

There are very few studies done regarding GDM in Ethiopia, for instance recent study done in southern part of Ethiopia estimated the magnitude of GDM to be 4.2% (Woticha, Deressa & Reja, 2019). Another study done in public health facilities located in Gondar Town, revealed the prevalence of GDM to be 12.8% (Muche, Olayeni & Gete 2019a:73), but still, very little data is available in Ethiopia with regards to the burden of GDM and its associated risk factors.

Therefore, the researcher believes that there is not enough information regarding the burden of GDM, its associated factors and its related maternal morbidity and mortality as well. And hence, it resulted in its relative inattention by HPs and policy makers. Besides having comprehensive information is a requirement for health action because without information it is impossible to neither create an advocacy nor create strong programs for addressing it.

Moreover, identifying women with GDM will help women to bring changes in their lifestyle to inhibit development of DM in the future. It also provides an opportunity to improve pregnancy outcomes.

Consequently, the above-mentioned reasons have motivated the researcher to examine the burden of GDM and associated risk factors, as well the experience of gynaecologists/obstetricians and midwives for monitoring and prevention of maternal morbidity and mortality related with GDM with a view to develop best practice guidelines with intention of bringing a solution.

1.4 AIM OF THE STUDY

1.4.1 Research purpose

A statement that determines the aim of the whole investigation (Creswell 2014:123) is referred to as a research purpose. It is also defined as a clear, concise statement of the specific goal or aim of a study, which is generated from a research question (Burns & Grove 2013:74).

The aim of this study is to develop best practice guidelines to monitor and prevent maternal morbidity and mortality related to GDM in Addis Ababa, Ethiopia. The intent of the guidelinesis to contribute to improve the ability of health facilities to monitor and prevent maternal morbidity and mortality related to GDM.

1.4.2 Research objectives

The objectives were:

- To determine the magnitude of GDM in Addis Ababa, Ethiopia.
- To identify associated factors with GDM in Addis Ababa, Ethiopia.
- To explore the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal morbidity and mortality related to GDM in Addis Ababa, Ethiopia.
- To develop best practice guidelines to monitor and prevent adverse maternal outcomes related to GDM in Addis Ababa, Ethiopia.

1.4.3 Research questions

A research question is about the associations between the dependent and the independent variables that an investigator intends to identify (Creswell 2014:143).

The research questions of this study were the following:

- What is the magnitude of GDM in Addis Ababa, Ethiopia?
- What are the associated factors of GDM in Addis Ababa, Ethiopia?
- What are the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal morbidity and mortality related to GDM in Addis Ababa, Ethiopia?
- What are best practice guidelines to monitor and prevent adverse maternal outcomes related to GDM in Addis Ababa, Ethiopia?

1.5 SIGNIFICANCE OF THE STUDY

The findings of the study may have numerous prospective importance for clinical practice, advocacy and community familiarization to alleviate health and economic consequences of GDM. Thus, the study will directly contribute to the demands of the beneficiaries who are the health professionals, community, as well as policy makers as follows:

1. Improves medical practice and patient care through development of guidelines.

The guidelines will help as a standard for monitoring and prevention practices to enhance quality of patient care and minimize differences in health service provision by improving medical practice.

2. Improving health services to care for patients.

The guidelines; which are the result of this study, will provide standardized suggestions about health education services and engagement of patients.

3. Contribution to policy makers and health planners.

The final product of this study is a standardized intervention (health actions that are consistent and regular) and will generate evidence about GDM and its related adverse maternal outcomes. Thus, this will assist policy makers and health planners to create an enabling situation to timely monitor andprevent GDM and its related adverse maternal outcomes.

1.6 DEFINITION OF TERMS

1.6.1 Best practice guideline

Best practice describes the process of developing and following a standard way of doing things and are useful to maintain quality as an option to compulsory legislated standards and can be based on self-assessment or benchmarking (Dembowski 2013).

Guidelines are systematically developed statements assisting HPs and patient decisions about proper health care for specific clinical conditions (Shekelle, Woolf, Grimshaw, Schünemann, & Eccles 2012:62). They are also viewed as useful tools for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports, (Shah, Mason, Kurt, Schaefer, Montori & Smith 2011:1).

In this research study, guidelines refer to the recommendations for monitoring and prevention of GDM related adverse maternal outcomes. These guidelines will help in strengthening quality patient care if utilized consistently and efficiently. The gaps in

clinical practice and support from literature evidence can be minimized through guidelines implementation when rendering care to pregnant mothers.

1.6.2 Gestational diabetes mellitus (GDM)

GDM is a glucose intolerance that starts or is first identified in pregnancy which is not obviously diabetes (American Diabetes Association 2014:85-86).

In this study, GDM refers to a high blood sugar condition that occurs during thegestational age of 24 - 28 weeks of pregnancy as obtained from medical records of women.

1.6.3 Maternal morbidity

Is any health condition attributed to and or aggravated by pregnancy and childbirth that has a negative impact on the women's wellbeing (WHO 2013:794-796).

1.6.4 Maternal mortality

Is a death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes (Say, Chou, Tuncalp, Moller, Daniels & Alkema 2014:323).

1.7 THEORETICAL FOUNDATIONS OF THE STUDY

1.7.1 Research paradigm

A paradigm is an ideological position, a world view or a general perspective on the complexities of the world (Polit & Beck 2012:11). Research paradigm is the philosophical underpinnings from which specific research approaches stem (Andrew & Halcomb 2009:17).

Likewise, paradigms or world views refer to a basic set of beliefs (assumptions) that answer to basic questions and have been explained as ontological (assumptions about the nature of reality and humanity), epistemological (the affiliation between the investigator and those being investigated), and methodological (how that knowledge may be gained) grounds (Creswell 2014:6 ; Curtis & Drennan 2013:20).

Whilst no paradigm explains all the facts, in the execution of the current study, pragmatism as a research paradigm will be used. Pragmatism is a philosophical stance that embraces multiple viewpoints of a research problem (Polit & Beck 2012:602). Pragmatism is not committed to any one system of philosophy and reality. This applies to mixed methods research in that inquirers draw liberally from both quantitative and qualitative assumptions when they engage in their research (Creswell 2009:11).

Ontological assumptions

Ontology is the nature of social phenomena and beliefs that researchers hold about the nature of social reality (Omston, Spencer, Barnard & Snape 2014:52-55). Pragmatists do not see the world as an absolute unity. Truth is what works at the time. It is not based on duality between reality independent of the mind or within the mind (Polit & Beck 2012: 602). Consequently, investigators will have a better understanding of the research problem by using both quantitative and qualitative data.

Epistemological assumptions

According to Curtis and Drennan (2013:19-21), epistemology is an ideological position which explains the association between the inquirer and those being studied or how we come to know. Pragmatism is not dedicated to any one system of viewpoint and reality, instead it focuses on methods, and in pragmatism researchers focus on the research problem and use all methods available to recognize the problem. Therefore, this applies to mixed methods research in that inquirers draw freely from both quantitative and qualitative beliefs (Creswell 2009:11).

Methodological assumptions

The opinions of the researcher regarding the kind of knowledge and exploration in a study is referred to as methodological assumptions (Watts & Stenner 2012). As aresult, methodological assumptions direct the researcher in choosing the most suitable methods to be used in a study (Watts & Stenner 2012). In mixed methods, instead of condoning to only one way of data collection, researchers use various methods of data collection and

analysis techniques. Since this research study used mixed methods, pragmatism research paradigm guides the researcher to have a broader view of the phenomenon under investigation. Ithas broadly encompassed quantitative methods; determining the prevalence of GDM related maternal morbidity and mortality and its associated factors and qualitative methods; in order to explore gynaecologists and midwives' experiences towards monitoring and preventing maternal morbidity and mortality related to GDM.

1.7.2. Theoretical framework

The theoretical framework guides the development connections between the results of the study and the present or available knowledge (Burns et al. 2011:238).

1.7.2.1 Neuman Systems Model Nursing Theory

The researcher was guided by the Neuman Systems Model (NSM). NSM focuses on the client (an individual, family group or public) as a system (this includes physiological, psychological, sociocultural, developmental, and spiritual aspects) and as well on the client 's response to stressors (Freese & Lawson 2010:311-15). This model provides a complete, adaptable, universal and system-based standpoint for nursing and health care.

According to NSM, HPs treating women with GDM need to use prevention strategies as an intervention (i.e. three levels of prevention).

- Primary prevention of GDM and its related adverse maternal outcomes starts at the pregnant woman's first ANC visit using baseline evaluation to detect risks andtackle preventable ones.
- Secondary prevention is about early recognition of signs of GDM. Regular monitoring of health status is crucial in secondary prevention.
- Tertiary prevention is about rehabilitation of women with GDM and its adverse maternal outcomes.

In general, the NSM model provides a complete, adaptable, universal and system- based standpoint for nursing and health care. The model is based on the subsequent important points:

1. The client system (a person, family or society);
2. Interacting variables of the client system (i.e. physiological, psychological, spiritual, developmental and sociocultural);
3. Client ‘s response to actual or potential environmental stressors (which areinternal, external and created environments), the reaction to it, and reconstitutionfactors that are dynamic in nature;
4. Emphasis on prevention, as intervention (for retention, attainment, and maintenance) of optimal client system wellness;
5. The goal of the nurse is to preserve the client system's stability through the three levels of prevention (i.e. primary, secondary and tertiary prevention).
6. Neuman's System Model guides a structure for the development of complete diagnoses, determination of appropriate interventions and evaluation of outcomes.
7. The partnership between the nurse and client can be applied to identify a stressor(s) that may infiltrate the adaptable defence and lead to divergence from wellness as in the case of pregnant women with GDM. The variation fromwellness and how to monitor and prevent GDM and its related adverse maternal outcomes is the aim of this study. Above all, NSM offers a structure that summarizes the stages of the medical process as a continuum (Neuman & Fawcett 2002a).

1.7.3. Conceptual framework

NSM offers a structure that aids in the establishment of complete screening and diagnostic techniques, determination of apt interventions and assessment of results. The relationship of the nurse and the client can be useful to distinguish a stressor(s)that may infiltrate the adaptable defence and lead to change from wellness as in the event of GDM. The variation from wellness and how to monitor and prevent this was theinterest of this study.

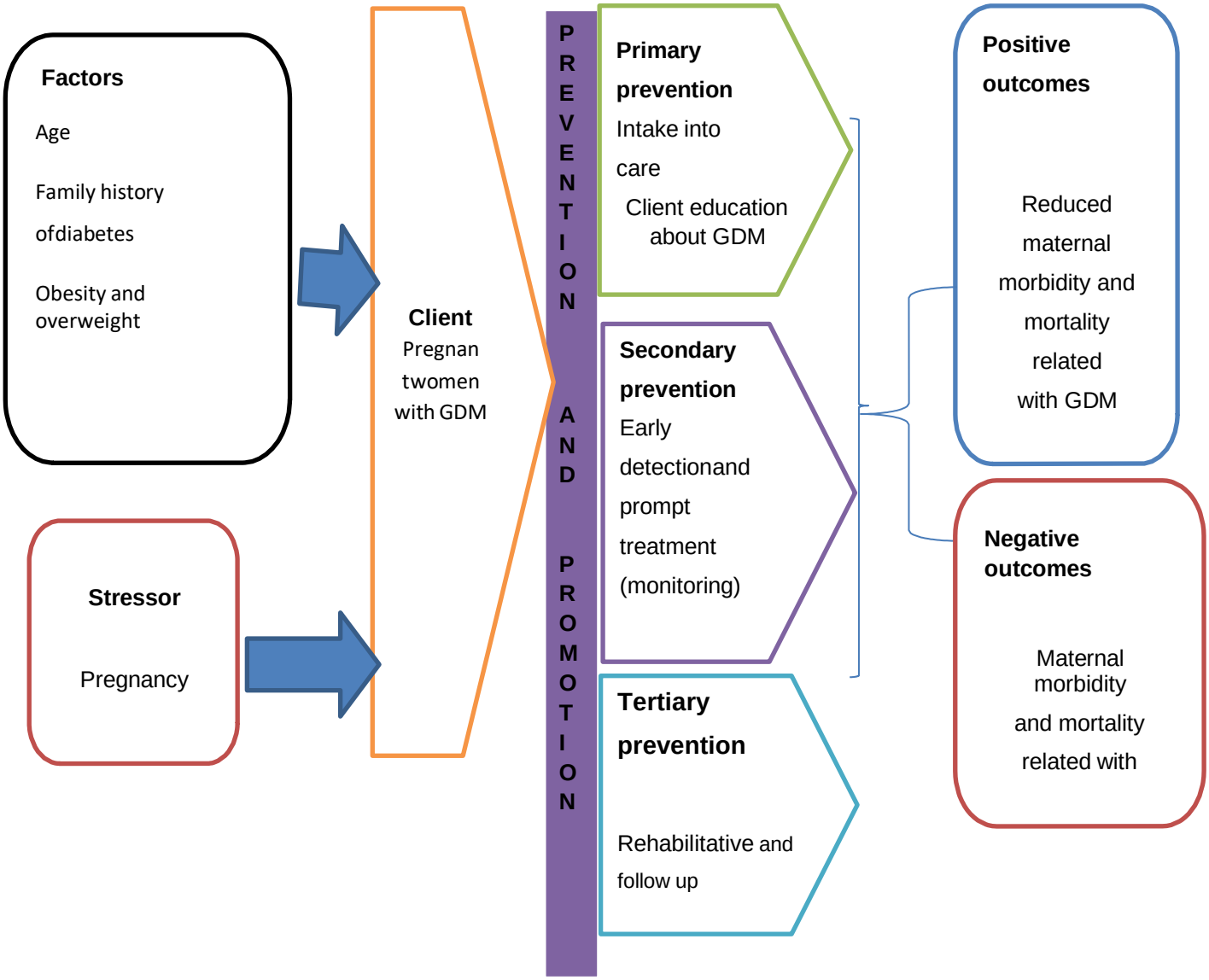

Figure 1.1 A conceptual framework for study of effectiveness of educational intervention regarding self-care management of GDM among primigravida mothers attending outpatient departments (Adapted from Betty Neumann's Systems model)

(Neuman & Fawcett 2002b).

1.8 RESEARCH DESIGN AND METHODS

1.8.1 Research design

It is the bigger plan for managing the study, which encompasses the plan of data gathering, utilization, measurement and analysis (Curtis & Drennan 2013:131).

The proposed research design for this study was concurrent mixed methods since mixed method is concerned with the quality of information and attempts to gain understanding of fundamental explanations for actions and interpret how gynaecologists and midwives comprehend their experiences and the world around them. In this study retrospective cohort study with in-depth interviews was used.

A mixed method study focuses on gathering, analysing and mixing both quantitative and qualitative data in a study or series of studies. Its central premises are that of quantitative and qualitative approaches, in combination, provides a better understandingof research problems than either approach alone (Creswell, Clark, & Smith, 2011:2098).

1.8.2 Research methods

Research methods is about the methods of data collection, analysis and interpretation that the study employs for the research (Creswell 2014:16-17). Whereas, methodology is the steps, strategies and procedures that are used to collect and analyse data in a study (Polit & Beck 2008:723). It gives guidance on which methods are better fitted to the kind of research to be conducted.

In this research study, concurrent mixed method was used. In concurrent mixed method the reseracher can collect qualitative and quantitative data at the same time or in parallel. Research methods of this study are summarized below:

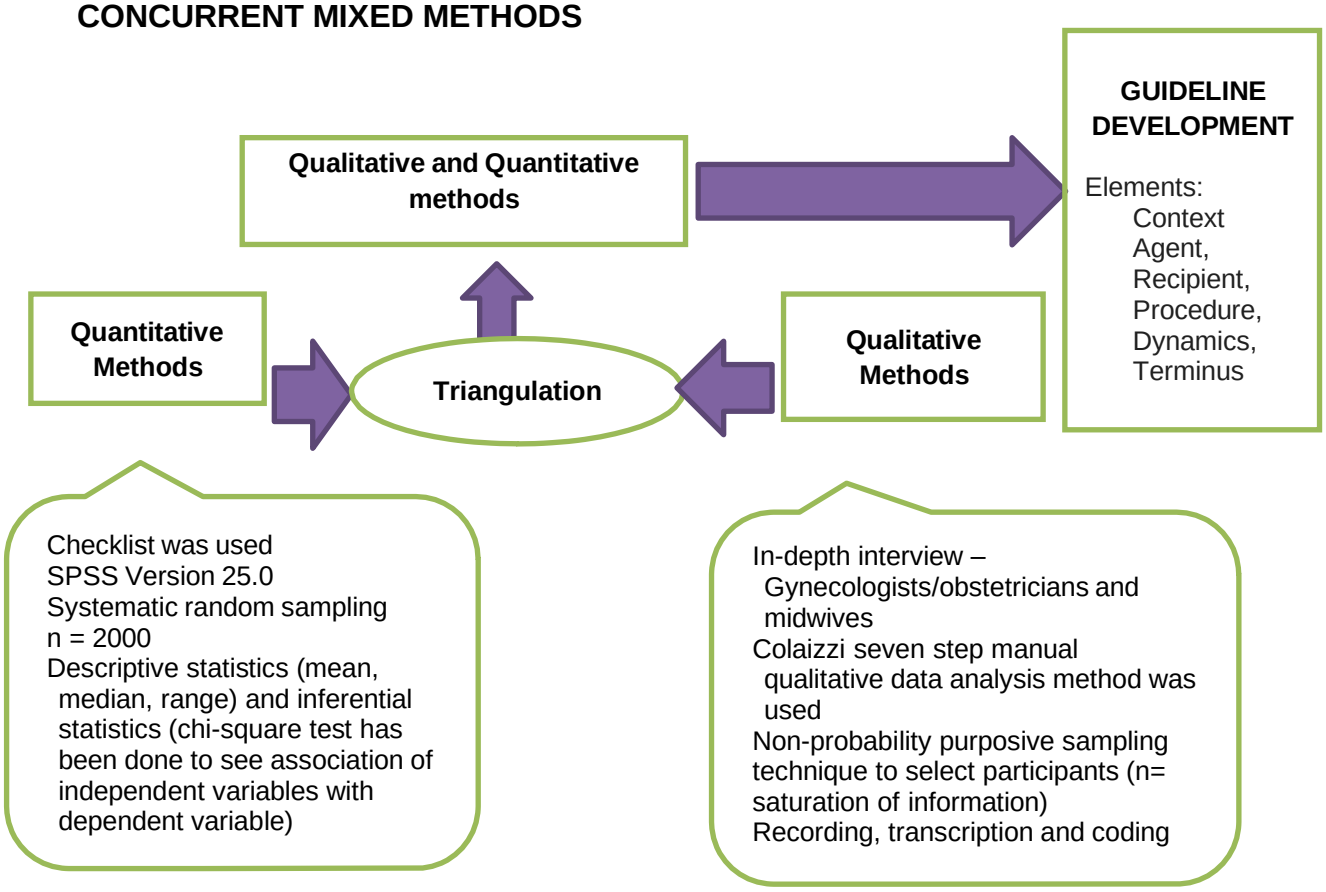

Figure 1.2: Structural overview of research methodology

1.8.3 Research setting and study population

Setting refers to the physical location and situations in which data gathering takes place in a research (Polit & Beck 2010:568). Gandhi Memorial Hospital was the place where the research study was conducted. This hospital was purposely selected because the flow of pregnant women for ANC follow up is very high compared to other hospitals in

Addis Ababa. Gandhi Memorial Hospital is a government hospital in Addis Ababa, Ethiopia. It was established by Mahatma Gandhi in 1948 and it provides health care services for women and new-born babies. There are 9 gynaecologists/obstetricians, 38 midwives and around 670-750 women are provided care during a month's time.

A study population is a specific unit of individuals, which are the emphasis of the research (Burns & Grove 2011:299). Study population were pregnant women who had ANC follow up and delivered in Gandhi Memorial Hospital during the cohort (2013-2017) in Addis Ababa for the quantitative part of the research study, whereas gynaecologists/obstetricians and midwives that work in Gandhi Memorial Hospital were included for the qualitative part of the study.

1.8.4 Data collection, sampling techniques and sample size determination

Data collection refers to the process of gathering information to tackle a particular research problem (Polit & Beck 2012:293). Summary of data collection, sampling techniques and sample size determination procedures (plan) for this study are described below using two different phases which were conducted simultaneously (i.e. Phase 1a and Phase 1b) (Table 1.1).

TABLE 1.1: SUMMARY OF DATA COLLECTION, SAMPLING TECHNIQUES AND SAMPLE SIZE DETERMINATION PROCEDURES.

Concurrent mixed methods	Objectives	Data collection instruments	Population	Sampling methods	Sample size
Phase 1a Quantitative	1and 2	Checklist	Mothers who attended ANC care and who delivered in Gandhi Memorial hospital during the cohort (2013-2017)	Systematic random sampling	2000
Phase 1b Qualitative	3	In-depth Interview guide	Gynaecologists/obstetricians and midwives	Non-probability purposive sampling method	7 gynaecologists and 12 midwives were interviewed

For the **qualitative** part of the study, participants were purposely recruited and were requested to participate voluntarily. Data was gathered from the participants using an interview guide until data saturation was reached. To safeguard credibility of results, observation and field notes were utilized. The interviews were also tape recorded as this helped the researcher to develop a note which assisted during analysis of codes. The checklists as well as the interview guides were pre-tested prior data gathering.

Validity and **reliability** measure the precision (accuracy) and extent of a measurement tool: to which a measurement produces similar measurements on a repetitive measure. This researcher had ensured validity and reliability in this study. Details about validity and reliability will be discussed in chapter 3.

Moreover, trustworthiness of the results was recognized by using the criteria suggested by Lincoln and Guba (1985) cited in Streubert & Carpenter (2011: 47-49; Polit & Beck 2012: 584-586). The components of trustworthiness are highlighted below:

Credibility is the certainty in the "truth" of the findings, and it included increasing the likelihood of producing reliable findings (Polit & Beck 2012:585). This study ensured credibility through prolonged engagement (spending more time with participants during data gathering).

Dependability is similar to the concept of reliability in quantitative study, and is defined by Polit and Beck (2012:585) as a standard for appraising the integrity of qualitative studies. It is also about stability of data over period and over circumstances.

In this study dependability was ensured by the consistency of the interview guide irrespective of where it is going to be used. The interview guide was prepared meticulously by consulting experts on the area, supervisor and by reviewing literatures.

Confirmability is about the possible similarity of the views of two or more independent people in relation to the data's precision, importance, or connotation (Polit & Beck 2012:585). All in all, confirmability is about objectivity. This standard is concerned with

determining data that represents the information which participants are given, and that the interpretations of the data are not invented by the inquirer. It was ensured by using reflexivity to avoid using own opinions, beliefs and knowledge about the study phenomenon in order not to contaminate the data.

Transferability is the likelihood that the study findings can be meaningful when transmitted to other comparable situations or groups (Polit & Beck 2012:585). Transferability in this study was safeguarded using dense explanation of the overall research process in order to assist other researchers to verify applicability of the research by duplication.

Authenticity refers to the extent to which researchers fairly and faithfully show a range of realities (Polit & Beck 2012:585). Therefore, in this study, data collection and analysis were done with integrity and honesty in order to ensure authenticity. The researcher also obeyed the principles of authenticity by recognizing all the sources that were utilized.

Criticality refers to critical appraisal of every decision made by the researcher through the steps of the research (Polit & Beck 2012:586). In the course of the study process, the researcher appraised every decision made.

Integrity is about ensuring interpretations of findings are valid and grounded in the data through ongoing self-reflection and self-scrutiny (Polit & Beck 2012:586). In this study, the researcher safeguarded integrity, by constantly consulting supervisor and experts in the area, the researcher also made sure that interpretation of the data was valid.

1.8.5 Data Analysis

Data analysis in this research started following concurrently collected data as shown in figure 1.2. Quantitative data was entered, cleaned, and analysed using SPSS version 25.0. Data was analysed for descriptive statistics (such as mean, median, range, percentage) and inferential statistics such as chi-square test was made to see

associations of each independent variable with the dependent variable. Tables, texts and graphs were used to present results of the study. Qualitative data was analysed after transcription and coding was done following Colaizzis' seven steps manual qualitative data analysisprinciple, as presented in Figure 1.3 and then triangulation was made.

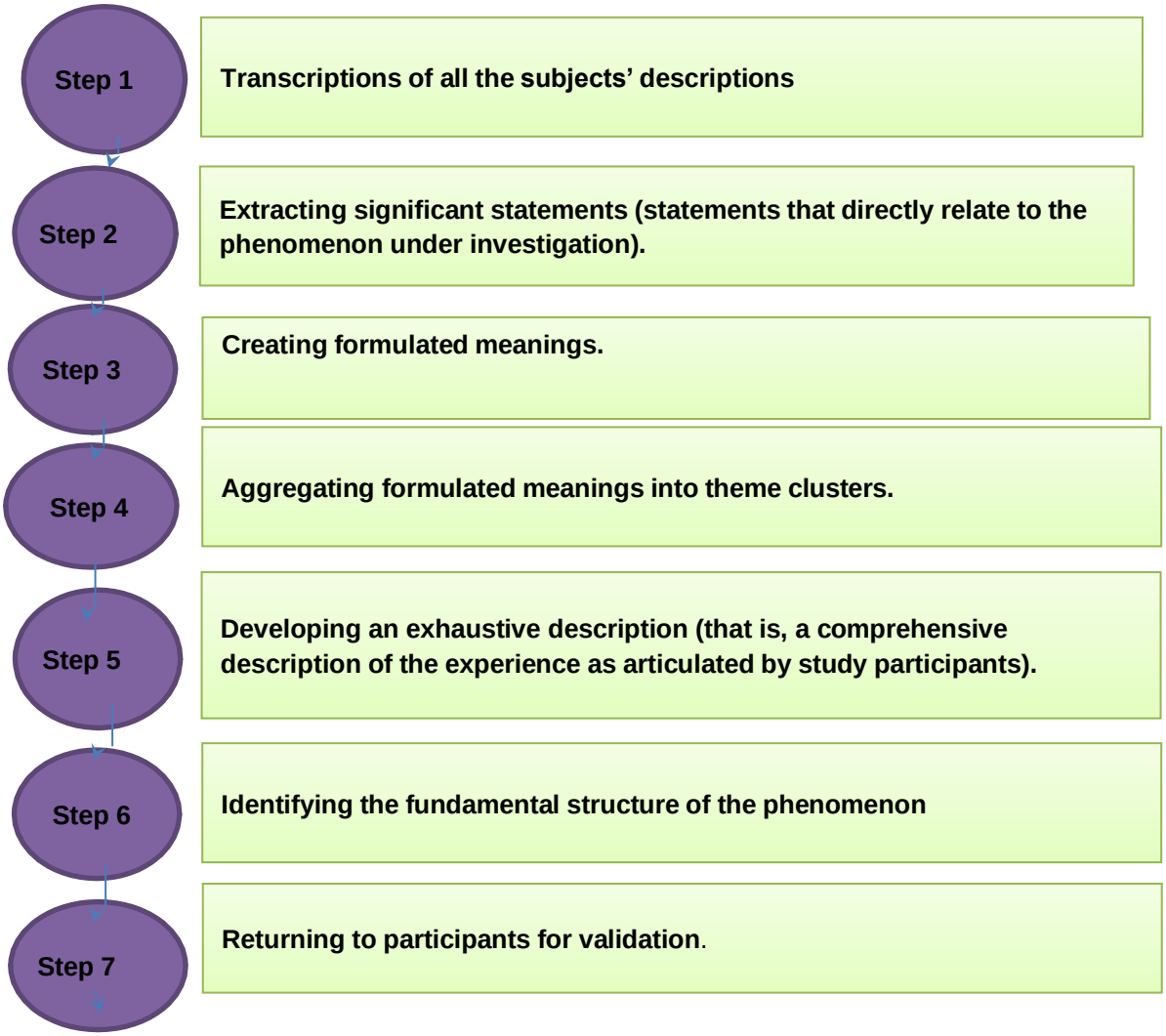

Figure 1.3 Summary of Colaizzi's seven steps of manual qualitative data analysis

(Colaizzi, 1978).

1.8.6 Ethical considerations

According to Polit and Beck (2008: 753), ethical considerations implies a method of moral principles that is involved with the extent to which research techniques hold to professional, legal and social requirements to the study participants.

The Higher Degrees Committee of the Department of Health Studies of University of South Africa (Annex A1) and Addis Ababa Health Bureau Research Review Committee (Annex A2) has granted the researcher with written ethical approval. Verbal permission was also obtained from the participating government hospital.

