PREVALENCE OF GESTATIONAL DIABETES MELLITUS IN THE GREATER GIYANI AREA, MOPANI DISTRICT, LIMPOPO PROVINCE.

By

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MINI-DISSERTATION

Submitted in partial fulfilment of the requirements for the degree of

MASTER OF PUBLIC HEALTH

in the

FACULTY OF HEATH SCIENCES
(School of Health Care Sciences)

at the

UNIVERSITY OF LIMPOPO

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2020

DECLARATION

I declare that the mini-dissertation hereby submitted to the University of Limpopo, for the degree of Master of Public Health has not previously been submitted by me for a degree at this or any other university; that it is my work in design and in execution, and that all material contained herein has been duly acknowledged.

Ntshauba, ET (Ms) 07 July 2020

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Surname, Initials (title) **Date**

TABLE OF CONTENTS

Table of Contents

DEDICATION

This study is dedicated to my parents, Ntshengedzeni Abel Ntshauba and Maungedzo Betty Ntshauba who have given me invaluable educational opportunities. Thank you for supporting and encouraging me……I love you.

ACKNOWLEDGEMENTS

I want to thank the following persons for their respective contributions to this dissertation:

- God Almighty for giving me the strength, knowledge, ability, and opportunity to undertake this research study. Without His Grace, this achievement would not have been possible.
- My siblings, Jerry Ntshauba; Thikolelwi Ntshauba; Advocate Absalom Ntshauba and Dr Phumudzo Ntshauba, for their unconditional love, support, and reassurance during this journey.
- My pastors; the late Pastor Ramarumo J, Pastor Mabara N.S and Pastor Rathidili S.D for their continuous prayers, words of encouragement and guidance.
- My supervisors; Dr Maimela E and Dr Ntuli T.S for their guidance, support, encouragement, support, knowledge, expertise, and willingness to assist in this study. It was a long journey but we made it.
- My research study participants for their willingness to participate in this study.
- My Nkhensani Hospital Occupational Therapy Department staff for their support and encouragement throughout.
- Nkhensani Hospital CEO; Giyani Health Centre nurse manager and Nkhensani Gateway Clinic manager for a warm welcome in your institution to conduct my research.
- The Limpopo province; Department of Health, Mopani District Health Department for giving me permission to conduct the study.

ABSRACT

The purpose of this study was to determine the prevalence of gestational diabetes mellitus (GDM) and the associated risk factors in the Greater Giyani Area, Mopani District. Quantitative cross-sectional descriptive study was conducted to determine the prevalence rate and risk factors of GDM. Data was collected using questionnaire and data entry form. One hundred and one (101) pregnant women who were attending antenatal clinic visits at Nkhensani Hospital, Nkhensani Gateway Clinic and Giyani Healthcare Centre participated in the study. The SPSS programme was used and p-value of <0.05 was considered significant. The study found that the prevalence of GDM in the area was 1.9%. Pregnant women above 30 years with secondary education, employed, obese and at gestational age of 31-35 weeks were more likely to present with GDM. A family history of diabetes was significantly associated with development of GDM. In conclusion, the universal screening approach for GDM needs to be adopted by all health institutions.

Key concepts

Gestational diabetes mellitus; prevalence; risk factors

LIST OF ABBREVIATIONS

ASGODIP	ASEAN Federation of Endocrine Societies Study Groups in Diabetes in Pregnancy
BMI	Body Mass Index
DM	Diabetes Mellitus
GWG	Gestational Weight Gain
HCT	HIV counselling and testing
HELLP	Haemolysis Elevated liver enzymes Low Platelet count
IADPSG	International Association of Diabetes in Pregnancy study Groups
ICU	Intensive Care Unit
IFG	Impaired Fasting Glycemia
IGT	Impaired Glucose Tolerance
LMICs	Low-or-middle-income countries
MMC	Medical Male Circumcision
NCDs	Non-communicable Diseases
NICE	National Institute for Health and Excellence
NICU	Neonatal Intensive Care Unit
OGTT	Oral glucose tolerance test
PE	Pre-eclampsia
PGDM	Pre-gestational diabetes mellitus
SDGs	Sustainable Developmental Goals
SOP	Standard of Practice
SPSS	Statistical Package for Statistical Social Sciences
WHO	World Health Organisation

KEY DEFINITION OF CONCEPTS

Birth trauma: injuries to the infant that result from mechanical forces, i.e. compression and traction, during the birth process (Laroia, 2015). In the context of the current study, birth trauma refers to fracture of the clavicle, fracture of the humerus and shoulder dystocia.

Congenital malformations: include all disorders which are present at birth and can either be inherited or caused by the environment (Oxford Concise Colour Medical Dictionary, 2010). In the context of the current study, congenital malformations will be used as defined above.

Gestational diabetes mellitus (GDM): is a glucose tolerance disorder which is diagnosed for the first time in pregnancy (Bener, Saleh & Al-Hamaq, 2011). In the context of the current study, gestational diabetes mellitus will be used as defined above.

Prevalence: refers to the "proportion of persons in a population who have a particular disease at a specified point in time or over a specified period of time" (Centers for Disease Control and Prevention, 2012, pp. 3-16). In this study, prevalence refers to the number of pregnant women diagnosed with GDM attending antenatal clinic at Nkhensani Hospital, Giyani Healthcare Centre and Nkhensani Gateway Clinic.

Risk factors: are defined as factors that are casually related to a change in the risk of a relevant health process, outcome or condition (A Dictionary of Epidemiology, 2014). In this study, risk factors are referred to as non-modifiable risk factors where these risk factors cannot be changed, which includes race, maternal age, family history of diabetes, hypertension and socio-demographic location. Modifiable risk factors are factors where measures can be taken to change them, which includes physical inactivity, pre-eclampsia, psychological stress, gestational weight gain, hormonal contraceptive use and unexplained recurrent parity.

Type 2 Diabetes Mellitus: refers to the body's incapacity to properly use insulin (Harris, 2013). In the context of the current study, type 2 diabetes mellitus will be used as defined above.

1. CHAPTER 1: ORIENTATION TO THE STUDY

1.1. Introduction and background

Diabetes is a chronic disease that occurs either when the pancreas does not produce sufficient insulin or when the body is not using the insulin it produces in an effective manner (World Health Organisation, 2017). Diabetes is a global health issue which impacts on the quality of life, socioeconomic status and increase mortality and morbidity (WHO, 2017). There are five types of diabetes, namely, type 1 diabetes mellitus (Type 1 DM), type 2 diabetes mellitus (Type 2 DM), gestational diabetes mellitus, impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG).

The current study investigated gestational diabetes Mellitus (GDM) which is defined as a glucose tolerance disorder diagnosed for the first time during pregnancy (Bener et al., 2011). One study conducted in one of Limpopo communities found the prevalence of GDM to be 8.8% using risk-factor based approach (Mwanri, Kinabo, Ramaiya and Feskens, 2013). Consensus on GDM screening has not yet been reached thus there is a variation of GDM prevalence across countries as each institution utilise criteria that is convenient to them. There is limited research on this topic has been done in the South African context, particularly in rural areas. This study is worthwhile to investigate as it will highlight the screening practice of GDM and inform Standard of practice which can be easy to utilise across health facilities in the Greater Giyani.

This chapter will present the background to the study; a statement of the problem; a literature review; the purpose of the study, along with the research aims and objectives; the research methodology employed; ethical considerations and the significance of the research.

1.2 Research problem

Goal No. 3 of the United Nations Organisation's Sustainable Developmental Goals (SDGs) focuses on ensuring healthy lives and promoting the well-being of people of all age groups (Sustainable Development Summit, 2015). The World Health Organisation (WHO) aims to end preventable deaths of newborns and children under 5 years of age (Sustainable Development Summit, 2015). However, there is still a high rate of infant mortality caused by GDM which is preventable and the outcomes of this disease can be controlled, if appropriate maternal care is provided during pregnancy.

The global prevalence of GDM has increased from 14 % to 17.8% (Stewart and Malhotra, 2015). Research has been conducted on the maternal and infant outcomes of GDM. However, few studies have been conducted on GDM in the South African context. The prevalence of GDM in Limpopo has been reported to be 8.8% (Mnwanri et al., 2013). GDM places the life of both the mother and infant at risk, especially when it is poorly managed.

Furthermore, these health risks can result in mortality and morbidity of both the mother and the infant. National guidelines have been developed to combat maternal and neonate mortality, such as National Obstetrics Guideline, Maternal Guideline and the Millennium Development Goals (MDGs). However, mortality and morbidity cases of maternal and infant associated with gestational diabetes mellitus are reported daily across the world. The level of reporting mortality and morbidity either remains the same or is higher despite the existence of the guidelines. The current study investigated the prevalence, the risk factors and the maternal and infant outcomes of gestational diabetes mellitus, so that interventions can be planned to reduce morbidity and mortality.

Statement of research problem

It has been noted in Nkhensani Hospital that there is a high prevalence of diabetes mellitus in the area as more than 300 patients are seen by healthcare workers at this hospital in a month (Statistics obtained from the

Hospital's Out-patient Department). Diabetes mellitus includes GDM, and the health risks associated with the disease can result in maternal and infant mortality and morbidity. Sustainable Development Goal No. 3 highlights the need to both ensure and promote healthy lives and well-being of people of all age groups (Sustainable Development Summit, 2015). Number of deaths of newborns and children underage of 5 years can be prevented through thorough investigations and management. Thus, the current study investigated the prevalence, risk factors, maternal and infant outcomes of GDM.

1.3 Literature

The literature review was undertaken and the process followed during this review of the literature was thematic. This means that small aspects of GDM were organised into five themes, namely, the global burden of diabetes, the prevalence of GDM; risk factors associated with GDM; maternal and infant outcomes associated with GDM; and public health interventions required in order to prevent and control GDM.

1.4 Purpose of the study

The purpose of this study was to provide information on the prevalence of GDM, the risk factors associated with GDM, and the maternal and infant health outcomes in the Greater Giyani Area. Furthermore, this study also highlighted common risk factors which make pregnant women in Greater Giyani Area more susceptible to developing GDM in order for the modifiable risk factors to be reviewed and addressed. This study aimed to benefit the Nkhensani Hospital and the clinics in the Greater Giyani Area, because the outcomes of the study will, hopefully, encourage screening practices for GDM during ante-natal clinics, will encourage confirmation investigations to be undertaken to ensure true positive (test that detects the condition when condition is present) for GDM, and will encourage the timely initiation of treatment of women diagnosed with GDM.

In addition, this study aimed to encourage the Limpopo Department of Health to strengthen interventions and screening for GDM among pregnant women, so that good maternal and infant health outcomes can be achieved. This will, in turn,

reduce maternal and infant mortality and morbidity, as well as reduce treatment related costs. To future researchers, this study may provide information on the current status of GDM in the Greater Giyani Area.

1.4.1 Aim of the study

To investigate the prevalence, the risk factors, and the maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo Province.

1.4.2 Objectives

- To determine the socio-demographic characteristics of pregnant women with diabetes in the Greater Giyani Area.
- To determine the prevalence and risk factors of gestational diabetes in the Greater Giyani Area.
- To describe the maternal and infant outcomes associated with gestational diabetes mellitus in the Greater Giyani Area.
- To determine the association of socio-demographics, risk factors with maternal and infant outcomes in the Greater Giyani Area.

1.5 Research question

What is the prevalence, risk factors, maternal and infant outcomes of gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo Province?

1.6 Methodology

1.6.1 Research design

Research design is defined as type of inquiry within qualitative, quantitative and mixed methods approaches used to provide specific direction for designing research (Creswell, 2013). A cross-sectional descriptive study design was used to help address the research question posed in this study and to determine the relationship between diseases or other health-related characteristics and other variables of interest as they exist within a defined population at a particular point in time (Detels, Gulliford, Karim & Tan, 2015).

1.6.2 Sampling

Simple random sampling of the study population was used in this study. Furthermore, it is a type of probability sampling wherein every member of the population has an equal chance of being selected to participate in the study (McCombes, 2019).

Inclusion criteria: this study included all pregnant women who visited the antenatal clinics at the Nkhensani Hospital, Giyani Healthcare Centre and Nkhensani Gateway Clinic.

Recruitment of the sample and gaining access to the site: Gaining access to the site commenced after ethical clearance was granted by the Turfloop Research and Ethics Committee. Access to the three health facilities was requested from the Department of Health in Limpopo and from the Mopani Health District in order for the researcher to be granted access to the pregnant women who visited the antenatal clinics.

No exclusion criteria were determined for the purposes of this study

1.6.3 Data collection

Data was collected using a questionnaire adapted from the Michigan Diabetes Research and Training Center DCP 2.0 to capture the socio-demographic characteristics of the participants. A questionnaire was chosen as an information gathering tool since information was collected from a large sample of participants within short period of time. A questionnaire is a cost-effective tool and the results obtained can easily be arranged and analysed.

Furthermore, a data entry form was also used to capture the medical information from the participants' medical files in order to ascertain maternal age, height, weight, obstetric history, past medical history, treatment currently received, past medical history, family history and investigations done in order to diagnose GDM.

1.6.4 Data analysis

Research data was captured in a Microsoft Excel spreadsheet and then transferred to Statistical Package for Social Sciences (SPSS) Version No. 22 (2013), which was used for data analysis. In addition, Univariate regression analysis was also done to analyse the data.

1.6.5 Reliability & Validity

1.6.5.1 Reliability

To ensure reliability of the measuring instruments used, the questionnaire responses from participants were cross-checked by the researcher's supervisor for consistency in the results. Consistency between participants' responses to the questions on the questionnaire indicated that the data collection tool was reliable.

1.6.5.2 Validity

To ensure validity, the use of the questionnaire was piloted before it was administered to the study participants in order to ensure that it measured what it was intended to measure.

