SUPPORTING DIABETES SELF-MANAGEMENT IN PREGNANCIES COMPLICATED BY TYPE 1 AND TYPE 2 DIABETES

Supporting Diabetes Self-Management in Pregnancies Complicated by Type 1 and Type 2 Diabetes: A Mixed Methods Sequential Comparative Case Study

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TITLE: Supporting Diabetes Self-Management in Pregnancies Complicated by Type 1 and Type 2 Diabetes: A Mixed Methods Sequential Comparative Case Study

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LAY ABSTRACT

Expectant mothers with type 1 and type 2 diabetes have a high risk of complications related to their glucose levels during pregnancy. The relationship between glucose control, mothers' self-confidence in managing diabetes and their experiences during pregnancy is not well understood. This study explored the factors that affect glucose control and their relationship with the support needs during pregnancy of mothers with type 1 and type 2 diabetes.

ABSTRACT

The occurrence of pre-existing type 1 and type 2 diabetes in pregnancy has been on the rise, parallel with the current "diabetes pandemic" (Albrecht et al., 2010; Coton et al., 2016; Feig et al., 2014; The Lancet, 2011). Currently, pre-existing diabetes affects up to 2.4% of pregnancies around the world (Deputy et al., 2018; Fadl & Simmons, 2016; Lopez-de-Andres et al., 2020; Tutino et al., 2014; Wahabi et al., 2017). Importantly, women with type 1 and type 2 diabetes are at a high risk of experiencing perinatal complications. Perinatal complications range from neonatal hypoglycemia to fetal and infant death (Feig et al., 2014; Kishida et al., 1989). The risk of complications is related to maternal glycemia; maintaining tight glycemic control within the recommended ranges for pregnancy is associated with a reduced risk of adverse outcomes (Feig et al., 2018; Inkster et al., 2006; Tennant et al., 2014). To achieve this, women experience a heavy burden of diabetes self-management during pregnancy. Little is known regarding the predictors of glycemic control during pregnancies complicated by type 1 and type 2 diabetes and their relationship with self-management factors, such as self-efficacy. Furthermore, the impact of these factors in combination with women's pregnancy experiences has not been explored.

The objective of this thesis was to explore how self-management and support experiences help explain glycemic control among women with pre-existing diabetes in pregnancy. There were four overarching questions: (a) What are the predictors of glycemic control during pregnancy among women with pre-existing diabetes? (b) What is the experience of managing diabetes during pregnancy? (c) What are the diabetes self-management education and support needs during pregnancy among women with pre-existing diabetes? (d) How do the self-management and support experiences of women with pre-existing diabetes in pregnancy help

explain their glycemic control? The results of this sandwich thesis aim to answer these questions. The findings showed that women achieved tight glycemic control during pregnancy as they were motivated by the worry of complications for their unborn child. Fear related to complications, feeling unsupported by the healthcare team and a lack of connection with other mothers with diabetes contributed to compromised mental health. Future research should explore the development, implementation and evaluation of interventions to increase mental health support, peer support and support from the healthcare team for this vulnerable population.

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LIST OF ABBREVIATIONS

A1C	glycated hemoglobin A1C
ADP	assistive devices program
BMI	body mass index
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CI	confidence interval
EMBASE	Excerpta Medica Database
GRAMMS	Good Reporting of a Mixed Methods Study
MEDLINE	Medical Literature Analysis and Retrieval System Online
OR	odds ratio
REB	research ethics board
RR	relative risk
SD	standard deviation
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
SPSS	Statistical Package for the Social Sciences
T1	time point 1
T2	time point 2
T3	time point 3
UK	United Kingdom
USA	United States of America

DECLARATION OF ACADEMIC ACHIEVEMENT

This sandwich thesis consists of five manuscripts that have been prepared for publication (Chapter 6) or published in peer-reviewed journals (Chapters 2, 3, 4 and 5). Katelyn Sushko (student) is the first author of all five manuscripts. She was responsible for research conception, research designs, data analysis, interpretation of findings, writing of manuscripts and revisions based on committee feedback and journal reviewers. Co-authors of the manuscripts included her thesis supervisor, Dr. Diana Sherifali, and her thesis committee members, Drs. Patricia Strachan, Michelle Butt and Kara Nerenberg. Two additional co-authors who were not on the committee were Holly Tschirhart Menezes and Dr. Muhamad Ali Usman. All co-authors contributed to and approved the final published and non-published material.

CHAPTER ONE

Introduction

The prevalence of diabetes is increasing rapidly. Between 2000 and 2017, the number of people with diabetes rose from 151 million to 424.9 million, representing 8.8% of the population worldwide (European Society of Cardiology, 2021). Nationally, up to 10% of the Canadian population has been diagnosed with type 1 or type 2 diabetes (Diabetes Canada, 2023). The occurrence of pre-existing type 1 and type 2 diabetes in pregnancy has also risen in parallel with the current "diabetes pandemic" (Albrecht et al., 2010; Coton et al., 2016; Feig et al., 2014; The Lancet, 2011). Globally, type 1 and type 2 diabetes affect between 0.5% to 2.4% of pregnancies (Deputy et al., 2018; Fadl & Simmons, 2016; Lopez-de-Andres et al., 2020; Tutino et al., 2014; Wahabi et al., 2017). Unfortunately, there is a high occurrence of perinatal complications among women with type 1 and type 2 diabetes. Complications can range from short stays in the neonatal intensive care unit for neonatal hypoglycemia to fetal and infant morbidity (Feig et al., 2014; Kishida et al., 1989). Evidence indicates that complication risk is associated with maternal glycemia, where optimal glycemic control is associated with a reduced risk of complications (Feig et al., 2018; Inkster et al., 2006; Tennant et al., 2014). While the treatment modalities available in diabetes care have advanced significantly within the past 15 years, the rate of pregnancy-related complications associated with diabetes remains suboptimal. Although the rates of congenital anomalies in the offspring of women with pre-existing diabetes experienced a decline between 1996 and 2010 (23%, $p = 0.017$), they remain significantly elevated in comparison to the general population. There is almost a twofold increased risk of congenital anomalies among the offspring of women with pre-existing diabetes compared to the offspring of women without diabetes (RR 1.86 [95% CI 1.49–2.33]) (Feig et al., 2014). Furthermore,

perinatal mortality, stillbirths and infant deaths within the first seven days of life did not significantly decline between 1996 and 2010 and remained elevated among women with pre-existing diabetes compared to women without diabetes (relative risk [RR] 2.33 [95% confidence interval {CI} 1.59–3.43]) (Feig et al., 2014). For women, the critical need for optimal glycemia to improve perinatal outcomes increases the already heavy burden of self-management during pregnancy. Yet little is known about the factors such as self-efficacy and self-care that predict glycemic control during pregnancy and relate to how women manage diabetes during pregnancy. Furthermore, it is not well understood how to best support women in managing type 1 and type 2 diabetes during pregnancy.

Background

The current thesis will focus on addressing the aforementioned gaps regarding self-efficacy, self-care and self-management of diabetes during pregnancy among women with type 1 and type 2 diabetes. Thus, the following section will provide an overview of the role of maternal glycemic control in mitigating complications and the importance of diabetes self-management education and support during pregnancy.

Maternal Glycemic Control in Pregnancy Complications

Diabetes-induced teratogenesis in the first trimester of pregnancy is the mechanism underlying the occurrence of congenital anomalies and fetal mortality associated with maternal diabetes in pregnancy (Zabihi & Loeken, 2010). The cellular processes underlying diabetes-induced teratogenesis are poorly understood. However, hyperglycemia is one of the most commonly cited responsible teratogens. Studies of animal models have demonstrated that hyperglycemia induces malformations in the developing embryo (Zabihi & Loeken, 2010). Maternal hyperglycemia also contributes to increased oxidative stress—an excess of harmful

reactive oxygen species relative to antioxidant presence. High levels of reactive oxygen species directly lead to three known causes of congenital anomalies and mortality: alterations in cell membranes, dysfunction of mitochondria and programmed cell death (Zabihi & Loeken, 2010). The consequences of these pathologic processes have been reported in the recent literature. A systematic review of 13 observational studies exploring the impact of glycemic control on perinatal complications demonstrated an increased risk of congenital anomalies, miscarriage and perinatal mortality associated with poor compared to optimal glycated hemoglobin (A1C), with pooled odds ratios (OR) of 3.44 [95% CI 2.30–5.15], 3.23 [95% CI 2.30–5.15], and 3.03 [95% CI 1.87–4.92], respectively (Inkster et al., 2006).

While maternal hyperglycemia in the first trimester is associated with an increased risk of congenital anomalies and miscarriage, hyperglycemia in the second and third trimesters also has significant post-birth consequences for the developing fetus. Some of the most common complications in the postpartum period associated with hyperglycemia in later pregnancy include macrosomia, respiratory disease and neonatal hypoglycemia. The occurrence of macrosomia, defined as a birth weight of 4,000 to 4,500 grams (American College of Obstetricians and Gynaecologists, 2020), among infants of mothers with diabetes occurs as a result of placental function. Women with type 1 and type 2 diabetes are treated with insulin during pregnancy to maintain normoglycemia. Although glucose crosses the placenta to the fetus, insulin does not. In response to maternal hyperglycemia, the fetal pancreas produces large amounts of insulin to maintain glucose homeostasis. Excess insulin acts as a growth hormone (Eidelman & Samueloff, 2002). Macrosomia compared to appropriate for gestational age birth weight is also associated with an increased risk of additional complications including Cesarean sections (OR 3.1 [95% CI, 2.6–3.6]), severe postpartum hemorrhage (OR 2.4 [95% CI, 2.0–3.0]), shoulder dystocia (OR

10.4 [95% CI, 8.6–12.6]), brachial plexus injury (OR 28.5 [95% CI, 8.9–90.7]) and hypoxic-ischemic encephalopathy (OR 4.4 [95% CI, 2.2–8.8]) (Beta et al., 2019).

Neonatal hypoglycemia (blood glucose of less than 2.6 mmol/L identified within the first 72 hours of life [Beta et al., 2019]) is also linked to maternal glycemic control during pregnancy. In the context of maternal hyperglycemia in the prenatal period, the fetal pancreas continuously produces insulin to maintain glucose homeostasis. After birth, when the maternal supply of glucose is cut off, the infant may continue to produce an excess of insulin (transient neonatal hyperinsulinism), which can result in hypoglycemia (Zabihi & Loeken, 2010). Neonatal hypoglycemia can necessitate intensive care in the short term (Zabihi & Loeken, 2010) and have adverse neurodevelopmental effects in the long term. A systematic review of 11 trials and cohort studies that included neonates born at $\geq$ 32 weeks' gestation to mothers with diabetes found that hypoglycemia compared to normoglycemia was associated with visual-motor impairment (OR = 3.46 [95% CI 1.13–10.57]) and executive dysfunction (OR = 2.50 [95% CI 1.20–5.22]) in early childhood (Shah et al., 2019). Hypoglycemia was also associated with neurodevelopmental impairment (OR = 3.62 [95% CI = 1.05–12.42]) and low literacy (OR = 2.04 [95% CI = 1.20–3.47]) and numeracy (OR = 2.04 [95% CI = 1.21–3.44]) in mid-childhood (Shah et al., 2019).

Infants of mothers with diabetes are also at an increased risk of experiencing respiratory complications after birth. Hyperinsulinism, stimulated by maternal hyperglycemia, leads to reduced fetal surfactant. With less surfactant, gas exchange is impaired, resulting in respiratory distress syndrome (Negrato et al., 2012). Infants with respiratory distress syndrome may require intensive care, supplemental oxygen, non-invasive respiratory support and mechanical ventilation (Puthiyachirakkal & Mhanna, 2013). Maternal hyperglycemia also inhibits the activity of fetal endothelial nitric oxide synthase, which results in reduced nitric oxide within

endothelial cells (Shu et al., 2020). This pathological process may hamper pulmonary vascular vasodilation at birth and contribute to an increased occurrence of persistent pulmonary hypertension (RR 1.37, [95% CI 1.23–1.51]) in infants of mothers with diabetes (Shu et al., 2020). The evidence is mixed regarding the long-term outcomes of infants with persistent pulmonary hypertension. Neurodevelopmental disabilities, cognitive delays and hearing deficits affect 6.4% of survivors. Feeding problems and short-term respiratory complications affect 24% of survivors (Puthiyachirakkal & Mhanna, 2013). Infants with persistent pulmonary hypertension at birth have also been found to have a higher prevalence of sensorineural hearing loss and chronic health problems, require bronchodilator therapy and need remedial education at the age of 5 to 10 years compared to infants without persistent pulmonary hypertension (Puthiyachirakkal & Mhanna, 2013).

Inadequate maternal glycemic control during pregnancy contributes to poor perinatal outcomes among women with diabetes and their infants. Therefore, to reduce maternal and fetal risk, it is recommended that women maintain tight glycemic control during pregnancy. According to Canadian guidelines, women should have an A1C of less than or equal to 6.1% by the third trimester, if they can do so safely without experiencing significant hypoglycemia. Targets for blood glucose levels during pregnancy are as follows: fasting and pre-meal blood glucose < 5.3 mmol/L, blood glucose < 7.8 mmol/L one hour post-meal and blood glucose < 6.7 mmol/L two hours post-meal (Feig et al., 2018).

Unfortunately, evidence indicates that women struggle to achieve recommended glycemic targets during pregnancy. A large cohort study in the United Kingdom that followed 3,036 women from conception to delivery found that only 14.3% of those with type 1 diabetes and 37.0% of those with type 2 diabetes met recommended glycemic targets during early

pregnancy. In late pregnancy, this increased to 40.0% for those with type 1 diabetes and 76.0% for those with type 2 diabetes (Murphy et al., 2017). Despite advances in diabetes care, a follow-up study three years later showed no significant improvements in the percentage of women who achieved recommended glycemic targets during pregnancy (Murphy et al., 2018). A retrospective study in Poland (n = 510) showed more promising results; 36.5%, 67.2% and 71.5% of women with type 1 diabetes reached recommended glycemic targets in their first, second and third trimesters, respectively (Cyganek et al., 2017). Yet, inadequate glycemic control during pregnancy remains a modifiable risk factor for poor perinatal outcomes among women with pre-existing diabetes in pregnancy.

The Importance of Diabetes Self-Management Education and Support

Among patients with chronic conditions such as diabetes, self-management and self-care are both integral components of day-to-day life. Often used interchangeably, self-management and self-care enable individuals to take control of their health conditions (Loh, 2018). However, although similar, these two concepts are not identical. Self-care involves an individual's actions related to their health independent from healthcare practitioners (Loh, 2018). In contrast, self-management is a subclass of self-care wherein people manage specific health condition(s) with the input of healthcare professionals (Loh, 2018). Figure 1 provides a pictorial representation of self-management compared to self-care (page 21).

The mastery of both self-care and self-management is critical for patients with diabetes. Diabetes self-management education has become a cornerstone of medical management for patients with diabetes. Empowering patients to be active participants in their diabetes care through monitoring of their health data, such as blood glucose measurements, is the goal of diabetes self-management education (Sherifali et al., 2018). Rather than a didactic, teacher-

centred approach to learning (Keegan, 1993), self-management education uses a learner-centred approach. Collaborative strategies that improve patient self-confidence in applying skills to their health condition are incorporated, for example, having patients self-monitor their blood glucose and report their results to healthcare providers (Sherifali et al., 2018). Self-management education includes goal-setting, problem-solving and patient empowerment strategies, such as ensuring that patients have empirical knowledge regarding their condition to sufficiently collaborate in decision-making with their healthcare provider (World Health Organization, 2009), among other practices (Sherifali et al., 2018). Guidelines suggest that self-management education can be supplemented by self-management support, which includes activities that enhance and reinforce education, such as text messages, email reminders, automatic phone reminders, peer support and mobile health interventions (Sherifali et al., 2018). Specifically, such strategies aim to improve patient self-efficacy, confidence and the ability to effectively self-manage diabetes. Among adults with diabetes, systematic reviews and meta-analyses indicate that self-management education and support interventions effectively improve clinical outcomes (Sherifali et al., 2018), including reducing A1C and diabetes complications such as foot amputations (Worswick et al., 2013).

In the context of pregnancy, diabetes self-management includes (a) self-monitoring of blood glucose up to seven times daily; (b) administering basal insulin using a pen or pump; (c) accurately counting carbohydrates and calculating bolus insulin via a pen or pump accordingly; and (d) undergoing frequent blood-work (Feig et al., 2018). As a result, pregnant women experience a heavy strain and burden of daily self-management as their degree of glycemic control is dependent on how well they manage diabetes between healthcare appointments (Heisler & Resnicow, 2008). Women with type 1 and type 2 diabetes undergo the strain and

burden of self-management, involving frequent self-monitoring of blood glucose, accurate titration of insulin doses to blood glucose measures and carbohydrate intake and close medical monitoring. However, their individual experiences may differ. Those living with type 2 diabetes may be more recently diagnosed than those with type 1 diabetes who were diagnosed as children or adolescents. It has been reported that women may also need to transition from oral hypoglycemics to insulin during pregnancy, and they are less likely to have attended preconception care and counselling than women with type 1 diabetes (Feig et al., 2018). Even though women with type 1 diabetes may have more experience in diabetes self-management, they also undergo related pregnancy-specific challenges. For example, they experience increased insulin requirements later in pregnancy due to the physiological impact of placental hormones (Feig et al., 2018). Interventions that provide women with self-management education and support during pregnancy are promising therapeutic options in the quest to improve diabetes self-management, glycemic control and perinatal outcomes.

Considerations of Race and Ethnicity

The impact of race and ethnicity on diabetes self-management education and support cannot be ignored. Race involves a person's defining physical characteristics and the social meanings ascribed to them, while ethnicity refers to cultural identification, including customs, language and religion (Washington University in St. Louis, 2023). Both race and ethnicity have implications for diabetes management. For example, increased prevalence of food insecurity among non-White compared to White individuals is a known contributor to higher A1C among non-Whites (Mendoza et al., 2018). In another example, having stable housing is a key factor that is associated with optimal control of chronic conditions, including diabetes. This may be due to the fact that accessing care services presents a challenge in the context of housing insecurity

(Hill-Briggs et al., 2021). Minority populations, including African Americans and Hispanic or Latinos comprise 62% of the homeless population in the United States (Hill-Briggs et al., 2021). Thus, the role of race and ethnicity must be considered in discussions of diabetes self-management education and support.

Problem Statement

The increasing prevalence of pre-existing diabetes in pregnancy and the associated perinatal risks highlight the critical need to focus on improving maternal glycemic control to improve pregnancy outcomes. Among non-pregnant adults with diabetes, self-management education and support induce statistically significant and clinically meaningful improvements in diabetes outcomes, including glycemic control. The literature shows that the major research focus is on prenatal diabetes education for women with gestational diabetes mellitus. In contrast, research on diabetes education for women with pre-existing diabetes in pregnancy, particularly type 2 diabetes, is lacking.

The overall purpose of this thesis is to understand how self-management and support experiences of women with type 1 or type 2 diabetes in pregnancy help to explain self-management practices and glycemic control. To accomplish this, a mixed methods, sequential, comparative case study will be used in which quantitative and qualitative data will be integrated to support the analysis of the cases. The specific objectives of the thesis are therefore three-fold:

1. To understand how the self-management and support experiences of women with type 1 and type 2 diabetes in pregnancy help explain glycemic control (mixed methods);
2. To determine the predictors of glycemic control during pregnancy among women with type 1 and type 2 diabetes (quantitative);

3. To describe the experience of managing diabetes during pregnancy and identify the diabetes self-management education and support needs during pregnancy among women with type 1 and type 2 diabetes (qualitative).

Theoretical Framework

Albert Bandura's Theory of Self-Efficacy was used as a framework to guide the overall thesis. The Theory of Self-Efficacy is based on the idea that individuals can exercise control over their behaviour (Resnik, 2014). The theory has several important concepts that all work together to influence one's belief in their ability to perform a behaviour, or their self-efficacy. Important theoretical concepts include efficacy expectations, outcome expectations, performance accomplishments, vicarious experiences, verbal persuasion and physiological state. Efficacy expectations, one of the integral components of the theory, refer to one's judgement of their ability to complete a certain task (Bandura, 1977). Outcome expectations, another central element of the theory, are one's expectations of the result of task completion. Outcome expectations are largely based on a person's efficacy expectations and may not significantly add to the prediction of behaviour (Resnik, 2014). According to Bandura (1977), personal efficacy is derived from performance accomplishments, vicarious experiences, verbal persuasion and physiological state. Performance accomplishments are one's previous experiences of engaging in a certain behaviour. Performance accomplishments have the greatest influence on one's personal efficacy. One's efficacy is also influenced after seeing someone else complete a desired behaviour. Encouragement from another person, also known as verbal persuasion, as well as one's bodily sensation in response to a stressful situation, also known as physiological state, impact one's personal efficacy. It is as a result of these factors that one's personal efficacy is developed (Bandura, 1977). For example, a person's belief in their ability to self-monitor their

blood glucose could be influenced by having previously accomplished this task (performance accomplishment), seeing a colleague with diabetes perform this behaviour (vicarious experience), receiving encouraging words from their diabetes educator (verbal persuasion) and/or experiencing a reduction in symptoms of hyperglycemia when their diabetes is well-managed as a result of frequent self-monitoring of blood glucose (physiological state). Figure 2 provides a pictorial representation of the Theory of Self-Efficacy.

Although the Theory of Self-Efficacy is helpful, Bandura misses a key component that has a large influence on behaviour change and health outcomes, namely the social determinants of health. These include income and social status, social support networks, education, employment and working conditions, physical and social environments, gender roles and culture (Bryant et al., 2011). The omission of the social determinants of health is significant and detracts from the overall adequacy of the theory to inform self-management education, as a great deal of one's ability to self-manage their diabetes depends on factors such as education, income, social support, gender and culture (Walker et al., 2014).

The social determinants of health have been described at global and individual levels. The World Health Organization emphasizes that the quality of one's health is directly influenced by living conditions (Mikkonen & Raphael, 2010). Within clinical practice, some patients are motivated to improve their health, but barriers, often financial, impact their ability to do so. In the context of diabetes self-management, some patients with type 1 diabetes experience superior glycemic control with the use of insulin pump therapy (Pozzilli et al., 2016). Unfortunately, the cost of these technologies is high without insurance coverage or adequate financial resources. Therefore, although a patient with type 1 diabetes may think that they are capable of using an insulin pump (efficacy expectation) and believe that it could help them achieve optimal glycemic

control (outcome expectation), they are impacted by their socioeconomic status, such as education and income, for which Bandura's theory does not account.

In addition to influencing the self-management of chronic conditions, social determinants of health may affect clinical outcomes for those living with diabetes (Hill et al., 2013). For example, among adults with type 2 diabetes, Walker et al. (2014) found significant relationships between glycemic control and education, social support and food security—lower A1C was associated with higher levels of education, social support and food security. Walker et al. (2014) concluded that attention should be paid to increasing social support and supporting patients in medication adherence to improve glycemic control.

The impact of intersectionality should also be considered in a discussion of self-efficacy and social determinants of health. Intersectionality refers to the idea that factors such as race, ethnicity, gender and socioeconomic status interact exacerbating inequalities (Center for Intersectional Justice, 2023). For example, research examining the relationship between the intersectionality of sex, race and diabetes indicates that African American women with type 2 diabetes undergo increased health disadvantages compared to non-black women and black and non-black men with diabetes (Nagvi et al., 2021). Thus, close examination of the intersectionality of sex, race and other factors among those with diabetes is warranted.

For healthcare providers, supporting patients in healthy behaviours is of great importance, particularly for conditions like diabetes that rely heavily on self-management (Hardcastle, 2015). For chronic disease management in general, promoting patient self-efficacy while considering social determinants of health is essential due to its potential to instigate and maintain healthy behaviours (Rapley & Fruin, 1999). With regard to supporting women with diabetes in pregnancy, understanding women's self-efficacy within the context of social

determinants of health is particularly important given the finite time that one has to optimize self-management education and support and subsequently pregnancy outcomes.

Researcher Reflective Statement

As part of this mixed methods thesis, I conducted qualitative research. Therefore, below I briefly outlined the importance of self-reflection for the qualitative researcher and engaged in my own process of reflexivity (Bradbury-Jones, 2007) or self-reflection to make clear my positionality in undertaking this research.

The product of qualitative research is accepted to be a joint creation between the researcher and the researched (Karnieli-Miller et al., 2009). As such, the qualitative researcher has a major influence on final study outcomes (Poggenpoel & Myburgh, 2003). It is therefore essential that their beliefs, values and assumptions be thoroughly examined and understood.

My passion for supporting women with pre-existing diabetes in pregnancy began when I was employed in a nursing role in the neonatal intensive care unit. In this role, I frequently cared for infants who had been exposed to maternal diabetes during pregnancy and required intensive care to treat conditions such as congenital anomalies, hypoglycemia and respiratory distress, among others. In caring for these infants, I often became close with their families, particularly the mothers, who expressed their postpartum worries, fears and frustrations to me. I tried to provide support to these families, but I was often at a loss to know how to help them. Later, in the early stages of my graduate nursing studies, I was fortunate to have a clinical placement in a tertiary diabetes clinic. In this rotation, I shadowed healthcare professionals who provided clinical care to women with type 1 and type 2 diabetes in the preconception and antenatal periods. This offered me the perspective of diabetes self-management during preconception and pregnancy, a time during which I learned that how a mother controls her diabetes has a

significant impact on her pregnancy outcome. While I was impressed with the knowledge and skills with which the healthcare team educated these mothers, I was left wondering if there were ways to offer better support as I talked with many women who were struggling with the day-to-day aspects of managing diabetes during pregnancy. As I began conducting my review of the literature on this topic, I was drawn to mixed methods as a potential research design because of how it allows for the incorporation of both quantitative and qualitative data, fitting well with the specialized and complex topic. Thus, I decided to focus my doctoral thesis on conducting a mixed methods study on the topic of self-management education and support for women with type 1 and type 2 diabetes during pregnancy.

Summary of Thesis Chapters

This sandwich thesis is comprised of four published manuscripts and one manuscript prepared for submission, of which I am the first author. The manuscripts are connected through the common objectives of the overall thesis, as described previously.

Chapter 2 – Self-Management Education Among Women with Pre-Existing Diabetes in Pregnancy: A Scoping Review

This chapter is a scoping review that was published in the *International Journal of Nursing Studies*. It lays the groundwork for the thesis by synthesizing the evidence regarding prenatal diabetes education and support for women with type 1 and type 2 diabetes. A lack of studies centred on education and support interventions during pregnancy for women with type 1 and type 2 diabetes was identified.

Chapter 3 – Supporting Self-Management in Women with Pre-Existing Diabetes in Pregnancy: A Protocol for a Mixed Methods Sequential Comparative Case Study

Chapter 3 is the research protocol for the current thesis that was published in *BMJ Open*. It outlined the methodology of the four-phased mixed methods study.

Chapter 4 – Trends and Self-Management Predictors of Glycemic Control During Pregnancy in Women with Pre-Existing Type 1 and Type 2 Diabetes: A Cohort Study

This chapter is a prospective cohort study that was published in *Diabetes Spectrum*. In this cohort of patients with type 1 and type 2 diabetes (n = 111), we demonstrated that, overall, women were able to achieve recommended glycemic targets during pregnancy. Furthermore, self-efficacy was high among the cohort and was a significant predictor of glycemic control.

Chapter 5 – Understanding the Self-Management Education and Support Needs During Pregnancy Among Women with Pre-Existing Diabetes: A Qualitative Descriptive Study

Chapter 5 is a qualitative descriptive study that was published in *BMC Pregnancy and Childbirth*. Through the results of qualitative interviews with 12 women (type 1 diabetes, n = 6; type 2 diabetes, n = 6), we found that women with diabetes described their experiences of pregnancy as terrifying, isolating, mentally exhausting and accompanied by a loss of control. Self-management support needs reported included healthcare that is individualized, inclusive of mental health support, and support from peers and the healthcare team.

Chapter 6 – Supporting Self-Management in Women with Pre-Existing Diabetes in Pregnancy: A Mixed Methods Sequential Comparative Case Study

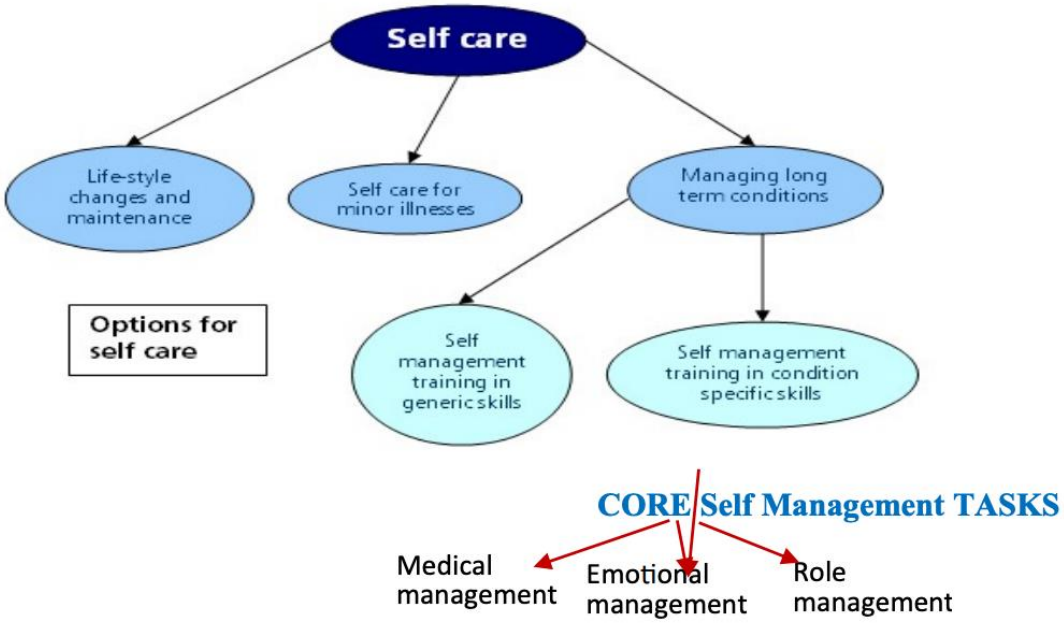
This chapter describes the mixed methods integration of the results of the cohort study (Chapter 4) and the results of the qualitative descriptive study (Chapter 5). A joint display table and a narrative approach that weaved together the statistics and qualitative themes to display the data integration was used to develop three cases of participant-derived support needs in pregnancy: mental health support, support from the healthcare team and peer support. This study is currently submitted for publication.

Chapter 7 – Conclusions

Chapter 7 is the concluding chapter that describes key contributions of the thesis and recommendations for education and clinical practice, research and policy as well as strengths and limitations. Plans for knowledge translation are also discussed.

Figure 1

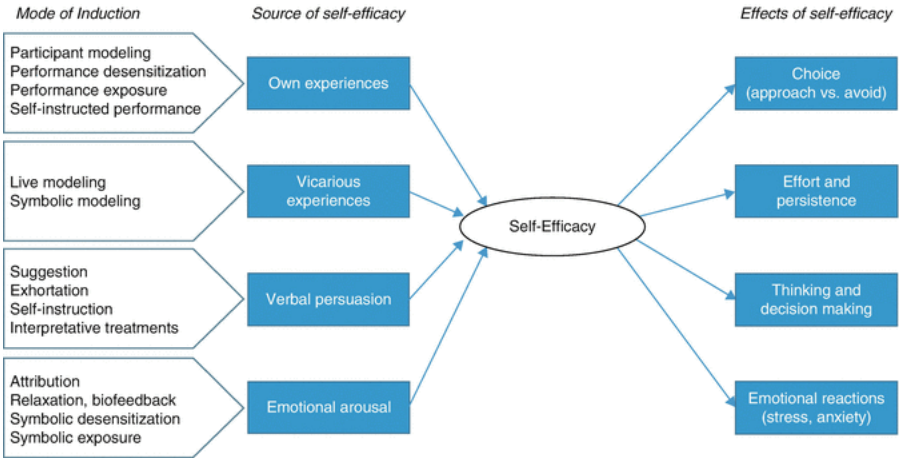
Pictorial Representation of the Theoretical Constructs of Self-Management versus. Self-Care



Note. From "Self-care or Self-management in Palliative Survivorship Care in Asia: A Call for More Research," by S. Y. Loh, 2018. Nursing & Palliative Care, 3(4), pp.1–3.

Figure 2

Pictorial Representation of the Theory of Self-Efficacy



Note. Lippke, 2017

CHAPTER 2

TITLE: Self-management education among women with pre-existing diabetes in pregnancy: A scoping review

AUTHORS: Sushko, K., Tschirhart Menezes, H., Strachan, P., Butt, M. & Sherifali, D.

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NOTE: The manuscript included in this thesis is the final peer-reviewed manuscript submitted for publication. It is a non-final version of the article published in final form in the International Journal of Nursing Studies.

Abstract

Background: Education is a cornerstone of self-management for adults with diabetes. Self-management is particularly important during pregnancy for women with type 1 and type 2 diabetes, as perinatal outcomes are affected by maternal glycemic control. To our knowledge, literature describing the provision of diabetes education and support during pregnancy for women with type 1 and type 2 diabetes has not been synthesized, nor examined within its context as a complex intervention.

Objectives and design: This scoping review aims to synthesize the evidence regarding prenatal diabetes education and support for women with type 1 and type 2 diabetes and to apply the Medical Research Council framework for complex interventions where appropriate.

Data sources and methods: We searched EMBASE, CINAHL, and MEDLINE from inception to February 2019 for primary studies focused on prenatal diabetes education among women with type 1 and type 2 diabetes. Two independent reviewers screened eligible studies against inclusion criteria. A narrative synthesis of the included studies was conducted.