The researcher has obeyed the ethical principles of autonomy, beneficence, non-maleficence and justice, as presented below:

Autonomy: is about self-rule and self-determination and to have the competence to make one's own choices involving one's own life (Schmidt & Brown 2011:482).

Autonomy in this study was adhered to by showing respect to the respondents and by providing full information about the research including the right to withdraw from the study at any given time, and this was helpful for the respondents to make informed decisions. Moreover, signed informed consent has been obtained as an indication of voluntary participation.

Beneficence: refers to the notion of doing 'good' and maximizing benefits of the participants (Schmidt & Brown 2011:475).

No names of participants appeared anywhere on the document which ensured that the privacy of the participants was protected. These documents were only accessible to the researcher as well as those who are directly involved with the research and were kept safely.

Non-maleficence: refers to the responsibility of the researcher to lessen harm, (Schmidt & Brown 2011:476).

Since this study does not entail any experimentation or manipulations, it did not pose any significant harm on study participants.

Justice: refers to the equity and fairness in the allocation of advantages and chances and providing equal treatment to equal people (Schmidt & Brown 2011:482).

For the qualitative part of the study, participants were purposively sampled. Since the researcher used the same kind of eligibility criteria to recruit participants for the study, equal access was given for both males and females. In addition, similar respect was given during interviews. Moreover, the quantitative part of the study used systematic random sampling technique.

1.9 SCOPE OF THE STUDY

This research is under the field of public health. This study had evaluated the incidence and risk factors of GDM and also experiences of gynaecologists and midwives towards monitoring and preventing maternal morbidity and mortality related to GDM in Addis Ababa, Ethiopia.

1.10 STRUCTURE OF THE DISSERTATION

Chapter	Title	Content description
1	ORIENTATION TO THE STUDY	It is a preliminary chapter which highlights the research problem, research aims, research methodology, theoretical and conceptual frameworks, as well as research paradigm, ethical considerations, significance of the research and also the scope of the study.
2	LITERATURE REVIEW	Reviewed literature is presented. The phenomenon GDM and its related adverse maternal outcomes are described. Monitoring and prevention strategies are also highlighted.
3	RESEARCH DESIGN AND METHODS	The overall methodology of both quantitative and qualitative part of the study was outlined.
4	ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDING	Results of the study were analysed and presented. Moreover, the results were scrutinized with other relevant literature.
5	GUIDELINE DEVELOPMENT	Guideline development and validation process was presented.
6	CONCLUSION, LIMITATIONS AND RECOMMENDATIONS	The summary, limitations and recommendations of the study was presented.

1.11 CONCLUSION

In this chapter, the introduction of the study was presented. It provided the background of the study problem, the aim and the objectives as well the theoretical foundations and conceptual framework were described. Moreover, the research methods werepresented.

In the subsequent chapter, the literature relevant to the research study will be described.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The previous chapter presented an overview of the study. This chapter presents a literature review which covers a wide range of interdependent topics consisting of definition of literature review, purpose of reviewing literature, and implementation of inclusion and exclusion criteria of relevant literature sources.

This chapter deals with the review of the literature on the notions of magnitude and associated factors of GDM with mechanisms for the monitoring, preventing and best practice of GDM related maternal outcomes as well the experience of gynaecologists/obstetricians and midwives towards monitoring and prevention of adverse maternal outcomes related with GDM.

This chapter also gave highlights of NSM and its application on the development of the guidelines. Moreover, it highlighted the training of gynaecologists/obstetricians and midwives in Ethiopia and described GDM guidelines in Ethiopia.

Literature review is the critical analysis of a published body of knowledge from scholars in research articles, journals, monographs, books and theses on the topic. Literature review is a systematic evaluation and summarizing of the research findings done previously on a topic similar to that of the researcher (Aveyard 2014:18). Besides, literature review is also important for other researchers and readers through sharing the findings of previously done research by different researchers and helping them to compare the research findings and discover gaps. Literature review is also used to describe the existing body of knowledge and problem about the topic (Aveyard 2014:18). In addition, a literature review is the comprehensive study and interpretation ofliterature that relates to a particular topic (Aveyard 2014:3). It is an ongoing processthat starts when the researcher immediately decides on a topic. Moreover, the literature review process is a research methodology in its own right and should commence with a research

question, followed by a research design, presentation of results and finally a discussion of results.

In contemporary academic parlance (Trafford & Leshem 2008:68) literature stands for either of the following:

- A physical corpus of published works on specific topic;
- The extended body of writing that relates to specific corpus of publishedworks;
- The accumulated knowledge that resides within the corpus;
- Work in progress that, when finished, will add to the corpus of knowledge.

Literature can be accessed from journal articles, books, departmental reports, conference proceedings and other forms of collated information. Its target is to conveyto the reader up-to-date information on the problem and develop a foundation foranother target, like for instance for the explanation of future research in the area. It alsoacts as guidance for the researcher on how to develop the aims and objectives of the study.

2.1.1. Purpose of Literature Review

The purpose of literature review according to Bhattacherjee (2012:21) include the following:

- To survey the current state of knowledge in the area of inquiry,
- To identify key authors, articles, theories, and findings in that area,
- To identify gaps in knowledge in that research area,
- Help researchers become familiar with the work that has already been conducted in their selected topic areas,
- Guide the researcher in an appropriate direction by answering several questions related to the topic area,
- Gives readers easy access to research on a particular topic by selecting high quality articles or studies that are relevant, meaningful, important and valid and summarizing them into one complete report,
- It ensures that researchers do not duplicate work that has already been done,
- It can provide clues as to where future research is heading or recommend areas on which to focus.

2.1.2. Implementation of inclusion and exclusion criteria

Inclusion criteria:

- Peer reviewed articles on the topics,
- Studies that focused on GDM incidence,
- Studies that discussed associated factors of GDM,
- Government data published through the government gazettes and policy guidelines and
- Studies focusing on GDM screening and prevention strategies,
- Books not older than 10 years unless necessary.

Exclusion criteria:

- Publications which were not written in English,
- Articles that were published longer than five years, as they would be too outdated to contribute to the current knowledge (unless justified as to be important) and
- Articles, which were not peer reviewed as the authenticity of such articles, could not be established.

2.2. DIABETES MELLITUS

Non-communicable diseases are globally becoming a major public health problem of the 21st century (WHO 2014). This ever-increasing prevalence, coupled with communicable diseases such as HIV/AIDS and tuberculosis, has become a significant health and economic burden on individuals, households and governments alike (WHO 2014).

Diabetes mellitus (DM) is a serious, chronic disease that occurs either when the pancreas does not produce enough insulin (a hormone that regulates blood sugar, or glucose), or when the body cannot effectively use the insulin it produces. Insulin is a pancreatic hormone maintaining glucose metabolism. Diabetes mellitus is not a single disease entity but rather a group of metabolic disorders sharing the common underlying feature of hyperglycaemia, which results from defects in insulin secretion, insulin action,or both (WHO 2014).

DM is a metabolic disorder categorized by hyperglycaemia due to impaired insulin production or insulin resistance. Insulin is a pancreatic hormone maintaining glucose metabolism. Insulin is a pancreatic hormone maintaining glucose metabolism (Dibart 2013:29).

In addition, diabetes is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. Pathogenic processes involved in the development of diabetes include destruction of pancreatic b-cells with consequent insulin deficiency to abnormalities that result in resistance to insulin action. The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels (American Diabetes Association 2014:82).

Diabetes is a serious public health problem, which is one of the four priority non-communicable diseases (NCDs) targeted for action by world leaders (WHO 2014). It is one of the largest health emergencies of the 21st century. The World Health Organization (WHO) estimates that globally, hyperglycaemia is the third highest risk factor for premature mortality, following high blood pressure and tobacco use. Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population. Over the past decade, diabetes prevalence has risen faster in low- and middle-income countries than in high-income countries (WHO 2014).

There are different types of diabetes. Assigning a type of diabetes to an individual often depends on the circumstances present at the time of diagnosis, and many diabetic individuals do not easily fit into a single class, a person diagnosed with GDM may continue to be hyperglycaemic after delivery and may be determined to have, in fact, type II diabetes (International Diabetes Federation 2017).

2.2.1. Types of diabetes mellitus

2.2.1.1. Type 1 diabetes mellitus

Immune-mediated diabetes mellitus: is a type 1 diabetes, which accounts for only 5–10% of diabetes, previously encompassed by the terms insulin-dependent diabetes or juvenile onset diabetes and results from a cellular mediated autoimmune destruction of the b-cells of the pancreas evidenced by markers such as islet cell autoantibodies, autoantibodies to insulin, autoantibodies to GAD (GAD65), and autoantibodies to the tyrosine phosphatases IA-2 and IA-2b. These auto antibodies are found in 85–90% of individuals when fasting hyperglycaemia is initially detected. Rate of b-cell destruction is rapid in some groups of individuals particularly inchildren and infants and slow in adults. It may be presented as ketoacidosis to bethe first clinical manifestation in children and adolescents (American Diabetes Association 2014:82-83).

Idiopathic Diabetes: Is a type 1 diabetes mellitus which has no known aetiologies. Some of these patients have permanent insulinopenia and are prone to ketoacidosisbut have no evidence of autoimmunity. Individuals with this form of diabetes suffer from episodic ketoacidosis and exhibit varying degrees of insulin deficiency between episodes. This form of diabetes is strongly inherited, lacks immunological evidence for b-cell autoimmunity, and is not Human Leukocyte Antigen (HLA) associated (American Diabetes Association 2014:83).

2.2.1.2. Type 2 diabetes mellitus

Type 2 DM is insulin dependent diabetes, adult-onset diabetes, which accounts for 90–95% of those with diabetes and encompasses individuals who have insulin resistance and usually have relative rather than absolute insulin deficiency. This form of diabetes frequently goes undiagnosed for many years because the hyperglycaemia develops gradually and is often not severe enough for the patient to notice any of the classic symptoms of diabetes at earlier stages. Patients with this type of diabetes are at an increased risk of developing macro vascular and micro vascular complications (American Diabetes Association 2014:83).

Risk of developing this form of diabetes increases with age, obesity, and lack ofphysical activity, more in women with prior GDM and in individuals with hypertension or dyslipidaemia and has strong genetic predisposition than type 1 diabetes (American Diabetes Association 2014:83).

2.2.1.3. Other specific types of diabetes

Genetic Defects of the b-cell:

Is referred as maturity-onset diabetes of the young (MODY), which is an inherited in an autosomal dominant pattern characterized by onset of hyperglycaemia at an early age (generally before 25 years of age), impaired insulin secretion with minimal or no defects in insulin action (American Diabetes Association 2014:83-84).

Together with genetic defects of the b-cell, other specific types of diabetes include genetic defects in insulin action, diseases of the exocrine pancreas, drug- or chemical- induced diabetes, infections, and uncommon forms of immune-mediated diabetes (American Diabetes Association 2014:83-84).

Gestational diabetes mellitus (GDM):

Gestational diabetes mellitus (GDM) is diabetes diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes (American Diabetes Association 2014:85-86).

GDM is a high blood sugar condition that some women acquire during pregnancy and it usually starts halfway through the pregnancy between the 24th and 28th week of pregnancy. It differs from the other type of diabetes because it is first recognized during pregnancy in previously undiagnosed patients and it usually resolves after pregnancy (American Diabetes Association 2014:83-84). This condition causes high levels of glucose in pregnant women because during pregnancy, placental hormones and increased fat deposits mediate insulin resistance thereby blocking insulin action to bind its receptors (American Diabetes Association 2014:83-84).

GDM is a public health problem that currently affects a large part of the female population and has short- and long-term consequences both for the foetus and the mother (Erem, Kuzu, Deger & Can 2015:724). It also represents the most common metabolic complication of pregnancy and is associated with maternal and fetal morbidity. Some of the maternal morbidities related with GDM are hypertension, pre- eclampsia, caesarean section, infection and polyhydramnios. In addition, macrosomia, birth trauma, hypoglycaemia, hypocalcaemia, hypomagnesaemia, hyperbilirubinemia, respiratory distress syndrome and polycythaemia are the fetal morbidities related with GDM (Hod 2015).

According to International Diabetes Federation Report of 2017, 21.3 million or 16.2% of live births had some form of hyperglycaemia in pregnancy, an estimated 85.1% were due to gestational diabetes making 1 in 7 births to be affected by GDM and the vast cases of hyperglycaemia in pregnancy were in low- and middle-income countries, whereaccess to maternal care is often limited (International Diabetes Federation 2017).

Besides, approximately 7% of all pregnancies are complicated by GDM, resulting in more than 200,000 worldwide cases annually and the prevalence may range from 1% to14% of all pregnancies depending on genetic characteristics and environment of the population under study, screening and diagnostic methods employed as well as on prevalence of type 2 diabetes mellitus (Jang 2011:1-7).

As the incidence of diabetes continues to rise and increasingly affect individuals of all ages, including young adults and childbearing age are at increased risk of diabetes during pregnancy (International Diabetes Federation 2017). More important is that when compared to the general population, women with GDM have an increased risk of developing diabetes after pregnancy, with a conversion rate of up to 3% per year (International Diabetes Federation 2017). Even though the response to Oral Glucose Tolerance Test (OGTT) returns to normal after pregnancy, in most cases, about 50% of women will develop Non-Insulin Dependent Diabetes Mellitus (NIDDM) within the next ten years (Herath, Herath & Wickremasinghe 2017).

It is therefore essential that these mothers are properly screened and diagnosed during pregnancy and that they have a regular postpartum follow-up for identification and treatment of any complications.

2.3. MAGNITUDE OF GDM

Though there are inconsistencies in the screening, diagnosis and reporting system of GDM, the prevalence of GDM is at an increasing pace (Lynch et al. 2015:320). In addition, the prevalence of GDM varies based on the country, socio-economic status and dietary habits. Prevalence may range from 1% to 14% of all pregnancies depending on genetic characteristics and environment of the population under study, screening and diagnostic methods employed as well as on prevalence of type 2 diabetes mellitus (Jang 2011:1-7).

The prevalence of GDM among women veterans deployed in service of operations in Afghanistan and Iraq was 5.2% (Katon et al. 2014:796). Besides, the magnitude of GDM ranges from 1% to 14% of all pregnancies and this depends on different situations like screening and diagnostic techniques used, genetic characteristics and setting of the population under study plus prevalence of type II DM. In addition, nearly 7% of all pregnancies are complicated by GDM, resulting in more than 200,000 worldwide cases annually (Jang 2011:1-7).

2.3.1 Magnitude of GDM by continent

2.3.1.1 Europe

The prevalence of GDM in Europe in the year 2016 was 5.4% (Eades, Cameron & Evans 2017). In Belgium for instance age standardized prevalence of GDM in 2014 was 5% whereas in France in the same year it was 11.6% (McCloskey, Bernstein, Winter, Iverson, & Lee-Parritz 2014:331).

2.3.1.2 Asia

A study in China revealed the prevalence of GDM to be 12.21% (Siyuan et al., 2015:5). In India, hyperglycaemia in pregnancy (HIP) was prevalent at 18.9% of the study population, where 16.3% and 2.6% of study population were GDM and diabetes in pregnancy (DIP) respectively (Kragelund, Courten & Anil 2016:6-8).

Moreover, the overall prevalence of newly detected diabetes during pregnancy in Qatar was 24.0% (95% CI: 22.1± 25.9) of which, 2.5 % (95%CI: 1.9± 3.3) and 21.5 %(95%CI: 19.7± 23.3) were type 2 diabetes mellitus (T2DM) and GDM respectively (Bashir et al., 2018:5).

2.3.1.3 North America and South America

A retrospective cohort on prevalence of GDM and associated factors among women in Pacific Island Nation of Palau showed that the prevalence of gestational diabetesmellitus among pregnant women was 5.5% (Sugiyama et al., 2017:1963).

In US, Tennessee, the prevalence of GDM was found to be at 5% (Chakkalakal, Gebretsadik, Jagasia, Shintani & Elasy 2015:2), whereas Garrison (2015:461 & 462) reported that GDM affects about 6% of pregnancies in the United States of America.

2.3.1.4 Australia

The age standardized prevalence of GDM in Australia in the year 2014 was 6.7% (McCloskey et al, 2014:331).

2.3.1.5 Africa

There is a high burden of GDM in Africa especially in sub-Saharan Africa, where the pooled prevalence of GDM in Africa was 13.6% whereas it was 14.3% in sub-Saharan Africa (Muche, Olayeni & Gete 2019b). Moreover, age standardized prevalence of GDM in Nigeria was 14.4% (McCloskey et al, 2014:331).

2.3.1.6 The case of Ethiopia

There has not been much studies done regarding prevalence of GDM and it was previously estimated that GDM occurs in 4 to 9% of pregnant women in Ethiopia, but these data are scant and old. It is also estimated that 80% of cases remain undiagnosed (Seyoum et al. 1999:149).

However, a cross-sectional study done in public health facilities located in Gondar Town, revealed the prevalence of GDM to be 12.8% (Muche, Olayeni & Gete 2019a:73).

In addition, a study done in Wolayita zone (southern part of Ethiopia) in the year 2017 estimated the prevalence of GDM to be 4.2% (Woticha, Deressa & Reja 2019: 86-91).

Ethiopia and other African countries

The prevalence of GDM in Tanzania in the year 1991 was 10%, whereas on the same year it was only 1.6% in South Africa. However, another study done in South Africa in the year 2010 had showed a prevalence of 3.8%. Moreover, a study done in Morocco in the year 2009 had shown a prevalence of 7.7% (Macaulay, Dunger & Norris 2014). However, in Ethiopia according to a research done in 1999 the prevalence of GDM was between 4 to 9% (Seyoum et al. 1999:149).

2.4. RISK FACTORS OF GDM

A risk factor is any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury (WHO 2004). The researcher reviewed the following literature Sugiyama et al., (2017:678); Latif, Iqbal and Aftab (2015:316); Kragelund et al., (2016:6-8); Wilmot and Mansell (2014:678); Rajput, Yadav, Nanda and Rajput (2013:730-732); Shen et al, (2017:595); Muche, Olayeni and Gete, (2019a:73), and found the following significantly associated factors: -

- Maternal age greater than 35 years,
- Body Mass Index (BMI equal to and greater than 30),
- Family history of diabetes mellitus,
- Previous history of a macrosomic baby weighing 4.5kg or above,
- Previous gestational diabetes,
- Ethnicity/Race,
- Other factors.

2.4.1 Maternal Age

Women who were 30 years and older, were more likely to have GDM than younger women (Sugiyama et al., 2017:1963). Moreover, maternal age greater than 35 years (p=0.00) were significantly associated with GDM (Latif et al, 2015:316).

A study done inIndia has also shown that maternal age is significantly associated with GDM (Rajput et al, 2013:730-732). In addition, women with GDM at their first birth were more likely to be older (Shen et al, 2017:595).

2.4.2. Body Mass Index (BMI equal to and greater than 30)

Risk factors for gestational diabetes include Body Mass Index (BMI) above 30kg/m2 as Wilmot and Mansell (2014:678) and Latif et al (2015:316) had reported.

Another researcher had also added that BMI greater or equal to 30 or being obese is significantly associated to risk factors of GDM (Kragelund et al, 2016:6-8).

2.4.3. Family history of diabetes mellitus

Having both parents or a mother with diabetes is a significant independent risk factor for GDM (Kragelund et al., 2016:6-8; Latif et al, 2015:316; Pu et al. 2015:439). Wilmot and Mansell (2014:678) had also added that family history of DM is a factor that is significantly associated with GDM.

2.4.4. Previous history of macrosomic baby weighing 4.5kg or above

Previous history of macrocosmic babies or baby (p=0.00) was one of the factors that was significantly associated with GDM (Latif et al, 2015:316). Previous macrosomic baby weighing 4.5kg or above was also mentioned as a significantly associated factor with GDM (Wilmot & Mansell 2014:678).

2.4.5. Previous gestational diabetes

Previous history of GDM is another risk factor that contributes to the development of GDM. Having a previous history of GDM (p=0.01), was significantly associated with GDM (Latif et al, 2015:316; Wilmot & Mansell 2014:678).

2.4.6. Ethnicity/Race

Race/ethnicity had variation on the association of GDM and gestational weight gain. Women with GDM had less mean gestational weight gain (GWG) than women without GDM (13.1$\pm$9.0 kg versus 14.5$\pm$ 8.0 kg).

Non-Hispanic white women with GDM experienced less GWG than those without GDM. Non-Hispanic black women with GDM experienced greater GWG than those without GDM and Hispanic women with GDM experienced GWG than those without GDM (Chakkalakal et al, 2015:2).

In contrast to this, a study done in Qatar revealed that the burden of GDM didn't vary across various ethnic groups (Bashir et al., 2018:5).

2.4.7. Other Factors

Educational level, socio-economic status, pregnancy weight, weight gain, early menarche and previous CS were some of the other factors associated with GDM.

A study done in India showed that **educational level, socio-economic status**, and **pregnancy weight** and **weight gain** were factors significantly associated with GDM, (Rajput et al, 2013:730-732).

Moreover, association between **early menarche** and GDM was investigated with a sample comprising of 5914 of mothers giving birth for the first time, where 3.4% mothers had self-reported GDM. This was done by grouping them into three heterogeneous menarche onset groups as early menarche, normal menarche and late menarche. It was foundthat early menarche groups had 1.75 (95%CI: 1.10-2.79) times odds of having GDM than normal menarche groups. In addition, women with GDM at their first birth were more likely to be older, or with family history of diabetes mellitus than those without GDM and women who were currently widowed were less likely to have GDM at their first live birth ($p<0.05$) (Shen et al, 2017:595).

According to Muche, Olayeni and Gete (2019a:73) the other factors that showed association with GDM were history of **previous spontaneous abortion and CS,** these two factors were found to be significantly associated with GDM (AOR 3.5; 95% CI 1.7-14.6, AOR 7.5; 95% CI 1.3-14.4) respectively.

2.5. GDM RELATED ADVERSE MATERNAL OUTCOMES

GDM is a public health problem that currently affects a large part of the female population and has short- and long-term consequences for the foetus and the mother, (Erem et al. 2015:724). GDM is among the common complications associated with pregnancy.

The trend in the GDM is increasing globally and associated with increased risks for child and maternal outcomes during pregnancy and later in their life (Oostdam,van Poppel, Wouters & van Mechelen 2011:1554-1557). GDM is one of the top common medical situations during pregnancy and assumed to increase risks of numerous adverse pregnancy outcomes. In general, GDM had a tendency of reducing the wellbeing of the mother and foetus.

It represents the most common metabolic complication of pregnancy, and is associated with maternal (hypertension, pre-eclampsia, caesarean section, infection, polyhydramnios) and fetal morbidity (macrosomia, birth trauma, hypoglycaemia, hypocalcaemia, hypomagnesaemia, hyperbilirubinemia, respiratory distress syndrome, polycythaemia) (Hod 2015).

The 7 most common reported maternal adverse health outcomes were hypertensive disorders, preterm polyhydramnios, postpartum haemorrhage, premature rupture of the membrane, ketoacidosis, postnatal infection, and uterine incision delivery (Xu et al., 2017:4-6).

Women with GDM were found to have significantly higher prevalence of high birth defects, caesarean sections, and neonatal deaths as compared to women withoutGDM. Women with GDM were five times more likely to have neonatal deaths than women without GDM ($p<0.05$) (Sugiyama et al. 2017:1963). Moreover, DM and GDM are the two significant risks for the primary caesarean and preterm birth in all women (Cho, Hur & Lee 2015).

In addition, GDM had several feto-maternal outcomes. A study done in India showed that GDM can cause termination of pregnancy by caesarean section, increased neonatal birth weight, inborn nursery (IBN) admissions and long-term progression to type 2 diabetes (Sreelakshmi et al. 2015:396 & 397).

Women with GDM had a higher risk of having a large-for-gestational-age, infant birth weight greater than 90 th percentile for gestational age (95%CI: 2.44-3.98, AOR 3.12), caesarean delivery (95%CI: 1.15- 1.81, AOR 1.44), and polyhydramnios (95%CI: 3.94-12.08, AOR 6.90) (Meek, Lewis, Patient, Murphy, & Simmons 2015:2007).

Another adverse maternal outcome of GDM is that women with GDM have poorer quality of sleep and higher degree of daytime sleepiness than the general population. A case-control study involving a sample of 130 pregnant women, of which 46 cases (those with GDM) and 84 controls on the association of GDM and sleep pattern revealed that BMI scores of women with GDM was of higher value. Family history of T2DM had statistically significant association with GDM ($p<0.001$). Women with GDM presented with worsening quality of sleep ($p<0.001$) than the control group (Ruiz González et al. 2015:1141-1142).

A longitudinal study on patient-reported outcomes in women with GDM revealed; insulin treatment, frequency of blood glucose measurements, lack of knowledge about GDM, and lack of family and health care providers support were significantly associated with GDM related distress (Kopec, Ogonowski, Rahman & Miazgowski 2015:209).

Moreover, complications of pre-existing diabetes in pregnancy consisted of maternal complications such as diabetic retinopathy, diabetic nephropathy, and hypertension. Miscarriage, birth defects, intra uterine growth retardation (IUGR), macrosomia, perinatal morbidity and mortalities were neonatal complications of pre-existing diabetes in pregnancy (Wilmot & Mansell 2014:678).

2.6 MONITORING OF GDM

Various screening and diagnostic criteria are being utilized worldwide for screening and diagnosing GDM. Regarding screening of GDM, there is a dilemma whether to perform selective screening or universal screening technique. **B**ecause if we screen the high-risk population (selective screening), up to 30% of GDM cases may be missed. However, in areas where the incidence of GDM is < 3% selective screening in a high-risk population is acceptable. But, if the prevalence of GDM is > 3% universal screening may be considered (Gunasekaran 2015: 284-295).

Diagnostic criteria

TABLE 2.1. SUMMARY OF DIAGNOSTIC CRITERIA FOR GDM

Organization	Recommended diagnostic criteria
World Health Organization (WHO) 1999	2h 75gm OGTT, fasting plasma glucose (FPG)= 125mg/dl, 2h= 140mg/dl
World Health Organization (WHO) 2013	**At 1st ANC visit** Screening is done with either FPG, HbA1C or Random plasma glucose (RBS) and GDM is diagnosed if FPG is between 92mg/dl to 126mg/dl: diagnosis of diabetes mellitus in pregnancy is made with one of the following values if FPG ≥ 126mg/dl or HbA1C ≥ 6.5% or RPG ≥ 200mg/dl, then confirm with FPG or HbA1C **At 24-28 wks of gestation** In all women previously not found to have DM in pregnancy or GDM, 2h 75gm OGTT is done If FPG ≥ 126mg/dl, DM in pregnancy is diagnosed, GDM is diagnosed with ≥ 1 abnormal values:- FPG ≥ 92mg/dl, 1h ≥ 180mg/dl, 2h ≥ 153 mg/dl
American College of Obstetricians and Gynecologists (ACOG)	1 h glucose challenge test, if plasma glucose value is 14omg/dl, a 3 h 100gm OGTT should be performed
Australian Diabetes in Pregnancy Society (ADIPS) 2013	GDM is diagnosed if > 1 of the following glucose level is elevated: 1. FPG > 5.1mmol/L, 2. 1h > 10.0mmol/L, 3. 2h> 8.5mmol/L
International Association of Diabetes and pregnancy study groups two phase strategy for the detection of hyperglycemia (IADPSG)	**At 1st ANC visit** Screening is done with either FPG, HbA1C or Random plasma glucose (RBS) and GDM is diagnosed if FPG is between 92mg/dl to 126mg/dl: diagnosis of overt diabetes is made with one of the following values if FPG ≥ 126mg/dl or HbA1C ≥ 6.5% or RPG ≥ 200mg/dl, then confirm with FPG or HbA1C **At 24-28 wks of gestation** In all women previously not found to have overt DM or GDM, 2h 75gm OGTT is done If FPG ≥ 126mg/dl, overt diabetes is diagnosed, GDM is diagnosed with ≥ 1 abnormal values:- FPG ≥ 92mg/dl, 1h ≥ 180mg/dl, 2h ≥ 153 mg/dl

There are a lot of universally accepted guidelines; however, there are very few validated guidelines that work in low resource set up. In addressing this issue, the WINGS strategy of India prepared the following algorithm for screening, diagnosis and management of GDM.