1.6.6. Bias

Selection bias was minimised by randomly sampling the participants to ensure that all participants who meet the study's inclusion criteria were selected to participate in the study. Administrating a questionnaire aided in addressing the possibility of missing data obtained from a participant's medical records. To address unavoidable bias, the researcher adhered to the research methodology and engaged with a statistician to check the data analysis in order to ensure that the data analysed was a true reflection of the data gathered from the research participants.

1.7 Ethical consideration

To ensure ethical considerations were taken into account in this study; permission to conduct the study was sought from University of Limpopo's Turfloop Research Ethics Committee and then from the Limpopo Department of Health Provincial and District offices by presenting these offices with a research information letter. In addition, participants were handed an information letter

outlining the purpose of the study as well as a consent form to for them to sign before participating in the study. For participants who were under 18 years, their parents/guardians were informed of the study and were asked to consent to their children's participation in the study. Furthermore, the child had to sign an assent form consenting to participate in the study. (**See appendices H to R.**)

Furthermore, a storage system was implemented, i.e. hard drive; compact disc and file for hard copies, in such a manner as not to reveal the identity of the participants in order to ensure their confidentiality, privacy and anonymity with respect to their participation in this study. There were no foreseeable risks associated with participation in this study since no samples, such as blood, were drawn from the participants.

Research findings will be presented to the Provincial Health Department and to the three study sites to ensure that the selected study sites and the Department benefit from the outcomes of this study.

Finally, participants were not compensated for participating in the study.

1.8 Significance of the research

Diabetes is characterised by complications which can lead to mortality or impair an individual's quality of life, as well as impacting on the socio-economic status of the country. The study highlighted the common risk factors in Greater Giyani Area which make pregnant women more susceptible to developing GDM so that the modifiable risk factors associated with the disease can be reviewed and addressed. This study could be beneficial to Nkhensani Hospital and the clinics in the Greater Giyani Area as the outcomes may encourage the implementation of screening practices for GDM during ante-natal clinic visits, the introduction of confirmation investigations to ensure a true positive diagnosis for GDM, as well as encourage the timely initiation of treatment of women diagnosed with GDM.

This study will inform the development of public health policies directed at maternal and infant care, as well as encourage a review of provincial regulations and frameworks, standards of practice (SOP) and guidelines for the treatment of

GDM. In addition, appropriate management of GDM will improve both maternal and perinatal outcomes (Bener et al., 2011). In addition, this study could encourage the Limpopo Department of Health to strengthen interventions and screening for GDM among pregnant women, so that good maternal and infant health outcomes can be achieved.

The study is significant because it sought to empower pregnant women with knowledge about risk factors associated with gestational diabetes mellitus. Moreover, this empowerment will ensure that they take precautionary measures with respect to some of the associated modifiable risk factors in order to reduce the likelihood of developing gestational diabetes by changing or modifying their lifestyle. The study also aimed to empower pregnant women with knowledge of the likely maternal and infant outcomes during gestational diabetes mellitus pregnancy.

1.9 Outline of the chapters

The information presented above provided an overview of this study. The next chapter, Chapter 2, describes the literature review was done to highlight previous research studies conducted across the globe on this research topic. Chapter 3 will highlight the research methodology employed; Chapter 4 deals with the presentation and representation of the study's research findings, while Chapter 5 presents a summary of the study and recommendations emanating from the results of this study.

1.10 Summary

Diabetes including Gestational diabetes mellitus is a global health concern with adverse health outcome. The aim of the study is to investigate the prevalence, risk factors, and maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area. In addition, this will assist in establishing measures which can be implemented to reduce maternal and infant mortality & morbidity as well as promoting good health and well-being. This chapter outlined the objectives and research question, methodology undertaken to address research question, ethical measures which were taken into consideration and the significance of the study.

2. CHAPTER 2: LITERATURE REVIEW

A literature review is a critical and analytical account of the existing research on a particular topic of study. In this literature review, the following themes are discussed: global burden of diabetes, prevalence of gestational diabetes mellitus (GDM); risk factors of GDM; maternal and infant outcomes associated with GDM, and public health interventions to prevent and control GDM.

2.1. Introduction

Non-communicable diseases (NCDs) are the leading causes of death, representing 43% of the global burden of disease (Maimela, Alberts, Modjadji, Choma, Dikotope & Ntuli, 2016). Furthermore, the rate of death caused by NCDs is expected to increase to 60% and 70% in 2020 (Maimela et al., 2016). One of the NCDs is diabetes mellitus, which is a group of metabolic diseases associated with abnormally high levels of glucose in the blood (Irving, Mills, Choo-Kang, Morrison, Kulkarni, Wright-Pascoe & McLaughlin, 2008). This is a serious chronic disease that occurs when the pancreas does not produce enough insulin, which is a hormone that regulates blood glucose, or when the body cannot effectively use the insulin hormone it produces (World Health Organisation, 2016).

Diabetes is one of the leading causes of mortality and has devastating health outcomes. There are five types of diabetes, namely, type 1 diabetes mellitus (Type 1 DM), type 2 diabetes mellitus (Type 2 DM), gestational diabetes (GDM), impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG). The current study investigated GDM, which is common and is characterised by a transient abnormality of glucose intolerance during pregnancy (Seshiah et al., 2008), and which resolves after pregnancy. The underlying causes of diabetes differ by type, and they include genetics, environmental factors, history of

gestational diabetes, excess weight, and sedentary lifestyle (Irving et al., 2008). The focus of this study was gestational diabetes mellitus (GDM).

2.2. Prevalence of gestational diabetes mellitus (gdm)

A greater proportion of women of reproductive age are now overweight or obese. Gestational diabetes mellitus and maternal obesity are associated with long-term adverse consequences in the offspring and subsequent generations and are important drivers of the escalating global burden of diabetes and cardiovascular disease (Ma, Chan, Tam, Hanson & Gluckman, 2013). During pregnancy, women with gestational diabetes display metabolic abnormalities similar to those of people with type 2 diabetes mellitus, such as insulin resistance and reduced β-cell compensation for that resistance. After delivery, most of these women return to a euglycemic state, but they are at increased risk for overt type 2 diabetes in the future (Feig, Zinman, Wang & Hux, 2008).

2.2.1. Global prevalence of GDM

The prevalence of GDM varies depending on the population and diagnostic criteria used (Mwanri, Kinabo, Ramaiya & Feskens, 2015). According to Adam and Rheeder (2017), variation of diagnostic criteria can result in discrepancies in prevalence. The prevalence of GDM is increasing all over the world (Bener et al., 2011). Global prevalence was reported by Dudhwadkar & Fonseca (2016) to range from 1.4 to 14%, with variations according to racial and ethnic groups. An indication that the prevalence of GDM is increasing is the fact that 2 to 17.8% of pregnant women in the United State of America (USA), develop gestational diabetes (Negrato, Mattar & Gomes, 2012).

The prevalence of GDM in North America, Europe and Australia was reported by Stewart & Malhotra (2015) to range from 3% - 5%. The data from the ASEAN Federation of Endocrine Societies Study Groups on Diabetes in Pregnancy (ASGODIP) highlighted the fact that, in the Southeast Asian region, GDM prevalence was reported to be 7.6% for low

risk pregnancies and 31.5% for high risk pregnancies (Lim-UY, Cunanan & Andag-Silva, 2010).

With regards to the various ethnic groups, one study reported that Indian women had a high prevalence of diabetes and that their relative risk of developing GDM is 11.3 times more than the relative risk of white women developing the disease (Dudhwadkar & Fonseca, 2016). In addition, the abovementioned finding resonates with a study conducted in the Jammu district of India which found that GDM prevalence was reported to be 6.7% in rural women (Dudhwadkar & Fonseca, 2016). The global prevalence of GDM amongst pregnant women of age group 20-49 years was estimated to be 16.9% and the disease was found to have affected 21.4 million live births (Guariguata, Linnenkamp, Beagley, Whiting & Cho, 2014). In 2013 it was reported that more than 90% of cases occurred in low- and middle-income countries (Mwanri et al., 2015).

2.2.2. Prevalence of GDM in Africa

In Sub-Saharan Africa, it was reported that the prevalence of GDM ranged from 0% - 9%, with Tanzania's GDM prevalence being 13.9% in high-risk women (Mwanri et al., 2015). The prevalence of GDM in rural Ethiopia was found to be 3.7% (Mwanri et al., 2013). An increase in prevalence of GDM in Africa has been observed (Ferrara, 2007).

Among high risk pregnant women in Ethiopia, GDM prevalence was reported to be 3.7% while the prevalence in Morocco was 7.7% (Macaulay et al., 2014). Moreover, GDM prevalence in Mozambique was reported to be 11% amongst women who experienced late foetal deaths and 7.3% among women who had delivered live newborns, while in Nigeria GDM prevalence was found to be 6.2%, and 2.5% after the investigators used their own diagnostic criteria (Macaulay et al., 2014). A prevalence of 0% was determined in Tanzania, which was likely due to the small sample size used in the study (Macaulay et al., 2014).

The variation of GDM prevalence across African countries has been attributed to the diagnostic test or diagnostic criteria used (Dias, Pheiffer, Rheeder & Adam, 2019). The oral glucose tolerance test (OGTT) was used in Ethiopia and South Africa, whereas in Morocco, and in some studies conducted in Nigeria, Carpenter and Coustan's criteria to diagnose gestational diabetes were used (Macaulay et al., 2014). Furthermore, a systematic review of gestational diabetes in Africa highlighted the fact that the prevalence of GDM increased when Carpenter and Coustan's criteria for the diagnosis of GDM was used, as compared to the results obtained when using the OGTT diagnostic test. The most common method for diagnosing GDM in Africa was using the OGTT, with reference ranges as stipulated by the WHO 1985 or 1999 diagnostic criteria (Macaulay et al., 2014).

It has been reported that, in Sub-Saharan Africa, the increase in prevalence of GDM was likely caused by lifestyle changes associated with urbanisation and dietary change which can subsequently lead to overweight and obesity (Mwanri et al., 2015). This finding resonates with the finding of the study conducted by Macaulay et al. (2014), which showed that the movement towards more western diets, which encompass increased consumption of fats, sugar and refined carbohydrates, in low-middle-income-countries (LMICs), results in a rapid increase in overweight, obesity and non-communicable diseases such as diabetes.

2.2.3. Prevalence of GDM in South Africa

In a South African study, the prevalence of GDM a Limpopo rural community was found to be 8.8% (Mwanri et al., 2013). The predominant practice in South Africa to diagnose GDM was found to be risk factor-based selective screening (Adams & Rheeder, 2017). This practice involves a health practitioner identifying pregnant women at risk of GDM, and the screening these women for GDM. Furthermore, Adams and Rheeder (2017) found that the risk factor-based criterion had poor sensitivity and specificity. In most LMICs, and in a few of high-income

countries, women were selected for screening only when they meet certain GDM risk-associated criteria (Macaulay et al., 2014).

The screening for GDM in South African populations varies across the provinces due to disparities in protocols. It was reported that in Pretoria, the International Association of Diabetes in Pregnancy Study Groups (IADPSG) criteria is used; while Johannesburg uses the National Institute for Health and Care Excellence (NICE) criteria and the Western Cape uses the abovementioned criteria as well as Western Cape criteria which were developed provincially (Adam & Rheeder, 2017).

If universal screening and NICE criteria are used together, the prevalence of GDM was found to be 17.0%; while GDM prevalence was found to be 25.8% when using universal screening, together with the IADPSG criteria, the (Adam & Rheeder, 2017).

2.3. RISK FACTORS FOR GESTATIONAL DIABETES MELLITUS

GDM was associated with various risk factors, some of them modifiable, while others are not modifiable. These risk factors are important catalysts for the development of GDM. Modifiable and non-modifiable risk factors of GDM are described below.

2.3.1. Modifiable risk factors of GDM

Physical inactivity, psychosocial stress during pregnancy, gestational weight gain, the use of hormonal contraceptives, a history of pre-eclampsia and unexplained recurrent parity have been proposed as potential modifiable risk factors for GDM (Chasan-Taber, Fortner, Gollenberg, Buonnaccorsi, Dole & Markenson, 2010).

2.3.1.1. Physical inactivity

Physical activity has been associated with a reduced risk of excessive weight gain, insulin resistance and type 2 Diabetes Mellitus (Dode & dos Santos, 2009). In addition, physical activity plays a vital role in improving glucose metabolism. A study done by Seshiah et al (2008) found that an

increased prevalence of GDM was observed in less physically active women. Women who participated in high household activity and exercise in mid-pregnancy were found to have a reduced risk of developing GDM, compared to women who were less physically active (Chasan-Taber et al., 2010).

2.3.1.2. Psychological stress

Pregnancy is characterised by hormonal and physical changes in a woman and this may result in psychological stress and anxiety in some women who are experiencing these changes. Psychosocial stress is a potentially modifiable risk factor which is common among pregnant women, particularly those diagnosed with GDM (Kubo, Ferrara, Brown, Ehrlich, Tsai, Quesenberry, Crites & Hedderson, 2017). High or low food consumption can be used as a mechanism to cope with stress and which may subsequently result in obesity or malnutrition during pregnancy (Parlee & MacDouglad, 2014).

2.3.1.3. Gestational weight gain

Gestational weigh gain (GWG) is associated with increased body-mass index (BMI), which is a risk factor for GDM. GDM is commonly observed in obese women and can be an important confounder of an association with birth weight (Bener et al., 2011). In addition, a study had shown that overweight and obese women were more likely to develop GDM (Bener et al., 2011).

Hedderson, Gunderson and Ferrara (2010) reported that high rates of GWG, particularly in early pregnancy, may increase a woman's risk of being diagnosed with GDM. According to Rajput, Yadav, Nanda and Rajput (2013), hyperglycaemia during pregnancy was found to be a risk factor for excess GWG.