Results: Of 511 identified citations, 30 studies were included in the final review. Approximately 44% of the pooled sample were women with type 1 diabetes, 46% had gestational diabetes mellitus, and 10% had type 2 diabetes. Education focused on self-monitoring of blood glucose, attaining glycemic targets, and following a healthy diet. Many studies included educational elements that went beyond traditional didactic teaching and promoted self-management skills and self-management support. The majority of education was delivered via one-on-one outpatient appointments every one to three weeks. About half of the reviewed studies used a multidisciplinary team approach, with most including a combination of physicians, nurses, dietitians, and midwives. Application of the Medical Research Council framework revealed that

most studies were limited in methods (i.e., randomization) and few examined process evaluation or intervention cost-effectiveness.

Conclusion: We identified a lack of studies centred on educational interventions for women with type 2 diabetes in pregnancy. As pregnancy for women with type 2 diabetes involves significant changes, including the transition from oral hypoglycemics to insulin therapy, often without exposure to diabetes-specific preconception care and counselling, future research may focus on optimizing preconception and prenatal education and support for this high-risk group. This is particularly relevant as the prevalence of type 2 diabetes is increasing worldwide. Future research ought to also design, implement and evaluate interventions in accordance with the Medical Research Council framework for complex interventions.

Keywords: pregnancy; self-management; education; diabetes mellitus, type 2; diabetes mellitus, type 1; diabetes, gestational; prenatal education; prenatal care; mobile applications; telemedicine

What is already known about the topic?

- The number of women with pre-existing diabetes in pregnancy is growing, attributed to the rising prevalence of obesity and type 2 diabetes, and leading to an increase in the number of women at risk of serious perinatal complications.
- Evidence demonstrates that the achievement of good glycemic control during pregnancy contributes to improvements in perinatal outcomes.
- Optimal diabetes self-management education and support are critical during pregnancy, yet literature regarding the provision of prenatal diabetes education and support has not been synthesized, nor has it been examined in the context of a complex intervention framework.

What this paper adds

- We synthesized the key characteristics of prenatal education and support interventions for women with type 1 and type 2 diabetes, finding that multidisciplinary healthcare teams provide frequent outpatient self-management education, supplemented with self-management support.
- Application of the Medical Research Council framework for complex interventions revealed that most of the included studies did not use randomized methods to evaluate interventions, many did not include information to conduct a process evaluation, and only one explored intervention cost-effectiveness. There is a lack of studies focused on prenatal education and support for women with type 2 diabetes, indicating that future research should be directed at optimizing education and support for this high-risk group,

as well as incorporating the Medical Research Council framework into the development and evaluation of such interventions.

1. Introduction and background

Pre-existing diabetes in pregnancy is defined as type 1 diabetes or type 2 diabetes that has been diagnosed before pregnancy (Feig et al., 2018). The number of women with pre-existing diabetes in pregnancy is increasing rapidly, with significant contributing factors that include a rise in the proportion of younger women affected by obesity and type 2 diabetes and those entering pregnancy at a later age (Feig et al., 2018). A large population-based study in Ontario, Canada (n = 1,109,605) found that the prevalence of pre-existing diabetes in pregnancy doubled from 0.7% to 1.5% between 1996 and 2010 (Feig et al., 2014). Globally, pre-existing diabetes in pregnancy presents a growing problem. Between 1995 and 2015, the occurrence of type 1 diabetes in pregnancy in the United Kingdom increased from affecting 1.56 to affecting 4.09 pregnancies per 1,000 (Coton et al., 2016). The occurrence of type 2 diabetes in pregnancy also increased from affecting 2.34 pregnancies per 1,000 in 1995 to affecting 10.62 pregnancies per 1,000 in 2012 (Coton et al., 2016). Other countries in North America, Europe, the Middle East, and Asia have experienced a similar phenomenon (Tutino et al., 2014, Deputy et al., 2018, Wahabi et al., 2017, Fadl and Simmons, 2016, López-de-Andrés et al., 2020).

The rising rate of pre-existing diabetes in pregnancy is concerning, particularly when the maternal and fetal risks associated with this condition are considered. Among women with type 1 and type 2 diabetes in pregnancy, there is a twofold higher risk of congenital anomalies, stillbirth, and death within the first seven days of life among their infants compared to those of women without diabetes (Feig et al., 2014). This heightened risk has largely been attributed to poor glycemic control (Inkster et al., 2006). With evidence demonstrating an association between good glycemic control and improved perinatal outcomes (Feig et al., 2018, Inkster et al., 2006), there has been a focus on interventions to improve prenatal glycemia to reduce maternal and fetal

risk. Currently, Canadian guidelines recommend that women aim to achieve glycated hemoglobin (A1C) of less than or equal to 6.5% throughout pregnancy and an A1C of less than or equal to 6.1% by the third trimester if it can be reached safely. Women should also aim to achieve a fasting and preprandial blood glucose of less than 5.3 mmol/L, one-hour postprandial blood glucose of less than 7.8 mmol/L, and two-hour postprandial blood glucose of less than 6.7 mmol/L (Feig et al., 2018).

Since the success that any patient has in attaining glycemic targets depends on how they manage their diabetes between appointments with their healthcare provider (Heisler and Resnicow, 2008), pregnant women experience a heavy burden of self-management. During the prenatal period, diabetes self-management is multifactorial and includes self-monitoring of blood glucose between four to seven times per day, administering basal insulin, engaging in accurate carbohydrate counting and administering bolus insulin according to a specified insulin-to-carbohydrate ratio, and completing routine blood-work, including A1C every three months (Feig et al., 2018). The provision of diabetes self-management education and support interventions during pregnancy provides a promising therapeutic option to lessen the burden of self-management and improve perinatal outcomes.

Diabetes self-management education is an approach to health education that empowers patients to be active in their care through actions such as monitoring personal health data or making care decisions in consultation with their healthcare provider (Sherifali et al., 2018). Self-management education is in contrast to didactic pedagogy, a teacher-centred approach to learning where students are primarily taught content through passive means (Keegan, 1993). Self-management education reaches beyond imparting knowledge and uses collaborative and learner-centred strategies to increase ability and confidence in applying relevant skills (Sherifali

et al., 2018). Practices that promote diabetes self-management include individual goal setting, problem-solving, patient empowerment initiatives, close patient-provider collaboration, and education specifically tailored to the individual (Sherifali et al., 2018). Self-management education strategies can also be supplemented by self-management support, which includes web-based education, text messages, email reminders, and peer support, among others (Sherifali et al., 2018).

Diabetes self-management education and support are considered complex interventions, characterized as those that consist of multiple interrelated components (Medical Research Council, 2000). The evaluation of complex interventions presents a challenge for several reasons, including a lack of standardization in design and delivery as well as outcomes that are complex or difficult to assess, among others (Medical Research Council, 2000). Consequently, the Medical Research Council established a framework to assist in the development and evaluation of such interventions. According to the Medical Research Council, an evaluation of complex interventions involves assessing effectiveness, understanding the change process, and exploring cost-effectiveness (Medical Research Council, 2000).

Despite the potential that prenatal diabetes self-management education and support has for improving glycemic control and perinatal outcomes, to our knowledge, literature regarding the provision of such interventions for women with pre-existing diabetes has not been synthesized, nor has it been examined within the context of a complex intervention framework. The objective of this scoping review is to synthesize the available literature from primary studies regarding prenatal self-management education and support for women with type 1 and type 2 diabetes. We intend to elucidate why education and support interventions are established, what materials are used in their implementation, how they are carried out, and who provides them. We

will also apply the Medical Research Council framework for complex interventions in an evaluation of these interventions where appropriate.

2. Methods

2.1. Information sources and search strategy

We developed our search strategy with the assistance of an experienced medical librarian. Search terms included medical subject headings and keywords such as “education” and “counselling.” We searched EMBASE, CINAHL, and MEDLINE from inception to February 2019. Supplemental Material Fig. 1 provides the search strategy for the MEDLINE database. The search strategies for the other databases are available upon request. We also searched the reference lists of relevant studies and grey literature (Google Scholar). We did not restrict based on the publication date. We only considered English language studies. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews guided the reporting of this review (Tricco et al., 2018).

2.2. Eligibility criteria

Studies were eligible for inclusion if they focused on prenatal education and support for women with type 1 and 2 diabetes. We excluded studies that only focused on gestational diabetes mellitus. Although we recognize that the preconception period is distinct from the prenatal period and preconception care is primarily provided to women with type 1 diabetes, we elected to include studies that had a preconception component if they also had a prenatal element to avoid omitting any relevant literature. We excluded studies that only focused on the preconception period.

2.3. Study selection process, data charting, and synthesis

All citations were exported to EndNote for deduplication and then transferred to DistillerSR for screening by two independent reviewers. Title and abstract screening assessed the following: Is the study in English? Are the study population women with type 1 or type 2 diabetes in pregnancy? Articles that passed the title and abstract screening were screened at the full-text level by the same reviewers and assessed the following: Is the study about diabetes education, self-management, or self-management support? Any disagreements were resolved through discussion or by the input of a third reviewer.

The characteristics of each study were extracted, including the year of publication, the country of study conduct, and the study design. We also extracted participant characteristics and calculated a pooled sample size. We used the Template for Intervention Description and Replication checklist (Hoffmann et al., 2014) to guide data charting and synthesis. The Template for Intervention Description and Replication checklist characterizes: a) a description of the intervention; b) the goal of the intervention; c) any materials used; d) intervention procedures; e) who provided the intervention; f) modes of intervention delivery; g) intervention location; h) intervention frequency and length; i) tailoring of the intervention to participants; j) modifications to the intervention during the study; and k) planned and actual intervention adherence or fidelity (Hoffmann et al., 2014). We also applied the Medical Research Council framework for complex interventions (Medical Research Council, 2000) in an evaluation of the interventions where appropriate. All data was extracted and verified by two reviewers and a narrative synthesis was conducted using the extracted information.

3. Results

A total of 647 articles were identified from the database, reference list, and grey literature searches. Following deduplication, 511 articles were screened at the title and abstract level and 180 were screened at the full-text level. Thirty studies were included in the narrative review (Fallucca et al., 1996, Owens et al., 2016, Plehwe et al., 1984, Steel et al., 1991, Stenhouse et al., 2013, Cousins, 1991, Dalfrà et al., 2009, Berg and Sparud-Lundin, 2009, Carral et al., 2015, Frost and Beischier, 2000, Feig et al., 2006, Jovanovic and Peterson, 1984, Mazze and Langer, 1988, Di Biase et al., 1997, Howorka et al., 2001, Joseph et al., 2018, Linden et al., 2018, Huddle, 2005, Ladyzyn´ski et al., 2001, Kushion et al., 1985, Kalwarf et al., 2001, Bartholomew et al., 2015, Adolfsson and Jansson, 2012, McElvy et al., 2000, Nørgaard et al., 2017, Rosenn et al., 1991, Simmons et al., 2001, Wojcicki et al., 2001, Tevaarwerk et al., 1981, Ringholm et al., 2013). Fig. 1 provides a flow diagram of the study screening process.

The included studies were published between 1981 and 2018. Twenty percent (n = 6) were published within the last five years, in 2015 or later. Thirty-seven percent (n = 11) were published within the last ten years, in 2009 or later. The majority were conducted in Europe (53%, n = 16) and North America (33%, n = 10). The remaining 13% (n = 4) were conducted in Australia, India, New Zealand, and South Africa. Studies predominantly used quantitative designs (90%, n = 27) and more than half of these were observational (70%, n = 19), including retrospective and prospective cohorts, cross-sectional studies, and program evaluations. Eight studies reported the results of clinical trials, of which five were randomized and three were non-randomized. Three studies used qualitative methods, including grounded theory, interactive focus groups, and a hermeneutic lifeworld approach.

A combined sample of 5,656 participants was studied across 28 of the included studies. The remaining two studies reported sample size in terms of the number of births. The first study reported 76 births by 59 women with type 1 diabetes that were matched with 76 births by women without diabetes. These were compared with all registered births in Austria between 1984 and 1999 (n = 1,342,993). The second study reported 445 births by 306 women; 61% of births were to women with type 1 diabetes and 39% of births were to women with type 2 diabetes. The number of participants with type 1 diabetes was 2,387 (44%); the number with type 2 diabetes was 519 (10%); and the number with gestational diabetes mellitus was 2,581 (46%). One study (n = 169) did not report the type of diabetes that participants had. Refer to Supplemental Material Table 1 for further details regarding the characteristics of included studies.

3.1. Individual study results

3.1.1. Description of educational intervention/exposure

We classified the name or phrase describing the education intervention or exposure in the included studies into two main categories – a clinic-based education and/or support intervention/exposure or a technology-based education and/or support intervention/exposure. Seventeen of the 27 quantitative studies described clinic-based education and/or support interventions/exposures that provided combined diabetes and obstetric care during pregnancy. Refer to Supplemental Material Table 2 for further details regarding intervention characteristics.

Ten of the 27 quantitative studies described technology-based education and/or support interventions/exposures. These included primarily telemedicine interventions (n = 8) that facilitated communication of self-monitored blood glucose data between participant and healthcare provider. In two instances, additional data, such as insulin dose, physical activity, symptoms of hypoglycemia, and markers denoting meals, were also transmitted. Of the two

remaining studies that comprised technology-based education and/or support interventions/exposures, one described a mobile application that provided evidence-based information on a variety of topics related to diabetes and pregnancy. The other was a website that supported diabetes self-management through the provision of evidence-based information on pregnancy, labour and child-birth, and life as a new mother with diabetes; a self-care diary for recording personal health data; a discussion forum for peer support; and a Frequently Asked Questions section.

The qualitative studies focused on participant experience with both technology-based education and/or support interventions/exposures (*n* = 1) and clinic-based education and/or support interventions/exposures (*n* = 2).

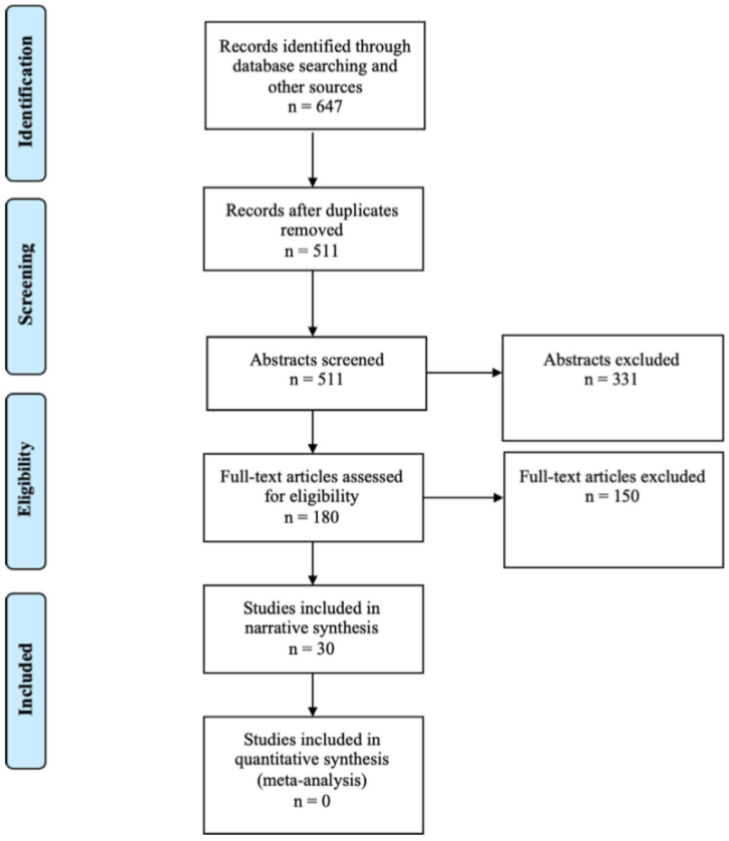

Fig. 1. PRISMA flow diagram.

3.1.2. Rationale, theory, or goal for intervention/program/exposure

Only one of the quantitative studies incorporated theory or framework. Linden et al. (2018) used the theoretical approach of person-centred care to guide the development of a web-based support tool aimed at increasing participant autonomy, capacity, well-being and diabetes self-efficacy. The remaining studies articulated a goal of improving perinatal outcomes for women with diabetes and their infants.

Only one of the three qualitative studies were guided by theory. Berg et al. (2009) used a reflective, hermeneutic, lifeworld approach to understand women's experiences with professional support services during pregnancy and birth. This was evident in their data analysis phase as the researchers focused on an intensive review of the interview text without preconceived ideas or hypotheses. For the other qualitative studies, the goal of the first was to understand the participant experience with a web-based self-management support tool (MODIAB-web). The remaining study was aimed at exploring the participant experience following exposure to a clinic-based education and/or support program during pregnancy.

3.1.3. Materials used in the intervention/exposure

All clinic-based education and/or support interventions/exposures described in the quantitative studies used face-to-face instruction and three supplemented this with written material (Ladyzyn´ski et al., 2001, Steel et al., 1991, Ringholm et al., 2013). The studies describing technology-based education and/or support interventions/exposures also provided face-to-face instruction as well as written information displayed on the mobile application or website. Education material focused on blood glucose self-monitoring (70%, n = 19), nutrition (56%, n = 15), glycemic targets (30%, n = 8), and general information related to managing diabetes during pregnancy (19%, n = 5). Several studies also provided education on weight gain

and exercise (15%, *n* = 4), avoiding hypoglycemia (15%, *n* = 4), and maintaining glycemic control during labour (15%, *n* = 4). Other education topics included teratogenic drugs, insulin pump therapy, insulin types and injection techniques, sick day management and avoidance of ketosis, diabetes complications, smoking cessation, and preparing for the postpartum period. Two studies included evidence and references related to the development of their educational resources. Three studies included education for healthcare providers.

For the qualitative studies, the first involved participant experience with a website that provided evidence-based information about managing diabetes during pregnancy and early motherhood. The second qualitative study focused on participant experience following exposure to a clinic-based education program, which provided face-to-face instruction on the prevention, early detection, and treatment of perinatal complications. The final qualitative study did not report the details of the educational materials that were used or the topics that were covered in their clinic-based program.

3.1.4. Procedures/activities/processes of intervention/exposure

For the 17 quantitative studies that described a clinic-based education and/or support intervention/exposure, these generally began with an initial visit to the clinic for assessment and commencement of medical treatment. Occasionally, women were admitted to hospital to undergo medical assessment and testing. Following this, one or more education sessions began, either one-on-one or in a group setting. Participants returned for follow-up approximately every one to three weeks, with frequency increasing with gestational age. Additional visits or education sessions were provided as needed.

Ten studies described telemedicine interventions, which typically held an initial education session to orient participants to the particular system. Following this, participants

transmitted self-reported data to healthcare providers frequently (usually daily or weekly) and received virtual treatment adjustment throughout pregnancy, supplemented with clinic visits. The study that described a mobile application provided the application as a supplement alongside usual care. Another study that comprised a web-based support tool also did so as a supplement to usual care.

Twenty-five studies incorporated educational elements that went beyond traditional didactic teaching and promoted self-management skills including self-monitoring of blood glucose and insulin adjustment, among others. Thirteen studies also supplemented self-management education with elements of self-management support, including telephone calls/telemedicine communication between clinic visits, reminder text messages, web-based peer support, and use of mobile applications.

The qualitative studies were focused on participant experience and provided limited details regarding the procedures involved in the education and/or support intervention/exposure of interest. The qualitative study by Adolfsson and Jansson (2012) explored women's experiences using a prototype of the web-based support tool, MODIAB-web. MODIAB-web was available for participants to access at any time throughout pregnancy and consisted of four sections, including an online journal to record personal health data, general information about diabetes, pregnancy, and new motherhood, answers to Frequently Asked Questions, and a discussion forum for peer support. Stenhouse, Letherby, and Stephen (2013) conducted a grounded theory study exploring women's experience following exposure to a combined diabetes and obstetric clinic at a district hospital in the southwest of England. This program involved frequent appointments throughout pregnancy, with each appointment beginning with a clinical assessment by a mid-wife and ending with a joint consultation involving the

multidisciplinary healthcare team. Berg and Sparud-Lundin (2009) used a hermeneutic lifeworld approach to understand women's experiences with professional support services during pregnancy and birth. The professional support services comprised several general prenatal clinics as well as specialized diabetes and obstetric clinics focused on high-risk pregnancies. Specific details regarding the provision of education and care in these clinics were not described.

3.1.5. Mode and location of the intervention/exposure delivery

All quantitative studies included a component of outpatient education that took place in a prenatal or diabetes clinic. Eight studies included an inpatient component, where women were hospitalized either initially to improve blood glucose levels, or during pregnancy when they had difficulty maintaining euglycemia. Three studies also included an element of group education. Eight studies evaluated the use of telemedicine interventions, three involved a web-based education and support program, and two involved a mobile phone application.

For the qualitative studies, one focused on a web-based education and support intervention and the others involved exposure to a clinic-based education and/or support program.

3.1.6. Duration/intensity/dose of intervention/exposure

Most of the quantitative studies (85%, $n = 23$) detailed the frequency with which women attended educational sessions or participated in virtual education or support via telephone, telemedicine, website, or mobile application. In over half of these studies (56%, $n = 15$), healthcare providers saw participants clinically every one to three weeks. In three studies, healthcare providers saw participants clinically every one to four weeks. Appointment frequency typically increased with gestational age. One study saw participants clinically every six to eight weeks with virtual support (telemedicine) every two weeks. In another study, participants

submitted glucose data virtually on a daily basis and received treatment adjustment by physician telephone-based consultation. Studies with a web- or mobile-based components were available for participants to access at any time.

Similarly, the qualitative study that focused on participant experience with a web-based support tool was available for use at any time throughout the duration of pregnancy. For the other two qualitative studies that involved exposure to clinic-based education and/or support programs, the first individualized appointment frequency throughout pregnancy based on participant need, ranging from monthly to weekly. The final qualitative study did not provide details regarding the intensity or dose of educational sessions.

3.1.7. Tailoring of intervention/exposure

Seventeen of the quantitative studies described some tailoring of the intervention or program to participant needs. These included specific instructions on insulin administration and adjustment, intensified insulin treatment, insulin pump therapy, oral hypoglycemic medication, hypoglycemia prevention, and education on complications such as hypertension, nephropathy, and weight control, as needed. Tailoring also involved the development of a personalized diet plan, provision of individualized summaries of personal health data, an online discussion forum for peer support, education on potential complications for those with very poor glycemic control, and the ability to customize what information was accessed on mobile applications.

One of the qualitative studies involved tailoring of the web-based support tool, as participants could customize what evidence-based information they accessed.

3.1.8. Modifications to interventions/exposure

Six quantitative studies modified their intervention or program at some point during the study. These modifications included continuing with studies when underpowered (high attrition

rate), including a control group of participants that were referred to the program late in pregnancy, and making changes to clinical practice. Most of the modifications were positive. However, one study was impacted by a loss of funding partway through which impaired the delivery of specialized care for all, regardless of medical insurance.

None of the qualitative studies discussed intervention modification.

3.1.9. Adherence (planned) to intervention/exposure

Twelve quantitative studies included information relating to the planned monitoring of adherence to the education intervention/exposure. Two focused on reminding participants to remain engaged in the intervention (reminder text messages to use the teletransmission system or to log on to the study website). Three studies were concerned with ensuring the face validity of study questionnaires, the accuracy of provided educational information, or the technical efficacy of study equipment (glucometers). Four studies concentrated on validating patient self-reported data, while three others were focused on training and supporting healthcare providers to ensure they were carrying out the intervention correctly.

Planned intervention adherence was not discussed in any of the qualitative studies.

3.1.10. Adherence (actual) to the intervention/exposure

Thirteen quantitative studies included information regarding actual participant adherence to the intervention/exposure. These studies mostly focused on describing participants that either did not complete the intervention, did not attend all education sessions, or dropped out of the intervention/program due to personal preference or medical reasons (spontaneous abortion, other health conditions). Other studies described eligible participants that were excluded as a result of missing data or evaluated the efficacy of their teletransmission system throughout the study duration.

None of the qualitative studies addressed participant adherence.

3.1.11. Providers of interventions/exposures

For the 26 quantitative studies that specified healthcare provider profession, 46% (n = 12) used a multidisciplinary approach, typically including a combination of physicians, nurses, dietitians, and midwives. Among the fourteen studies where healthcare providers of only one profession provided education, over half of these were physicians (71%, n = 10). Other members of the healthcare team included social workers, diabetes counsellors, and certified diabetes educators.

The primary healthcare provider in one of the qualitative studies was a midwife. The other two qualitative studies described a multidisciplinary team approach, with one involving a combination of diabetologists, obstetricians, midwives, nurses, and dietitians, while the other did not specify provider professions.

3.2. Application of the medical research council framework

According to the Medical Research Council framework, the comprehensive evaluation of complex interventions involves assessing effectiveness, conducting a process evaluation, and exploring cost-effectiveness (Medical Research Council, 2000). Our discussion of intervention effectiveness is prefaced with two caveats. First, study results should be interpreted cautiously as statistical significance may not necessarily equal clinical importance. Furthermore, in agreement with the scoping review methodology, we did not conduct a formal risk of bias assessment of the included studies.

3.2.1. Assessment of intervention effectiveness

An assessment of intervention effectiveness entails considering both the study design and the choice and characteristics of outcome evaluations (Medical Research Council, 2000). The

Medical Research Council framework places particular emphasis on randomized controlled trials as the gold standard design to determine intervention effectiveness. Eight of the studies included in this review employed an interventional design, of which five were randomized controlled trials (Linden et al., 2018, Di Biase et al., 1997, Fallucca et al., 1996, Bartholomew et al., 2015, Wojcicki et al., 2001) and three were non-randomized (Frost and Beischier, 2000, Dalfrà et al., 2009, Carral et al., 2015). Among the studies that randomized participants to an intervention or control group, the interventions comprised cell phone/internet transmission or teletransmission of self-monitored blood glucose data (n = 4) and web-based self-management support tools (n = 1) compared to usual care. Four of these studies found a statistically significant difference between the randomized groups. Bartholomew et al. (2015) observed improved blood glucose reporting in the cell phone/internet technology group compared to the control group (conventional voicemail system), with a compliance rate of 89.3% and 87.6% respectively (p = 0.049) (Bartholomew et al., 2015). Fallucca et al. (1996) noted that blood glucose profiles improved in both the teletransmission group and control group (usual care). However, the teletransmission group experienced statistically significant lower pre-breakfast levels compared to the control group (mean blood glucose 75 mg/dL compared to 104 mg/dL, $p < 0.002$) as well as after dinner levels (mean blood glucose 106 mg/dL compared to 124 mg/dL, $p < 0.050$) at follow-up (Fallucca et al., 1996). Di Biase et al. (1997) also found improved preprandial blood glucose profiles in the teletransmission compared to the control group (before breakfast mean blood glucose 104 mg/dL compared to 118 mg/dL, $p < 0.025$ and before dinner mean blood glucose 105 mg/dL compared to 123 mg/dL, $p < 0.050$, respectively) (Di Biase et al., 1997). Wojicicki et al. (2001) reported improved weekly mean blood glucose measurements in the teletransmission group compared to

the control in terms of weekly change in mean blood glucose level (−3.2 mg/dL compared to −1.4 mg/dL, $p = 0.007$) (Wojcicki et al., 2001).

The Medical Research Council also recommends considering the choice of outcome measures in the assessment of intervention effectiveness (Medical Research Council, 2000). None of the randomized controlled trials involved an assessment of the effect of the intervention on perinatal morbidity and/or mortality. Three of the five randomized controlled trials examined the impact of the intervention on blood glucose measures or A1C (Fallucca et al., 1996, Wojcicki et al., 2001, Di Biase et al., 1997). The remaining two randomized controlled trials assessed psychological outcomes, including acceptance and satisfaction with a teletransmission system and the impact of a web-based support tool on general well-being and diabetes self-efficacy (Linden et al., 2018, Bartholomew et al., 2015).

Two of the randomized controlled trials also conducted sub-group analyses (Linden et al., 2018, Wojcicki et al., 2001). The first study explored the effect of low compared to high intelligence (defined as an intelligence quotient less than 100 and an intelligence quotient greater than 100, respectively) on glycemic control and blood glucose variability. Participants in the intervention and control groups with lower intelligence had better glycemic control and less blood glucose variability (mean blood glucose 129 mg/dL, coefficient of variation 7.5% versus mean blood glucose 144 mg/dL, coefficient of variation 13.9%, $p = 0.283$) compared to intervention and control participants with higher intelligence (mean blood glucose 134 mg/dL, coefficient of variation 9.9% versus mean blood glucose 131 mg/dL, coefficient of variation 13.0%, $p = 0.829$). These results were not statistically significant and the investigators attributed the differences to the low number of participants included in the subgroup analysis (Wojcicki et al., 2001). The second study conducted a dose-response analysis to examine the impact of low

compared to high use of their web-based support tool on participants' questionnaire scores. The investigators found a difference that favored a higher degree of website use (higher mean scores among low frequency users on questionnaires measuring psychological variables such as fear of hypoglycemia [27.8 compared to 21.9 among low frequency users versus high frequency users respectively, $p = 0.140$] and diabetes distress [32.1 compared to 22.5 among low frequency users versus high frequency users, respectively, $p = 0.150$]) (Linden et al., 2018).

Follow-up length for three of the randomized controlled trials comprised the duration of pregnancy, appropriate for interventions focused on the prenatal period. However, follow-up length for one study was only six weeks (Bartholomew et al., 2015), while another study measured psychological outcomes related to diabetes at six-months postpartum using questionnaires, such as the Hypoglycemia Fear Survey and the Problem Areas in Diabetes Scale (Linden et al., 2018).

3.2.2. Understanding processes

Process evaluation can inform researchers regarding both the success and failure of an intervention as well as reveal how they can be optimized (Medical Research Council, 2000). Although none of the included studies conducted a formal process evaluation alongside their study, two of the negative trials and one other trial presented insight into the successes and failures of their intervention (Linden et al., 2018, Bartholomew et al., 2015, Dalfrà et al., 2009). Linden et al. (2018) reported a unique situation wherein there was a wide range of usage of their web-based support tool, ranging from no logins to 15 logins per day (Linden et al., 2018). They postulated that low usage was implicated in the negative results of the trial as a dose-response analysis found that psychosocial measures favored a higher degree of website use. In a written evaluation of the intervention, participants stated that the high demands in daily life contributed

to the low level of intervention use. Dalfrà et al. (2009) hypothesized that negative results could be due to several reasons, including the fact that all women were strongly motivated to achieve good glycemic control during pregnancy, that both intervention and control participants received the same training and used the same glucometers, and that there was considerable variability in glycemic levels, which may have masked medium-term changes in insulin needs and made it impossible to control daily variations in glycemia (Dalfrà et al., 2009). Finally, although Bartholomew et al. (2015) did find a statistically significant difference in compliance with self-monitoring of blood glucose in the intervention (cell phone/internet technology) compared to the control group (conventional voicemail system), the results were very similar between both groups and the investigators attributed this to the fact that both participants in the intervention and control groups received frequent reminder messages to submit blood glucose data (Bartholomew et al., 2015).

3.2.3. Assessment of intervention cost-effectiveness

The Medical Research Council framework also suggests exploring intervention cost-effectiveness to increase the value of study results for decision-makers (Medical Research Council, 2000). Only one of the studies included in this review reported this information. Simmons et al. (2001) found that the cost of their diabetes midwifery service over an eight-month period (NZ$40,000) was favourable when compared to the costs saved as a result of lower rates of hospital admissions, with an average of 325 bed days saved overall. As one obstetric bed had a cost of $250 per day, there was an estimated cost savings of NZ$81,250 (Simmons et al., 2001).

4. Discussion and conclusions

4.1. Summary

Our objective was to synthesize the available literature from primary studies regarding prenatal diabetes self-management education and support for women with type 1 and type 2 diabetes. To do this, we used the Template for Intervention Description and Replication checklist to elucidate the active components of each educational intervention/exposure. We found that only one of the quantitative and one of the qualitative studies utilized a theoretical approach in their design. Seventeen studies described an outpatient clinic-based education and/or support intervention/exposure that provided face-to-face instruction. Three studies supplemented this with written information. The technology-based interventions/exposures employed face-to-face education or written information displayed on the mobile application or website. Three studies involved education for healthcare providers. The outpatient clinic-based education and/or support interventions/exposures typically began with an initial clinic visit with follow-up every one to three weeks for the duration of pregnancy. The technology- based education interventions/exposures also commenced with an initial orientation session followed by frequent data transmission between the participant and healthcare provider. The studies that described a mobile application and a website intervention were available for participants to access at any time. Twenty-five of the quantitative studies included approaches that promoted diabetes self-management and 13 incorporated self-management support strategies. Seventeen studies tailored the intervention to individual participants. Six studies included a modification of the intervention at some point during its duration. Twelve studies included information about the planned monitoring of intervention adherence and thirteen studies provided information about actual

intervention adherence. Most education was provided by a team of multidisciplinary healthcare providers, primarily a combination of physicians, nurses, dietitians, and midwives.