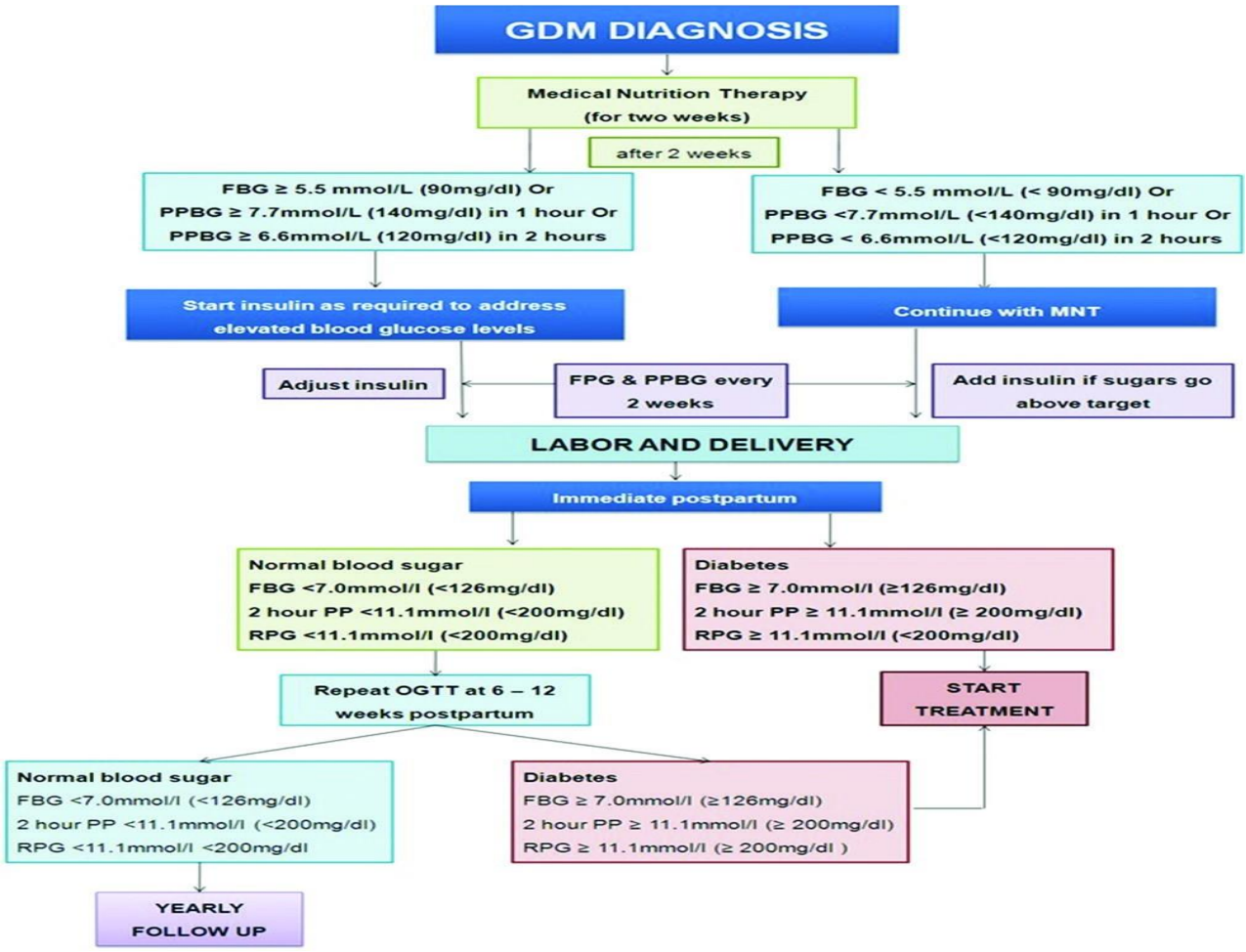

Figure 2.1. Women in India with GDM strategy (WINGS) management protocol for GDM (Kayal, Mohan, Malanda, et al, 2016:707).

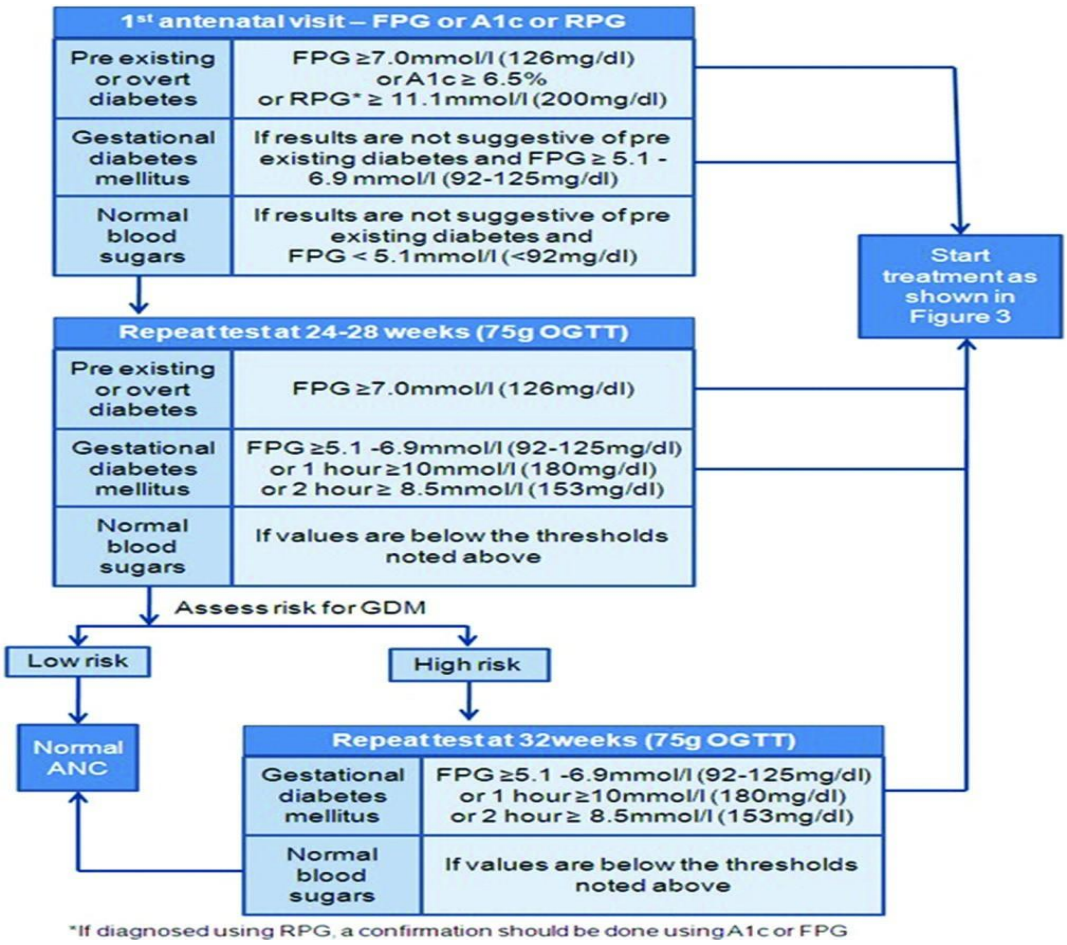

Figure 2.2. Diagnostic criteria for GDM under the WINGS strategy in India (Kayal, Mohan, Malanda, et al, 2016:707)

2.7 PREVENTION, TREATMENT AND MANAGEMENT OF GDM RELATED ADVERSE MATERNAL OUTCOMES

2.7.1 Basic concepts of natural history of disease occurrence

Prevention (primary, secondary, and tertiary) programs place emphasis on various parts of the natural history of disease. Thus, the concepts of primary, secondary, and tertiary prevention make use of these concepts as follows:

- The aim of primary prevention is hindering the occurrence of disease.

- The intention of secondary prevention is early identification and detection of disease, and accordingly prevent the possible progression or lessen complications.
- Tertiary prevention is all about rehabilitation.

As a result, appropriate intervention on risk factors of GDM can reduce the burden of the problem in the community. There are six types of Health Intervention for GDM, which are medication, dietary, health education, exercise, psychological and a combination of any of these interventions.

2.7.1.1. Medication

Since GDM contributes to adverse health outcomes for the mother and the foetus, appropriate treatment of GDM is mandatory. Treatment of GDM results in statistically significant reduction in incidence of preeclampsia, shoulder dystocia, and macrosomia (Garrison 2015:461 & 462)

2.7.1.2. Dietary

It is very important to intervene on modifiable factors such as diet because evidence suggests that dietary counselling has reduced the incidence of GDM (Oostdam et al. 2011:1554-1557).

2.7.1.3. Health Education

Health education interventions provided key information regarding GDM, appropriate diet, exercise and compliance with the prescribed medications. Though there was an increasing number of health care interventions, the emphasis to prevent GDM was low.

A meta-analysis in China showed that there were statistically significant strategies in reducing the odds of maternal and infant adverse outcomes. Dietary, western medication and combined interventions were among the most effective interventions in prevention of GDM related maternal and infant complication (Xu et al. 2017:4-6).

Raising the awareness of GDM in pregnant women is an important tool for the prevention of type 2 DM. A study in Samoa, to investigate the awareness of GDM and its factors among pregnant women revealed that 58% of women were aware thatdiabetes can occur for the first-time during pregnancy. Regarding their sources ofinformation, 44(37%) followed by 28 (22%) of participants reported doctors and their family members were their source of information respectively. In addition, only single pregnant women correctly identified all the risk factors of GDM while 79% and 78% recognized that eating a healthy diet and regular physical exercise could prevent GDM (Price, Lock, Archer, & Ahmed 2017:49).

However, a quasi-experimental study on the effect of GDM training on metabolic control, maternal and neonatal outcomes based on social-cognitive theory and health promotion model (HPM) in obstetrics and Gynaecology clinic of Ege University Hospital in Turkey, revealed that there was no statistically significant difference in the pre and post-test mean value baseline of the achievement test scores in the usual care group, whereas significant difference was observed in pre-test and post-test mean value scores of the intervention group. There was no significant difference between groups onpostpartum maternal and neonatal outcomes, first and fifth minute APGAR scores and length of stay at hospital for the baby and mother($p<0.05$) (Şen & Şirin 2014:318 & 319).

A study on the impact of health education intervention for prevention and early detection of type 2 diabetes mellitus in women with GDM, where constructs of health belief model was applied to measure knowledge, beliefs and self-reported practice, the percentage of women who had high knowledge and belief scores had significantly increased from <50% to more than 70% in the intervention group ($p<0.001$). More women in the intervention group practiced exclusive breast feeding (85.4%) and screening for type 2 diabetes mellitus (T2DM) (65%) as compared to the control group (63.3% and 19.4%) respectively (Tawfik 2017:504).

In addition, a qualitative study on knowledge of women about prevention of GDM illustrated that GDM occurs only during pregnancy, women who developed GDM had also risks of developing type 2 DM in life, most participants agreed to sugar being avoided for prevention of GDM, and walking was perceived to be important during pregnancy (Poth & Carolan 2013:693 & 694).

2.7.1.4. Exercise

GDM is amongst the common pregnancy complications globally with variation in magnitude of its burden. In women with GDM, vigorous physical exercise will help in the reduction of gestational weight gain. A prospective cohort study on the estimation ofthe association of moderate and vigorous physical exercise during pregnancy with gestational weight gain (GWG) rate from diagnosis of GDM to delivery was assessed and revealed that participation in vigorous physical exercise was associated with decreased odds of GWG as compared to no participation to vigorous exercise (95% CI: 0.40-0.99, AOR 0.63) (Ehrlich et al. 2016:1251-1253).

Physical activity had an association with 2 hours of plasma glucose levels and GDM. A study on Asian pregnant women on physical activity (PA) and sedentary behaviour (SB) in relation to fasting glucose (FG), and 2 hours postprandial glucose (2HPG) levels and GDM where a total of 1083 women were studied revealed that 8.6% participants had GDM (Padmapriya et al. 2017:4 & 5). Accordingly, SB was not associated with FG, 2HPG and GDM. A higher category of PA was associated with lower likelihood of GDM ($p<0.05$) while not associated with FG levels. Highly active women had a lower 2HPG levels as compared to insufficiently active women (95% CI: -.59, -0.05, OR -0.32) and less likely to have GDM (95% CI: 0.32-0.98, OR 0.56, P=0.040) (Padmapriya et al. 2017:4 & 5).

2.7.1.5. Psychological

Psychological factor is another domain that should be given emphasis in the management of GDM as higher stress exposure and perceived stress are associated with increased fasting glucose level in pregnant women (Horsch, Kang, Vial et al 2016:712-729). In addition, a research done in Shahid Beheshti University of Medical Sciences in 2013

indicated that incidence of GDM can be prevented through increased awareness and education of pregnant women about having appropriate lifestyles duringpregnancy and any intervention that would lead to improved lifestyle and revealed the importance of perceived social support during pregnancy (Javid, Simbar, Dolatian & Majd 2015:162). Therefore, it is imperative to integrate the psychological domain in the treatment of GDM.

2.7.1.6. Combination

Culture specific protocols for the management of diabetes in pregnancy are an important issue in the prevention and control of diabetes in pregnancy. A study in Zimbabwe revealed that participants had challenges in their way to adhere to diet, physical activity and medications. Financial and lack of support were among identified barriers to affect adherence of participants (Mukona, Munjanja, Zvinavashe, & Stray- Pederson 2017:4-6).

A study on follow-up of GDM in the postpartum period among a racially diverse group of women receiving care in Boston medical centre, by 6 months postpartum, 23.4% GDM women received any kind of glucose test, of these about half had completed within 10 weeks and 295 were recommended oral glucose tolerance test (OGTT). Women aged $\leq$ 35 years of age and women with family practice providers were significantly less likely to be tested than their counterparts (OR 0.51, 95%CI: 0.32-0.83) and (OR 0.36, 95%CI: 0.19-0.71) respectively. Women who attended a primary care visit within 180 days after birth had three times higher odds of being tested than those without a primary care visit (OR 3.10, 95%CI: 1.97-4.87) (McCloskey et al 2014:331).

A study on effects of preventive letters on the return rate of mothers after gestational diabetes mellitus was assessed on 468 mothers. Participants were assessed in two groups of GDM, those with preventive letters and without preventive letters. Both groups were similar with respect to age, and educational status. Return rate of 1 year after delivery was assessed with Kaplan-Meier test: 32% for the group without preventive letter and 76% for the group with preventive letter (p=0.001). The 1-year return rate afterdelivery of GDM mothers was 2.4 times higher for the group with preventive letters than groups without preventive letters (Olmos et al. 2015:942 & 943).

In addition, a descriptive cross sectional study done on knowledge and feelings of diabetes pregnant women about treatment and gestational diabetes revealed that women had fragmented and incomplete knowledge about the disease concepts, its treatment and possible complications (Mançú, Almeida, & Souza 2016:1478).

2.7.2 Application of the Neuman systems model for monitoring and prevention of maternal morbidity and mortality related to GDM

The NSM model provides a complete, adaptable, holistic and system-based viewpoint for nursing and health care. The model is a nursing theory based on following key concepts:

1. The client system (which is an individual, family or society);
2. Interacting variables of the client system (i.e. physiological, psychological, spiritual, developmental and sociocultural);
3. Client ‘s response to actual or potential environmental stressors (which areinternal, external and created environments), the reaction to it, and reconstitutionfactors that are dynamic in nature;
4. Emphasis on prevention, as intervention (for retention, attainment, and maintenance) of optimal client system wellness;
5. The goal of the nurse is to preserve the client system's stability through the three levels of prevention (i.e. primary, secondary and tertiary prevention). Primary prevention is applied for early client assessment and intervention, byearly screening and diagnosis in order to reduce possible or actual risk factors. Secondary prevention is about proper management of clients to reduce furthercomplications. Tertiary prevention is to re-adjust and alleviate worsening of conditions byrehabilitation.

2.8 BARRIERS FOR MANAGEMENT OF GDM

There are a lot of barriers that hinder appropriate screening and treatment of GDM, some of these are categorized as health system barriers, individual barriers and societal barriers, (Nielsen, Courten & Kapur 2012:12-33).

According to lessons learned from World Diabetes Foundation (WDF) which supports GDM projects found that lack of trained health care providers, high staff turnovers, lack of standard protocols, consumables and equipment; financing of health services and treatment; poor referral systems, lack of feedback mechanisms and follow-up systems; distance to health facility were listed as health system barriers. Likewise, perceptions of female body size and weight gain/loss in relation to pregnancy, practices related to pregnant women's diet; societal negligence ofwomen's health; lack of decision making power among women regarding their own health; stigmatization; role of women in society and expectations that the pregnant woman move to her maternal home for delivery were identified as barriers for management of GDM (Nielsen, Courten & Kapur 2012:12-33).

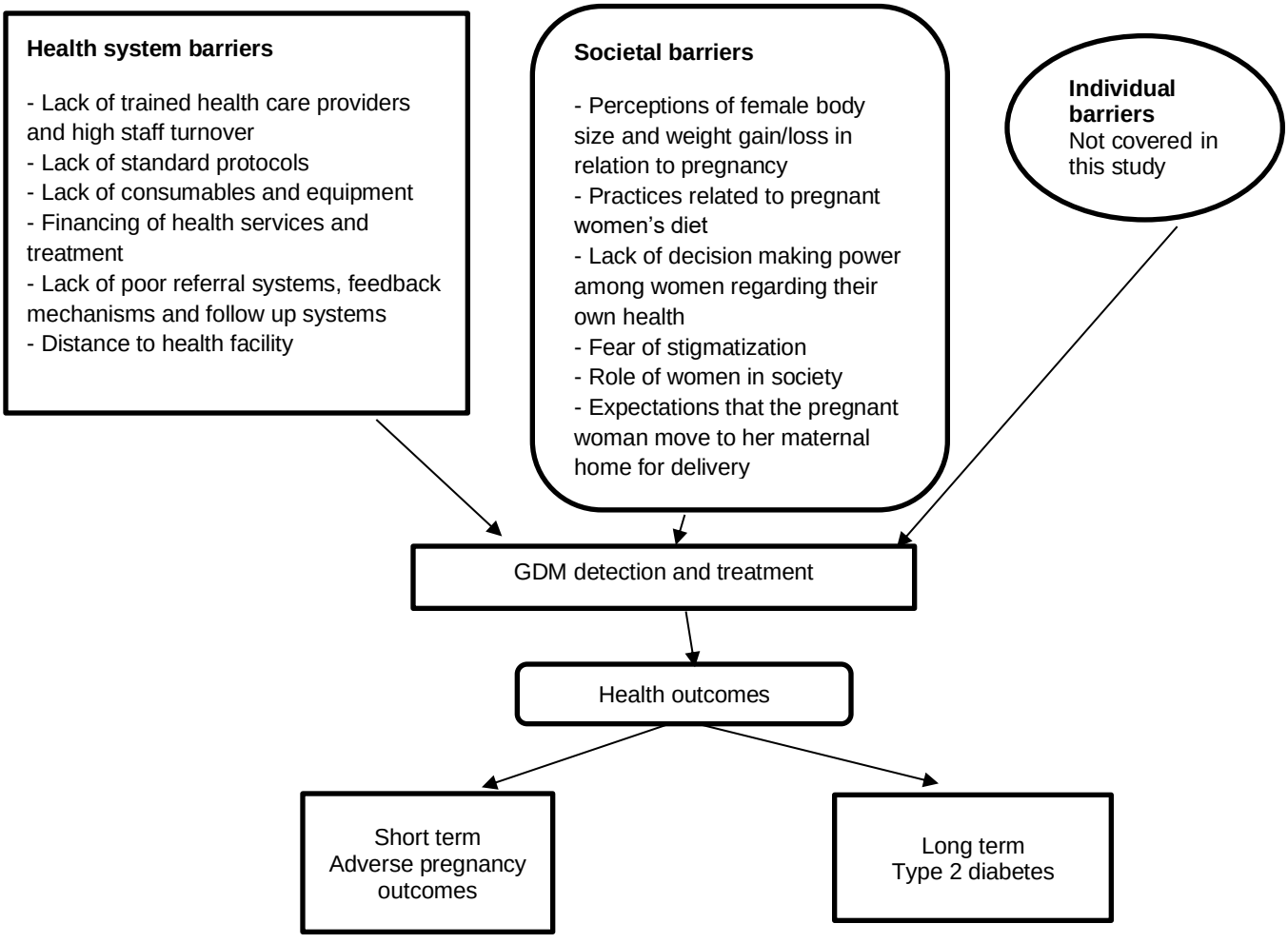

Figure 2.3 Overview of health system and societal barriers

(Nielsen, Courten and Kapur 2012:12-33)

2.9 TRAINING OF GYNECOLOGISTS/OBSTETRICIANS AND MIDWIVES IN ETHIOPIA

History of the school of medicine in Ethiopia

In Ethiopia, the school of medicine was established in 1964 in Addis Ababa, capital city of Ethiopia, with the intention of producing medical doctors for the purpose of solving the country's health problems. Before the year 1972, the school of medicine waslocated on the main campus of Addis Ababa University and then Princess Tsehai Memorial Hospital (now called the Armed Forces General Hospital) for clinical training. In 1972, Tikur Anbessa Specialized Hospital (Black Lion Specialized Hospital) was opened and then the hospital became the only site for training medical doctors for along time until other public hospitals started training medical doctors, (Deressa & Azazh 2012).

In 1998, this hospital became a university teaching hospital, it is also an institution where specialized clinical services that are not available in other public or privateinstitutions are provided to the whole nation, (Deressa & Azazh 2012).

Gynaecologists/Obstetrician education in Ethiopia

Gynaecologists/ obstetricians must receive a bachelor's degree in medicine which is 6 years of education, then after completing this, a medical doctor who wants to specialize in the department of gynaecology and obstetrics should complete four years of residency program, which is paid work under supervision.

History of midwifery education in Ethiopia

Till date midwifery and nursing education in Ethiopia are closely related. In Ethiopia nursing was the first regularly schooled medical profession. The first nurses were trained abroad in 1944. The first nursing training began in 1949 in Addis Ababa. At the beginning, nurses were recruited from grade eight and graduated after three and a half years of training, since then the school of nursing has encountered many changes in the years of training (Dolamo & Olubiyi 2013).

The first midwifery training model for Ethiopia in 1953 was the nursing-midwifery training model. This training constituted training as a nurse after 3 years of training followed by further 6 months to one-year training to become a midwife (Dolamo & Olubiyi 2013).

The first midwifery school which provided full-fledged midwifery training was opened in Addis Ababa as a post basic training program. This school joined Addis Ababa university in 1988 and later merged with the school of nursing in 2005. Since then the school started providing midwifery education at Bachelor of Science (BSc) degree level.The department of nursing and midwifery are in four campuses of Addis Ababa university, namely: - Tikur Anbessa Specialized Referral and Teaching Hospital, Saint Pauls Specialized Hospital, Zewditu Memorial Hospital and Sefere Selam Campus (Dolamo & Olubiyi 2013).

Midwifery education in Ethiopia

There are different forms of training to become a midwife in Ethiopia: -

- Bachelor in midwifery- takes 4 years to complete
- Diploma – 3 years of midwifery training
- Accelerated midwives – have 3 years of nursing and 1 year of midwifery training

There were 1200 midwives in Ethiopia in 2009, making a ratio of 1 midwife to 57,000 people, however, in 2015 the number of midwives were 7800, making the ratio of 1 midwife to 10,500 people. In 2019 the number of midwives was 12,500 (Bennett 2019).

2.10 GDM GUIDELINES IN ETHIOPIA

In Ethiopia, international guidelines of GDM are adopted. However, evidence suggests that there has been no well-established national guideline for GDM screening in the country, (Muche, Olayeni & Gete 2019a). As a result, most HPs screen GDM based on assessment of risk factors and this approach can leave women unnoticed until they develop overt diabetes and complications (Muche, Olayeni & Gete 2019a).

2.11 REFLECTIONS FROM THE LITERATURE

The literature reviewed in this chapter provided a conceptual structure for this study. The study tried to investigate the burden of GDM and associated factors as well GDM related adverse maternal outcomes. The issues of GDM related adverse maternal outcomes in Ethiopia were not directly addressed in any published studies. However, there is some evidence that GDM could cause adverse maternal outcomes.

2.12 CONCLUSION

The prevalence of GDM is increasing at a significant pace and causing adverse maternal outcomes. Therefore, it is crucial that pregnant mothers are early screenedand diagnosed during pregnancy and have a regular postpartum follow-up for detection and management of any complications that are related with GDM. In the following chapter, research design and methods are presented..

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

3.1 INTRODUCTION

In the previous chapter, literature emphasizing on the gaps in knowledge within the corpus of the study were discussed. The purpose of this chapter is to present the process of how the study ‘s objectives were recognized. The study aims of this study which were stated in Chapter 1 influenced the research design and methodology.Moreover, details about the study population, sampling methods, tools and process of data collection and data analysis and ethical considerations was presented. In addition, the process of ensuring trustworthiness, validity and reliability were described.

3.2 RESEARCH DESIGN

It is the bigger plan for managing the study, which encompasses the plan of data gathering, utilization, measurement and analysis (Curtis & Drennan 2013:131). The proposed research design for this study was concurrent mixed methods. This study used retrospective cohort study with in-depth interviews. Mixed methods focus on collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that, the combined use of quantitative and qualitative approaches, provides a better understanding of research problems than either approach alone (Creswell, Clark, & Smith, 2011:2098).

The researcher combined both qualitative and quantitative data. As a result, the quantitative study offered a way to collect quantifiable data for measuring the incidence of GDM and to assess associated factors related with GDM. Besides, a qualitative research method identifies why and how decisions are made, and not just when, where and what with small and focused samples (Burns & Grove 2011:61). Therefore, the qualitative part explored the experience of gynaecologists/obstetricians and midwives towards monitoring and prevention of GDM related maternal morbidity and mortality.

3.2.1. Rationale for choosing a mixed research design

Selection of mixed research methods is dependent on the research purpose, research expertise, resources, stakeholder's priority and dissemination plan (Andrew & Halcomb 2009:32). The rationale of choosing a mixed research design was because mixed method research is appropriate in that it consists of a combination of qualitative and quantitative methods. It also provides adequate information for policy makers, as mixed methods can convey the details of the problem including extent (quantitative) and nature (qualitative) of the problem and how they are interrelated.

3.2.1.1 Quantitative research

According to Donmoyer (2008), quantitative research refers to approaches which are used to gather, analyse and present numerical data rather than in narrative form. In addition, according to Curtis & Drennan (2013:133) quantitative research designs use quantitative approaches to generate results that are: valid, objective, reliable, and reproducible. As a result, in order to establish the magnitude of GDM and associated factors, this study used retrospective cohort study design.

3.2.1.2 Qualitative research

Qualitative research has a unique aspect of discovery, which is necessary in providing in-depth understanding of people's insights, feelings, plans, behaviour and experience, (Bowling 2014). Data collection in qualitative study is said to be one of the highest trustworthy research methods in exploring health service and its delivery.

For this study, the researcher used an in-depth interview with gynaecologists/obstetricians and midwives to explore their experience towards monitoring and prevention of GDM related maternal morbidity and mortality.

3.3 RESEARCH METHOD

Research methods is about the methods of data collection, analysis and interpretation that the study employs for the research (Creswell 2014:16-17). Whereas, methodology is

the steps, strategies and procedures that are used to collect and analyse data in a study (Polit & Beck 2008:723). It gives guidance on which methods are better fitted to the kind of research to be conducted.

This research study used a concurrent mixed method. Concurrent methods use the combination of quantitative and qualitative designs to better understand the research problem as well to offset the flaws of one method with the strong part of the other method or the strength of one method can add to the strength of the other method, (Creswell 2009:213).

The quantitative approach quantified the magnitude of GDM, and factors associated with it, whereas the qualitative approach was used to generate information on the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal morbidity and mortality related to GDM. Therefore, the use of mixed methods approach enabled the researcher to achieve the research objectives.

3.3.1 Sampling

Sampling is the process of choosing a group of participants for a study in a way that the participants represent the larger group from which they were chosen, (Curtis & Drennan 2013:135-136). Besides, according to Curtis & Drennan (2013:180) conducting a study to the whole population is not feasible and it is very costly as a result the reason behind sampling is to choose a representative subset of the population. However, selecting the sample that truly represents the population of interest is one of the crucial steps in scientific research in order to generalize the information obtained from the sample to the general population.

Therefore, for the qualitative part of the current study, non-probability purposive sampling was used whereas for the quantitative part of the study systematic random sampling was used. Systematic sampling is a type of probability sampling method in which sample members from a larger population are selected according to a random starting point but with a fixed and periodic interval. This interval is calculated by dividing the population size by the desired sample size and this interval is called sampling interval (Daniel 2012:168).

3.3.1.1 Population

Burns and Grove (2011:299) define a population as a specific unit of people, which is the core of the research and a population is a full set of people with specific established characteristics. Moreover, there are three types of population in a research, and these are namely target, study and sample population.

