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Screening and Intervention for Women With Hyperglycemia During Pregnancy

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College of Health Sciences

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LaDonna Williams

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Walden University
2015

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Abstract

Screening and Intervention for Women With Hyperglycemia During Pregnancy

by

LaDonna L. Williams

MS, Walden University, 2010

BS, Old Dominion University, 1999

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

November 2015

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Abstract

Gestational diabetes mellitus occurs in up to 10% of pregnancies and often leads to labor and delivery complications for both the mother and the baby. Early identification of gestational diabetes and educational intervention are needed to improve the self-management and knowledge among pregnant women. The purpose of the project was to implement newly established national guidelines to ensure that women with gestational diabetes are identified during the first trimester of pregnancy and begin diabetes education early in gestation. Lewin's planned change theory was selected as the theoretical framework, and the six sigma approach was used to facilitate the change process. The project used a pretest and posttest design in a convenience sample of 35 women with gestational diabetes who were referred for the educational intervention and completed the education and the questionnaires. The anticipated outcomes were for (a) women to be screened during the first trimester of their pregnancy and (b) the post education scores on the self-management questionnaire to demonstrate an increase in knowledge about contacting the provider for abnormal blood sugar results and making appropriate dietary choices. Data were entered into SPSS and were analyzed using descriptive statistics. A *t* test was used to compare pretest and posttest knowledge scores. During the project, 57% of the participants were screened in the first trimester of pregnancy. The difference in the pretest (M = 75.43) and the posttest scores (M = 91.71) was statistically significant ($p < .0001$). These findings have important social change implications because early screening and early intervention will help to reduce birth complications and long-term development of Type 2 diabetes.

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Section 1: Project Overview

Screening and Intervention for Women With Hyperglycemia During Pregnancy

Hyperglycemia during pregnancy is a serious but common complication of pregnancy that is associated with poor labor and delivery outcomes for both the mother and the baby. *Gestational diabetes mellitus* (*GDM*) is often defined as hyperglycemia identified during pregnancy or as an intolerance of carbohydrates during pregnancy. Overt or pregestational diabetes refers to any type of diabetes diagnosed prior to pregnancy. It is estimated that GDM occurs in 4.8% of pregnant women according to a Centers for Disease Control and Prevention (CDC) prevalence report in 2009; however, the international Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study demonstrated that 6.7% of pregnant women met the Carpenter and Coustan (CC) criteria for GDM (Agency for Healthcare Research and Quality [AHRQ], 2012). In 1982, the CC criteria recommended that women with fasting plasma glucose levels greater than or equal to 95 mg/dL receive a diagnosis of GDM (Carpenter & Coustan, 1982). The International Association of the Diabetes in Pregnancy Study Group (IADPSG; 2010) reported that 17.8% of women were diagnosed with GDM as a result of their lower glucose threshold (i.e., plasma glucose levels greater than or equal to 92 mg/dL.) The IADPSG also recommended screening all or at least high-risk women at their first prenatal visit with a random plasma glucose, HbA1C, or random blood sugar to help identify undiagnosed pre-existing diabetes prior to pregnancy (IADPSG, 2010).

The HAPO study was an observation study that examined the various relationships of GDM and obesity with pregnancy outcomes. The study began with 53,295 eligible women from 15 centers in nine countries with 23,316 of those women agreeing to participate and completing the study between July 2000 and April 2006. Participants and caregivers were blinded to glucose

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values, and no recommendations were made to alter diet or other treatments related to glucose intolerance or obesity. The participants underwent a 75-gram oral glucose tolerance test (OGTT) between 24 and 32 weeks, and GDM was diagnosed utilizing the IADPSG criteria. The HAPO study determined that GDM and obesity are associated with adverse pregnancy outcomes, but the combination of GDM and obesity has a much greater effect (IADPSG, 2012).

In addition, screening at the first prenatal visit will help identify gestational diabetes and the undiagnosed overt diabetic early in the pregnancy, which will allow for interventions and treatment to start in the first trimester versus the third trimester (Metzger, 2010). Providing intervention in the first trimester could have a direct effect on macrosomia and large for gestational age (LGA) rates, which could also prevent future cases of Type 2 diabetes mellitus in both the mother and the infant.

The current GDM guidelines for Winchester Medical Center (WMC), the site for the current project, were established in 1999 and need revision. In particular, the guidelines do not align with national screening guidelines related to hyperglycemia in pregnancy. Obstetricians at WMC were utilizing the American Diabetes Association (ADA) and American College of Obstetrics and Gynecology (ACOG) screening guidelines for hyperglycemia in pregnancy based on the CC criteria. With the ADA and ACOG screening guidelines, the LGA rate for deliveries is 27% (WMC, 2011). The goal is for this number to be as close to zero as possible to prevent adverse labor and delivery outcomes for the mother and baby.

To address these issues, a team of nurses and maternal and fetal medicine physicians reviewed the recommendations of national guidelines to develop new practice guidelines for the organization. Because there are varying recommendations, the team believed that research on the effectiveness of any new guidelines within WMC was needed. The team reviewed the literature

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on GDM screening recommendations and decided to revise the guidelines to reflect many of the IADPSG recommendations, including screening all pregnant women at the first prenatal visit with a HbA1C and adopting the lower threshold for diagnosis to plasma glucose levels of 92 mg/dL for OGTT. Please refer to Appendix B for full details of the pregnancy and diabetes guidelines.

Establishing a standardized screening guideline is expected to provide consistency in hyperglycemia screening among all pregnant women seen at the center and to allow for earlier diagnosis and intervention for both overt diabetes and GDM. Once a patient is diagnosed with diabetes of any type, interventions may begin, which include referral to the Diabetes Management Program (DMP) for education on meal planning, self-monitoring blood glucose, and monitoring daily urine for ketones. Interventions also include referral to maternal and fetal medicine specialists for follow up related to high-risk pregnancy and, possibly, prescription medications if necessary. Tight glycemic control throughout the pregnancy may reduce complications such as LGA, macrosomia, caesarian section, shoulder dystocia, and infant hypoglycemia; therefore, the length of stay for both the mother and the baby will be decreased and infant admission to the neonatal intensive care unit (NICU) may be completely avoided (IADPSG, 2010).

Providing obstetricians with solid guidelines for managing hyperglycemia in pregnancy may improve their compliance and tighter glycemic control for the patients. Nurses within the DMP will provide GDM patients with proper education on diet, testing blood sugars and ketones, and instructions on when to notify their physician regarding blood sugar values. Follow-up for blood sugar values and ketone results will be the responsibility of the obstetrician or the maternal fetal medicine specialist.

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Background

Risk factors related to GDM vary but often include older maternal age, higher body mass index (BMI), polyhydramnios, past history of GDM, macrosomia in previous pregnancy, and family history of diabetes; further, ethnic groups with increased risk for developing Type 2 diabetes, such as Hispanics; Africans; Native Americans; and South, East Asian, or Pacific Islanders have a higher risk of GDM (AHRQ, 2012). However, modifiable risk factors are also associated with GDM, which include obesity, diets high in saturated fat, physical inactivity, and smoking. The combination of modifiable risk factors and the societal trend of older maternal age contribute to increase the prevalence of GDM (Ferrara, 2007).

Complications associated with GDM for the infant include LGA, macrosomia, shoulder dystocia, prematurity, and infant hypoglycemia. These complications may increase the length of stay for the infant and may even require the infant to be admitted to the NICU for observation or possibly an extended period (ACOG, 2011). Complications for the mother include hypertension, preeclampsia, episiotomy, and cesarean section delivery. These complications may lead to premature labor, hemorrhage, and changes in the delivery plan from vaginal to cesarean section due to the increased size of the infant. Each of these complications may result in an increased length of stay for the mother requiring additional treatments and interventions (U. S. Preventive Services Task Force [USPSTF], 2013).

Problem Statement

The problem addressed by this project was the need for early identification of GDM and educational intervention to improve the self-management and knowledge of pregnant women.

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Project Purpose

The purpose of this project was to use newly established guidelines for screening hyperglycemia in pregnancy to ensure that patients with GDM will be identified during their first trimester and begin education and other interventions/treatments earlier in gestation in the clinic setting. The project proposed that early detection of gestational diabetes and early referral for diabetes education would improve the self-management and knowledge of pregnant women diagnosed with GDM. Although beyond the scope of this project, the ultimate goal was to reduce complications associated with GDM such as preterm labor, hypertension, preeclampsia, hemorrhage, and shoulder dystocia, while decreasing adverse labor, delivery, and infant outcomes such as macrosomia, LGA, cesarean delivery, and infant hypoglycemia.

In addition to decreasing complication rates and improving outcomes, the early diagnosis and intervention may also improve future outcomes related to GDM such as the development of Type 2 diabetes in both the mother and the baby. By reducing the prevalence of GDM, fewer mothers will have an increased risk for developing Type 2 diabetes in the future. Fewer infants born with macrosomia and LGA will also reduce the number of infants at risk of developing Type 2 diabetes in the future. For women identified with GDM, the new guidelines establish criteria for follow-up blood glucose testing with their primary physician after delivery to monitor for the development of Type 2 diabetes.

Project Outcomes

The anticipated outcomes of the project were:

1. Women receiving care in the project clinic will be screened for GDM during the first trimester of their pregnancy.

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2. The pretest scores compared to the posttest scores on a questionnaire to examine knowledge of GDM and its treatment will demonstrate that the participating patients have learned when to contact their physician for abnormal blood sugar results and appropriate dietary choices.

Frameworks of the Project

Kurt Lewin's planned change theory was selected as the theoretical framework for the project. Lewin's theory includes three elements: field theory, group dynamics, and the three-step model. Field theory and group dynamics are utilized during the three-step model of unfreezing, moving, and refreezing to create and maintain change (Burnes, 2009). Changing one's views/perceptions is referred to as the process of unfreezing. The next stage is changing the thoughts, feelings, and/or behaviors of the providers to introduce the revised practice guidelines. The final stage is refreezing, which incorporates the changes and allows them to become the new standard practice for all GDM patients (Kaminski, 2011).

The providers at the clinical site needed to understand that the current GDM guidelines were antiquated and in need of revision to ensure optimal patient outcomes. Changing the providers' views/perceptions of the current GDM guidelines was Step 1, unfreezing. The next step was changing the thoughts, feelings, and/or behaviors of the providers to introduce the revised practice guidelines. The final step was refreezing, which incorporates the changes and allows them to become the formal new standards of practice for all GDM patients (Kaminski, 2011).

Planned change was also applicable to the pregnant woman with the new diagnosis of GDM. During the unfreezing step the woman attended a class on GDM that addressed various challenges such as learning about diabetes, a new diet, and an exercise plan, and monitoring

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blood sugars and ketones. The next step was changing their behaviors and adhering to the new diet, exercise, and monitoring regimen as recommended by the DMP and the patients' obstetrician. The final step was refreezing, which allowed the women to accept the changes in diet and exercise and the monitoring of blood sugars and ketones as their new way of life. It was important for the mothers to understand the importance of continuing to watch their diet and to exercise to help prevent or delay the onset of Type 2 diabetes in the future.

The six sigma approach was utilized for program evaluation. In health care, it is important to include the patients' perspectives or opinions regarding programs. One method was to complete pretests and posttests to measure the effectiveness and/or satisfaction with the service provided. Six sigma utilizes the DMAIC methodology, which stands for define, measure, analyze, improve, and control. The process begins with defining the goal and overall scope of the project and then creating baseline evidence for comparison. The purpose of the next phase (measure) was to continuously monitor the performance and collect data that were used to analyze and interpret whether the performances and/or outcomes are as expected (analyze) or if change needed to be made (improve). The final stage (control) was to remove the actual cause of the problem so the focus could stay on the actual improvement (Brandyopadhyay & Coppens, 2005).

With regard to hyperglycemia in pregnancy, the six sigma approach provided the evaluation plan/tool to determine the effectiveness of the education presented to the project participants. Continuous clinical support and evaluation took place, whereas pretests and posttests were utilized to evaluate the patients' perceptions and knowledge related to the education intervention. On completion of data collection, I analyzed the data and determined recommendations for revisions to the guidelines as deemed necessary.

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Nature of the Project

The project used a pretest and posttest design in a convenience sample of women with GDM who were referred for an educational intervention and agreed to complete the education and the questionnaires. The pretest was completed on arrival for the first of three education sessions on meal planning, self-monitoring blood glucose, and self-monitoring daily urine for ketones, possible prescribed diabetic medications, and when to notify the physician. On completion of the education, the women completed the posttest and client satisfaction survey. The educator conducting the class reviewed the answers to the test to ensure appropriate understanding and to ensure a positive learning experience.

WMC is one of six nonprofit hospitals within Valley Health (VH). WMC is a designated magnet hospital with 445 beds and is located in Winchester, Virginia. In 2012, WMC reported 255 live births to women with GDM; in 2013, WMC reported 278 live births to women with GDM; and in 2014 WMC reported 373 live births to women with GDM. The 2013 and 2014 data demonstrate a significant increase in GDM prevalence at WMC if current GDM birth trends continue. The WMC cesarean section rate in 2012 was 33.2%, which is slightly higher than the national average of 32.8% (Martin, Hamilton, Ventura, Osterman, & Mathews, 2011). However, the cesarean section rate in 2012 for women with GDM was 44%. At Valley Health, both macrosomia and LGA rates are on the rise. Macrosomia rates increased significantly from 6% in 2011 to 11.6% in 2012 and 11% in 2013. In addition, LGA rates have increased from 25% in 2011 to 27.3% in 2012 and 27.7% in 2013. In 2012 at WMC, 27 neonates required treatment to address hypoglycemia, whereas in 2013 at WMC, 25 neonates required treatment for hypoglycemia. In 2012, eight of those neonates required admission to the NICU to manage serious complications associated with infant hypoglycemia and GDA and seven of those

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neonates required NICU admission in 2013. As LGA and macrosomia are not reportable statistics for neonates, no date is available for comparison on the state, regional, or national level.

Definition of Terms

Diabetes mellitus (*DM*) is a group of diseases that affect how the body uses glucose (Van Leeuwen et al., 2013).

Diabetes management program (*DMP*) is an outpatient diabetes program through WMC that provides education and other resources related to Type 1, Type 2, and gestational diabetes mellitus.

Fasting blood glucose (*FBG*) is a blood test after a minimum of 8 hours with no caloric intake. It is used to confirm a diagnosis of diabetes mellitus (Van Leeuwen et al., 2013)

GCK is a common genetic variant associated with high blood glucose levels (Freathy et al., 2010).

Gestational diabetes mellitus (*GDM*) is hyperglycemia first diagnosed in pregnancy (Ferrara, 2007).

Glycated hemoglobin (*HbA1C*) is the average blood glucose levels over the previous 3 months. It is used to monitor effectiveness of treatment over a long period of time (Van Leeuwen et al., 2013).