4.2. Medical Research Council framework

4.2.1. Assessment of intervention effectiveness

We also sought to apply the Medical Research Council framework in an evaluation of the educational interventions where appropriate. We aimed to assess intervention effectiveness, conduct a process evaluation, and explore intervention cost-effectiveness. In our assessment of intervention effectiveness, it became evident that the included studies were limited in methods (i.e., randomization). However, the traditional randomized controlled trial is not always the most appropriate or feasible method for the evaluation of complex interventions (Medical Research Council, 2000). In some cases, interventions or exposures may present a clinic or system-wide change in practice (Raine et al., 2016). Consequently, investigators may not be able to randomize participants to one group or another. In another situation, it may be difficult to randomize those attending a single clinic to different groups without introducing the possibility of contamination (Raine et al., 2016). It may also be unethical to randomize patients if clinical equipoise does not exist (Cook and Sheets, 2011). However, although the ethics, feasibility, and pragmatism of the randomized controlled trial are debatable, this design is considered the gold standard for determining intervention effectiveness. As such, the Medical Research Council has made recommendations for situations where a traditional randomized controlled trial is not optimal. These include cluster randomized trials, stepped wedge designs, preference trials and randomized consent designs, and N-of-1 designs (Medical Research Council, 2000). Regrettably, the included studies did not take any of these approaches, leaving room for considerable bias. For the studies that did employ randomization, four out of five observed statistically significant

results in the intervention compared to the control group. These studies that described statistically significant results involved telemedicine interventions. The literature on such interventions among non-pregnant adults with diabetes have found that they induce clinically important improvements in A1C for participants with type 1 and type 2 diabetes (Timpel et al., 2020, Tchero et al., 2018). Timpel et al. (2020) conducted an umbrella review of systematic reviews and meta-analyses to evaluate the effectiveness of telemedicine as a supplement to usual care among adults with diabetes, dyslipidemia, and hypertension (Timpel et al., 2020). This review found that telemedicine leads to clinically important and statistically significant reductions in A1C as a result of interventions that include prescription (−0.75%, $p = 0.13$), teleconsultation (−0.62%; $p < 0.001$), and health information technologies (−0.57%, $p < 0.05$) (Timpel et al., 2020). In another meta-analysis comparing the effectiveness of telemedicine to usual care among adults with type 1 and 2 diabetes, Tchero et al. (2018) also concluded that telemedicine is more effective for improving glycemic control compared to usual care (Tchero et al., 2018). Based on the results of 42 randomized controlled trials, telemedicine was shown to induce a mean reduction in A1C of 0.37% ($p < 0.001$).

Although our review did not include a formal risk of bias assessment, it was evident that the randomized controlled trials that found statistically significant results suffered from a degree of bias, particularly regarding sample size, with a median sample of 25 participants. Three of these studies were also rather old, conducted in 1996, 1997, and 2001. In contrast, the trial that did not find statistically significant results was adequately powered with 174 participants and was more current, published in 2017. Thus, the statistically significant results may have occurred as a result of bias at the study level or at the publication level.

Regarding study outcomes, investigators have multiple factors to consider when making such a critical decision. Some of these factors include clinical importance of the outcome, whether to include an objective or patient-reported outcome, the utility of surrogate outcomes, and whether or not subgroup analysis is suitable (Medical Research Council, 2000). The length of follow-up should also be considered. Finally, monitoring unintended consequences or adverse events may be necessary (Medical Research Council, 2000). Arguably, two of the most important clinical outcomes for women with diabetes during pregnancy are perinatal morbidity and mortality (Feig et al., 2014). Given its association with perinatal outcomes (Feig et al., 2018), measures of glycemic control, such as mean blood glucose levels and A1C, are also relevant. While none of the randomized controlled trials included in this review involved an assessment of the effect of the intervention on perinatal morbidity and/or mortality, three of five trials examined the impact of the intervention on blood glucose measures or A1C (Fallucca et al., 1996, Wojcicki et al., 2001, Di Biase et al., 1997).

4.2.2. Understanding process

Regarding the process evaluation component of intervention evaluation, only three studies provided information to allow for such an assessment, all of which were negative trials. Linden et al. (2018) attributed statistically non-significant results between the intervention and control group to low participant use of the web-based support tool (Linden et al., 2018). This was supported by a sub-group analysis showing higher well-being and diabetes self-efficacy among participants with high compared to medium or low intervention use (Linden et al., 2018). Engagement and retention of participants are commonly acknowledged challenges for researchers, particularly for studies involving complex interventions (Datta and Petticrew, 2013). Acceptable retention rates have been described as at least 80% (Dumville et al., 2006). The five

studies that included information regarding participant loss to follow-up reported retention rates between 61% and 90% (median 85%) (Dalfrà et al., 2009, Carral et al., 2015, Linden et al., 2018, Kalwarf et al., 2001, Bartholomew et al., 2015). Datta and Petticrew (2013) addressed the challenge of participant retention in studies of complex interventions in a content analysis of published studies (Datta and Petticrew, 2013). The studies that they analyzed highlighted the importance of actively engaging participants to optimize retention, as well as providing renumeration in recognition of time committed (Datta and Petticrew, 2013). Although Linden et al. (2018) used strategies to engage participants, such as reminder messages to log in to the study website, this was not enough to induce high intervention utilization (Linden et al., 2018). Furthermore, written feedback from trial participants revealed that they were busy with the demands of pregnancy and motherhood, which contributed to low engagement with the intervention (Linden et al., 2018).

4.2.3. Assessment of intervention cost-effectiveness

Unfortunately, we were only able to explore the cost-effectiveness of one of the included studies, given a general lack of such information presented. Simmons et al. (2001) found that their diabetes midwifery service saved an estimate of NZ$81,250 by reducing the rate of hospital admissions (Simmons et al., 2001). Diabetes management comes at a significant expense, costing the healthcare system in the United States $327 billion in 2017 (Yang et al., 2018). As such, intervention cost-effectiveness is critical to consider and the lack of such information in the included studies represents an important gap. An examination of the literature among non-pregnant adults with type 2 diabetes has found that self-management education interventions have generally shown promise in terms of cost-effectiveness (Brownson et al., 2009). Future

research focused on the cost-effectiveness of prenatal diabetes education and support interventions are warranted.

4.3. Focus on type 2 diabetes

This review highlighted a lack of literature focused on pregnant women with type 2 diabetes. Although we aimed to characterize the literature that focused on education and support among women with pre-existing diabetes in pregnancy, over 45% of the review's pooled sample were women with gestational diabetes mellitus and only about 10% had type 2 diabetes. In Canada, it is estimated that by 2020, one in three Canadians will have diabetes (Canadian Diabetes Association, 2011) and nine out of ten of these will have type 2 diabetes (Government of Canada, 2018). In the prenatal period, women with type 2 diabetes face clear challenges in diabetes management, perhaps more so than those with gestational diabetes mellitus or type 1 diabetes. For women with type 1 diabetes, they have often been managing diabetes for many years, might be more practiced with frequent blood glucose checks and the techniques of insulin administration and adjustment, and have likely received intensive preconception care and counselling for the avoidance of pregnancy until good glycemic control has been achieved (Feig et al., 2018). In contrast, women with type 2 diabetes who are pregnant may have only had diabetes for a few years or less, likely had been taking oral hypoglycemics for medical management, and may not have been exposed to intensive preconception care and counselling. Once becoming pregnant, these women must switch to insulin therapy (Feig et al., 2018) and all that this entails including frequent blood glucose testing and monitoring for hypoglycemia, among other responsibilities. This is a significant adjustment and comes with the need for much self-management education and support. Given the lack of evidence currently focused on

prenatal education for women with type 2 diabetes as well as their heightened need for education and support, future studies may focus on optimizing education and support for this population.

4.4. Limitations

One of the limitations of this scoping review was that only English language studies were included due to the abilities of the authors. In addition, we did not conduct a formal risk of bias assessment. However, this is in agreement with the scoping review methodology (Peters et al., 2015). Finally, there was a lack of inclusion of current literature. Just under 40% of the included studies were published within the last ten years. It is possible that this may have occurred due to our errors as authors if our search strategy was not as comprehensive as we thought. Nevertheless, we approached the search in as systematic a way as possible, working with an experienced medical librarian, searching multiple databases, and performing extensive hand and grey literature searches.

4.5. Conclusion

This review found that prenatal education for women with type 1 and type 2 diabetes consists of frequent outpatient sessions focused on diabetes self-management, is provided by multidisciplinary healthcare teams, and is supplemented with self- management support. The application of the Medical Research Council framework for complex interventions revealed that the included studies were limited in methods (i.e., randomization). Furthermore, only three studies provided information to conduct a process evaluation and we could only explore the cost-effectiveness of one study intervention. Finally, we highlighted a lack of research focused on women with type 2 diabetes. As the prevalence of type 2 diabetes continues to increase, research may focus on optimizing prenatal education and support interventions for these women as they experience the significant changes in diabetes management that accompany pregnancy. Such

interventions should incorporate the Medical Research Council framework for complex interventions into their development and evaluation.

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Supplemental Material Figure 1. MEDLINE Search Strategy

1. exp Pregnancy/
2. pregnan*.ti, ab, kf.
3. Child bearing .ti,ab,kf.
4. Childbearing .ti,ab,kf.
5. Pregnant Women/
6. gestation* .ti,ab,kf.
7. Antenatal .ti,ab,kf.
8. Prenatal .ti,ab,kf.
9. or/3-8
10. Patient Education as Topic/
11. exp Health Promotion/
12. Health education/ or consumer health information/
13. Counseling/ or exp directive counseling/ or distance counseling/
14. E-counsel?ing .ti,ab,kf.
15. Health Educators/
16. Counsel?ing .ti,ab,kf.
17. Client centered therap* .ti,ab,kf.
18. Client centred therap* .ti,ab,kf.
19. Motivational interviewing .ti,ab, kf.
20. Handout* .mp
21. Health promotion .ti,ab,kf.
22. Consumer health .ti,ab,kf.
23. ((diabet* or health or peer or caregiver* or care giver* or patient*) adj2 (educat* or train* or teach* or instruct*)) .ti,ab,kf.
24. Education/
25. Patient education handout/
26. exp Teaching/
27. (teaching adj2 (tool* or aid* or device* or program*)) .ti,ab,kf.
28. Teaching materials/ or exp audiovisual aids/
29. ((telephone* or mobile or email or e-mail or texting instant messag*) adj2 (support or educat* or counsel*)) .ti,ab,kf.
30. ((peer* or social) adj1 support) .ti,ab,kf.
31. or/10-30
32. Diabetes Mellitus/
33. exp Diabetes Mellitus, Type 1/
34. exp Diabetes Mellitus, T2/
35. Diabet* .ti,ab,kf.
36. (T1DM or T2DM or T1D or T2D) .ti,ab,kf.
37. IDDM .ti,ab,kf.
38. NIDDM .ti,ab,kf.
39. ((non insulin or noninsulin or insulin) adj2 depend*) .ti,ab,kf.
40. or/32-39

Supplemental Material Table 1. Characteristics of included studies

First Author, Year, Country	Study Design	Sample size	Intervention/Exposure vs. Control	Outcomes	Results
Adolfsson, 2012, Sweden	Qualitative (interactive focus group)	3	Web-based support tool (MODIAB-web), No comparison group	Experience using the MODIAB-web prototype	Qualitative content analysis revealed two themes – "easily understood interface, but needs more blood glucose-focused orientation" and "a forum for interaction with both equals and experts." The MODIAB-web prototype is potentially useful as a web-based tool to support women with T1D during pregnancy.
Bartholomew, 2015, USA	Randomized cross-over trial	74	Cell phone-internet technology system to transmit data between participant and HCP vs. Conventional voicemail system	Compliance with SMBG reporting, Patient satisfaction	Those who used the cell phone-internet technology intervention first had the highest compliance with SMBG reporting at fasting ($p = 0.048$), at 2-hours postprandial ($p = 0.048$), and in total ($p = 0.049$). More women preferred the cell phone-internet technology system compared to the voicemail method ($p < 0.001$).
Berg, 2009, Sweden	Qualitative (hermeneutic lifeworld)	23	Primary and secondary antenatal clinics, No comparison group	Experience of pregnancy in relation to glycemic control, well-being, and provided care.	Five themes relating to pregnancy were identified, including "feeling pressure," "carrying a child gives you priority," "advice occasionally unreliable," "being a messenger in a disconnected care organization," and "needing to share experience." Women worried about the effect that diabetes had on the health of their baby. Their stress was exacerbated when they felt that they had to take responsibility for their prenatal care, such as in the case of acting as a messenger between HCPs or when they felt that their HCPs lacked competence.
Carral, 2015, Spain	Non-randomized trial	104	Web-based telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	A1C, Perinatal outcomes, Healthcare visits	There were no significant differences between the intervention and control group in terms of glycemic control or perinatal outcomes. Participants in the intervention group had a lower number of visits to the Gestational Diabetes Unit ($p < 0.001$), nurse educator ($p < 0.001$), and general practitioner ($p < 0.034$).
Cousins, 1991, USA	Prospective cohort	1879	Preconception and prenatal program vs. Usual care (historical controls)	A1C, Perinatal outcomes	A1C decreased from the first to third trimester, ($p < 0.0001$ to < 0.0006). Birth defects were lower among those who attended the program prior to conception as opposed to post-conception. Perinatal outcomes were comparable to the literature. Mortality was lower in White's classes D, F, and R, but higher in A, B, and C.
Dalfra, 2009, Italy	Non-randomized trial	235	Telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	A1C, Timing/mode of delivery, Perinatal outcomes	There was no significant difference in glycemic control or maternal or neonatal complications between women with pre-existing diabetes in the intervention and control groups. Women with GDM in the intervention group had a lower rate of caesarean section ($p = 0.02$).
di Biase, 1997, Italy	Randomized controlled trial	20	Telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	Insulin requirement, Blood glucose, Hypoglycemia	The intervention group had improved glycemic control in terms of glucose values that were lower before breakfast ($p <$L 0.0025) and after dinner ($p < 0.05$) but higher insulin doses when compared to the control group ($p < 0.05$). There was a significant reduction in hypoglycemic episodes in the intervention group ($p < 0.025$).
Fallucca, 1996, Italy	Randomized controlled trial	17	Telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	Insulin requirement, Blood glucose Hypoglycemia	Blood glucose profiles were significantly lower in the intervention group when compared to the control group before breakfast ($p < 0.0025$) and after dinner ($p < 0.05$). However, higher insulin requirements were observed in the intervention group ($p < 0.05$). There were also fewer hypoglycemic episodes in the intervention group ($p < 0.025$).

Feig, 2006, Canada	Retrospective cohort	64	Intensive diabetes management program, No comparison group	A1C, Frequency of SMBG and insulin injection, Level of insulin adjustment	Participants experienced improved glycemic control ($p < 0.0001$), increased frequency of SMBG ($p < 0.001$) and insulin adjustment ($p = 0.0001$) between entry to the program and delivery. Follow-up post-partum revealed that glycemic control worsened slightly from program entry to the present ($p < 0.0001$), although frequency of insulin adjustment remained increased ($p = 0.004$) as did frequency of insulin injection ($p = 0.0004$).
Frost, 2000, Germany	Non-randomized trial	21	Telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	Healthcare visits, A1C Blood glucose, Hypoglycemia	There was no significant difference in glycemic control, hypoglycemic episodes, or time between healthcare visits between groups. Mean blood glucose and mean fasting glucose were reduced for the intervention group from before to after the intervention ($p < 0.05$) and the variation in blood glucose was also reduced ($p < 0.01$).
Howarka, 2001, Austria	Retrospective cohort	59*	Functional insulin treatment vs. Usual care (historical controls)	A1C, Blood glucose, Hypoglycemia, Perinatal outcomes	Weekly mean SMBG for all participants was 6.2 mmol/L in the first trimester, 5.6 mmol/L in the second trimester, and 5.3 mmol/L in the third trimester. Eighty-five percent of A1C measurements were within target. Eighteen percent had severe hypoglycemia. Intervention participants had a reduction in major complications compared to historical controls and a lower rate of neonatal complications, similar to non-diabetic women.
Huddle, 2005, South Africa	Retrospective cohort	733	Specialist clinic vs. Unexposed group (participants who attended the clinic no more than 2 weeks before delivery)	Mode of delivery, Perinatal outcomes	Caesarean section rates exceeded 60% in exposed and unexposed groups. Perinatal mortality was lower in exposed compared to unexposed patients ($p < 0.001$). Overall, 13% of women had hypertension, 31.3% of whom had proteinuric hypertension. None had progressive pre-eclampsia.
Joseph, 2017, India	Cross-sectional	85	Nutrition counseling for women with pre-existing diabetes vs. GDM, No comparison group	A1C Nutrient intake, Perinatal outcomes	Mean A1C was 6.3% and was higher in those with pre-existing diabetes ($p = 0.004$). All had lower than recommended levels of micro- and macronutrients. Those with pre-existing diabetes had better intake compared to those with GDM, attributed to more counselling earlier in their care, but no differences in perinatal outcomes.
Jovanovic, 1984, USA	Program evaluation	140	Two prenatal education programs, No comparison group	Blood glucose, A1C	Inpatient participants took five days to normalize blood glucose levels, six weeks to normalize A1C, and at six months, all had normal A1C. Outpatient participants took five days to normalize blood glucose, six weeks to normalize A1C, and at six months, 60% had normal A1C.
Kalkwarf, 2001, USA	Prospective cohort	141	Nutrition counselling, No comparison group	Fiber intake, Insulin requirements, Blood glucose, A1C	Higher maternal fiber intake was associated with lower daily insulin requirements. There was no association between mean blood glucose (pre-prandial), A1C and fiber intake. Nutrition counseling should include a focus on the importance of dietary fiber intake.
Kushion, 1985, USA	Retrospective cohort	50	Education program in two settings – high-risk obstetric clinic vs. private physician clinic	A1C, Perinatal outcomes	In both settings there was a trend toward improved glycemic control, similar rates of maternal complications, and no fetal deaths.

Ladyzynski, 2001, Poland	Program evaluation	15	Teletransmission system for transmitting data between participant and HCP, No comparison group	System effectiveness, A1C, Patient satisfaction	There were no technical difficulties with the system, there was high patient satisfaction, as well as significant improvements in glycemic control ($p = 0.005$). Effectiveness of the system was not influenced by the intelligence level, education level, or place of residence of the patient ($p < 0.05$).
Linden, 2018, Sweden	Randomized controlled trial	174	Web-based support tool (MODIAB-web) vs. Usual care	General well-being, Self-efficacy in diabetes management	The web-based support program did not result in significant improvements in general well-being or self-efficacy of diabetes management at the 6-month postpartum follow-up. A dose-response analysis regarding the impact of low, high, or medium use found a difference that favoured a higher degree of use, but this was not statistically significant.
Mazze, 1988, USA	Program evaluation	346	Primary, secondary, and tertiary prevention program vs. usual care (historical controls)	Perinatal outcomes	A reduction in perinatal complications was observed in the prevention program compared to historical controls (not significant).
McElvy, 2000, USA	Retrospective cohort	306	Preconception and prenatal program vs. Usual care (two cohorts of historical controls)	A1C Perinatal outcomes	A1C decreased with each consecutive cohort ($p < 0.001$ to 0.003). Perinatal mortality and the rate of congenital malformations decreased from the first to third cohort, although not significantly.
Nørgaard, 2017, Denmark	Cross-sectional	139	Mobile application, No comparison group	A1C, Awareness/use of application, Feeling of security in diabetes management	Mean A1C was 6.5% for women who used the application when they were planning pregnancy compared to 6.7% for those who first used the app during early pregnancy. 75% of women had downloaded the application and 48% had obtained information from the application before their pregnancy. The application had been downloaded 27,361 times worldwide. The most frequent information topics that were visited were “diet and carbohydrates,” “blood glucose,” and “possible complications.” Most women found that using the application contributed to feelings of increased security about their diabetes and pregnancy.
Owens, 2016, Ireland	Retrospective cohort	445*	Diabetes in pregnancy clinic program, supplemented by a website and mobile application vs. Usual care (historical controls)	Perinatal outcomes, A1C	There were noted improvements in pregnancy outcomes, including reduced congenital anomalies ($p = 0.04$) and stillbirths ($p = 0.09$), despite older maternal age, increased obesity, and higher gestational weight gain. Improved glycemic control was also observed ($p < 0.001 – 0.06$).
Plehwe, 1984, Australia	Retrospective cohort	232	Diabetes in pregnancy program, No comparison group	Mode of delivery, Perinatal outcomes	There were high rates of intervention during labour and delivery, particularly among those with pre-existing diabetes ($p = 0.045$). Congenital malformations occurred in 5.6% of infants and caused the death of six infants.
Ringholm, 2013, Denmark	Retrospective cohort	212	Focused education intervention vs. Usual care (historical controls)	Hypoglycemia, A1C, Insulin requirements, Perinatal outcomes	As a result of this focused intervention there was a reduction in the occurrence of severe hypoglycemia during pregnancy ($p = 0.0006$) without a compromise in glycemic control or perinatal outcomes. Insulin doses were lower in the group exposed to the education intervention ($p = 0.0006$).

Rosenn, 1991, USA	Prospective cohort	110	Exposure to a diabetes program for the first-time during pregnancy vs. Controls who were attending the program for a second pregnancy	A1C, Perinatal outcomes	Compared to the matched controls undergoing their first experience in the prenatal program, women who were going through the program for the second time had improved glycemic control ($p = 0.02$) and reduced perinatal complications ($p < 0.01$).
Simmons, 2001, New Zealand	Retrospective cohort	169	Diabetes midwifery service vs. Usual care (historical controls)	Insulin requirements, Blood glucose, Resource utilization, Perinatal outcomes	After the diabetes midwifery educator was introduced improvements were observed including lower insulin doses ($p < 0.05$), reduced post-prandial glucose levels ($p < 0.001$), and less resource utilization. Outcomes such as infant birthweight and rates of caesarean sections were not impacted.
Steel, 1990, United Kingdom	Retrospective cohort	239	Pre-pregnancy and prenatal clinic vs. Usual care	A1C, Perinatal outcomes, Hypoglycemia	Results found that women who participated in the antenatal program had improved glycemic control ($p < 0.0001$) and lower rates of congenital anomalies ($p < 0.05$) in their offspring. However, they also had an increased occurrence of hypoglycemia during pregnancy ($p < 0.001$).
Stenhouse, 2013, United Kingdom	Qualitative (grounded theory)	12	Maternity care services for those with diabetes, No comparison group	Experience with maternity care service	Three themes were identified, including "empathetic care," "feeling judged," and "the notion of expertise." Women wanted healthcare providers to be more empathetic to the challenge that diabetes during pregnancy presents. They also felt judged and that their expertise as patients was not valued by HCPs.
Tevaarwerk, 1981, Canada	Program evaluation	83	Program for normoglycemia before meals, No comparison group	Blood glucose, Hypoglycemia, Perinatal outcomes	Blood glucose improved and few hypoglycemic events occurred. Obstetric complications included hypertension and hydramnios. One fetal death occurred and neonatal complications included anomalies, somatomegaly, hypoglycemia, hypocalcaemia, hyperbilirubinemia, and RDS.
Wojcicki, 2001, Poland	Randomized controlled trial	30	Telemedicine system for transmitting data between participant and HCP vs. Usual care	A1C	There was improved glycemic control in the intervention ($p = 0.0065$), more similar results in glycemic control among members of the intervention group compared to each other ($p = 0.0318$), and better glycemic control among participants with lower intelligence in the intervention group (not significant).

*Sample size reported as number of births or pregnancies

GDM, gestational diabetes mellitus. HCP, healthcare provider. SMBG, self-monitoring of blood glucose. RDS, respiratory distress syndrome. T1D, type 1 diabetes. USA, United States of America

Supplemental Material Table 2. Characteristics of interventions in included studies

	Template for Intervention Description and Replication Checklist Criteria											
First Author, Year	Intervention Description	Intervention Goal	Materials Used	Procedures	Providers	Mode	Location	Frequency/Dose	Tailoring	Modification	Adherence (planned)	Adherence (actual)
Bartholomew, 2015	Cell phone-internet technology to transmit SMBG data between participant and HCP vs. Conventional voicemail system	Cell phone-internet technology could eliminate the inaccuracies of patient-reported SMBG and improve patient satisfaction.	One 3-hour, in-person education session that focused on a carbohydrate-controlled diet, exercise, SMBG, and reporting SMBG.	SMBG values were reported to the HCP weekly using the cell phone-internet method. HCPs reviewed the data and communicated treatment modifications by phone.	MD, RN	Individual, Outpatient	Participant home, Antenatal clinic	Weekly communication between participant and HCP via cell phone-internet system for the 3-week duration of the intervention, followed by weekly communication via conventional voicemail system for the 3-week crossover period.	Participants who required insulin or glyburide were provided personalized instruction regarding correct administration.	Only 74 of 100 enrolled participants went on to complete the study, which did not meet the minimum a priori sample size. The study continued while underpowered.	Participants received text messages to encourage participation such as “You didn’t submit readings for the second week in a row. Try to submit your readings every week.”	Twenty-six participants did not complete the study and were not included in the analysis. Reasons included personal preference, never having begun the intervention, discontinued participation in the diabetes program, preterm delivery, and spontaneous abortion.
Carral, 2015	Web-based telemedicine system to transmit SMBG data between participant and HCP vs. Usual care	Telemedicine could increase access to health care and improve glycemic control during pregnancy.	Participants received in-person education focused on SMBG and glycemic targets.	SMBG data was submitted via the telemedicine system every 2 weeks. Clinic visits were every 6-8 weeks where weight, BP, SMBG, insulin, and A1C were reviewed.	MD. RN	Individual, Outpatient	Participant home, Antenatal clinic	Glycemic data was submitted every 2 weeks with clinic visits every 6-8 weeks.	Participants were instructed to follow a personalized diet and could download educational documents of interest from a study website.	Not reported	Not reported	Two participants were lost to follow-up in the intervention group compared to nine in the control group, with two miscarriages in each group.
Cousins, 1991	Program for pre-conception and prenatal care vs. Usual care	The program was developed with the goal of reducing congenital	Education focused on sick-day rules, SMBG, diet, exercise, and medical and obstetrical care. Details are	Outpatient-based education focused on active patient participation. A1C, frequent SMBG,	MD, CDE, RD, SW	Individual, Outpatient	Antenatal clinic	Clinic visits every 1-3 weeks	Not reported	Not reported	Education was provided to HCPs, details not described.	Of the 2,532 women registered in the prenatal clinic, 1,879 had pregnancies that

	(historical controls)	anomalies through good glycaemic control.	available in the CDAPP Teaching and Learning Guides (CDAPP, 1986), for training HCPs.	and assessments of fetal growth and wellbeing as a supplement to usual care.								were followed to completion during the study period.
Dalfra, 2009	Telemedicine system to transmit SMBG from participant to HCP vs. Conventional outpatient clinic visits	Telemedicine could improve glycemic control in individuals with diabetes by facilitating communication with their HCP.	Participants received education on performing SMBG and glucose targets.	SMBG was transmitted via the telemedicine system. HCPs reviewed the data and recorded prescriptions via the system. Clinic visits occurred every 2 weeks.	MD	Individual, Outpatient	Participant home, Antenatal clinic	Glycemic data was submitted weekly and clinic visits occurred every 2 weeks.	Participants with GDM were educated on diet control. Those with T1D and GDM on insulin were educated on insulin usage and recognizing hypoglycemia.	Not reported	Not reported	235 participants of the recruited 276 were included in the analysis, with the remaining participants excluded for not completing the questionnaires at the end of the study.
di Biase, 1997	Telemedicine system to transmit data between participant and HCP vs. Conventional outpatient clinic visits	Good glycemic control may improve perinatal outcomes. This may be achieved using telephone modems for the transmission of SMBG.	Participants were educated with an overview of diabetes in pregnancy treatment guidelines.	Participants recorded SMBG, insulin dose, diet, exercise, hypoglycemia, ketonuria, and glycosuria and sent this data weekly via modem to their HCP who reviewed it and provided treatment recommendations. The control group visited the antenatal clinic weekly.	MD	Individual, Outpatient	Participant home, Antenatal clinic	Glycemic data could be submitted at any time for participant convenience for the intervention group; Weekly clinic visits occurred throughout pregnancy for the control group.	Participants were provided with personalized weekly summaries of their insulin use, diet, exercise, and blood glucose tests compared to insulin administration, statistical summaries, including averages and ranges.	None stated	Not stated	Not stated
Fallucca, 1996	Telemedicine system to transmit data from patient	SMBG is an essential part of diabetes self-	Participants were educated with an overview of therapy	SMBG, insulin dose, diet, exercise, hypoglycemia,	MD	Individual, Outpatient	Participant home,	Glycemic data submitted weekly via	Participants were provided with personalized	Not reported	Not reported	Not reported

	to HCP vs. Conventional outpatient clinic visits	management. Telemedicine-based approaches may improve SMBG efficiency.	guidelines for diabetes and pregnancy and instruction on performing SMBG.	ketonuria, and glycosuria was sent via modem weekly to the HCP who reviewed it and communicated treatment recommendations.			Antenatal clinic	telemedicine system.	graphs of blood glucose tests in relation to information about their insulin doses and diet, and statistical summaries of such data.			
Feig, 2006	Intensive diabetes management program, No comparison group	Those in an intensive therapy program are seen more frequently and for longer compared to non-pregnant individuals. As such, they may retain self-care behaviours which may translate to better glycemic control.	Participants were instructed on diabetes self-management behaviours including SMBG, multiple-dose insulin administration, and carbohydrate counting.	The intensive therapy program included multiple-dose insulin or insulin pump and teaching of insulin dose adjustment and carbohydrate counting. Behaviours were reinforced every 1-2 weeks for the duration of pregnancy during clinic visits.	MD, RN, RD	Individual, Outpatient	Antenatal clinic	Clinic visits every 1-2 weeks throughout pregnancy	Personalized insulin adjustment was taught based on the participant's glucose level, food, and activity.	Not reported	Face validity of the administered questionnaire (through which self-reported data was collected from participants) was assessed by asking HCPs if they agreed with the content and modifications were made based on this feedback.	Data from 4 eligible participants were not included as their data could not be located.
Frost, 2000	Telemedicine system to transmit SMBG from participant to HCP vs. Conventional outpatient clinic visits	Prenatal care may be improved through telemedicine, which facilitates patient and HCP communication.	Participants were educated on performing SMBG, appropriate glucose targets, and insulin adjustment.	Participants transmitted SMBG weekly using a modified modem phone line to the HCP who advised them on insulin dose adjustments.	MD	Individual, Outpatient	Participant home, Antenatal clinic	Glycemic data submitted and treatment adjustments made weekly.	Not reported	Not reported	Not reported	Not reported
Howarka, 2001	Functional Insulin Treatment	FIT (differentiating	Five group education modules were offered.	There was a combination of	Diabetes counsellor	Individual,	Antenatal clinic	Clinic visits occurred every	Two education modules were	Not reported	Not reported	Six participants were excluded from

	adapted for pregnancy vs. Usual care (historical controls)	between basal, meal-related and correctional insulin) promotes normal, flexible eating and effective glycemic control and might contribute to near-normal control during pregnancy.	All participants were offered 3 that focused on preconception care, SMBG, glucose targets, complications, weight control, diet, hypoglycemia, insulin during labour, and emerging treatments. Education modules were based on a developed curriculum in *Biomedizinische Technik* (Howarka, 1998).	one-on-one counselling and group FIT modules. Participants were instructed to perform SMBG 6-8 times per day and check for ketonuria daily in the last trimester. Regular checks on fetal wellbeing were conducted.		Group, Outpatient		1-4 weeks and as needed.	tailored to specific groups – participants using insulin and those on intensified insulin treatment. Further modules on hypertension, nephropathy, hypoglycemia prevention, and weight control were also offered for those who required it.			analysis due to the occurrence of spontaneous abortion.
Huddle, 2005	Combined specialist clinic for management of diabetic pregnancies vs. Unexposed group who entered the program later in pregnancy for no more than 2 weeks	In areas of Africa the resources for diabetes management are lacking, resulting in a situation reminiscent of the pre-insulin era. Therefore, a combined specialist clinic for pregnant diabetic women was established.	Participants received education on performing SMBG and diet control.	Participants were hospitalized initially for clinical assessment. Insulin was initiated as needed. Following initial in-hospital assessment, clinic visits occurred every 2 weeks until 32 weeks and then weekly until 37 weeks when they were readmitted.	MD, RN	Individual, In- and outpatient	Inpatient hospital ward, Antenatal clinic	Clinic visits every 2 weeks throughout pregnancy	Not reported	As the program progressed it became necessary to include a control group of participants who, because of late referral, only received 2 weeks of management and education.	Not reported	Not reported
Joseph, 2018	Diabetes education focused on nutrition therapy, No comparison group	Diet, exercise, and nutrient composition are important in reducing rates of adverse pregnancy	Participants received education on diabetes care during pregnancy as well as nutrition therapy.	A one-on-one interview with an RD involved a food frequency questionnaire during the first visit. Participants	RD	Individual, Group, Outpatient	Antenatal clinic	Not reported	Participants with GDM attended additional group counselling sessions that used power point presentations,	Not reported	Collected self-reported data was validated with the participant's medical records.	Not reported

		outcomes. Assessing nutritional intake and educating women may help reduce poor outcomes.		then attended an education session on diabetes care and nutrition therapy and recorded food intake and medication weekly, thereafter.					food models, standardized vessels and pictorial representation of balanced meals.			
Jovanovic, 1984	Two programs (one inpatient and one outpatient) for diabetes management during pregnancy, No comparison group	The optimal program for diabetes education has not been agreed upon. Program comparison may aid in evaluating optimal strategies to improve glycemic control.	Participants received education on skills (SMBG) to sustain normoglycemia in the outpatient setting with a focus on insulin adjustment.	Inpatient participants were hospitalized for 5 days and taught skills to sustain normoglycemia as an outpatient. Outpatient care was focused on insulin adjustment protocols.	MD, RN, RD	Individual Group, In- and outpatient	Inpatient hospital ward, Outpatient antenatal clinic	Not reported	Not reported	None reported	Not reported	Not reported
Kalkwarf, 2001	Dietary counseling, No comparison group	Diets high in fiber may have health benefits for those with diabetes and improve glycemic control. The effects of moderate fiber intake on insulin requirements during pregnancy has not been investigated.	Participants received dietary counseling focused on eating a wholesome diet and balancing food intake to maintain target glucose levels.	At each clinic visit participants were counselled on eating a wholesome diet and balancing food intake as a way to maintain target glucose levels. Participants kept a food record each trimester to assist in dietary counselling. SMBG was done at least 3 times per day and A1C monthly.	RD	Individual, Outpatient	Antenatal clinic	Clinic visits occurred every 1-2 weeks throughout pregnancy.	Individualized recommendations were given to participants regarding percentage of calories from carbohydrates, protein, and fat to help achieve target glucose values.	Not reported	Not reported	Only 141 of 231 eligible participants provided at least 3 food records during pregnancy and were included in the analysis.