3.3.1.1.1 Target population

Target population is defined as the population of interest to which the researcher would generalize the findings of the study and from which a representative sample is drawn. (Polit & Beck 2012:274). The target population for this study are all women with GDM in Addis Ababa, Ethiopia.

3.3.1.1.2 Study (source) population

Study population is the subset of the population included in the sample and the actual group in which the study is conducted (Polit & Beck 2008: 733).

In the current study, for objective 1 and 2, the study population were all pregnant women who had ANC follow up and delivered at Gandhi Memorial Hospital during the cohort (2013-2017) in Addis Ababa, Ethiopia; and for objective 3, the study population were gynaecologists/obstetricians and midwives that work in Gandhi Memorial Hospital during data collection.

3.3.1.1.3 Sample population

Sample population is a subcategory of population chosen to take part in the study (Polit & Beck 2008:731).

Quantitative Phase

The sample populations were complete medical records of mothers who had ANC follow-up and delivered in Gandhi Memorial Hospital within the cohort of the study.

Qualitative Phase

The sample population were purposely selected gynaecologists/obstetricians and midwives that work in Gandhi Memorial Hospital during data collection.

Inclusion criteria

Inclusion criteria are measures that stipulate population characteristics to take part in a research (Polit & Beck 2008:311). The following inclusion and exclusion criteria were used for this study.

Inclusion criteria for quantitative part

- Complete medical records of mothers who had antenatal care follow-up and delivered in Gandhi Memorial Hospital within the study cohort (2013-2017).

Inclusion criteria for qualitative part

- Gynaecologists/obstetricians and midwives who work in Gandhi Memorial Hospital with more than two years of experience and who volunteered to participate.

Exclusion criteria for quantitative part

- Incomplete medical records of mothers who had ANC follow-up and delivered in Gandhi Memorial Hospital within the study cohort (2013-2017).
- Medical records of mothers with known DM.

Exclusion criteria for qualitative part

- Gynaecologists/obstetricians and midwives who did not volunteer to participate.

3.3.1.3 Sample

Sample size is the number of people who participate in a study (Polit & Beck 2012:742). Moreover, a general rule of the thumb for quantitative study is to always use the largest sample possible.

Sample size for this qualitative part of the study

There are no fixed rules for sample size in qualitative research. In qualitative studies, sample size should be based on informational needs (Polit & Beck 2012:521). The sample size was based on saturation of information and the total sample size after data saturation has been reached was 19 health professionals (HPs) working in Gandhi Memorial Hospital i.e. 7 gynaecologists/obstetricians and 12 midwives.

Sample size for the quantitative part of the study

The sample-size was determined by the assumption that 50% of pregnant women had GDM with 5% margin of error and 95% CI and considering 5% for incomplete data, lost for follow-up and the likes. The following formula was used:

$$n = \frac{N (Z)^2 p q}{D^2 (N-1) + Z^2 pq}$$

Where n = sample size,

N = Total number of pregnant mothers who attended ANC and delivered in Gandhi Memorial Hospital in each year (2013-2017)

Z = Z statistic for a level of confidence, value corresponding to a 95% level of significance is 1.96,

P = Expected proportion (In proportion of one; if 50%, P = 0.5),

q = (1 - p) = (1-0.5) = 0.5

D = precision (In proportion of one; if 5%, d = 0.05)

Since the researcher used systematic sampling technique to select a sample of 400 participants for every year from the population at Gandhi Memorial Hospital, the researcher took the largest population i.e. 7984, 7984/400= 19.96^ 20. Therefore, K= 20, hence one sample was selected out of every 20 units in order to end up with a total of 400 samples for each specific year in the cohort. Consequently, the total sample size was 2000.

Though the sample of each year showed a minimal variation, from the above assumptions and calculations, the final sample size was approximated to 400 for each year as shown below (Table 3.1).

TABLE 3.1. TOTAL SAMPLE SIZE CONSIDERED FOR EACH SPECIFIC YEAR(2013-2017)

Year	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
N	7288	6355	7579	7984	6661	35867
N	364	363	365	366.5	363.1	1821.6
Adding 10%	400.4	399.3	401.5	403.1	399.4	2003.3

3.3.1.4 Ethical issues related to sampling

Ethical issues or considerations should be obeyed to in order to safeguard the rights of the participants. The rights include *respect for the human person, right to be given informed consent to be part of a research*, the *right to privacy*, and the *right to confidentiality and anonymity*, furthermore, these rights are commonly summarized as the ethical principles of: *autonomy*, *justice*, *beneficence* and *non-maleficence* (Curtis & Drennan 2013:77-85). The researcher followed the following procedures:

3.3.1.4.1 Ethical approval

The Higher Degrees Committee of the Department of Health Studies at the University of South Africa (Annex A1) and Addis Ababa Health Bureau Research Review Committee (Annex A2) has granted the researcher a written ethical approval. Verbal institutional approval has also been obtained from the participating government hospital.

3.3.1.4.2 Respect for the human dignity

It is about not exposing the study respondents to significantly burdensome, unreasonable, known or predictable risks (Curtis & Drennan 2013:81). The researcher had provided adequate information to the respondents (information on the purpose, procedures and rights, risks, discomforts and constraints of participation in the study). The researcher obtained informed consent from all respondents and, they had the opportunity to ask questions freely. The researcher emphasized that participation is voluntary and participants can withdraw from the research at any given timewithout any repercussions. Moreover, the contact details of the researcher, supervisory teams and relevant ethics committees were presented to the respondents on the consent form.

3.3.1.4.3 Voluntary informed consent

Informed consent refers to the respondent's full awareness of the research which they are involved in (Polit & Beck 2012:159). Informed, voluntary and signed consent was requested from the study respondents for the qualitative part of the study (Annex C).

Therefore, partaking in the study was based on the willingness of the participants to be part of the study. The study respondents were adequately and properly informed about the research.

3.3.1.4.4 Anonymity and Confidentiality

Respondents need to know that they will not be identified through the research and that their information is going to be private and remain anonymous in a study (Polit & Beck 2012:157).

Anonymity means without a name (Pattern & Newhart 2017:32). Respondents were reassured that the researcher would not disclose possibly identifying data and items when presenting the research findings, and that their identity and personal information would not be revealed, the same holds true for the medical records. Moreover, respondents' responses were obtained in a private room and the in-depth interview guides had codes and not names. Moreover, no names appeared on the checklist rather checklist identifiers were used.

Confidentiality in a research refers to a condition in which the researcher knows the identity of a research subject but takes steps to protect the identity from being discovered by others, as a result no names of participants appeared anywhere on the document which ensured that their privacy was protected (Pattern & Newhart 2017:32). Besides, these documents were only accessible to the researcher as well as those who were directly involved with the research and were kept safely.

3.3.1.4.5 Justice

According to National Ethics Advisory Committee (2012:8-9) the study respondents or participants should be treated equally in the study, the participants should share the

benefit and burden fairly, and the inclusion and exclusion criteria should be fair for all study participants.

In this research, the researcher safeguarded the right of the respondents to be treated fairly/equally through application of the same type of assessment tools and methods for all participants. The researcher also obtained informed and signed consent from all respondents.

3.3.1.4.6 Beneficence and non-maleficence

The two ethical principles, beneficence and non-maleficence where beneficence refers to the notion of doing 'good' and maximizing advantages for the participants (Schmidt & Brown 2011:475) and non-maleficence refers to the responsibility of the researcherto lessen harm (Schmidt & Brown 2011:476). Since this study does not entail any experimentation or manipulations, it did not pose any significant harm on study participants.

Consequently, the researcher followed the following methods in order to adhere with the ethical principles:

- Ensure that the chosen research question is valid, and hence it will not be a waste of time and that the study design will provide an answer to the research question;
- Adequate information was provided regarding the aim of the study and thepossible inconvenience and risks of the study;
- Anonymity and confidentiality issues were properly addressed;
- There was no discrimination during the process of selecting of respondents.

3.3.2 Data collection

There are two types of data in a research. The two types of data are primary data (this refers to data that is collected directly from new observation) and secondary data (this refers to data attained from published or stored resources which can be borrowed for research purposes) (Burns & Grove 2011:52).

Qualitative Phase

Respondents who volunteered to take part in the study were included. They were purposely recruited based on the judgments of the researcher that those with more experience (more than 2 years) are knowledgeable about the research question. As described by Speziale and Carpenter (2007:29) in qualitative research, individuals who are selected to participate should have the experience of the phenomenon of interest.

In-depth interviews were conducted and an interview guide (Annex B2) was used to collect data. Data was collected until data saturation was reached. To safeguard credibility of results, observation and field notes were utilized. The interviews were also tape recorded as this helped the researcher to develop a note which assisted during analysis of codes.

Quantitative Phase

For the quantitative part, the researcher used a carefully structured checklist data collection tool (Annex B1).

3.3.2.1 Data collection approach and method

Grove et al (2013:690) define data collection as the systematic gathering of information relevant to the research purpose or specific objectives. The development of research instruments is crucial and the first step in the process of conducting research (Kumar 2019).

To address specific objectives 1 and 2, a checklist was designed by the researcher by consulting the supervisor as well as experts on the subject. For the specific objective 3, an in-depth interview guide was employed to explore experiences of gynaecologists/obstetricians and midwives about monitoring and prevention of adverse maternal outcomes related with GDM. Accordingly, the researcher was the sole data collector for the in-depth interviews and part of data collectors for reviewing medical records of mothers within the quantitative aspect of the research. Apart from the researcher, four midwives were recruited, and one-day training was done to provide

information about data collection and to make the data collectors familiar with the tool of data collection.

3.3.2.2 Development and testing of the data collection instrument

The development of a data collection instrument started with searching for the availability of a study tool. In doing so, the researcher considered whether the tool was conceptually applicable and whether the tool could produce necessary data. In addition,the researcher also well-thought-out of resource accessibility and understanding the nature of the tool, as a result, standards and comparability, study population suitability, executive issues and reputation were taken into consideration.

After thorough considerations of the above issues as well as after defining criteria and reviewing literatures, data collection instrument has been self-developed mainly focusing on variables such as demographic characteristics, factors for GDM, basic obstetric characteristics, past obstetric and medical history, provision of health education and laboratory investigations in English language. Then the drafted data collection instrument was sent to the supervisor and other experts in the field and shared, discussed and implemented the changes required. Pre-test was also done.

Qualitative Part

An in-depth interview guide was used to explore experiences of gynaecologists/obstetricians and midwives. The researcher was the sole data collector. To safeguard credibility of results, observation and field notes were utilized. The interviews were also tape recorded as this helped the researcher to develop a note which assisted during analysis of codes. The Interviews were held in a quiet and privateplace.

Quantitative Part

Checklist has been self- designed by the primary researcher by consulting experts in the area and supervisor and as well after reviewing literature**.** Four midwives were recruited for data collection and one-day training was done to provide information about data collection and to make them familiar with the study tool. Only medical records with complete data were taken to be filled on the checklist.

3.3.2.3 Data collection process

Quantitative Part

For the determination of the outcome variable, a self-designed checklist was used, and four midwives were recruited for data collection, data collection was done after pre-test. Letter authorizing permission to conduct the study was submitted to the hospital manager. All the data collectors were formally introduced to the hospital manager and record room staff by the researcher before the data collection process, to be allowed to access medical records of mothers.

Collected data was protected from access by people except those involved in data collection and filled checklists were kept in a locker. Data entered the computer wasalso kept in a secured, password protected folder.

Qualitative Part

Data was gathered from the participants using in-depth interview methods. To safeguard credibility of results, observation and field notes were utilized. The interviews were also tape recorded as this helped the researcher to develop a note which assisted during analysis of codes.

The study respondents were adequately and properly informed about the research. Informed, voluntary and signed consent was requested from the study respondents who were willing to participate and consented to being audio recorded.

Data was collected in a private and quiet place at the hospital's manager office. The interviews were conducted in June, July and August 2019 and additional in-depth interviews were conducted between the end of May to half of June 2020. A prior appointment was made to organize with the HPs, concerning date and time and the interviews lasted approximately for 60 minutes. No names appeared on the in-depth interview guides and memos. Audio recorded data was only accessible to the researcher and was kept safe.

3.3.2.4 Ethical considerations related to data collection

- Verbal approval was obtained from the hospital manager for participation at the hospital.
- Permission was obtained for data collection from the hospital staff. The respondents for the qualitative part of the study were provided with information about ethical principles.
- Appropriate behaviour such as respecting the decision of participants and the hospital staff, being open and friendly was guaranteed from the researcher as well as from data collectors during collection data.
- The respondents were provided with information regarding their rights if any unforeseen risks are noted, they are to notify the principal investigator.

3.3.3 Data analysis

Quantitative Data Analysis

Statistical Package for Social Sciences (SPSS) version 25:0 was used for data analysis. Data was entered, cleaned and analysed by the researcher. Descriptive summary of findings was made with descriptive statistics such as mean, median and standard deviation. Inferential statistics were also used to measure the association ofindependent variables with the dependent variables. In doing so, Chi-square test was used. Texts, tables, and graphs were used to present study findings.

Qualitative Data Analysis

Qualitative data were analysed after transcribing and coding was done using Colaizzi's seven steps manual qualitative data analysis principle. Details of the seven steps of qualitative data analysis which were followed are described below.

Step 1: Transcribing all the subjects' descriptions

Each transcript was read several times to gain a sense of the whole content. Any thoughts, feelings, and ideas that emerged from the due to his/her previous work with the topic helped the researcher to explore the phenomenon as experienced by participants themselves.

Step 2: Extracting significant statements (statements that directly relate to the phenomenon under investigation).

In this stage, significant statements and phrases pertaining to experience of gynaecologists and midwives in monitoring and prevention of GDM related to maternal morbidity and mortality were extracted from each transcript. These statements were written in separate sheets and coded based on their "transcript, page, and line numbers". After extracting the significant statements from transcripts, it was evaluated by experts.

Step 3: Creating formulated meanings.

Meanings were formulated from the significant statements. Each underlying meaning was coded in one category as they reflect an exhaustive description. Then, an experienced qualitative researcher reviewed the formulated meanings.

Step 4: Aggregating formulated meanings into theme clusters.

After agreeing on all formulated meanings, the next step was grouping the formulated meanings into categories. Every group of the formulated meanings or themes were given a code. Then, the coded groups based on a specific view were integratedtogether to form a unique construct of theme.

Step 5: Developing an exhaustive description (that is, a comprehensive description of the experience as articulated by participants).

At this stage of analysis, all emergent themes were defined into an exhaustive description. After merging all study themes, the whole structure of the phenomenon “experiences of gynaecologists and midwives” were obtained. Then, the findings were evaluated for depth and completeness by experienced qualitative researchers.

Finally, avalidation to this exhaustive description was confirmed with the supervisor.

Step 6: Identifying the fundamental structure of the phenomenon

This step is about reduction of findings as a result, redundant, misrepresented or overrated description were removed from the fundamental structure.

Step 7: Returning to participants for validation.

The aim of this step was to confirm research results using the "member checking" method. The research results were taken to the respondents and a discussion was made with the study participants.

3.4 INTERNAL AND EXTERNAL VALIDITY

There is no one way or specific set of standards to ensure validation in mixed methods research. Rather there is a need to understand what is being mixed, to decide whether or not more than one set of validation strategies should be applied (Andrew & Halcomb 2009:143). The quantitative part of this study was tested against validity and reliability as shown below.

Validity

Validity refers to the degree to which a research tool measures what it is supposed to measure. The three types of validity that were used by the researcher are discussed below:

Statistical conclusion validity

Statistical conclusion validity is concerned with whether there is truly an empirical relationship, or correlation, between the presumed cause and effect. Statistical methods are used to support inferences about whether relationships exist. Design decisions can influence whether statistical tests will detect true relationships, so researchers need to make decisions that protect against reaching false statistical conclusions. The researcher's job is to provide the strongest possible evidence that the relationship is real and was given a fair test (Polit & Beck 2012:236 &241).

The researcher ensured statistical conclusion validity through managing statistical power (the ability to detect true relationships among variables) in doing so. The researcher used a large sample size.

Internal validity

Internal validity refers to the extent to which it is possible to make an inference that the independent variable, rather than another factor, is truly causing variation in the dependent variable. The researcher's job is to develop strategies to rule out the plausibility that something other than the independent variable accounts for the observed relationship (Polit & Beck 2012:236;244).

As a result, the researcher has done the following to ensure internal validity:

- Professionals in the area evaluated the content of the checklist and in-depth interview guide to validate the questions. The experts included the supervisor, gynaecologists and midwives and have provided independent views and suggestions on the content,
- The questions were chosen after reviewing literature to examine what is known on the topic and the tools were also pre-tested.

External validity

External validity is concerned with whether inferences about observed relationships will hold over variations in persons, setting, time, or measures of the outcomes. External validity, then, is about the generalizability of causal inferences, and this is a critical concern for research that aims to yield evidence for evidence-based practice (Polit & Beck 2012:250).

Consequently, external validity was ensured in the following manner:

- The study participants were chosen from the largest Maternal and Child Health (MCH) centre in Ethiopia, to make sure that the sample is a representative of the target population.
- In order to increase the probabilities of generalizability, optimal statistical considerations were taken into account in the calculation of the sample size to attain very high power.

Reliability

Reliability is the degree of consistency or dependability with which an instrument measures the attribute it is designed to measure (Polit & Beck 2008:730). It is also a measure of the consistency of a method, as such, is the extent to which an instrument produces the same result when it is used in the same subject on more than one occasion (Peat 2001:205). If an instrument constantly produces the same results when administered to the same or comparable individuals then it is considered reliable (Fletcher, Fletcher & Fletcher 2014:6). As a result, the researcher gave emphasis on the translation of the questionnaire from English to Amharic language and pre-test was also conducted to ensure reliability. Moreover, the researcher trained data collectors and ensured that data collectors understood and agreed on the data collection tool and has used observation techniques during data collection and operationalized the necessary categories in order to ensure inter-rater reliability.

3.5 QUALITATIVE DATA TRUSTWORTHINESS

Trustworthiness (credibility, criticality, confirmability**,** dependability, transferability, authenticity, and integrity) of the results was recognized by using the criteria suggested by Lincoln and Guba (1985) cited in Streubert & Carpenter (2011: 47-49; Polit & Beck 2012: 584-586).

Credibility refers to the confidence in the "truth" of the findings and it included increasing the probability of producing credible findings (Polit & Beck 2012:585). This study ensured credibility through prolonged engagement (spending more time withparticipants during data gathering) and carrying out the study in a way that increasesthe trustworthiness of outcomes.

The research results were taken to the respondents and a discussion was made with the study participants to ensure member check.

Dependability is similar to the concept of reliability in quantitative study and is defined by Polit and Beck (2012:585) as a standard for evaluating the integrity of qualitative studies, and it is also about stability of data over period and over circumstances.

It was ensured by the consistency of the interview guide irrespective of where it is going to be used, i.e. the interview guide was prepared meticulously by consulting experts on the area, supervisor and reviewing literature.

Confirmability *is* about the possible similarity of the views of two or more independent people in relation with data's accuracy, relevance, or meaning (Polit & Beck 2012:585). All in all, confirmability is about objectivity. This standard is concerned with determining data that represent the information which participants are given, and that the interpretation of the information is not formulated by the explorer. It was ensured by using reflexivity to avoid using own opinions, beliefs and knowledge about the study phenomenon in order not to contaminate the data.

Transferability is the likelihood of findings of a study can be meaningful when transmitted to other similar settings or groups (Polit & Beck 2012:585). Transferability inthis study was safeguarded through dense explanation of the overall research procedures in order to assist other researchers to verify applicability of the research by duplication.

Authenticity refers to the extent to which researchers fairly and faithfully show a range of realities (Polit & Beck 2012:585).
Therefore, in this study, data collection and analysis were done with integrity andhonesty in order to ensure authenticity.

Criticality refers to critical appraisal of every decision made by the researcher while conducting research (Polit & Beck 2012:586). During the study process, the researcher appraised every decision made.

Integrity is about ensuring interpretations of findings are valid and grounded in the data through ongoing self-reflection and self-scrutiny (Polit & Beck 2012:586). The researcher ensured integrity by constantly consulting the supervisor and experts in the area, the researcher also made sure that interpretations of the data was valid.

3.6 CONCLUSION

This chapter offered a detailed description and explanation of study methods and methodology.

The next chapter will present the findings of the research study.

CHAPTER 4

ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

4.1 INTRODUCTION

In the preceding chapter, the research overall methodology was broadly presented. In this chapter, the results of the study with discussion are offered as they focus on the aims of the study, which was conducted from June 2019 to August 2019, besides additional in-depth interviews were conducted from May 2020 till half of June 2020. As stated in methodology section, data was collected using a checklist for quantitative research and in-depth interview was done for the qualitative part of the research.Findings are presented using tables and figures.

Presentation of the result is divided into sections as follows:

- Socio-demographic characteristics
- Basic obstetric characteristics
- Family history of DM
- Urine analysis results
- Past medical and obstetric history
- Current delivery status
- Provision of health education
- Quantitative findings of the study regarding magnitude of GDM and factors associated with GDM
- Qualitative findings of the experience of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal outcomes related to GDM
- Discussion

The study is guided by the following objectives:

- Established the magnitude of GDM in Addis Ababa, Ethiopia.
- Identified associated factors for GDM in Addis Ababa, Ethiopia.
- Explored the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal outcomes related to GDM.

- Developed best practice guidelines to monitor and prevent maternal outcomes related to GDM.

4.2 DATA MANAGEMENT AND ANALYSIS

Presentation and analysis of both quantitative and qualitative data were done simultaneously following the requirements of embedded concurrent mixed methods approach.

The quantitative part of this study addressed the burden of GDM as well as factors associated with it, in doing so, the researcher used a checklist to review medicalrecords of mothers between the years 2013-2017. After data cleaning, the filled checklist has been entered into Statistical Package for Social Sciences (SPSS) version 25:0 for data analysis. Data was entered, cleaned and analysed by the researcher.

Descriptive summary of findings was made with descriptive statistics (mean, median and standard deviation). Inferential statistics were also used to measure the association of independent variables with dependent variables. In doing so, Chi-square test was used. Collected data was protected from access by people except those involved in data collection and filled checklists were kept in a locker. Data entered the computer were also kept in a secured, password protected folder.

The qualitative part of this study primarily focused on exploring the experiences of gynaecologists/obstetricians and midwives towards monitoring and preventing maternal outcomes related to GDM. In depth-interviews were conducted with 4 gynaecologists/obstetricians and 3 midwives that work in Gandhi Memorial Hospital. The interviews were transcribed and were translated in English and data was analysed using Colaizzi's seven steps manual qualitative data analysis principles. No names appeared on the in-depth interview guides and memos. Audio recorded data was only accessible to the researcher and was kept safe. Moreover, embedding of both quantitative and qualitative data findings was then made after analysis of qualitative and quantitative data.

4.3 QUANTITATIVE RESEARCH RESULTS

4.3.1 Sample characteristics

The total sample size required for this study was 2000 i.e. for each year 400 medical records were reviewed, revealing the following findings,

4.3.1.1. Age of mothers

2000 medical records of mothers who attended ANC and delivered in Gandhi Memorial Hospital between the years 2013-2017 were reviewed. Of the 2000 medical records reviewed, the majority 825(41.2%) were among the age of 26-30 years, followed by 21-25 years old mothers accounting 615(33.3%) and the mean age was 27.4(±4.7) (Table 4.1).

TABLE 4.1: SUMMARY OF AGE OF MOTHERS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017 (N=2000)

Age	Frequency	Percent
16-20	121	6.0
21-25	615	30.8
26-30	825	41.2
31-35	338	16.9
>35	101	5.0
Total	2000	100

TABLE 4.2: SUMMARY OF AGE OF MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017

Age	2013 N=400		2014 N=400		2015 N=400		2016 N=400		2017 N=400	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%	Frequency	%
16-20	36	9.0	12	3	34	8.4	14	3.5	25	6.2
21-25	133	33.3	107	26.7	131	32.8	135	33.8	109	27.2
26-30	145	36.3	180	45	160	40.0	173	43.2	167	41.8
31-35	61	15.3	83	20.8	59	14.8	57	14.2	78	19.5
>35	25	6.1	18	4.5	16	4.0	21	5.3	21	5.3
Total	400	100	400	100	400	100	400	100	400	100

4.3.2. Basic obstetric characteristics of mothers

Basic obstetric characteristics were reviewed in this study. Almost half 936 (46.8%) of mothers were gravida one, with least (3.6%) being multi- gravida (5 and more). Where almost half 977 (48.9%) of mothers were nulliparous. Moreover, all mothers were screened for HBsAg (Hepatitis B surface Antigen), VDRL (Venereal Disease Research Laboratory), HIV (Human Immunodeficiency Virus) and RH (Rhesus factor), of which only 2(0.1%) were positive for the VDRL test. In addition, 6(0.3%) and 12(0.6%) were positive for HIV and HBsAg test respectively, besides most 1806 (90.3%) of mothers were RH positive (Table 4.3).

TABLE 4.3: SUMMARY OF BASIC OBSTETRIC CHARACTERISTICS OF MOTHERS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017 (N=2000)

Characteristics		Frequency	Percent
Gravida	1	936	46.8
	2	605	30.2
	3	256	12.8
	4	130	6.5
	Greater and equal to 5	73	3.6
Parity	Null Para	977	48.9
	Para one	341	17.0
	Multipara (2-4)	266	13.3
	Grand multipara (5 or more)	416	20.8
VDRL	Positive	2	0.1
	Negative	1998	99.9
HBsAg	Positive	12	0.6
	Negative	1988	99.4
PIHCT	Positive	6	0.3
	Negative	1994	99.7
RH	Positive	1806	90.3
	Negative	194	9.7

TABLE 4.4: SUMMARY OF BASIC OBSTETRIC CHARACTERISTICS OF MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013- 2017

Characteristics		2013 N=400		2014 N=400		2015 N=400		2016 N=400		2017 N=400	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Gravida	1	184	46.0	199	49.8	179	44.8	182	45.5	192	48.0
	2	119	29.8	125	31.3	117	29.2	129	32.2	115	28.8
	3	50	12.5	44	11.0	60	15.0	50	12.5	52	13.0
	4	28	7.0	19	4.8	28	7.0	25	6.2	30	7.5
	Greater and equal to 5	19	4.8	13	3.3	16	4.0	14	3.5	11	2.8
Parity	Null para	200	50.0	215	53.8	109	27.2	125	31.2	213	53.3
	Para one	118	29.5	118	29.5	64	16.0	51	12.8	105	26.3
	Multi Para (2-4)	78	19.5	64	16.0	22	5.5	24	6.0	78	19.5
	Grand multi Para (5 or more)	4	1.0	3	0.8	205	51.2	200	50.0	4	1.0
VDRL	Positive					1	0.2	1	0.2		
	Negative	400	100	400	100	399	99.8	399	99.8	400	100
HBsAg	Positive			1	0.3	6	1.5	3	0.8	2	0.5
	Negative	400	100	399	99.8	394	98.5	397	99.2	398	99.5
HIV	Positive					3	0.8	2	0.5	1	0.3
	Negative	400	100	400	100	397	99.2	398	99.5	399	99.8
RH	Positive	339	84.8	389	97.3	360	90.0	392	98.0	326	81.5
	Negative	61	15.3	11	2.8	40	10.0	8	2.0	74	18.5

4.3.3. Family history of DM

Out of the 2000 medical records reviewed, 161 (8%) had family history of DM whereas 1839 (92%) had no family history of DM (Figure 4.1).