Large for gestational age (*LGA*) is birth weight greater than the 90th percentile for their gestational age (Ricci, Kyle, & Carman, 2013).

Macrosomia is birth weight greater than 4000 grams or 8 pounds, 13 ounces (Ricci et al., 2013).

Oral glucose tolerance test (*OGTT*) measures the body's ability to metabolize glucose. It is used to diagnose diabetes mellitus (LeMone, Burke, & Bauldoff, 2011).

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Multiparity is the birth of two or more children (Ricci et al., 2013).

Polyhydramnios is an excessive amount of amniotic fluid in the uterus (Mayo Clinic, 2011).

TCF7L2 is a common genetic variant associated with higher blood glucose levels (Freathy et al., 2010).

Project Assumptions

During the project, I presumed patient truthfulness and honesty in completion of the pretest and posttest questionnaires and client satisfaction surveys. I also presume provider compliance with the new guideline (see Appendix E) regarding the type and timing of the GDM screening. Using the new recommendations, I presumed providers would screen for GDM at the first prenatal visit utilizing HgA1C, which would lead to an earlier referral for intervention for those individuals with a positive hyperglycemia screening. In addition, interventions to improve glycemic control would also begin at an earlier point in pregnancy compared with the previously used guidelines.

Project Limitations

One main limitation of this project was related to the correctness of data being entered by the registered nurses (RNs) regarding the timing of glucose screening for GDM. The computer program is standardized, but if the RNs did not complete the screening section in its entirety, testing and results may be omitted therefore limiting the availability of data. Even though the diabetes class content was consistent, the presentation may vary based on the RN or dietician teaching the class; therefore, a second limitation may exist due to inconsistencies in client learning based on teaching styles. A third limitation was that the study population is a

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convenience sample. Therefore, generalization to the population was limited and selection bias was a possibility.

Evidence-Based Significance of the Project

Type 2 diabetes is serious chronic health issue affecting 25.8 million children and adults in the United States. One in every 400 children and adolescents has diabetes, which converts to 0.26% of persons under 20 years of age in this country having diabetes. Diabetes is associated with high levels of morbidity and premature mortality, contributing to 231,404 deaths in 2007. Complications associated with diabetes include heart disease, stroke, high blood pressure, blindness, kidney disease, neuropathy, and amputations (CDC, 2011). As a result of diabetes and the associated complications, the cost of health care in those diagnosed with diabetes is 2.3 times higher than in those without diabetes. In the U. S., the total cost of health care for diabetic patients was $245 billion in 2012 (American Diabetes Association [ADA], 2013).

GDM occurs in 2% to 10% of pregnancies, with 5% to 10% of those women being diagnosed with diabetes, usually Type 2, immediately after pregnancy (CDC, 2011). As the number of cases of GDM increases, the potential labor and delivery complications and medical costs associated with the necessary treatments for both the mother and the baby increase as well. In addition to the increase in labor and delivery complications, it is important to consider the increased risk to both the mother and the baby of developing Type 2 diabetes in the future. Approximately 50% of women with GDM will develop Type 2 diabetes within 5 years of pregnancy. Infants have an increased risk for obesity, impaired glucose tolerance, and Type 2 diabetes as children or young adults if their mother had GDM. Hyperglycemia during pregnancy and the development of Type 2 diabetes increase the need for follow-up during pregnancy and postpartum for both the mother and the baby to monitor for the onset of diabetes as well as

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recommended health behaviors to prevent or delay the onset of the disease. Additional resources will need to be available to manage the increased number women with GDM and the infants born to these women (Ferrara, 2007).

Implications for Social Change

Overt diabetes is a chronic disease linked to morbidity and premature mortality (CDC, 2011). Researchers have presented an increased risk for a mother with GDM to develop Type 2 diabetes within 5 years and current research has indicated a correlation between infants of GDM mothers also having an increased risk for developing Type 2 diabetes (Ferrara, 2007). Early screening and early intervention will help to reduce the baby's birth weight, which will help to prevent later issues with both obesity and the development of Type 2 diabetes in the child. In addition, the mother will have better control over glucose levels, which will reduce the amount of insulin the infant must produce, thereby reducing the risk for both the mother and the baby to later develop Type 2 diabetes. If hyperglycemia can be avoided, both the mother and the baby may be able to avoid Type 2 diabetes as well as all the complications associated with it. These changes will significantly reduce the societal burden related to preventable excess diabetes.

Summary

GDM is a common complication of pregnancy with many potential adverse outcomes for both the mother and the baby. Screening for hyperglycemia at the first prenatal visit will help to identify overt diabetes and GDM early in the pregnancy. This will allow the mother to participate in earlier interventions and to have improved glycemic control throughout the pregnancy (Metzger, 2010). Specific interventions included the three-day education sessions on meal planning, self-monitoring blood glucose, monitoring daily urine for ketones, and when to notify the physician.

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Section 2 will provide the results of an in depth literature review related to hyperglycemia in pregnancy. The literature review explores the research conducted regarding timing of screening for hyperglycemia and the results that indicate a positive screening. In addition, the literature review includes opinions and reviews of various governing bodies related to the new practice recommendations.

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Section 2: Review of the Literature

The problem addressed by this project was whether early identification and intervention consisting of education can improve the self-management and knowledge of pregnant women diagnosed with GDM. The current project established, in a clinic setting, new and consistent guidelines among Valley Health obstetricians for screening hyperglycemia in pregnancy to ensure that patients with GDM would be identified in the first trimester and begin education and other interventions/treatments earlier in gestation in a clinic setting. I evaluated the effectiveness of the education through pretest and posttest questionnaires. This section will discuss the literature search strategy, the theories utilized, and how the literature relates to current practice.

Literature Search Strategy

The search strategy objective was to identify published research articles related to hyperglycemia in pregnancy, focusing on timing and type of diagnostic screening. I conducted a standard search through Walden University's library for the literature review, which involved queries of MEDLINE, CINAHL, and the Cochrane Central Registry of Controlled Trials to identify relevant articles written in the English language. The search included key words such as *gestational diabetes mellitus*, *screening*, *hyperglycemia*, *pregnancy*, *diabetes*, and *HgA1C*. I used words individually and in combination to expand the search. Relevant organizational websites such as ACOG, AHRQP, IADPSG, and the USPSTF were also included in the literature review to access specific organizational interpretations, reviews, and position statements with regard to screening for hyperglycemia in pregnancy.

Eleven quantitative research articles and 13 reviews, summaries, and clinical practice articles were included in the literature review. Nine of the articles were longitudinal case-controlled studies, one was a randomized controlled trial, and one was a descriptive study.

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Approximately 17 identified articles were not included in the literature review due to lacking relevance for screening for hyperglycemia in pregnancy or educational interventions related to GDM. Specifically, articles were excluded due a focus on the effects of obesity and GDM rates as well as a focus on inpatient treatment and/or inpatient education.

Theoretical Model

When considering practice change theories, Kurt Lewin's planned change theory was the optimal choice due to the project affecting change in practices of the obstetric staff, the certified diabetes educators (CDEs), and the patients. Change often creates social conflict, and Kurt Lewin believed that the key to resolving social conflict was planned change through learning. Planned change enables those involved to understand the purpose and to evaluate the effect of change in their world. Lewin's planned approach included four elements: field theory, group dynamics, action research, and a three-step model of change. Lewin believed that the current state of a group of individuals, also known as status quo, is a result of the group environment or field. The field is responsible for the perceived individual behaviors represented within the group. When dealing with change, the focus in group dynamics should be on what is best for the group as a whole versus the interests of any one individual. It should use the group to pressure any isolated individual to conform to ensure the focus of change remains at the group level. In action research, the success of change relies on the ability of individuals to understand their environment and the effect change will have. Action research involves a process of research causing action, which leads to evaluation and further action. Action research utilized field theory and group dynamics to understand group behaviors as the success of change requires participation and collaboration of the group members involved.

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The final element of Lewin's planned change through learning involves the three-step model of unfreezing, moving, and refreezing. Unfreezing is a challenging process that refers to disturbing the current state or equilibrium and discarding old behaviors to provide the opportunity for new behavior to be adopted. As unfreezing opens the door to change, the moving step identifies and evaluates the forces at play and determines the most suitable options to move the group toward the new behaviors. The final step, refreezing, establishes a new state of equilibrium that includes the newly learned behaviors. When looking at change in a group or organization, the refreezing step includes changing the culture, norms, policies, procedures, and practices (Burnes, 2004).

With any change, time must be allowed for individuals to process the thought of change and consider the implications, while being nudged in the direction of the proposed change. Educating all parties to the change in practice or behavior is the second phase and must be comprehensive to ensure comfort, competence, and participation. Through field theory, group dynamics, and the three-step model, equilibrium is disrupted to allow for change to take place and then re-established during the refreezing step, which helps to ensure forward progress continues toward project goals and objectives (Burnes, 2004).

Literature Review Related to Methods

The literature review will demonstrate the previously mentioned screening test controversy among the governing bodies, physicians, and healthcare professionals invested in the care of women with hyperglycemia in pregnancy. Various studies address the debate of who to screen, when to screen, and what test to utilize, whereas others focus on where the diagnostic criteria should be set for diagnosing GDM and/or overt diabetes. Additional studies focus on the potential complications, immediate adverse outcomes, and long-term overall health outcomes for

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both the mother and the infant. Several reviews of the current literature are provided not only to summarize and establish the continued controversy, but also to identify the gaps in research remain.

Longitudinal Case-Control Studies

The first of eight longitudinal case-control studies was conducted by the Hyperglycemia and Adverse Outcomes (HAPO) study (2008) "to clarify the risks of adverse outcomes associated with various degrees of maternal glucose intolerance less severe than that in overt diabetes mellitus" (p. 1,991). The study included 25,505 women at 15 centers in nine countries. The study determined that LGA and infant hyperinsulinemia were strongly associated with maternal hyperglycemia, but cesarean section, neonatal hypoglycemia, premature delivery, shoulder dystocia or birth injury, NICU admission, and preeclampsia also showed linear associations with the 1-hour plasma glucose level, the 2-hour plasma glucose level, and the FBS. Essentially, the study determined the need for current diagnostic criteria to be revised due to significant associations with adverse outcomes and higher than expected levels of hyperglycemia in pregnancy among those currently considered nondiabetic (HAPO, 2008).

The HAPO study (2008) was also conducted to determine if two specific common genetic variants GCK and TCF7L2 were associated with hyperglycemia of pregnancy in European and Asian women as they are in non-pregnant diabetic women of European and Asian ancestry. The study determined that the GCK was associated with a higher FBS in both European and Asian women, while the TCF7L2 was associated with higher FBS and OGTT testing results in only the European women. In addition, according to the new IADPSG recommendations, both the GCK and the TCF7L2 were associated with higher odds of GDM in both populations (Freathy et al., 2010).

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Another study from HAPO (2012) was conducted to evaluate the association of GDM and obesity with adverse pregnancy outcomes. Ultimately, the study determined that both GDM and obesity were independently associated with adverse pregnancy outcomes such as primary cesarean section, preeclampsia, and fetal hyperinsulinemia. In addition, when GDM and obesity are combined, the relationship significantly increases and also includes an increased prevalence of shoulder dystocia (Catalano et al., 2012).

A study by O'Sullivan et al. (2011) was conducted to evaluate the effect the new diagnostic criteria defined by the IADPSG when compared to the previous WHO criteria would have on the prevalence and the outcomes of GDM in a predominantly European population. A total of 5,500 women were given an OGTT between 24 and 28 weeks gestation and, based on the IADPSG criteria, 12.4% of the participants were diagnosed with GDM compared to 9.4% with the WHO criteria. In addition, the IADPSG GDM participants were also associated with a significant increase in adverse maternal and neonatal outcomes compared to the WHO participants. One particular limitation of this study was that treatment for hyperglycemia was determined by the WHO criteria not the IADPSG criteria. The study was not intended to evaluate hyperglycemia management, but it must be considered when determining the validity of the data (O'Sullivan et al., 2011).

A study by Katon, Reiber, Williams, Yanez, and Miller (2012) was conducted to determine if there was an increased risk of delivering a LGA or macrosomic infant based on the timing of the HbA1C. The study included 502 women and determined no trend of increased LGA or macrosomia infant births based on the timing of the HgA1c or the diagnosis of GDM. However, there was limited evidence of increased risk of delivering a LGA or macrosomia infant among women in the highest quartile of HbA1C levels at diagnosis when compared to those

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women in the lowest quartile of HbA1C at diagnosis. In addition, when women of Asian, Indian, or other race/ethnicity were excluded, there was a trend of increased risk of LGA or macrosomia associated with higher HbA1C quartile at time of diagnosis. It is also important to note an important limitation of this study was not including the effect of aggressive hyperglycemia management on the overall results of this study (Katon et al., 2012).

A study by Cavassini, Lima, Calderon, and Rudge (2012) was conducted to estimate the cost-benefit relationship and social benefit of treating women with hyperglycemia in the hospital compared to outpatient care. The study determined that successful treatment of GDM avoided costs and that outpatient management was more cost effective than hospitalization. The study divided the patients into groups based on diet therapy or diet and insulin therapy. However, there was no consideration for approved medication protocols in combination with diet therapy in the outpatient category, which demonstrates a limitation to the study (Cavassini et al., 2012).

In 2012, a study by Mehta, Kruger, and Sokol was published that evaluated whether hyperglycemia in pregnancy was a risk factor for childhood obesity. Data were collected from 493 inner-city, African-American children between the ages of 2 and 5 and their mothers. The study did show that children born to diabetic mothers were more likely to be obese and when other covariates associated with diabetes were included in the model, both diabetes and maternal pre-pregnancy BMI demonstrated a significant correlation to childhood obesity. One other factor to consider is the relationship of LGA in the model because when LGA was added into the equation, diabetes was no longer significant in childhood obesity. However, the authors of the study suggested that LGA is affected by diabetes in utero, therefore, having an indirect relationship with childhood obesity (Mehta et al., 2012).

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Other Studies

A randomized controlled trial was conducted by O'Connor et al. (2012) to determine if trimester-specific references for HbA1C should be utilized in pregnancy. A total of 311 non diabetic Caucasian pregnant and non-pregnant women were included in the study. The study was able to establish a reference interval of 4.8% to 5.5% for the healthy, non-pregnant woman, which is consistent with a previous study by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC); however, the study also determined that this was not an appropriate reference interval to be utilized in pregnancy. In pregnancy, trimester-specific HbA1C reference intervals were shown to be the appropriate method to manage GDM, prevent complications associated with diabetes, or both. A normal reference interval for HbA1C in a non-pregnant woman was determined to be 4.8% to 5.5%. The normal reference intervals for HgA1c during pregnancy were determined to be 4.3% to 5.4% in the first trimester, 4.4% to 5.4% in the second trimester, and 4.4% to 5.4% in the third trimester (O'Connor et al., 2012).