2.3.1.4. Other modifiable risk factors for GDM

A study conducted Lim-UY et al. (2010) found that hormonal contraceptive use was structurally related to increase level of testosterone, which may produce androgenic side effects. The effects of androgens can lead to reduced glucose tolerance and weight gain, which makes women taking contraceptive pills more vulnerable to metabolic stress induced by placental hormones during late pregnancy (Lim-UY et al., 2010). A strong correlation between pre-eclampsia and the occurrence of GDM during a second pregnancy was found, and attributed to the fact that both pre-eclampsia and GDM have a pathophysiology in common, which is characterised by systemic endothelial dysfunction (Lee, Ouh, Ahn, Hong, Oh, Kim & Cho, 2017).

Pre-eclampsia has been linked to the degree of glucose intolerance (Lee et al, 2017), and it was well established that women who have had a pregnancy complicated by preeclampsia (PE) are at increased risk of hypertension, ischemic heart disease, and premature cardiovascular death, compared with women with normotensive pregnancies (Smith, Walker, Liu, Wen, Swansburg, Ramshaw, White, Roddy & Hladunewich, 2009). According to Dobjanschi and Miulescu (2015), multiparity was one of the pregnancy complications occurring during or prior pregnancy which was frequently associated with the occurrence of GDM in subsequent pregnancies.

2.3.2. Non-modifiable risk factors of GDM

Race, maternal age, family history of diabetes and hypertension has been proposed as non-modifiable risk factors of GDM (Chasan-Taber, Fortner, Gollenberg, Buonnaccorsi, Dole & Markenson, 2010).

2.3.1.5. Race

It was reported that Indian women had high prevalence rates of diabetes, and their relative risk of developing GDM was high, compared to white women (Dudhwadkar & Fanseca, 2016). According to Lim-UY et al (2010), Asians were found to have high prevalence rates of GDM. A study conducted among Hispanic women found that Hispanic women have a two

to four times greater risk of developing GDM, compared to white women (Chasan-Taber et al., 2010).

2.3.1.6. Maternal age

A high prevalence of GDM was found in women in the age group of 30-34 years (Seshiah, Balaji, Balaji, Paneerselvam, Arthi, Thamizharasi & Datta, 2008). The increased risk of GDM for pregnant women under 20 years old was 0.15%, and 4.2% for pregnant women over 30 years old (Dobjanschi & Miulescu, 2015).

2.3.1.7. Family history of diabetes

A significant association has been found between family history of diabetes and occurrence of GDM amongst pregnant women (Seshiah et al., 2008). GDM was found to have a recognised familial association. This means that the causes of the aggregation of 1st degree relatives with a history of other forms of diabetes or GDM were determined by genetic factors of susceptibility, epigenetic influences and shared environmental influences (Dobjanschi & Miulescu, 2015).

2.3.1.8. Hypertension

The risk of developing GDM has been found to increase in women with prehypertension and escalates among women with hypertension during early pregnancy (Hedderson & Ferrara, 2008). Furthermore, women with hypertension are known to be at risk of developing GDM, i.e. obese or overweight women during the early trimester had threefold increased risk of developing GDM (Hedderson & Ferrara, 2008). GDM was found to be positively associated with a family history of hypertension (Rajput, Yadav, Nanda & Rajput, 2013).

2.3.1.9. Socio-demographic location

It has been found that GDM is more prevalent in women living in urban areas than in women living in rural areas. This is attributed to the notion that the low prevalence of GDM in rural areas might be as a result of the adoption of less mechanised agriculture-based lifestyles (Seshiah et al.,

2008). The findings of this study finding resonate with the findings of a study done by Bener et al. (2011) that GDM women were more likely to come from a lower economic status.

2.4. Maternal and infant outcomes associated with GDM

Gestational diabetes mellitus has short- and long-term outcomes for both the mother and infant. GDM can cause perinatal mortality or morbidity, where the infant will be vulnerable to health risks outcomes, and maternal morbidity can occur.

2.4.1. Maternal health outcomes associated with GDM

A study conducted by Bener et al. (2011) found that women with GDM were at greater risk of developing pregnancy-induced hypertension, pre-eclampsia, antepartum haemorrhage, preterm labour, and premature rupture of membranes which, consequently, led to early delivery or the performance of a caesarean section than women with normal blood glucose levels (Bener et al., 2011).

It was also established that elevated liver enzymes, low platelets (HELLP) syndrome, hypoglycaemia, renal insufficiency and retinopathy deteriorates in women with pre-existing diabetes or pre-gestational diabetes mellitus (Negrato et al., 2012). Maternal obesity was found to be a confounding factor associated with the need for caesarean section delivery and pre-eclampsia (Stewart & Malhotra, 2015).

2.4.2. Infant health outcomes associated with GDM

According to Bener et al (2011), infants born to mothers with GDM are at risk of developing early onset of type 2 diabetes mellitus, as well as childhood obesity. This finding resonates with the findings of Dudhwadkar and Fonseca (2016), who reported that, in a GDM pregnancy, both the mother and child are at risk of developing future diabetes. Moreover, 35-60% of women with GDM develop type 2 diabetes within 10 years of their pregnancy (Varghese et al, 2012). Mothers who have poor glycaemic control have an increased risk of poor perinatal outcomes, which include hypoglycaemia and perinatal distress,

and these two outcomes were found to be the reason for neonatal intensive care unit (NICU) admission amongst infants born to a mother with GDM (Devi, Narayana & Srinivasan, 2017).

The impact of increased maternal insulin on the foetus was found to result in intrauterine foetal death and perinatal asphyxia which resulted from foetal hyperinsulinism. Foetal hyperinsulinism increases tissue oxygen consumption which leads to foetal hypoxia and, subsequently, and increase in the risk of intrauterine death (Stewart & Malhotra, 2015).

Other foetal outcomes associated with GDM consist of large for gestational age (weight, height or head circumference that lies above 90th percentile for that gestational age) and macrosomia (Varghese et al, 2012). Some infants develop cardiac defects (Devi et al., 2017), which was found to be the most common defect associated with GDM. Birth traumas, such as shoulder dystocia, brachial plexus injury, fracture of the clavicle and humerus, were found be GDM-infant outcomes (Devi et al., 2017).

2.5. Public health interventions to prevent and control GDM

An increasing number of healthcare interventions aimed at controlling GDM were found in China, however, there were no interventions aimed at preventing GDM (Xu, He, Dainelli, Yu, Detzel, Silva-Zolezzi, Volger & Fang et al., 2017). A study conducted in China showed that diet, western medication and combined interventions were the most effective interventions (Xu et al., 2017). Furthermore, diet and western medications were found to be effective, although dietary interventions did not have a statistically significant effect on pre-eclampsia (Xu et al., 2017). Furthermore, diet and exercise interventions were found to be less common in China, compared to interventions in Western countries (Xu et al., 2017).

According to Wang, Ma and Yang (2015), lifestyle interventions provided to women during the first trimester resulted in a reduction of the GMD rate. Moderate exercise was found to be helpful during pregnancy, as it helped with metabolism. Furthermore, physical activity during early pregnancy was reported

to reduce the positive rate of GDM (Wang, Ma & Yang, 2015). One study has shown that GDM can be prevented in high-risk pregnant women by applying lifestyle interventions (Koivusalo et al., 2016).

3. CHAPTER 3: RESEARCH METHODOLOGY

3.1. Introduction

Research methodology is a systematic process and a theoretical analysis of the methods applied during a research study. In this chapter, research method; research design; sampling; data collection; data analysis; and the internal and external validity of the study will be discussed in detail.

3.2. Research method

A quantitative research method was used to investigate the prevalence, risk factors, maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo Province. Quantitative research focuses on gathering numerical data and generalising it across groups of people or explains a particular phenomenon (Babbie, 2010). The advantage of using a quantitative research approach is the fact that it involves a large number of participants. This enhances generalisation of the results and means that the research can be replicated, analysed and compared to similar studies. The outcomes of quantitative research provide summaries of data that support generalisations about the phenomenon under study, and this allows for greater accuracy and objectivity of the research findings (Babbie, 2010).

Limitations of using the quantitative method include missing contextual detail; the fact that research findings provide less detail on behaviour, attitudes and motivation; the responses of the participants do not necessarily reflect the subject; and the results are limited as they provide numerical descriptions rather than a detailed narrative and generally provide less elaboration on human perception (Babbie, 2010).

3.3. Research design

Research design is a framework of methods and techniques chosen by a researcher to combine various components of research in a reasonably logical manner so that the research problem is efficiently handled.

The research design that was used to study the prevalence, risk factors, maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo province was a cross-sectional descriptive study design. This study design allowed for the examination of the relationships between diseases or other health-related characteristics and other variables of interest, as they exist in a defined population at a particular point in time (Detels et al., 2015).

3.3.1. Study site

There are 27 clinics in the Greater Giyani Area and only three clinics were chosen as study sites.The study was conducted in three (3) health facilities, namely, the Nkhensani Hospital, the Giyani Healthcare Centre and the Nkhensani Hospital Gateway Clinic. These three clinics were chosen as they serve as referral centres in Greater Giyani and their monthly statistics for Antenatal clinic visit (ANC) is high. The three health facilities are described in detail below:

3.3.1.1. Nkhensani Hospital

The Nkhensani Hospital, which is a level 1 district hospital, provides comprehensive and integrated health care to the Greater Giyani Area. The hospital offers allied health services, clinical services, nursing services, forensic services, trauma counselling services and male circumcision services. In addition, the hospital has 250 beds available, a day clinic, three theatres, and 24 hours emergency services. There are no Intensive-care unit (ICU) beds, thus, patients who require ICU specialised care are referred to either the Mankweng or Polokwane hospitals.

3.3.1.2. Giyani Healthcare Centre

The Giyani Healthcare Centre is a community clinic located 2.5 km from the Nkhensani Hospital and provides HIV and TB-related treatment services, HIV counselling and testing (HCT), medical male circumcision (MMC), treatment for opportunistic infections and maternity services for pregnant women, including short-term admissions for a maximum of 6 hours post-delivery. The health centre refers patients to the Nkhensani

Hospital for further medical treatment and operates 24 hours a day, 7 days a week.

3.3.1.3. Nkhensani Hospital Gateway Clinic

The Nkhensani Hospital Gateway Clinic is a health clinic situated at the gate of the Nkhensani Hospital. The clinic renders HIV and TB services, HIV counselling and maternity services.

3.4. Study Population

The population comprised of all individuals that were of interest to the researcher (Cozby & Bates, 2015). The population in this study referred to all pregnant women attending antenatal clinics at Nkhensani Hospital, Giyani Healthcare Centre and Nkhensani Hospital Gateway Clinic. The population size was obtained from the average number of pregnant women attending antenatal clinics at the three health facilities per month.

At Nkhensani Hospital the average number of pregnant women seen at antenatal clinic was reported to be 360 patients, the Giyani Healthcare Centre reported 230 visits and Nkhensani Gateway Clinic reported 90 visits per month. Thus, the population size in this study was the sum of the number of pregnant women attending antenatal clinic visits at all three health facilities in a month, which is equal to 680 pregnant women.

Outlined below is a description of the study sites where the study population was drawn from:

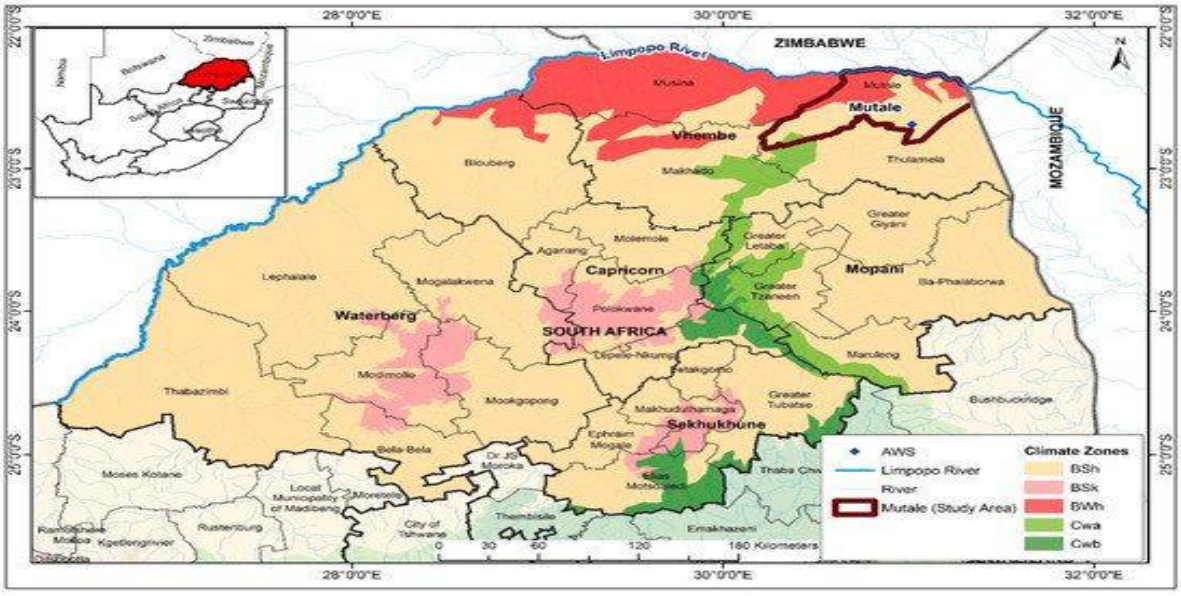

Figure 1: Area map of research site
Retrieved from Adeola, Botai, Rautenbach, Adisa, Ncongwane, Botai and Adebayo-Ojo (2017)

3.4.1. Sampling

Sampling is the process of selecting a sample from a group or population which becomes the foundation for estimating and predicting a particular the outcome of that population. The strengths of sampling are that it is convenient; cost effective; allows for generalisation to be made within a relatively small proportion of the study and there is accuracy of data as a sample represents population. The limitations of employing sampling in the research process are that there are chances of bias; and the researcher must have informed knowledge of sampling.