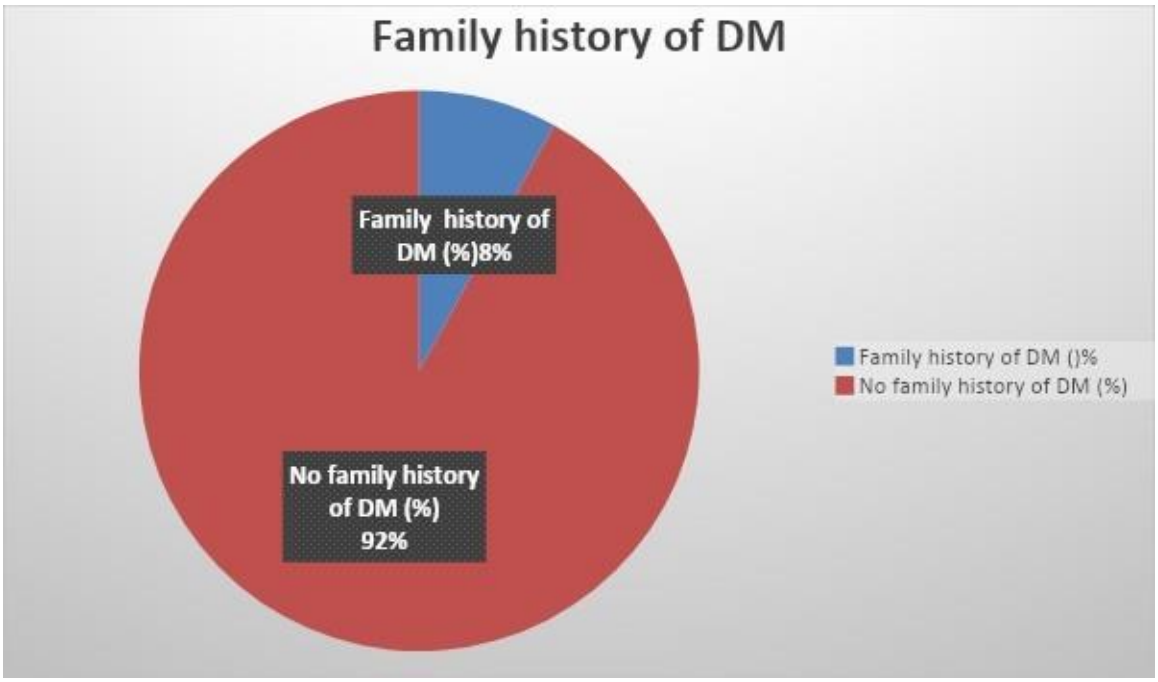

Figure 4.1. Summary of family history of DM among mothers at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013-2017

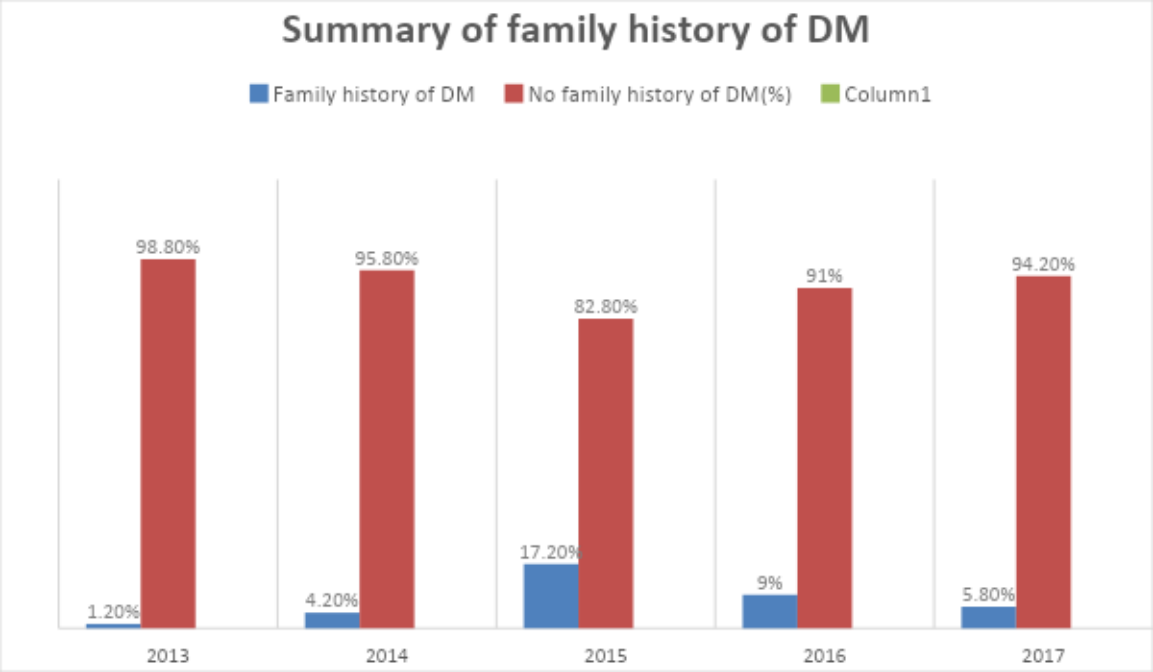

Figure 4.2. Summary of family history of DM among mothers per specific year at Gandhi Memorial Hospital, Addis Ababa, Ethiopia 2013- 2017

4.3.4. Urine sample results of participants

Urine examination for sugar, protein, ketone, and bacteria showed that only (1.4%), (4%), (3.1%) and (0.8%) of mother's urine examination revealed positive for sugar, protein, ketone, and bacteria in the urine sample analysis respectively (Figure 4.3).

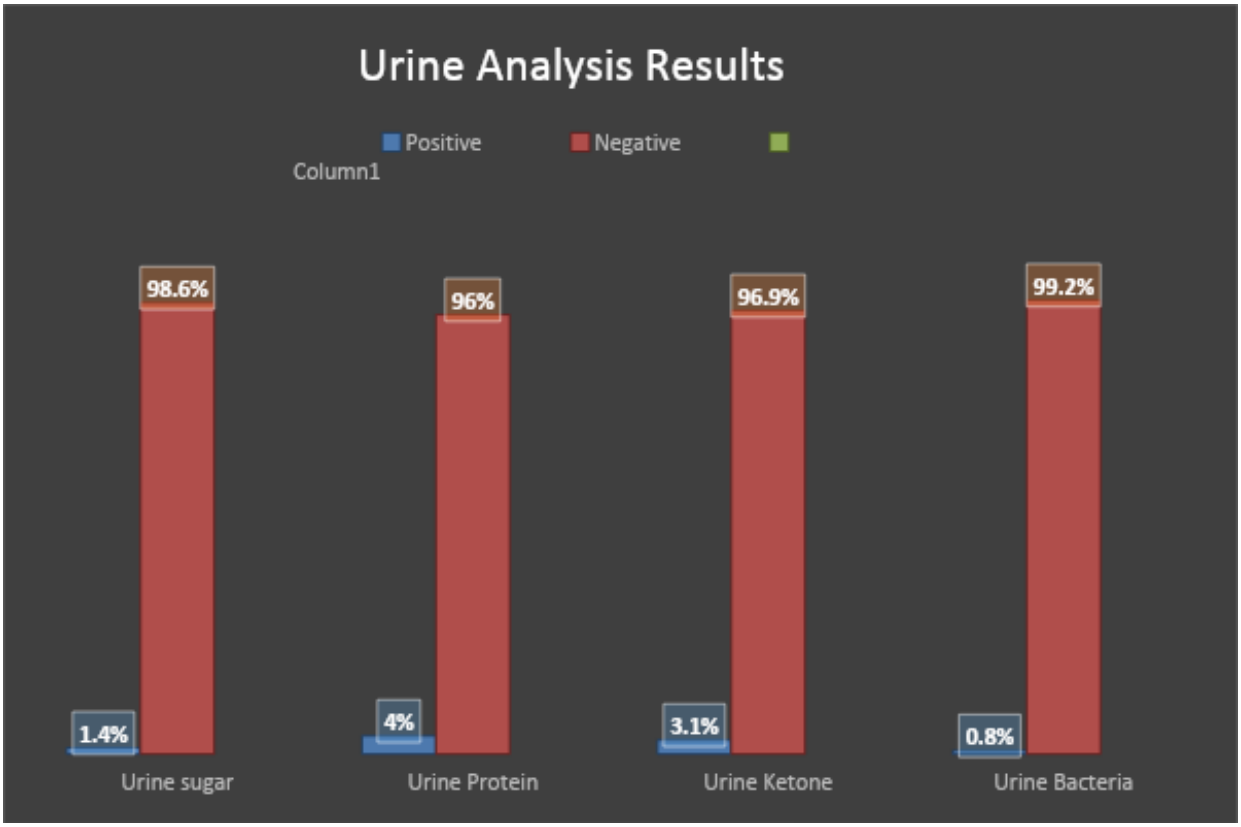

Figure 4.3. Summary of urine analysis reports of mothers at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013-2017.

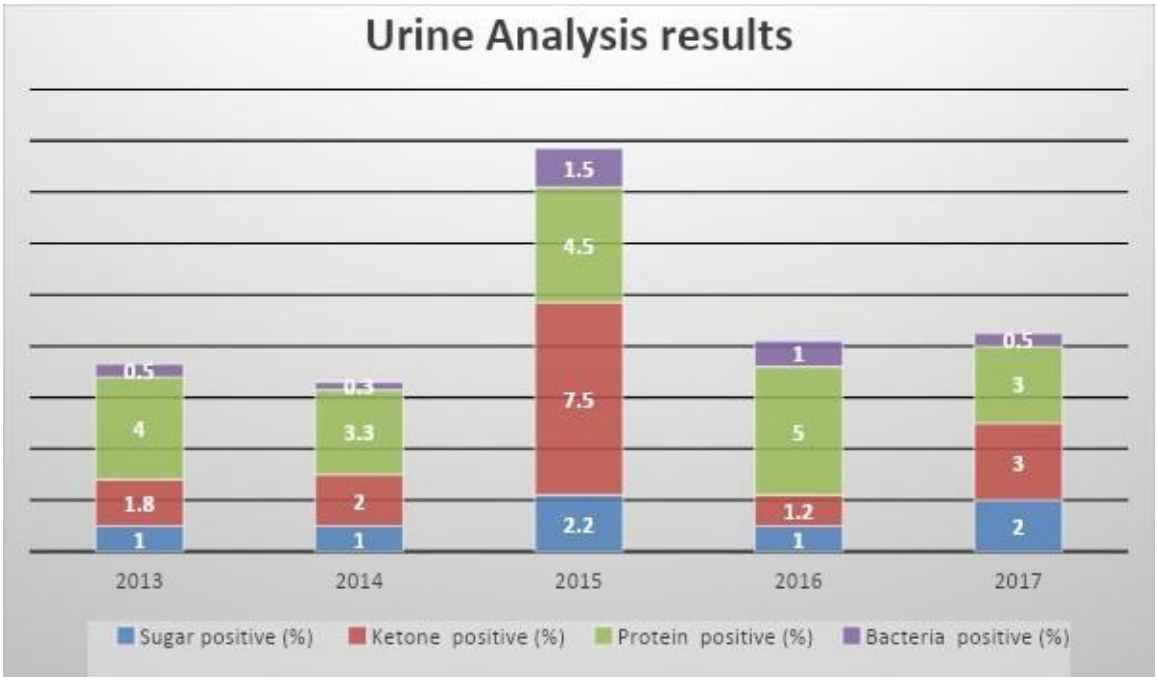

Figure:4.4. Summary of urine analysis result of mothers per specific year at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013- 2017.

4.3.5. Previous obstetric and medical history

In this study, past obstetric history (i.e. previous history of delivery mechanism) and past medical history (i.e. past surgical history, past medical history, any known allergies and history of previous admission) were assessed and it was found that only 22 (1.1%) had a history of any known allergies, whereas, 641 (32%), 770 (38.5%), and 285 (14.2%), of the mothers had a history of previous admission, history of spontaneous vaginal delivery (SVD) and caesarean section (CS) respectively. In addition, majority of the mothers 770 (38.5%) had a history of SVD and the least mode of delivery was forceps delivery which accounted for 1% (19) (Table 4.5).

TABLE 4.5. SUMMARY OF PREVIOUS OBSTETRIC AND MEDICAL HISTORY OF MOTHERS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017 (N=2000)

Characteristics		Frequency	Percent
Previous Spontaneous vaginal Delivery	Yes	770	38.5
	No	1230	61.5
Previous Forceps Delivery	Yes	19	1.0
	No	1981	99.0
Previous Vacuum Delivery	Yes	33	1.6
	No	1967	98.4
Previous Caesarean Section	Yes	285	14.2
	No	1715	85.8
Past surgical history	Yes	245	12.2
	No	1755	87.8
Past medical history	Yes	45	2.2
	No	1955	97.8
Any known allergies	Yes	22	1.1
	No	1978	98.9
History of Previous admission	Yes	641	32.0
	No	1359	68.0

TABLE 4.6. SUMMARY OF PAST OBSTETRIC AND MEDICAL HISTORY OF MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA 2013- 2017.

Characteristics		2013 N=400		2014 N=400		2015 N=400		2016 N=400		2017 N=400	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Previous Spontaneous vaginal Delivery	Yes	155	38.8	141	35.3	180	45.0	155	38.8	139	34.8
	No	245	61.3	259	64.8	220	55.0	245	61.2	261	65.3
Previous Forceps Delivery	Yes			2	0.5	9	2.2	6	1.5	2	0.5
	No	400	100	398	99.5	391	97.8	394	98.5	398	99.5
Previous Vacuum Delivery	Yes	3	0.8	7	1.8	7	1.8	10	2.5	6	1.5
	No	397	99.2	393	98.3	393	98.2	390	97.5	394	98.5
Previous Caesarean Section	Yes	56	14.0	68	17.0	40	10.0	58	14.5	62	15.5
	No	344	86.0	332	83.0	360	90.0	342	85.5	338	84.5
Past surgical history	Yes	56	14.0	68	17.0	22	5.5	43	10.8	56	14.0
	No	344	86.0	332	83.0	378	94.5	357	89.2	344	86.0
Past medical history	Yes	6	1.5	4	1.0	15	3.8	11	2.8	2	0.5
	No	394	98.5	396	99.0	385	96.2	389	97.2	398	99.5
Any known allergies	Yes	1	0.3	1	0.3	27	6.8	3	0.8	2	0.5
	No	399	99.8	399	99.8	373	93.2	397	99.2	398	99.5
History of Previous admission	Yes	158	39.5	186	46.5	121	30.2	121	30.2	149	37.3
	No	242	60.5	214	53.5	279	69.8	279	69.8	251	62.7

4.3.6. Current delivery status

Regarding the current delivery status, more than half 1104 (55.2%) of mothers gave birth through SVD, and less than half 875 (43.8%) of deliveries were through CS, where vacuum and forceps delivery accounted for 1.9% and 6.6% respectively (Table 4.7).

TABLE 4.7. SUMMARY OF CURRENT DELIVERY STATUS OF MOTHERS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017 (N=2000)

Characteristics		Frequency	Percent
Spontaneous vaginal Delivery	Yes	1104	55.2
	No	896	44.8
Caesarean Section	Yes	875	43.8
	No	1125	56.2
Forceps Delivery	Yes	131	6.6
	No	1869	93.4
Vacuum delivery	Yes	38	1.9
	No	1962	98.1

TABLE 4.8. SUMMARY OF CURRENT DELIVERY STATUS OF MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA 2013-2017.

Characteristics		2013 N=400		2014 N=400		2015 N=400		2016 N=400		2017 N=400	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Spontaneous vaginal Delivery	Yes	212	53	192	48.0	276	69	216	54.0	207	51.8
	No	188	47	208	52	124	31	184	46	193	48.2
Cesarean Section	Yes	180	45	208	52.0	116.8	29.2	179	44.8	189	47.3
	No	220	55	192	48	283.2	70.8	221	55.2	211	52.7
Forceps Delivery	Yes	16	4	3.2	0.8	0.8	0.2	5	1.2	1	0.3
	No	384	96	396.8	99.2	399.2	99.8	395	98.8	399	99.7
Vacuum delivery	Yes	17.2	1.3	7	1.8	7.2	1.8	4	1.0	6	1.5
	No	382.8	98. 7	393	98.2	392.8	98.2	396	99	394	98.5

4.3.7. Provision of health education

As depicted in the medical records of mothers, health education was provided topregnant women mostly on family planning, immunization, and exclusive breastfeeding at a rate of 76.7%, 71.2%, and 83.5% correspondingly. Whilst less emphasis was given to nutritional advice, adequate rest and disease prevention with a rate of 7.4%, 5.9% and 2% respectively (Figure 4.5).

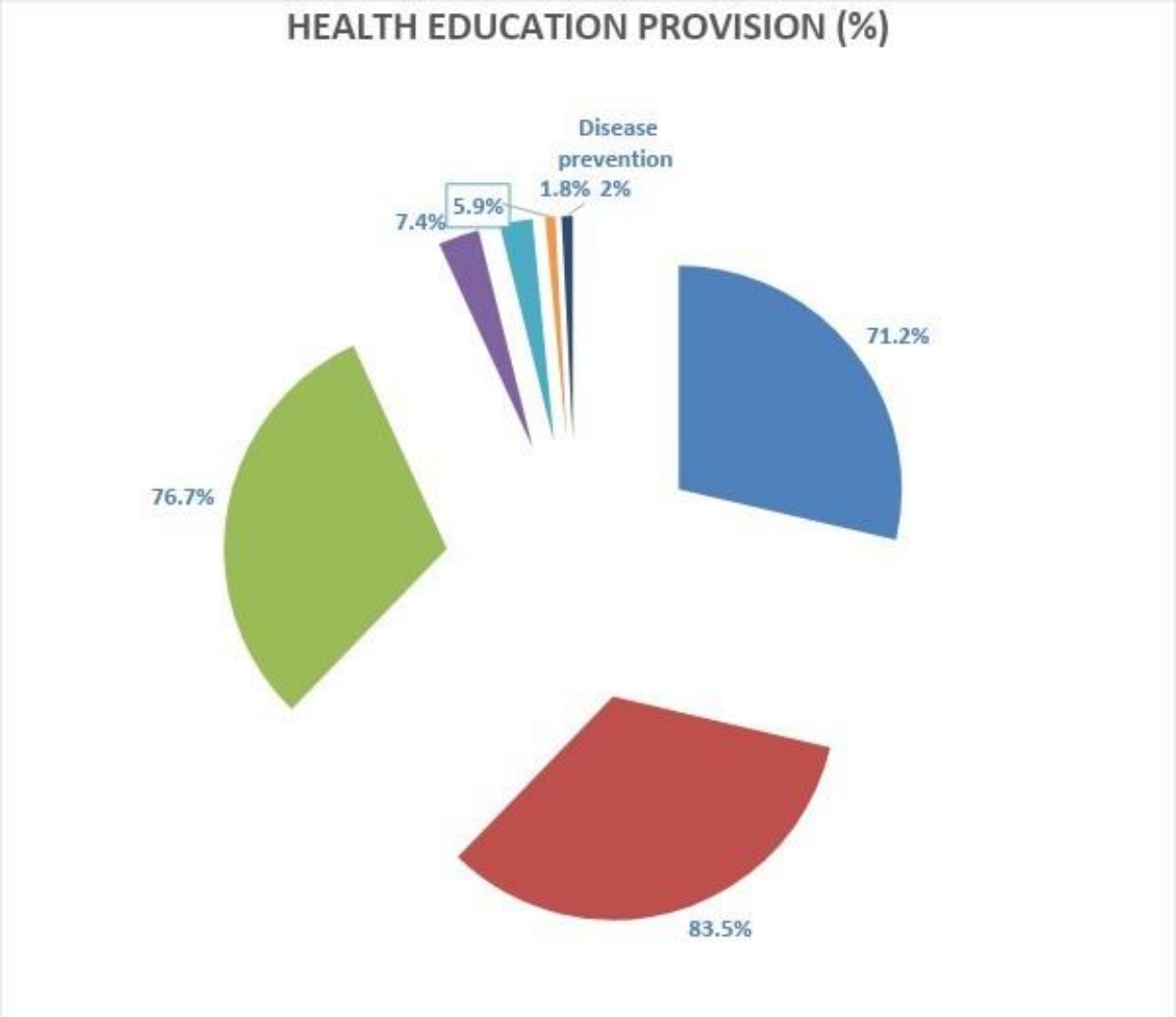

Figure 4.5. Summary of provision of health education for mothers at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013-2017.

TABLE 4.9. SUMMARY OF PROVISION OF HEALTH EDUCATION FOR MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017

Characteristics		2013 N=400		2014 N=400		2015 N=400		2016 N=400		2017 N=400	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Proper Nutrition	Yes	33	8.3	27	6.8	32	8	24	6	13	3.2
	No	367	91.7	373	93.2	368	92	376	94	387	96.8
Adequate Rest	Yes	25	6.3	24	6	13	3.2	16	4	8	2
	No	375	93.7	376	94	387	96.8	384	96	392	98
Hygiene	Yes	6	1.5	2	0.5	16	4	3	0.8	4	1
	No	394	98.5	398	99.5	384	96	397	99.2	396	99
Family Planning	Yes	396	99	399	99.8	144	36	257	64.2	128	32
	No	4	1	1	0.2	256	64	143	35.8	272	68
Exclusive Breast Feeding	Yes	394	98.5	399	99.8	85	21.2	239	59.8	116	29
	No	6	1.5	1	0.2	315	78.8	161	40.2	284	71
Immunization	Yes	395	98.8	399	99.8	239	59.8	289	72.2	148	37
	No	5	1.2	1	0.2	377	40.2	111	27.8	252	63
Disease prevention	Yes	3	0.6	1	0.2	19	4.8	8	2	0	0
	No	397	99.4	399	99.8	381	95.2	392	98	400	100

4.3.8. Maternal morbidities

Of the 2000 medical records reviewed, it was found that only 19 (1%) had polyhydramnios, 21 (1%) had eclampsia, 63 (3.2%) had pre-eclampsia, and 24 (1.2%) had hypertension and 1873 (93.6%) did not have any off the above-mentioned morbidities (Figure 4.6).

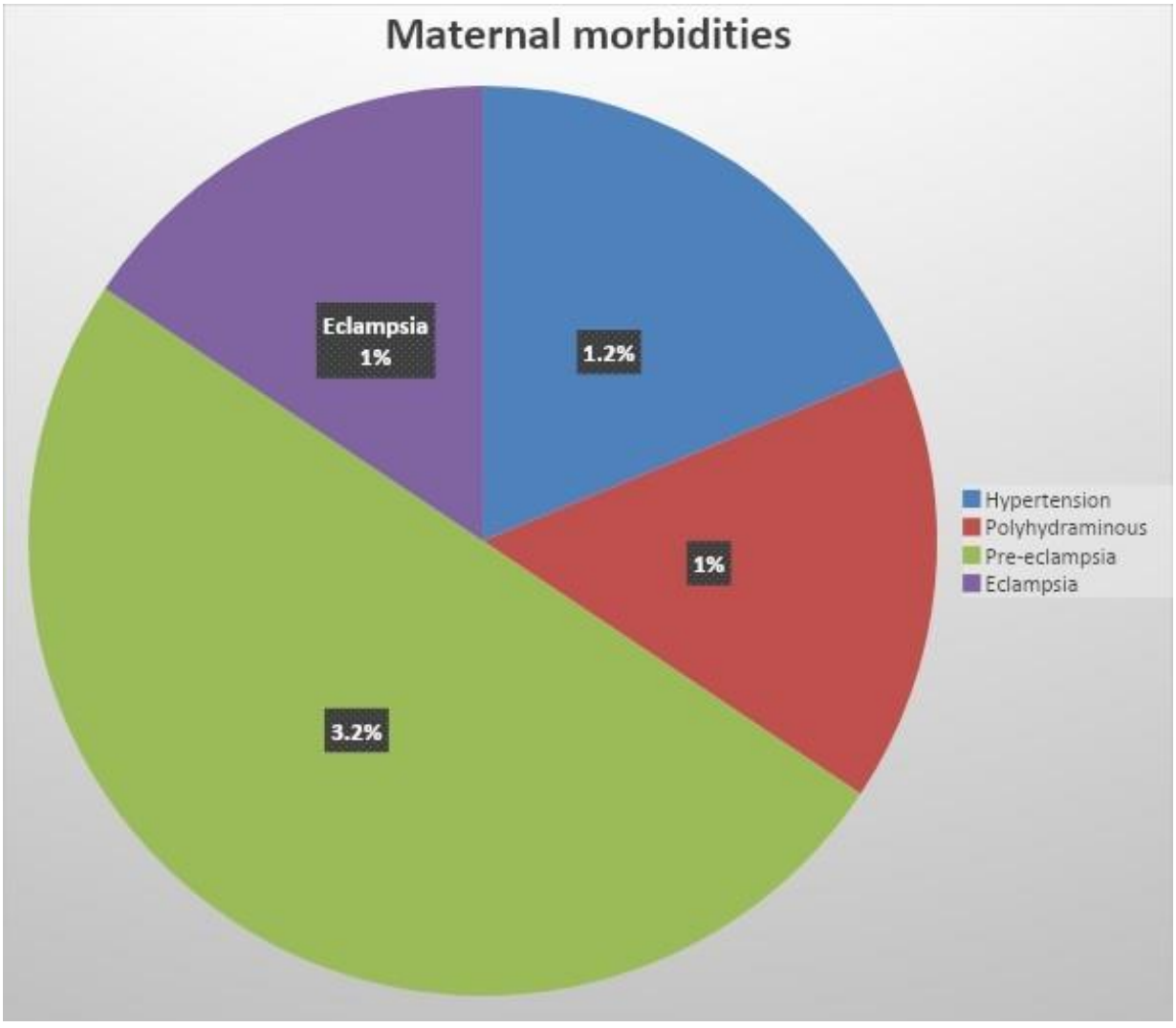

Figure 4.6. Summary of maternal morbidities of mothers at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013-2017.

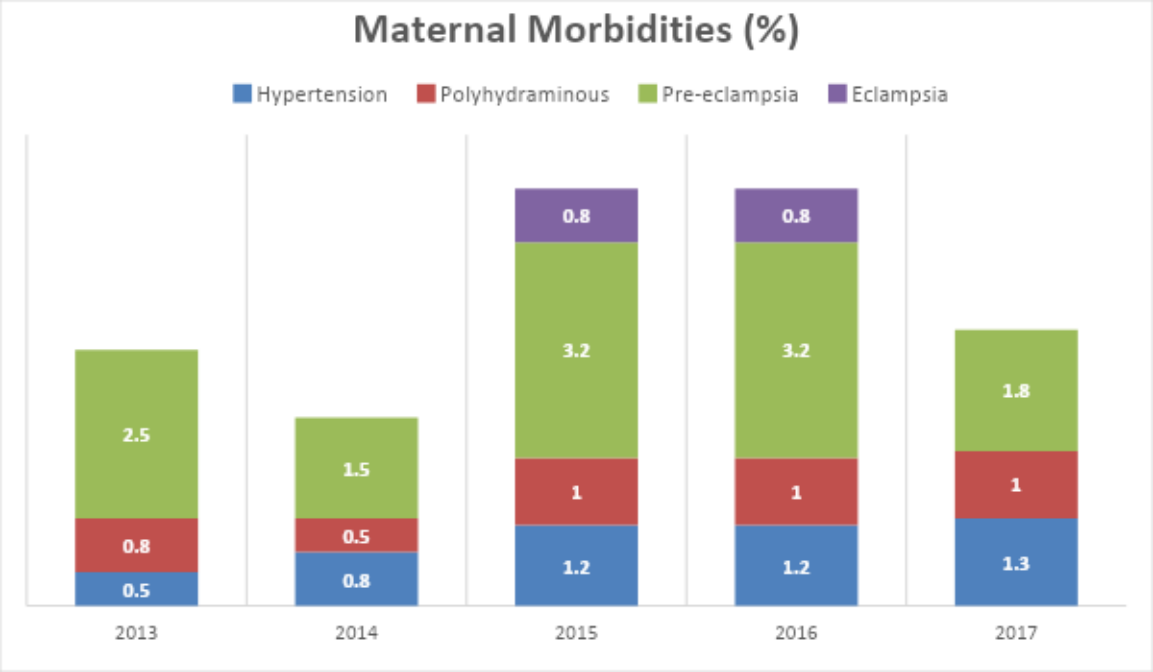

Figure 4.7. Summary of maternal morbidities of mothers per specific year atGandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013- 2017.

4.3.9. Magnitude of GDM

Overall prevalence of GDM was 2.2% (Figure 4.8). The medical records reviewed had revealed that there are variations in the magnitude of GDM from year to year aspresented in figure 4.9, for instance, the prevalence of GDM in the year 2014 was 3.8% whereas in 2013 it was only 0.8%.