Kushion, 1985	Program for diabetes management during pregnancy (two settings), No comparison group	The management setting (high risk obstetric clinic vs. private physician office) may make a difference in the outcome of a pregnancy complicated by diabetes.	Participants received instruction on SMBG, glucose targets, urine testing for ketones, avoidance of hypoglycemia, multiple-dose insulin administration and insulin adjustment, diet, and how diabetes and pregnancy affect each other.	Participants were examined at each visit, had vital signs, psychosocial variables, and educational needs assessed, and reported any concerns. SMBG values were reviewed at each visit. If targets were not achieved, participants were hospitalized or they phoned in SMBG values daily to the HCP until under control.	MD, RN	Individual, In- and outpatient	Inpatient hospital ward, Antenatal clinic	Weekly clinic visits throughout pregnancy and follow-up phone calls between visits, frequency not stated, Private Physician, initial visit was 1.5 – 2 hours; Follow-up visits 30 minutes 2-4 weeks after the initial visit and as needed. HRO, initial visit 1 hour and follow-up 20 minutes weekly.	Follow-up visits provided personalized ongoing support for assistance in solving day to day problems, specifically with meal planning.	Early on, few used SMBG, but were making weekly visits to the laboratory for blood glucose tests. Later, all patients used SMBG. Early on, clinic patients received the same follow-up as private patients. Later, the dietician began seeing clinic patients at most visits.	To validate self-reported glucose, participants brought developed Chemstrips to appointments for review with the HCP. Techniques for SMBG were reviewed and corrected as needed. Participants who had difficulty reading strip colours used meters for accuracy.	Not reported
Ladyzynski, 2001	Teletransmission system to transmit SMBG data between participant and HCP, No comparison group	Memory glucometers and telemonitoring could be beneficial in the treatment of women with diabetes during pregnancy.	Each participant received uniform medical and technical education with detailed written manuals on SMBG teletramission operation during two days of hospitalization.	Participants use a small, personal computer to record SMBG results, markers of hypoglycemia, insulin doses, meals, and physical activity. This data is automatically transmitted each night to the HCP. who evaluates and analyzes it and makes therapeutic adjustments via phone.	MD	Individual, In- and outpatient	Inpatient hospital ward, Participant home	Glycemic data submitted to and viewed by HCP daily; Treatment adjustments made as needed	Not reported	Not reported	Not reported	The total effectiveness and technical effectiveness of the teletransmission system was evaluated throughout the study duration as 69.3% and 91.5%, respectively.

Linden, 2018	Person-centred, web-based support program to supplement usual care vs. Usual care alone	The theoretical basis for the intervention was person-centred care, and it was designed to assist in decision-making, based on the woman's own documentation, to support self-care and to facilitate contact with peers.	Participants received evidence-based information on pregnancy, labour and childbirth, and life as a new mother.	The website had three components: (1) evidence-based information on pregnancy, labour and motherhood and diabetes; (2) self-care diary for SMBG, insulin, diet, activity, and mood; and (3) a discussion forum for peer support with a FAQ section.	MD, MW	Individual, Outpatient	Participant home	Website always available to access	An online discussion forum for peer support that was moderated by the research group was available for personalized support.	Not reported	Participants who were inactive on the website received a short reminder text message every 2 weeks to encourage engagement with the intervention.	Several participants were excluded because of loss of baseline data and miscarriage. Of the 78 participants in the intention-to-treat analysis, 11 did not fulfil the criteria of two individual logins to the website, leaving usage data from 67 active users to be analysed.
Mazze, 1988	Program for primary, secondary, and tertiary prevention of diabetes in pregnancy vs. Usual care (historical controls)	A comprehensive program in prevention (primary, secondary, and tertiary), may reduce both maternal and fetal complications.	Participants were counseled on careful monitoring of metabolic control, microvascular complications and other risk factors during the preconception period. For all participants, counseling concerning fetal and maternal complications was offered along with instruction on SMBG.	Participants were either evaluated immediately after diagnosis for insulin or diet-only therapy (GDM) or had their insulin therapy reassessed upon entry. Participants underwent an education program on recognizing the importance of diabetes in pregnancy. All performed SMBG and received instruction on insulin administration or	MD, RN, RD	Individual, In- and outpatient	Inpatient hospital ward, Antenatal clinic	Not reported	For those who had very poor glycemic control and severe diabetes complications, they were hospitalized to gain glucose control and received counseling concerning the increased risk of possible fetal anomalies and maternal health consequences.	During the first year of the program, treatment for GDM was instituted within 10 days after confirmation of diagnosis. By the second year, treatment was initiated no later than 5 days after diagnosis.	HCPs participated in training programs for 1 to 2 months depending on their level of clinical responsibility. The trainee moved from observer to case manager as training progressed. In the latter role, the trainee assumed overall responsibility for management of the participant.	Not reported

				diet, as applicable. SMBG data was reviewed between the participant and HCP and adjustments were made as needed.									
McElvy, 2000	Focused preconception and pregnancy program for T1D vs. Usual care (3 cohorts were observed with earlier cohorts serving as historical controls)	A focused program specializing in early care of women with T1D may reduce congenital malformations.	Comprehensive instructions with respect to time of response to insulin, techniques of SMBG, and management of diabetes during pregnancy were reviewed. Participants were informed of the risks associated with diabetes in pregnancy, including poor perinatal outcomes and congenital malformations, and they were kept aware of the importance of good glycemic control to minimize the risks for these outcomes.	Participants were seen every 1-2 weeks. Participants performed SMBG (6 to 8 times per day) and this data was reviewed with the HCP and adjustments were made as needed. Participants followed a 35 kcal/kg ideal body weight diet and met with a dietician every 1-2 weeks to review a dietary diary for the preceding week. Participants administered 3-4 insulin doses per day. A1C was checked monthly. Standard maternal assessment and fetal growth and wellbeing checks were completed	MD, RN, RD	Individual, Outpatient	Antenatal clinic	Clinic visits every 1-2 weeks throughout pregnancy.	Intensive diabetes education was tailored to each patient's needs and adjusted according to their progress.	Early in the program, daily unconjugated serum estriol concentrations were measured and used with the oxytocin challenge test to establish fetal well-being. Later, the nonstress test was used. Delivery mode during the initial cohort was caesarean section. By the third cohort, vaginal delivery was attempted in all women. Routine amniocentesis was discontinued during the second cohort.	Not reported	Not reported

				throughout pregnancy.						Later, lack of funding did not allow for free preconception care, specialized care, equipment for SMBG, or intense diet monitoring, regardless of insurance status		
Norgaard, 2017	Mobile application providing health information related to diabetes, No comparison group	A mobile application is an easily accessible tool that can communicate important health information and may have positive effects on glycemic control during pregnancy.	Education provided through the application included: What is diabetes? Pregnancy planning; possible complications; blood glucose; weight gain; diet and carbohydrates; physical activity; the fetus; insulin dose; in need of assistance; scans; delivery; and after birth.	Participants were able to access the application topics at any time prior, during, and after pregnancy.	NA	Individual, Outpatient	Participant home	Application was always available to access	Use of the application is inherently personalized as participants could select topics relevant to their needs and not view topics that they judge are not relevant for them.	Not reported	The information included in the application was evidence-based, judged by two experienced clinical scientists in the area of diabetes and pregnancy with both obstetric and endocrine experience.	Questionnaires were obtained from 175 of 274 eligible women. Thirty-six were excluded due to missing information, leaving available questionnaires from 139 women.
Owens, 2016	Program for diabetes management during pregnancy vs. Usual care (historical controls)	A diabetes management program may improve perinatal outcomes among women with diabetes during pregnancy.	Participants were educated on the timing of pregnancy, contraception during planning, management of complications, BP control, medications, glycemic control, insulin, target A1C, avoidance of	Participants attended clinic visits every 2 weeks with increased/decreased frequency as needed. A website and smartphone app developed by the researchers was	MD, RN, RD	Individual, Outpatient	Participant home, Antenatal clinic	Website and smartphone app always available to access; clinic visits every 2 weeks and as needed throughout pregnancy	Not reported	Not reported	Not reported	Not reported

			hypoglycemia and teratogenic drugs.	available to access at all times.								
Plehwe, 1984	Program for diabetes management during pregnancy, No comparison group	This study was undertaken to assess the course of pregnancy complicated by diabetes in a large teaching hospital and to determine whether any alterations in the programme of management might further improve pregnancy outcomes.	Participants received diabetes education focused on management of diabetes during pregnancy, including SMBG and insulin administration.	Participants were admitted to hospital for stabilization, assessment of complications, and to start SMBG, where they attended an education session on diabetes management during pregnancy. Upon discharge they were followed-up every 2 weeks when glucose levels were assessed, insulin adjusted, and A1C checked.	MD	Individual, In- and outpatient	Inpatient hospital ward, Antenatal clinic	Clinic visits occurred every 2 weeks throughout pregnancy	Instruction on insulin pump therapy was provided to one participant with brittle insulin dependent diabetes.	Early in the study, women were admitted to hospital at 32 weeks' gestation and diabetic control and fetal status were monitored intensively. Later in the study period, women began performing SMBG so admission to hospital was then delayed to 36-37 weeks' gestation.	Not reported	Due to the retrospective nature of this study and the inclusion of all women with diabetes in pregnancy, irrespective of the stage of gestation at which they were referred, the data were incomplete and wide variation of the values of individual parameters was observed.
Ringholm, 2013	Diabetes management program focused on reducing hypoglycemia vs. Usual care (historical controls)	Severe hypoglycemia is the main limiting factor for optimization of glycemic control in pregnant women with T1D. Implementation of a focused intervention in a routine care setting may	Oral and written information was provided to participants regarding insulin analogues and insulin pump therapy; reduction of insulin by 10-20% at 8-16 weeks GA; avoidance of supplementary insulin between meals; and consumption of extra carbohydrates if bedtime glucose is <6.	Participants reported severe hypoglycemia events in the year before pregnancy and hypoglycemia awareness at an initial visit. Insulin dose was reduced by 10-20% at 8-16 weeks. Minimal extra insulin was administered outside of 4 extra	MD	Individual, Outpatient	Antenatal clinic	Not reported	Women reporting a history of severe hypoglycemia or impaired hypoglycemia awareness were informed about their high risk of severe hypoglycemia during pregnancy and extra focus on reducing insulin dose and	None stated	Events of severe hypoglycaemia were validated according to Whipple's triad: (1) symptoms consistent with hypoglycaemia; (2) blood glucose value <3.9 mmol/L; and (3) adequate response to glucose/glucagon treatment.	Among 155 eligible women fulfilling the inclusion criteria, 123 were included. Four women with spontaneous miscarriages, and 15 women participating in both the first and the second cohort were excluded from the second cohort.

		reduce severe hypoglycemia.		units before main meals. Extra carbohydrates were taken if bedtime glucose was < 6 mmol/L. Participants then contacted the HCP within 24 hours of a hypoglycemic event. SMBG data was evaluated at each visit.					adjusting diet was provided.		The HCPs caring for the women were educated about the importance of avoiding severe hypoglycaemia during pregnancy planning and early pregnancy.	
Rosen, 1991	Program for diabetes management during pregnancy, vs. Controls who were attending the program during a second pregnancy	The success of specialized programs for those with diabetes depends on patient motivation. Experience gained during a first pregnancy may improve compliance in a second pregnancy in the program.	Participants were educated on the risks associated with diabetes and pregnancy as well as the importance of early glycemic control. The risks were reemphasized in follow-up visits.	Participants were seen every 1-2 weeks for the duration of pregnancy. Records of SMBG were reviewed at each clinic visit along with measurement of body weight, blood pressure, and insulin dose. A1C was measured monthly.	Multidisciplinary	Individual, Outpatient	Antenatal clinic	Clinic visits every 1-2 weeks throughout pregnancy	Not reported	None reported	The glucose meter was calibrated weekly and its accuracy verified every 4 weeks with simultaneous samples measured in a clinical laboratory.	Not reported
Simmons, 2001	Program for diabetes management during pregnancy vs. Usual care (historical controls)	A midwifery education service may help normalise pregnancy outcomes for those with diabetes.	Education was provided regarding maintaining good glycemic control, SMBG, diet, labour, and potential complications.	Participants attended clinic monthly up to 28 weeks; fortnightly up to 36 weeks; and weekly to term. SMBG was performed regularly and	MW	Individual, Outpatient	Participant home, Antenatal clinic	Clinic visits every 1-4 weeks throughout pregnancy; home visits and phone calls between clinic visits, frequency not stated	The overall program followed a standardized format but was adjusted to the particular requirements of each participant.	Not reported	Support for the MW was provided by weekly patient review meetings with a team that included a MW, a diabetologist,	Not reported

				insulin was initiated as needed.							an obstetrician, and an RD.	
Steel, 1990	Diabetes and pregnancy program vs. Usual care	High maternal glucose during pregnancy is associated with poor outcomes. A pregnancy program may improve this.	Oral and written information was provided on diet, insulin, hypoglycemia, testing for ketones, management of vomiting, and counselling against smoking.	At the initial visit, medical history and complications were assessed, and education provided. Insulin was adjusted to achieve targets. A1C was checked each trimester.	MD	Individual, Outpatient	Antenatal clinic	Not reported	Not reported	None reported	In the last 25 participants, hypoglycemic events were recorded prospectively to increase accuracy.	Not reported
Tevaarwerk, 1981	Program for diabetes management during pregnancy, No comparison group	Improved perinatal outcomes have been reported when maternal glucose levels are carefully controlled. A program to control glucose before meals may improve perinatal outcomes.	Participants were taught principles of diabetic management focused on insulin adjustment, SMBG, urine ketone testing, and diet.	Clinic visits occurred monthly, increasing in early/late pregnancy. Glucosuria and SMBG were checked and insulin adjusted based on this. Participants were admitted to hospital if they had poor glycemic control.	MD	Individual, In- and outpatient	Inpatient hospital ward, Antenatal clinic	Clinic visits every 4 weeks on average throughout pregnancy, with increased frequency in early and late pregnancy	Participants followed an individualized diet. Those who had not previously been educated adequately were admitted to hospital for 4 days of intensive education.	Not reported	Not reported	Not reported

Wojcicki, 2001	Telemedicine system to transmit data from patient to HCP vs. Usual care	Teletransmission of SMBG data may facilitate more frequent SMBG and better glycemic control than is possible with usual care.	All participants were educated during a 3-day program (which included 2 days of hospitalization) and throughout study duration focused on SMBG and multiple-dose insulin therapy.	Participants transmitted SMBG, insulin dose, markers of meals, physical activity, and symptoms of hypoglycemia daily via the telemedicine system to the HCP who reviewed it and made treatment modifications via phone. Data was reviewed in-person every 3 weeks.	MD	Individual, In- and outpatient	Inpatient hospital ward, Participant home, Antenatal clinic	Glycemic data was submitted and reviewed by the HCP daily; clinic visits occurred every 3 weeks throughout pregnancy.	Not reported	Not reported	Each glucometer used in the study was tested in the laboratory prior to its use.	Two participants enrolled in the study were not included in the analysis due to the presence of comorbid disease (pneumonia and Meniere's disease) not initially diagnosed.

CHAPTER 3

TITLE: Supporting self-management in women with pre-existing diabetes in pregnancy: A protocol for a mixed-methods sequential comparative case study

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Abstract

Introduction: For women with pre-existing type 1 and type 2 diabetes, glycaemic targets are narrow during the preconception and prenatal periods to optimise pregnancy outcomes. Women aim to achieve glycaemic targets during pregnancy through the daily tasks of diabetes self-management. Diabetes self-management during pregnancy involves frequent self-monitoring of blood glucose and titration of insulin based on glucose measures and carbohydrate intake. Our objective is to explore how self-management and support experiences help explain glycaemic control among women with pre-existing diabetes in pregnancy.

Methods and analysis: We will conduct a four-phased mixed-methods sequential comparative case study. Phase I will analyse the data from a prospective cohort study to determine the predictors of glycaemic control during pregnancy related to diabetes self-management among women with pre-existing diabetes. In phase II, we will use the results of the cohort analysis to develop data collection tools for phase III. Phase III will be a qualitative description study to understand women's diabetes education and support needs during pregnancy. In phase IV, we will integrate the results of phases I and III to generate unique cases representing the ways in which self-management and support experiences explain glycaemic control in pregnancy.

Ethics and dissemination: The phase I cohort study received approval from our local ethics review board, the Hamilton Integrated Ethics Review Board. We will seek ethics approval for the phase III qualitative study prior to its commencement. Participants will provide informed consent before study enrolment. We plan to publish our results in peer-reviewed journals and present our findings to stakeholders at relevant conferences/symposia.

Strengths and limitations of this study

- Mixed-methods sequential comparative case study designs facilitate the development of detailed and nuanced information.
- However, the single-centre design of the cohort study will limit the generalisability of our findings.
- The use of qualitative methods may further limit study generalisability.

INTRODUCTION

Pre-existing diabetes in pregnancy

There has been a rise over the past 20 years in the prevalence of pre-existing diabetes (type 1 or type 2 diabetes) in pregnancy. Currently, pre-existing diabetes affects approximately 1% or 4,000,000 pregnancies in the USA annually.[1,2] Worldwide, other countries are also experiencing a similar phenomenon, contributing to what has been called the 'diabetes pandemic.'[3–8]

The increased occurrence of pre-existing diabetes in pregnancy presents a clear threat to maternal–child health. Compared with women without diabetes, infants of women with pre-existing diabetes have an increased risk of experiencing congenital anomalies and stillbirths, and infant death—relative risk (RR) 1.86 (95% CI 1.49 to 2.33) and RR 2.33 (95% CI 1.59 to 3.43), respectively.[3] Infants born to mothers with diabetes also experience increased postbirth complications, including macrosomia, respiratory distress and hypoglycaemia. For example, up to 60% of infants born to mothers with type 1 or type 2 diabetes may be macrocosmic[9]; respiratory distress syndrome is approximately twofold higher (OR 2.66 (95% CI 2.06 to 3.44)) among infants of mothers with pre-existing diabetes compared with infants of non-diabetic mothers[10]; and the occurrence of neonatal hypoglycaemia is approximately 27% among infants born to mothers with diabetes, compared with 3% in the background population.[11]

Role of diabetes self-management education and support

Research suggests that glycaemic management is associated with perinatal complications.[12] Thus, glycaemic targets are narrow during the preconception and prenatal periods to optimise pregnancy outcomes.[13] Women with pre-existing diabetes in pregnancy achieve glycaemic targets through the daily tasks of diabetes self-management, which includes frequent self-monitoring of blood glucose and accurate titration of insulin doses to blood glucose measures

and carbohydrate intake.[13] However, the evidence suggests that expectant mothers often struggle to meet recommended glycaemic targets. A large cohort study in the UK that followed women from conception to delivery found that only 14.3% of those with type 1 diabetes and 37.0% of those with type 2 diabetes met recommended glycaemic targets during early pregnancy (less than 13 weeks gestation).[14] Therefore, recent attention has focused on promoting diabetes self-management education and diabetes self-management support during pregnancy.

Diabetes self-management education focuses on individual goal setting, problem-solving and patient empowerment strategies. The intent is to ensure that patients have knowledge regarding their condition to sufficiently collaborate in decision-making with their healthcare providers and receive tailored care.[15,16] Clinical practice guidelines suggest that self-management support should augment education. Self-management support may include activities that reinforce and enhance education and behaviours. Support strategies include text messages, email reminders, automatic phone reminders, peer support and mobile health interventions, among others.[16] Specifically, such strategies aim to improve patient self-efficacy, confidence and one's ability to optimally self-manage diabetes. Among non-pregnant adults with diabetes, systematic reviews and meta-analyses indicate that self-management education and support interventions improve clinically important outcomes,[16] including improved glycaemic control and reduced diabetes complications, such as foot amputations.[17] Thus, diabetes self-management education and support may improve glycaemic control and other clinically important outcomes among women with diabetes in pregnancy. However, the existing research on diabetes self-management education and support in pregnancy is limited and primarily focused on gestational diabetes mellitus.[18]

Objective

Our objective is to explore how self-management and support experiences help explain glycaemic control among women with pre-existing diabetes in pregnancy.

METHODS AND ANALYSIS

Study design and overview

We will conduct a four-phased mixed-methods sequential comparative case study. This mixed-methods design will begin with the analysis of collected quantitative data. A phase of qualitative data collection and analysis will follow the quantitative phase. The study will conclude by integrating the quantitative and qualitative findings to generate unique cases. The mixed-methods sequential comparative case design is ideal because we aim to develop detailed information about diabetes self-management among women with pre-existing diabetes during pregnancy. Furthermore, diabetes self-management during pregnancy varies based on diabetes type (type 1 or type 2). Thus, the mixed-methods sequential comparative case design will portray this variation in self-management in the form of constructed cases that can be compared and contrasted. Ultimately, it is our goal that the information from the generated cases will guide subsequent research in designing, evaluating and implementing self-management education and support interventions for women with pre-existing diabetes in pregnancy.

The research questions are threefold, as we will integrate the quantitative and qualitative data within the overall mixed-methods design.

1. Quantitative research question
    a. What are the predictors of glycaemic control during pregnancy?

2. Qualitative research questions
    a. What is the experience of managing diabetes during pregnancy?
    b. What are the diabetes self-management education and support needs during pregnancy among women with pre-existing diabetes?
3. Mixed-methods research question
    a. How do the self-management and support experiences of women with pre-existing diabetes in pregnancy help explain their glycemic control?

Figure 1 provides a diagram depicting the study flow. Phase I will involve the analysis of data from a prospective cohort study to determine the predictors of glycaemic control during pregnancy related to diabetes self-management (eg, the level of self-efficacy) among women with pre-existing diabetes. Phase II will use the results of the cohort data analysis to inform the interview guide for phase III. Phase III will be a qualitative descriptive study to understand the diabetes education and support needs during pregnancy among women with pre-existing diabetes. Phase IV will integrate the results of phases I and III to generate unique cases representing the various ways in which self-management and support experiences explain glycaemic control in pregnancy.

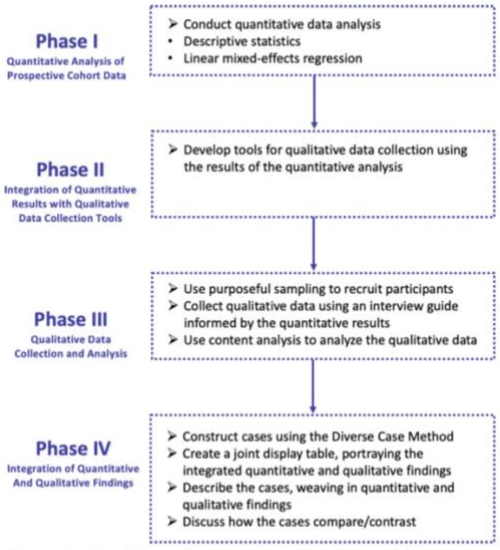

Figure 1 Provides a diagram depicting the study flow.

Study phases I, II, III and IV

Study phase I: prospective cohort

Study design and setting

Phase I will involve the analysis of quantitative data collected as part of the 'Assessing the Determinants of Pregestational Diabetes in Pregnancy: A Prospective Cohort Study.' This study took place at the Maternal-Fetal Medicine clinic at McMaster University Medical Centre in Ontario, Canada. Ethics approval was granted by the Hamilton Integrated Research Ethics Board (REB #14-222).

Participants and recruitment

Consecutive convenience sampling was employed to recruit eligible participants who met the following criteria: (1) a diagnosis of type 1 or type 2 diabetes; (2) attending the Maternal-Fetal Medicine clinic at McMaster University Medical Centre clinic for obstetrical care; and (3) age 18 years or older.

Sample size calculation

The minimum required sample size was calculated by selecting the following options in G*Power: (1) test family, F tests; (2) statistical test, linear multiple regression: Fixed model, R2 deviation from zero; and (3) type of power analysis, a priori: compute required sample size—given α, power and effect size.[19,20] The required sample size varied based on if Cohen's effect size was small, medium or large.[21] In a meta-analysis exploring the effect of nurse-led diabetes self-management education on A1C, Tshiananga *et al*[22] found that nurse-led diabetes self-management education had a medium effect on A1C. Therefore, using an alpha of 0.05, 80% power, a medium effect size of 0.1521 and accounting for three predictors (self-efficacy, self-care and care satisfaction), the minimum required sample size is 77. A total of 111women were recruited as part of the 'Assessing the Determinants of Pregestational Diabetes in Pregnancy: A Prospective Cohort Study.'

Data collection

Data collection occurred from April 2014 to November 2019. Data were collected three times during pregnancy, between 0 to 16 weeks (time point 1 (T1)); 17–28 weeks (time point 2 (T2)); and 29–40 weeks (time point 3 (T3)). Participants completed a demographic questionnaire, which inquired about characteristics such as age, ethnicity, marital status, household income, education level, living arrangements and employment status.

Participants also completed a survey to assess the following clinical characteristics:

- Current type of diabetes (type 1 or type 2).
- Gestational diabetes in a previous pregnancy.
- Duration of diabetes.
- Method of diabetes treatment (insulin pump or multiple daily injections).

- Daily frequency of self-monitoring of blood glucose.
- Status of insurance coverage for diabetes supplies.
- Gestational age.
- Gravida.
- Multiple or single gestation.
- Use of assistive reproductive technology.

Glycaemic control was assessed through participant self-report of A1C at each time point. The self-reported values were confirmed with the medical chart.

Self-efficacy was measured using an eight-item Likert scale called the Self-Efficacy for Diabetes scale.[23] Participants rated their confidence in activities, such as knowing what to do when their blood glucose is higher or lower than the target. Responses ranged from 1 to 10 (not at all confident to totally confident). The total score is the mean of the eight-item responses, with a maximum score of 10. A higher score indicates higher self-efficacy in diabetes management.[23] Self-care was assessed using the Summary of Diabetes Self-Care Activities Measure.[24] Eleven questions over four categories asked participants to indicate how many days in the last week they performed a variety of self-care behaviours. The scale sections included diet, exercise, blood glucose testing and foot care. The scores from each subsection are averaged to create a total score, with a maximum score of 7. A greater frequency of performed activities indicates better self-management and adherence to treatment.[24]

Care satisfaction was assessed using the Patient Assessment of Care for Chronic Conditions scale.[25] This scale measured the degree to which a patient perceived that their medical care was congruent with the Chronic Care Model.[25] The Chronic Care Model involves

optimising the following components—healthcare organisation, delivery system design, clinical information systems, decision-support, self-management support and community resources.[25] This tool had 20 items that asked participants to quantify the care they received from their healthcare team over the past 6 months. Participants indicated how often they were given choices about treatment or asked to talk about their treatment goals. Responses ranged from none of the time (1 point) to always (five points). There were five subscales: Patient Activation, Delivery System Design/Decision Support, Goal Setting, Problem-Solving/Contextual Counselling and Follow-up/Coordination. The overall score is an average of the combined subscale scores, with a maximum score of five. Higher scores indicate that the patient is receiving care congruent with the chronic care model.[25]

Data analysis

We will conduct descriptive statistics to understand the distribution of participant demographic and clinical characteristics, and participant levels of self-efficacy, self-care and care satisfaction. We plan to explore differences in variable distribution, stratified by diabetes type. We will use linear mixed-effects modelling to explore trends in glycaemic control and examine self-efficacy, self-care and care satisfaction as predictors of A1C. To control for potential confounding factors on the relationship between self-efficacy, self-care, care satisfaction and glycaemic control, we will adjust for participant age, diabetes duration, ethnicity, education level, household income and insurance coverage. The decision to control for these factors was based on the knowledge that they may be independently associated with both the proposed independent variables (self-efficacy, self-care and care satisfaction) and dependent variable (A1C), making them potential confounders of any association between the independent and dependent variables. For example,

evidence indicates that diabetes duration is associated with self-efficacy[26] and glycaemic control among non-pregnant adults with type 2 diabetes.[27]

Study phase II: planning the qualitative data collection

In phase II, we will use the results of the quantitative data analysis, which aims to determine the predictors of glycaemic control during pregnancy for women with pre-existing diabetes, to develop the interview guide for phase III. Using the quantitative results to inform the qualitative interviews will allow us to focus on areas of the quantitative results that require further exploration.

Study phase III: qualitative description

Study design and setting

We will use a qualitative description design for Phase III. Fundamental qualitative description allows researchers to gather rich narrations from participants regarding the phenomenon of interest.[28] The Consolidated Criteria for Reporting Qualitative Studies will be used to guide the reporting of phase III.[29]

Albert Bandura's Theory of Self-Efficacy will be used as a framework to guide this study phase. The Theory of Self-Efficacy proposes that individuals can exercise control over their behaviour.[30] Two integral concepts of the Theory of Self-Efficacy include efficacy expectations and outcome expectations. Bandura describes efficacy expectations as a person's judgement in their ability to complete a certain task. On the other hand, outcomes expectations represent what a person thinks will occur as a result of successfully completing a task.[31] Bandura further outlines that personal efficacy is derived from four sources: performance accomplishments,

vicarious experiences, verbal persuasion and physiological state.[31] Performance accomplishments represent a person's past experiences, both positive and negative, of performing the targeted behaviour. This is the source that has the most influence on the development of personal efficacy. High or low personal efficacy is also developed vicariously through viewing someone else performing the desired behaviour. Verbal persuasion—encouragement from another person—as well as the physiological state—a person's bodily sensation in response to a stressful situation—also influence a person's confidence in their capabilities. These sources of information come together to shape a person's perceived ability to accomplish a task.[31] Supporting patients to engage in healthy behaviours to the best of one's ability presents a challenge for healthcare providers, even for diseases that can be self-managed, such as diabetes.[32] Therefore, the notion of self-efficacy within an understanding of the impact of the social determinants of health is key, for it strongly influences the initiation and maintenance of behaviour change, a component essential in chronic disease management.[33] Arguably, understanding one's self-efficacy is paramount for women with pre-existing diabetes in pregnancy, as there is a limited window of time within which self-management education and support can be provided to optimise diabetes-related and pregnancy-related outcomes.

Participants and recruitment

We will use the principles of purposeful sampling to recruit women aged 18 years or older, with type 1 and type 2 diabetes, who are currently or who were previously pregnant. These women will participate in individual semi-structured interviews to describe their experience of managing diabetes and determine their needs regarding diabetes self-management education and support during pregnancy. Additional sampling strategies such as snowball sampling and theoretical sampling, in which initial data analysis guides future recruitment to explore emerging themes,

will also be used.[34] The guidelines regarding sample sizes in fundamental qualitative description studies focus on recruiting an adequate number of participants to generate descriptions of the phenomenon of interest.[35] Sample sizes are usually small to facilitate in-depth exploration of participant descriptions.[35] For qualitative description studies that employ individual interviews, sample sizes are typically in the range of eight to 20 participants.[35] The sample size for this study will be between 10 and 20 participants. Data saturation will guide the completion of recruitment and data collection.[35]

Data collection

Interviews provide first-hand knowledge regarding participant experiences.[36] As such, individual interviews will be the primary means of data collection. A literature review and the phase I study results will inform the development of the semi-structured interview guide. The interviews will be conducted face-to-face via videoconferencing (Zoom, WebEx, Skype or Microsoft Teams) or by telephone and will have an approximate duration of 30–60 minutes. All interviews will be audiorecorded. The primary researcher (KS) will conduct all interviews to maintain consistency. Several pilot interviews will be completed with the first few recruited participants to evaluate the appropriateness of the interview guide. The interview questions may be modified based on the pilot interviews.[37] Questions may also be added or removed as the number of interviews progresses, depending on emerging themes and content. We will collect baseline demographic and clinical characteristics before the interview and write supplementary field notes immediately after. We will also verbally summarise the interview with the participants and ask them to confirm or expand on the summary as a way of member checking.[38]

Data analysis

Following the completion of the interviews, the recorded audio will be transcribed verbatim and imported into NVivo (NVivo. QSR International; 2020) for analysis. The goal of data analysis in qualitative description is to elicit the participant's viewpoint regarding the phenomenon of interest and remain close to the surface of the data.[35] Therefore, we will employ conventional content analyses, as described by Hsieh and Shannon.[39] This method of analysis is appropriate for studies with the aim of description because it allows codes and categories to be derived directly from the data rather than from preconceived ideas informed by existing literature or theories.[39] Content analysis in this study will begin with repeated reading of interview transcripts to facilitate immersion in the data. We will then identify codes through a line-by-line review and highlight relevant concepts. Simultaneous note-taking and reflection on initial impressions will allow code labelling derived from the interview text. We will then group related codes into 10–15 categories and develop definitions for each.[39]

Study phase IV: integration of quantitative and qualitative findings and case construction

The purpose of the mixed-methods procedures will be to integrate the quantitative and qualitative data to develop a deep description and analysis of diabetes self- management in women with type 1 and type 2 diabetes during pregnancy. The recommendations by Creswell and Clark for integration procedures will guide our mixing process.[40]

The mixed-methods integration will occur following the completion of the qualitative study when the results of the cohort data analysis and the qualitative interview findings are combined to construct cases. We will integrate the quantitative and qualitative data following their separate analyses through data displays and the development of meta-inferences.[40] The

Diverse Case Method[41] will be used to construct cases that describe how diabetes self-management and support experiences explain glycaemic control in pregnancy. For categorical variables, such as diabetes type, we will construct cases for each category. For example, we will select participant groups with type 1 diabetes and good and poor glycaemic control and participant groups with type 2 diabetes and good and poor glycaemic control to assemble cases. For continuous variables, such as self-efficacy score, we will create cases using high compared with low values of the variable. For example, we will choose participant groups with high compared with low levels of self-efficacy and examine differences in their glycaemic control. Supporting data will then be selected from the qualitative interview results to contextualise and complete case construction.