3.4.1.1. Sampling of study sites:

Convenience sampling of the study sites was used in this study. This is a type of non-probability or non-random sampling, where members of target population that meet certain practical criteria, such as easy accessibility, geographical proximity, availability at a given time or the willingness to participate, are included for the purpose of the study (Etikan et al., 2016).

The study sites were convenient for the researcher as data collection was less expensive and time efficient. In addition, the study participants were easily accessible to the researcher as they were attending antenatal clinics

at the study sites which were in close proximity to where the researcher was based.

3.4.1.2 Ethical issues related to sampling

A researcher who avoids approaching certain groups (e.g. socially marginalized individuals, people who speak little English, and disabled people), can cause the research to be excessively narrow, arguably unethically narrow. In this research, every pregnant woman was considered for participation in the study, regardless of their socioeconomic status, occupation, or education level. This highlights the fact that, in this study, every woman attending antenatal clinics at the three health facilities had an equal chance of being chosen to participate in the study.

During the determination of the sample size, the sample size can become an ethical issue if the sample is over-sized and under-sized. Over-sample size occurs when there are more people in the sample that needed in order to help address the research question. Whereas under-sample size occurs when there are insufficient individuals in the sample. Furthermore, small sample size affects the generalization of research findings. In this study, the sample size was representative of the study population and the inclusion of a 10% non-response rate was done to ensure that the non-response rate of participants did not result in an under-size sample, thereby affecting the generalization of the findings.

3.4.2. Study sample

A sample refers to a sub-unit drawn from the study population. How the sample size was determined and sample procedure for the study participants is described below:

3.4.2.1.Sampling size determination

Sample size determination refers to mathematical process of deciding, before a study begins, how many subjects should be studied (A Dictionary of Epidemiology, 2014). The sample size in this study was estimated using

a Cochran's formula (when a variable of interest is a dichotomous variable), as GDM statistics from the three study sites were not available. GDM prevalence in rural communities in the Limpopo Province was found by Mwanri et al. (2013) to be 8.8%.

The sample size was calculated as follows:

Where,

n is the sample size
Z is the 95% confidence interval
p is the prevalence of GDM (8.8%)
d is the sampling error (5%)

$$n = \frac{\left(Z\ 1-\frac{n}{2}\right)^2 pq}{d^2}$$

$$=\frac{(1.96)^2(0.088)(1-0.088)}{(0.05)^2}$$

=124

∴ 10% was added to the sample size, i.e. 124 + 10% of 124 = 136.4. The addition of 10% to the sample size was to allow for a non-response rate among the participants in instances where, for example, the participants provided incomplete information on the questionnaire, refused to complete the questionnaire or withdrew from participating in the study. Response rate refers to the number of completed or returned survey instruments (questionnaires or interviews) divided by the total number of persons who would have been surveyed if all had participated (A Dictionary of Epidemiology, 2014).

Therefore, the sample size in this study was **136.4.**

Below is the breakdown of total sample size (number of pregnant women) at each study site:

Population size (P) = Sum of pregnant *women attending antenatal clinic visit at all three health facilities in a month.*

C *= average number of pregnant women seen during antenatal clinic visit*

Study sample size *= 136.4*

Nkhensani Hospital	**Giyani Health Centre**	**Nkhensani Gateway Clinic**
$\frac{C}{P}$ × study sample size : $\frac{360}{680}$ × 136.4 : 72.2 pregnant women.	$\frac{C}{P}$ × study sample size : $\frac{230}{680}$ × 36.4 : 46 pregnant women	$\frac{C}{P}$ × study sample size : $\frac{90}{680}$ × 136.4 : 18 pregnant women.

3.4.2.2.Sampling procedure

Research participants were sampled using a random sampling method. Random sampling is a method where each individual has an equal probability of being selected from the population, ensuring that the sample will be representative of the population (Creswell, 2013). A random sampling procedure was chosen as it maximises external validity and optimise the sample size. In this study, the sample population was all pregnant women attending antenatal clinics at the study sites.

To randomly sample the participants, the researcher utilised a lottery method, where each pregnant woman was assigned a unique number, i.e. 1, 2, 3, 4, and so on. Each number assigned was placed in a bowl and thoroughly mixed together. The researcher closed her eyes and then picked up two numbers from the bowl. Thereafter, pregnant women were assigned the number that had been picked up by the researcher were then chosen as participants in the study. Questionnaires were numbered on top of the page with the participant number, i.e. participant 1, participant 2, participant 3. The sample size was distributed proportionally to the average number of women attending antenatal clinics across the three health facilities.

3.4.2.3 Recruitment of sample and gaining access to the study site

Recruitment of study participants commenced after ethical clearance was granted to researcher by University of Limpopo's Turfloop Research Ethics Committee (TREC). Access to the study site was gained by sending relevant documentation to the Department of Health and Mopani District Health Office in Limpopo, requesting permission to access the study sites. Access to the study participants was requested after the Department of Health in Limpopo granted permission for the study to be conducted at the three health facilities.

The study sample was recruited on a Wednesday during antenatal clinic visits; and the pregnant women were given brief description of study before randomization of sample was done. Thereafter, those who agreed to participate in the study were randomly assigned and later given informed consent forms to sign, prior to completing a questionnaire.

3.4.3 Inclusion Criteria

An inclusion criterion identifies a study population in a consistent, reliable, uniform and objective manner (Rakesh, 2016). In this study, the inclusion criteria included all pregnant women attending antenatal clinic visits at the Nkhensani Hospital, the Giyani Healthcare Centre and the Nkhensani Gateway Clinic.

3.4.4 Exclusion Criteria

Exclusion criteria include participant factors or characteristics that make the recruited population not qualified to participate in the study (Rakesh, 2016). In this study, there were no exclusion criteria.

3.5 Data collection

Data collection is the process of gathering information in a meaningful and reliable manner (A Dictionary of Epidemiology, 2014).

3.5.1 Development and testing of the data collection instrument

A questionnaire with open and closed-ended questions adapted from Michigan Diabetes Research and Training Center DCP 2.0 (The University of Michigan, 1998) was used to collect data (**See appendices E to G**). Additional questions for the questionnaire and data entry form were adapted from a study conducted in India by Varghese et al (2012). A questionnaire was chosen as the data gathering tool as information was collected from a large sample within short period of time. The use of this tool is cost effective and the results obtained can easily be arranged and analysed.

The questionnaire was translated from English to Xitsonga as this is the predominant language of the Greater Giyani Area. One of the limitations of using a questionnaire is the fact that there might be misinterpretation of the questions by participants and that their responses may be based on their interpretation of the question, which would subsequently, compromises the internal validity of the tool. There might be bias when developing questionnaires if questions are based on assumptions of what causes GDM.

The data entry form was adapted from the study conducted by Varghese et al (2012). The entry form was used to collect data from participants' medical files and there was no direct interaction between the researcher and the research participants. The data entry form had sections which the researcher completed using the participant's medical file (**See Appendice G**). The limitation of the method lies with the fact that some of the required information was missing from the medical file. e.g. insufficient recording of progress notes.

3.5.1.1 Testing of data collection instrument

With regards to testing the testing of the data collection instrument, a pilot study was conducted to test the questionnaire before it was administered to the study participants. A pilot study is a trial run of research conducted in preparation for a full scale of study so as to pre-test the research instrument (Dikko, 2016). This allowed for questions to the rephrased, if

necessary, to ensure that the questionnaire measured what it was intended to measure.

3.5.1.2 Characteristics of the data collection instrument

A questionnaire is an instrument consisting of a series of questions and prompts developed with the purpose of gathering information from participants. The questionnaire was clear and easy to comprehend; questions were structured in a logical manner – from general to more specific questions; made use of open- and closed-ended questions; and used a large font, with sufficient spacing between questions. In addition, the questionnaire was kept short as possible and the directions provided were clear and complete. Questions were structured in a way that sought to obtain specific information only, e.g., asking two questions in one question was avoided. The measuring instrument was designed to collect only information which was to be used as data for analysis.

3.5.2 Data collection approach and method

The data collection approach which was used in this study was the structured approach. The structured approach is commonly used in quantitative research when; data is collected in the same way, the sample is large, variables which need to be measured are known, there is a need to show results numerically and there is a need to make comparisons across different sites or interventions. In this study, data was collected the same way using a structured questionnaire.

The obstructive method was used in this study to collect data as the information was directly obtained from the participants through the employment of questionnaires. This method also includes interviews, surveys and focus groups. In obstructive data collection, the participants are aware that they are being studied, which may influence their response or behaviour.

3.5.2.1 GDM Screening process

The screening process which was supposed to be undertaken in this study was to ascertain whether a woman was pregnant or not. Based on the aim

and objectives of this study, we could not select only pregnant women with diabetes because the prevalence of diabetes would have been difficult to determine. Thus, the study sample included pregnant women, and the clinic's standard operating procedure was used to determine who had diabetes amongst our study participants. In other words, the researcher relied on the clinic/ hospital results for pregnant women who had been screened for diabetes to determine the prevalence of GDM.

The OGTT is used to diagnose GDM at the hospital or clinics in the study area. This entails a patient being given 75g 2-hour oral glucose and the test is scheduled to take place between 24 and 28 weeks of gestation. When the 2-hour period has elapsed after the patient has been given oral glucose, glycated haemoglobin (HbAlc) is measured. If the patient's random glucose level is found to be >11.1 mmol/L or HbAlc level >6.5%, the patient is referred to the local hospital for further management of DM (Adam & Rheeder, 2017).

Risk assessment is also undertaken during first prenatal visit. This assessment includes the screening pregnant women who present with clinic characteristics that are consistent with high risk of GDM, i.e. obesity, a history of GDM, a family history of diabetes, or glycosuria (excretion of glucose into the urine). Targeting women at increased risk based on a risk assessment using antenatal risk factors might reduce the number of missed cases. Thereafter, the validity of GDM cases will be minimally compromised.

3.5.2.2 Case definition for GDM as diagnosed at the health facilities:

Case definition is defined as a set of criteria (not necessarily diagnostic criteria) that must be fulfilled in order to identify a person as representing a case of a particular disease or condition (A Dictionary of Epidemiology, 2014). GDM is the degree of glucose intolerance with first recognition during pregnancy. GDM only occurs during pregnancy. Factors which put the pregnant women at risk of being diagnosed with, or developing, diabetes during pregnancy include obesity; advanced maternal age; a

family history of GDM; physical inactivity; poor diet; diabetes in previous pregnancy; or increased body mass index of ≥ 25 kg/m². Gestational diabetes is usually tested between 24 and 28 weeks of pregnancy. However, if it is noted that the patient has an increased chance of developing gestational diabetes, she may be tested for diabetes during first visit.

At the selected three study sites, they are using National Department of Health Guideline for maternity care in South Africa: A manual for clinics, community health centres and district hospitals (**See appendice S**). There is lack of agreement regarding best screening method. The guideline recommended that for the convenience of both patient and practitioner, screening method chosen should be the one which can be done at clinic/hospital on the same day that the woman is seen, and one which uses glucometer readings rather than laboratory tests (National Department of Health, 2015).

3.5.3 Data collection process

Data was collected from multiple sources as outlined by Table 1 below:

Data source	Data method	Data analysis
1. Pregnant women attending antenatal clinic visits.	Questionnaire.	Microsoft Excel spreadsheet.
2. Patient's hospital/clinic file.	Data entry form.	Microsoft Excel spreadsheet.
3. Documents on maternal and infant health, i.e. guidelines/policies/regulations.	Reading documents.	Text from relevant document.

3.5.4 Ethical considerations related to data collection

3.5.4.1 Informed consent

Informed consent is voluntary consent given by a subject or a responsible proxy (e.g., a parent) for participation in a study, immunization program, or treatment regimen, after being informed of the purpose, methods, procedures, potential benefits and potential harms, and, when relevant, the degree of uncertainty about the outcomes (A Dictionary of epidemiology, 2014). Participants were handed an information letter informing them of the study, as well as a consent form to sign, before participation in the study. For participants who were under 18 years, their parents/guardians were informed of the study and they had to consent to their children's participation in the study. Furthermore, the child had to sign a consent form indicating their willingness to participate in the study. (**See appendice R**).

The researcher explained to the participants that their participation was voluntary and that they could withdraw from the study at any time if they wished to do so, without any penalties (autonomy) to them. The consent form was also given to the Nkhensani Hospital CEO, Giyani Healthcare Centre Manager and Nkhensani Hospital Gateway Clinic manager to obtain their consent for the study to be conducted at their particular institution. Consent was also sought from the district office.

3.5.4.2 Measures to protect participants' confidentiality, privacy and anonymity

Medical research must protect the life, health, dignity, integrity, privacy and confidentiality of research participants' personal information (Helsinki Declaration Fortaleza Brazil, 2013). The researcher protected and respected participants' privacy, and rights to confidentiality and avoided intrusion into their personal affairs. Information provided by the participants was kept confidential, and securely stored, and only the researcher, the researcher's supervisor and co-supervisor had access to the data storage system, i.e. the hard drive, compact disc and hard copies of the data. The participants' identities were not revealed during the research report writing or presentation. In order to maintain anonymity, participants were not requested to write their

names or identity numbers on the questionnaire. Questionnaires were being numbered as participant 1, participant 2…

3.5.4.3 Minimisation of risks

There were no foreseeable risks to the participants as no samples, such as blood, were drawn from participants. There were no participants who showed signs of emotional distress.

3.5.4.4 Compensation for Research-related Costs and Inconvenience

Participants were not paid for participation in the study.

3.6 Data analysis

Data analysis is an on-going process during research and involves analysing participant information through using analysis guidelines or software tools (Creswell, 2013). Data was captured in a Microsoft Excel spread sheet and then transferred to the Statistical Package for Social Sciences (SPSS) software programme version No. 22 (2013) for analysis. Assistance in analysing the results was sought from the statistician at the University of Limpopo. Categorical variables were presented as percentages and frequencies, while continuous variables were presented as mean, median and standard deviation. Furthermore, comparison of categorical variables was done using a Chi-Squared test, whereas continuous variables were compared using a t-test. P-value of <0.05 was considered significant.