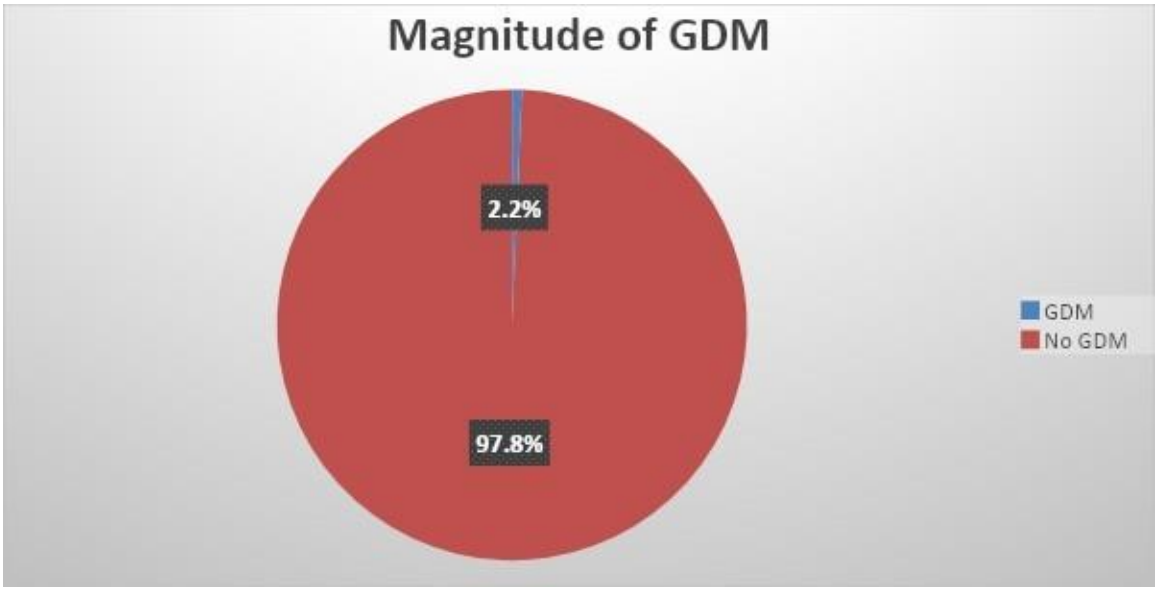

Figure 4.8. Summary of magnitude of GDM among mothers at Gandhi Memorial Hospital, Addis Ababa, Ethiopia, 2013-2017.

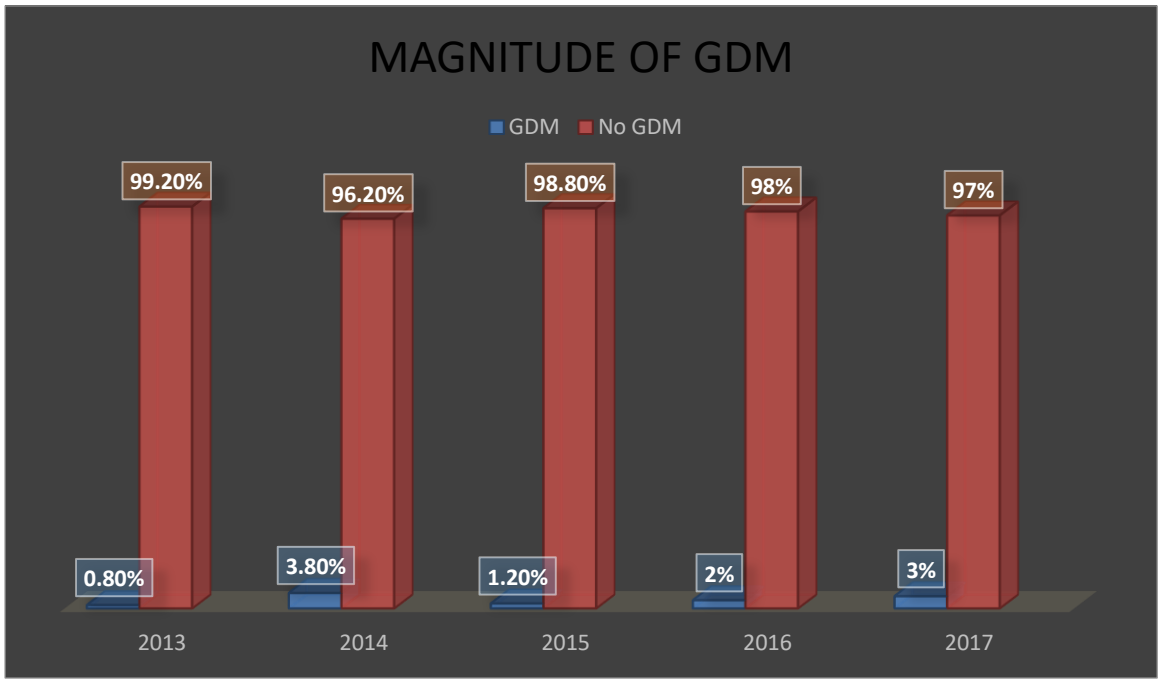

Figure 4.9. Summary of magnitude of GDM among mothers per specific year at Gandhi Memorial Hospital, Addis Ababa, Ethiopia 2013-2017.

4.3.10. Factors associated with GDM

Factors associated with GDM were identified using chi-square tests. Per the finding of the study, age of mothers (X^2=30.92, df=4, P≤0.000) and family history of DM were found to be statistically associated with GDM (X^2=1.631, df=1, P≤0.001) (Table 4.8).

TABLE 4.10. ANALYSIS OF FACTORS ASSOCIATED WITH GDM AMONGMOTHERS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013- 2017.

Characteristics		GDM		X^2	df	p-value
Age		**Yes**	**No**			
16-20		0	121	30.927	4	0.000
21-25		2	613			
26-30		31	794			
31-35		4	334			
>35		6	95			
Gravida				7.942	4	0.094
1		19	917			
2		14	591			
3		9	247			
4		0	130			
Greater and equal to 5		1	72			
Parity				2.326	3	0.507
Null para		23	954			
Para one		8	333			
Multipara (2-4)		7	259			
Grand multipara (5 or more)		5	411			
Family history of DM	**Yes**	26	135	1.631	1	0.000
	No	17	1822			
Previous CS	**Yes**	12	273	6.708	1	0.010
	No	31	1684			

TABLE 4.11 SUMMARY OF ANALYSIS OF FACTORS ASSOCIATED WITH GDM AMONG MOTHERS PER SPECIFIC YEAR AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2013-2017.

Characteristics		2013		2014		2015		2016		2017	
		GDM		GDM		GDM		GDM		GDM	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Age	16-20	0	36	0	12	0	33	0	14	0	25
	21-25	0	133	1	106	0	131	0	135	1	108
	26-30	1	144	14	166	3	157	4	169	9	158
	31-35	0	61	0	83	1	58	2	55	0	78
	>35	2	23	0	18	1	15	1	20	2	19
		(X^2=19.398, df=4, P≤0.001)		(X^2=18.206, df=4, P≤0.001)		(X^2=6.858, df=1, P≤0.009)		(X^2=4.727,df=1, P≤0.030)		(X^2=11.157, df=4, P≤0.025)	
Gravida	1	0	184	9	190	2	176	2	179	6	186
	2	2	117	4	121	1	116	4	125	3	112
	3	1	49	1	43	2	58	1	49	3	49
	4	0	28	0	19	0	28	0	25	0	30
	Greater and equal to 5	0	19	1	12	0	16	0	14	0	11
		(X^2=4.80, df=4, P≤0.382)		(X^2=0.283, df=1, P≤0.595)		(X^2=4.075, df=8, P≤0.850)		(X^2=3.718,df=8, P≤0.882)		(X^2=2.709, df=4, P≤0.608)	
Parity	Null para	1	199	9	206	1	108	3	122	6	207
	Para one	1	117	4	114	2	62	1	50	3	102
	Multi Para (2-4)	1	77	2	62	0	22	0	24	3	75
	Grand multi Para (5 or more)	0	4	0	3	2	202	3	197	0	4
		(X^2=0.510, df=3, P≤0.917)		(X^2=0.342, df=3, P≤0.952)		(X^2=3.272, df=6, P≤0.774)		(X^2=0.821,df=3, P≤0.845)		(X^2=0.348, df=3, P≤0.951)	
Family history of DM	Yes	1	4	10	7	4	65	2	45	9	14
	No	2	393	5	378	1	329	5	348	3	374
		(X^2=25.143, df=1, P≤0.000)		(X^2=1.492, df=1, P≤0.000)		(X^2=14.157, df=2, P≤0.001)		(X^2=1.944,df=1, P≤0.163)		(X^2=1.095, df=1, P≤0.000)	
Previous CS	Yes	2	55	3	65	1	39	2	56	3	59
	No	1	342	12	320	4	355	5	337	9	329
		(X^2=6.796, df=1, P≤0.009)		(X^2=0.099, df=1, P≤0.753)		(X^2=0.671, df=2, P≤0.715)		(X^2=1.138,df=1, P≤0.286)		(X^2=0.852, df=1, P≤0.356)	

4.4. QUALITATIVE RESEARCH FINDINGS

The findings in this part related to data collected from gynaecologists/obstetricians and midwives that work at Gandhi Memorial Hospital are discussed further in the following sections.

4.4.1. Biographical profile of participants

Seven gynaecologists/obstetricians and 12 midwives who work at Gandhi Memorial Hospital participated. Out of which 6 were male gynaecologists/obstetricians, 1 female gynaecologist/obstetrician and 2 male midwives and 10 female midwives. All themidwives who had participated in the study have bachelor's degrees in midwifery.
Table 4.12. depicts the age, gender, profession and experience of the participants.

TABLE 4.12 BIOGRAPHICAL PROFILE OF PARTICIPANTS AT GANDHI MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA, 2019.

No.	Gender	Age	Profession	Experience in years
1	Female	48	Gynaecologist/obstetrician	22
2	Male	37	Gynaecologist/obstetrician	11
3	Male	53	Gynaecologist/obstetrician	27
4	Male	42	Gynaecologist/obstetrician	16
5	Male	49	Gynaecologist/obstetrician	23
6	Male	51	Gynaecologist/obstetrician	24
7	Male	56	Gynaecologist/obstetrician	28
8	Male	26	Midwife	4
9	Female	31	Midwife	9
10	Female	35	Midwife	13
11	Female	47	Midwife	25
12	Female	43	Midwife	30
13	Female	40	Midwife	15
14	Female	38	Midwife	10
15	Female	28	Midwife	6
16	Male	31	Midwife	9
17	Female	42	Midwife	17
18	Female	36	Midwife	11
19	Female	39	Midwife	13
Total	19 HPs			

TABLE 4.13. SUMMARY OF PARTICIPANTS' PROFILE.

Participants profile	**Description**	
Age	Mean+ standard deviation = 40.6+ 8.29	
Gender	Male = 8	Female = 11
Profession	Gynaecologist/obstetrician = 7	Midwife = 12

Key: A stands for age, M for male, F for female, G for gynaecologists/obstetrician, and MW for midwives.

4.4.2 Analysis and results from the in-depth interviews

The analysis of the interviews generated 5 themes, namely: magnitude, risk factors, management of GDM, GDM related adverse maternal outcomes as well as barriers for management of GDM. In the following section each theme will be discussed with its categories and subcategories. Table 4.14 describes the themes, categories and subcategories.

TABLE 4.14 SCHEMATIC PRESENTATION OF THEMES, CATEGORIES PLUS SUBCATEGORIES.

THEMES	CATEGORIES	SUBCATEGORIES
Magnitude of GDM	Magnitude of GDM	• Gynaecologists/obstetricians estimates • Midwives estimates
Factors related to GDM	Risk Factors of GDM	• Age of the mother • Family history of DM • Multiple gestation • Obesity (BMI > 30) • Previous history of GDM • Previous history of having a macrosomic baby
Management of GDM	Monitoring of GDM	• Screening and diagnosis modalities
		• Management of GDM
	Prevention of GDM	• Preventive mechanisms
Adverse maternal outcomes related to GDM	Maternal morbidities related with GDM	• Preterm labour and delivery • Hypertension • Polyhydramnios • Increased rate of CS
	Maternal mortality related with GDM	• Maternal death
Barriers for management of GDM	Barriers for screening	• Cultural practice • Late visit to ANC clinic • Cost of diagnostic tests • Poor access to health-related information • Lack of guidelines
	Barriers for treatment	• Cost of medication • Attitudes of pregnant women towards medication • Lack of contextualized guidelines

Following, is a discussion of each theme, categories and subcategories. In each section the theme is explained, and the results are presented.

4.4.2. Experience of health professionals (HPs) towards monitoring and prevention of GDM related maternal morbidity and mortality

4.4.2.1 Theme 1: Magnitude of GDM

4.4.2.1.2. Category 1: Magnitude of GDM

4.4.2.1.2.1 Subcategory 1: Gynaecologists/obstetricians estimates

The gynaecologists/obstetricians who participated in this study expressed their estimates towards magnitude of GDM. A participant was able to estimate the magnitude of GDM and stated the following: -

> *"To my views the prevalence of GDM can lie between 2-3%." (A37MG)*

This was also reflected in the statement verbalized by another participant below:

> *"The prevalence of GDM is increasing from time to time but from my experience I can say maybe 3% of pregnant mothers may develop GDM. "(A53MG)*

The above ideas were also shared by another participant as expressed in the following comment:

> *"Many researches done throughout the world states that prevalence of GDM is increasing ….I am not sure whether this is true for our country because more researches have to be done in our setup….to clarify this issue, but from my clinical experience I can simply say maybe 1 or maximum of 3 out 100 pregnant women can have GDM."(A48FG)*

4.4.2.1.2.2 Subcategory 2: Midwives estimates

The midwives who participated in this study have estimated the magnitude of GDM as follows:

":……. It won't be easy for me to estimate; we do not encounter many cases of GDM, but I can say maybe 1 out of hundred." (A26MMW)

"Before two years or so I never encountered GDM cases but these days there are very few cases….to put it in number 1 to 2%." (A31FMW)

The above commentaries by the HPs indicated that the magnitude of GDM is a little bit increasing from time to time and they have described that the magnitude of GDM lies between 1 to 3%. Even though HPs were not with absolute evidence about the magnitude of GDM, their suggestion revolves around an ever-fluctuating burden ofGDM as explained above by the informants.

4.4.2.2 Theme 2: Factors related with GDM

The participants indicated that there are many risk factors related with GDM and some of the statements that were verbalized are presented below

4.4.2.2.1 Category 1: Risk factors related with GDM

HPs views alluded that the risk factors that influence the development of GDM were age (>35), obesity, previous history of GDM, family history of DM, previous history of having a macrosomic baby, multiple gestation and ethnicity or race. Moreover, as reflected by the participants, those with first-line family members who had DM had a higher tendency of developing GDM. Same way, those obese women had more tendency of developing GDM than their counterparts.

4.4.2.2.1.1 Subcategory 1: Age of the mother

According to the participants, age of the mother is one risk factor that contributes to the incident of GDM. Participants indicated their opinions as follows:

"Women who are above 35 years old have a greater chance of developing GDM." (A48FG)

"In my opinion; the older women get, the more likely they develop GDM." (A31FMW)

“The older the age of the pregnant woman, the higher risk that she develops GDM.” (A49MG).

4.4.2.2.1.2 Subcategory 2: Family history of DM

As reflected by the participants, those with first-line family members (like father, mother, sister and brother) who have DM have a higher tendency of developing GDM than their equivalents. Regarding family history of DM, the following views were highlighted.

“To my understanding it is not only getting older, but also women with family history of DM had more chance of developing GDM than their counterparts.” (A26MMW)

“With my experience I can say family history of DM is one of the commonest risks factors for GDM as well for DM.” (A53MG)

“Family history of DM, highly contributes towards having GDM.” (A43FMW)

This was specifically noted by one of the HPs, who indicated that,

“Family history of DM is a common risk factor for GDM, what we call first generation or first line family members that means sister, brother, father and mother, if they have DM the risk of developing GDM will be higher.” (A42MG)

4.4.2.2.1.3 Subcategory 3: Multiple gestation

Multiple gestations were one of the risks factors mentioned by the HPs who participated in this study as verbalized by their opinion as follows: -

“The risk factors for GDM are many like obesity, previous history of GDM, multiple gestation history of having a macrosomic baby, age, ethnicity, family history of DM, are the commonest.” (A53MG)

“The most common risk factors are family history of DM, age (>35), obesity, previous history of GDM and multiple gestation.” (A48FG)

4.4.2.2.1.4 Subcategory 4: Obesity

According to the participants, risk factors for GDM includes being obese or having a body mass index (BMI) of 30kg/m^2. Participants verbalized their opinion on obesity as follows,

> *"Being obese or overweight (BMI of 30kg\m^2) leads pregnant women to develop GDM." (A31MMW)*

> *"Another risk factor for GDM is obesity." (A47FMW)*

> *"Obesity or it is better if I say excessive weight gain sometimes you can make a clinical judgment about the weight gain of your client highly contributes for the development of GDM." (A37MG)*

4.4.2.2.1.5 Subcategory 5: Previous history of GDM

Participants indicated that having a previous history of GDM is one common risk factor that contributes to having GDM in later pregnancies. This statement was verified in the responses of HPs as follows: -

> *"Even though there are many factors that contribute to the development of GDM, the previous history of GDM significantly contributes to having GDM." (A40FMW)*

> *"Another common risk factor is previous history of GDM; it is obvious that women with the history of previous GDM will develop GDM in the following pregnancies." (A56MG)*

> *"Previous history of GDM, older age…are the common risk factors for GDM." (A37MG)*

> *"It is almost certain that if you have a history of GDM you will definitely develop GDM in the next pregnancies." (A31MMW)*

4.4.2.2.1.6 Subcategory 6: Previous history of a macrosomic baby

The other risk factor that was mentioned as a risk factor for the development of GDM was previous history of having a macrosomic baby, as described below: -

> *"……previous history of having a macrosomic baby is another risk factor for the development of GDM. Most importantly HPs should be curious in assessing risk factors since GDM have no symptoms." (A48FG)*

> *"A woman who has a history of a big baby or a baby who weighed more than 4.5kgs during delivery is at higher risk for having GDM in her next pregnancies." (A31FMW)*

4.4.2.2.7 Subcategory 7: Ethnicity

Ethnicity was one of the risk factors mentioned by the participants. One of the participants verbalized his opinion as follows,

> *"Though it is not common in our country ethnicity/race are the common risk factors for GDM." (A37MG)*

The above-mentioned views of HPs regarding risk factors of GDM reflected that GDM is common among pregnant women with family history of DM, older age, obese and multiple gestations. Moreover, in pregnant women with a previous history of GDM, their tendency of having GDM is higher. As observed from the reflections of the participants above, several issues were directly or indirectly linked with the development of GDM. Ofthe commonly perceived factors to have a role in the occurrence of GDM; family history of DM was one of it. Moreover, getting older is another factor playing a role in having GDM. The older the women, the higher risk the women have to have GDM. Likewise, multiple gestations were also mentioned to be a factor that plays a pivotal role in the development of GDM.

4.4.2.3 Theme 3: Management of GDM

4.4.2.3.1 Category 1: Monitoring of GDM

The HPs indicated the importance of timely and appropriate screening and management of GDM for the wellbeing of the mother as well for the infant. Some participants stated the following about management of GDM and its adverse maternal outcomes: -

4.4.2.3.1.1 Subcategory 1: Screening and diagnosis of GDM

Concerning whether or when and how every woman has undergone screening for GDM, reflections of participants presented as follows. A participant explained the screening approach for GDM as stated below,

> *"Well, what we normally do is we check for fasting blood sugar level between 24-28wks of gestational age and if the fasting plasma level is ≥ 110mg/dl we say that the pregnant women have GDM and act accordingly" (A53MG)*

Another participant described the above-mentioned screening approach with a different testing procedure:

> *"I normal send all pregnant women for oral glucose tolerance test (OGTT) test between 24-28wks then if in case there is a pregnant woman who comes after this week, I will send her for RBS test and if the value is >140mg/dl, I will send her for OGTT test the next morning" (A48FG)*

In addition, another participant stated that OGTT is the standard laboratory test for GDM, and described this as follows,

> *"…recently we started testing all pregnant women for RBS at their first ANC visits, and at this time if the RBS value is >140mg/dl we appoint the pregnant women to come the next morning without consuming any food or drinks and we will perform the OGTT test as this is the recommended diagnostic test; and if the value of RBS is <140mg/dl we will do the OGTT test between 24-28wks of gestation." (A37MG)*

This was further explained by other participants as follows: -

"There are some routines we usually do for pregnant women at their first ANC visit, therefore, during this time we send the woman for RBS and if it is in the normal range we wait until the woman reaches between 24-28wks of gestational age and perform OGTT." (A47FMW)

"All pregnant women at their first ANC visit will be sent to the laboratory for RBS test, and if this turns to be >140mg/dl we send the women for anothertest (OGTT or HgA1C) to rule out whether it is a pre-existing diabetes or not, ifthe results are not suggestive of pre-existing diabetes we wait until 24wks of gestational age and perform OGTT test between 24-28wks. …We use these cut-off points for the OGTT test, FBS 90-120mg/dl, after 1hr 180mg/dl and after 2hr if it is greater or equal to 150mg/dl." (A42MG)

Though there were some inconsistencies in the screening procedure, the recommended protocol stated that every pregnant woman could be screened for GDM in a period of 24-28 weeks of gestation using OGTT which was also supported by their practice. Even more, there were variations in the diagnostic technique of GDM by health professionals. As stated above with views of the participants, some used RBS, whereas others use FBS, or HgbAIC, or OGTT as a screening and diagnostic modality. And hence the cut-off points regarding women having GDM varies with variations in gynaecologists/obstetricians.

4.4.2.3.1.2 Subcategory 2: Management of GDM

According to the views of HPs, the management of GDM depends on the level of blood glucose level, all in all they have mentioned that they use exercise, medication or education on diet as a management protocol for GDM. The participants verbalized their opinion on the above-mentioned concepts as follows: -

"Well the simple way of managing GDM is controlling her blood sugar level either by medications or by modifying her lifestyle like diet and exercise." (A39FMW)

"Women with GDM should be advised about the importance of doing simple

exercise and controlling her sugar by regularly checking her blood sugar level and controlling her diet." (A48FG)

"In the management of GDM exercise plays a great role hence women with GDM should be advised in doing simple exercise." (A42FMW)

"Lifestyle modifications like controlling diet and avoiding sedentary lifestyle as much as possible is mandatory in the management of GDM, but this is not always enough there will be time that the woman needs to take medications to control her blood sugar level." (A31FMW)

"The management of GDM differs depending on the level of blood sugar what I am saying is for instance if fasting blood glucose level is greater than 90mg/dl we have to start medication treatment (insulin treatment) and advise her on diet and exercise, but if the blood glucose level is less than 90mg/dl we give advice about diet and exercise and appoint her for follow up after 2weeks." (A37MG)

Per the reflections of participants as stated above, the role of doing physical exercise, diet and sugar level control on GDM management were emphasized. Pregnant women with GDM were encouraged by the HPs to do physical exercise, to have control over their blood glucose level, diet management and to adhere to prescribed medicationsthat promote their health.

4.4.2.3.2 Category 2: Prevention of GDM

4.4.2.3.2.1 Subcategory 1: Preventive mechanisms

All the HPs agreed on the fact that awareness creation or providing health education is the key for prevention of development of GDM as well to prevent its adverse maternal outcomes. They also added lifestyle modification and early detection are essential for prevention of GDM and its adverse maternal outcomes. This was explicitly noted by one of the participants, who indicated that,

"Creating awareness or providing health education is essential for preventing

GDM as well for prevention of its complications and we should advise not only pregnant women but also all people about lifestyle modifications like healthy eating habits, having regular exercise, adequate sleep and also about avoiding smoking, drinking alcohols and avoiding stress as much as possible." (A42MG)

This was further explained by other two participants as follows: -

"We all know that prevention is better than cure. That is why I think we should work on prevention mechanisms for all diseases. In doing so, health education is the best tool for prevention of GDM and its complications for both the mother and the foetus. As a result, in the process of providing health education we must make sure that we advise about lifestyle modifications." (A26 MMW)

"Health education is the best cost-effective strategy for prevention of any disease and in case of GDM and its adverse outcomes, it plays a crucial role in hindering negative outcomes of GDM and in promoting the health of the mother as well as the foetus." (A56MG)

Participants had a strong understanding that health education is a key tool for the prevention of GDM. On the focus to fight against development of GDM, creating awareness plays a pivotal role for the promotion of health during pregnancy.

4.4.2.4 Theme 4: Adverse maternal outcomes

The HPs that participated in this study explained that if GDM is not early detected and managed properly it has some adverse health outcomes for both the mother and the foetus. Some of the adverse outcomes of GDM as stated by HPs were pre-term labour as well as preterm delivery, unexplained fetal death, hypertension, big baby and this will lead to shoulder dystocia, hypertension (HTN), polyhydramnios and an increased rate of CS. They also added that GDM is not a fatal condition, but it can indirectly contribute to the death of the mother as well for the foetus. This was explained asfollows: -

4.4.2.4.1 Subcategory 1- Pre-term labour and delivery

The results of this study indicate that preterm labour as well delivery is one of the adverse maternal outcomes related to GDM.

> *"It is very common that pregnant women with GDM have an increased rate of preterm delivery and preterm labour." (A37MG)*

> *"From my experience, most pregnant women with GDM go through preterm labour and delivery, so you must make sure that you have advised the women about this." (A28FMW)*

4.4.2.4.2. Subcategory 2 – Hypertension

Participants mentioned that hypertension is one of the common adverse maternal outcomes related with GDM. This was noted by participants as follows,

> *"As much as we are concerned in managing and controlling blood sugar level in pregnant women with GDM, we must also be concerned with the measurements of her blood pressure as GDM increases the chance ofhaving hypertension, and this will complicate the pregnancy if we fail to manage it." (A39FMW)*

> *"GDM increases the chance of developing HTN; HTN is one of the common causes of maternal death in our country." (A42MG)*

4.4.2.4.3. Subcategory 3 – Polyhydramnios

The participants reported that polyhydramnios was one of the adverse maternal outcomes related with GDM. Regarding polyhydramnios, the following was verbalized by the participants,

> *"Another maternal morbidity that is caused by GDM is polyhydramnios, and this will lead us to terminate the pregnancy early and possibly the women will go for CS, for your surprise most of the adverse maternal outcomes of GDM are interrelated." (A42MG)*

"There are many adverse maternal outcomes that are related to GDM like polyhydramnios." (A31FMW)

4.4.2.4.4. Subcategory 4 – Increased rate of CS

The findings of this study revealed that the probability of delivering through CS is higher in women with GDM than women without GDM. This was explained by the participants as follows,

"If you have GDM, you will have a big baby, you will develop HTN, and you will probably have preterm labour. As a result, one of these conditions willincrease the chance of delivering through CS." (A49MG)

"It doesn't mean that all women with GDM will go through CS but women with GDM will have many reasons to go through this mode of delivery." (A38FMW)

4.4.2.4.5. Subcategory 5 – Maternal death

Participants indicated their opinion regarding maternal death related to GDM as follows,

"GDM is not a fatal condition but it indirectly contribute for the death of a mother in different ways for instance, a women can die out of an infection of wound that was caused by performing CS because GDM makes wound healing process slow, and the reason why the women went for CS is because she had GDM or simply she can die out of not properly managed HTN and we say she died because of HTN but what we don't usually give focus is for the fact that the cause of HTN might be improperly managed GDM." (A37MG)

"I don't think that GDM can cause the death of a mother but for sure I can say it indirectly contributes to the death of the mother. For instance, GDM increases the chance of HTN and hence HTN might kill the mother." (A43FMW)

"Most of HPs including myself don't worry that much about GDM because it will go away after the delivery of the baby, but what we have to be curious is about screening as well its management because if we fail to detect it as soon as possible we can lose the baby at 36wks of gestation or more and this is

very painful both for the mother and also for the HP this is one of the complication of GDM and we call this unexplained fetal death." (A42MG).

4.4.2.5 Theme 5: Barriers for management of GDM

4.4.2.5.1 Category 1: Barriers for screening of GDM

The HPs who participated in this research study have explained that barriers for screening GDM could come from within and outside of the healthcare system.