Displaying the data will be done in several ways to link the quantitative and qualitative phases. We will represent the points of integration in two ways. First, we will develop a statistics-by-theme joint-display table to present the cases constructed from the quantitative and qualitative data.[40] The joint display will depict the quantitative results alongside the qualitative themes to portray the results of the mixed-methods integration.[40] Second, we will mix the data in our write-up of the study results by using an approach that weaves together quantitative statistics with narrative themes.

DISCUSSION

This study will use a mixed-methods design to provide a comprehensive understanding of how self-management and support experiences influence glycaemic control for women with diabetes in pregnancy. Specifically, a better understanding will be gained of the following: the prevalence and correlates of self-management support and glycaemic control in women with pre-existing

diabetes in pregnancy; and the self-management experience of women with pre-existing diabetes in pregnancy.

This study will also lay the groundwork for future research that could include collecting further quantitative data to confirm the results—locally, regionally, provincially and nationally. The study results also have the potential to inform medical care for high-risk patients with pre-existing diabetes during the critical finite, intensive period of pregnancy. However, this study also has limitations. Specifically, the single-centre design of the cohort study and the use of qualitative methods will limit the generalisability of our findings. In addition, our study is subject to biases inherent in self-report data, such as recall bias. In an attempt to address recall bias, we have made the recall period short (6 months or less), are studying participants with a chronic disease and made the duration of the study relatively short (over the 9 months of pregnancy), all factors known to be related to impact recall bias.[42]

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were not involved in the protocol design. We plan to make study results available to participants on request. We also plan to use the results of this study to provide the basis for the development, evaluation and implementation of a patient-centred intervention based on the constructed cases to inform models of self-management education and support, including the use of technology, peer support and health coaching interventions, among others.

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CHAPTER 4

TITLE: Trends and self-management predictors of glycemic control during pregnancy in women with pre-existing type 1 and type 2 diabetes: A cohort study

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Abstract

Background: As much of diabetes management during pregnancy occurs at home, self-management factors, including self-efficacy, self-care activities and care satisfaction, may affect glycemia. Our objective was to explore trends in glycemic control during pregnancy in women with type 1 and type 2 diabetes, assess self-efficacy, self-care and care satisfaction and examine these factors as predictors of glycemic control.

Methods: We conducted a cohort study from April 2014 to November 2019 at a tertiary centre in Ontario, Canada. Self-efficacy, self-care, care satisfaction and A1C were measured three times during pregnancy (T1, T2, T3). Linear mixed-effects modelling explored trends in A1C and examined self-efficacy, self-care and care satisfaction as predictors of A1C.

Results: We recruited 111 women, (55 with type 1 diabetes; 56 with type 2 diabetes). Mean A1C significantly decreased by 1.09% (95% CI -1.38, -0.79) from T1 to T2 and by 1.14% (95% CI -1.43, -0.86) from T1 to T3. Self-efficacy significantly predicted glycemic control for women with type 2 diabetes, associated with a mean change in A1C of -0.22% (95% CI -0.42, -0.02) per unit increase in scale. The exercise sub-score of self-care significantly predicted glycemic control for women with type 1 diabetes, associated with a mean change in A1C of -0.11% (95% CI, -0.22, -0.01) per unit increase in scale.

Conclusion: Self-efficacy significantly predicted A1C during pregnancy in a cohort of women with pre-existing diabetes in Ontario, Canada. Future research will continue to explore self-management needs and challenges in women with pre-existing diabetes in pregnancy.

Introduction

Evidence indicates that diabetes is rising globally and nationally, both in the general population and among pregnant women (1). The growing rate of diabetes in pregnancy is of particular concern, as it is associated with a significant increase in adverse perinatal outcomes (3-7). Research indicates that maternal glycemic control during pregnancy is one of the significant predictors of pregnancy outcomes (8-14). Women who maintain optimal glycemic control during preconception and pregnancy have a lower risk of complications (8-14). Thus, A1C targets are close to non-diabetes targets during the preconception and prenatal periods (15).

Glycemic control in pre-existing type 1 and type 2 diabetes in pregnancy is affected by physiological variables, such as the degree of insulin resistance, and social determinants of health factors, such as education and income level (16-19). Multiple clinical interventions aim to improve glycemic control during pregnancy including preconception care, frequent education and counselling and the provision of medical care by a multidisciplinary healthcare team, among others (15). In addition, healthcare providers prescribe various methods of glucose monitoring (finger-stick glucose monitoring versus continuous glucose monitoring) and insulin delivery (multiple daily injections of insulin versus continuous subcutaneous insulin infusion) in an attempt to optimize glycemia during the prenatal period (15). However, the majority of diabetes self-management during pregnancy occurs at home, between appointments with healthcare providers. Thus, self-management factors, such as self-efficacy, defined as confidence in one's ability to succeed in specific situations or accomplish specific tasks, may also affect glycemic control.

Similarly, diabetes self-care behaviours, which include healthy eating, being physically active, self-monitoring blood glucose, taking medications, using problem solving and healthy coping skills and engaging in risk-reduction behaviours, could be linked to prenatal glycemia (20). Finally, patient satisfaction with support from their healthcare team may also contribute to meeting glycemic targets.

Among non-pregnant adults, research has indicated that self-efficacy, self-care and patient satisfaction with medical care are significant predictors of glycemic control (21-23). For example, diabetes self-care behaviours are moderately correlated with A1C (r = -0.37, $p < 0.05$) among adults with type 2 diabetes, aged 30 to 55 years (22). Thus, the specific clinical interventions prescribed by healthcare providers may have less of an impact on prenatal glycemia than self-management factors, including women's levels of self-efficacy and self-care and satisfaction with their medical care (24).

Research has explored the relationship between diabetes self-efficacy, self-care and care satisfaction and diabetes management and control among women with gestational diabetes (25, 26). The evidence suggests that self-efficacy is a predictor of a healthy lifestyle among women with gestational diabetes, with higher self-efficacy associated with increased physical activity, a healthier diet and a lower Body Mass Index (BMI) (26). However, to our knowledge, no investigations to date have focused on these self-management factors as predictors of diabetes management and control in pregnancies complicated by type 1 or type 2 diabetes.

The objective of this study was to explore trends in glycemic control during pregnancy in women with type 1 and type 2 diabetes. We also aimed to assess self-management factors, such as self-efficacy, self-care and care satisfaction and examine these factors as predictors of glycemic control.

Methods

Study design and participants

We conducted a cohort study from April 17, 2014 to November 28, 2019. Consecutive convenience sampling was employed to recruit women from a high-risk pregnancy clinic at a tertiary centre in Ontario, Canada. We recruited women who met the following eligibility criteria: (a) a diagnosis of type 1 or type 2 diabetes and (b) age 18 years or older. This study received ethics approval from our local Research Ethics Board (REB #14-222). The conduct and reporting of this study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (27).

Data collection and outcomes

Data collection occurred three times during pregnancy to align with the conventional trimesters: between 0 to 16 weeks (time point 1 [T1]); 17 to 28 weeks (time point 2 [T2]); and 29 to 40 weeks (time point 3 [T3]). Women completed a questionnaire at baseline to capture demographic and clinical characteristics such as age, ethnicity, the current type of diabetes (type 1 or type 2) and gravida. Glycemic control was assessed through self-report of A1C at each time point and confirmed by a healthcare provider at the clinic visit.

Self-efficacy was measured at each time point using the Self-Efficacy for Diabetes scale (27). The Self-Efficacy for Diabetes scale is an eight-item Likert scale, which asks the participant to rate their confidence in activities, such as choosing healthy foods to eat or knowing what to do when their blood glucose is higher or lower than the target. Responses range from 1 (not at all confident) to 10 (totally confident). The total score is calculated by determining the mean of the eight-item responses, with a maximum score of 10. A higher score indicates higher self-efficacy in diabetes management (28). The literature indicates that the Self-Efficacy for Diabetes scale is reliable (strong internal consistency [Cronbach's alpha = 0.85] and test-retest reliability [intraclass correlation coefficient = 0.80]) and has convergent validity, with item-scale correlations exceeding 0.50 (29, 30).

Self-care was assessed at each time point using the Summary of Diabetes Self-Care Activities scale, which includes 11 questions over five subscales, to assess self-care behaviours (31). The subscales include general diet, specific diet, exercise, blood sugar testing and foot care. Scores are determined by calculating the mean score for each subscale; the tool was not designed to yield a total score across subscales. A higher frequency of activities performed indicates better self-management and adherence to treatment (31). This scale has been widely used for over 20 years and has demonstrated both reliability (adequate internal consistency [Cronbach's alpha > 0.5] and test-retest reliability [intraclass correlation coefficient = 0.47]) and strong construct validity (Comparative Fit Index > 0.90 and Goodness of Fit Index > 0.90) (32, 33).

The Patient Assessment of Care for Chronic Conditions scale measures the degree to which a patient perceives that their medical care is congruent with the Chronic Care Model (34). The

Chronic Care Model seeks to optimize the following components—healthcare organization, delivery system design, clinical information systems, decision-support, self-management support and community resources (34). This tool has 20 items that ask participants to quantify the care they received from their healthcare team over the past six months. Responses range from none of the time (1 point) to always (5 points). The Patient Assessment of Care for Chronic Conditions instrument has five subscales: Patient Activation, Delivery System Design/Decision Support, Goal Setting, Problem-Solving/Contextual Counseling and Follow-up/Coordination. Items in each subscale are averaged to calculate a subscale score. The overall score for the instrument is an average of the combined subscale scores, with a maximum score of five. Higher scores indicate that the patient is receiving care that is congruent with the chronic care model, care that is planned, proactive population-based and patient-centred (34). This scale is reliable (strong internal consistency [Cronbach's alpha = 0.93]; adequate test-retest reliability [intraclass correlation coefficient = 0.58]) and has moderate to strong convergent validity with existing measures of patient activation (r = 0.42 to 0.60) (34).

Statistical analysis

Descriptive statistics were completed to understand the distribution of baseline characteristics, and levels of diabetes self-efficacy, self-care and care satisfaction. Descriptive statistics were reported as means and standard deviations (SD) for continuous data, or frequencies and percentages for categorical data. Independent Samples t-Tests, Chi-squared tests and Fisher's exact tests explored differences in baseline variable distribution, stratified by diabetes type. Linear mixed-effects modelling was used to explore trends in glycemic control and examine self-efficacy, self-care and care satisfaction as predictors of A1C. We reported model parameters and

95% confidence intervals. To control for potential confounders on the relationship between self-management factors and glycemic control, we adjusted the model for participant age, diabetes duration, ethnicity, education level, household income and insurance coverage. A *p*-value of < 0.05 was considered statistically significant. SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Macintosh, Version 28) was used to perform all statistical analyses.

Results

Characteristics of participants

Of the 128 women approached to participate in the study, 111 women were recruited—55 with type 1 diabetes and 56 with type 2 diabetes. Of the seventeen women who were approached but did not participate in the study, sixteen declined citing time as the most common reason for non-participation, and one woman was deemed too medically complex by the healthcare team to participate. The mean age of the study participants was 30.23 (SD 4.97) years, the majority identified as European (81.3%, n = 87), were married (65.5%, n = 72), had a college/trade level of education (45.9%, n = 51) and had third party insurance (39.8%, n = 43). A significantly higher percentage of women with type 2 diabetes had a college/trade level education compared to those with type 1 diabetes (57.1%, n = 32 versus 34.5%, n = 19, $p = 0.02$). A significantly higher percentage of women with type 1 diabetes had a university level of education compared to those with type 2 diabetes (40.0%, n = 22 versus 17.9%, n = 10, $p = 0.01$). The current pregnancy was the first for 43.2% (n = 48) of women and was a singleton pregnancy for nearly all women (98.2%, n = 109). A significantly higher percentage of women with type 2 diabetes used assistive reproductive technology compared to those with type 1 diabetes (14.3%, n = 8 versus 1.8%, n = 1, $p = 0.03$). Diabetes duration was significantly longer among women with

type 1 diabetes compared to type 2 diabetes (mean 15.3 [SD8.38] years versus 5.14 [SD 5.39], $p < 0.0001$). A significantly higher percentage of women with type 2 diabetes compared to type 1 diabetes used oral medications (10.7%, n = 6 versus 0%, n = 0, $p = 0.03$) and insulin injections (87.5%, n = 49 versus 50.9%, n = 28, $p < 0.001$) to manage diabetes. A significantly higher percentage of women with type 1 diabetes compared to type 2 diabetes used insulin pumps to manage diabetes (49.1%, n = 27 versus 0%, n = 0, $p < 0.001$). A significantly higher percentage of women with type 1 diabetes compared to type 2 diabetes had insurance coverage through the provincial Assistive Devices Program (47.2%, n = 25 versus 3.6%, n = 2, $p < 0.001$). In contrast, a significantly higher percentage of women with type 2 diabetes compared to type 1 diabetes had third-party insurance (50.9%, n = 28 versus 28.3%, n = 15, $p = 0.02$) or no insurance (23.6%, n = 13 versus 5.7%, n = 3, $p = 0.01$). There were no other statistically significant differences in baseline characteristics between women with type 1 and type 2 diabetes (Table 1).

Glycemic control

Overall, the cohort's change in mean A1C was significant, decreasing by -1.09% (95% CI -1.38, -0.79; $p < 0.001$) from T1 to T2 and by -1.14% (95% CI -1.43, -0.86; $p < 0.001$) from T1 to T3. The change from T2 to T3 was not significant (-0.51%; 95% CI -0.33, 0.22; $p = 0.71$). Stratified by diabetes type, the change in mean A1C was significant from T1 to T2 and T1 to T3 for type 1 diabetes (-0.77%, 95% CI -1.13, -0.39; $p < 0.001$; -0.89%, 95% CI -1.25, -5.21; $p < 0.001$) and type 2 diabetes (-1.45%, 95% CI -1.91, -0.99; $p < 0.001$; -1.49%, 95% CI -1.85, -0.96, $p < 0.001$). The change from T2 to T3 remained non-significant (Table 2).

Patient-reported outcomes

Self-efficacy:

For women with type 1 and type 2 diabetes, the overall mean self-efficacy score rose from 7.83 (SD 1.31) in T1 to 7.96 (SD 1.20) in T3. There were no statistically significant differences in self-efficacy scores in women with type 1 compared to type 2 diabetes across any time point (Table 3).

Self-care:

The mean sub-scale score for self-monitoring of blood glucose in T1 was significantly higher among women with type 1 compared to type 2 diabetes (mean 6.68 [SD 0.70] vs. 6.12 [SD 1.26], $p = 0.03$). The mean sub-scale score for diet in T3 was significantly higher among women with type 1 compared to type 2 diabetes (mean 4.08 [SD 1.16] vs. 3.59 [1.06]; $p = 0.03$) There were no other statistically significant differences in self-care scores in women with type 1 compared to type 2 diabetes (Table 3).

Care satisfaction:

The mean care satisfaction score improved for the whole cohort from 3.32 (SD 0.88) in T1 to 3.39 (SD 0.81) in T3. There were no statistically significant differences in care satisfaction scores in women with type 1 compared to type 2 diabetes (Table 3).

Self-management predictors of glycemic control

We used linear mixed-effects modeling to examine self-efficacy, self-care and care satisfaction (independent variables) as predictors of A1C (dependent variable). After adjustment for

confounders, self-efficacy significantly predicted glycemic control for women with type 2 diabetes, associated with a mean change in A1C of -0.22% (95% CI -0.42, -0.02, $p = 0.03$) per unit increase in scale. The exercise sub-score of self-care significantly predicted glycemic control for women with type 1 diabetes after adjustment for confounders, associated with a mean change in A1C of -0.11% (95% CI, -0.22, -0.01, $p = 0.04$) per unit increase in scale. Other factors that significantly predicted A1C after adjustment for confounders were baseline characteristics, including ethnicity ($p = 0.01$ to 0.04) and education level ($p < 0.001$) (Table 4).

Discussion

This study explored trends in glycemic control during pregnancy, assessed self-efficacy, self-care and care satisfaction, and examined these factors as predictors of glycemic control among a cohort of women with type 1 and type 2 diabetes receiving obstetrical care at a tertiary centre in Ontario, Canada. We found that the overall cohort achieved an A1C of $\leq$6.5% by T2 and maintained this target in T3. In both T2 and T3, women with type 1 diabetes had a higher mean A1C than did women with type 2 diabetes (mean A1C at T2, 6.72% and T3, 6.60% for type 1 diabetes vs. mean A1C at T2, 6.08% and T3, 6.12%). The difference may be clinically significant, as a reduction in A1C of $\leq$ 0.5 % has been deemed clinically meaningful (35). A previous population-based cohort study in Ontario reported on-target A1C by mid-pregnancy (mean A1C 6.4% [SD 1.1]) among women with pre-existing diabetes in pregnancy (36). However, the authors did not stratify A1C by diabetes type. Thus, we do not know if there was a difference in glycemic control between those with type 1 and type 2 diabetes. Duration of diabetes may contribute to insulin resistance (37). The longer duration of diabetes and insulin resistance among women with type 1 compared to type 2 diabetes may have contributed to the

higher mean A1C. Furthermore, the goal for women with type 1 diabetes is to target A1C as low as it is safe to do so while avoiding frequent and severe hypoglycemia (15). Therefore, avoidance of hypoglycemia may have contributed to the higher mean A1C among women with type 1 compared to type 2 diabetes. However, we did not collect data on the occurrence of hypoglycemia among this cohort.

Maternal self-efficacy improved from T1 to T3. There was also some variation in maternal self-care from T1 to T3. For example, the score for the subscale of Foot Care increased for the entire cohort from 2.56 in T1 to 2.72 in T2 to 2.99 in T3. However, the score for the subscale of Diet, General increased from 4.89 to 4.96 from T1 to T2 but then decreased to 4.84 in T3. Maternal care satisfaction improved from T1 to T3 in the entire cohort and women with type 1 diabetes. However, care satisfaction decreased from T1 to T3 among women with type 1 diabetes. None of the self-management variable scores have a cut-off. Thus, we cannot comment on whether women reached a target score. However, all of the mean questionnaire scores among our cohort appear to be relatively high. With maximum possible scores of 10 and five for self-efficacy and care satisfaction (28, 34), the overall mean scores in our cohort by T3 were 7.96 (SD 1.20) and 3.39 (SD 0.81), respectively. For self-care, the sub-scale scores for self-monitoring of blood glucose and diet were significantly higher at T1 and T3, respectively, for women with type 1 compared to type 2 diabetes. Given their clinical heterogeneity, a significantly higher percentage of women with type 2 diabetes used oral medications to manage diabetes, compared to women with type 1 diabetes who exclusively used insulin injections or insulin pumps. Insulin comes with a higher risk for hypoglycemia than do oral medications. The higher risk of hypoglycemia

may have contributed to the higher frequency of glucose monitoring in the group that self-administered more insulin.

After adjustment for confounders, increased self-efficacy was significantly associated with improved glycemic control for women with type 2 diabetes and the exercise sub-score of self-care was significantly associated with improved glycemic control for women with type 1 diabetes. Transitioning to parenthood, in general, is associated with intentions for making positive lifestyle changes, such as increasing healthy eating (38). Thus, women may be motivated during pregnancy to optimize glycemia for the well-being of their infant. Participant interviews could explore this finding and further examine the impact that parenthood has on diabetes self-management and glycemic control during pregnancy (39).

Several baseline factors, including the level of education, income, insurance status and ethnicity, significantly predicted glycemic control. Household income between $81,000 and $100,00 was associated with a mean change in A1C of -1.15 (95% CI -2.16, -0.13) among women with type 1 diabetes. Household income over $100,000 was associated with a mean change in A1C of -0.84 (95% CI -1.64, -0.05) for the entire cohort and a mean change in A1C of -1.19 (95% CI -2.19, -0.21) for women with type 1 diabetes. Having insurance other than ADP or third party was associated with a mean change in A1C of 0.76 (95% CI 0.16, 1.36) for the entire cohort and a mean change in A1C of 1.19 (95% CI 0.19, 2.19) for women with type 1 diabetes. Being of East Asian ethnicity was associated with a mean change in A1C of 3.19 (95% CI 1.00, 5.39) for the entire cohort and a mean change in A1C of 4.18 (95% CI 1.79, 6.57) for women with type 2 diabetes. Hispanic ethnicity was associated with a mean change in A1C of -2.80 (95% CI -4.97,

-0.64) for the entire cohort. Having a Middle Eastern background was associated with a mean change in A1C of 0.47 (95% CI 0.09, 2.85) for the entire cohort and a mean change in A1C of -2.64 (95% CI -4.95, -0.34) for women with type 2 diabetes. Being of Indigenous ethnicity was associated with a mean change in A1C of -1.27 (95% CI -2.17, -0.36) for the entire cohort. These findings correlate with existing literature that demonstrates a negative association between social determinants of health and glycemic control (18, 19).

Our study had a number of strengths. First, pre-existing type 1 and type 2 diabetes make up only about one-fifth of those with diabetes in pregnancy. Although this is a small population, we amassed a comparatively large data set by recruiting women over five years. In addition, the tertiary centre that we recruited from is the regional centre for all women with type 1 and type 2 diabetes in pregnancy, encompassing two regional health networks.

Our study also has several limitations. First, we observed a mean higher A1C in T1 than recommended in the preconception period of < 7% and ideally < 6.5% (15). We also noted that mean A1C in T1 was lower among women with type 1 versus type 2 diabetes. Lower A1C may have occurred if more women with type 1 diabetes received preconception care and counselling, as this is more common among those with type 1 compared to type 2 diabetes (40). However, we did not inquire about preconception care, which is a significant limitation of our study. Furthermore, we did not collect data on baseline diabetes complications, BMI, pre-pregnancy A1C, hypoglycemia or number of missed medications, which are further limitations. The lack of data on pregnancy outcomes is another limitation as the recommended glycemic targets in pregnancy are in place to improve perinatal outcomes. (15). Although it is well established that

achieving target A1C reduces the occurrence of perinatal morbidity and mortality (15), it would have been valuable to link our data on self-management behaviours and perinatal maternal glycemia to pregnancy outcomes. Finally, the study relied on self-reported data which may be impacted by social desirability and recall bias. In order to address recall bias, we have attempted to make the recall period short (six months or less) and the duration of the overall study relatively short (over the nine months of pregnancy), factors that are known to be related to recall bias (41).

In conclusion, in this cohort of expectant mothers with type 1 and type 2 diabetes, we demonstrated that glycemic control improved and reached target as pregnancy progressed. Self-efficacy, self-care and care satisfaction also improved, remaining relatively high from T1 to T3. Furthermore, the self-management variables, self-efficacy and self-care, were significant predictors of A1C. Specifically, self-efficacy was associated with a mean change in A1C of -0.22% (95% CI -0.42, -0.02) per unit increase in scale among women with type 2 diabetes.

The data in this cohort provides valuable insight for future studies. As such, we have several forthcoming projects that will build on the results of this study. First, we plan to continue recruitment to expand the cohort. However, we foresee augmenting our methods to incorporate the collection of data on preconception care and hypoglycemia. Furthermore, as continuous glucose monitoring is now widely used, particularly among women with type 1 diabetes, we plan to collect data from these devices, when available, to provide additional glycemic control outcomes. We also plan to link collected perinatal data with pregnancy outcomes, including fetal outcomes. Finally, we aim to conduct a qualitative study to further explore findings from the

current study as well as to examine the experience of managing diabetes during pregnancy and identify the diabetes self-management education and support needs among expectant mothers with type 1 and type 2 diabetes.

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TABLE 1. Participant Baseline Characteristics, Stratified by Type of Diabetes

	Total (*N* = 111)*	**T1D (*n* = 55)**	**T2D (*n* = 56)**	***P***
Age (years)	30.23 (4.97)	29.45 (4.69)	30.98(5.15)	0.105
Ethnicity				
African	2 [1.9]	2 [3.8]	0 [0]	0.243
East Asian	2 [1.9]	1 [1.9]	1 [1.9]	1.000
European	87 [81.3]	47 [88.7]	40 [74.1]	0.053
Hispanic	1 [0.9]	0 [0]	1 [1.9]	1.000
Middle Eastern	2 [1.9]	1 [1.9]	1 [1.9]	1.000
South Asian	4 [3.7]	0 [0]	4 [7.4]	0.118
Indigenous	6 [5.6]	1 [1.9]	5 [9.3]	0.205
Unsure	2 [1.9]	1 [1.9]	1 [1.9]	1.000
Other	3 [2.8]	1 [1.9]	2 [3.7]	1.000
Marital Status				0.784
Single	12 [10.9]	5 [9.1]	7 [12.7]	
Supportive Partner	26 [23.6]	14 [25.5]	12 [21.8]	
Married	72 [65.5]	36 [65.5]	36 [65.5]	
Education Level				
Grade School	3 [2.7]	0 [0]	3 [5.4]	0.243
High School	24 [21.6]	13 [23.6]	11 [19.6]	0.609
College/Trade	51 [45.9]	19 [34.5]	32 [57.1]	0.017†
University	32 [28.8]	22 [40.0]	10 [17.9]	0.010†
Other	1 [0.9]	1 [1.8]	0 [0]	0.495
Household Income (dollars)				0.606
<20,000	9 [8.3]	4 [7.5]	5 [9.1]	
20-40,000	26 [24.1]	9 [17.0]	17 [30.9]	
41-60,000	11 [10.2]	7 [13.2]	4 [7.3]	
61-80,000	19 [17.6]	10 [18.9]	9 [16.4]	
81-100,000	18 [16.7]	10 [18.9]	8 [14.5]	
>100,000	25 [23.1]	13 [24.5]	12 [21.8]	
Employment				0.677
Not Working	30 [27.0]	12 [21.8]	18 [32.1]	
Casual/Part-Time	24 [21.6]	13 [23.6]	11 [19.6]	
Full-Time	55 [49.5]	29 [52.7]	26 [46.4]	
Other	1 [1.8]	1 [1.8]	1 [1.8]	
Primiparous	48 [43.2]	25 [45.5]	23 [41.1]	0.641
Singleton Gestation	109 [98.2]	54 [98.2]	55 [98.2]	1.000
Used ART	9 [8.1]	1 [1.8]	8 [14.3]	0.032†
Previous GDM			7 [12.5]	
Diabetes Duration (years)	10.09 (8.61)	15.13 (8.38)	5.14 (5.39)	<0.000†
Diabetes Treatment Method				
Diet/Exercise	1 [0.9]	0 [0]	1 [1.8]	1.000
Oral Medications	6 [5.4]	0 [0]	6 [10.7]	0.027†
Insulin Injections	77 [69.4]	28 [50.9]	49 [87.5]	<0.001†
Insulin Pump	27 [24.3]	27 [49.1]	0 [0]	<0.001†
SMBG at least Four Times per Day	61 [57.0]	29 [54.7]	32 [59.3]	0.635

Insurance Coverage for Diabetes Supplies ADP				
Third Party	27 [25.0]	25 [47.2]	2 [3.6]	<0.001†
Other	43 [39.8]	15 [28.3]	28 [50.9]	0.016†
None	22 [20.4]	10 [18.9]	12 [21.8]	0.704
	16 [14.8]	3 [5.7]	13 [23.6]	0.009†

ADP, assistive devices program; ART, assisted reproductive technology; GDM, gestational diabetes mellitus; SMBG, self-monitoring of blood glucose; T1, time point 1; T2, time point 2; T3, time point 3; T1D, type 1 diabetes; T2D, type 2 diabetes.
Note: Mean (SD), Number [%]
*All totals do not equal 111 due to missing observations
†p value statistically significant at < 0.05

TABLE 2. Trends in A1C Across Time Points, Stratified by Type of Diabetes

	Total (*N* = 111)		**T1D (*n* = 55)**		**T2D (*n* = 56)**	
A1C at T1	7.49% (7.23, 7.77)		7.49% (7.15, 7.83)		7.53% (7.11, 7.95)	
T2	6.41% (6.15, 6.67)		6.72% (6.39, 7.06)		6.08% (5.68, 6.48)	
T3	6.36% (6.11, 6.60)		6.60 (6.28, 6.93)		6.12% (5.78, 6.49)	
Change in A1C from		***p***		***p***		***p***
T1 to T2	-1.09% (-1.38, -0.79)	<0.001*	-.77% (-1.14, -0.39)	<0.001*	-1.45% (-1.91, -0.99)	<0.001*
T2 to T3	-0.05% (-0.33, 0.22)	0.713	-.12% (-0.47, 0.24)	0.509	-0.04% (-0.46, 0.38)	0.848
T1 to T3	-1.14% (-1.43, -0.86)	<0.001*	-0.89% (-1.25, -0.52)	<0.001*	-1.41% (-1.85, -0.97)	<0.001*

T1, time point 1; T2, time point 2; T3, time point 3; T1D, type 1 diabetes; T2D, type 2 diabetes
Note: Mean or Mean Change (95% Confidence Interval)
**p* value statistically significant at < 0.05

TABLE 3. Questionnaires Results Assessing Diabetes Self-Efficacy, Self-Care and Care Satisfaction Across Time Points, Stratified by Type of Diabetes

	Total (*N* = 111)	**T1D (*n* = 55)**	**T2D (*n* = 56)**	***P***
SED Scale				
T1	7.83 (1.31)	8.06 (1.22)	7.56 (1.38)	0.098
T2	7.76 (1.33)	7.85 (1.33)	7.66 (1.34)	0.521
T3	7.96 (1.20)	8.12 (1.14)	7.81 (1.26)	0.219
SDSCA Scale				
T1				
Diet, General	4.89 (1.56)	4.95 (1.63)	4.84 (1.49)	0.761
Diet, Specific	3.80 (1.47)	3.99 (1.42)	3.59 (1.51)	0.246
Exercise	2.92 (1.98)	2.88 (1.96)	2.97 (2.02)	0.837
SMBG	6.42 (1.03)	6.68 (0.70)	6.12 (1.26)	0.026*
Foot Care	2.56 (2.07)	2.79 (2.26)	2.29 (1.88)	0.310
T2				
Diet, General	4.96 (1.38)	4.98 (1.44)	4.85 (1.32)	0.929
Diet, Specific	3.88 (1.18)	4.02 (1.09)	3.72 (1.26)	0.246
Exercise	2.72 (1.75)	2.62 (1.79)	2.83 (1.73)	0.586
SMBG	6.32 (1.10)	6.54 (0.78)	6.09 (1.34)	0.072
Foot Care	2.72 (2.05)	2.76 (2.28)	2.69 (1.79)	0.858
T3				
Diet, General	4.84 (1.41)	4.72 (1.58)	4.95 (1.23)	0.436
Diet, Specific	3.84 (1.13)	4.08 (1.16)	3.59 (1.06)	0.032*
Exercise	2.92 (1.98)	2.94 (1.86)	2.89 (2.09)	0.922
SMBG	6.50 (0.89)	6.68 (0.64)	6.33 (1.06)	0.051
Foot Care	2.99 (2.21)	3.27 (2.32)	2.71 (2.07)	0.216
PACCC Scale				
T1	3.32 (0.88)	3.48 (0.74)	3.14 (1.00)	0.111
T2	3.42 (0.80)	3.29 (0.69)	3.57 (0.89)	0.116
T3	3.39 (0.81)	3.26 (0.79)	3.51 (0.82)	0.124

PACCC, Patient Assessment of Care for Chronic Conditions; SED, Self-Efficacy for Diabetes; SDSCA, Summary of Self-Care Activities; SMBG, self-monitoring of blood glucose; T1, time point 1; T2, time point 2; T3, time point 3; T1D, type 1 diabetes; T2D, type 2 diabetes

Note: Mean (SD)

*p value statistically significant at < 0.05

TABLE 4. Predictors of A1C, Stratified by Type of Diabetes

	Total (*N* = 111)		**T1D (*n* = 55)**		**T2D (*n* = 56)**	
	Unadjusted	Adjusted†, ***P***	Unadjusted	Adjusted†, ***P***	Unadjusted	Adjusted†, ***P***
SED Scale	-0.18* (-0.31, -0.05)	-0.06 (-0.19, 0.07), 0.339	-0.16 (-0.34, 0.03)	0.01 (-0.19, 0.19), 0.989	-0.22* (-0.40, -0.04)	-0.22* (-0.42, -0.02), 0.034
SDSCA Scale						
Diet, General	-0.19* (-0.31, -0.08)	-0.08 (-0.19, 0.03), 0.175	-0.18* (-0.32, -0.04)	-0.11 (-0.24, 0.03), 0.111	-0.21* (-0.39, -0.03)	-0.04 (-0.03, 0.15), 0.667
Diet, Specific	0.09 (-0.22, 0.03)	-0.05 (-0.17, 0.07), 0.414	-0.11 (-0.23, 0.48)	-0.09 (-0.25, 0.08), 0.306	-0.11 (-0.29, 0.07)	-0.05 (-0.22, 0.12), 0.579
Exercise	-0.07 (-0.16, 0.02)	-0.07 (-0.16, 0.01), 0.084	-0.09 (-0.20, 0.02)	-0.11* (-0.22, -0.01), 0.037	-0.04 (-0.18, 0.09)	-0.06 (-0.19, 0.08), 0.431
SMBG	-0.06 (-0.22, 0.10)	0.05 (-0.10, 0.20), 0.525	-0.21 (-0.52, 0.10)	-0.07 (-0.40, 0.27), 0.692	-0.05 (-0.25, 0.15)	0.09 (-0.08, 0.28), 0.282
Foot Care	-0.02 (-0.09, 0.05)	-0.03 (-0.10, 0.04), 0.422	-0.07 (-0.17, 0.02)	-0.08 (-0.17, 0.01), 0.08	0.04 (-0.09, 0.16)	0.06 (-0.05, 0.18), 0.283
PACCC Scale	-0.08 (-0.28, 0.11)	-0.07 (-0.25, 0.12), 0.482	0.20 (-0.09, 0.50)	0.07 (-0.22, 0.36), 0.611	-0.17 (-0.44, 0.10)	-0.19 (-0.45, 0.07), 0.155
Age (years)	-0.07** (-0.11, -0.04)	-0.03 (0.06, 0.01), 0.168	-0.07* (-0.12, -0.02)	-0.02 (-0.07, 0.04), 0.585	-0.07* (-0.13, -0.01)	0.04 (-0.03, 0.10), 0.262
Diabetes Duration (years)	-0.02 (-0.03, 0.02)	0.01 (-0.01, 0.04), 0.305	-0.02 (-0.05, 0.02)	-0.01 (-0.04, 0.04), 0.874	-0.03 (-0.09, 0.02)	-0.02 (-0.06, 0.02), 0.380
Ethnicity						
European	Reference	Reference	Reference	Reference	Reference	Reference
African	-0.42 (-2.02,1.18)	-0.51 (-2.24, 1.22),	-0.62 (-2.21, 0.98)	-0.74 (-2.48, 0.99),	--	--