Dall et al. (2011) conducted a quasi-experimental study to evaluate the association of health care use and cost with the intensity of participation as well as prior uncontrolled diabetes among their TRICARE DMP participants. A total of 37,370 participants ranging from 18 to 64 years of age were included in the study. Women were included if they had any diabetes-related emergency department visits, hospitalizations, or more than twenty 30-day prescriptions for diabetic medications in the previous year. The study determined that participation in the DMP was cost effective, especially for the uncontrolled diabetics, and that active program participation demonstrated a larger reduction in inpatient days and emergency department visits. With program participation, inpatient days and emergency department visits decreased, while

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outpatient visits, retinal examinations, HgA1c tests, and urine microalbumin tests increased in comparison to those of the control patients (Dall et al., 2011).

A descriptive study was conducted by Dijk et al. (2011) to evaluate what effect total healthcare utilization had on Type 2 diabetes patients that is actually disease specific and could be utilized in the development of a disease management program. Essentially, it was determined that any program should be developed to assist the patient in coordinating care not to replace coordination by the patient. In addition, it was determined that a disease management program should focus on all chronic diseases not just diabetes, especially since many diabetics also have other chronic conditions such as heart disease and chronic obstructive pulmonary disease (Dijk et al., 2011).

Opinions, Reviews, and Summaries

The IADPSG was formed in 1998 to facilitate collaboration among regional and national groups focusing on diabetes and pregnancy in an attempt to enhance quality of care by facilitating research and advancing education related to diabetes in pregnancy. In 2008, a workshop was sponsored by the IADPSG to review published and unpublished HAPO study findings and other works that were related to hyperglycemia in pregnancy and infant and maternal outcomes. A consensus panel was convened and further reviewed the HAPO study. A consensus detection strategy for hyperglycemia in pregnancy was reached. The panel recommended a two–phase approach. During the first phase, all or only high risk women complete a universal screening (FBS, RBS, or HbA1C) at their first prenatal appointment utilizing tighter diagnostic criteria such as a RBS of < 92 mg/ dL versus < 95 mg/dL. The results indicate overt diabetes, GDM, or moving to the second phase. The second phase consists of a fasting 75 gram, 2-hour OGTT between 24 and 28 weeks gestation for all women with a normal

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screening at their first prenatal visit or the woman who has received no screening to date for hyperglycemia in pregnancy. The results again can indicate overt diabetes, GDM, or a normal value. The consensus panel acknowledged that further research will be needed to determine the cost effectiveness of treatment for GDM utilizing the IADPSG criteria, optimal glycemic targets, appropriate follow-up of the mothers to evaluate for later development of Type 2 diabetes, and follow-up of children to evaluate associations of maternal hyperglycemia with obesity and altered glucose metabolism (IADPSG, 2010).

A mini review by Hadar, Oats, and Hod (2009) discussed the various controversies surrounding GDM. Much of the controversy evolves from the lack of correlation in diagnostic criteria to maternal and infant outcomes. The HAPO study was designed to answer some of these controversies and, essentially, this mini review concluded that the HAPO study had already provided answers to many of these controversies. Ultimately, the HAPO study demonstrated that FBS and post 75 gram, 2-hour OGTT correlate to maternal, perinatal, and neonatal outcomes. Based on this review, it is predicted that international recommendations using these criteria for GDM diagnosis will soon be published (Hadar et al., 2009).

The USPSTF conducted a systematic review to test the various screening methods for GDM utilizing a range of glucose threshold recommendations. Two reviewers extracted and reviewed data from 51 cohort studies. Ultimately, the review confirmed both a FBS and an OGTT are good at identifying women who do not have GDM, but the OGTT was better at identifying women who do have GDM. However, data are minimal for screening prior to 24 weeks gestation, nor has any validation taken place utilizing the new IADPSG recommendations (Donovan et al., 2013).

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In 2011, the American College of Obstetric Practice (ACOG) released a committee opinion with their recommendations for GDM screening and diagnosis. ACOG recommended that all women be screened for GDM, but the screening may be conducted by patient history, clinical risk factors, or a 50-gram, 1-hour OGTT between 24 and 28 weeks gestation. Further, ACOG continues to recommend the two-step approach utilizing the 50-gram, 1-hour OGTT followed by the 75-gram, 2-hour OGTT to confirm GDM diagnosis compared to the 1-step approach utilizing the 75-gram, 2-hour OGTT proposed by the IADPSG recommendation to simplify the process for screening and diagnosing GDM (The American College of Obstetricians and Gynecologists, 2011).

Buckley et al. (2011) reviewed the literature to evaluate the relevance of GDM, current screening practices, and barriers to screening in Europe. The review determined a GDM prevalence rate of 2% to 6%, which fluctuated based on patient location. Screening practices vary across Europe due to inconsistent guidelines for testing methods, diagnostic glycemic thresholds, and the value of routine screening. In addition poor clinician awareness of GDM, the GDM diagnostic criteria, and variations in local guidelines also affect the detection of GDM (Buckley et al., 2011).

An article by Ryan (2011) discussed the effects of the newly proposed diagnostic criteria which are recommended by the IADPSG. The author suggested the criteria will increase the prevalence of GDM to 17.8%, which is double the current number of women with GDM. In addition, the majority of women with LGA have normal glucose levels during pregnancy based on the criteria and the stronger predictor of LGA is maternal obesity. It is estimated using these criteria that the GDM diagnosis would prevent an estimated 140 cases of LGA, 21 cases of shoulder dystocia, and 16 cases of birth injury out of over 23,000 pregnancies (Ryan 2011). The

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author did not find the OGTT to be a reliable test for diagnosing mild hyperglycemia. Based on these three factors, further debate should take place prior to implementing the proposed recommendations (Ryan, 2011).

A review article by Cundy (2012) discussed new recommendations from the IADPSG for diagnosis of GDM. Cundy (2012) questioned much of the research with regard to the extent to which GDM affects particular outcomes such as cesarean section and the risk for future development of Type 2 diabetes for both the mother and the infant. Cundy (2012) raised another question as to the direction of research being focused on hyperglycemia in pregnancy when possibly the focus should shift to maternal obesity. In conclusion, Cundy (2012) strongly recommended that providers review the IADPSG criteria and compare the benefits to the risks and costs associated with early universal and lower levels of detection, which will increase the number of GDM diagnoses.

Hagar and Hod (2010) reviewed the process of GDM from defining the problem to the end point of possibly achieving a world-wide policy change. GDM is associated with poorer maternal and neonatal outcomes as well as morbidity. There is also speculation that long-term exposure to hyperglycemia in utero may predispose the infant to obesity and diabetes later in life. Current diagnostic criteria are more than 40 years old and were often based on non-pregnant populations. The major issue is the lack of correlation of the criteria to actual maternal and neonatal outcomes. The elusive questions are what is the true diabetic threshold for hyperglycemia in pregnancy and at what point is there a risk to the fetus? There are numerous other factors that can affect the health of the fetus such as maternal age, weight, hypertension, previous GDM, macrosomia, and other medical complications. In addition, there is the risk of under diagnosis of diabetes with the current criteria that may lead to avoidable adverse

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outcomes. Controversy also revolves around screening or not screening as well as when to screen and what type of screening to utilize. The HAPO study was conducted to help answer some of these questions. The IADPSG reviewed multiple studies, including the HAPO study, and developed a strategy for detection and diagnosis of hyperglycemia in pregnancy. The recommendations focused on early testing at the first prenatal visit to detect overt diabetes as well as on those women who are at high risk for developing GDM. The second phase focused on the remaining non GDM population and recommended a 75-gram, 2-hour OGTT between 24 and 28 weeks gestation. At some point, another form of testing may be developed that is simpler and more cost effective than the OGTT. Ultimately, these recommendations if put into practice will increase the frequency of a GDM diagnosis (Hagar & Hod, 2010).

The AHRQ (2012) conducted a literature review to evaluate current screening tests for GDM, time of screening, various diagnostic thresholds, and to determine if modifying treatment will have an effect on outcomes for those diagnosed with GDM. The review was also searching for previous evidence gaps that have been resolved. These gaps included determining if maternal and fetal complications were reduced by screening, lack of screening studies to evaluate health outcomes, evidence regarding accuracy of screening, and insufficient evidence that treating GDM would improve health outcomes. Five key questions were developed to synthesize the evidence found and to provide information as treatment guidelines were developed. They reviewed studies published between 1995 and 2012, which included 14,398 citations and 97 studies. The review determined that there are limited data to clarify issues regarding the timing of screening, before or after 24 weeks gestation, and treatment for GDM. In addition, the evidence also fails to establish a clear threshold regarding diagnostic criteria for GDM. The study did acknowledge the importance of identifying overt diabetes even if in pregnancy and that

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it should not be considered GDM to help identify the true risk of GDM for pregnancy outcomes; however, there are no diagnostic criteria to diagnosis overt diabetes in pregnancy. The evidence found also was not sufficient to provide evidence that there is a direct link between macrosomia and childhood obesity. The review identified several gaps in the current literature that need to be clarified to determine the true effect of maternal hyperglycemia on long-term metabolic outcome, and the true effect of GDM treatment on outcomes, especially if initiated before 24 weeks gestation. In addition, there was emphasis on the need to identify how to diagnose and treat the overt diabetic who is diagnosed during pregnancy. The goal of the review was to fill in gaps in the research but, ultimately, found there are still several important gaps in need of clarification in order to resolve the current controversies so that global diagnostic screening criteria and management of hyperglycemia in pregnancy can be established (AHRQ, 2012).

In 2010, the Joslin Diabetes Center and Joslin Clinic published guidelines for detection and management of diabetes in pregnancy. The purpose of the guidelines was to assist physicians in establishing individualized plans for hyperglycemia in pregnancy. The guidelines were established after a review of the current literature, current practice, and clinical practice with the goal of improving pregnancy outcomes. The guidelines outlined care for pre-existing diabetes, GDM, nutritional therapy for both pre-existing diabetes and GDM, and post-partum care. The Joslin Center recommendations included universal screening for all pregnant women at the first prenatal visit with a FBS, RBS, or HbA1C unless they are identified as high risk. If high risk, the woman will complete a 75-gram, 2-hour OGTT as soon as possible (Joslin Diabetes Center, 2010).

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Diabetes Management Reviews

Abayomi, Wood, Spelman, Morrison, and Purewal (2013) provided an overview of a multidisciplinary approach for the management of Type 2 diabetes and GDM in pregnancy. The first step in a multidisciplinary approach is pre-conception care, which is lacking for a large number of women. They found that less than 17% of the maternity clinics offered a structured, multidisciplinary service for pregnant women that includes information on glycemic control, diet, contraception, supplementation, and alcohol-related complications. It was determined that all women with diabetes should have access to a multidisciplinary team which included an obstetrician, a diabetes physician, a diabetes specialist nurse, a diabetes specialist midwife, and a dietician. Women with Type 2 diabetes and GDM should be referred for education and followed very closely throughout the pregnancy to ensure optimal glycemic control and outcomes for both the mother and the baby. The team will be important during the delivery and post-partum phases as well to ensure optimal care and outcomes. Prior to discharge, it will be very important to provide contraception and follow-up information to prevent another pregnancy as well as ensure monitoring for future development of Type 2 diabetes. With increasing numbers of metabolic disorders, the multidisciplinary approach will help to ensure optimal care is provided to meet the needs of the woman with hyperglycemia in pregnancy (Abayomi et al., 2013).

The Project Dulce model combined pieces of the chronic care model and the medical home model to create primary homes where these models could be integrated and implemented to improve outcomes associated with chronic diseases such as diabetes. Project Dulce used a patient registry to identify patients at risk for diabetes, and then trained diabetes registered nurses (RN/CDEs) to lead a multidisciplinary team to provide evidence-based care in community health centers. Registered dieticians, medical assistants, and peer educators combined with the RNs to

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make up the multidisciplinary team. Ultimately, this was a nurse-driven approach to chronic care management in the community setting for the underserved "at risk" populations. The nurse driven approach was not only economical and effective, but it has demonstrated significant improvement in diabetes and overall health outcomes (Philis-Tsimikas et al., 2012).

The nurse's role in managing the overall care of diabetics is growing, especially as the number of patients affected by diabetes continues to climb. Nurses can provide tools and strategies to help empower many diabetics who often feel hopeless. Improving glycemic control can be obtained through education by teaching the diabetic patient how to live with and successfully manage their diabetes every day while living their life. In addition, nurses are the largest population of healthcare providers and, therefore, will come in contact with more patients across the spectrum of healthcare. As a result, nurses must participate in all aspects of diabetes from screening to treatment. Education will play a vital role in all phases. Nurses educate about the disease, how to test and monitor blood sugar levels, how to treat both high and low blood sugar levels, how to make adaptations in diet and exercise, and how to manage the disease on a daily basis. In addition, nurses play an important role in the monitoring of diabetic patients with not only their blood sugar levels but also with ensuring appropriate physician follow-up and testing related to their diabetes (Peimani, Tabatabaei-Malazy, & Pajouhi, 2010).

Context of the Project

WMC is a 445-bed, nonprofit hospital and Level 2 trauma center located in Winchester, Virginia, which serves over 400,000 residents in Virginia and parts of West Virginia and Maryland. WMC is a Magnet-designated hospital and 1 of the 6 hospitals within the non-profit organization known as VH (Valley Health, 2014). In addition to the 6 hospitals, VH has 3 urgent care centers, 1 quick care, center, 1 surgi-center, and Valley Regional Enterprises, Incorporated,

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which includes Valley Home Care, Valley Medical Transport, and Valley Pharmacy. In 2012, VH had 30,000 inpatient admissions, over 140,000 emergency room visits, approximately 800,000 outpatient visits, and more than 2,600 births (Valley Health, 2014).

All hospitals within VH share the same mission and vision. The VH mission is "Serving Our Community by Improving Health" and the vision is "One System - One Purpose: Leading with Innovative Healthcare" (Valley Health, 2014, para. 1). Diabetes Management Programs are established at all six VH hospitals, ADA certified, and share the same mission to " . . . serve our regional community by educating and supporting individuals with, or at risk for diabetes and their family members." The DMPs offer outpatient services provided by CDEs such as medical nutrition therapy, diabetes education, gestational diabetes education, and individual consultations (Valley Health Intranet, 2014, para. 1).

Governing Bodies

Health care is dictated by several governing agencies that establish practice recommendations and guidelines, as well as provide national benchmarks for healthcare organizations to meet or exceed. A few of the organizations affecting pregnancy and labor and delivery include the Joint Commission (TJC), Medicaid and Medicare Services (CMS), ACOG, and the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN). In addition to governing bodies affecting healthcare and patient outcomes, healthcare reform continues to play a role in clinical practice and the development and/or revitalization of current programs (AWHONN, 2013).