4.4.2.5.1.1 Subcategory 1: Cultural practices

Participants indicated that cultural practices are one of the common barriers they face in the screening of GDM. It was mentioned by the participants that there is a cultural practice in the community concerning going to a health facility for check-up of pregnancy. Some people suppose that a pregnant woman must go to a health facility after she reaches 4 months. This was explained by participants as follows,

> *"A pregnant woman usually comes for ANC after 4 months because this is something related with culture and this might affect the timely screening process of GDM." (A35FMW)*

> *"There are some cultural practices in our country that hinders on time visit of ANC, that means women have to at least be four or more months pregnant (that is according to their counting) to seek ANC visit and as a result on time screening for GDM will be missed." (A48FG)*

4.4.2.5.1.2. Subcategory 2: Late ANC visits

Late ANC visits were indicated by participants as one of the barriers in the screening pregnant women with GDM. Participant said the following related to this,

> *"Barriers for screening of GDM could come from within and outside of the health system: one of them is late visit to ANC clinics." (A48FG)*

> *"I don't know why but most pregnant women start their ANC service very late*

and this makes it very difficult for us to timely screen GDM." (A47FMW)

4.4.2.5.1.3 Subcategory 3: Cost of diagnostic tests

Participants point out that they failed to screen and diagnose women with GDM due to the cost of diagnostic tests. One of the participants said the following,

> *"Since the flow of pregnant women is very high in this hospital there is a shortage of different equipment and we are forced to send out pregnantwomen to another diagnostic clinic for different diagnostic tests especially when it comes to GDM most of the diagnostic tests are very expensive andthis one of the biggest challenges I face." (A56MG)*

This was specifically noted by another participant as follows,

> *"From time to time the cost of diagnostic tests are alarmingly increasing and as this is a government hospital, most of the women who come here have low economic status and they cannot afford the cost, and this is a challenge." (A36FMW)*

4.4.2.5.1.4 Subcategory 4: Poor access to health-related information

Participants verbalized that pregnant women have poor access to health-related information and that this hinders the screening of GDM. Participants verbalized their views as follows,

> *"Still there are many people with poor access to health-related information and this is like a big barrier in the screening process of GDM as GDM screening requires different diagnostic tests. As a result, when you send a pregnant woman for different tests, she perceives it as if we are doing this forour own good" (A40FMW)*

> *"Pregnant women have poor access for health-related information, and this is a challenge." (A48FG)*

As alluded by HPs who participated in this study, barriers for screening of GDM are: cultural practices, late visit to ANC clinics, cost of diagnostic tests and poor access to

health-related information.

4.4.2.5.2 Category 2: Barriers for treatment of GDM

Regarding barriers for treatment of GDM, HPs mentioned that the biggest challenge they are currently facing is the cost of medication as it is becoming expensive, adding to these attitudes of pregnant women towards medication and also lack of contextualized guidelines were some of the barriers.

4.4.2.5.2.1 Subcategory 1: Cost of medication

Participants mentioned that the cost of medication was a challenge in the treatment of women with GDM. This was explained by one of the participants as follows,

> *"The continuously increasing cost of medication is one of the biggest challenges we are facing nowadays in the treatment of GDM." (A31FMW)*

4.4.2.5.2.2 Subcategory 2: Attitudes of pregnant women towards medication

Attitudes of pregnant women towards medication were one of the barriers which were mentioned by the participants. The following points were highlighted by the participants,

> *"Pregnant women have very strange feelings about taking medications during pregnancy… From my experience, if you order a medication for them,they would prefer to stay at their home and never come back for an ANC visit …. I do not know why but that is the case, this is one of the challenges I face in treating GDM cases." (A53MG)*

> *"It is really hard to convince most pregnant women to take medication as you can sense their fear that the medication can harm their foetus, and this is a challenge for us." (A39FMW)*

> *"From my experience the only way I can convince a pregnant woman about taking medication is, if she had a history of fetal loss, I will use this as a weapon and explain the consequence of not taking medication can cost her the life of her foetus." (A49MG)*

4.4.2.5.2.3 Subcategory 3: Lack of contextualized guideline

Regarding lack of contextualized guidelines to manage GDM, the participants reported that there was no contextualized guideline. They also indicated that they managewomen with GDM based on what they had been educated in school and by referring clinical books when necessary. This was verbalized by the participants as follows,

> *"There is no contextualized guideline regarding GDM." (A31FMW)*
>
> *"We are treating pregnant women with what we learned in the school, there is no guideline regarding GDM." (A26MMW)*
>
> *"Expense of medications and lack of contextualized guidelines are the barriers I am facing in treating women with GDM." (A37MG)*

In general, it was pointed out by the HPs that the above-mentioned barriers should have some solutions as these have an overriding influence on delivering a full package of health care in general and specifically in the prevention and treatment of GDM and its related adverse maternal outcomes.

4.4 DISCUSSION OF THE RESEARCH FINDINGS

This section discusses the researcher's interpretation of the study results as supported or contrasted with relevant literature.

4.4.1 Magnitude of GDM

This research study assessed the magnitude of GDM, and it found that the prevalence of GDM is 2.2%, this was also supported with the views of HPs who participated in this study as they emphasized the prevalence of GDM can range from 1% to 3%. However, prior research done in Ethiopia indicate the prevalence of GDM to be higher than 3%, a recent study done in Gondar town indicated the prevalence of GDM to be 12.8%, (Muche, Olayeni & Gete 2019a:73), another research done in Wolayita zone (southern part of Ethiopia) in the year 2017 estimated the prevalence of GDM to be 4.2%,(Woticha, Deressa & Reja 2019: 86-91). This difference might be attributed to differencein study design, as the latter used cross-sectional study design and due thedifference in

study year. Moreover, this study used secondary data as the others used primary data.

In addition, several studies done in different parts of the world states that the magnitude of GDM may range from 1% to 14% of all pregnancies depending on genetic characteristics and environment of the population under study, screening and diagnostic methods employed as well as on prevalence of type 2 DM (Jang 2011:1-7).

4.4.2 Risk factors for GDM

According to the views of the HPs who participated in this study, there are many factors that can contribute to the development of GDM, of these age (>35), family history of DM, multiple gestation, obesity (BMI equal to and greater than 30), previous history of GDM, previous history of having a macrosomic baby and ethnicity were some of the factors which were mentioned by the participants.

4.4.2.1 Age

As per the findings of this study, age of mothers was statistically associated with GDM (x^2=30.92, df=4, p≤0.000) this was also supported with some of the feedback of HPs from the in-depth interviews within this study.

The findings of the study were supported by another study done in Pacific Island nation of Palau, which revealed that women who were 30 years and older, have a higher risk of developing GDM than younger women (Sugiyama et al. 2017:1963). However, a study done in Gondar town in Ethiopia revealed that age was not statistically associated with GDM (Muche, Olayeni & Getea 2019a:73).

4.4.2.2 Obesity

Though the quantitative part of the study failed to show an association, the results from in-depth interviews had revealed that obesity influences the development of GDM. Obesity has remained to be consistently mentioned as a risk factor for GDM in many studies and as well a review of different literature supports that there is an interconnection between obesity and GDM. The study finding was consistent with a study done in United Kingdom by Wilmot and Mansell (2014:678), which stated that riskfactor that contributes for GDM include body mass index (BMI) above 30kg/m2 or being obese.

4.4.2.3 Family history of DM

Family history of DM was statistically associated with GDM (X^2=1.631, df=1, P≤0.001), in this study, this was also supported by the results of the in-depth interview. Moreover, this result was supported by a research done in different parts of India stating that having a mother only or both parents with diabetes were significant independent risk factors for GDM (Kragelund et al, 2016:6-8: & Pu et al. 2015:439).

4.4.2.4 Previous gestational diabetes

Qualitative results of this study had revealed that women who had a previous history of GDM are more prone to develop GDM in the following pregnancies. In line with this study, different studies stated that having a previous history of GDM (p=0.01), was significantly associated with GDM (Wilmot & Mansell 2014:678).

4.4.2.5 Previous history of macrosomic baby weighing 4.5kg or above

The HPs who participated in this study had mentioned that having a previous history of macrosomic babies or baby is a risk factor for GDM. This was also mentioned by Wilmot and Mansell (2014:678) as a significantly associated factor with GDM.

4.4.3 Management of GDM

4.4.3.1 Monitoring of GDM (Screening and diagnosis)

This study revealed that there are some differences in GDM screening and diagnostic approaches between the gynaecologists/obstetricians who had participated in this study. Interviews with HPs revealed that there are some differences in GDM screening approaches which include different time of GDM testing, different testing procedures, and different diagnostic criteria.

However, the recommended screening for GDM should be done on the risk factor evaluation within 24-28 weeks using the OGTT test (Kayal, Mohan, Malanda, et al. 2016:707).

4.4.3.2 Prevention of GDM

All the HPs agreed on the fact that awareness creation or providing health education is the key for prevention of development of GDM as well to prevent its adverse maternal outcomes. They also added lifestyle modification and early detection as an essential prevention strategy of GDM as well its adverse maternal outcomes.

The above opinion was supported by meta-analysis done in China which depicted that there were statistically significant strategies in dropping the odds of maternal and infant adverse outcomes (Xu et al. 2017:4-6). Dietary, western medication and combined interventions were among the most successful interventions in prevention of GDM related maternal and infant complication (Xu et al. 2017:4-6). Moreover, raising the awareness of GDM in pregnant women is an important tool for the prevention of type 2 DM (Price, Lock, Archer, & Ahmed 2017:49).

Though, all of the HPs who participated in this study agree that health education plays a pivotal tool for prevention of GDM as well its adverse maternal outcomes the quantitative part of the study revealed that much has to be done regarding provision of health education as it have showed that out of the 2000 medical records reviewed therewere only 2% who have had received health education regarding disease prevention.

4.4.4 Adverse maternal outcomes related with GDM

The current study tried to assess adverse maternal outcomes of GDM, and it found out that some of the adverse outcomes of GDM as stated by HPs were pre-term labour as well as preterm delivery, unexplained fetal death, big baby and this will lead to shoulder dystocia, hypertension (HTN) and also increased rate of CS. They also added that GDM is not a fatal condition, but it can indirectly contribute for the death of the mother as well for the foetus.

The findings from this study were in line with a study done in India which stated that GDM, can cause termination of pregnancy by CS, increased neonatal birth weight, inborn nursery (IBN) admissions and long term progression to type 2 DM (Sreelakshmi et al. 2015:396 & 397). Another study has also added that women with GDM will have a

higher risk of having a large-for-gestational-age as well infant birth weight greater than 90th percentile for gestational age (95%CI: 2.44-3.98, AOR 3.12), caesarean delivery (95%CI: 1.15-1.81, AOR 1.44), and polyhydramnios (95%CI: 3.94-12.08, AOR 6.90) (Meek, Lewis, Patient, Murphy, & Simmons 2015:2007).

4.4.5 Barriers for management of GDM

This study has also depicted barriers for screening and treating of GDM to be cultural practices, cost of diagnostic tests, late visit to ANC clinics, cost of medications, attitude of pregnant women towards medication, lack of contextualized guidelines and poor access to health-related information.

In support to these findings, a qualitative study done in southern part of Ethiopiarevealed that barriers for screening and management of GDM were: lack of standard guidelines and protocols, lack of awareness among mid-level health care providers on GDM, inadequate trained health care providers, shortage of supplies plus equipment aswell as late ANC visits. Moreover, this study has also recommended that policy makers should avail standard guidelines and protocols (Woticha, Deressa & Reja 2019).

However, Nielsen, Courten and Kapur (2012:12-33), point out health system barriers for GDM management as follows; lack of trained health care providers, high staff turnovers, lack of standard protocols, consumables and equipment; financing of health services and treatment; poor referral systems, lack of feedback mechanisms as well follow-up systems and distance to health facility. The author also added barriers that hinder screening and treatment of GDM, could come from practices related to pregnant women's diet; societal negligence of women's health; lack of decision-making power among women regarding their own health; stigmatization; role of women in society and expectations that the pregnant woman move to her maternal home for delivery were identified.

4.5 OVERVIEW OF RESEARCH FINDINGS

4.5.1 Summary of quantitative study findings

A description of major findings as evidenced with descriptive statistics comprising of age of participants, basic obstetric characteristics, and previous and current obstetric characteristics and past medical history were presented. Family history of DM and urine analysis results were addressed including health education that was provided to pregnant women. Magnitude of GDM as well as factors associated with GDM was identified. Even though the prevalence of GDM varies from year to year, theoverall magnitude of GDM was found to be 2.2%. Age and family history of DM were found to be statistically associated with GDM (X^2=30.92, df=4, P≤0.000, (X^2=1.631, df=1, P≤0.001 respectively).

4.5.2 Summary of qualitative research findings

The experience of HPs towards monitoring and preventing GDM related maternal outcomes were also assessed and it was found that most HPs contemplate that the magnitude of GDM to be between 1% and 3% which is almost similar with the finding of the quantitative part of the study. They have also mentioned that age (>35), family history of DM, multiple gestation, obesity (BMI equal to and greater than 30), previous history of GDM, previous history of having a macrosomic baby were some of the common risk factors that influence the development of GDM.

Apart from this, the current study tried to explore HPs experience towards screening, management and prevention approaches of GDM and adverse maternal outcomes related to GDM and barriers for management of GDM. It has revealed that thereare some differences in screening and diagnostic techniques. It has also outlined that lifestyle modification (physical exercise, diet management) and medication are utilized for managing women with GDM.

All the HPs had agreed that creating awareness is the best tool for preventing GDM as well its adverse maternal outcomes. Regarding adverse maternal outcomes related to GDM, this study points out that GDM does not directly contribute to maternal death, however, it can cause different maternal morbidities like HTN, polyhydramnios, preterm labour and delivery and increased rate of CS. Moreover, barriers for management of GDM were explored in this research study and it has showed that cultural practices, late visit to ANC clinics, cost of diagnostic tests and medications, attitudes of pregnant women towards medications, poor access to health-related information and lack of guidelines were some of the barriers for the management of GDM.

4.6 CONCLUSION

This chapter presented the findings of the research and discussion on magnitude of GDM, associated factors, the experience of gynaecologists/obstetricians and midwives towards monitoring and prevention of adverse maternal outcomes related to GDM. Barriers for the management of GDM were addressed. Discussions for the results were also made by contrasting with the results of similar literature.

Based on the results from this study, a monitoring and prevention guideline of adverse maternal outcomes related with GDM will be developed and discussed in the next chapter.

CHAPTER 5

BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED WITH GDM

5.1 INTRODUCTION

> *A guideline within a patient care context is a document that focuses on how an individual patient should be treated and draws up on evidence concerning the effectiveness, risks and costs of specific interventions, (Party 2012:12).*

This chapter deals with presenting the process developing guidelines to monitor and prevent maternal morbidity and mortality related to GDM and validation process. GDM monitoring and prevention is a multi-layered activity that needs prompt action of every individual and engagement of stakeholders in their perspective task. These guidelines are developed using the findings of the current study, expertise opinion, researcher insights and as well aspects of relevant reviewed literature.

5.2 BACKGROUND AND PRINCIPLES OF THE GUIDELINE DEVELOPMENT

Guideline within a patient care context is a document that aims on how an individual patient should be treated and draws up on evidence concerning the effectiveness, risks and costs of specific interventions (Party 2012:12). A guideline also provides information to the user on how the user can perform tasks in particular circumstances toattain the best health outcomes possible both individually and collectively.

WHO handbook for development of guideline (WHO 2012), listed the following principles for process of guideline development:

- Guidelines replicate the core WHO value of the “right to health”,
- Guidelines focus on a situation of ambiguity and an unfulfilled prerequisite for direction,
- The method of developing recommendations is explicit and transparent,
- The procedures and means employed in every stage of guideline development focuses on minimizing the risk of prejudice in the suggestions,

- Suggestions can be executed in and improved to the local situations and environments and
- Guidelines must be personalized to a certain target.

Therefore, the current guidelines target all the direct recipients, policy makers and community by enduring the above-mentioned guideline development principles.

5.3. THEORETICAL MODEL OF THE STUDY

The proposed guideline was developed based on concepts in Betty Neuman's System Model (NSM). The NSM was based on the client system which considers the following contexts and situations: -

- Individual, family or public;
- The physiological, psychological, spiritual, developmental and sociocultural influences; which are referred to as interacting variables of the client system;
- Client 's reaction to definite or possible environmental stressors (internal, external and created environments), the reaction to it, and modifying factors that are dynamic in nature;
- Focus on prevention, as intervention for withholding, achievement, and preservation of optimum client system wellness.

As a result, the role of HPs is to maintain the client system's stability by utilizing the 3 levels of prevention. Furthermore, NSM guides a structure for the development of complete screening and diagnostic technique, determination of suitable interventions and assessment of end results. Thus, the NSM model focuses on disease prevention which comprises of three levels of disease prevention as mentioned above. Theselevels of disease prevention were applied in this guideline as a preventive measure for GDM related maternal morbidity and mortality. The variation from wellness and how to monitor and prevent GDM related adverse maternal outcomes is the fundamental focus of these guidelines.

5.4. PURPOSE AND OBJECTIVES OF DEVELOPING GUIDELINES

5.4.1 Purpose

The drive of developing these guidelines is to lessen the adverse maternal outcomes of GDM and its late consequences among women in a custom-made fashion of providing adequate indications, creating consciousness and suggesting actions to be undertaken by different levels of the health care system.

5.4.2 Objectives

The overall objectives of these guidelines are as follows: -

- To provide information on pertinent risk factors of GDM and its magnitude to the target beneficiaries,
- To facilitate timely identification, diagnosis and treatment of GDM,
- To improve the implementation of GDM related adverse maternal outcomes prevention mechanisms by health care providers,
- To create community awareness for GDM prevention,
- To help policy makers and other concerned shareholders to interfere in eliminating impediments of screening, diagnosis and management strategies as well in prevention of GDM and its related adverse maternal outcomes.

5.5 SCOPE OF THE GUIDELINES

The scope of a guideline is recognized based on the range of preparation that the guideline works, the significant areas that the recommendations are planned to touch, benefits and harms that may affect, all in all scoping of guideline focuses on what the guideline will incorporate and will not incorporate (WHO 2014).

As a result, the scope of the guideline development began with registering of possible matters cantered on study findings in a way that covers issues in the monitoring and prevention of GDM related adverse maternal outcomes. In general, the main purposes of these guidelines are to provide a solution-oriented method towards early monitoring and management GDM and its related adverse maternal outcomes.

5.6 GUIDELINES DEVELOPMENT PROCEDURE

The researcher used the following procedures while developing the guidelines:

- Defined the objective and extent of the guidelines,
- Evaluated the results of the current research,
- Reviewed relevant literatures,
- Developed the first draft of the guidelines and sent it for experts (gynaecologist/obstetrician, midwife and researcher),
- Reviewed and incorporated experts' comments and suggestions,
- Sent to expert evaluators to validate the guidelines,
- Revised the guidelines.

5.7 APPLICATION OF THE "SURVEY LISTS" FOR GUIDELINE DEVELOPMENT

WHO (2014), suggests that before opting to develop guidelines specific questions like "Is there already a guideline which focuses on the topic of interest?", "Are the guidelines developing based on the suggestions of WHO?", "Who are the targets of the guideline?" should be raised. Accordingly, Dickoff survey list in Dickoff, James and Wiedenbach (1968) provided answers for the questions, and as a result it was used for the development of the guideline as follows:

Purpose or terminus

Collins English Dictionary (2014) defines purpose as the rationale for which everything is performed, established or exists; it is also the ending of an act or attempt.

The purpose of this guideline is to monitor and prevent adverse maternal outcomes related to GDM by introducing appropriate and effective preventive measures.

Procedure

A set of rules that directs actions on a valid and recognized method is called procedure, (Dickoff et al. 1968). It is also a means of continuing, a way of executing or altering something in an organized manner (American Heritage Dictionary of English 2016).

As a result, this research's procedures were the actions stated in directing the target audience about what to perform to inhibit adverse maternal outcomes related with GDM.

Agent or target audience

Agent or target audience is a person, who possesses information, power and skill to carry out classified actions (WHO 2012). Moreover, agent is a being or phenomenon that has an authorization or power to act (Collins English Dictionary 2014).

GDM related adverse maternal outcomes prevention entails a process of continuous instruction and actions to be performed, beginning from high ranking authority to individual level. Therefore, the agent or target audience for this research implies to policy makers, health professionals and health care managers.

Dynamics

Dickoff et al. (1968), mentioned dynamics as power suppliers of the actions within a person or the core activating reasons for achievement. It also describes the community, rational or ethical forces that generate action (American Heritage Dictionary of English 2016).

Consequently, the dynamics in the current guideline are those factors that facilitate the prevention of adverse maternal outcomes related to GDM. This includes providing all the necessary resources and the benefit of applying preventive measures.

Recipient

A person or group of people who benefits from specific suggestions and carries out actions proposed by the provider (Dickoff et al. 1968). The recipients for this study were pregnant women as well as their families and the society.

Framework or context

American Heritage Dictionary of English (2016), defines framework as a perspective in which an incident or situation happens. Therefore, the overall health care system of the country is the framework or context of this guideline development.

5.8 GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED WITH GDM

5.8.1 Guidelines for primary prevention

Rayner & Mendis (2017:6) described primary prevention as any form of activities that applies before the onset of a disease and is aimed at preventing it from occurring. As described in the result part of the study, health education provided about disease prevention was very low; out of the 2000 medical records reviewed it was found that only 2% of the mothers had been provided with health education regarding disease prevention. However, all the HPs agree with the fact that providing health educationis essential for prevention of GDM and its adverse maternal outcomes.

5.8.2 Guidelines for secondary prevention

Secondary prevention is a form of prevention which occurs before the onset of disease with individuals at risk of developing a given disease with the aims of detecting those individuals as early as possible (Rayner & Mendis 2017:6). Therefore, the aims of secondary prevention are to reduce the impact of GDM as early as possible and it is done through early detection and prompt care, with the intention to halt, slow or reverse disease progression, by fostering personal measures to prevent deterioration or recurrence and by taking measures to restore people's original health and function whilecontinuing preventing new ones. Pregnant women with GDM need to have sound management of their situations.

5.8.3 Tertiary prevention

According to Rayner & Mendis (2017: 6), tertiary prevention applies when the person already has disease and aims to prevent or limit the condition from worsening, to slow down its progression or to prevent complications. Pregnant women with GDM require continuous and prompt follow-up for reducing GDM related adverse maternal outcomes.

5.9 SUMMARY OF GUIDELINES TO PREVENT ADVERSE MATERNAL OUTCOMES RELATED TO GDM.

TABLE 5.1 GUIDELINES TO PREVENT ADVERSE MATERNAL OUTCOMES RELATED TO GDM BASED ON NSM

Guidelines	Findings of current study
Guideline 1: Primary prevention For pregnant women free of GDM and its adverse maternal outcomes: • *Lifestyle modifications- regular exercise before and during pregnancy, healthy eating habits, controlling weight and weight gain and regular monitoring of blood glucose level.* • *Targeted health education to all women and especially pregnant women are encouraged.* • *Comprehensive assessments of risk factors could be done*	• Only 2% of mothers were provided information regarding disease prevention • Pregnant women with history of previous GDM, family history of DM, obese andgreater than 35 years old have a risk of developing GDM
Guideline 2: Secondary prevention For pregnant women with GDM who tend todevelop some morbidities related with GDM • *Comprehensive management (like blood glucose, blood pressure and urine protein monitoring, taking medications, reducing risks and healthy eating) of GDM as well early detection and prompt care of itsrelated morbidities should be offered.*	• If GDM is not early detected and managed properly it causes adverse health outcomes for both the mother as well as the foetus. • Few of the adverse outcomes of GDM arepre-term labour as well as preterm delivery, unexplained fetal death, hypertension, big baby (shoulder dystocia), hypertension (HTN) and increased rate of CS.
Guideline 3: Tertiary prevention For pregnant women with GDM with maternal adverse outcomes related with GDM • *Continuous and timely follow up is mandatory. At every ANC visits and as necessary pregnant mothers with GDM should be checked for blood glucose level, blood pressure and urine protein level and should be appointed for regular and consistent follow-up.*	• GDM is not a fatal condition but it can indirectly contribute to the death of themother as well the foetus.

5.10 GUIDELINES, SUMMARY OF EVIDENCE AND RECOMMENDATIONS FOR IMPLEMENTATION

TABLE 5.2 GUIDELINES, SUMMARY OF EVIDENCE AND RECOMMENDATIONS FOR IMPLEMENTATION

Guidelines	Summary of evidence	Recommendations for Implementation
Guideline 1: Primary prevention	• Health education is the best tool for prevention of GDM and itsadverse outcomes for both the mother as well the foetus • Barriers for screening of GDM could come from within andoutside of the health system: some of theseare late visits to ANC clinics. • Raising the awareness of pregnant women about GDM in is an important tool for the prevention of type 2 DM (Price, Lock, Archer, & Ahmed, 2017:49). • Dietary, western medication and combined interventions were among the most efficient interventions in prevention of GDM related maternal and infant complications (Xu et al., 2017:4-6)	In order to prevent GDM and its related adverse maternal outcomes the following activities were recommended as primary level preventive mechanisms: - • Health education regarding GDM should be given to pregnant women • Teaching regarding lifestyle modifications has to be given to all pregnant women (like eating habits, regular exercise, controlling body weight….) • Disseminate targeted messages for women having a risk factor for GDM (like family history of DM...) to visit medical facilities for regular check-ups. • Perform community mobilizations to create alertness about GDM and its adverse maternal outcomes. • The perception regarding health care seeking behaviour of the society must be amended.
Guideline 2: Secondary	• The management of GDM differs depending on the level	To prevent GDM and its related adverse maternal outcomes the following activities are recommended as

prevention	of blood sugar • Women with GDM should be advised about the importanceof doing simple exercise and controlling blood sugar level and diet • GDM is one of the top medical situations during pregnancy and assumed to increase risks of numerous adverse pregnancy outcomes like hypertension, pre-eclampsia, increased CS rate, infection and polyhydramnios (Hod, 2015).	secondary level preventive mechanisms: - • All pregnant women need to be screened for GDM between 24wks-28wks of gestation. • Any pregnant women with GDM should be advised about diet, regular exercise, controlling excessive weight gain, glycaemic control, taking prescribed drugs, regular check-up of blood glucose level and as well blood pressure (BP) level. • Create awareness about early testing and prompt care. • Realize that GDM is related with other medical problems • Continuous and regular assessment of blood glucose • level and BP level should be made by HPs' at all visits.
Guideline 3: Tertiary prevention	• Pregnant women have very strange feelings about taking medications during pregnancy. • women had fragmented and incomplete knowledge about the disease concepts, its treatment and possible complications (Mançú, Almeida, & Souza, 2016:1478).	As tertiary level prevention of GDM related adverse maternal outcomes the following activities are recommended: - • Continuous and regular follow up • Pregnant women should be encouraged to monitor their blood glucose level regularly • Pregnant women should be advised to continue having regular check-ups for blood glucose level after delivery

5.11 ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

TABLE 5.3 STAKEHOLDERS' ROLES AND RESPONSIBILITIES FOR MONITORING AND PREVENTION OF GDM RELATED ADVERSE MATERNAL OUTCOMES.

Stakeholder	Roles and responsibilities
Policy makers	- Create a policy environment and mobilize resources for the execution of efficient GDM control programs towards promoting the health of pregnant women by reducing the burden of GDM and its adverse maternal outcomes. - Perform advocacy activities such as community mobilization to bring change in policy improvements and expansion of institutional arrangements to assist pregnant women with GDM. - Providing weight and height measurements tools at health service stations. - Help on improvements of hospital services facilities and assess the capacity of hospitals to provide GDM prevention services. - Support implementation of surveillance programs to manage adverse maternal outcomes of GDM and as well GDM itself.
Hospital administrator/ manager	- Conduct advocacies on GDM for higher-level authority - Develop a facility specific plan for reducing GDM related adverse maternal outcomes and align it with the health sector plan. - Establish a system that manages clients/patients records. - Make sure the availability of enough and appropriately trained HPs. - Avail guidelines and job aids. - Avail appropriate drugs and supplies. - Employ onsite inspection to make sure that each healthcare facility is properly fit for screening and treating GDM and its related adverse maternal outcomes. - Make sure that preliminary and continuous assessments for each pregnant woman regarding the reduction of risk factors for GDM are performed.
Health practitioners	- Examine pregnant women for symptoms and carry out diagnostic tests.

	- Identify risk factors and comorbidities. - Monitor blood glucose level regularly. - Monitor treatment adherence. - Prescribe appropriate drugs and inform pregnant women on lifestyle modifications. - Conduct screening, diagnostic tests and follow-up according to standard guidelines. - Provide health education to the society about early screening and treatment modalities. - Complete patients' medical records.
Patients	- Visit health facilities early for ANC. - Comply with health professional's advice. - Monitor blood glucose level and present early to appropriate facilities if any problems exist. - Adhere to treatment advice - Communicate information about GDM and its adverse maternaloutcomes with pregnant women and the society to protect the health of pregnant women.
Community health workers	- Educate pregnant women and the community on early detection as well as treatment modalities of GDM, using health teaching and society awareness campaigns. - Guide and support pregnant women with GDM to ensure risks are managed. - Support pregnant women with GDM to continuously check their blood glucose level and adhere with health professional's advice.