		0.561		0.392		
East Asian	2.27 (0.68, 3.87)*	3.19 (1.00, 5.39)*, 0.005	0.79 (-1.32, 2.90)	--‡,	4.18(1.79, 6.57)**	--‡,
Hispanic	0.13 (-1.87, 2.12)	-2.80 (-4.97, -0.64)*, 0.012	--	--	0.38 (-1.54, 2.29)	-2.64 (-0.04, 3.04), 0.055
Middle Eastern	1.61 (0.01, 3.21)*	1.47 (0.09, 2.85)*, 0.038	0.44 (-1.68, 2.55)	--‡,	3.28 (0.89, 5.67)*	-2.64 (-4.95, -0.34)*, 0.026
South Asian	-0.85 (-1.97, 0.27)	-0.75 (-1.69, 0.20), 0.122	--	--	-0.55 (-1.66, 0.56)	-0.17 (-1.47, 1.13), 0.796
Indigenous	-0.59 (-1.63, 0.46)	-1.27 (-2.17, -0.36)*, 0.007	--	--	-0.29 (-1.32, 0.73)	0.20 (-0.84, 1.12), 0.693
Unsure	0.79 (-0.62, 2.22)	0.84 (-0.29, 1.96), 0.142	-0.21 (-2.23, 1.80)	0.36 (-1.22, 1.94), 0.641	1.84 (-0.07, 3.76)	1.50 (-0.04, 3.04), 0.055
Other	-0.49 (-1.77, 0.79)	-0.52 (-1.59, 0.56), 0.342	0.19 (-1.93, 2.29)	-1.64 (-3.50, 0.22), 0.082	-0.64 (-2.20, 0.93)	-0.43 (-1.75, 0.88), 0.509
Education Level						
Grade School	Reference	Reference	--	--	Reference	Reference
High School	-1.20 (-2.34, -0.07)*	-2.30(-3.64, -0.97)** <0.001	1.44 (0.87, 2.01)**	0.53 (-0.38, 1.45), 0.242	-1.53 (-2.76, -0.30)*	-3.63 (-5.09, -2.18)**, <0.001
College/Trade	-2.03 (-3.12, -0.93)**	-2.81(-4.16, -1.46)** <0.001	-2.25 (-3.38, -1.12)**	0.53 (-0.13, 1.19), 0.110	-2.25 (-3.38, -1.12)**	-3.90 (-5.37, -2.44)**, <0.001
University	-2.50 (-3.61, -1.39)**	-3.36(-4.79, -1.93)** <0.001	Reference	Reference	-2.82 (-4.06, -1.59)**	-4.39 (-6.00, -2.78)**, <0.001
Other	-1.51 (-3.65, 0.63)	-2.48 (-4.69, -0.27)*, 0.028	0.91 (-0.79, 2.59)	--‡,	--	--
Household Income (dollars)						
<20,000	Reference	Reference	Reference	Reference	Reference	Reference
20-40,000	0.09 (-0.69, 0.89)	0.15 (-0.61, 0.92), 0.690	0.20 (-0.85, 1.25)	0.39 (-0.69, 1.46), 0.471	0.15 (-0.99, 1.29)	0.67 (-0.37, 1.70), 0.195

41-60,000	-0.49 (-1.41, 0.42)	-0.09 (-0.98, 0.79), 0.835	-0.91 (-1.98, 0.17)	-0.31 (-1.43, 0.82), 0.577	-0.39 (-1.90, 1.12)	0.40 (-1.07, 1.87), 0.581
61-80,000	-0.25 (-1.08, 0.59)	0.02 (-0.82, 0.86), 0.975	-0.85 (-1.88, 0.18)	-0.07 (-1.15, 0.99), 0.885	0.23 (-1.05, 1.49)	0.69 (-0.51, 1.91), 0.249
81-100,000	-0.77 (-1.59, 0.06)	-0.15 (-1.02, 0.72), 0.734	-1.15 (-2.16, -0.13)*	-0.04 (-1.18, 1.11), 0.946	-0.54 (-1.81, 0.73)	0.27 (-1.08, 1.62), 0.681
>100,000	-0.84 (-1.64, -0.05)*	0.01 (-0.87, 0.88), 0.989	-1.19 (-2.19, -0.21)*	-0.09 (-1.29, 1.09), 0.872	-0.63 (-1.82, 0.57)	0.38 (-0.88, 1.64), 0.543
Insurance Coverage						
None	Reference	Reference	Reference	Reference	Reference	Reference
ADP	-0.31 (-0.95, 0.33)	0.18 (-0.49, 0.84), 0.599	-0.41 (-1.32, 0.50)	-0.24 (-1.36, 0.88), 0.661	-1.06 (-2.84, 0.72)	-0.17 (-1.90, 1.56), 0.841
Third Party	-0.31 (-0.91, 0.29)	0.09 (-0.48, 0.66), 0.758	-0.33 (-1.27, 0.61)	-0.25 (-1.34, 0.84), 0.642	-0.37 (-1.12, 0.39)	0.14 (-0.67, 0.96), 0.739
Other	0.52 (-0.16, 1.19)	0.76 (0.16, 1.36)*, 0.013	1.19 (0.19, 2.19)*	1.34 (-0.19, 2.66), 0.087	-0.21 (-1.13, 0.72)	-0.40 (-1.25, 0.45), 0.344

ADP, assistive devices program; PACCC, Patient Assessment of Care for Chronic Conditions; SED, Self-Efficacy for Diabetes; SDSCA, Summary of Self-Care Activities; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; T2D, type 2 diabetes. Note: Mean Change (95% Confidence Interval); **p* value statistically significant at < 0.05; ***p*-value statistically significant at <0.001; †Adjusted for participant age, diabetes duration, ethnicity, education level, household income and insurance coverage; ‡Only one participant, no adjusted value rep

CHAPTER 5

TITLE: Understanding the self-management education and support needs during pregnancy among women with pre-existing diabetes: A qualitative descriptive study.

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ABSTRACT

Background: With the increasing prevalence of pre-existing type 1 and type 2 diabetes in pregnancy and their associated perinatal risks, there is a need to focus on interventions to achieve optimal maternal glycemia to improve pregnancy outcomes. One strategy focuses on improving diabetes self-management education and support for expectant mothers with diabetes. This study's objective is to describe the experience of managing diabetes during pregnancy and identify the diabetes self-management education and support needs during pregnancy among women with type 1 and type 2 diabetes.

Methods: Using a qualitative descriptive study design, we conducted semi-structured interviews with 12 women with pre-existing type 1 or 2 diabetes in pregnancy (type 1 diabetes, n=6; type 2 diabetes, n=6). We employed conventional content analyses to derive codes and categories directly from the data.

Results: Four themes were identified that related to the experiences of managing pre-existing diabetes in pregnancy; four others were related to the self-management support needs in this population. Women with diabetes described their experiences of pregnancy as terrifying, isolating, mentally exhausting and accompanied by a loss of control. Self-management support needs reported included healthcare that is individualized, inclusive of mental health support and support from peers and the healthcare team.

Conclusions: Women with diabetes in pregnancy experience feelings of fear, isolation and a loss of control, which may be improved through personalized management protocols that avoid "painting everybody with the same brush" as well as peer support. Further examination of these simple interventions may yield important impacts on women's experience and sense of connection.

Keywords: Type 1 Diabetes; Type 2 Diabetes; Pregnancy in Diabetics; Self-Management; Qualitative Research

BACKGROUND

Introduction

The global prevalence of diabetes is increasing rapidly. Recent estimates place the current number of people affected by diabetes at 424.9 million, representing 8.8% of the world's population [1]. In tandem, there has been a rise in the occurrence of type 1 and type 2 diabetes in pregnancy [2-7], which presents serious risks to maternal-child health, including congenital anomalies, stillbirths and maternal death [2]. As evidence suggests that high glucose levels play an important role in these complications [8,9], recent attention has focused on improving diabetes self-management education and support for expectant mothers with diabetes [10].

Diabetes self-management education and support is a cornerstone of diabetes management that empowers patients' active participation in their diabetes management [11]. Self-management is a continuous process, accomplished through various means with tailoring to the patient's knowledge, skills and abilities [11, 12]. The goal is to improve cardiometabolic and quality of life outcomes [11, 13]. Through self-management education, patients take on an active role in their care with support from their healthcare team [11]. For example, patients may trend their blood glucose measurements and self-adjust their insulin administration to better reach their target range. Offering diabetes self-management education and support is particularly important during times of life changes [14]. Critical changes include when a child transitions to adult diabetes services [14] or when planning and becoming pregnant, among others. Diabetes educators play a major role in providing diabetes self-management education. Clinical practice guidelines suggest that self-management education should be supplemented by self-management support tools, which enhance and reinforce education, and may include text messages, email

reminders, automatic phone reminders, peer support and mobile health interventions [11, 12, 13, 14]. Such strategies are utilized to improve patient self-efficacy, confidence and ability to effectively self-manage diabetes [11].

Pregnant women with type 1 and type 2 diabetes experience regular strain and burden associated with daily self-management, involving frequent self-monitoring of blood glucose, accurate titration of insulin doses to blood glucose measures and carbohydrate intake and close health monitoring [11]. Although sharing similar self-management tasks during pregnancy, women with type 1 and type 2 diabetes may have different experiences of self-management. For instance, women with type 2 diabetes could have been recently diagnosed, may switch to insulin injections during pregnancy from usual oral medications and are less likely to have had specialized preconception care and counselling [10]. Although arguably more practiced in self-management, women with type 1 diabetes may also face pregnancy-specific challenges, albeit different from those experienced by women with type 2 diabetes. For example, reduced counterregulatory hormones during pregnancy contributes to a high occurrence of hypoglycemia. This is particularly true during the first trimester when severe hypoglycemia may occur in up to 71% of women [10]. Furthermore, increased insulin requirements often occur during pregnancy due to the “anti-insulin” effects of placental hormones later in the second and third trimesters [10].

Study Objective

The purpose of this study was to describe participants’ experiences of managing diabetes during pregnancy and identify the diabetes self-management education and support needs during pregnancy among women with type 1 and type 2 diabetes.

METHODS

Study Design

We used qualitative description as our underpinning methodological qualitative approach. With this qualitative approach, semi-structured interviews and open-ended questions are used to explore the experiences of a purposeful sample of participants [15]. The collected data is analyzed with the intent of allowing the study results to stay as close to the participant's language as possible. The end result is a rich participant-centred narration regarding their experience with the phenomenon of interest [15]. This study received ethics approval from the local Research Ethics Board (Hamilton Integrated Research Ethics Board Project ID #13847). Study reporting followed the Consolidated Criteria for Reporting Qualitative Research framework [16].

Recruitment and Participants

We used purposeful sampling [17] to recruit women 18 years and older with type 1 and type 2 diabetes in pregnancy living in southern Ontario. We also used snowball sampling to aid in the recruitment of eligible participants. As this study was conducted during the COVID-19 global pandemic, we recruited participants who were currently pregnant or who were recently pregnant (within 12 months prior to recruitment) virtually through advertisements on local and regional pregnancy and diabetes online communities (e.g., Facebook). A total of 12 women with pre-existing diabetes in pregnancy were recruited between March and July 2022 (type 1 diabetes, n=6; type 2 diabetes, n=6). Participants were recruited until thematic saturation was achieved.

Data Collection

The interviews were conducted face-to-face via secure video conferencing software (Zoom) and ranged between 30 to 60 minutes. Interviews were directed by an interview guide that was informed by a review of the literature and consultation with experts in the field of pre-existing diabetes in pregnancy (see the Appendix). All interviews were audio-recorded and conducted by the first author (KS). Informed consent was acquired and participant demographic information was collected before the interview commenced.

Data Analysis

The audio recordings were transcribed verbatim into Microsoft Word for analysis by the first author (KS). We employed conventional content analyses, as outlined by Hsieh and Shannon, allowing codes and categories to be derived directly from the data rather than from preconceived ideas informed by existing literature or theories [18]. Analysis began following the completion of the first interview with repeated reading of the interview transcripts to facilitate our immersion in the data and to gather an impression of the data as a whole [18]. The first author then derived codes following a word-by-word re-reading of the text and the highlighting of exact words used by participants. Subsequent reviewing of the text and codes first allowed related codes to be grouped into themes, and then into two overarching categories related to the study objectives. The first author (KS) completed an initial analysis. The senior author (DS) then reviewed samples of the transcribed records and conferred with the first author regarding the development of codes, themes and categories throughout the remaining duration of the analysis. Thematic saturation was achieved after ten interviews. The emergence of no new themes was confirmed following the completion of the last two interviews. In addition, the first author, an experienced

healthcare provider in the field of maternal-child health, and the senior author, an experienced qualitative researcher and expert on the topic of diabetes self-management education and support, concurred that the findings were credible and confirmable.

Rigour and Trustworthiness

We took several steps to ensure trustworthiness in this study. The interviewer spent a prolonged time in the interview stage and completed multiple interviews to ensure credibility. Triangulation was also used to verify the data sources of interview notes against the actual interview transcripts. The concurrent data collection and iterative analysis also served as a verification method for trustworthiness in this study. Transferability was facilitated through a clear description of the study participants, as well as the methods used to sample the participants. The collection of characteristics of included participants (demographic and clinical characteristics) also supported the transferability of findings to other populations. The study processes were also documented through field notes, interview guides, recorded interviews and data analysis and interpretation notes. Finally, the first author (KS) engaged in self-reflection by writing a reflexivity statement in order to make clear their positionality as a qualitative researcher [19].

RESULTS

Twelve women (see Table 1 for demographics) participated in individual semi-structured interviews to describe their experience of managing diabetes and their needs regarding self-management education and support during pregnancy. From these interviews, we identified a total of eight qualitative themes. As per the study's purpose, we organized the themes into two overarching categories—(1) themes describing patient experiences of managing diabetes in

pregnancy; and (2) themes identifying suggested needs for diabetes self-management education and support during pregnancy.

Experience of Diabetes Self-Management in Pregnancy

Theme 1: Terrifying

Women with type 1 diabetes had experienced intensive counselling regarding the need for optimal glycemia before and during pregnancy to avoid having a baby that was "gigantic" or having a baby that was "at risk of dying." Those with type 2 diabetes were often grappling with a newer diabetes diagnosis, as compared to their counterparts with type 1, and feared how this condition, which they were relatively unfamiliar with, would impact their baby's health. Thus, one of the most common things that participants described was fearing the medical complications that could happen to their baby due to diabetes during pregnancy.

"It [pregnancy] was probably one of the most challenging times of my life in managing diabetes because of that background fear that something bad was going to happen."

[Participant 2, type 1 diabetes]

Another participant discussed her feelings as,

"You feel guilty when your blood sugar is high… you're like, 'What important body part is being formed right now? And am I ruining it?'"

[Participant 6, type 2 diabetes]

Understanding from the healthcare team that running "very, very tight" was the best way to reduce complications, any small period of hyperglycemia was enough to induce terror, even for those women whose glycemia was near "perfect." There was an aspect of feeling "guilty" and blaming themselves for the occurrence of these feared complications. Women rationalized their self-blame by suggesting that their baby "didn't ask for this [diabetes]." Thus, they wanted to do everything in their power to not just be doing "great" with diabetes management but to be actually "eliminating the risk" of complications. One participant described the cause of her fear:

"I think that some healthcare practitioners who are not well-versed in talking to people with diabetes about complications and babies inadvertently scare them... I think that a lot of them should probably receive additional training in how to talk to women without scaring them and making them worry that everything will be their fault… Most of us are really aware… [we] reach out and learn as much as [we] can before [we] become pregnant."

[Participant 1, type 1 diabetes]

Finally, a participant discussed how reading medical journals further emphasized her fears:

"It's constant worry and anxiety that you know I'm messing something up for this…kiddo… I go on and find you know what the academic journal articles say about risks and like it's just awful."

[Participant 5, type 2 diabetes]

Theme 2: Out of Control

Due to their feelings of fear and guilt regarding the effect of diabetes on their baby, participants with both type 1 and type 2 diabetes described the need to control their diabetes management as much as possible, including bargaining with physicians and healthcare providers to remain on the

devices (i.e., insulin pumps) that give women autonomy and control of their diabetes management.

"I had, you know built up the courage 'cause you're like, 'I'm gonna tell this doctor how I want things done' and so I was like 'I want to be in charge. I don't want to take off my pump like under no circumstances.' I was like 'I will teach my husband to use it before I am taking it off.'"
[Participant 7, type 1 diabetes]

Another participant articulated the following:
"Very early on I was asking like 'I want to control my diabetes at the end.''… and they were like 'That's not what we do here. The protocol here is you will be put on an insulin IV'…
Just basically flat out told me 'No that's not what we do here.'
…If I pushed back it was always like 'We have to do this or your baby's at risk of dying. You're at risk of dying.' So then how do you as a mother like advocate and ask questions when the answer is like 'If you don't do what we're telling you to do, your baby will probably die and it will be your fault'"?
[Participant 10, type 1 diabetes]

Outside of pregnancy, many of the women were used to having total control of their blood glucose. They revealed the great lengths that they went to determine accurate carbohydrate counts for their meals when they could not eat at home due to career demands, for example. Some women pored over nutrition information from restaurant websites. Others took the "exact same" meals to work every day with the carbohydrate count permanently marked on the

containers. These actions resulted in their blood glucose being in the "non-diabetic or very minimally-diabetic range" during pregnancy. Having experienced being in full control of their glycemic management before and during pregnancy, participants conveyed their desire to be in control of their diabetes management during labour and delivery. Unfortunately, they frequently received pushback from their healthcare team. With glucose management out of their control, women worried about the complications that could happen to themselves and their babies if hyperglycemia occurred during labour. Thus, they made great efforts to remain in control, resorting to giving themselves their insulin from home, without the knowledge of their healthcare team. A participant noted the following:

"You had to surrender a lot of control, because… they put you on an insulin drip [during labour]… but afterwards they… stopped the insulin drip too early and so I had ridiculously high blood sugars and they wouldn't sign over control back to me… So needless to say, I had my own pump that I ran myself and gave myself a bolus of insulin… it would have been a potential DKA admission."

[Participant 2, type 1 diabetes]

Finally, one mother expressed her concern about control and autonomy related to her diabetes management as:

"I told my Endo[crinologist], you know, 'I know that normal protocol is to go on IV Insulin. Never in a million years will I let another person touch my blood sugars. Please, please write the little note that I am going to be managing all of that myself in the hospital. No one is touching my blood sugars.'"

[Participant 1, type 1 diabetes]

Many of the described self-management behaviours, such as determining accurate carbohydrate counts for meals, apply to women with type 1 diabetes. However, for women with type 2 diabetes that are on insulin during pregnancy, they also expressed similarly going to great lengths to ensure optimal glycemia. One participant described:

"At work sometimes I would check my blood sugar in a meeting. Because I was very like concerned about like not getting like the data and I was like 'Well too bad.' Like I'm gonna, I just put my hand under the table and I would just like do it and whatever get the reading and then yeah at lunchtime again I would take my insulin and then I would make sure that I eat my lunch 15 minutes later."

[Participant 11, type 2 diabetes]

Theme 3: Isolating

Perhaps as a result of receiving such close medical monitoring during pregnancy compared to their peers, as well as the immense effort that they had to put into maintaining optimal glycemia, participants relayed that the experience of having diabetes in pregnancy made them feel isolated and different from other expectant mothers without diabetes. For example, women revealed having to do extensive preparation when doing simple outings like going for a walk or going out with friends who didn't have diabetes.

"It's like I can't, I feel like I can't be a normal person because I'm constantly having to check my blood sugar, constantly having to remember to take my insulin or if I'm going out like I have to make sure 'OK do you have your insulin? Do you have your meter just in case your sensor goes wrong?'... I just I wish I was a normal person, but I'm not."

[Participant 4, type 2 diabetes]

"I had never done this before and I didn't know anyone else that was pregnant that had diabetes..."

[Participant 2, type 1 diabetes]

Thus, participants reported attempting to seek out others with diabetes in their area with whom to connect.

"It would have been nice to have, like a pregnant diabetic friend. I've never had one of those… There was this woman in my old neighbourhood… and she obviously had diabetes. The way I knew was because before she wore a CGM, I could hear the test strips bouncing in her bag. And then she started wearing a CGM and she was a runner. So I called her the diabetic runner. I used to joke to my husband that I was going to follow her and find her."

[Participant 7, type 1 diabetes]

Unfortunately, they did not have much success in connecting with other expectant mothers with diabetes. In addition, women with diabetes in pregnancy felt isolated when with others with diabetes who were not pregnant. Some participants described attending a diabetes education

class or a support group and feeling like they didn't fit in with the other attendees, who they perceived as less advanced in diabetes management. Thus, they experienced a paradox of being isolated with those without diabetes and when with others with diabetes. Women described this as:

"They make you like do these you know pump groups to learn about pumps and carb counting and all this and I've had to do them somewhat recently and it's like 'OK, I'm seeing people that don't have the same experience as me. You know, newly diagnosed or whatever and its mind-numbing.'"

[Participant 5, type 2 diabetes]

"I went to a diabetes support group once and I hated it, like hated it. There was one really cool old man who had had diabetes for like 60 years. And then everybody else, it was just like these stories about like one woman who lost her driver's license because she was low and hit someone. And like someone was losing their vision and then like this, is not, these are not my people."

[Participant 7, type 1 diabetes]

Theme 4: Mentally Exhausting

Finally, participants reported that managing diabetes during pregnancy took a toll on their mental health. The tasks that they had to complete related to diabetes self-management were numerous. These included, but were not limited to, planning meals with their carbohydrate count in mind when going to work and when attending social events; measuring their blood glucose at frequent intervals throughout the day, even "under the table" at work during meetings; and taking time off work at least once a week towards the end of pregnancy for medical appointments, sometimes

driving long distances to the tertiary centre where their medical care occurred if they lived further away.

"I think from a stress standpoint, like it was very tough because I was just learning how to be pregnant and then there was like this extra pressure because it was like a high-risk pregnancy and then on top of that I'm now trying to learn how to manage like diabetes and the monitoring. Like making sure that I was checking my blood sugars like two hours after I ate, making sure I was eating."

[Participant 11, type 2 diabetes]

"I think like my mental health is definitely a big challenge in terms of my diabetes. Because, like I have a history of like anxiety and depression and being diabetic on its own is stressful enough to me… and then being diabetic and pregnant, taking an even bigger toll on my mental health… Like sometimes I'll I get overwhelmed and it's like I don't care anymore, …I'm just like, 'I know I'm defeated. I don't want to do this anymore.' … my mental health and my diabetes definitely, they definitely fight a lot in my head."

[Participant 4, type 2 diabetes]

One woman even revealed needing to coordinate having someone drive her since the hospital was a long distance away and she was worried about having a hypoglycemic episode and needing to stop at the side of the highway, something she had experienced before. All of this took a significant toll on women's mental health. A participant's quotes demonstrating this theme can be found below:

"Everyone's experience will be very different. But for someone like myself who has to do it every day, anyway, I mean the burnout is real … sometimes I just look at my husband like 'Diabetes! I just want a week of vacation.'"

[Participant 1, type 1 diabetes]

Patient-Identified Diabetes Self-Management Support Needs in Pregnancy

Theme 1: Care Needs to be Individualized

Since women with type 1 and 2 diabetes have a high-risk pregnancy, they require close medical monitoring at a tertiary centre. This means that they undergo frequent testing, such as ultrasounds, sometimes without individualizing care needs and issues.

"You need to like talk to the person beforehand rather than just going through your like predefined list of all the thing. I think like all principles of adult education, like, asking first, 'Is this something you would like me to talk about? Are you aware of this? And I think that needs to be included more in initial conversations by healthcare providers."

[Participant 1, type 1 diabetes]

Although some of the testing may be required to ensure fetal well-being, such as measuring fetal growth, participant's described other testing as being done "to decide whether or not I want to continue with the pregnancy [should the baby have Down Syndrome]." After stating she didn't want a certain test as she would be continuing with the pregnancy regardless, she was told "Well, that's, you know that's part of it, you're getting that test." The participant was frustrated expressing "I still had the test, right like so my lack of ability to like choose and even be

informed if I hadn't asked…" Experiences like these prompted participants to desire their clinical care to feel individualized and tailored to their unique needs, not having things done just because it was protocol. Participant quotes demonstrating this theme can be found below:

"What remains my biggest thing with like diabetes care in pregnancy is that they sort of like treat everybody as if they're all the same level of risk, when in fact the risk is very different based on what's actually happening with each individual person. And so yeah, I just wish there was a, uh, a better way for people to feel like they're being treated like their own person. And like all of their circumstances, are being taken into account and not just 'You have type 1 diabetes so your baby is going to be giant. They're going to have a low blood sugar and you have terrible control…' 'Well, we just paint everybody with the same brush because we don't want anybody slipping through the cracks.' And for me I was like, 'Well, what if you just actually paid attention to everybody so that they didn't slip through the cracks?'"

[Participant 10, type 1 diabetes]

Theme 2: Peer Support

As noted in one of the previously mentioned themes, the experience of diabetes in pregnancy was isolating. Participants reported not fitting in with pregnant women or mothers without diabetes as well as not fitting in with non-pregnant individuals with diabetes.

"My best friend is great. She's wonderful …I can go to her and I can be like, 'Oh my, my blood sugars are all over the place and everything' but all she's gonna say is 'Oh, you know, like you got this, you can do it' or you know, 'Talk to your doctor.' Like she's just gonna be that like little bit of support whereas like I need someone that's like gone through it… I love my best friend but

I need a diabetic best friend to go through this with me… like I'd rather have someone be like 'Bro, I know it sucks, but we got this like we can do this.' Not just being like 'You got this' saying like 'We have this' so I know that like there's somebody else in my corner, that's actually going through this and understands everything…"

[Participant 4, type 2 diabetes]

Thus, stemming from the feelings of isolation during pregnancy with diabetes, women expressed the need for social support from other women with diabetes who they could "share experiences with" and "learn with."

"It would have been nice to have that in-person connection to someone else like me… to connect to somebody else who would have been, like you know someone who's not just on Facebook. That would have been nice… If they offered me that while I was pregnant that would have been good."

[Participant 1, type 1 diabetes]

One participant described reading a book about diabetes in pregnancy with each chapter correlating to a different week in pregnancy. Although she found this helpful, she desired a "diabetic friend" to "bounce ideas off of" when managing diabetes and pregnancy was challenging. Another woman described reaching out to online communities for troubleshooting when her insulin requirements became too high for her pump sensor sites. Having in-person support from someone who understood what she was going through would have been helpful rather than the "trial and error" way that she solved it. A participant described the following:

"Here I am pregnant and there's gotta be people like me. And I've asked multiple times about like if there's anyone on your caseload that is asking the same like please pass my name along… Like I'm happy to share that experience, or at least be a sounding board. And it's been 'Well, when you're at the clinic, you know when you come in on Thursdays 'cause that's when the diabetic moms are in, don't hesitate to talk to someone in the waiting room' and I was like 'No, I don't know that I'm going to do that cause not everybody necessarily wants to do that.' But yeah. It seems like a real missed opportunity…"

[Participant 5, type 2 diabetes]

Theme 3: Mental Health Support

Women described that the mental health burden of daily self-management was high during pregnancy. For women with type 1 diabetes, they were so experienced in their diabetes management that they knew "exactly what a skittle would do" to their blood glucose. However, during pregnancy, they could eat one thing and have a certain response in their blood glucose and the next day eat the same thing and the blood glucose response would be completely different. For women with type 2 diabetes, particularly those who were relatively newly diagnosed, it was difficult to navigate the new diagnosis along with the pregnancy and the addition of insulin to their diabetes management.

"Sometimes it's not that I need diabetic help, like medical help. It's like I just need some mental clearance."

[Participant 4, type 2 diabetes]

"The piece that wasn't a part of the high-risk clinic was the mental health piece and… I don't think that people look at it so seriously. And I don't think anybody talked to me about like the fact that like I was feeling stressed out… So I think that that was something that was missing."
[Participant 11, type 2 diabetes]

Their pregnancies also occurred during the COVID-19 pandemic. Thus, they had to attend their medical appointments alone, without their partner, due to hospital policies. These factors, among others, culminated in women expressing the need for mental health support.

"It was really hard and especially… 'cause my husband was back home and I'm alone here… I didn't eat so I lost lots of weight because, you know, stressed out. Every day I'm crying, I'm emotionally – it's not easy."
[Participant 3, type 2 diabetes]

Theme 4: Support from Healthcare Team

Finally, participants expressed the need for support for diabetes self-management from the healthcare team. Support from the healthcare team was desired for a variety of instances. We developed two subthemes to represent two of the common instances: (1) support in self-management of diabetes during the labour and delivery process; and (2) supportive health professional communication. One of the experiences expressed by several participants with type 1 diabetes was the desire to control their insulin management during labour and delivery (described in a previous theme). However, women expressed that they were not supported by their healthcare team in this area. More than one participant explained that they kept themselves

in “non-diabetic” glucose ranges before and during pregnancy, without experiencing hypoglycemia. Nevertheless, during labour and delivery, they experienced hyperglycemia when insulin management was done by the healthcare team. One woman described her experience as follows:

“I could have kept myself between 5 and 6 and you [healthcare team] took over and you did not. I was like over 10 for much of it and at one point like my husband was like calling the OB and like literally yelling at him on the phone. ‘Why aren't they listening? Why can't we just give like a bolus to bring her blood sugar down, it's like been over 10 for an hour. Like can we at least give a bolus?’ And it was like, ‘Nope, we're just going to follow the protocol,’ which is not based even on me. It's like they give this same amount for everyone… It makes no sense.”

[Participant 10, type 1 diabetes]

She managed to convince the team to let her control her insulin during her second labour and delivery but was surprised when they would not help her determine appropriate pump settings before delivery and she was left to fend for herself.

"I remember just asking like 'All I want from you [endocrinologist] is like a suggestion on where my insulin like starting point should be. Should I be basing it on what I'm taking now? Should I be basing it on what I was taking pre-pregnancy?' And he just was like 'Well that's up to you.' Like he wouldn't help me at all… I was so dumbfounded that like he was sort of like 'Fine, you can be in control, but I'm not going to help you…' I reached out to my community, to kind of get a read on what I thought was pretty standard [pump settings for labour and delivery] and just I tried to figure it out on my own…"

[Participant 10, type 1 diabetes]

Thus, more support from the healthcare team was a general theme that many women expressed. Another participant also expressed the need for support, with emphasis on how healthcare providers communicate with women with diabetes in pregnancy:

"After I had the baby… the breastfeeding topic comes up, and I elected not to because I was tired of low blood sugars… Nine months of extreme lows that I've had already, you know between pregnancies, and I got pregnant back-to-back all three times. So, I was like, 'No more, I don't even want to deal with that. I just want to let the hormones go back to normal.' Babies can live on formula, I did, I'm fine. Um, but the way they talked to you after was just really, I can't even remember what he said, I remember thinking 'This guy has never learned how to talk to women about this topic.' What he should have done is come in and go 'Would you like me to talk to you about it?' Cause chances are, most of us have already decided what we're going to do. He didn't even ask my reasons for not breastfeeding. He just went on about how I should be."

[Participant 1, type 1 diabetes]

DISCUSSION

Our study described the participant experiences of managing type 1 and 2 diabetes in pregnancy and identified self-management support needs of this population. In our exploration of this topic, three main areas to improve the experience of these women stood out. These are: (1) early facilitated connection with other moms also experiencing type 1 and type 2 diabetes in pregnancy; (2) clinical management pathways to allow for self-management of diabetes during the labour and delivery process; and (3) health professional communication with women with pre-existing diabetes in pregnancy.

Peer support is means by which people with similar experiences give and receive support related to their shared experiences [20]. It was first pioneered over 40 years ago in the mental health field to increase coping abilities and reduce depression and anxiety [21, 22]. Peer support has also existed as an intervention in the literature on diabetes self-management for several years. National guidelines have included peer support as a component of diabetes self-management support [11]. Self-management support in combination with diabetes self-management education have demonstrated advantages for both optimized glycemia and reduced diabetes distress [11]. A meta-analysis showed that peer support, as a form of diabetes self-management support, among adults with type 2 diabetes may reduce A1C by an average of -0.57% [23]. The existing literature on peer support in diabetes and pregnancy is limited. Friedman et al. conducted a needs assessment for peer support in the postpartum period for women with gestational diabetes and type 2 diabetes [24]. This study found that nearly half of the participants were interested in a Diabetes Buddy Program [24]. A qualitative study involving women with previous gestational diabetes found peer support instrumental in healthy behaviour changes [25]. Two studies, one by

Berg et al. and one by Linden et al., described the development of a web-based support program that contained an element of online peer support and its subsequent evaluation in a randomized controlled trial [26, 27]. The randomized controlled trial found that active participation in the web-based program was low and resulted in no differences in well-being or diabetes self-management. Participants in our study emphasized their desire for peer support in person. Thus, perhaps participation would have been more active had the peer support not been virtual. Further research is needed to advance the evidence supporting this type of intervention.