Healthcare reform is centered on improving patient outcomes as well as increasing overall productivity of healthcare in general. As a result, the AWHONN has been challenged to develop nursing care quality (NCQ) measures that are aimed at improving patient outcomes. An

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advisory panel was convened in 2012 to develop the NCQ measures that are currently being distributed for review. Many of the NCQ measures align with other governing organizations; however, the NCQ measures focus on how nursing may affect patient outcomes and quality of care (AWHONN, 2013).

Stakeholders

Stakeholders are individuals who have a vested interest in the project and who can help to ensure it is accurate, relevant, and useful (AHRQ, 2011) Key stakeholders identified in this project include the CDEs, obstetric providers (physicians, nurse practitioners, and registered nurses), maternal and fetal medicine physicians, and the WMC senior leadership. Senior leadership specifically involved in the project consisted of the interim director of the DMP, the director of the Chronic Disease Resource Center, the physician liaison for the DMP, the executive director of medicine, the executive director of women and children, and the physician liaison for pregnancy outcomes.

Practicing as a medical/surgical nurse has provided me with extensive opportunity to work with diabetic patients and witness firsthand the struggles of management while hospitalized. Based on this experience, when the opportunity arose to participate in a committee challenged to improve glycemic control for the inpatient population, I was quick to volunteer as the educator on the committee. While on this committee, I had the opportunity to implement a change in clinical practice regarding the approach to inpatient glycemic control from a sliding scale approach to a basal-bolus approach. Basically, the new basal-bolus order set took a proactive approach to treating diabetes compared to the sliding scale reactive approach. In addition, the committee determined the need for registered nurse diabetes champions on every unit. A conference was developed to educate nurses on diabetes and their role as a champion. As

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a result of working on this committee, it was clear that I wanted to do a DNP project related to diabetes.

The project needs of the DMP were discussed and, after researching each of the topics, this researcher was curious about GDM as well as surprised at the amount of controversy among the governing bodies. Therefore, this researcher felt the need to develop a project aimed at improving outcomes related to GDM. I participated in the literature review to determine the best practices in screening and the diagnostic criteria for GDM as well as the revision of the Center's guidelines and the presentation to the obstetricians for feedback and approval. I also assisted in content review for the three-day education sessions as well as the development and piloting of the pretest and posttest questionnaires and the client satisfaction survey. Previous experience as an educator at WMC has been instrumental in navigating the computer system, identifying resources, reviewing policies/procedures, and questioning clinical contacts, while expanding my knowledge of obstetrics.

Summary

Controversies remain on how to diagnose and manage hyperglycemia in pregnancy. Gaps in research continue to exist especially with regards to the effects of early screening, how to diagnose and manage the undiagnosed overt diabetic, and the effects of GDM on adverse outcomes and future health outcomes. There was much support in the organization for the new IADPSG guidelines to screen all women at the first prenatal visit and to lower the diagnostic criteria threshold from greater than 95 mg/dL to greater than 92 mg/dL. However, there were some concerns with the implications for healthcare and women. The concerns include the implications of early screening, increased numbers of GDM diagnoses, and the financial implications. Nurses play an important role in chronic care management but especially in

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diabetes care. Many diabetes programs are nurse-led and play a vital role in the overall management of diabetes but also of the patient's overall health. This project will help establish the effectiveness of GDM education provided through one-on-one consultation and classroom education provided by CDEs.

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Section 3: Methodology

The purpose of this project was to use the newly established guidelines in a clinic setting for screening hyperglycemia in pregnancy to ensure that patients with GDM will be identified earlier and will be able to begin education and implement other interventions/treatments earlier in gestation. This paper discusses the project approach, sample, and participants, and it outlines the step-by-step data collection process. In addition, a budget and a program evaluation plan are provided.

Approach and Rationale

Six sigma methodology was created by Motorola, but it has been adopted and utilized throughout health care. Six sigma provides a well organized and systematic approach for process improvement that revolves around statistics and scientific methods to facilitate necessary change. The philosophical underpinnings of the six sigma approach include problem identification, measurement, statistical analysis, improvement, and controls. Within health care, six sigma has been utilized to facilitate change in programs regarding hand hygiene compliance, surgery turnaround times, clinic appointment access, catheter-related bloodstream infections, antibiotic prophylaxis in surgery, meeting Centers for Medicare and Medicaid Services cardiac indicators, nosocomial urinary tract infections, and operating room throughput. The broad applicability of the six sigma methodology allows for easy adaptability and adoption (Vest & Gamm, 2009).

Six sigma utilizes the DMAIC methodology, which stands for define, measure, analyze, improve, and control. The process began with defining the goal and overall scope of the project and then created baseline evidence for comparison. The next phase was to monitor the performance continuously and collect data that was used to analyze and interpret whether the performances and/or outcomes wee as expected or if change need to be made. The final stage

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was to remove the actual cause of the problem so the focus can stay on the actual improvement (Brandyopadhyay & Coppens, 2005).

With regard to this project, the six sigma approach provided the evaluation plan/tool to determine the effectiveness of the 3-day education program completed by the project participants. Continuous support and evaluation took place for the CDEs and pretests and posttests were utilized to evaluate the patients' perceptions and knowledge. The methods to gather patient data included completion of pretest and posttest questionnaires to measure the effectiveness of the educational intervention and a survey to determine satisfaction with the education provided. On completion of data collection, I analyzed the data and determined recommendations for revisions to the education program.

Project Setting and Sample Population

Regardless of the controversies about screening tests, the guidelines for hyperglycemia in pregnancy at WMC were in need of revision as they were based on a combination of 1999 recommendations from ACOG, the International Diabetes Center, and the ADA. At that time, the recommendations were to screen pregnant women between 24 and 28 weeks gestation with a 50-gram glucose challenge; however, if the woman had one or more risk factors, it was recommended to screen for GDM at the first prenatal visit. In addition, the practice physicians were not using consistent glucose levels to diagnose GDM; therefore, another goal was to establish standardization among glucose levels for diagnosing a pregnant woman with GDM within the clinic. While working closely with the interim director of the DMP and the physician liaison for maternal and fetal outcomes, new guidelines were established based on the review of the literature, opinions of the team, and the population trends. The ultimate goal was to identify pregnant women early in their pregnancy to provide early referral for nurse-led education that

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could play a role in improving the overall health outcomes for the mothers and their unborn children. Expected project outcomes were established to reflect the effectiveness of the nurse-led education by evaluating the knowledge gained by the participants regarding when to contact their physician for abnormal blood sugar results and appropriate dietary choices.

The population was one of convenience and included all pregnant women referred by a local obstetrician to the DMP with an abnormal glucose result. For the women to be included in the study, they completed a GDM consultation with a CDE and completed the 3-day education. Previously diagnosed Type 1 and Type 2 diabetics were excluded from the population sample as well as women who do not complete the consultation and education requirement. The goal was to have a minimum sample population of 30 women. The post-implementation population included all women who attended the GDM class during a 6-week period after Institutional Review Board (IRB) approval in February 2015.

Participants

Key participants in this project included the CDEs, obstetric providers (physicians, nurse practitioners, and registered nurses), maternal and fetal medicine physicians, and WMC senior leadership. In the infancy stages of the project, it was presented to the CDEs at the monthly Gestational Council meeting. The goal was to solicit feedback as well as cooperation as the project moved forward. Several meetings took place with the maternal/fetal medicine physicians to revise the hyperglycemia in pregnancy guidelines due to the current guidelines no longer being consistent with national practice recommendations. The revised guidelines were presented to the obstetricians (OB) for review at the monthly department meeting by the physician liaison for pregnancy outcomes. In October 2013, the guidelines as well as a timeline for implementation were presented at the OB department meeting for formal adoption in January

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2014. The DMP interim director and the Director of the Chronic Disease Resource Center were key participants in the project and played an integral role in access to the physicians, CDEs, and patient information. Meetings have also taken place with the Director of Women and Children Services and the Executive Director of Medicine to discuss the project, current data collection plans, and concerns with maternal hyperglycemia and infant hypoglycemia outcomes. The new guidelines were implemented January 1, 2014.

Stakeholders

An open relationship was established early on with many of the stakeholders to ensure optimal success. The CDEs, OBs, fetal and maternal specialists, and the nurses and office staff played an integral role in the effectiveness of the project and improving patient outcomes. Attendance at the OB departmental meeting to discuss and present the timeline for implementation allowed the OBs an opportunity to discuss concerns or suggest possible revisions. In addition, I offered to hold in-services for the OBs and their office staff to provide education on the new guidelines as well as how to facilitate a smooth transition with the changes. I attended the OB departmental meeting in April 2014 to follow-up after the first quarter of project implementation of the guidelines.

Data Collection

Pretest and posttest questionnaires were used to collect data from women with a diagnosis of GDM who participated in the educational session to evaluate the comprehension of class material regarding when to notify their physician with blood sugar readings as well as the necessary changes to their diet. The pretest and posttest questionnaires are provided in Appendix F. Walden University IRB approval was obtained prior to data collection.

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Reliability and Validity

In order to establish survey reliability, the CDEs who are considered content experts reviewed the pretest, posttest, and satisfaction survey and provided feedback for revision. After the pretest, posttest, and satisfaction survey were deemed appropriate, the questionnaires were given to the GDM patients in December 2013 to establish validity prior to the new guidelines being implemented in January 2014. The validity testing timeline was extended through March 2013 as the patient population was very limited due to inclement weather, the holidays, and the relocation of the DMP. In April 2014, the completed pretests and posttests were evaluated by the CDEs and me with regard to the clarity of the questions, patient success in completing the surveys, and written comments. Based on the evaluation, the wording and/or answers were changed on two of the questions to prevent any confusion. Steps to limit threats to reliability and validity included having a consistent group of CDEs involved in the project from the beginning as well as testing the instrument prior to full implementation. A copy of the initial pretest/posttest is attached in Appendix D and the final version of the pretest/posttest is attached in Appendix F.

Data Collection Process

Currently, a pregnancy assessment is completed during a one-on-one consultation with a CDE that includes questions regarding type and timing of GDM screening, medical and pregnancy history, family history, and current diet to include food and beverages consumed on a daily basis. The consultation also includes a nutrition consultation to determine caloric needs based on pre-pregnancy BMI, weeks of gestation, and presence of multiples. This assessment provided data related to physician compliance with the new GDM screening guidelines of conducting an HbA1C at the first prenatal visit.

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The patients with GDM will also attended a class that includes education on diabetes, blood glucose and ketone monitoring instructions, food and beverage choices, and guidelines for physician notification. The patients completed the pretest and posttest as part of the GDM classes, which will provide the data for patient knowledge regarding when to notify the provider of abnormal blood glucose values as well as the data necessary to determine comprehension of nutrition educational content. No patient demographic data will be collected. The data as well as best practice recommendations will be presented to the stakeholders. The plan was to present the data to the CDEs and the Executive Directors' of Medicine and Women and Children.

Performance measurement was an ongoing process that began at implementation and continued throughout the project to ensure success as identified through improved health outcomes for the mother and the baby. During the month of January (2014), informal checks took place with the CDEs as well as the obstetric providers to monitor compliance with the new guidelines and to provide support through the change. In April 2014, feedback was formally solicited at the obstetric department meeting.

The short-term effect of the project was to increase patient understanding of GDM self-management during their pregnancy. The intermediate effect of the program was to improve glycemic control of pregnant mothers throughout their pregnancy in order to decrease pregnancy complications such as LGA, macrosomia, and infant hypoglycemia rates. Long-term health benefits are related to a decrease in risk for future development of Type 2 diabetes for both the mother and the infant as well as a decreased risk of childhood obesity (Metzger, 2010).

Data Analysis

Data from the pretest and posttest questionnaires and the patient satisfaction survey was entered into SPSS and was analyzed using descriptive statistics such as frequencies and

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percentages. A *t* test was used to determine if posttest scores were significantly higher than pretest scores on the self-management knowledge questionnaire.

Resource and Time Restraints

The initial resource constraint could be due to providers not following the new guidelines and not conducting screenings for GDM at the first prenatal visit. A later screening would delay a referral for education and intervention and reduce the number of participants. The GDM classes were to be held six times a month which also limits the possible number of participants as each class is limited to eight women. In addition, the participants must actually show up for their consultation and class before they can be included as participants. Unfortunately, people were no shows on a regular basis causing class sizes at times to be very small. In 2013, 121 women did not show for the class, and in 2014 119 women were no shows for the classes. All participants who attended a GDM consultation and education class were invited to participate, with a goal of recruiting at least 30 participants. Time constraints were a final issue due to the timeline of the DNP program.

Budget

In order to start an education program for GDM, a budget was established. Due to the classes being in an existing outpatient DMP office, the actual startup costs were minimal. Initial purchases for computers, copier, AV equipment, desks, telephones, and office supplies were not be necessary as the outpatient office already exists; however, actual expenses included both labor and materials. Labor included office staff and CDEs. The material expenses included office supplies such as paper, folders, pens, pencils, and flow sheets as well as snacks such as peanut butter, crackers, milk, juice, and water for the clients who attended the education class The

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majority of the educational material were provided free of charge by various pharmaceutical companies and the National Institute of Health.

Table 1

Proposed Budget

Revenue	Consultation fee	Class fee	Revenue per month	Semiannual revenue
Insurance and mdicare	$80	$180	$9,360	$56,160

Expenses	Per class	Hours Per month	wage	Expenses per month	Semiannual expenses
Office employees	2	24	$11	$528	$3,168
CDEs		56	$34	$1,904	$11,424
Total labor				$2432	$14,592
Snacks				$10	$60
Office supplies	1			$36	$216
Total material				$46	$276
Uninsured patients				$1,560	$9,360
Total expenses				$4,152	$24,912

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Table 2

Profit/Loss

	Month	Semiannual
Total revenue	$9,630	$56,160
Total expenses	$4,152	$24,912
Profit/(loss)	$5,478	$31,248

Classes were held every Friday and every other Tuesday equaling six classes per month with an average of six clients per class for a total of 36 women per month. The uninsured clients were considered in the equation as there was no reimbursement for those clients. No client was turned away and the cost of the consult and class was written off for the uninsured clients. Based on 15.4% of Americans being uninsured that equaled approximately six clients per month and 36 clients over 6 months (Kaiser, 2013).

Evaluation Plan

A specific evaluation plan was necessary to serve as a guide through the various steps of evaluation while ensuring the appropriate data were collected in a timely manner. Upon project completion, the data were evaluated and presented to the stakeholders (Hodges & Videto, 2011). As mentioned above, in January 2014 the new guidelines for managing hyperglycemia in pregnancy were implemented among all obstetric providers and CDEs within the Valley Health System.

Beginning in February 2014, informal checks with the obstetric providers took place to answer questions, offer assistance, and briefly evaluate if all pregnant women were receiving the GDM screening at their first prenatal visit. After Walden University IRB approval, the pretest and posttest data were collected and analyzed to measure whether patients' knowledge of the

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GDM increased upon completion of education. All data were reviewed to evaluate the effects of the new program and determine possible recommendations for change.