Univariate regression analysis was done to determine the contributory factors to GDM. Univariate regression analysis is a type of regression analysis used to distinguish the distribution of a dependent variable from the distribution of several independent variables. A dependent variable is a variable which depends on the independent variables and is an outcome or result of the influence of the independent variable. An independent variable is defined as a variable which probably causes, influences or affects outcomes (Creswell, 2013).

The dependent variable was GDM and the independent variables were modifiable risk factors of GDM, i.e., physical inactivity; psychological stress; gestational weight

gain; hormonal contraceptive use; history of pre-eclampsia and unexplained recurrent parity, as well as the non-modifiable risk factors of GDM, i.e., race; maternal age; family history of diabetes; hypertension and socio-demographic location.

3.7 Internal and external validity of the study

Validity is when the instrument is able to produce results that reflect the purpose it was initially designed to measure (Bastos, Duquia, Ganzalez-Chica, Mesa & Bonamigo, 2014).

3.7.1 Internal validity

Internal validity is the degree to which a study is free from bias or systematic errors (A Dictionary of Epidemiology, 2014). To ensure internal validity, the questionnaire was checked by the researcher's supervisor to ensure the validity of this data collection tool. In addition, a pilot study was conducted to test the questionnaire questions so that questions could the rephrased, if necessary, to ensure that the questionnaire measured what they intended to measure.

3.7.2 External validity

This is the extent to which the results of a study can be generalised to other populations and settings (Cozby & Bates, 2015). The sample size in this study afforded the data collection tool good external validity, as the size was representative of the women with GDM in the population.

3.6 CONCLUSION

The next chapter will present research findings.

4 CHAPTER 4: PRESENTATION AND INTERPRETATION OF THE RESULTS

4.1 Introduction

This chapter describes the analysis of the data and the interpretation of the research findings, which were guided by the research question posed in the study. The data was analysed to determine the prevalence of, and risk factors associated with, gestational diabetes mellitus; as well as the socio-demographic characteristics of pregnant women with gestational diabetes mellitus. Data was obtained through the administration of a questionnaire to pregnant women who were attending antenatal clinic visits at Nkhensani Hospital; Nkhensani Gateway Clinic and Giyani Health Centre. The questionnaire was completed by 101 pregnant women (n=101) out of the sample size of 136 pregnant women. Therefore, the response rate was 74%. Thus, 101 (74%) pregnant women participated in the study.

There were pregnant women who refused to participate in this study, mainly citing the fact that they were not interested in taking part. This contributed to the low response rate observed in this study. The questionnaire comprised of 18 questions, both open-ended and closed-ended questions. The questionnaire questions consisted of demographic data such as age; marital status; level of education; employment status; home language; ethnicity. In addition, questions were posed relating to the past obstetric history of the participants; any family history of diabetes; gravidity/parity; weight; height and treatment received. In addition to the questionnaire, a data entry form was employed to capture participants' medical information from their maternity case record booklet. The data entry form sought to capture the participants' gestational age; weight; height; past obstetric history; tests used to diagnose medical conditions during pregnancy; test results; and pregnancy complications, as well as treatment currently being received.

This chapter describes how the data was managed and analysed; outlines the results; as well as provides interpretations of the research data findings.

4.2 Data management and analysis

After the data collection process was finalised, the completed questionnaires were stored in files. The information captured on a Microsoft Excel spreadsheet was stored on a compact disc for confidentiality and privacy reasons. Descriptive statistical analysis was undertaken using the Statistical Package for Social Sciences (SPSS) programme in order to identify frequencies and percentages of answers to the questions in the questionnaire. The statistical significance of the relationships between the selected variables was determined using the t-test. The level of significance was set at 0.05.

4.3 Research results

4.3.1 Socio-demographic characteristics of pregnant women with diabetes

One hundred-thirty-six (136) pregnant women were asked to participate in this study and only one hundred one (74%) pregnant women consented to participate in the study. Of these women, seventy-two (71.4%) pregnant women attended their 1st ANC visit after 8 weeks of gestation. Nine(9) pregnant women (8.6%) attended their 1st ANC visit at or less than 4 weeks of gestation (**Figure 4.1**).

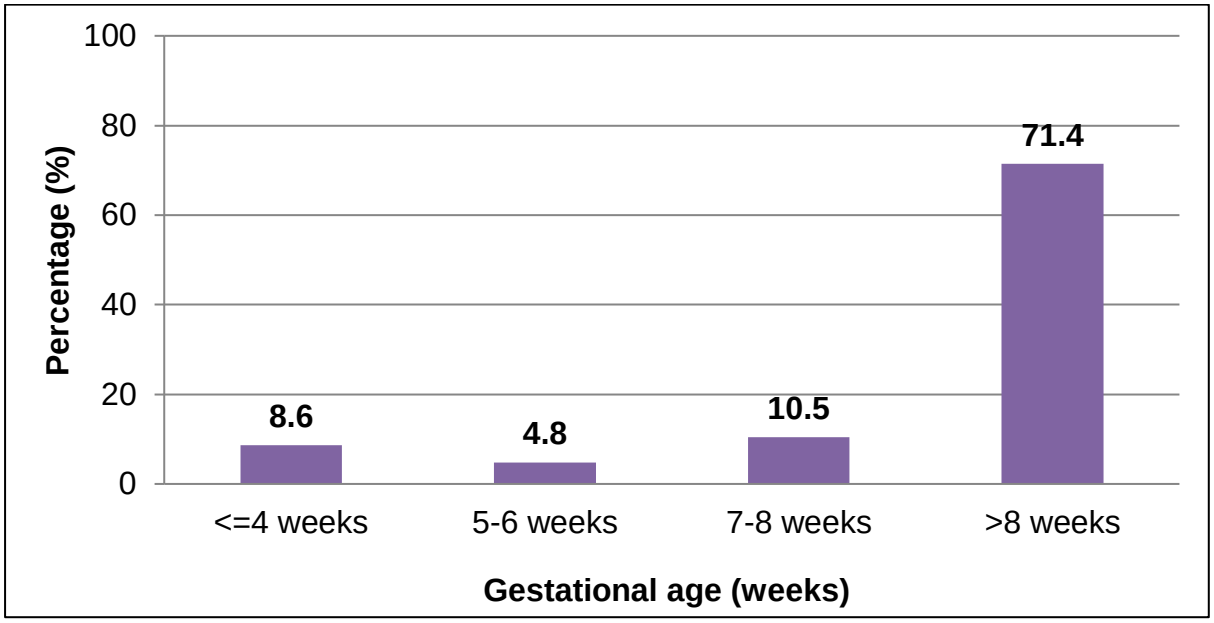

Figure 4.1: First antenatal clinic visit attendance by pregnant women

Table 4.1: Demographic information of the pregnant women participants

	No	(%)
Age (years)		
<20	16	15.8
20-24	24	23.7
25-29	22	21.8
30-34	25	24.8
35+	14	13.8
Level of Education		
None	3	3
Primary	10	10
Secondary	69	68
Tertiary	19	19
Marital status		
Married	48	47
Unmarried	53	53
Body Mass Index (BMI)		
Underweight:(<18.5 kg/m²)	-	-
Normal weight (18.5 – 25 kg/m²)	26	26
Overweight (25 - 30 kg/m²)	44	44
Obese (30 kg/m²)	31	31
Employment		
Employed	32	32
Unemployed	69	64
Family history of diabetes		
No history of diabetes	87	86
History of diabetes	14	14

Table 4.1 above shows the demographic characteristics of the pregnant women who participated in this study. Sixty-two(62) (61.4%) pregnant women were aged <30 years. Their mean age was 27±6.9 years, ranging from 14 to 43 years. Sixty-eight percent of the participants had secondary education, while fifty-three (53) (52.5%) of the participants were unmarried. With regard to BMI, forty-four (44) 44% of the participants were overweight and thirty-one (31) (31%) were obese. 69 (64%) of the participants were unemployed and 14 (14%) of the participants had a family history of diabetes.

Table 4.2: Association of age of pregnant women with selected demographics

	Age (years)					p-value
	<20	20-24	25-29	30-34	≥35	
Marital status						
Single	12(71)	17(68)	10(50)	10(40)	4(29)	0.052
Married	5(29)	8(32)	10(50)	15(60)	10(71)	
Employment status						
Employed	1(6)	3(12)	8(40)	10(40)	10(72)	<0.001
Unemployed	16(94)	22(88)	12(60)	15(60)	4(28)	
1st ANC visit (weeks)						
≤4	1(6)	5(20)	-	3(12)	-	0.055
5 – 8	6(35)	3(12)	3(15)	4(17)	-	
>8	10(59)	17(68)	17(85)	17(71)	14(100)	
Mother's gravida						
1	15(88)	11(44)	3(15)	1(4)	-	
2	2(12)	14(56)	10(50)	8(32)	1(7)	<0.001
≥3			7(35)	16(64)	13(93)	
Mother's parity						
0	16(94)	14(56)	4(20)	2(8)		
1	1(6)	11(44)	10(50)	8(32)	1(7)	<0.001

	Age (years)					p-value
	<20	20-24	25-29	30-34	≥35	
≥2			6(30)	15(60)	13(93)	
Family history of DM						
Yes	3(18)	2(8)	4(20)	1(4)	4(29)	0.161
No	14(82)	23(92)	16(80)	24(96)	10(71)	

The association between the ages of the participants with selected demographics is shown in Table 4.2 above. The older women in the age group 35 years and older were more likely to be married and employed. However, the results for employment status was not statistically significant (p>0.05). Women in the age group 35 years and older were more likely to have attended their 1st ANC visit after 8 weeks of gestation, compared to the other age groups, but the finding was not statistically significant (p>0.05). Pregnant women in the age group 25-29 years and those aged ≥35 years were more likely to have a family history of diabetes when compared to other groups (p>0.05) using t-test.

The mother's gravida decreased with increase in age, from 15 pregnant (88%) women in the age group <20 years, to 1 (4%) pregnant woman in age group 30 – 34 years for women who had one pregnancy. Whereas, in women who had had 2 or more pregnancies, mother's gravida increased with increasing age (*p<0.001*). The proportion of mothers who had pregnancies which reached a viable gestational age (including live births and stillbirths) decreased with increasing age for mothers with parity zero, from 16(94%) women in age group <20 years, to 2 (8%) in age group 30 – 34 years. Whereas, in women who had had 1 or more parity, the proportion of mothers who had pregnancies which reached a viable gestational age increased with increasing age (*p<0.001*). Family history of diabetes mellitus was not associated with the age of the pregnant woman (*p=0.161*).

4.3.2. Prevalence and risk factors of gestational diabetes

The overall, prevalence of gestational diabetes in Mopani District Limpopo Province was 1.9% (95% CI: 0.24-6.97). The association between gestational diabetes and selected demographics of the participants is shown in Table 4.3 below. There was no significant association between GDM and any of the following participant demographics: maternal age, level of education, marital status, employment status, BMI, and gestational age. However, women aged ≥30 years, with secondary education who were employed, obese, and with gestational age of the foetus between 31-35 weeks were more likely to present with gestational diabetes than their counterparts. A significantly greater proportion of women with a family history of diabetes were more likely to present with gestational diabetes than women without such a family history (14% (2), versus 0% (0), p<0.05%).

Table 4.3: Selected demographics associated with GA

	N	Gestational Diabetes		p-value
		Yes	No	
Maternal Age (years)				
<30	62	1(2)	61(98)	1.000
≥30	39	1(3)	38(97)	
Education				
None	3	-	3(100)	
Primary	10	-	10(100)	1.000
Secondary	69	2(3)	67(98)	
Tertiary	19	-	19(100)	
Marital status				
Married	48	1(2)	47(98)	1.000
Unmarried	53	1(2)	52(98)	
Employment status				
Employed	32	1(3)	31(97)	0.535
Unemployed	69	1(1)	68(99)	
BMI				1.000

Normal weight (18.5 – 25 kg/m²)	26	-	26(100)	
Overweight (25 - 30 kg/m²)	44	1(2)	43(98)	
Obese (30 kg/m²)	31	1(3)	30(97)	
Gestation Age (weeks)				
≤25	22	-	22(100)	0.530
26-30	16	-	16(100)	
31-35	33	2(6)	31(94)	
36 - 40	30		30(100)	
Family history diabetes				
Yes	14	2(14)	12(86)	0.018
No	87	-	87(100)	

4.4. Overview of research findings

The prevalence of gestational diabetes mellitus in the women participating in this study was found to be 1.9% (95% CI: 0.24-6.97). Women aged ≥30 years with secondary education, who were employed, obese and with gestational age of the foetus of between 31-35 weeks were more likely to present with gestational diabetes mellitus than their counterparts from other demographic groups. Furthermore, a greater proportion of women with a family history of diabetes were likely to present with GDM than pregnant women with no family history of diabetes were.

4.5. Conclusion

In this chapter, the results of the study were presented and interpreted. The next chapter discusses these findings and compares the findings of this study to the relevant literature.

5 CHAPTER 5: DISCUSSION, CONCLUSION,LIMITATIONS AND RECOMMENDATIONS

5.1 Introduction

In the previous chapter, the findings of this study were presented and interpreted. In this chapter, the results of this study are discussed and compared to the relevant literature. The chapter is divided into the following sub-sections: (1) introduction (2) prevalence of gestational diabetes and (3) risk factors of gestational diabetes, (4) study limitations, (5) conclusion and (6) recommendation.

5.2 Prevalence of gestational diabetes

Globally, the prevalence of GDM ranges from 1.4 to 14% (Dudhwadkar & Fonseca, 2016). In China, the total incidence of GDM in mainland China was 14.8%, according to a study undertaken by Gao, Sun, Lu, Liu and Yuan (2019). In India, using the newer International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria, the prevalence of GDM was 41.9%, according to a study done by Gopalakrishnan, Singh, Pradeep, Kapoor, Rani, Pradhan, Bhatia & Yadav (2015).