Women described intense resistance from the healthcare team regarding self-management of diabetes with their insulin pump, particularly during labour. However, outside of pregnancy, it is common practice for adults with diabetes to self-manage insulin administration during medical procedures, such as short surgeries [28]. Guidelines and protocols for diabetes self-management using insulin pumps in the perioperative period were established by the Joint British Diabetes Society in 2011 [29]. Protocols also exist in parts of the United States, Australia and Canada [30-32]. Research on insulin pump therapy during labour has shown that it is safe and may contribute to improved optimized glycemia [33-35]. Women in our study described their desire to control insulin administration during labour and adverse outcomes due to poor management by their healthcare team. Future research should focus on advancing the evidence on this topic to allow women to remain in control of their diabetes management during labour and delivery.

Women articulated multiple instances of poor communication from healthcare providers. These ranged from how potential pregnancy complications related to diabetes were discussed to the way advice or lack thereof was delivered regarding insulin pump settings during labour, among

others. Communication between healthcare providers and those with diabetes has been established as an important factor that influences diabetes outcomes [36]. Communication styles that are patient-centred are linked to better self-care and quality of life, for example, among adults with diabetes [37]. Unfortunately, evidence suggests that communication from healthcare provider to patient is often not patient-centred [37]. Evidence indicates that best practice for healthcare provider-patient communication includes: (1) fostering the relationship by building rapport and connection; (2) gathering information by attempting to understand the patient needs; (3) providing information in response to patient needs; (4) engaging in collaborative decision-making; (5) enabling disease and treatment-related behaviour, such as self-management; and (6) responding to patient expression of emotion related to their condition [38]. Engaging in a communication style that reflect these practices will contribute to improved positive patient outcomes [38].

Of the three areas that we identified to improve the experience of managing diabetes in pregnancy, the literature indicates that at least two of them are also applicable to women diagnosed with gestational diabetes during pregnancy. These include the desire for peer support and the need for patient-centred communication from healthcare providers. As previously mentioned, women with diabetes in pregnancy, including gestational diabetes, have indicated interest in peer support interventions [24]. Furthermore, women with previous gestational diabetes have expressed that peer support influenced healthy behaviour change [25]. To our knowledge, these are the only studies that have examined the use of peer support among women with gestational diabetes. Furthermore, a recent systematic review of reviews identified the use of peer support on gestational diabetes as a research gap [39]. Regarding healthcare provider

communication with women with gestational diabetes, research reveals shortcomings reported by women. For example, women have reported communication with healthcare providers to be difficult and confusing, expressing that they desire a non-judgemental and patient-centred approach [40]. Thus, it appears that an exploration of peer support and improving healthcare provider communication is also warranted for women with gestational diabetes by investigators who are focused on this population.

Strengths and Limitations

This study has several strengths. First, we sampled women from a diverse geographic region of southern Ontario. Thus, the resulting participants varied in terms of ethnicity, education and other sociodemographic factors. In addition, we achieved an equal number of women with type 1 and 2 diabetes, further contributing to the diversity and richness of experience. However, our study also has limitations. Although our participants were socioeconomically diverse in some respects (ethnicity), the majority were well educated and had a high household income. Furthermore, the sample size was relatively small. Thus, like any qualitative research, the generalizability of our results to other populations is limited.

CONCLUSIONS

This study found that the experience of managing diabetes during pregnancy was terrifying, isolating and mentally exhausting, leaving the woman with diabetes feeling out of control. Furthermore, women with diabetes during pregnancy expressed the need for individualized care, social and mental health support and support from their healthcare team in all aspects of diabetes management. To adequately support women with diabetes during pregnancy, policy and

decision-makers should re-evaluate current clinical management protocols and consider the use of patient self-management of insulin administration, particularly during labour and delivery. Furthermore, facilitating peer support between expectant mothers is desired and has the potential to reduce feelings of isolation and increase feelings of connection and support. These simple interventions may have important impacts on the pregnancy experience of women with type 1 and 2 diabetes.

DECLARATIONS

Ethics approval and consent to participate

This study received ethics approval from the local Research Ethics Board (Hamilton Integrated Research Ethics Board Project ID #13847). All methods were carried out in accordance with the ethical standard of the ethics board and with the Helsinki Declaration. All participants gave informed consent.

Consent for publication

Not applicable.

Availability of data and materials

Study participants were advised that their raw data would remain confidential and not be shared publicly due to the sensitive nature of the interview questions. Upon reasonable request, the data are available from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KS drafted the manuscript. All authors contributed to its critical revision and approved the final manuscript.

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Table 1 Participant characteristics

Characteristic	Mean (SD)	n [%]
Age (years)	36 (5)	
Ethnicity		
European		7 [58]
Asian		2 [17]
Middle Eastern		1 [8]
African or Caribbean		2 [17]
Indigenous		
Education		
Grade school		
High school		3 [25]
College/trade		
University		9 [75]
Annual household income		
< $20,000		1 [8]
$20,000 - $40,000		
$41,000 - $60,000		
$61,000 - $80,000		
$81,000 - $100,000		2 [17]
>$100,000		9 [75]
Diabetes type		
Type 1		6 [50]

Type 2		6 [50]
Diabetes duration (years)		
Type 1	19 (11)	
Type 2	2.5 (1)	
Diabetes treatment method		
Oral medications		
Oral medications and insulin injections		6 [50]
Insulin injections		1 [8]
Insulin pump		5 [42]
Diabetes complications		
Neuropathy		1 [8]
Retinopathy		1 [8]
Singleton pregnancy		12 [100]
Use of Assisted Reproductive Technology		3 [25]

SD, standard deviation

Appendix: Interview Guide

Introduction

So, as you may have learned from the Study Information Package and Consent Document, with this study, I will be exploring how expectant mothers manage diabetes during pregnancy. I am especially interested in understanding how things, such as the diabetes education that you received as well as other things, like your financial or employment situation during pregnancy, made managing diabetes easier or harder for you.

Opening question:

To start off, can you tell me about your day-to-day experience of managing diabetes during pregnancy?

Main Questions

Did your experience of managing diabetes during pregnancy differ from how you managed your diabetes before pregnancy? If so, can you describe how?

How important was it to manage your diabetes during pregnancy?

Was there any social, employment, or financial factors that made managing diabetes challenging for you?

Were there any other things that made managing diabetes during pregnancy challenging that I have not mentioned?

Can you tell me about your experience of receiving medical care for diabetes and diabetes education during pregnancy?

How did the medical care and diabetes education that you received during pregnancy influence or impact how you managed your diabetes during pregnancy?

Was there anything about the medical care or diabetes education that you found helped you to better manage diabetes during pregnancy? If so, can you describe what was helpful?

Was there anything that may have been helpful, but was not provided or offered?

Was there anything that was unhelpful or that made managing diabetes harder?

In a future pregnancy, what would be the best way that diabetes education could be provided to you? For example, in-person, online web-conferencing, etc.

Probing Questions

Can you tell me about your experience of checking your blood sugar?

Can you tell me about your experience of counting carbohydrates?

Can you tell me about your experience of giving yourself insulin?

How confident do you feel about your ability to do these activities that we just talked about, such as checking your blood sugar, counting carbohydrates, giving yourself insulin?

[If you feel confident], what do you think contributes to this?

[If you do not feel confident], what do you think contributes to this?

[If you do not feel confident], what do you think could help to increase your confidence?

Can you tell me what makes managing diabetes easier for you?

Can you tell me what makes managing diabetes harder for you?

Conclusion

Thank you for taking the time to participate in this interview. Is there anything that we haven't discussed that you would like to tell me about?

Now that we are at the end of the interview, I am going to briefly summarize the things that we have discussed. While I am doing this, please reflect on what we have talked about and let me know if you would like to expand on anything or add to anything that we have talked about. Please also let me know if I have misunderstood something or got something wrong that we talked about.

CHAPTER 6

TITLE: Supporting self-management in women with pre-existing diabetes in pregnancy: A mixed-methods sequential comparative case study

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ABSTRACT

Introduction: Maternal glycemia is associated with pregnancy outcomes. Thus, supporting the self-management experiences and preferences of pregnant women with type 1 and type 2 diabetes is crucial to optimize glucose control and perinatal outcomes.

Research Design and Methods: This paper describes the mixed methods integration of a sequential comparative case study. The purpose of the mixing was to integrate the quantitative and qualitative data to develop rich descriptive cases of how diabetes self-management and support experiences and preferences in women with type 1 and type 2 diabetes during pregnancy help explain glucose control. A narrative approach was used to weave together the statistics and themes and the quantitative results were integrated visually alongside the qualitative themes to display the data integration.

Results: The quantitative results found that women achieved "at target" glucose control (mean A1C of the cohort by the third visit: 6.36% [95% Confidence Interval 6.11%, 6.60%]). The qualitative findings revealed that feelings of fear resulted in an isolating and mentally exhausting pregnancy. The quantitative data also indicated that women reported high levels of self-efficacy that increased throughout pregnancy. Qualitative data revealed that women who had worked hard to optimize glycemia during pregnancy were confident in their self-management. However, they lacked support from their healthcare team, particularly around self-management of diabetes during labour and delivery. The findings from our integration led to three cases of participant-derived preferences in pregnancy: mental health support, support for autonomy in self-management and peer support.

Conclusions: The achievement of optimal glycemia during pregnancy was motivated by fear of pregnancy complications and came at a cost to women's mental health. Mental health support,

allowing women autonomy and the provision of peer support may improve the experience of diabetes self-management during pregnancy. Future work should focus on developing, evaluating and implementing interventions that support these preferences.

Keywords: Type 1 Diabetes; Type 2 Diabetes; Diabetes in Pregnancy; Self-Management; Qualitative Research; Quantitative Research; Mixed Methods

What is already known on this topic

- Pregnant women living with type 1 and type 2 diabetes have an increased risk of perinatal complications, including fetal and infant death.
- As maternal glycemia is associated with pregnancy outcomes, supporting women in diabetes self-management may optimize glycemia and reduce perinatal complications.

What this study adds

- Women who achieved optimal glycemia during pregnancy reported high levels of self-efficacy in diabetes self-management.
- Diabetes self-management negatively impacted women's mental health and made for an isolating pregnancy experience.
- Mental health support, peer support and autonomy in diabetes self-management is preferred by patients to improve their pregnancy experiences.

How this study might affect research, practice or policy

- Peer support and mental health interventions were unavailable for study participants.
- Policies supporting maternal self-management of diabetes during labour and delivery were also lacking.
- Appropriate peer and mental health interventions, as well as policies to support autonomy of self-management during labour and delivery, are required.
- Future research should focus on developing interventions related to these desired supports and implementing them into the standard of care for this population.

INTRODUCTION

With the rising prevalence of overweight and obesity and an older average maternal age during childbirth, type 2 diabetes in pregnancy has been steadily increasing.[1-3] The incidence of type 1 diabetes has also been rising, with an etiology that remains largely unknown.[4] These factors have contributed to the increased prevalence of pre-existing type 1 and type 2 diabetes in pregnancy, affecting 0.5% to 2.4% of pregnancies worldwide.[5-9]

Pregnancies impacted by pre-existing diabetes are at an increased risk for many complications, from congenital anomalies to fetal and infant death.[10] Maternal glycemia is closely linked to perinatal morbidity and mortality; each 0.1% increase of periconception A1C above 4.9% confers a 2% and 3% relative increase in fetal and infant death, respectively.[11] As a result, women experience a heavy burden of diabetes self-management during pregnancy, typically occurring outside of the healthcare system. Supporting women in diabetes self-management is important to optimize glycemia during pregnancy and subsequently, perinatal outcomes. How to best support women with pre-existing diabetes during pregnancy in self-management to attain optimal glycemia is not well understood.

Women with pre-existing diabetes in pregnancy are unique in their self-management experiences and preferences compared to women with gestational diabetes. First, the management of pregnant women with type 1 and type 2 diabetes is more complex than women with gestational diabetes due to their higher risk of experiencing serious perinatal complications and the need for insulin therapy.[10] Furthermore, in type 1 and type 2 diabetes, attention during pregnancy is focused on titrating insulin dosing using pens, continuous infusion sets (e.g., pumps) and

continuous glucose monitors, while avoiding hypoglycemia. This is in contrast to the general focus on nutrition and exercise-related interventions for many women with gestational diabetes.[1] Glycemic targets during pregnancy among women with pre-existing diabetes are also much more stringent than those for non-pregnant adults with diabetes.[1] As such, the experiences and supports that women with pre-existing diabetes during pregnancy need likely differ from those with gestational diabetes and non-pregnant adults with diabetes. We aimed to explore how self-management and support experiences help to explain glycemic control among women with pre-existing diabetes in pregnancy.

METHODS

This paper reports the mixed methods integration of a four-phased mixed methods sequential comparative case study.[12,13] This is a complex mixed methods design that involves the integration of diverse types of data (quantitative and qualitative) to develop enhanced analyses and case descriptions of the topic of interest.[12,13] This design provides detailed and contextualized data that is beneficial when there is a need to portray and understand complex variation regarding the subject under study.[12] Both the quantitative and qualitative phases received ethics approval from the Hamilton Integrated Research Ethics Board (REB #14-222 and #13-847).

In the context of this study, the use of a mixed methods sequential comparative case study was ideal as we aimed to develop detailed and particularized information about the self-management experiences and preferences of women with pre-existing diabetes during pregnancy. Furthermore, we expected that the self-management experiences and preferences during

pregnancy might vary based on diabetes type. Thus, the use of the mixed methods sequential comparative case study enabled us to understand the potential variation between these two populations. Our goal was to portray realistic and practical information about the evidence on this topic to guide subsequent research in designing, evaluating and implementing self-management education and support interventions for this population.

We have previously published the study protocol[13] and the quantitative[14] and qualitative phases.[15] These provide details regarding our methodology. Briefly, the sequence of the mixed methods study was as follows: 1) Phase I: Prospective cohort; 2) Phase II: Planning the qualitative data collection; 3) Phase III: Qualitative descriptive; 4) Phase IV: Integration of quantitative and qualitative findings and case construction (Appendix A).

Mixed Methods Integration

The purpose of the mixed methods procedures was to integrate the quantitative and qualitative data. The goal was to develop a rich analysis and description of the diabetes self-management and support experiences and preferences during pregnancy of women with pre-existing diabetes and how these factors may help explain glycemia. Through the integration of the quantitative and qualitative data, cases were developed and refined based on these experiences and preferences. We used Creswell and Plano Clark's recommendations for mixed methods research integration procedures to guide the mixing process.[12] Integration first occurred following the completion of the quantitative study when we analyzed the results to plan the interview guide. It also informed the participant selection approach for the qualitative study. The second integration, reported in

the current paper, illustrates the sequential mixing of the quantitative and qualitative results and the development of cases to represent the main findings.

We incorporated Stake's approach to instrumental and collective case studies,[16,17] which is utilized when the goal of the study is to facilitate an understanding of a phenomenon of interest,[16] particularly for social sciences and human services research.[18] Stake's approach allows for researcher flexibility and values the emergence of cases as the study progresses, aligning with the sequential ordering of our mixed methods approach.[18] We endeavoured to understand how factors related to self-management support (e.g., diabetes management behaviours and self-efficacy) and the pregnancy experience help to explain glycemic control among women with pre-existing diabetes. In the instrumental and collective derivatives of Stake's approach to case study research, cases are developed through categorical aggregation, based on repeated patterns and categories that emerge following researcher immersion in the data.[17] Also in keeping with Stake's approach, we utilized methodological, data source and investigator triangulation to promote the validity of the case developemnt, as Stake's approach values intituion and impression over rigid, preplanned case definitions and binding.[17] Finally, cases were defined through: 1) holistic (considers the connectivity of the phenomoenon and its context); 2) empirical (observations/data); and 3) interpretive (intuition or researchers) approaches, recognizing that each case is a complex and integrated entity, which is not limited or bound to working parts.[16,17] Following our quantitative study, we developed an interview guide for the qualitative study to ensure that similar questions were asked across participants. Data source triangulation was achieved when participants provided similar answers across questions.[17] Investigator triangulation was attained when the first author conferred with the senior author throughout case

construction.[17] To promote study transparency, quality and rigour, we followed the Good Reporting of a Mixed Methods Study tool (Appendix B).[19]

RESULTS

Our mixed methods sequential comparative case study findings are presented in two approaches. First, results are presented using a narrative approach, weaving together the quantitative statistics and the qualitative themes. Second, we created a joint display to present the quantitative results and qualitative findings alongside cases that were derived from the mixed methods integration.

Quantitative Results

In phase I (cohort), we explored the trends in glycemia and assessed self-efficacy,[20] self-care[21] and care satisfaction[22] during pregnancy in 111 women (55, type 1 diabetes; 56, type 2 diabetes), across three time points during the perinatal period (time point one, zero to 16 weeks; time point two, 17 to 28 weeks; time point three, 29 to 40 weeks). Overall, the cohort's average A1C was "at target" ($\leq$6.5%) by time point two and remained "at target" at time point three. Measurements of self-efficacy and care satisfaction were relatively high among the cohort (Table 1). A one unit increase in self-efficacy (e.g., total score of 8 to a total score of 9) was associated with a mean reduction in A1C of 0.22% (95% CI -0.42, -0.02, p = 0.03). In using the self-care[20] tool, every one unit increase in the exercise sub-score (e.g., total score of four to a total score of five) was associated with a mean reduction in A1C of 0.11% (95% CI, -0.22, -0.01, p = 0.04). These associations were present after adjustment for confounders.[14]

Qualitative Results

In phase III (qualitative description), we described the experience of managing diabetes during pregnancy and identified the self-management education and support preferences among 12 women (6, type 1 diabetes; 6, type 2 diabetes). We identified eight qualitative themes within two overarching categories: 1) themes describing patient experiences of managing diabetes in pregnancy; and 2) themes identifying preferences for diabetes self-management education and support during pregnancy. In general, women described the experience of managing diabetes during pregnancy as terrifying, isolating, and mentally exhausting and they had feelings about being out of control. Preferences were expressed for individualized health care, mental health support and support from peers and the healthcare team.[15]

Mixed Methods Integration

The purpose of the mixed methods integration was to determine how the self-management and support experiences and preferences of women with pre-existing diabetes helped to explain their glycemia during pregnancy. When conceiving this study, we examined the literature and hypothesized that glycemic control would be sub-optimal among this cohort. Thus, we planned to quantify glycemic control through the cohort study, use findings from the qualitative study to explain the reasons behind sub-optimal control and develop suggestions to optimize glycemia based on participant experiences and preferences. However, after analyzing and integrating the quantitative and qualitative data, we found that a different story emerged. In contrast to the hypothesized findings, the study cohort demonstrated high self-efficacy and achieved on-target A1C. Thus, in addition to using the qualitative study to explore the reasons behind glycemic control, we explored the pregnancy experience through participant-derived suggestions and

preferences for support. As the findings did not mirror the hypotheses, and in accordance with Stake's case study approach,[18] we modified how we constructed the cases from the plan outlined in the protocol.[13] Rather than developing cases based on variation in glycemia and covariates (e.g., self-efficacy, care satisfaction) across diabetes type, we used Stake's approach that facilitated the highlighting of repeated patterns in the data to aid in the construction of cases for support in pregnancy that were participant-derived. Our mixed-methods approach produced confirmatory and expansionary insights and as a result, three cases regarding participant-suggested self-management support preferences emerged: 1) Mental Health Support; 2) Support for Autonomy in Self-Management; and 3) Peer Support. Figure 1 depicts the constructed cases and supporting quantitative and qualitative data in a joint display. Below we have used a narrative approach that weaves together the quantitative statistics and the qualitative themes to further display the data integration.

Women in the study cohort demonstrated optimal glycemia across both types of diabetes, meeting the recommended national A1C guidelines of $\leq 6.5\%$.[14] By the third follow-up, the overall mean A1C remained "at target" at 6.36% (95% CI 6.11%, 6.60%). Confidence in self-management, represented by self-efficacy, was also relatively high and improved throughout pregnancy. By the third follow-up, the overall mean score on the self-efficacy scale was 7.96 (SD 1.20), out of a total possible score of 10.[14,19]

Upon reflecting on the qualitative findings in light of the quantitative results, we hypothesized that lower glycemic control may have manifested from women feeling out of control and fearing diabetes-induced pregnancy complications *("You feel guilty when your blood sugar is high…*

you're like, what important body part is being formed right now? And am I ruining it?"). Unfortunately, the price of such tight control was an isolating and mentally exhausting pregnancy experience. *("It's like I can't, I feel like I can't be a normal person because I'm constantly having to check my blood sugar, constantly having to remember to take my insulin or if I'm going out like I have to make sure 'OK do you have your insulin? Do you have your meter just in case your sensor goes wrong?'… I just I wish I was a normal person, but I'm not.").* Such experiences contributed to the first constructed case, the desire for **Mental Health Support** ("*The piece that wasn't a part of the high-risk clinic was the mental health piece and… I don't think that people look at it so seriously. And I don't think anybody talked to me about like the fact that like I was feeling stressed out… So, I think that was something that was missing").* Possibly due to feeling out of control and scared, women put a lot of effort and research into their diabetes management, resulting in feelings of self-confidence *("… My A1C was 5.3… you get to feel annoyingly confident because you're like 'Look at me, I'm doing better than a real pancreas'"*).

After women had worked hard to have tight control during pregnancy and were confident in their self-management, they wanted to be able to manage insulin administration during labour and delivery (*"Very early on I was asking like 'I want to control my diabetes at the end"*; *"I had, you know built up the courage 'cause you're like, 'I'm gonna tell this doctor how I want things done' and so I was like 'I want to be in charge. I don't want to take off my pump, like under no circumstances.'"*). However, they found that they lacked support from the healthcare team to have autonomy in self-management during labour ("*They were like 'That's not what we do here. The protocol here is you will be put on an insulin IV'… Just basically flat out told me 'No that's not what we do here.' …If I pushed back, it was always like 'We have to do this or your baby's at*

risk of dying…"; *"So like at the end of the day I did end up having to go on the insulin IV... They did a terrible job. My blood sugar level was perfect when I went in… of course, my blood sugar went up. And it did not go down for the rest of labour and delivery…"*). These reported experiences were the basis for the development of the second case, the desire for **Support for Autonomy in Self-Management**.

Perceiving a lack of support from the healthcare team, women found that they needed to turn to their diabetes community for advice regarding diabetes management and thus the third constructed case was the desire for **Peer Support** (*"I have gastroparesis too... I found that my Endo and OB, that wasn't even something that they'd ever really considered."* ; *"I remember just asking like 'All I want from you [endocrinologist] is like a suggestion on where my insulin like starting point should be… And he … wouldn't help me at all… … I reached out to my community, to kind of get a read on what I thought was pretty standard [pump settings for labour and delivery]…"*). In addition to looking to the diabetes community for advice on diabetes management during pregnancy, women expressed a desire for regular companionship with fellow mothers with pre-existing diabetes who would understand their unique day-to-day struggles (*"My best friend is great. She's wonderful …I can go to her and I can be like, 'Oh my, my blood sugars are all over the place and everything' but all she's gonna say is 'Oh, you know, like you got this, you can do it'... but I need a diabetic best friend... so I know that like there's somebody else in my corner, that's actually going through this and understands everything…"* ; *"It would have been nice to have that in-person connection to someone else like me… to connect to somebody else who would have been, like you know, someone who's not just on Facebook. That would have been nice…"*).

DISCUSSION

The quantitative results indicate that participants were confident in diabetes management. As a result, they achieved optimal glycemia during pregnancy. The qualitative findings, in contrast, show a different perspective: women appeared to be in significant mental distress and wanted support during pregnancy from peers and professionals. Thus, integrating both findings resulted in an apparent discordance: women may be confident in diabetes self-management, yet, they still desired support during a challenging pregnancy. There was also an expressed desire for autonomy in diabetes management during labour and delivery. The quantitative results show that women maintained optimal glycemia during pregnancy by closely measuring carbohydrate intake and carefully administering insulin, changing the timing and dosing as they progressed through the pregnancy trimesters. However, once they began to labour, they were forced to surrender diabetes management to the healthcare team. The stripping of autonomy at this critical time was another contributor to the significant distress that women revealed. The findings of this integration have important implications for future research and policies that affect clinical practice focused on this population.

Implications for research

Women in our study demonstrated high self-efficacy and achieved optimal glycemia. Their motivations were clear; the main priority was to avoid potential diabetes-induced complications for their infant. The fear of consequences for their infant and the strain of stringent self-management resulted in poor mental health. This is an example of the previously noted discordance: women appeared confident in diabetes management and achieved optimal glycemic control but they still had a strong desire for mental health support. Unfortunately, participants

expressed that the healthcare team did not address their mental health concerns. Diabetes is often concomitant with mental health disorders among non-pregnant adults. Depression, for example, is two to three times more common among those with diabetes than those without diabetes.[23] Anxiety disorders are also more common among adults with diabetes, with a 20% higher prevalence when compared to the background population.[23] Pregnancy is a time when women are particularly susceptible to mental illness.[24] Research on mental health disorders and pre-existing diabetes in pregnancy is limited. However, a recent meta-analysis that studied women with gestational and pre-existing diabetes in combination found that they are at a significantly higher risk of developing depression during pregnancy than women without diabetes.[25] Few studies have focused on mental health among women with diabetes.[26] Thus, there is an opportunity for future research to examine more closely the prevalence of mental health disorders in pregnancy among women with pre-existing diabetes and to develop interventions to optimize mental health during this vulnerable time.

Although the women were confident in their diabetes management and met their target glucose levels during pregnancy, they voiced a strong desire for peer support. The previously noted discordance remained: women were high functioning from a diabetes self-management perspective but still wanted connection and support. Some women explained that they engaged with peers in national and international online support groups for expectant mothers with pre-existing diabetes. Others described interacting with expectant mothers in their friend group who did not have diabetes. Neither of these social connections provided them with sufficient support. Thus, they wished for in-person peer support facilitated by the healthcare team. Research on peer support during pregnancy without diabetes is limited but shows that peer support may be

beneficial for improving mental health outcomes. A narrative review of six studies on peer support and the development of postpartum depression showed some evidence for lower Edinburgh Postpartum Depression Scale scores following peer support interventions and reports of positive experiences and maternal satisfaction.[27] Other research indicated the beneficial effects of peer support on mood and anxiety may occur by decreasing feelings of isolation and stress.[28] To our knowledge, research focused on in-person peer support during pregnancy for pre-existing diabetes is limited to one study that assessed the need for peer support among those with gestational and type 2 diabetes, finding that almost half of the participants were interested in such an intervention.[29] Independent of diabetes, the literature indicates that up to 21% of women experience mood disorders during pregnancy and early parenthood.[28] Mental health disorders are even more common during a pregnancy complicated by pre-existing diabetes.[23] As such, the evidence indicates that peer support may contribute to reduced isolation and stress during pregnancy and early parenthood for women without diabetes.[28] Future research should focus on developing such interventions for those with pre-existing diabetes who are even more vulnerable to such feelings.

Implications for policy

The quantitative results showed that the women in our study were confident in diabetes self-management, meeting recommended glycemic targets throughout pregnancy. However, once they began to labour, they were forced to allow the healthcare team to take over diabetes management. Women reported this was to the detriment of their physical and mental health: their glucose levels were allowed to run dangerously high, causing them significant stress and frustration. Thus, there was a strong desire for autonomy and diabetes self-management during

labour. Currently, the policies at the regional centre where we conducted our studies do not support diabetes self-management during labour. Thus, the women in our study reported that they had to turn off their insulin pump, for example, and receive insulin via an intravenous controlled by the healthcare team. Management by the healthcare team was problematic because women revealed that when their glucose levels became too high, the team would not consider their requests to increase the insulin dose. This resulted in glucose levels near diabetic ketoacidosis, delayed hospital discharge and caused women to have to administer their insulin from home without the knowledge of the healthcare team. In other clinical settings, diabetes self-management using insulin pumps, for example, during short surgeries, is commonplace.[30] Established protocols exist in parts of the United States, Canada, Australia and Europe[31-34] and current research indicates that insulin pump use during labour is safe and may result in improved glycemic control.[35-40] Thus, it is imperative for policymakers and healthcare team members to use knowledge translation strategies that bridge the gap between evidence and clinical practice. Knowledge translation strategies that are effective for policymakers include providing information packages, one-on-one meetings and tailored summaries.[41] Effective strategies for healthcare team members include education workshops, webinars and in-services.[41] The implementation of these strategies to facilitate change in clinical practice is critical to allow for autonomy and diabetes self-management during labour.

Strengths and limitations

Our mixed methods study has several strengths. First, through the quantitative phase, we demonstrated the prevalence and correlates of self-management support and glycemic control during pregnancy in women with type 1 and type 2 diabetes, offering insights related to women

with type 2 diabetes, a population of women with limited research. We also revealed the diabetes self-management support experiences and preferences during pregnancy in this population in the qualitative phase. Finally, our mixed methods integration generated cases that provided deeper understandings regarding participant-derived support preferences related to diabetes self-management among women with type 1 and type 2 diabetes in pregnancy using methodological, data source and investigator triangulation to promote the validity of the case study.

However, our study also had limitations. First, the quantitative phase had several limitations, including the reliance on self-reported data surveys. Further details can be found in the published paper.[14] The qualitative phase also had limitations, including a relatively small sample size. This resulted in limited transferability of the study findings. Finally, the mixed methods integration had limitations. One of these was the need to find a method for case construction that better fit with the repeated and emerging findings in the data. In the original protocol, we described our plan to construct cases based on variation in glycemia and covariates (e.g., self-efficacy, care satisfaction) across diabetes type, using the Diverse Case Method[42] for case section.[13] This was based on the idea that glycemic control might be sub-optimal among our population and there could be variation in glycemic control and self-efficacy across the different diabetes types. As the study results revealed that this was generally not the case; we had to modify how we developed the cases. However, the guiding literature on mixed methods case study designs suggests a sequential and flexible approach to case development and emphasizes the importance of allowing the emergence of cases as the research progresses.[12] Thus, we used Stake's approach to case construction that allowed for the development of cases based on emerging, repeated patterns in the data.

CONCLUSIONS

In conclusion, overall, women with pre-existing diabetes are able to achieve tight glycemic control during pregnancy. They are motivated and display high self-efficacy in diabetes self-management. However, the achievement of optimal glycemia appeared to be driven by fear, which took a toll on their mental health and pregnancy experience. Thus, women desired mental health support, support for autonomy in self-management and peer support. We plan to use the findings from this study to provide the basis for the development, evaluation and implementation of interventions related to these participant-described support preferences.

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Contributors

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Conflict of Interest

The authors declare that they have no competing interests.

Data Sharing Statement

Study participants were advised that their raw data would remain confidential and not be shared publicly, particularly due to the sensitive nature of the interview questions. Upon reasonable request, the data are available from the corresponding author.