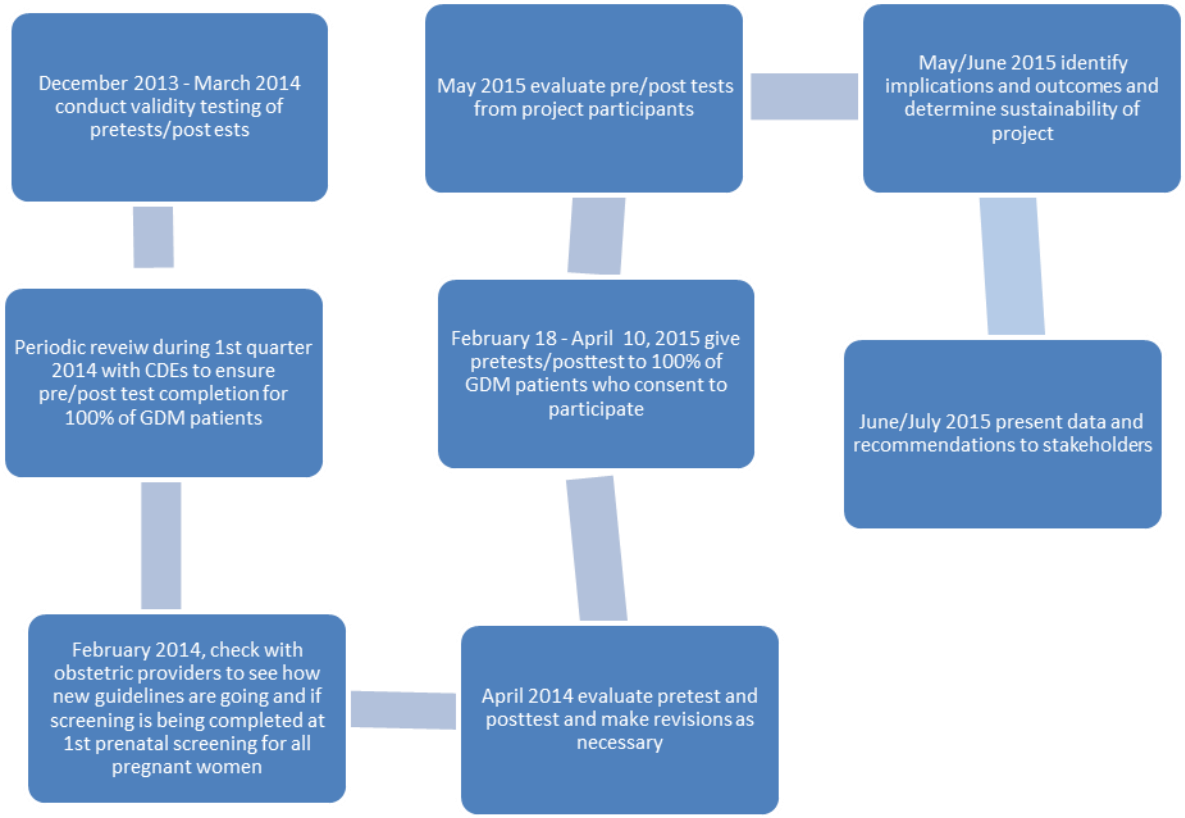

Figure 1. Process flow timeline.

Summary

Hyperglycemia in pregnancy is a serious complication of pregnancy with implications for both the mother and the fetus even after delivery due to the increased risk of developing Type 2 diabetes (Metzger, 2012). A program designed to help educate on diet, exercise, and monitoring was expected to help improve overall glycemic control, which in turn will reduce hyperglycemia associated complications. Six sigma methodology was utilized to achieve the goal of the project. The evaluation measured the program effectiveness based on the pretest/posttests and a satisfaction survey to evaluate the service provided. The budget provided above demonstrated

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that the benefits of the GDM program overall should out way the minimal associated costs. Section 4 will further discuss the evaluation and findings based on the data collection outlined above. Implications regarding the data, the new guidelines, and the program will be outlined as well as the overall strengths and weakness of the project. A self-analysis is also included.

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Section 4: Findings, Discussion and Implications

The purpose of this DNP project was to use the newly established guidelines in a clinic setting for screening hyperglycemia in pregnancy to ensure that patients with GDM will be identified earlier and will be able to begin education and implement other interventions/treatments earlier in gestation. Expected project outcomes were established to reflect the effectiveness of the nurse-led education by evaluating the knowledge gained by the participants regarding when to contact their physician for abnormal blood sugar results and appropriate dietary choices. The ultimate goal was to identify pregnant women early in their pregnancy to provide early referral for nurse-led education that could play a vital role in improving the overall health outcomes for the mothers and their unborn children.

The project took place during a 6-week period between February and April 2015. The intended sample size was 30 women with GDM who were referred for GDM education but ultimately included 37 women with 35 fulfilling the requirements of completing the pretest, posttest, and the patient satisfaction survey. The first outcome of the project was to ensure that women receiving care in the project clinic were screened for GDM during the first trimester of their pregnancy. Of the 35 participants, 20 women (57% of the sample) were screened prior to 20 weeks gestation. Two different obstetric practices, which included 11 different practitioners, referred patients for GDM education. Five of the practitioners referred patients both prior to 20 weeks gestation and after 20 weeks gestation. Four of the practitioners solely referred women prior to 20 weeks gestation where only two practitioners solely referred after 20 weeks gestation.

With regard to the pretest and posttest of the 35 participants, the mean pretest score was 75.43 with a standard deviation of 15.782. The scores on the pretest ranged from 40 to 100

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points. The posttest mean score was 91.71 with a standard deviation of 10.706. The posttest scores ranged from 60 to 100 points. The pretest/posttest is provided in Appendix F.

Table 3

Statistics

		Pretest	Posttest
N	Valid	35	35
Mean		75.43	91.71
Median		80.00	90.00
Mode		80	100
Std. Deviation		15.782	10.706
Skewness		-.607	-1.582
Std. error of Skewness		.398	.398
Minimum		40	60
Maximum		100	100

The differences in results between the pretest and posttest by individual were significantly better on the posttest ($p > 0.000$). This is demonstrated by the statistical charts below.

Table 4

Paired Samples Statistics

		Mean	N	Std. deviation	Std. Error Mean
Pair 1	Pretest	75.43	35	15.782	2.668
	Posttest	91.71	35	10.706	1.810

Table 5

Paired Sample Correlation

		N	Correlation	Sig.
Pair 1	Pretest & posttest	35	.605	.000

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Table 6

Paired Samples Test

		Paired differences					t	df	Sig. (2 tailed)
		Mean	Standard deviation	Standard. error mean	95% Confidence interval of the differences				
					Lower	Upper			
Pair 1	Pretest-posttest	-16.286	12.623	2.134	-20.622	-11.950	-7.633	34	.000

The participants also completed a patient satisfaction survey (Appendix E), which demonstrated high scores on all eight questions with regard to satisfaction of the class and meeting class outcomes. The participants had the opportunity to provide additional comments. Those comments included: "Very educating class," "Excellent," "Thank goodness for this class, I would have not figured this out on my own. Thanks," "Class was a little long," "Very helpful," "Thanks," "Great class,", "Good info," and " Having this class before you begin testing would be helpful in being able know how to range your blood sugar."

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Table 7

Statistics

		Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8
N	Valid	37	37	37	37	37	37	37	37
	Missing	1	1	1	1	1	1	1	1
Mean		5.00	4.97	4.95	5.00	4.78	4.78	4.81	4.81
Median		5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
Mode		5	5	5	5	5	5	5	5
Std. deviation		.000	.164	.329	.000	.534	.479	.518	.518
Std. Error of skewness		.388	.388	.388	.388	.388	.388	.388	.388
Minimum		5	4	3	5	3	3	3	3
Maximum		5	5	5	5	5	5	5	5
Skewness			-6.083	-6.083		-2.498	-2.203	-2.794	-2.794

The theoretical framework utilized for this project was Kurt Lewin's change theory. As outlined above, the obstetric provider compliance with screening for GDM during the first trimester was 57%, which presented a significant margin for improvement. As this study did not investigate why the screening rate was only 57%, one can only assume that it was partially due to physicians adjusting to new guidelines and with patients' first appointment being outside the first trimester. There remains work to be done with the physicians to encourage the use of the new screening guidelines Change is difficult for many, but it is important to revisit the 3-step process of change theory: unfreezing, moving, and refreezing. If the physicians do not truly believe in, understand, or see the value in the guidelines, then it will be impossible for them to move and refreeze with the process for GDM screening (Kaminski, 2011).

The study participants overall demonstrated an increased knowledge related to diet choices and physician notification of blood sugar levels. What was not assessed with this study is the actual change made by the participants. The participants may know what to eat, how often to check blood sugars, and when to notify the physician but may choose not to make any changes.

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With no changes the mother and child will continue to be at a greater risk for complications regardless of GDM education and significant improvement in posttest knowledge scores. The hope is that the unfreezing step and beginning of the moving step took place during the GDM class and are followed with full movement and refreezing as the participants go home and put their new knowledge into practice (Kaminski, 2011)

Implications

Projects have the potential for practice implications and future research. This study in itself has a social effect as the participants take their knowledge and put it into practice at home. This will not only effect the participant but also her family and anyone in her social network. Pregnancy is usually a very social event and people become interested and often seek out information and/or strategies to improve their health during this time.

Effect on Practice/Action

The newly established guidelines for GDM screening have been utilized to an extent by the providers. However, there is definitely room for improvement as the rate of screening prior to 20 weeks gestation was only 57%. This project did not investigate potential causes for the delay in screening; therefore; physician compliance and timing of initial appointment may have played a role in delay of screening. As physicians continue to adjust to the new guidelines, I expect to see an increase in the percentage of women screened prior to 20 weeks gestation.

The GDM class was beneficial to the participants, but the actual long-term effectiveness of the class is unknown. The CDEs will continue to track macrosomia and LGA rates to evaluate potential positive implications from the GDM classes with regard to the delivery of large neonates.

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Effect on Future Research

The project did substantiate both of the proposed outcomes; however, the need continues for additional research to optimize the screening process for GDM as well as the GDM classes. This is especially true for women being screened for GDM during their first trimester. Future research could specifically track each physician and referral practices to identify any trends and/or limitations leading to the delay in screening. As far as the effectiveness of the GDM classes, future research could follow women who participated in the educational intervention from the initial GDM screening throughout the pregnancy and even the delivery to evaluate overall blood sugar management and fetal outcomes. In addition, the research could continue long term to evaluate the probability of women with GDM and/or the macrosomia/LGA neonates developing type 2 diabetes mellitus in the future.

Project Strengths and Limitations

Strengths of the project include consistency among the educators. The CDEs were trained and certified in diabetes education and, therefore, maintained the required knowledge to present the GDM classes. In addition, the sample size of 35 participants was larger than the originally proposed sample size of 30. An accidental strength of the project was due to the delay in implementation as it provided the physicians approximately a year to adjust to the new screening guidelines prior to the project being implemented and screenings for GDM being measured.

Limitations

Limitations are a part of research and this project has proven no different. The participant population was one of convenience, and even though the population size was larger than originally proposed, it was still small in size. The length of the project could also be considered a limitation as it was only conducted for 6 weeks. Considering that GDM classes take place every

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week, this time frame is short to obtain an accurate picture of the population. Another limitation specifically related to the GDM class has to do with the number of week's gestation of the woman when she attended the classes and learned the information. For example, if a woman was 24 weeks gestation when she attended the classes and began managing her GDM, The outcomes may be different from those of a woman who attended the classes at 12 weeks gestation.

Recommendations for remediation of limitations

Recommendations to overcome the limitations would include a larger sample size, possibly through an alternative method than convenience sampling. In addition, lengthening the time frame may help provide a more accurate picture of the population outcomes. Women not showing up for the education continues to be a problem as there were eight no shows during the project time frame. Reminder phone calls prior to each class either by a person or through automaton may be beneficial in decreasing this number or help facilitate the women successfully completing the education program. The final recommendation refers back to the timing of the GDM screening taking place during the first trimester for all women to ensure early referral to GDM education if deemed appropriate. The earlier these women receive education, the more prepared they are to manage their GDM throughout their entire pregnancy. This could have a substantial effect on neonatal outcomes related to GDM if blood sugars are well controlled throughout the entire pregnancy.

Analysis of Self

Developing and conducting research is very exciting but also very challenging. The time required is more than most could ever imagine but definitely worth it in the end. I had many challenges throughout this process but found ways to overcome and persevere. It is interesting to reflect and analyze yourself as a scholar, a practitioner, and as a project developer.

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As Scholar

As someone who was well versed in diabetes but not necessarily in GDM, this project was very interesting and challenging. I have gained important knowledge in screening, treating, and providing education for GDM. I also now possess the awareness and knowledge of the many potential complications both mother and child may be subjected to as a result of poorly controlled blood sugars.

As Practitioner

My main experience prior to this project and the doctoral practicum was focused on inpatient management of diabetes mellitus. When working with an outpatient population, there were many challenges to overcome, which were discovered throughout the implementation process. Challenges identified in the outpatient setting include financial issues, lack of or limited transportation, and lack of adequate health care and among many others. As a result, identifying women during their first trimester of pregnancy for GDM can be very difficult, which can delay GDM education.

As Project Developer

Project development is challenging and rigorous, but overall an educational experience that cannot be obtained in any other format. I have a better understanding and appreciation of the various steps necessary to conduct a quality project. The process starts with an idea and develops into project with an implementation plan and identified project outcomes. Next, it involves IRB approval, which is an experience in itself but very necessary not only to ensure valid interventions but also to protect study participants. It is very exciting in the end to have the data, analyze it, and determine if the project objectives were met. The final step is to evaluate the

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results and develop potential recommendations for the future. I will be more prepared for future research endeavors as a result of this project.

Future Professional Development

I plan to continue with professional development in research; however, the research may not necessarily be focused on hyperglycemia in pregnancy. The topic is very interesting and important, but it no longer aligns with my professional focus. The research currently of interest is related to nursing education and how to improve upon specific program outcomes as well as improvements within the classroom. Simulation and alternative clinical experiences may also be future research topics.

Recommendations

Project recommendations include continuing to screen for GDM in first trimester, but to work with the obstetricians on how to improve the screening rate. Meeting with the obstetric providers to discuss the current rate, why certain cases were not screened early, and possible ways to improve the screening rate would help provide answers to important unanswered questions as well as providing possible solutions. It is important to continue with early referral for education, but it is also important to stress to the participants the importance of them attending GDM education as soon as possible as it will provide important information and guidance related to GDM. The CDEs should continue to monitor LGA and macrosomia rates but may consider adding cesarean section rates, infant hypoglycemia admissions to the newborn nursery, and NICU admissions due to infant hypoglycemia. Other data to consider collecting would include complications rates of shoulder dystocia, hypertension, prematurity, and preeclampsia.