A systematic review conducted in sub-Saharan Africa reported the prevalence of GDM ranging from between 0 and 9% (Mwanri et al., 2015). In Nigeria, one study found the prevalence of GDM to be 3.8%, 8.1%, 7.5%, and 8.6%, depending on which criteria were used, the 1999 WHO criteria, the new 2013 WHO criteria, the modified IADPSG criteria, or the IADPSG criteria, respectively (Olagbuji, Atiba, Olofinbiyi, Akintayo, Awoleke, Ade-Ojo & Fasubaa., 2015).

A recent prospective cohort study conducted at a level 1 clinic in the Gauteng province of South Africa reported the prevalence of GDM at 7%, 17% and 26% depending on which criteria were used, the 1999 WHO criteria, the National Institute for Health and Care Excellence (NICE) criteria, or the IADPSG criteria, respectively (Adam & Rheeder, 2017). The reason for the low prevalence of GDM in this study is not documented; however, the small sample size may have contributed to this. Another contributing factor could be that studies reported on

used different diagnostic criteria to determine the prevalence of GDM. In the present study, the prevalence of GDM was found to be 1.9%. In addition, this prevalence is low compared to study conducted in level 1 clinic situated in Gauteng, South Africa. In this study, the sample size was small as most pregnant women were reluctant to participate in the study. Moreover, most of pregnant women were not screened for GDM in their first or second trimester. The study found that only those women who were at risk to develop GDM i.e. obese; hypertension or had family history of diabetes, etc were screened. Risk-factor based approach was mainly used in the three study sites. Thus, the prevalence found in this study might not be a true reflection of GDM in Mopani district.

5.3 Risk factors of gestational diabetes

The prevalence rate of GDM in a given population may possibly be reduced by identifying and controlling the risk factors associated with the development of GDM. In this section, the risk factors associated with GDM in this study are presented and discussed.

5.3.1 Maternal age, BMI and Family history of diabetes mellitus

A number of studies have reported various risk factors associated with GDM. Contrary to the findings of many studies on risk factors of gestational diabetes mellitus, in the present study, maternal age and BMI were not statistically associated with GDM. This can be attributed to the small sample size and, as a result, few cases of GDM identified in this study (2 cases from n=101). In this study, women with GDM were not significantly more obese or overweight than those without gestational diabetes (*P=1.000*) using t-test. Moreover, this is not in line with other studies which showed that diabetes is highly correlated with obesity (Meharry, Tengera, Rilusa, Byambu, Neitert, Byiringio, Habimana, Gishoma & King, 2019).

In agreement with previous studies (Mwanri et al., 2015; Lee, Ching, Ramachandran, Yee, Hoo, Chia, Wan Sulaiman, Suppiah, Mohamed & Veettil., 2018; Macaulay, Ngobeni, Dunger & Norris., 2018; Gao et al., 2019), a family history of diabetes mellitus was significantly associated with GDM. A family history of diabetes in first degree relatives has been found to be the most

significant risk factor for gestational diabetes, which further emphasizes the role of genetics in susceptibility towards this condition (Kiani, Naz, Sayehmiri, Sayehmiri & Zali, 2017). Similarly, GDM was found to have a recognisable familial association by Dobjanschi & Miulescu (2015).

Furthermore, this risk factor can be controlled by using a universal approach to screening for gestational diabetes. This is done in order to ensure that pregnant women who report a family history of diabetes can be tested further, and monitored closely during their pregnancy, so as to minimize the development of GDM, or to promptly initiate treatment, should that woman develop gestational diabetes, with the aim of improving health outcomes. This approach can help in reducing the prevalence of GDM. One study proposed that screening and early identification of this possible risk factor in pregnant women would be a helpful and cost-effective way in which the planning maternal health services could be undertaken, providing high quality prenatal care to women who may develop gestational diabetes mellitus (Carroll et al., 2018).

Several studies have shown that increased maternal age and BMI significantly increase the risk of GDM (Mwanri et al., 2015; Wang and Luo., 2019; Lee, Ching , Ramachandran , Yee , Hoo, Chia , Wan Sulaiman, Suppiah, & Veettil , 2018; Gao et al., 2019). Studies conducted in Australia and America have found that risk factors, such as BMI, positive family of diabetes, age, obesity, and unexplained still birth put women at risk of gestational diabetes (Kiani et al., 2017). The reason for high BMI being a risk factor for GMD is because weight gain in pregnancy is more likely to promote hyperglycaemia.

5.3.2 Level of education

A prospective study conducted in China among Chinese women found that higher educational level was related to reduce risk of gestational diabetes, after adjustment for potential confounders (Song, Shen, Li, Liu, Zhang, Xu & Wang, 2017). Similarly, Oppong and co-authors, in their cross-sectional study conducted amongst pregnant women attending their first prenatal clinic at Korle-Bu Teaching Hospital in Accra, Ghana, found that a higher level of education positively associated with the development of GDM (Oppong, Ntumy, Amoakoh-

Coleman, Ogum-Alangea and Modey-Amoah, 2015). A study conducted in Italy found that high levels of maternal education were associated with reduced risks of gestational diabetes, compared to the risks in less educated women. The reason for this might be the notion that higher educational level provides pregnant women with more knowledge and understanding of the risk factors associated with GDM (Song et al., 2017).

Contrary to the abovementioned finding, a matched pair case-control study conducted with 276 GDM women and 276 non-GDM women in two hospitals in Beijing China found that the number of women who developed GDM was significantly higher in those who received more than 12 years of education when compared to those who received less than 9 years of education with p-value of 0.001 (Carroll et al., Liang, Zhang, Zhang, Liu, Turner & Leeper-Woodford, 2018). The reason for this may be associated with lifestyle change and diet, e.g. the consumption of fast food.

A study conducted in Beijing highlighted the fact that education, income and place of residence showed no correlation with GDM diagnosis (Zhu, Yang, Wang, Su, Feng & Kapur, 2017). Similar to this finding, the finding of the present study, showed no significant association between level of education and GDM, however, pregnant women with secondary education were more likely to show signs of GDM. In Netherlands, one study found that low maternal education level was associated with GDM (Liu, Liu, Leng, Pan, Zhang, Li, Li, Huo, Chan, Yu, Hu & Yang, 2018). This may be because lower education status is related to a traditional diet, which is inexpensive but has a high concentration of fat and carbohydrate contents.

5.3.3 Marital status

The present study found that there was no significant association between marital status and the development of GDM using t-test(*P=1.000*). This finding suggests that GDM affects every pregnant woman, irrespective of her marital status. This study did, however, highlight the fact that married pregnant women were more likely to be above 35 years of age (*P=0.052*), t-test was used. In contrast, a cross-sectional study conducted in the north and the south of China, no

statistically significant association was found between marital status and GDM (Xu et al., 2017). In agreement with this study, a study conducted in Beijing, China showed that more pregnant women in the control group were married compared to those with GDM who were married. In addition, using t-test the study found that there was no statistically significant association between marital status and GDM with p-value of 0.069 (Carroll et al., 2018).

5.3.4 Employment status

Socioeconomic status refers to social and economic factors that reflect what positions and prestige individuals or groups hold within the structure of a society, such as education level, occupation and income. A population-based prospective study conducted in Netherlands showed that maternal lower income was associated with an increased the risk of GDM (Liu et al., 2018). In contrast to this study, no significant association between employment status and GDM using t-test used (*P=0.535*) in the Liu et al. (2018) study. This finding is in line with previous studies which found no significant relationship between household income and GDM (Khan, Ali & Khan 2013; Song et al., 2017).

Additionally, the reason for the current study finding regarding the association of socio-economic status and GDM using t-test(*P=1.000*) may be attributed to the study setting. This research was conducted in a rural setting and the majority of study participants were from rural villages located in the Giyani Area. Pregnant women from this area who are in the high employment status group visit private general practitioners or medical clinics for their antenatal clinic visits. Therefore, the sample of this study is possibly not representative of the general population of pregnant women in Greater Giyani Area, Mopani District. A study involving women of high employment status needs to be conducted to determine the prevalence of GDM among this group in a rural context.

5.4 Limitations of the study

A limitation of this study is the fact that the sample size was small, thus affecting the validity of the results and, consequently, the generalizing of the results to the overall population. The clinical characteristics of the study participants and their unborn babies were not documented in the antenatal medical records. As a result,

the adverse maternal and neonatal health outcomes were not known, especially in pregnant women affected by gestational diabetes. Lack of available data on participants' antenatal medical records was also a limit to this study as this affected the data captured. The time available to thoroughly investigate this research problem, due to master's dissertation submission deadline, is also a possible limitation of this research.

5.5 Conclusion

The prevalence of gestational diabetes in the rural area of the Mopani District in the Limpopo Province was found to be 1.9%, and women with a family history of diabetes were more likely to present with gestational diabetes. In addition, pregnant women who were above 30 years of age, obese, and with a gestational age of between 31 – 35 weeks, were also more likely to present with gestational diabetes.

5.6 Recommendations

5.6.1 Policies

The study findings bring with them a number of recommendations for policy makers to consider when developing policy for public health facilities, such as hospitals, clinics and health centres, particularly relating to the adoption of universal screening, where all pregnant women are screened for gestational diabetes and hyperglycaemia. Furthermore, uniform criteria for screening and diagnosing gestational diabetes need to be adopted across all public health institutions, which will benefit our socio-economic and clinical context.

5.6.2 Health facilities

It is recommended that awareness campaigns be conducted to educate women about the risk factors associated with gestational diabetes and its adverse outcomes. This will enable women who are pregnant to be cognizant of this obstetric condition and take precautionary healthy measures to avoid modifiable risk factors. It is also recommended that more studies of this nature be conducted with a large sample size to allow for generalization of the results to the population at large.

5.6.3 Research

The study further recommends that more research be done on the development of an ideal strategy for the screening of gestational diabetes in a South African context. This is to ensure relevancy.

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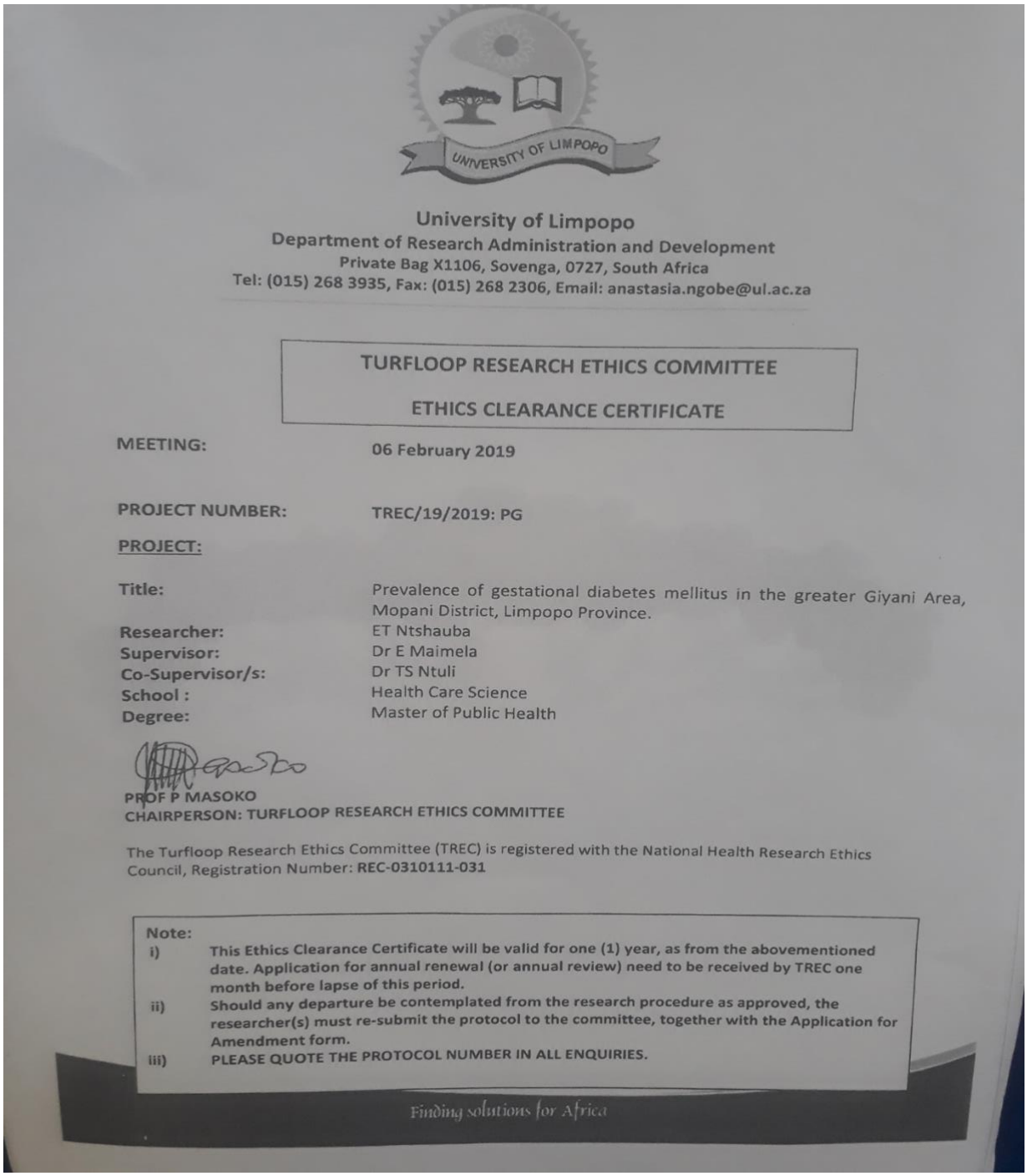
APPENDICES / ADDENDA

APPENDICE A: APPROVAL FROM THE UNIVERSITY (TREC)



University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 3935, Fax: (015) 268 2306, Email: anastasia.ngobe@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE

ETHICS CLEARANCE CERTIFICATE

MEETING: 06 February 2019

PROJECT NUMBER: TREC/19/2019: PG

PROJECT:

Title: Prevalence of gestational diabetes mellitus in the greater Giyani Area, Mopani District, Limpopo Province.