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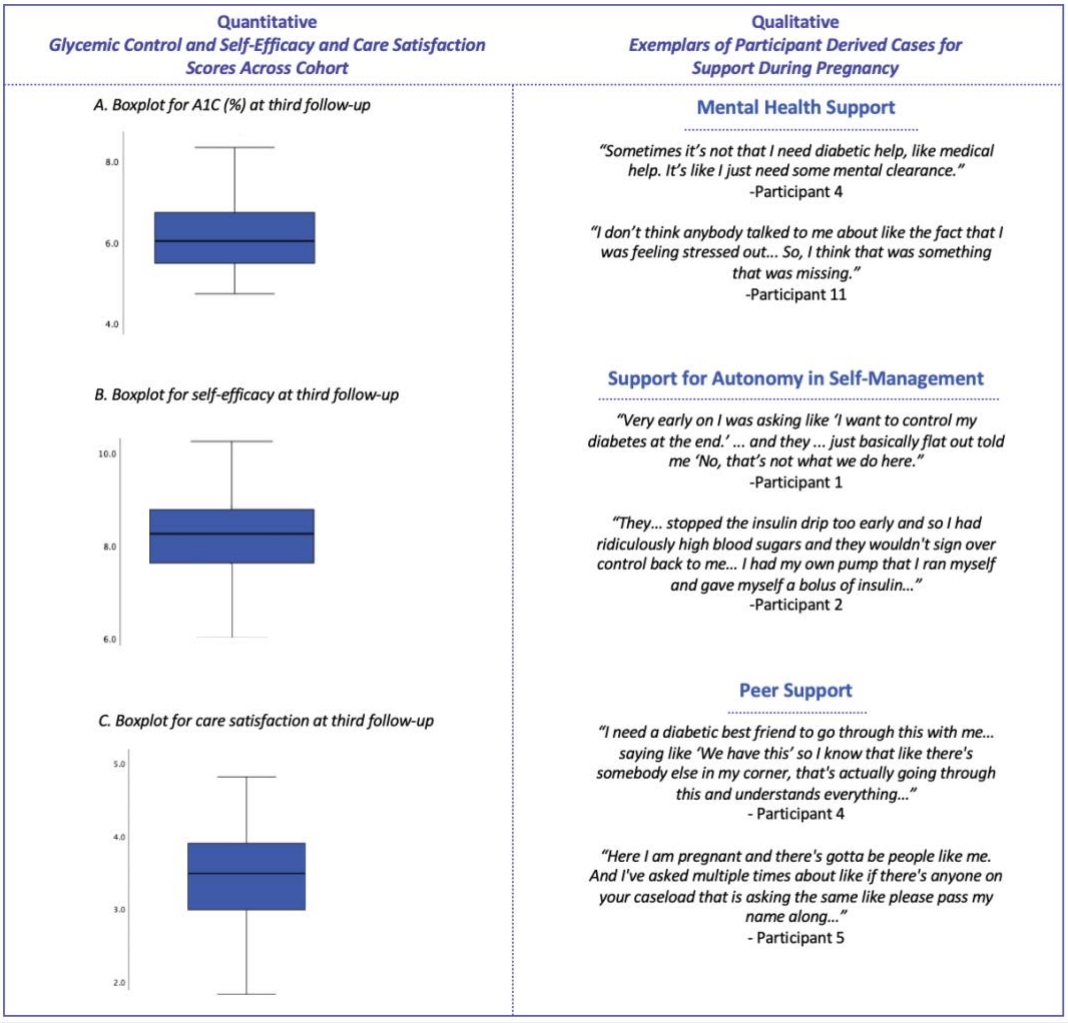
TABLE 1. Trends in A1C and Results of Questionnaires Assessing Diabetes Self-Efficacy, Self-Care and Care Satisfaction Across Time Points, Stratified by Type of Diabetes

	Total (*N* = 111)	**Type 1 Diabetes (*n* = 55)**	**Type 2 Diabetes (*n* = 56)**
A1C, %			
T1	7.49 (7.23–7.77)	7.49 (7.15–7.83)	7.53 (7.11–7.95)
T2	6.41 (6.15–6.67)	6.72 (6.39–7.06)	6.08 (5.68–6.48)
T3	6.36 (6.11–6.60)	6.60 (6.28–6.93)	6.12 (5.78–6.49)
SED Scale			
T1	7.83 ± 1.31	8.06 ± 1.22	7.56 ± 1.38
T2	7.76 ± 1.33	7.85 ± 1.33	7.66 ± 1.34
T3	7.96 ± 1.20	8.12 ± 1.14	7.81 ± 1.26
SDSCA Scale			
T1	4.89 ± 1.56	4.95 ± 1.63	4.84 ± 1.49
Diet, general	3.80 ± 1.47	3.99 ± 1.42	3.59 ± 1.51
Diet, specific	2.92 ± 1.98	2.88 ± 1.96	2.97 ± 2.02
Exercise	6.42 ± 1.03	6.68 ± 0.70	6.12 ± 1.26
Glucose monitoring	2.56 ± 2.07	2.79 ± 2.26	2.29 ± 1.88
Foot care			
T2	4.96 ± 1.38	4.98 ± 1.44	4.85 ± 1.32
Diet, general	3.88 ± 1.18	4.02 ± 1.09	3.72 ± 1.26
Diet, specific	2.72 ± 1.75	2.62 ± 1.79	2.83 ± 1.73
Exercise	6.32 ± 1.10	6.54 ± 0.78	6.09 ± 1.34
Glucose monitoring	2.72 ± 2.05	2.76 ± 2.28	2.69 ± 1.79
Foot care			
T3	4.84 ± 1.41	4.72 ± 1.58	4.95 ± 1.23
Diet, general	3.84 ± 1.13	4.08 ± 1.16	3.59 ± 1.06
Diet, specific	2.92 ± 1.98	2.94 ± 1.86	2.89 ± 2.09
Exercise	6.50 ± 0.89	6.68 ± 0.64	6.33 ± 1.06
Glucose monitoring	2.99 ± 2.21	3.27 ± 2.32	2.71 ± 2.07

PACIC Scale			
T1	3.32 ± 0.88	3.48 ± 0.74	3.14 ± 1.00
T2	3.42 ± 0.80	3.29 ± 0.69	3.57 ± 0.89
T3	3.39 ± 0.81	3.26 ± 0.79	3.51 ± 0.82

Data are mean (95% CI) or mean ± SD; SED, self-efficacy for diabetes; SDSCA, summary of diabetes self-care activities; T1, time point one, zero to 16 weeks gestation; T2, time point two, 17 to 28 weeks gestation; T3, time point three, 29 to 40 weeks; PACIC, the patient assessment of chronic illness care.

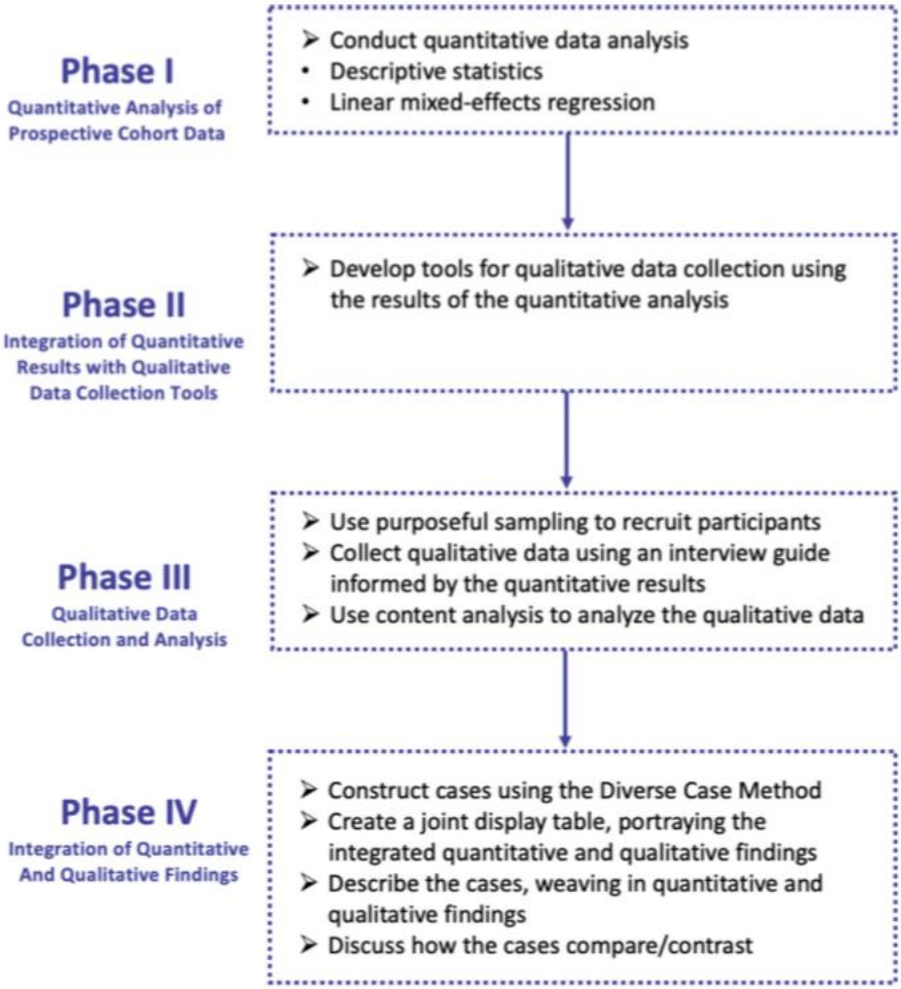
FIGURE 1. Joint-Display Table with Box Plots Depicting Quantitative Results (Good Glycemic Control, High Self-Efficacy, Low Satisfaction with Care) Side-by-Side with Qualitative Text of Participant-Derived Cases for Support during Pregnancy



Note: The box plots visually show the distribution of glycemic control (mean 6.36 [95% CI 6.11–6.60]), self-efficacy (range of the scale: 0 to 10; cohort mean 7.96 ± 1.20) and care satisfaction (range of the scale score: 0 to 5; cohort mean 3.39 ± 0.81) by the third follow-up.

Appendix A

Figure 1. Study Flow Diagram



Appendix B

TABLE 1. Application of the Good Reporting of a Mixed Methods Study (GRAMMS) Checklist[16]

GRAMMS Criteria	Study Information
Describe Justification for Using Mixed Methods Approach	There is a need to utilize quantitative and qualitative methods to understand the complexities of diabetes self-management and support experiences and needs in pregnancy and link these to glycemic control among women with type 1 and type 2 diabetes.
Describe Study Purpose	Our objective was to explore how self-management and support experiences help explain glycemic control among women with type 1 and type 2 diabetes in pregnancy.
Describe Study Priority	The quantitative and qualitative phases had equal priority because both sets of data were compared to develop contextualized cases of participant-derived diabetes self-management support needs.
Describe Study Sequence	A sequential comparative case study design was used, wherein initial quantitative data was collected and analyzed, followed by collection and analysis of qualitative data. Both sets of data were then integrated to develop contextualized cases.
Describe Sampling, Data Collection, and Analysis	Refer to the protocol for information regarding sampling, data collection, and analysis.[13]
Describe the Integration	Refer to the protocol and the current paper for details regarding integration processes.[13]
Describe Limitations of One Phase Caused by Presence of the Other	N/A
Describe Insights Gained from Integration	The use of a mixed methods design enhanced the study results so that they are more than the sum of the quantitative and qualitative studies alone. The association between self-management behaviours and glycemic control was determined and the impact that managing diabetes during pregnancy had on self-management behaviours and glycemic control was also explored. The resulting information lays the groundwork to guide subsequent research in designing, evaluating, and implementing self-management education and support interventions for this population in the future.

CHAPTER 7

Introduction

In this concluding chapter, the key findings of the thesis are summarized followed by recommendations for clinical practice, research and policy. Strengths and limitations and plans for knowledge translation are also discussed.

Summary of Key Findings

The overall purpose of this mixed methods thesis was to explore how self-management and support experiences helped to explain glycemic control among women with pre-existing diabetes in pregnancy. This involved separate quantitative and qualitative study phases and integration of the resulting data in a final mixed methods phase. The quantitative results were noteworthy for several reasons. First, the quantitative results showed that the women with pre-existing diabetes in our study (type 1 diabetes, n = 55; type 2 diabetes, n = 56) met the recommended glycemic target of < 6.5% during pregnancy (Feig et al., 2018). This finding contrasted with expectations developed from the existing literature showing that women with type 1 and type 2 diabetes have difficulty reaching glycemic targets during pregnancy (Cyganek et al., 2017; Murphy et al., 2017; Murphy et al., 2018). Second, the women in this study also demonstrated high levels of self-efficacy. These findings are aligned with Bandura's Theory of Self-Efficacy, which describes the role of confidence in motivation and goal achievement (Bandura, 1977; Resnik, 2014). In this study, self-efficacy was a significant predictor of glycemic control for women with type 1 diabetes, associated with a mean change in A1C of -0.22% (95% CI -0.42, -0.02) per unit increase in scale (Sushko et al., 2022). Overall, the

quantitative findings depicted a group of women who were confident in diabetes management and achieved target glycemic control throughout pregnancy.

The findings of the qualitative study (type 1 diabetes, n = 6; type 2 diabetes, n = 6) shed light on the mental struggles that women experienced. Although confident in diabetes self-management, women described feeling terrified, out of control, isolated and mentally exhausted during pregnancy. Stress during uncomplicated pregnancies is relatively common, with nearly 80% of women experiencing low to moderate stress levels (Dunkel & Tanner, 2012). Women with the added stress of managing diabetes are even more likely than the background population to experience mood disorders during pregnancy (Lee et al., 2020). Thus, the women in this study revealed a strong desire for mental health support and support from the healthcare and peer support teams to alleviate their worries.

The integrated findings of the quantitative and qualitative studies illustrate that managing diabetes during pregnancy is akin to an iceberg. On the surface, everyday tasks, such as self-monitoring blood glucose and counting carbohydrates, are manageable. The quantitative findings indicated this manageability, as women had high levels of self-efficacy and optimal glycemic control. However, under the surface, the qualitative findings revealed the difficult emotional and psychological aspects of self-management. Thus, the integrated findings reveal the enormity of the issue and suggest patient-derived needs for support during pregnancy.

Recommendations

The following recommendations reflect the future directions needed to support women in their ability to self-manage pre-existing diabetes in pregnancy.

Education and Clinical Practice

The mixed methods integration revealed that women desired mental health support. Research indicates that approximately 25% of women of childbearing age have a mental health disorder (Björkstedt et al., 2022). During pregnancy, when additional stressors compound the stresses of everyday life, the occurrence of mental health disorders may be even higher. A recent meta-analysis that quantified the occurrence of common mental health disorders during pregnancy found a prevalence of 37%, 31%, 70% and 49% for anxiety, depression, psychological distress and insomnia during pregnancy, respectively (Yan et al., 2020). The prevalence of mental health disorders among adults with diabetes is already higher when compared to those without diabetes. Anxiety disorders among those with diabetes are approximately 20% higher than the occurrence among those without diabetes, for example (Centers for Disease Control and Prevention, 2022). Women with diabetes in pregnancy are even more likely to be affected by mental health disorders, such as depression (Lee et al., 2020). Poor maternal mental health is associated with an increased risk of pregnancy complications, including miscarriage and stillbirth (Björkstedt et al., 2022). A mother's mental health status during the antenatal period is also related to the health of their infants, with poor mental health associated with premature delivery and low birth weight (Björkstedt et al., 2022). Women with pre-existing diabetes are already at an increased risk of pregnancy complications and adverse outcomes (Feig et al., 2014). Thus, investing in strategies to support mental health for women with diabetes during pregnancy is critical to optimize health outcomes for this population.

Currently, there is a single clinic that supports the mental health needs of women during the pregnancy and postpartum periods in the region in which this study was located (St. Joseph's Healthcare Hamilton, 2014). The Women's Health Concerns Clinic is accessible through referral

by a healthcare provider or self-referral (St. Joseph's Healthcare Hamilton, 2014). To our knowledge, there is no formal screening for mental health disorders during pregnancy at the regional high-risk pregnancy clinic. Thus, referral to the Women's Health Concerns Clinic occurs after physician or patient identification of the need for mental health support. Unfortunately, research indicates that 70% of people with mental health disorders do not receive treatment from healthcare professionals (Henderson et al., 2013). The lack of treatment may be due to: (a) a lack of knowledge to identify the symptoms of mental health disorders; (b) not knowing how to access treatment; (c) stigma against people with mental health disorders; and (d) anticipated discrimination by those with mental health disorders (Henderson et al., 2013). Due to the treatment gap, defined as the disparity between the true prevalence of mental health disorders and the treated prevalence, many people only access mental health support once they have experienced substantial impairment (Henderson et al., 2013). Women in the study presented in this thesis expressed a need for mental health support. However, they perceived that the healthcare team did not address their mental health. As healthcare providers were not interviewed for this study, this perception is unexplored from the provider's perspective. It is possible that healthcare providers did not pick up on mental health problems and thus did not address them. Alternatively, the pressures and demands of a busy clinic may not have allowed enough time for healthcare providers to address mental health issues with patients. Regardless of the reason, the lack of a formal screening for mental health disorders by the high-risk pregnancy team combined with a potential reluctance to disclose mental health concerns may result in women not receiving needed mental health support during pregnancy.

A potential solution to address the perceived lack of mental health support is routine screening for common mental health disorders upon baseline assessment at the high-risk

pregnancy clinic. According to the Diabetes Canada guidelines, everyone with diabetes should undergo regular mental health assessments as it is established that people with diabetes are at a higher risk than the background population of experiencing mental health disorders (Robinson et al., 2018). Regarding screening for mental health disorders in pregnancy, a recent systematic review and meta-analysis found moderate to high-quality evidence that screening programs for depression and anxiety during pregnancy improve maternal mental health and infant outcomes (Wagas et al., 2022). The screening programs examined in this systematic review were delivered by a variety of individuals, including nurses, midwives, psychology students and physicians, and were conducted in a range of settings, such as general practitioner offices, antenatal care centres and hospitals (Wagas et al., 2022). Tools used for screening included the Edinburgh Perinatal/Postnatal Depression Scale, the Patient Health Questionaire-9 and the Beck Depression Inventory, among others (Wagas et al., 2022). The screening was delivered in-person, online and via mailed questionnaires (Wagas et al., 2022). The authors concluded that to alleviate the added burden on healthcare providers, initial screening could be done by non-healthcare professionals, such as students, and using shortened screening tools, like the Patient Health Questionaire-9 consisting of only nine questions (Wagas et al., 2022). Most self-report measures of mental health disorders are easy to administer (Kagee et al., 2013) and could serve as a flag for the healthcare team to provide a referral to the Women's Health Concerns Clinic, for example. There has also been some research on computer- or tablet-based screening methods (Diez-Canseco et al., 2018; Martel et al., 2021; Parker et al., 2020). Research on routine screening for mental health disorders in pregnancy and its effect on referral to the Women's Health Concerns Clinic, for example, is required. Implementing routine screening, and subsequent follow-up with the

Women's Health Concerns Clinic, could increase the frequency with which women receive mental health support and therefore decrease distress.

Research

The mixed methods integration indicated there is a need for peer support during pregnancy. Peer support is a process wherein people who share a similar experience, such as a medical diagnosis, give and receive support based on their shared experience (Penney, 2018). It can be delivered in a variety of ways. For example, it can be delivered one-on-one or in a group setting, formally by trained peers or informally by untrained peers, virtually or in-person (Canadian Medical Association, 2021). Peer support originated in the field of mental health in the 1970s and is still used to date (Shalaby & Agyapong, 2020). The benefits of peer support in the mental health field include increased happiness, self-esteem and coping and reduced depression, anxiety and loneliness (Richard et al., 2022). The benefits appear to exist among a variety of demographic groups, including ethnic minorities, and via different modes, including individuals and groups (Richard et al., 2022). Outside of the mental health field, the benefits of peer support have included the provision of emotional and social support, assistance with accessing and navigating health care and help with coping with stressors that accompany health problems, among others (Peers for Progress, 2014). Peer support has been heralded for its cost-effectiveness and feasibility, including in low-income settings (Peers for Progress, 2014). More recently, peer support has found a place in other healthcare fields such as cancer, cardiovascular disease and kidney disease (Thompson et al., 2022).

In the field of diabetes, peer support is recognized by the Diabetes Canada clinical practice guidelines as a component of diabetes self-management support (Jones et al., 2013;

Sherifali et al., 2018). A meta-analysis has demonstrated that peer support interventions have a significant effect on lowering A1C (-0.57%, 95% CI -0.78 to -0.36), with individualized interventions having the greatest impact (-0.91%, 95% CI -1.10 to -0.71) (Qi et al., 2015). Peer support has also been found to have a beneficial impact on mental health, with a systematic review finding that peer support reduced feelings of depression and increased feelings of social support (Dale et al., 2012). Regarding the population with diabetes in pregnancy, although other studies, including this one, have found a desire for peer support (Elton, 2021; Freidman et al., 2015; Luo et al., 2022), research on this topic is very limited. This is particularly true for in-person peer support, which is what the participants in this study desired, having not felt satisfied with existing online networks. To our knowledge, there are only two existing peer support programs available to women in the area in which the current study was undertaken: (a) Diabetes Canada's National Peer Connect Program for adults living with type 1 diabetes (Diabetes Canada, 2023); and (b) the Juvenile Diabetes Research Foundation's Talk T1D—a peer support program for adults living with type 1 diabetes (Juvenile Diabetes Research Foundation, 2023). However, neither of these programs is pregnancy-specific, nor are they in-person—two important components desired by the women in the reported study. Furthermore, there were no identified peer support programs for women with type 2 diabetes. Given that the study presented in this thesis established that a need for an in-person peer support program for women with pre-existing diabetes in pregnancy exists, future research should be directed at developing such a program. The first steps could be to conduct a survey of expectant mothers with pre-existing diabetes to explore specifics regarding the characteristics of such a program, and then develop and conduct a pilot study.

Policy

This mixed methods integration revealed that women desired autonomy in diabetes self-management during labour and delivery. During pregnancy, women were used to having optimal control of their glucose levels, for example, utilizing continuous glucose monitors and insulin pumps to meet precise glucose targets. Unfortunately, once women began to labour, they lost their autonomy in self-management since hospital protocol required them to have insulin administered intravenously with dosing managed by the healthcare team. This practice proved distressing for women as they had high self-efficacy and desired to control their insulin administration. In some cases, having insulin administration managed by the healthcare team during labour proved dangerous for women as their glucose levels rose to levels high enough to induce diabetic ketoacidosis. They avoided diabetic ketoacidosis by administering their insulin without their healthcare team being aware.

Outside of pregnancy, among adults with diabetes who are undergoing short medical procedures, self-management of insulin administration is commonplace and protocols exist to allow for the safe implementation of this practice (Alberta Health Services, n.d.; Joint British Diabetes Societies for Inpatient Care Group, 2011; Partridge et al., 2016; University of Virginia Health System, 2010). There is currently some limited evidence on the use of patient-controlled insulin pump therapy during labour (Cordua et al., 2013; Drever et al., 2016; Fresa et al., 2013; Kallas-Koeman et al., 2014; Mukhopadhyay et al., 2007; Stewart et al., 2018). The existing evidence indicates that self-management of insulin by women during labour is safe and may even contribute to improved glycemic control.

Given that the existing evidence is favourable toward this practice and given women's desire to be autonomous in diabetes self-management during labour, policies to promote

autonomy in diabetes self-management during labour ought to be developed. Knowledge translation of the existing evidence needs to be communicated to stakeholders, who could also work with patient partners to develop such policies. For example, the women in our study reported that they knew of other women with diabetes during pregnancy who gave birth in a neighbouring region and were allowed to self-manage insulin administration during labour. Using a combination of knowledge translation strategies of the existing evidence to reach stakeholders along with the support of patient partners and healthcare providers at centres that already have protocols in place is a critical step to promote autonomy in diabetes self-management during labour for women in this population.

Implications for policy should also go beyond the hospital level, extending to the provincial and federal government levels. Evidence indicates that women with diabetes in pregnancy are more likely to experience mental health disorders (Lee et al., 2020). Furthermore, the current thesis established that women with diabetes have a strong desire for mental health support. Women with diabetes and poor mental health individually are at an increased likelihood of experiencing pregnancy complications, including premature delivery, among others (Björkstedt et al., 2022). Thus close attention ought to be paid to ameliorating the negative effects of poor mental health among expectant mothers with diabetes, not only for their own wellbeing but for the health of their children. Programs and funding at the government level are needed to ensure adequate support for expectant mothers with diabetes; this is needed for both the impact on maternal but also neonatal outcomes.

Considerations of Race and Ethnicity

The role of race and ethnicity must also be incorporated with regards to the implications of this thesis. For example, a person's race and ethnicity may impact their mental health. Mental health in turn is a known factor that impacts diabetes self-management and health outcomes. Evidence indicates that African Americans adults are 20% more likely toexperience mental health distress than White adults (U.S. Department of Health and Human Services Office of Minority Health, 2023). The presence of a mental health condition, such as depression, is associated with low utilization of health services and lower diabetes self-management scores (Alkhormi, et al., 2022). Thus, a lens that considers the impact of race and ethnicity should be incorporated into the planning of mental health support, peer support and support in self-management of diabetes during labour.

Strengths and Limitations

The studies incorporated within this thesis have several strengths. First, the population of women with type 1 and type 2 diabetes in pregnancy is relatively small, making up only about 20% of those with diabetes in pregnancy. However, the quantitative phase followed a comparatively large cohort of women (n = 111) by continuing recruitment for five years. In addition, in the qualitative phase, 12 women were recruited from a diverse geographic region of southern Ontario. Study participants also exhibited a wide range of socioeconomic characteristics. This diversity contributed to the richness of experiences described. It is also important to consider that recruitment for the qualitative study phase occurred during the COVID-19 global pandemic. At this time, virtually no research activity that was not related to COVID-19 was allowed within hospitals. Thus, innovative strategies were required for

recruitment. This resulted in recruiting participants entirely via pregnancy and diabetes online communities (e.g., Facebook) and word-of-mouth.

Second, through the mixed methods integration, participant-derived cases were developed that outline support needs and have the potential to contribute to the improvement of diabetes self-management experiences during pregnancy. By integrating the quantitative and qualitative findings, the advantages of both quantitative and qualitative research were harnessed. For example, quantitative research has the advantage of allowing study results to be generalized to other populations due to larger sample sizes. However, quantitative research has been criticized for not providing enough context regarding the everyday lives of participants (Creswell & Plano Clark, 2018). On the other hand, qualitative research has the advantage of allowing the voices of participants to be at the forefront of research findings. However, results are not typically as generalizable due to small sample sizes (Creswell & Plano Clark, 2018). Integration of quantitative and qualitative data leveraged the strengths of both methods to develop relevant contextualized and participant-derived recommendations related to clinical practice, research and policy.

Despite the strengths of the thesis, there are also limitations. First, the cohort study that comprised the quantitative phase was missing several key components that would have enhanced its overall contributions to the literature. These included collecting data on preconception care, baseline diabetes complications, BMI, pre-pregnancy A1C, hypoglycemia and pregnancy outcomes. In addition, the sample size for our qualitative phase was relatively small (n = 12). Thus, the ability to transfer findings to other populations is limited, similar to other qualitative studies. Finally, when conducting the mixed methods phase, the method of case construction was changed from what was described in the protocol. Based on an expectation arising from the

literature—that glycemic control would be poor among study participants—we intended to use the Diverse Case Method (Seawright & Gerring, 2008) for case selection to portray variation in glycemic control and self-efficacy across diabetes types. The Diverse Case Method is based on the assumption that there will be differing variables from which diverse cases can be constructed (Seawright & Gerring, 2008). For categorical variables, such as diabetes type, it was planned that cases would be constructed for each category. For example, we would select participant groups with type 1 diabetes and good and poor glycaemic control and participant groups with type 2 diabetes and good and poor glycaemic control to assemble cases. For continuous variables, such as self-efficacy score, we wanted to create cases using high compared with low values of the variable. For example, we would choose participant groups with high compared with low levels of self-efficacy and examine differences in their glycaemic control. We would then select supporting data from the qualitative interview results to contextualise and complete case construction. However, following our analysis, we found that on average, the participants in our study demonstrated good glycemic control and high levels of self-efficacy, without any significant outliers. As a result, we had to re-examine our assumptions that were derived from the literature and instead follow our participant data. Rather than showing us diverse results in terms of glycemic control and self-efficacy in diabetes management, the women showed us that on average they were confident and competent in managing diabetes in pregnancy. The qualitative results further backed this up, but shed light on the fact that, universally, women desired emotional and psychological support. Thus, we amended our original plan, instead using Stake's approach to case selection and derived cases from repeated patterns in the data (Stake, 2003). Using this approach that is grounded in the data allowed us to ensure that our findings were participant-driven.

Quality Considerations

To ensure study quality, corresponding guidelines for study reporting were followed for each component of the thesis. These included the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (Tricco et al., 2018), the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2007) and the Consolidated Criteria for Reporting Qualitative Research framework (Tong et al., 2007). For the overarching mixed methods study, we adhered to the Good Reporting of a Mixed Methods Study (GRAMMS) by O'Cathain et al. (2008) to promote study quality and rigour. We have briefly outlined the GRAMMS criteria concerning this thesis below.

Describe the Justification for Using a Mixed Methods Approach

There was a need to utilize quantitative and qualitative methods to understand the complexities of diabetes self-management and support experiences and needs in pregnancy, and link these to glycemic control among women with type 1 and type 2 diabetes. Through the use of mixed methods, we were able to understand this complex topic in a way that would not have been possible using quantitative or qualitative methods alone (Creswell & Plano Clark, 2018). For example, we were able to use multiple data collection tools, not restricted to those associated with quantitative or qualitative research alone. Furthermore, we were able to generate new knowledge and insights regarding our topic that would not have been possible using only quantitative and qualitative methods (Creswell & Plano Clark, 2018). These are just a few of the reasons that justified our use of a mixed methods approach.

Describe the Study Purpose

Our overall study purpose was to explore how self-management and support experiences during pregnancy help explain glycemic control among women with type 1 and type 2 diabetes. To fulfill the study purpose, we first answered the individual quantitative and qualitative research questions (see Chapters 4 and 5). In our final study phase, we integrated the answers to these questions using mixed methods procedures.

Describe Study Priority

In mixed methods research, study priority can be on the quantitative phase, the qualitative phase or the priority can be equal (Creswell & Plano Clark, 2018). Typically, the priority in an explanatory design would be quantitative, while the priority in an exploratory design would be qualitative and the priority in a comparative study would be equal (Creswell & Plano Clark, 2018). In our study, the quantitative and qualitative phases had equal priority because both sets of data were compared to develop contextualized cases of participant-derived diabetes self-management support needs.

Describe Study Sequence

We conducted a sequential comparative case study. In this design, the quantitative and qualitative phases are consecutive and then the occurring results are integrated to develop contextualized cases. In the current thesis, we first conducted the quantitative phase (cohort study), followed by the qualitative phase (qualitative description study). Finally, we integrated the quantitative and qualitative results using Stake's approach to develop participant-derived cases regarding diabetes self-management support needs during pregnancy.

Describe Sampling, Data Collection, Data Analysis and Integration

Each of the methodological components (sampling, data collection and analysis) are described throughout the thesis. Chapter 3 provides the overall study protocol, summarizing the methods of each study phase. Chapters 4 and 5 provide further details regarding the methodological decisions for the quantitative and qualitative study phases, respectively. Finally, Chapter 7 describes in detail the methods that we used to integrate the quantitative and qualitative study findings.

Describe Limitations of One Phase Caused by the Presence of the Other

We did not identify any limitations for one phase caused by the presence of the other phase. Rather, we found that the presence of both study phases enhanced the overall results of the thesis. The quantitative phase allowed us to explore trends in glycemic control during pregnancy in women with type 1 and type 2 diabetes, assess self-efficacy, self-care and care satisfaction and examine these factors as predictors of glycemic control. On the other hand, the qualitative phase enabled us to understand the experience of managing diabetes during pregnancy and identify the diabetes self-management education and support needs during pregnancy among women with type 1 and type 2 diabetes. Finally, the mixed methods phase allowed us to integrate the quantitative and qualitative results and develop contextualized cases regarding the self-management support needs during pregnancy among our population.

Describe Insights Gained from Integration

The insights gained from integrating the quantitative and qualitative results are in the form of participant-derived cases of self-management support needs during pregnancy. These are thoroughly described in Chapter 6. Briefly, we developed cases for the need for mental health support, peer support and autonomy in diabetes self-management during pregnancy.

Plans for Knowledge Translation

The translation of the results of studies to knowledge that impacts clinical decision-making and supports change in clinical practice is a critical component of any research endeavour (Straus et al., 2009). Unfortunately, translation of knowledge has been particularly lacking in the fields of sexual, reproductive, maternal, newborn, child and adolescent health (Curran et al., 2022). Barriers to knowledge translation related to the aforementioned fields include limited resources for funding and healthcare staff and constraints related to time and resistance to change, among others (Curran et al., 2022). On the other hand, enablers to knowledge translation in these fields are the support of stakeholders and the availability of resources and knowledge, such as skills training for healthcare providers (Curran et al., 2022).

According to the Canadian Institute of Health Research, six occasions within a cycle of research provide opportunities to facilitate knowledge translation (Sudsawad, 2007). These include: (a) defining the research question and methodologies; (b) conducting participatory research; (c) publishing research findings in plain language and accessible formats; (d) placing research findings in the context of other knowledge and sociocultural norms; (e) making decisions and taking action informed by research findings; and (f) influencing subsequent rounds of research based on the impacts of knowledge use (Sudsawad, 2007). In the current research cycle of the studies presented in this thesis, we have completed the first and second opportunities—defining our research questions and methodologies in our study protocol (Chapter 3) and conducting participatory research by developing participant-derived cases for diabetes self-management support needs during pregnancy (Chapter 6). We are in the process of completing the third opportunity. We have already published Chapters 2, 3, 4 and 5 in peer-reviewed journals and have presented study findings at relevant conferences. Our next steps will

be to complete the third opportunity and begin the fourth. We plan to accomplish this by publishing Chapter 6 and presenting findings at additional conferences. We also plan to summarize our results using plain language to be presented to relevant stakeholders. These will include those who provide obstetrical care to women with type 1 and type 2 diabetes in order to influence decision-making and clinical practice as well as providing study results to study participants (the fifth opportunity). Cochrane Training has a Six-Step Stakeholder Engagement Framework (Cochrane Training, 2023) that we plan to follow to increase the translation and impact of our research findings. The steps are outlined as follows:

1. Be clear about the purpose for stakeholder engagement;
2. Reflect on previous stakeholder engagement and consider capacity;
3. Identify relevant stakeholders;
4. Connect with stakeholders;
5. Report stakeholder engagement; and
6. Evaluate and maintain stakeholder relationships (Cochrane Training, 2023).

In our case, the purpose of stakeholder engagement is to translate our research findings to invoke changes in clinical practice, research and policy. Specifically, we plan to advocate for routine screening of mental health disorders in pregnancy, and peer support and autonomy in diabetes self-management during labour. These are the participant-derived areas arising from our mixed-methods integration that are needed to improve the experience of diabetes self-management during pregnancy. Relevant stakeholders include members of the healthcare team who care for women with diabetes in pregnancy, such as physicians, nurses and social workers, as well as women with diabetes in pregnancy. One of the first steps for connecting with stakeholders could be at relevant conferences. For example, the annual Diabetes Canada/Canadian Society of

Endocrinology and Metabolism Professional Conference provides networking opportunities for researchers and clinicians as well as patient partners (Diabetes Canada, 2023). Our research has been presented in previous years at this conference. Thus, presenting the current thesis findings at that conference is a feasible way to begin connecting with stakeholders. The sixth opportunity of the six occasions within the research cycle to facilitate knowledge translation may be realized in the future by evaluating the impact of the implementation of any resulting changes to clinical practice.

Conclusion

In this thesis, separate quantitative and qualitative study phases were completed, as well as integrated, to determine how self-management and support experiences help explain glycemic control among women with pre-existing diabetes in pregnancy. The results showed that women had high self-efficacy and good glycemic control, achieving recommended glucose targets throughout pregnancy. The qualitative results, however, revealed that women felt terrified, out of control, isolated and mentally exhausted during pregnancy. Thus, there was an apparent discordance when the quantitative and qualitative findings were compared. In mixing the quantitative and qualitative results, we developed three cases for participant-derived needs during pregnancy: mental health support, peer support and autonomy in diabetes self-management. The information resulting from this thesis reveals key opportunities for research and policy and lays the groundwork to guide subsequent research in designing, evaluating and implementing self-management education and support interventions for this population in the future. Specifically, results from this thesis reveal the need for the development of interventions related to peer and mental health support, as well as support for autonomy in diabetes self-

management during labour and delivery, and that these interventions should be incorporated into the standard of care for women with pre-existing diabetes in pregnancy.

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