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Summary and Conclusions

The purpose of this DNP project was to use newly established screening guidelines for hyperglycemia in pregnancy to ensure that clinic patients with GDM will be identified during their first trimester and begin education and other interventions/treatments earlier in gestation. The project proposed that early detection of gestational diabetes and early referral for diabetes education would improve the self-management and knowledge of pregnant women diagnosed with GDM. The first project objective was partially met as 57% of the women were screened for GDM prior to 20 weeks gestation. In addition, the education intervention resulted in a significant improvement in knowledge of GDM and its management. These data met the second objective, which was that the participating patients would learn when to contact their physician for abnormal blood sugar results and appropriate dietary choices.

While beyond the scope of this project, the ultimate goal was to reduce complications associated with GDM such as preterm labor, hypertension, preeclampsia, hemorrhage, and shoulder dystocia, while decreasing adverse labor, delivery, and infant outcomes such as macrosomia, LGA, cesarean delivery, and infant hypoglycemia. WMC statistics demonstrated a decrease in caesarian sections rates from 37.4% in 2013 to 35.4% in 2014. January through April 2015 demonstrated a continuing decline in caesarian sections, currently at a rate of 34.3%. Macrosomia rates decreased from 11.6% in 2013 to 10% in 2014; however, LGA rates increased from 27.7% in 2013 to 28.3% in 2014. Infant hypoglycemia has also decreased from 18 newborn nursery admissions in 2013 to 14 in 2014, with seven NICU admissions in 2013 down to five in 2014. Macrosomia, LGA, and infant hypoglycemia for 2015 are not yet available. As WMC has demonstrated, a continuing decline in macrosomia and LGA as well as a decrease in newborn nursery and NICU admissions for infant hypoglycemia, these results do correlate to the

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implantation of the new screening guidelines for hyperglycemia in pregnancy and project implementation but cannot be directly attributed to the change in clinical practice or the decline in presented data.

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Section 5: Dissemination of Scholarly Project Outcomes

The problem addressed by this project was the need for early identification of GDM and educational intervention to improve the self-management and knowledge of pregnant women. The purpose of this project was to use newly established guidelines for screening hyperglycemia in pregnancy to ensure that patients with GDM will be identified during their first trimester and begin education and other interventions/treatments earlier in gestation in the clinic setting. The project proposed that early detection of gestational diabetes and early referral for diabetes education would improve the self-management and knowledge of pregnant women diagnosed with GDM. The anticipated outcomes of the project were:

1. Women receiving care in the project clinic will be screened for GDM during the first trimester of their pregnancy.
2. The pretest scores compared to the posttest scores on a questionnaire to examine knowledge of GDM and its treatment will demonstrate that the participating patients have learned when to contact their physician for abnormal blood sugar results and appropriate dietary choices.

Kurt Lewin's planned change theory was selected as the theoretical framework for the project. Lewin's theory includes three elements: Field theory, Group Dynamics, and three step model. Field theory and Group Dynamics are utilized during the three step mode of unfreezing, moving, and refreezing to create and maintain change (Burnes, 2004). Changing one's views/perceptions is referred to as the process of unfreezing. The next stage is changing the thoughts, feelings, and/or behaviors of the providers in order to introduce the revised practice guidelines. The final stage is refreezing, which incorporates the changes and allows them to become the new standard practice for all GDM patients (Kaminski, 2011).

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The six sigma approach was utilized for program evaluation. In healthcare, it is important to include the patients' perspectives or opinions regarding programs. One method was to complete pre and post tests to measure the effectiveness and/or satisfaction with the service provided. Six sigma utilizes the DMAIC methodology, which stands for define, measure, analyze, improve, and control. The process begins with defining the goal and overall scope of the project and then creating baseline evidence for comparison. The purpose of the next phase (measure), was to continuously monitor the performance and collect data that will be used to analyze and interpret whether the performances and/or outcomes are as expected (analyze) or if change needs to be made (improve). The final stage (control) was to remove the actual cause of the problem so the focus can stay on the actual improvement (Brandyopadhyay & Coppens. 2005).

The project and its results were presented to the CDEs, the Director of CDRC, and the Executive Director of Medical Service Line, the Executive Director of Women and Children, and the previous Interim Director of DMP utilizing a Power Point presentation. The Power Point is provided in a separate document. After the presentation discussion began regarding physician compliance and their observations of one physician group screening at first visit versus the second group not being as consistent. One of those physicians one has now retired so they are interested to see if he is replaced and if so will that help improve their compliance. This is the same group that came up in discussion as the screening guidelines were being revamped as not being as receptive or willing to follow. They would also like to see if there is a true correlation between women who are screened, receive education, and manage their blood sugars with maternal/fetal outcomes. Basically, following the participants through their entire pregnancy and evaluating during the pregnancy and after delivery for both the mother and infant. At this time

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there are no plans for further research with regards this. I also do not believe they are planning to continue the pretest and posttest. However they will continue with the consultation, education, and satisfaction survey.

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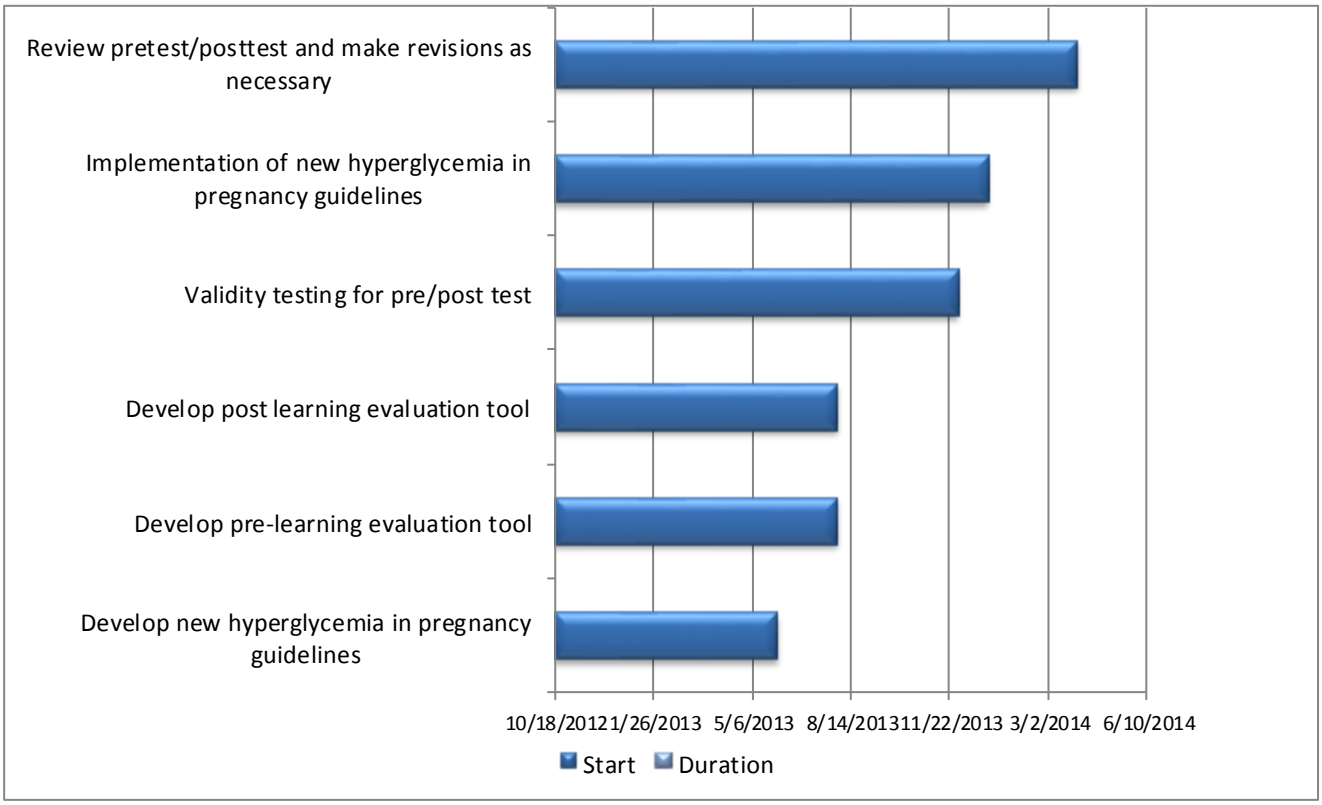
Appendix A: Gantt Chart



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Appendix B: Pregnancy and Diabetes Guidelines

SHENANDOAH VALLEY MATERNAL FETAL MEDICINE **PREGNANCY AND DIABETES GUIDELINES** **VALLEY HEALTH**

******* For management of pregnant women with pre-existing type 1 or type 2 diabetes, optional local endocrinology referral and MFM fetal assessment OR complete diabetes management by MFM. See below, page 3.

A. Screen all pregnant women on the first prenatal visit with serum HbgA1c.If the patient has no risk factors listed below, her status is low risk. If she has **one or more** of the risk factors, her status is high risk.

B. Historical risk factors (from completed maternal history)
   1. Diabetes in a parent or sibling
   2. Previous pregnancy with gestational diabetes
   3. Previous child with birth weight > 4,000 grams
   4. Stillbirth of unknown cause
   5. Unexplained congenital malformations of a previous child (i.e., not due to a virus, toxin, karyotypic abnormality).
   6. Age >35 years

C. Physical risk factors (from initial and interim maternal/fetal assessments)
   1. Obesity (BMI > 27)
   2. Glucosuria (one specimen of 3+ or greater or two specimens of 2+ or greater)
   3. Polyhydramnios
   4. Large for gestational age fetus (>90 percent by ultrasound)
   5. Complaint of hypoglycemic problems
   6. Ethnicity: American Indian, African American, Asian American, Mexican/Hispanic and/or Pacific Islander descent

SCREENING

1. Obtain a HgbA1c at NOB on all patients. ****Patient does not need to be fasting for HgbA1c**.
2. If HgbA1c is ≥ is 6.5%, consider has pre-existing type 2 diabetes, previously undiagnosed.
   FYI- If HgbA1c is between 5.7-6.4% it is considered pre-diabetes in the non-pregnant. Discuss diet.
3. If HgbA1c is < 6.5 and high risk, check fasting. If fasting is < 92 mg/dL, follow up as low risk.
4. If HgbA1c is < 6.5 and patient is low risk, then (at 26-28 weeks) obtain 2-hour OGTT with 75 gram load **OR** one hour 50 gram glucola test; if result ≥ 130 mg/dL, then 3-hour OGTT.

DIAGNOSIS

A. Procedure for the 75 gram oral glucose tolerance test (OGTT) is "one-step testing":
   a. The patient should fast from midnight to the morning of the test.
   b. A fasting serum sample should be obtained.
   c. The patient is given 75 gm of Glucola orally and instructed not to eat, drink, smoke or leave the waiting room until completion of the test.

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d. Plasma blood samples are drawn at 1 and 2 hours following ingestion of the test solution.

B. Evaluating results of 2-hour 75 gram OGTT serum testing: (These values apply for serum and plasma testing, not for whole blood.) If **one or more** value is elevated, then diagnosis of GDM.

FBS		≥92 mg/dL	-GDM one abnormal value
1 hour postprandial	≥	180 mg/dL	-GDM one abnormal value
2 hour postprandial	≥	153 mg/dL	-GDM one abnormal value

***If fasting blood glucose result is ≥ 126 mg/dL**, consider has pre-existing type 2 diabetes mellitus. See below.

C. Procedure for the 50 gram glucola + 3-hour OGTT:

a. Fasting status not necessary; low carbohydrate meal recommended.

b. The patient is given 50 gram glucola orally and instructed not to eat, drink, smoke, or leave the waiting room.

c.Serum sample at 1 hour.

d..Positive test if BG ≥ 130 mg/dL

e.If positive 50 gram result, then refer for 3-hour 100 gram OGTT.

Plasma fasting level drawn before the 100 gram glucose load.

The patient is given 100 gram glucola orally and instructed not to eat, drink, smoke or leave the waiting room until completion of the test.

Serum samples at one, two and three hours.

Positive test is **two or more elevated values = GDM**

Fasting	BG	≥	95 mg/dL
1 hour	BG	≥	180 mg/dL
2 hour	BG	≥	155 mg/dL
3 hour	BG	≥	140 mg/dL

For pregnant women with a history of gastric bypass, plasma fasting and one hour postprandial is the diagnostic test. Fasting BG should be less than 92 mg/dL and one hour post prandial BG should be less than 140 mg/dL.

If a patient is not able to tolerate an OGTT or it is logistically too late to do an OGTT, then suggest a serum fasting and one hour post prandial test. Fasting should be less than 92 mg/dL and one hour post prandial BG should be less than 140 mg/dL.

MANAGEMENT OF GLUCOSE INTOLERANCE OF PREGNANCY

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ANTEPARTUM

A. Referral to outpatient Diabetes Management Program (DMP) for GDM class. This will include instruction on BG monitoring and ketone testing, as well as nutrition consultation to determine caloric needs
based on pre-pregnant BMI, weeks of gestation and presence of multiples. The DMP will offer the patient
a one week follow-up appointment at the DMP.

B. Patient will perform self-monitoring of blood glucose four times a day; fasting and one hour after meals.
(Post prandial reading is taken following the first bite of a meal.) The patient will initially monitor urine
each morning with ketone dipstick. Provider can decrease ketone testing to three times a week if all results
are negative. Patient to bring GDM flowsheet with BG and ketone results to all OB appointments for
review by provider. OB provider can elect less frequent testing if blood sugars are normal after two weeks.

C. If one hour post prandial BG readings are consistently ≥ 130 mg/dL, and/or fasting ≥ 92 mg/dL, the
physician should consider oral Glyburide or insulin therapy. (Or, if the patient is already on insulin,
adjustment of insulin therapy). Referral to MFM diabetes clinic recommended if insulin start is needed.
The OB physician will be responsible for decision to initiate medical therapy for BG control.

- Glyburide start dose 1.25-2.5 mg daily versus twice a day depending on when blood glucose is elevated).
    - The patient will call/fax BG flow sheet to primary OB or Shenandoah Valley MFM (if they are consulted) every 2-3 days until fasting < 92 mg/dL, 1 hour <130 mg/dL.
    - Thereafter, once BG readings are at goal, the patient will call/fax BG flowsheet to managing practice weekly
    - Office visits every two weeks with primary OB
    - SVMFM diabetes clinic visit at least monthly if consulted

D. The patient will keep record of kick counts beginning at 28 weeks

E. Consider ultrasound for sizing at 30-32 weeks. If > 90 %, manage as macrosomia. If AC >75 %, consider insulin/glyburide therapy.