Researcher: ET Ntshauba
Supervisor: Dr E Maimela
Co-Supervisor/s: Dr TS Ntuli
School : Health Care Science
Degree: Master of Public Health

PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

The Turfloop Research Ethics Committee (TREC) is registered with the National Health Research Ethics Council, Registration Number: **REC-0310111-031**

Note:

i) **This Ethics Clearance Certificate will be valid for one (1) year, as from the abovementioned date. Application for annual renewal (or annual review) need to be received by TREC one month before lapse of this period.**

ii) **Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee, together with the Application for Amendment form.**

iii) **PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.**

Finding solutions for Africa

APPENDICE B: LETTER SEEKING CONSENT FROM DEPARTMENT OF HEALTH: LIMPOPO PROVINCE

P.O Box 21
Tshilwavhusiku
0938

The Head of Department
Department of Health
Private Bag x 9307
Polokwane
0700

Dear: Sir/Madam

Request for permission to conduct research at Nkhensani Hospital; Giyani Healthcare Centre and Nkhensani Gateway clinic.

I Ms Ntshauba Elelwani Thelma hereby request permission to conduct a research study at Nkhensani Hospital; Giyani Healthcare Centre and Nkhensani gateway clinic. The study is "prevalence of gestational diabetes mellitus in the greater Giyani area, mopani district, Limpopo province". This study is conducted in partial fulfillment of the requirements for the Master of Public Health degree in the School of Health Sciences at the University of Limpopo.

The aim of the study is to investigate the prevalence, risk factors, maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo Province

I am looking forward to a favourable response from you.

Yours faithfully

Ntshauba ET

076 968 5588; Email: elelwani.thelma@gmail.com

APPENDICE C: LETTER OF APPROVAL: DEPARTMENT OF HEALTH: LIMPOPO PROVINCE

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Ref: LP 201903_001
Enquiries: Stander SS
Tel: 015 293 6650
Email: research.limpopo@gmail.com

Ms Ntshauba ET

University of Limpopo
Private Bag X 1106
Sovenga
0727

Greetings,

RE: PREVALENCE OF GESTATIONAL DIABETES MELLITUS IN THE GREATER GIYANI AREA, MOPANI DISTRICT , LIMPOPO PROVINCE.

Permission to conduct the above mentioned study is hereby granted.

1. Kindly be informed that:-
    - Research must be loaded on the NHRD site (http://nhrd.hst.org.za) by the researcher.
    - Further arrangement should be made with the targeted institutions, after consultation with the District Executive Manager.
    - In the course of your study there should be no action that disrupts the services, or incur any cost on the Department.
    - After completion of the study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
    - The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
    - The above approval is valid for a 1 year period.
    - If the proposal has been amended, a new approval should be sought from the Department of Health.
    - Kindly note, that the Department can withdraw the approval at any time.

Your cooperation will be highly appreciated.

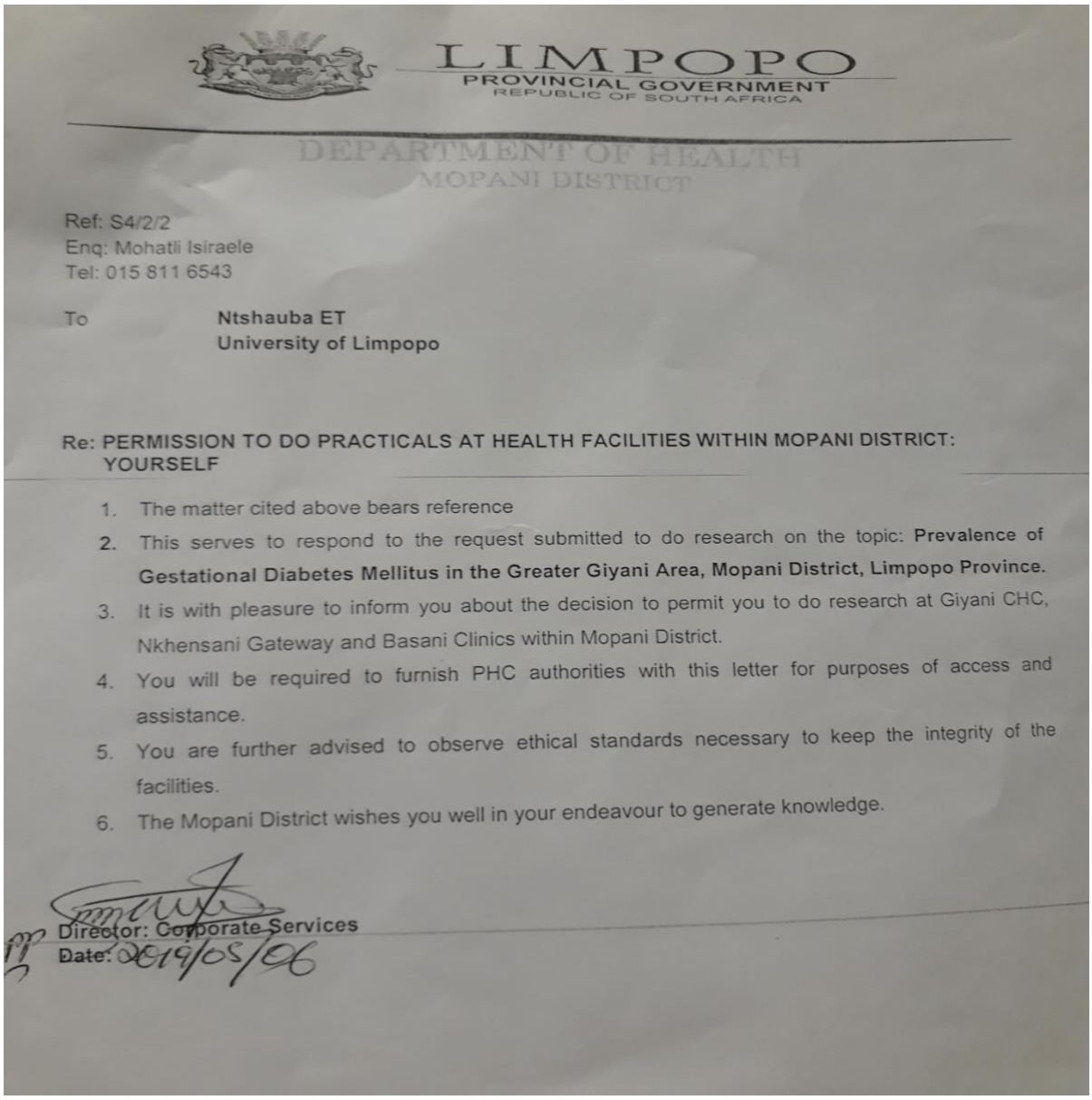
Head of Department

02/04/2019
Date

Private Bag X9302 Polokwane
Fidel Castro Ruz House. 18 College Street. Polokwane 0700. Tel: 015 293 6000/12. Fax: 015 293 6211.

The heartland of Southern Africa – Development is about people!

APPENDICE D: LETTER OF APPROVAL: DEPARTMENT OF HEALTH: MOPANI HEALTH DISTRICT



LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
MOPANI DISTRICT

Ref: S4/2/2
Enq: Mohatli Isiraele
Tel: 015 811 6543

To Ntshauba ET
University of Limpopo

Re: PERMISSION TO DO PRACTICALS AT HEALTH FACILITIES WITHIN MOPANI DISTRICT: YOURSELF

1. The matter cited above bears reference
2. This serves to respond to the request submitted to do research on the topic: **Prevalence of Gestational Diabetes Mellitus in the Greater Giyani Area, Mopani District, Limpopo Province.**
3. It is with pleasure to inform you about the decision to permit you to do research at Giyani CHC, Nkhensani Gateway and Basani Clinics within Mopani District.
4. You will be required to furnish PHC authorities with this letter for purposes of access and assistance.
5. You are further advised to observe ethical standards necessary to keep the integrity of the facilities.
6. The Mopani District wishes you well in your endeavour to generate knowledge.

Director: Corporate Services
Date: 2019/05/06

APPENDICE E: QUESTIONNAIRE – XITSONGA TRANSLATED

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Xikongomelo xa ndzavisigo lowu iku kumisisa nhlayo, nxungweto, mbuyelo ka ku biha e mihrini na vana eka va xisati lava nga ni vuvabyi bya chukele eka va yimani e Greater Giyani, Mopani District, Limpopo province. Ndzavisiso wu endliwa na Univhesiti ya Limpopo. Kuna swi vutiso swa 18 ena papilla leri. Ku hlamula swivutiso swiga teka 15-20 wa ti minetse. Swivutiso leswinga nyikiwa ti nhlamulo to hlaya, kombisa hi xixambani (X) endzeni ka bokisi. Swivutiso leswinga na ndzhawu yo hlamulela ka yona, mi komberiwa ku tsala nhlamulo.

Siku ro velekiwa			

Q1 Mi na malembe ma nghani? | | Wa malembe

Q2 Hi rihi ririmi ra le kaya?

Tshivenda	Xitsonga	
Sepedi	Xilungu	
Sesotho	Other (specify)	

Q3 Xa mi tekiwile?

Ani tekiwangi	Hi thalanili
Ni tekiwili	Ni lovele hi nuna / nsati

Q4 Xa mi rixukamuni?

Muntima	Mulungu
Indiya	Khaladi

Q5	Ni tshama miri vangani kaya?	
Q6	Xana mi dyondze ku fika kwihi?	Ku hava / Xikolo xa le hansi Xikolo xa le henhla / Xikolo xa le univhesithi
Q7	Xana ma tirha?	Ina / E-e
Q8	Xana loko minga tirhi, mi tihanyisa hi yini?	
Q9	Mi tshama kwi?	
Q10	Mi sungule rini ku ya eka tliliniki ya vu yimani?	≤4 Weeks / 7-8 Weeks 5-6 Weeks / >8 Weeks
Q11	Mi switivile riwi leswaka una ma byavi eka vuyimana? (vulani siku)	
Q12	Mi thsame ma va muyimani khale?	Ina / E-e
Q13	Xana mi kumeke uri na vuvabyi bya chukele ra va yimani lowu a wu tikile?	Ina / E-e
Q14	Xana kuna loyi angina vuvabyi bya chukele e kaya (ku ngava vatswari, vamakwano, maxana ya le kusuhi ?	Ina / E-e
Q15	Mi tshama mivana xiphoqo eka vuyimani hebyi minga handzo?	Ina / E-e

Q16 Loko swikona, mi nga swi vulana?

Q17 Xana i yini

Ntiko ____ Kg

Ku leya ____ M

Q18 Xana mi kuma vutshunguri bya njhani?

Hi khensa matiriselo a nwina

APPENDICE F: QUESTIONNAIRE – ENGLISH TRANSLATED

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

The aim of the study is to investigate the prevalence, risk factors, maternal and infant outcomes of women with gestational diabetes mellitus in the Greater Giyani Area, Mopani District, Limpopo Province. The study is being conducted through the University of Limpopo. There are 20 questions in this questionnaire. The questionnaire might take you 15 – 20 minutes to complete. For questions with alternative options, indicate by crossing (x) in the box. For questions with blank spaces, please provide an answer in writing.

ID			

Q1 What is your age: | | Years

Q2 What is your home language?

Tshivenda	Xitsonga	
Sepedi	English	
Sesotho	Other (specify)	

Q3 What is your marital status?

Single	Divorced
Married	Widowed

Q4 What is your ethnic origin/race?

Black	White
Indian	Coloured

Q5 How many people live with you | |

Q6 What is your level of education?

None	Primary
Secondary	Tertiary

Q7	Are you working?	Yes	No
Q8	If not employed, what is your source of income?		
Q9	Where do you live?		
Q10	When did you start attending antenatal clinic visits?	≤4 Weeks	7-8 Weeks
		5-6 Weeks	>8 Weeks
Q11	Which medical condition are you diagnosed with during this pregnancy? (specify date)		
Q12	Have you been pregnant before?	Yes	No
Q13	Were you diagnosed with gestational diabetes mellitus in your previous pregnancy?	Yes	No
Q14	Is there anyone in your family i.e. Parents, siblings, close relatives who have diabetes?	Yes	No
Q15	Have you experienced past pregnancy complications before?	Yes	No
Q16	If yes, what were they?		
Q17	What is your	Weight	Kg

Height [ ] M

Q18 What treatment are you receiving for your medical condition?

[ ]

Thank you for your participation

APPENDICE G: DATA ENTRY FORM FOR COLLATETAL INFORMATION FROM PARTICIPANT MEDICAL FILE

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Participant's medical records will be reviewed and the following data will be extracted from the file using the data entry form outlined below:

ID	Age	Gestational age	Weight (kg)	Height (m)	Past obstetric history	Test/s conducted to diagnose Medical condition in pregnancy	Test result	Complications	Treatment received

APPENDICE H: INFORMATION LETTER FOR NKHENSANI HOSPITAL'S CEO

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Nkhensani Hospital CEO

Thank you for taking the time to read this information letter. I am a Master of Public Health Student from the University of Limpopo and I am busy conducting a research study to find out the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM).

There is an increased prevalence of GDM and this medical condition can place the life of both the mother and infant at risk especially when it is poorly managed. GDM is associated with health risks which can result in mortality and morbidity of both the mother and infant. The study wishes to inform interventions and policies which can be planned to reduce the prevalence of GDM in the country and subsequently reduce infant & maternal mortality and morbidity as well as informing the Limpopo Department of Health to adopt a universal screening practice for GDM to ensure that pregnant women who are meant to receive GDM treatment receive it on time to avoid adverse health outcomes for both the mother and infant.