5.12 PROCEDURES FOR HEALTH CARE PROFESSIONALS

TABLE 5.4 PROCEDURES FOR HEALTH CARE PROFESSIONALS

Action	Description	Responsibility
Assessing pregnant women risks for developing GDM	Health professionals are expected to perform the following: • Take the pregnant women history (like, family history of DM, previous history of GDM, previous history of a macrosomic baby, age, measure height and weight….) • Counsel pregnant women with pre-existing risks for development of GDM • Conduct tests to assess GDM and document evidences	Gynaecologists/obstetricians and midwives
Diagnosis and monitoring of blood glucose level	• History taking and physical examination • Detecting GDM (testing for GDM) and provide appropriate care • GDM related health education should be given regularly • Regular monitoring of blood glucose level and BP • Screening for other common GDM related maternal morbidities • Education about self-care • Follow up and recording evidences	Gynaecologists/obstetricians
Health Education	• Counselling pregnant women about lifestyle modifications, type of treatment and adhering with treatment.	Gynaecologists/obstetricians and midwives
Follow-up	• Regular follow-up is mandatory during and after pregnancy to halt adverse maternal outcomes as well its long effects, i.e. development of type II DM.	Gynaecologists/obstetricians

5.13 VALIDATION OF THE GUIDELINES

The objective of validating these guidelines was to make sure that the guidelines have acceptable and attainable value. The process of guidelines validation started with searching for criteria for evaluating the guidelines and contextualizing it for this study. In doing so, Thomson and Dowding (2002:150) guided the researcher. the guiding principles are:

- **Clarity** – user friendly, explicit and exact
- **Meticulous** – documentations and recording of participants, assumptions and methods should be precise
- **Validity** – correct interpretation of available evidences
- **Cost-effectiveness** – cost of making health improvements should be acceptable
- **Specificity**- specific and focused
- **Reproducibility** – another group should make similar recommendations using the same data/proof
- **Clinical applicability** – beneficiary population is identified using evidence
- **Reliability** – in similar situations, other HPs would utilize the guidelines in the same way
- **Representatively** – the development of the guidelines was aided by concerned groups and all major disciplines
- **Clinical flexibility** – According to patient's choices exclusions are identified
- **Scheduled review** – at what time and by what means they will be reassessed
- **Utilization review** – techniques in which adherence may be monitored should be indicated

The summary of the research was given to the evaluators (Table 5.5). The summary included the topic, aims of the study, background of the problem, and the methodology used, besides, the proposed guidelines. The evaluators were asked to evaluate the guidelines and to rate them in accordance with the criteria provided (Table 5.6) for validation of the guidelines. These evaluators were purposely selected, and it included two senior academic lecturers who are teaching in MCH department, one MCH hospital manager, one gynaecologist/obstetrician and one midwife.

TABLE 5.5 EXPERT EVALUATORS' INFORMATION

No.	Profession	Qualification
1	Lecturer	PhD
2	Lecturer	MSc.
3	Hospital manager	Medical doctor
4	Gynaecologist/obstetrician	Specialist medical doctor
5	Midwife	BSc

A Likert scale with 4 assessment choices (i.e. strongly disagree, disagree, agree and strongly agree) was utilized. The 5 evaluators were asked to use the above-mentioned choices to assess, rate and suggest whether each of the guidelines met the standards. When necessary evaluators were requested to provide a written view.

TABLE 5.6 STANDARDS AND SCORING THAT WAS GIVEN TO EVALUATORS TO VALIDATE THE GUIDELINES.

Standards	Score			
	Strongly disagree	Disagree	Agree	Strongly agree
Clarity **Guideline is precise and easily understandable**				
Reliability **In similar situations, other HPs would utilize the guidelines in the same way**				
Validity **Correct interpretation of available evidences**				
Cost-effectiveness **The guideline can generate health improvementswith acceptable cost**				
Specificity **The guideline should be specific and focused**				
Clinical flexibility **Exceptions are identified**				
Applicability **The target users are clearly defined**				
Acceptability **Realistic and ambitious**				
Achievability **Can be executed by HPs in MCH clinics**				
Utilization review **Techniques in which adherence may be monitored should be indicated**				
Relevance **Guideline is appropriate for implementation in MCH clinic**				

A total score of 40 was considered for each guideline, with the notion that a guideline that scored 30 and more points was considered as suitable as this represented a 75% acceptance rate. The five evaluators were asked to score each guideline and to comment if they have any suggestions. Fortunately, the scores of the five evaluators were consistent and above 30 points. However, there were some comments on guideline 1 that health related information regarding risk factors for GDM should be provided for all women as a result these comments were reviewed and included in the final guideline.

5.14 SUMMARY OF THE CHAPTER

This chapter explained the formulation of the guidelines. Each guideline was based on study findings, researcher insights, review of pertinent literatures, and view of expertise on the area. In addition, each guideline was supported by a list of suggestions to be carried out by collaborators. Moreover, the validation process of the guidelines has been explained.

The succeeding chapter will deal with summary, recommendations and limitations of the research.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

This chapter presents the summary of the study results, limitations and recommendations.

6.2 RESEARCH DESIGN AND METHOD

The research concurrently employed quantitative as well as qualitative study design to answer the specified research queries. Retrospective cohort study was used; medical documents of pregnant women who had ANC visits and delivered in Gandhi Memorial Hospital within the cohort (2013-2017) were included for the quantitative part of the research to assess the magnitude of GDM and its associated risk factors. Besides, an in-depth interview was conducted for the qualitative part of the research to explore the experiences of gynaecologists/obstetricians and midwives towards monitoring and prevention of GDM related adverse maternal outcomes.

Betty Neuman's System Model guided the study. Study tools were pre-tested prior to the data collection. SPSS version 25.0 was used for the analysis of the quantitative dataand manual qualitative data analysis using Colaizzi's procedure was used for the analysis of data from the in-depth interviews.

Proposed guidelines were developed by integrating information from the data collected, relevant literature, insights of the researcher and views of experts. In general, the researcher had made sure that ethical issues were incorporated into all aspects of the study.

6.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

The results of the current research are summarized and outlined according to the study objectives.

6.3.1 Establish the magnitude of GDM in Addis Ababa, Ethiopia

The study established the burden of GDM and it revealed that two in a hundredpregnant women will develop GDM (2.2%) and this finding was supported by the views of HPs who participated in the qualitative part of the study, even though HPs were not with absolute evidence about the magnitude of GDM, they have suggested that the burden of GDM lies between 1 to 3%. This report is relatively low compared to other studies done in the country; this may be due to differences in the year of study andstudy design.

6.3.2 Determine risk factors associated with GDM

Risk factors like age (>35), obesity (BMI $\geq$ 30), family history of DM, history of previous GDM, multiple gestation and previous history of macrosomic babies or baby were the risk factors that were mentioned by the HPs who participated in this study. Whereas in the quantitative part of the research, age and family history of DM were the ones which showed statistical association with GDM.

6.3.3 Explore the experiences of gynaecologists/obstetricians and midwives towards monitoring and prevention of adverse maternal outcomes related to GDM

Using qualitative parameters, this study explored HPs perspectives regarding their experience towards monitoring and prevention of GDM related to maternal adverse outcomes, HPs indicated that their experience of monitoring and prevention of GDM related adverse outcomes is no different from monitoring and prevention of GDM. They suggested that early detection and prompt care will hinder all the adverse outcomes of GDM. Moreover, they added that women should be advised about controlling her sugar level, diet and as well having regular exercise.

"Women with GDM should be advised about the importance of doing simple exercise and controlling her sugar by regularly checking her blood sugar level and controlling her diet" (A48FG)

Health education was mentioned as a key preventive mechanism for the developmentof GDM as well to prevent its adverse maternal outcomes. They also added lifestyle modification and early detection are essential for prevention of GDM and its adverse maternal outcomes. The HPs have also indicated that there are barriers for monitoring and prevention of GDM and its related adverse maternal outcomes. Cultural practices, late visit to ANC, cost of diagnostic tests as well cost of medications, poor access to health-related information, attitude of pregnant women towards medication and lack of contextualized guideline were the barriers which were indicated by HPs.

6.3.4 Developing guidelines to monitor and prevent adverse maternal outcomes related to GDM

A best practice guidelines were developed and the guidelines will act as a tool for helping HPs to make the rightdecisions when dealing with pregnant women with GDM and for policy planning techniques. In general, the purposes of the guidelines are to: -

- Provide information on risk factors of GDM and its magnitude to the target beneficiaries,
- To facilitate timely identification, diagnosis and treatment of GDM,
- To improve the implementation of GDM related adverse maternal outcomes monitoring and prevention mechanisms by health care providers,
- To create community awareness for GDM prevention,
- To help policy makers and other concerned bodies to interfere in eliminating impediments of screening, diagnosis and management strategies as well in prevention of GDM and its related adverse maternal outcomes.

6.4 CONCLUSIONS

The research highlighted the magnitude and associated risk factors of GDM, and it has shown that only 2.2% of the women had GDM, besides it also outlines risk factors associated with it in chi-square test as follows: -

- Age of mothers ($p \leq 0.000$),
- Family history of DM ($p \leq 0.001$), were found to be contributing factors for development of GDM

And according to the views of HPs who participated in the qualitative part of study; age (>35), family history of DM, multiple gestation, obesity (BMI equal to and greater than 30), previous history of GDM, previous history of having a macrosomic baby were mentioned as risk factors for GDM. Moreover, this study has explored the experience of gynaecologists and midwives towards monitoring and prevention of adverse maternal outcomes related to GDM besides, it also highlighted the barriers they encounter.

In wrapping up, although the magnitude of GDM is low in this study, GDM still weighs heavily on health resources in Ethiopia. Women who come with advanced age, family history of DM, obesity, previous history of GDM, multiple gestations and previous history of having a macrosomic baby should be screened for GDM at the right time with the proper diagnostic techniques, in order to alleviate adverse maternal outcomes of GDM.

6.5 RECOMMENDATIONS

According to the results of this research, the subsequent recommendations are provided below:

6.5.1 Recommendations for policy makers and health managers

- **Create a policy** environment and mobilize resources for execution of efficient GDM control programs in order to promote the health of pregnant women by lessening the burden of GDM and its adverse maternal outcomes.
- Perform advocacy activities such as community mobilization to bring change in policy improvements and expansion of institutional arrangements to assist pregnant women with GDM.
- Incorporate the guidelines to policy documents to be enforced for implementations.
- Enough medical supplies need to be provided for health facilities
- HPs capacity must be built by giving training and ensure enough and appropriate trained HPs are employed to provide quality care.
- Provide guidance on a routine basis concerning improvements of hospital services facilities and evaluate the capacity of hospitals to provide GDM prevention services.
- Support implementation of surveillance programs to manage adverse maternal outcomes of GDM and as well GDM itself.
- Support implementation of surveillance programs to manage adverse maternaloutcomes of GDM and as well GDM itself.
- Establish patient record management system.

6.5.2 Recommendations for health practitioners

As per the results of the study the following activities are recommended for health practitioners:

- Comprehensive attempt is required from HPs to provide health education to the society about early screening and treatment modalities.
- When dealing with pregnant women with GDM HPs should take an adequate amount of time in order to properly manage GDM and its related adverse maternal outcomes, their risky behaviour and arrange follow-ups.
- HPs should conduct screening, diagnostic tests and follow-up according to

standard guidelines and must have a tradition of utilizing guidelines when necessary.

- Prescribe appropriate drugs and inform pregnant women on lifestyle modifications.
- HPs should complete patients' medical records.
- HPs especially community health workers should work to bring a change on the wrong views of the society about early visit of ANC clinics.
- HPs should strongly advise pregnant women with GDM related morbidities to adhere to treatment and advice provided.

6.5.3 Recommendations for future researchers

DM is a modern-day public health issue that is placing developing countries like Ethiopia in a double load of disease. GDM as being a type of DM, directly or indirectly contributes to this burden. Therefore, in order to know the magnitude of the problem sufficient proof is required and feasible suggestions for its prevention should be provided.

The subsequent points can be applied by future researchers to pursue additional information on the problem:

- Prospective cohort study is recommended. As this study employed a retrospective cohort study, it lacks complete data and quality because of missing data
- Studies based on other types of models are recommended, upcoming researchers are recommended to come up with other types of models.
- Commissioning of a community based randomized control trial about burden of GDM and its related adverse maternal outcomes. Randomized controlled trials are the golden benchmark in most of studies for elucidating the actual figure of the problem.
- Studies should be conducted to assess client's perceptions and facilities readiness for provision of services in monitoring and prevention of GDM related adverse maternal outcomes.

6.6 CONTRIBUTIONS OF THE STUDY

It is believed that this study produced additional data to fill up certain knowledge gaps related to GDM. In addition to raising awareness, the knowledge produced has numerous potential purposes like, revealing additional information gaps and recognition of new topics of research, encouragement for empowering policies and resources, and policy development. The possible implications of the study relate to: -

- **Guidance to policy makers and health managers** – As this study proposed guidelines, these would assist policy makers and health managers.
- **Improving clinical practice** – Inputs from this study would hopefully improve clinical practice and promote the wellbeing of pregnant women.
- **Raising awareness** – will add to the body of knowledge.

In general, the major contributions of this research can be summarized as follows: -

- Sensitization of policy makers, hospital managers and HPs about GDM and its adverse maternal outcomes,
- Generation of local evidence,
- Proposing of guidelines for implementation

6.7 LIMITATIONS OF THE STUDY

The researcher accepts the subsequent limitations of the study:

- It is difficult to interpret or generalize the results of this study as this study included women with GDM which are different from their counterparts.
- The findings of the study may perhaps have been different if the study was conducted in private hospitals, as this cannot show the perspectives of private hospitals.
- The study was institution-based; the findings could have been different if it had been community-based study.

- Retrospective cohort studies are prone for missing data and this could affect the quality of this study.
- The study did not include the views of policy makers, health managers and pregnant women with or without GDM and the findings could have been different if it had included the aforementioned individuals.

6.8 CONCLUDING REMARKS

In Ethiopia, GDM and its adverse maternal outcomes are under recognized and under prioritized compared to other health problems due to different infectious disease burdens. This may be due to insufficient epidemiological data, non-existent GDM service policies, rare reproductive health services and lack of resources and poor awareness of the community. In order to strengthen the effort of monitoring and preventing GDM and its related adverse maternal outcomes, we need to have government commitment and policy to consider GDM as a public health priority. Therefore, many researches must be done.

In conclusion, one at a time to successfully propose, execute and maintain a prevention program for GDM and its adverse outcomes, good data from across multi-disciplinary sectors are needed. Moreover, much must be done to equip the community with health information and to make HPs develop the tradition of using guidelines when managing pregnant women.

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ANNEXURE

ANNEXURE A: SUPPORTING LETTERS

A1: Ethics Certificate from Higher degree research and ethics committee of Unisa

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES

REC-012714-039 (NHERC)

11 October 2017

Dear Sinetsehax Alemayehu Getahun

HSHDC/711/2017
Sinetsehax Alemayehu Getahun
Student No 6195-837-9
Supervisor: -Dr TG Lumadi
Qualification: D Litt et Phil
Joint Supervisor: -

Decision: Ethics Approval

Name: Sinetsehax Alemayehu Getahun

Proposal Best practice guidelines to monitor and prevent maternal morbidity and mortality related to gestational diabetes mellitus in Ethiopia

Qualification: **DPCHS04**

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted from 11October 2017 to 11 October 2022.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 11 October2017.

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.*

3) *The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.*

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4) *[Stipulate any reporting requirements if applicable].*

Note:
The reference numbers [top middle and right corner of this communiqué] should be clearly indicated on all forms of communication [e.g. Webmail, E-mail messages, letters] with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

Kind regards,

Prof JE Maritz
CHAIRPERSON
maritje@unisa.ac.za

Prof MM Moleki
ACADEMIC CHAIRPERSON
molekmm@unisa.ac.za

Prof A Phillips
DEAN COLLEGE OF HUMAN SCIENCES

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A2:Permission Letter From Addis Ababa Health Bureau Research Review Committee

አዲስ አበባ ከተማ አስተዳደር ጤና ቢሮ
City Government of Addis Ababa Health Bureau

Ref.No. ጤአመጽ/38667/22
Date. 16/9/2011

- **Gandhi Memoria Hospital**
  Addis Ababa

Subject: Request to access Health Facilities to conduct approved research

This letter is to support **Sinetsehay Alemayehu Getahun** is to conduct research, which is entitled as "**EVIDENCE BASED BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GDM, ADDIS ABABA, ETHIOPIA, 2019.**" was duly reviewed and approved by Addis Ababa Health Bureau IRB, and the principal investigator is informed with a copy of this letter to report any changes in the study procedures and submit an activity progress report to the Ethical Committee as required. Therefore we request the Health facility and staffs to provide support to the Principal investigator.

The Addis Ababa City Administration Health Bureau

With Regards

Dr. Yohannes W/Kidan
Ethical Clearance committee

Cc
- **Sinetsehay Alemayehu Getahun**
- **Ethical Clearance Committee**
  Addis Ababa

LANGUAGE EDITING CERTIFICATE

This certificate is presented to

Sinetsehay Alemayehu Getahun

This certificate confirms that the manuscript titled:
BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GESTATIONAL DIABETES MELLITUS IN ETHIOPIA has been edited by Rosemary's Proofreading & Editing Services.
Date issued: September 2020

Rosemary Maluleke

Director

ANNEXURE B: QUESTIONNAIRE B1: MEDICAL RECORDS REVIEW CHECKLIST

Card No ---------- Year----------

OBJECTIVE- TO DEVELOP BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED WITH GESTATIONAL DIABETES MELLITUS IN ADDIS ABABA, ETHIOPIA.

GDM: Yes……. No…….

Age: _____

Weight: 1) ----------2) ---------3) ----------4) …….

FBS: 1) ----------2) ---------3) ----------4) ……

RBS: 1) ----------2) ---------3) ----------4) ……

OGTT…….

Height ……

Estimated date of delivery: ----------

Delivery date: ----------

Last menstrual period (LMP): ----------

Gravida: ----------

Parity: --------

Gestational age: _____

General appearance: _____

Presentation: _____

VDRL: _____

HBSAg: _____

PIHCT: _____

RH: _____

Family history of DM: Yes…… No…….

s/no	Parameters	Measurement		Remark
1	**Haemoglobin level in g/dl**			
	First trimester	---------- g/dl		
	Second trimester	---------- g/dl		
	Third trimester	---------- g/dl		
	Fourth trimester	---------- g/dl		
2	**Urine analysis**			
	Sugar levels	+ve----------/-ve----------		
	Protein	+ve----------/-ve----------		
	Ketones	+ve----------/-ve----------		
	Bacteria	+ve……. / -ve…….		
3	**Past obstetric history**			
	Type of previous delivery	SVD		
		Forceps		
		Vacuum		
		C/S		
	Past surgical history	Yes		
		No		
	Past medical history	Yes		
		No		
	Any known allergies	Yes		
		No		
	History of admission	Yes		
		No		
4	**Nutritional Assessments**			
	MUAC			
	BMI			
5	**Screening for GDM**	Yes	No	

	24 weeks		
	25 weeks		
	26 weeks		
	27 weeks		
	28 weeks		
6	**Mode of Current delivery**	SVD	
		C/S	
		Forceps	
		Vacuum	
7	**Was health education for pregnant women given on**	Good nutrition	
		Adequate rest	
		Good hygiene	
		Family planning	
		Exclusive breastfeeding	
		Immunization	
		Disease prevention	
		Hypertension	

8	**Morbidity**		
		Polyhydramnios	
		Excessive weight gain	
		Pre-eclampsia	
		Eclampsia	
		Urinary tract infections	
9	**Mortality due to GDM**	Yes	
		No	

QUESTIONNAIRE B2: IN-DEPTH INTERVIEW GUIDE

TITLE OF THE STUDY: BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GESTATIONAL DIABETES MELLITUS IN ADDIS ABABA, ETHIOPIA.

Interviewer introduction and directives to participants

Thank you for volunteering to be part of this interview. You are requested to take part in this study as your involvement is valuable. I understand you are busy, and I appreciate your time.

Introduction: This interview is designed to assess your thoughts, feelings and experiences towards adverse maternal outcomes related to GDM, as well as the magnitude and risk factors of GDM. The in-depth interview will take no more than an hour. The researcher will tape the interview to facilitate its recollection.

Anonymity: Despite being taped, the researcher would like to confirm that the interview will be anonymous. The tapes will be kept safely and then they will bedestroyed after the completion of the research.

PARTICIPANTS DEMOGRAPHIC DETAILS

Please answer the following questions

1. Age_____years
2. Sex
   1. Male 2. Female
3. Profession
   1. Gynaecologist 2. Midwife
4. Experience in maternity department_____years

Guiding questions

1. **Understanding of incidence of GDM.**
   - ✔ What do you think about the incidence of GDM?
2. **Risk factors of GDM**
   - ✔ What are the risk factors for GDM?
   - ✔ Could you describe the effect of the risk factors on GDM?
3. **Mechanism to monitor and prevent maternal morbidity and mortality related to GDM**
   - ✔ How do you think you can monitor GDM?
   - ✔ How do you describe your experience regarding providing health care services to mothers with GDM?
   - ✔ How can you prevent and control GDM and its related maternal morbidity and mortality?
   - ✔ What do you think can be done to help people make a change in their diet habits?
   - ✔ Would you please explain your past experiences of managing mothers withGDM?
4. **Adverse maternal outcomes related with GDM**
   - ✔ What are the maternal morbidities related with GDM?
   - ✔ How do you explain the relation between maternal death and GDM?
5. **Barriers for the management of GDM**
   - ✔ What barriers have you faced during the management of mothers with GDM?

Concluding question

- Of all the things we've discussed, what would you say are the most important issues you would like to express and if there is anything you want to add.

Conclusion

- Thank you for your participation. This has been a very successful interview.
- Your views will be a helpful resource to the study.
- We hope that the interview was interesting.

ANNEXURE C: CONSENT

ANNEXURE C1: INTERVIEW CONSENT

Respondent's Identifier……. Date…….

Dear participant, you are requested to take part in a research. The details of the research are listed below.

Topic of Research Study: Best practice guidelines to monitor and prevent maternal morbidity and mortality related to GDM in Ethiopia.

Investigator's Name: Mrs. Sinetsehay Alemayehu Getahun, Doctoral student at the University of South Africa, Department of Public Health, salsinehay@gmail.com. Or use +251938171440 (+251913021050).
Supervisor: Prof. Lumadi TG, University of South Africa, Department of Health Studies, lumadtg@unisa.ac.za.
Chair of the University of South Africa, Department of Health Studies, Research Ethics Committee, Prof J E Maritz, maritje@unisa.ac.za.

Research Entity: University of South Africa

Objective of research: To determine magnitude and risk factors of GDM and maternal morbidity and mortality related to GDM, develop best practice guidelines to monitor and prevent maternal morbidity and mortality related to GDM, and direct policy makers to integrate GDM monitoring and prevention strategies as essential part of the antenatal

care strategy. This research study is being done in partial fulfilment of the requirements for the degree of Doctor of Literature and Philosophy.

Consenting for the Research Study:

This is a crucial paper. Please take your time to read it carefully and then kindly authorize the University of South Africa and its researchers to include you as a participant for this research study.

Procedures:

If you volunteer to be part of the research: you will be interviewed about your experiences towards monitoring and preventing maternal morbidity and mortality relatedto GDM.

Your right to privacy and confidentiality:

At the end of this consent form, you are provided with information about your right to privacy and confidentiality. We also require your authorization to utilize and disclose the information that we may collect about your experiences during this research. To be part of this research, you must first read and sign the form.

Risks and discomforts:

By no means the study procedures involve visible risk and discomforts.

Benefits:

It is expected that the outcomes from this study will help all women. Moreover, for some participants, being part of these interviews might offer a prospect to reassess their overall experiences in a more meaningful way.

Voluntary participation:

You should understand that your participation is based on your willingness, if you don't want to be involved in this study you have the right, in the meantime you can also leave the interview at any given time.

Confidentiality and privacy:

The following section provides you with additional information about the privacy and confidentiality of your interview.

A. **Information that will be gathered**: You will be interviewed about your thoughts, feelings and experiences towards monitoring and prevention of maternal morbidity and mortality related to GDM, as well the incidence and risk factors of GDM.

B. **Who will see and use your information**: The researcher and other authorized persons engaged in the research study will see your information and may give out your information during the research study. The authorized persons include the institutional review board and their staff, the research investigator and research staff. Moreover, other individuals who would like to know that the study is properly going, might also ask for your information. The results will be published in peer reviewed research journals.

C. **Why your information will be used and given out:** The researcher and other authorized person will utilize your information in order to assess the findings of the study. The results will be published in peer reviewed research journals.

D. **If you do not want to give authorization to use your information:** The right to provide authorization to utilize or provide information is at your hand. However, if you don't give authorization that means you cannot be part of the study.

E. **How to cancel your authorization:** You may revoke your authorization by sending a written notification at any time.

F. **When your authorization ends:** Your authorization will come to an end as soon as the research is completed. However, once the study is completed, the data will be maintained in a research database. But you must note that the investigator shall not re-

use or re-disclose the information in this database for other reasons unless you give written permission to do so. However, the Scientific and Ethics committee and Institutional Review Board may allow other researchers to see and utilize your information under passable privacy precautions.

CONSENT:

- ✔ The researcher has notified me of the rationales for this research study.
- ✔ The study has been clearly explained to me.
- ✔ All of my queries were answered.
- ✔ I have meticulously read this consent form.
- ✔ According to the information described in this consent form I permit the use anddisclosure of my information.
- ✔ I voluntarily give my consent.

Participants Name _____

Participants signature_____ Date _____

Investigator's name _____

Investigator's signature_____ Date _____

I, Sinetsehay Alemayehu Getahun (researcher) herewith confirm that the above participant has been provided with adequate information about the purpose, behaviour and risks of the above study.

Thank you very much

ANNEXURE C2: IN-DEPTH INTERVIEW CONFIDENTIALITY AGREEMENT

TITLE OF THE STUDY: BEST PRACTICE GUIDELINES TO MONITOR AND PREVENT MATERNAL MORBIDITY AND MORTALITY RELATED TO GESTATIONAL DIABETES MELLITUS IN ADDIS ABABA, ETHIOPIA.

I_____ consent to the information I communicate throughout the interview could be utilized by the investigator, Sinetsehay Alemayehu Getahun, for research reasons. I have been informed that the interview will be recorded. I also consent to the recordings, given that my confidentiality will be safeguarded. In order to maintain confidentiality, I agree to protect every information that is communicated during the interview of this research study.

Participant's Name _____

Participant's Signature: _____

Researcher's Name: Sinetsehay Alemayehu Getahun

Researcher's Signature: _____

Date: _____

ANNEXURE D: DESCRIPTION OF THE TOTAL SCORES OF THE GUIDELINES BY THE EVALUATORS.

Evaluator 1

Criteria	Guideline 1	Guideline 2	Guideline 3
Clarity	3	3	3
Reliability	4	3	4
Validity	4	4	4
Cost-effectiveness	4	3	2
Specificity	3	3	3
Clinical flexibility	3	2	3
Applicability	3	3	3
Acceptability	4	3	3
Utilization review	3	3	3
Relevance	4	4	4
Total	**35**	**31**	**32**

Evaluator 2

Criteria	Guideline 1	Guideline 2	Guideline 3
Clarity	3	3	3
Reliability	3	3	3
Validity	4	3	3
Cost-effectiveness	3	3	3
Specificity	3	3	3
Clinical flexibility	3	3	3
Applicability	4	3	3
Acceptability	4	3	3
Utilization review	3	3	3
Relevance	3	3	3
Total	**33**	**30**	**30**

Evaluator 3

Criteria	Guideline 1	Guideline 2	Guideline 3
Clarity	3	3	4
Reliability	4	4	3
Validity	4	4	4
Cost-effectiveness	3	3	4
Specificity	3	3	3
Clinical flexibility	2	3	3
Applicability	3	4	3
Acceptability	3	3	3
Utilization review	3	3	3
Relevance	3	3	4
Total	**31**	**33**	**34**

Evaluator 4

Criteria	Guideline 1	Guideline 2	Guideline 3
Clarity	4	4	4
Reliability	4	4	4
Validity	4	4	4
Cost-effectiveness	4	2	2
Specificity	4	3	3
Clinical flexibility	4	3	4
Applicability	4	4	4
Acceptability	4	4	4
Utilization review	4	3	4
Relevance	4	4	4
Total	**40**	**35**	**37**

Evaluator 5

Criteria	Guideline 1	Guideline 2	Guideline 3
Clarity	3	4	4
Reliability	4	4	4
Validity	4	4	4
Cost-effectiveness	3	3	3
Specificity	3	3	3
Clinical flexibility	3	4	4
Applicability	3	3	3
Acceptability	3	4	3
Utilization review	3	3	3
Relevance	3	4	4
Total	**32**	**36**	**35**