F. Begin antenatal testing at 34 weeks if pregnancy requires insulin or glyburide, if there is a history of stillbirth, or have hypertension, macrosomia, or if there is evidence of poor control.

G. If not on glyburide or insulin, begin NSTs at 40 weeks if undelivered.

H.

LABOR MANAGEMENT

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A. What is your EFW?
B. No meds or meds and well-controlled: consider induction if undelivered by 40 weeks.
C. Meds and poor control delivery 34-39 weeks depending on compounding factors.
D. Ultrasound EFW if ≥ 4500 grams with GDM consider Cesarean section depending on maternal size, pelvis and history of births.

POSTPARTUM

In hospital, check fasting postpartum day one if GDMA 2.

As outpatient in first year**:**

HgbA1c	≥ 6.5%	referral to internal medicine
Random blood sugar	≥ 200	referral to internal medicine
Fasting blood sugar	≥ 126	referral to internal medicine

MANAGEMENT OF WOMEN WITH TYPE 1 & 2 DIABETES OR PATIENTS REQUIRING INSULIN MANAGEMENT BEFORE 20 WEEKS

INITIAL ORDERS

A. Ophthalmology referral in the first trimester and then per consultant's recommendation.
B. Nutrition- diabetes management
C. Social work, if indicated
D. Referral to outpatient Diabetes Management Program for "pregnancy and diabetes" education
E. If on insulin pump, referral to DMP for "insulin pump pregnancy and diabetes education"
F. Referral to Shenandoah Valley MFM Diabetes Clinic

Laboratory work:

A. Serum electrolytes, creatinine, BUN, GFR (Chem 14)
B. Urine culture
C. Baseline 24-hour urine for creatinine clearance and total protein
D. An initial HGB A1C should be drawn for assessing control over the 2-3 months to assist with counseling regarding congenital malformations. Also use to check compliance throughout pregnancy.
E. Consider EKG based on patient history (chest pain, MI, early FH MI), habits (cigarette smoker), and age >35 years.

Management:

A. Glucometer instruction. Four times a day BG testing; fasting and one hour postprandial. If poorly controlled, add before meal and bedtime testing; BG 7 times a day.
B. Teach family members/significant others about Glucagon treatment for hypoglycemia and give patient prescription for glucagon kit.
C. Switch all women with preexisting Type 2 diabetes that were managed on oral agents to insulin in the first trimester. Use NPH insulin for the basal and Humalog or NovoLog insulins for the meal coverage. Because NPH is the most studied basal insulin in pregnancy, it should be the first long-acting insulin offered to the patients. Switch patients on Lantus to NPH insulin or Levemir insulin (1:1 conversion).- Both pregnancy category B.
D. 15-18 weeks- Consider AFP due to increased OSB risk

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E. 18-20 weeks- Perinatal ultrasound for anomalies
F. 22-26 weeks- Fetal echocardiography
G. 28 weeks- Kick counts
H. 28-30 weeks- Weekly NST in all poorly-controlled Type I **or** if history of stillbirth, has hypertension
or has macrosomia
I. 30-32 weeks- Perinatal ultrasound for predicting macrosomia
Repeat ophthalmologic examination if indicated
J. 32 weeks- Two times weekly NST for those poorly-controlled.
Check amniotic fluid if non-reactive; consider OCT
K. 34 weeks- Begin antenatal testing two times weekly for well-controlled diabetes (Type I and II)
NST and AFI (2 x 2 pocket) or BPP
L. 39 weeks- Cervical check, induce if favorable

Classify 1. Good control Deliver at 39-40 weeks if cervix is ripe and if average fasting
< 85 mg % and 1-hour < 140 mg %.

2. Poor control (one of these)

1=	Pyelonephritis	5=	Macrosomia
2=	Ketoacidosis	6=	Polyhydramnios
3=	Preeclampsia	7=	Falling insulin requirements
4=	Poor control	8=	Vascular disease

Poor control- Consider delivery at 37-39 weeks.

INSULIN PUMP THERAPY: If patient is on insulin pump therapy prior to pregnancy, refer to outpatient diabetes education for "insulin pump therapy adjustment and nutritional counseling with pregnancy". The Certified Pump Trainer (CPT) will attempt frequent communication and follow-up with the patient and will alert the referring physician if the patient is not in communication and/or is not following the plan of care. The CPT and the patient will establish a plan of care for insulin pump adjustments for BG management during labor and delivery, and post partum. If the patient is a candidate for insulin pump initiation during the pregnancy, refer to outpatient diabetes education for evaluation of insulin pump therapy.

LABOR-

1. Monitor glucose with hourly BG testing with point of care testing (POCT).
2. Order urine for ketones if BG greater than 250 mg/dL in patient with pre-existing type 1 diabetes.
   Bolus D5NS if > trace, then D5NS at 125 mL/hr and start insulin drip.
3. Insulin drip for blood glucose > 140 mg/dL
4. If epidural planned, load with normal saline
5. BG goal approximately 100 mg/dL
6. IV insulin drip orders: finger stick blood glucose monitoring q 1 hour

Start IV insulin drip at 1 unit/hr for blood glucose > 140 mg/dL.

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Pharmacy to mix insulin drip- regular insulin in N.S. 100 units in 100 cc NS.

For insulin drip:

< 100mg/dL, D/C drip. Restart when blood sugar > 140 mg/dL (if symptoms bolus 150 cc D5NS)

If BG 140 – 180mg/dL, infuse at 1 unit/hr
If BG 181 – 220mg/dL, infuse at 2 units/hr
If BG 221 – 280mg/dL, infuse at 3 units/hr
If BG 281 – 350mg/dL, infuse at 4 units/hr
If BG greater than 350mg/dL, notify MD.

*If BG is greater than 220mg/dL for two consecutive hours, notify MD.

If scheduled induction, use one half of patient's usual NPH dosing with breakfast, and usual Humalog dose.

Check blood glucose hourly and dip all urine for ketones.
When blood glucose greater than 140mg/dL, begin IV insulin as above.
Avoid lactated ringers solution.
Cesarean delivery- NPO No a.m. insulin. Treat post Cesarean section as per all postpartum orders. Consider scheduling as early, am case.

POSTPARTUM- Type 1 and 2 Diabetes

1. Keep blood glucose < 200mg/dL
2. May use one half of patient's pre-pregnancy regimen or sliding scale Humalog.
3. An insulin drip may help while a patient is NPO.
4. Discuss periconception control prior to next pregnancy

PRECONCEPTION GOALS

1. HgbA1C < 6.5%
2. Assess renal function
3. Folic acid
4. Check rubella
5. Encourage children within 10 years of diagnosis
6. Consider switching insulin to Humalog or NovoLog before each meal; with bedtime dose of NPH insulin.
7. Treat retinopathy prior to conception; annual retinal exams for screening

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Appendix C: Literature Review Summary Table

Author	Aim	Sample	Method	Strength/Weakness	Level of Research
O'Sullivan, Avalos, O'Reilly, Dennedy, Gaffney, & Dunne	Evaluate the impact of new diagnostic criteria on GDM prevalence and outcomes in predominant-ly European populations.	5,500 women	Longitudi-nal case-control study	Large sample size, identified that new criteria is applicable to European populations; prevalence results may not be as accurate due to population distribution higher in age and BMI, no consideration for management of hyperglycemic treatment	IIa, B
Mehta, Kruger, & Sokol	Determine if relation exists between diabetes in pregnancy and childhood obesity in inner-city African-American (AA) population.	493 mother and child pairs	Longitudi-nal case-control study	Only study to show association between diabetes and childhood obesity in urban AA population; retrospective study, lack of information about blood glucose compliance, include Type I, II, and GDM.	IIa, B
Gillespie, O'Neill, Avalos, O'Reilly, & Dunne	To estimate the cost of universal screening for GDM	30,429 women	Longitudi-nal case-control study	Sample size, Included estimates for undiagnosed as well as those diagnosed with GDM, no estimates for adverse outcomes for the mother or infant, no consideration for mother/infant outcomes, assumptions and estimates – how accurate?	IIa, B
Katon, Reiber, Williams, Uanez, & Miller	To determine if HgA1C at time of GDM	502 women	Longitu-dinal case-control	Population diversity, Standard GDM diagnosis at 24 weeks	IIa, B

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	diagnosis is associated with increased risk of LGA or macrosomia infant		study	or greater gestation, No considerations for glycemic control in third trimester could explain null finding, research took place in two clinics which are very aggressive in treating GDM	
O'Connor, O'Shea, Owens, Carmody, Avalos, Nestor, & Dunne	To establish trimester-specific reference intervals in pregnancy for IFCC standardized A1C in non-diabetic Caucasian women	311 women	Random-ised controlled trial	Normal BMI, determined that semester specific A1C references should be utilized in pregnant women	Ib, A
Dall et al.	Determine if participation intensity and prior indication of uncontrolled diabetes are associated with healthcare use and costs for those enrolled in TRICARE's diabetes management program	23,778 people ages 18 to 64 living in U.S.	Quasi-experimen-tal	Sample size, Patients chose level of participation intensity, Selection bias due to highly motivated individuals participation, intensity of participation, and management of disease; no natural/true comparison group, no consideration for external education/information, inability to determine blood glucose control	IIb, B
Van Dijk, Verheij, Swinkels, Rijken, Schellevis, Groenewegen, & Bakker	Determine what part of total care consumed by Type 2 diabetes is directly related to	208 self-reports and 9,023 electro-nic medi-	Descriptive study	Data collected from different databases that were not linked and caused some outcomes to be based on a much smaller sample size, identified a gap in national	III, B

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	diabetes and the implications for disease management programs	cal records		DMPs	
Cavassini, Lima, Calderon, & Rudge	Estimate cost-benefit relationship and social profitability ratio of hospitalization compared to outpatient care for pregnant women with diabetes	50 women	Longitudi-nal case-control study	Proved outpatient management is more cost effective than inpatient, Small sample size, no consideration for oral agents or insulin in outpatient group, no consideration of adverse outcomes for the mother or infant	IIa, B
Metzer et al.	Clarify the risks of adverse outcomes associated with various degrees of maternal glucose intolerance less severe than that in overt DM.	25,500	Longitudi-nal case-control study	Sample size, similarity in results across the 15 centers in 9 countries primary and secondary adverse outcomes considered, nutritional status, previous GDM, maternal BMI, previous macrosomia, and gestation weight gain were not considered	
Catalano, et al.	Determine associations of GDM and obesity with adverse pregnancy outcome	25,505 women	Longitudi-nal case-control study	Evaluates the impact of GDM and obesity but also their combined impact on adverse outcomes, observational study	IIa, B
Metzger et al.	Clarify the risks of adverse outcomes associated with various degrees of	25,505 women	Longitudi-nal case-control study	Large sample size, nutritional status and maternal weight gain not considered, Previous GDM, child with macrosomia, and maternal BMI may	IIa, B

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	maternal glucose intolerance less severe than that in overt diabetes mellitus			have causally affected adverse outcomes	

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Appendix D: Gestational Class Pre/Posttest Original

Gestational Diabetes Pre-Education Test

1. Which of the following foods will affect your blood glucose the most:

A. French dressing, margarine, olive oil
B. Bread, orange juice and cereal
C. Cheese, cottage cheese and peanut butter
D. I don't know

2. When checking your urine for ketones, you would check your

A. First urine after midnight
B. Last urine before going to bed
C. First urine when getting up for the day
D. I don't know

3. When checking your fasting blood sugar, you should notify your physician if your blood sugar is consistently greater than

A. 75
B. 92
C. 85
D. 80

4. **When checking your one hour blood sugar, you should notify your physician if your blood sugar is consistently greater than:**

A. 110
B. 120
C. 130
D. 140

5. When checking your blood sugar, you should notify your physician if your blood sugar is consistently lower than

A. 70
B. 80
C. 90
D. 100

6. A diabetes meal plan

A. Should consist of fruits, vegetables, proteins, and starches
B. Is a diet requiring special, expensive foods
C. Does not allow any starches or sweets
D. Allows unlimited starches and sweets

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7. One starch exchange is approximately
A. 60 grams
B. 30 grams
C. 90 grams
D. 15 grams

8. A dairy exchange is
A. 1 cup cottage cheese
B. 1 cup milk
C. ½ cup flavored yogurt
D. 2 slices Swiss cheese

9. **Which of the following is one fruit exchange?**
A. A large banana
B. A small apple
C. 2 cups of blackberries
D. 1 cup of applesauce

10. Which of the following is an example of one protein exchange?
A. 6 ounces of cooked lean chick, fish, or pork
B. 1 cup of tofu
C. 2 eggs
D. 2 TBSP peanut butter

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Appendix E: Gestational Class Survey

Please rate each of the following from 1 to 5 with 1 being not at all and 5 being always or completely.