Information will be collected using questionnaire and data entry form to capture information from the participant's medical records. To ensure confidentiality, information gathered will be stored in a storage system which is only accessible to the researcher and research supervisor. There will be no direct harm and rewards to participants and participants can withdraw from the study at any time.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethical approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Limpopo (HREC Reference number……...).

Please forward any question or concern you may have regarding this research to the contact details provided below.

Student researcher:

Ntshauba Elelwani Thelma 076 968 5588 elelwani.thelma@gmail.com

Research supervisor:

Dr Maimela E eric.maimela@ul.ac.za

Dr Ntuli T.S thembelihle.ntuli@ul.ac.za

Chairperson of the Health Sciences Human Research Ethics Committee:

APPENDICE I: CONSENT FORM FOR NKHENSANI HOSPITAL CEO

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Title: 'Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes'.

Dear Nkhensani Hospital CEO

By signing this form, I am allowing the researcher to conduct her research study in this institution.

I…… (Surname &Initials);…… (Rank) hereby consent for the research study to be conducted in this institution.

Thank you,

Place: ……

Signed: ……. **Date**: …….

Researcher: ……..... **Signed**: ……

APPENDICE J: INFORMATION LETTER FOR GIYANI HEALTHCARE CENTRE

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Giyani Healthcare Centre Manager

Thank you for taking the time to read this information letter. I am a Master of Public Health Student from the University of Limpopo and I am busy conducting a research study to find out the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM).

There is an increased prevalence of GDM and this medical condition can place the life of both the mother and infant at risk especially when it is poorly managed. GDM is associated with health risks which can result in mortality and morbidity of both the mother and infant. The study wishes to inform interventions and policies which can be planned to reduce the prevalence of GDM in the country and subsequently reduce infant & maternal mortality and morbidity as well as informing the Limpopo Department of Health to adopt a universal screening practice for GDM to ensure that pregnant women who are meant to receive GDM treatment receive it on time to avoid adverse health outcomes for both the mother and infant.

Information will be collected using questionnaire and data entry form to capture information from the participant's medical records. To ensure confidentiality, information gathered will be stored in a storage system which is only accessible to the researcher and research supervisor. There will be no direct harm and rewards to participants and participants can withdraw from the study at any time.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethical approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Limpopo (HREC Reference number……...).

Please forward any question or concern you may have regarding this research to the contact details provided below.

Student researcher:

Ntshauba Elelwani Thelma 076 968 5588 elelwani.thelma@gmail.com

Research supervisor:

Dr Maimela E eric.maimela@ul.ac.za

Dr Ntuli T.S thembelihle.ntuli@ul.ac.za

Chairperson of the Health Sciences Human Research Ethics Committee:

APPENDICE K: CONSENT FORM FOR GIYANI HEALTHCARE CENTRE MANAGER

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Title: 'Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes'.

Dear Giyani Healthcare Centre Manager

By signing this form, I am allowing the researcher to conduct her research study in this institution.

I…… (Surname &Initials);…… (Rank) hereby consent for the research study to be conducted in this institution.

Thank you,

Place: ……

Signed: ……. **Date**: …….

Researcher: ……..... **Signed**: ……

APPENDICE L: INFORMATION LETTER FOR NKHENSANI GATEWAY CLINIC MANAGER

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Nkhensani Gateway Clinic Manager

Thank you for taking the time to read this information letter. I am a Master of Public Health Student from the University of Limpopo and I am busy conducting a research study to find out the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM).

There is an increased prevalence of GDM and this medical condition can place the life of both the mother and infant at risk especially when it is poorly managed. GDM is associated with health risks which can result in mortality and morbidity of both the mother and infant. The study wishes to inform interventions and policies which can be planned to reduce the prevalence of GDM in the country and subsequently reduce infant & maternal mortality and morbidity as well as informing the Limpopo Department of Health to adopt a universal screening practice for GDM to ensure that pregnant women who are meant to receive GDM treatment receive it on time to avoid adverse health outcomes for both the mother and infant.

Information will be collected using questionnaire and data entry form to capture information from the participant's medical records. To ensure confidentiality, information gathered will be stored in a storage system which is only accessible to the researcher and research supervisor. There will be no direct harm and rewards to participants and participants can withdraw from the study at any time.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethical approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Limpopo (HREC Reference number…….).

Please forward any question or concern you may have regarding this research to the contact details provided below.

Student researcher:

Ntshauba Elelwani Thelma 076 968 5588 elelwani.thelma@gmail.com

Research supervisor:

Dr Maimela E eric.maimela@ul.ac.za

Dr Ntuli T.S thembelihle.ntuli@ul.ac.za

Chairperson of the Health Sciences Human Research Ethics Committee:

APPENDICE M: CONSENT FORM FOR NKHENSANI GATEWAY CLINIC MANAGER

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Title: 'Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes'.

Dear Nkhensani Gateway Clinic Manager

By signing this form, I am allowing the researcher to conduct her research study in this institution.

I…… (Surname &Initials);…… (Rank) hereby consent for the research study to be conducted in this institution.

Thank you,

Place: ……

Signed: ……. **Date**: …….

Researcher: ……..….. **Signed**: ……

APPENDICE N: INFORMATION LETTER FOR THE PARTICIPANT

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Participant

Thank you for taking the time to read this information letter. I am a Master of Public Health Student from the University of Limpopo and I am busy conducting a research study to find out the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM).

There is an increased prevalence of GDM and this medical condition can place the life of both the mother and infant at risk especially when it is poorly managed. GDM is associated with health risks which can result in mortality and morbidity of both the mother and infant.

The study wishes to inform interventions and policies which can be planned to reduce the prevalence of GDM in the country and subsequently reduce infant & maternal mortality and morbidity as well as informing the Limpopo Department of Health to adopt a universal screening practice for GDM to ensure that pregnant women who are meant to receive GDM treatment receive it on time to avoid adverse health outcomes for both the mother and infant.

The researcher requests your participation in this research. Information will be collected using questionnaire and data entry form to capture information from the participant's medical records. To ensure confidentiality, information gathered will be stored in a storage system which is only accessible to the researcher and research supervisor. There will be no direct harm and rewards to you and you can withdraw from the study at any time.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethical approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Limpopo (HREC Reference number…….).

Please forward any question or concern you may have regarding this research to the contact details provided below.

Student researcher:

Ntshauba Elelwani Thelma 076 968 5588 elelwani.thelma@gmail.com

Research supervisor:

Dr Maimela E eric.maimela@ul.ac.za

Dr Ntuli T.S thembelihle.ntuli@ul.ac.za

Chairperson of the Health Sciences Human Research Ethics Committee:

APPENDICE O: CONSENT FORM FOR THE PARTICIPANT

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Title: 'Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes'.

Dear Participant

By signing this form, I am declaring my participation in this study.

I…… (Surname &Initials) hereby consent to be part of the study.

Thank you,

Place: ……

Signed: ……. **Date**: …….

Researcher: ……..….. **Signed**: ……

APPENDICE P: INFORMATION LETTER FOR PARENT OF PARTICIPANT UNDER 18 YEARS OLD

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Participant/Guardian

Thank you for taking the time to read this information letter. I am a Master of Public Health Student from the University of Limpopo and I am busy conducting a research study to find out the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM).

There is an increased prevalence of GDM and this medical condition can place the life of both the mother and infant at risk especially when it is poorly managed. GDM is associated with health risks which can result in mortality and morbidity of both the mother and infant.

The study wishes to inform interventions and policies which can be planned to reduce the prevalence of GDM in the country and subsequently reduce infant & maternal mortality and morbidity as well as informing the Limpopo Department of Health to adopt a universal screening practice for GDM to ensure that pregnant women who are meant to receive GDM treatment receive it on time to avoid adverse health outcomes for both the mother and infant.

The researcher therefore asks permission from you for your child to participate in the study. Your child is no under no pressure to participate in this study and you have the right to withdraw at any point without providing an explanation. There will be no penalty involved should you wish to withdraw. There are no risks in taking part in the study and there will not be any reward. Findings from the study will be analysed by the research team and used for presentations, reports and research publications.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethical approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Limpopo (HREC Reference number…….).

Please forward any question or concern you may have regarding this research to the contact details provided below.

Student researcher:

Ntshauba Elelwani Thelma 076 968 5588 elelwani.thelma@gmail.com

Research supervisor:

Dr Maimela E eric.maimela@ul.ac.za

Dr Ntuli T.S thembelihle.ntuli@ul.ac.za

Chairperson of the Health Sciences Human Research Ethics Committee:

APPENDICE Q: CONSENT FORM FOR PARENT OF PARTICIPANT UNDER 18 YEARS OLD

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Title: 'Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes'.

Dear Parent/Guardian

By signing this form, you are declaring your child's participation.

I, ……. (Surname & initials) have read (or had read to me by …….) the Information Sheet. I understand what is required of my child. I do / do not consent for my child to participation in the study (Circle appropriate response).I agree/ do not agree for my child's voice to be recorded (Circle appropriate response). I do not feel that my child is being forced to participate in this study. I am aware that my child can withdraw from the study at any time should they wish to do so. I have been assured that if I refuse to allow my child to participate in the study or choose to withdraw at a later stage there will be no consequences for me or my child.

Caregiver/Parent Full Name: ……

Place:……. Date:……

Signed: …….

Researcher:…….…. Date:…….

Signed:……..

APPENDICE R: INFORMATION LETTER & CONSENT FORM FOR PARTICIPANT UNDER 18 YEARS OLD

Department of Public Health

Faculty of Health Sciences

Private Bag X1106, Sovenga, 0727, South Africa

Tel: (015) 268 4113/4614 Fax: (015) 268 3384

Dear Participant

Your Parent/Guardian/Caregiver has given permission for you to be in research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you do not understand, please ask questions. You can choose to be in the study, not be in the study or take more time to decide.

What is the name of the study?

Gestational Diabetes Mellitus: Prevalence, Risk factors, Maternal and Infant Outcomes.

Who is in charge of the study?

Master of Public Health student at University of Limpopo

What is the study about?

This research study wants to understand the prevalence, risk factors, maternal and infant outcomes of Gestational Diabetes Mellitus (GDM) in Limpopo Province. The information obtained will inform interventions and policies directed at treating this medical condition (GDM).

What will happen to me in the study?

If you choose to be in the study, you will be asked to complete a questionnaire and information on your medical file will be captured on the data entry form. Your name and personal information will be kept safe at all times and only the researcher & research supervisor will have access to the information.

Will I be paid to be in this study?

You will not be paid for participating in this study.

Do I have to be in the study?

You do not have to be part of the study if you do not want to. Once you are in the study, you can stop being in it at any time. Nobody will be upset with you if you do not want to be in the study or if you want to stop being in the study. No harm will come to you for being part of this study. If you have any questions or do not like what is happening, please tell the researcher.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

Your full name:…… Date:……..

Parent / Guardian Date and place

……. ……

Researcher Date and place

……. ……..

Witness Date and place

……. ……

APPENDICE S: GUIDELINES FOR MARTENITY CARE IN SOUTH AFRICA: A manual for clinics, community health centres and district hospitals

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Guidelines for martenity care in South Africa: A manual for clinics, community health centres and district hospitals

GESTATIONAL DIABETES MELLITUS

This is diabetes that develops during pregnancy or is diagnosed for the first time during the current pregnancy.

Screening and diagnosis

All pregnant women with risk factors for diabetes in pregnancy should be screened at the first antenatal visit and again at 28 weeks, if the initial screen was negative.

> **Note:** for patients with pre-gestational diabetes (i.e. already known to be diabetic before pregnancy), there is no need for diabetes screening. Screening is for at risk women who have not yet been diagnosed as diabetic.

Figure 11.1: Risk factors for gestational diabetes

Underlying patient factors	Patient from an ethnic group with high prevalence of diabetes (e.g. Indian)
	Obesity (patient BMI ≥35)
	Age ≥40 years
Previous history	Previous history of gestational diabetes (diabetes in a previous pregnancy)
	First degree relative with diabetes
	Previous unexplained intrauterine fetal death
	Previous macrosomic baby (birth weight ≥4 kg)
Current pregnancy	Polyhydramnios
	Fetus large for gestational age
	Glycosuria (glucose 1+ or more on urine dipstick)

Screening method

There is a lack of consensus regarding the best screening method for gestational diabetes. Different screening methods may be used depending on the preference at the local specialist referral centre. Clinics and district hospitals are therefore advised to liaise with their specialist referral centre and follow their local recommendations regarding screening method and diagnostic criteria.

For the convenience of both patients and health care professionals, it is recommended that the screening method chosen should be one which can be done on-site on the same day that the women is first seen, and one which uses glucometer readings, rather than laboratory tests.

Example of a screening method

- When the woman arrives at the antenatal clinic (unfasted) give oral glucose 75 g dissolved in 250-300 mL water and take glucometer reading 1 hour after giving glucose.
- A value of ≥7.8 mmol/L is a positive test and indicates that a diagnostic glucose tolerance test is required. This requires the patient to come back fasted on another day and may be done on-site or may require referral to a high-risk clinic, depending on local specialist referral centre protocol.

Example of a diagnostic test

- The patient must be fasting (drink only water from 22h00 the night before). Do screening first thing in the morning.
- Take a fasting glucose test, and then give oral glucose 75 g dissolved in 250-300 mL water and take blood for glucose level 2 hours after giving glucose.
- A fasting blood glucose level of ≥5.6 or a 2 hour value of ≥7.8 mmol/L indicates diabetes and the woman should be managed as a gestational diabetic.
- Alternatively, the patient can bring her own breakfast to the clinic instead of the glucose load.

MANAGEMENT OF DIABETES MELLITUS

Referrals

- All pregnant women with pre-gestational diabetes should be referred to a specialist clinic with expertise in managing these conditions in pregnancy, usually at a specialist hospital.
- Follow-up care may be continued at a district hospital, in accordance with instructions from the specialist clinic, depending on facilities, levels of skill, and the stability / control of her diabetes.
- Screening for gestational diabetes can be done at clinics/CHCs.