1. Do you understand what gestational diabetes is and the effect that blood glucose control has on the baby's birth weight?
   1 2 3 4 5

2. Do you know when to check your blood glucose?
   1 2 3 4 5

3. Do you know how to check your blood glucose?
   1 2 3 4 5

4. Do you know when to contact your physician with blood glucose readings?
   1 2 3 4 5

5. Did this class meet your needs**?**
   1 2 3 4 5

6. Based on what you learned today, do you know what changes to make in what you eat and drink?
   1 2 3 4 5

7. Did this class meet your expectations?
   1 2 3 4 5

8. How would you rate this class overall?
   1 2 3 4 5

Comments or suggestions:

_____

_____

_____

Thank you for your comments **Gestational Diabetes Class**

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Appendix F: Gestational Class Pre/Posttest Revised

Gestational Diabetes Pre-Education Test

1. Which of the following foods will affect your blood glucose the most:
A. French dressing, margarine, olive oil
B. Bread, orange juice and cereal
C. Cheese, cottage cheese and peanut butter
D. I don't know

2. When checking your urine for ketones, you would check your
A. First urine after midnight
B. Last urine before going to bed
C. First urine when getting up for the day
D. I don't know

3. Checking your fasting blood sugar, you should notify your physician if your blood sugar is consistently greater than
A. 75
B. 92
C. 85
D. 80

4. **When checking your one hour blood sugar, you should notify your physician if your blood sugar is consistently greater than:**
A. 110
B. 120
C. 130
D. 140

5. When checking your blood sugar, you should notify your physician if your blood sugar is consistently lower than
A. 70
B. 80
C. 90
D. 100

6. A diabetes meal plan
A. Should consist of fruits, vegetables, proteins, and starches
B. Is a diet requiring special, expensive foods
C. Does not allow any starches or sweets
D. Allows unlimited starches and sweets

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7. One starch exchange is approximately
A. 60 grams
B. 30 grams
C. 90 grams
D. 15 grams

8. A dairy exchange is
A. 1 cup cottage cheese
B. 1 cup milk
C. 1 cup flavored yogurt
D. 2 slices Swiss cheese

9. **Which of the following is one fruit exchange?**
A. A large banana
B. A small apple
C. 2 cups of blackberries
D. 1 cup of applesauce

10. Which of the following is an example of one protein exchange?
A. 6 ounces of cooked lean chick, fish, or pork
B. 1 cup of tofu
C. 1 eggs
D. 2 TBSP peanut butter or any nut butter

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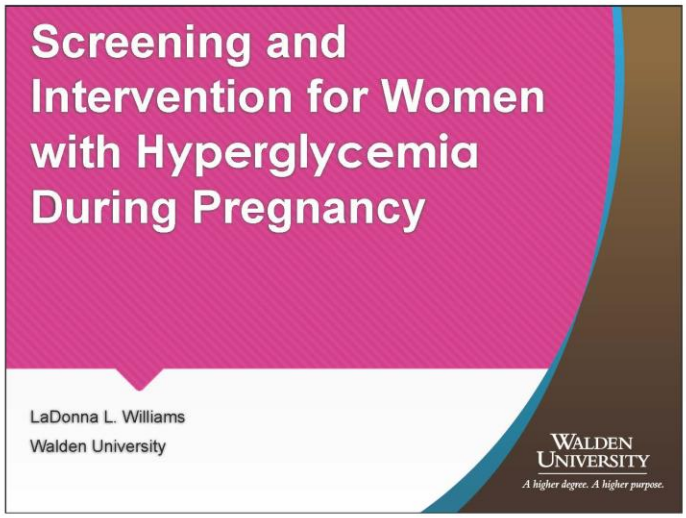
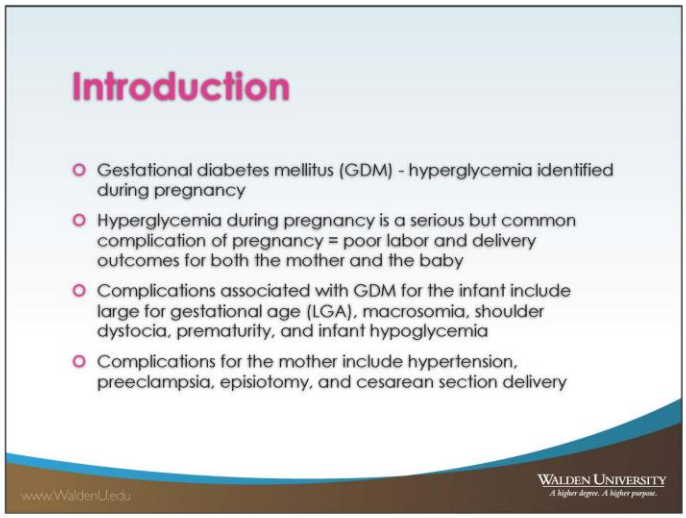
Appendix G: Screening and Intervention Presentation





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Risk Factors

Historical

- Historical risk factors (from completed maternal history)
- Diabetes in a parent or sibling
- Previous pregnancy with gestational diabetes
- Previous child with birth weight > 4,000 grams
- Stillbirth of unknown cause
- Unexplained congenital malformations of a previous child (i.e., not due to a virus, toxin, karyotypic abnormality).
- Age >35 years

Physical

- Obesity (BMI > 27)
- Glucosuria (one specimen of 3+ or greater or two specimens of 2+ or greater)
- Polyhydramnios
- Large for gestational age fetus (>90 percent by ultrasound)
- Complaint of hypoglycemic problems
- Ethnicity: American Indian, African American, Asian American, Mexican/Hispanic and/or Pacific Islander descent

Background

- Carpenter & Coustan (CC) criteria recommended in 1982 that women with fasting plasma glucose levels ≥ 95 mg/dL meet criteria for GDM
- 4.8% of pregnant women according to a Centers for Disease Control and Prevention (CDC) prevalence report in 2009 met CC criteria for GDM
- International Hyperglycemia and Adverse Pregnancy Outcomes (HAPO, 2010) study demonstrated that 6.7% of pregnant women met criteria for GDM in 2012
- New IADPSG criteria recommended that women with fasting plasma glucose levels ≥ 92 mg/dL

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Background

- IADPSG also recommended screening all or at least high risk women at their first prenatal visit with a random plasma glucose, HgA1c, or fasting blood sugar to help identify undiagnosed pre-existing diabetes prior to pregnancy
- IADPSG recommended standardizing the oral glucose tolerance test (OGTT) conducted between 24 and 28 week gestation to consist of the 2 hour 75 gram test versus the 3 hour 100 gram test

Research

- Longitudinal Studies
  - HAPO (2008)
  - Catalano et al. (2012)
  - O' Sullivan (2011)
  - Katon, Reiber, Williams, Yanez, & Miller (2012)
  - Mehta, Kruger, & Sokol (2012)
- Other Studies
  - O' Connor et al. (2012)

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Research

- Opinions, Reviews, & Summaries
  - IADPSG (2010)
  - Hadar, Oats, & Hod (2009)
  - Donovan et al. (2013)
  - ACOG (2011)
  - Cundy (2012)
  - AHRQ (2012)
  - Joslin Center (2010)

Valley Health Data

- Macrosomia and large for gestation age (LGA) rates are on the rise
- Macrosomia rates increased significantly from 6% in 2011 to 11% in 2012 to 11% in 2013
- LGA rates increased from 25% in 2011 to 27.3% in 2012 to 27.7% in 2013
- In 2012, 25 neonates required admission to the newborn nursery and 8 to the NICU to manage complications associated with infant hypoglycemia and GDM
- Cesarean section rate in 2012 was 33.2%
  - Slightly higher than the national average of 32.8%
  - GDM rate was 44.3%

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New Guidelines

- Screen all pregnant women on the first prenatal visit with serum HbgA1c. If the patient has no risk factors listed below, her status is low risk. If she has **one or more** of the risk factors, her status is high risk
  - If HgbA1c is ≥ is 6.5%, consider has pre-existing type 2 diabetes, previously undiagnosed.
  - FYI- If HgbA1c is between 5.7-6.4% it is considered pre-diabetes in the non-pregnant. Discuss diet.
  - If HgbA1c is < 6.5 and high risk, check fasting. If fasting is < 92 mg/dL, follow up as low risk.
  - If HgbA1c is < 6.5 and patient is low risk, then (at 26-28 weeks) obtain 2-hour OGTT with 75 gram load **OR** one hour 50 gram glucola test; if result ≥ 130 mg/dL, then 3-hour OGTT.

New Guidelines - Diagnosing

- 75 gram oral glucose tolerance test (OGTT) is "one-step testing"
  - Patient is given 75 gm of Glucola orally and instructed not to eat, drink, smoke or leave the waiting room until completion of the test.
  - Plasma blood samples are drawn at 1 and 2 hours following ingestion of the test solution.
- If **one or more** value is elevated, then diagnosis of GDM.
  - FBS ≥ 92 mg/dL
  - 1 -hour postprandial ≥ 180 mg/dL
  - 2 -hour postprandial ≥ 153 mg/dL
  - ***If fasting blood glucose result is ≥ 126 mg/dL**, consider has pre-existing type 2 diabetes mellitus. See below.

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New Guidelines - Diagnosing

- 50 gram glucola + 3-hour OGTT
- Positive test if **BG ≥ 130 mg/dL**, positive 50 gram result refer for 3-hour 100 gram OGTT.
- Patient is given 50 gram glucola orally and instructed not to eat, drink, smoke, or leave the waiting room.
- Serum sample at 1 hour
- 3-hour 100 gram glucola OGTT
- Plasma fasting level drawn before the 100 gram glucose load.
- Patient is given 100 gram glucola orally and instructed not to eat, drink, smoke or leave the waiting room until completion of the test.
- Serum samples at one, two and three hours.
- Positive test is **two or more** elevated values = GDM
- Fasting BG ≥ 95 mg/d
- 1 hour BG ≥ 180 mg/dL
- 2 hour BG ≥ 155 mg/dL
- 3 hour BG ≥ 140 mg/dL

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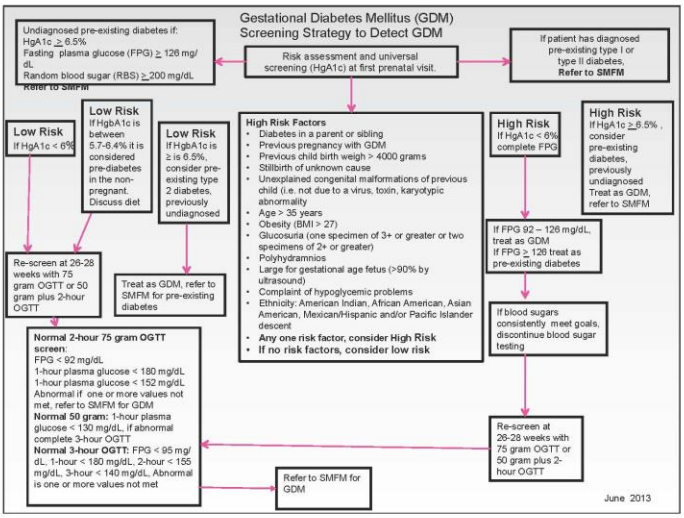

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Problem, Purpose, & Proposal

- **Problem** – need early identification of GDM and educational intervention to improve the self-management and knowledge of pregnant women.
- **Purpose** – to use newly established guidelines for screening hyperglycemia in pregnancy to ensure that patients with GDM will be identified during their first trimester and begin education and other interventions/treatments earlier in gestation in the clinic setting.
- The **project proposes** that early detection of gestational diabetes and early referral for diabetes education will improve the self-management and knowledge of pregnant women diagnosed with GDM.

Theoretical Framework – Kurt Lewin's Change Theory

- Four elements - field theory, group dynamics, action research, and a 3-step model of change
  - The field is responsible for the perceived individual behaviors represented within the group.
  - Action research is ability of individuals to understand their environment and the effect change will have.
  - Group dynamics focuses on what is best for the group as a whole
- 3-step model of unfreezing, moving, and refreezing.

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Approach – Six Sigma

- Six sigma methodology has been used by organizations for program evaluation since its development in the 1980s by Motorola.
- In health care there are challenges due to the involvement of patients versus machines.
  - Must determine the best way to use data to inspire change in behaviors.
- Include the patients' perspectives or opinions regarding the program.
  - Six sigma utilizes the DMAIC methodology, which stands for define, measure, analyze, improve, and control.
- Process begins with defining the goal and overall scope of the project and then creating baseline evidence for comparison.
- Next phase is to continuously monitor the performance and collect data that will be used to analyze and interpret whether the performances and/or outcomes are as expected or if change needs to be made.
- The final stage is to remove the actual cause of the problem so the focus can stay on the actual improvement

Nature of Project

- Pretest posttest design in a convenience sample of women with GDM who are referred for an educational intervention and agree to complete the education and the questionnaires
- Pretest will be completed upon arrival for the first of three education sessions
- Women will complete their consultation and GDM education
- Upon completion of the education, the women will complete the posttest and client satisfaction survey

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Limitations

- Correctness of data being entered by the RNs regarding the timing of glucose screening for GDM.
- Inconsistencies in client learning based on teaching styles.
- Study population is a convenience sample.

Anticipated Outcomes

- Women receiving care in the project clinic will be screened for GDM during the first trimester of their pregnancy.
- The pretest scores compared to the posttest scores on a questionnaire to examine knowledge of GDM and its treatment will demonstrate that the participating patients have learned when to contact their physician for abnormal blood sugar results and appropriate dietary choices.

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Impact

- Short-term - increase patient understanding of GDM self-management during their pregnancy
- Intermediate -improve glycemic control of pregnant mothers throughout their pregnancy in order to improve pregnancy outcomes such as large for gestational age (LGA), macrosomia, and infant hypoglycemia rates
- Long-term - decrease risk for future development of Type 2 diabetes for both the mother and the infant as well as a decreased risk of childhood obesity

Implementation

- January 2014 the new guidelines for managing hyperglycemia in pregnancy were implemented among all obstetric providers and CDEs within Valley Health System.
- Beginning in February 2014, informal checks with the obstetric providers took place to answer questions, offer assistance, and briefly evaluate if all pregnant women were receiving the GDM screening at their first prenatal visit.
- April 2014 evaluate pretest and posttest and revisions were made necessary

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Implementation

- The project took place over a six week period between February and April 2015.
- Sample size included all women who attended a GDM class during the specified time frame
- Goal was to have a minimum of 30 participants
- 37 women participated on some level with 35 fulfilling full requirements of completing the pretest, posttest, and the patient satisfaction survey

Data Analysis

- Data from the pretest and posttest questionnaires and the patient satisfaction survey was be entered into SPSS
- Descriptive statistics such as frequencies and percentages.
- A *t* test was used to determine if posttest scores are significantly higher than pretest scores on the self-management knowledge questionnaire.

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Statistics

- Screened for GDM during the first trimester of their pregnancy.
- 20/35 women were screened prior to 20 weeks gestation
  - 57% of the study population
- Two different obstetric practices referred patients for GDM education
  - 11 different practitioners
  - Five of the practitioners had patients referred on both lists, referrals prior to 20 weeks gestation as well as after.
- Four of the practitioners solely referred women prior to 20 weeks gestation
- Two practitioners solely referred after 20 weeks gestation

Statistics

Pretest

- Mean – 75.43
- Standard deviation – 15.782
- Range of scores - 40 to 100

Posttest

- Mean – 91.71
- Standard deviation – 10.706
- Range of scores – 60 to 100

Table 1. Statistics

		Pretest	Posttest
N	Valid	35	35
Mean		75.43	91.71
Median		80.00	90.00
Mode		80	100
Std. Deviation		15.782	10.706
Skewness		-.607	-1.582
Std. Error of Skewness		.398	.398
Minimum		40	60
Maximum		100	100

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Table 2. Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pretest	75.43	35	15.782	2.668
	Posttest	91.71	35	10.706	1.810

Table 3. Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Pretest & Posttest	35	.605	.000

Table 4. Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	pretest - post_test	-16.286	12.623	2.134	-20.622	-11.950	-7.633	34	.000

The differences in results between the pretest and posttest by individual were significantly better on the posttest by 16.3 points ($p > 0.000$).

Statistics

- The participants also completed a patient satisfaction survey
- Demonstrated high scores in all 8 questions with regards to satisfaction of the class and meeting class outcomes.
- The participants had the opportunity to provide additional comments. Those comments included:
  - "Very educating class"
  - "Excellent"
  - "Thank goodness for this class, I would have not figured this out on my own. Thanks"
  - "Class was a little long"
  - " Very helpful"
  - "Thanks"
  - "Great class"
  - "Good info"
  - " Having this class before you begin testing would be helpful in being able know how to range your blood sugar."

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Statistics

Table 5. Statistics

		Question1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8
N	Valid	37	37	37	37	37	37	37	37
	Missing	1	1	1	1	1	1	1	1
Mean		5.00	4.97	4.95	5.00	4.78	4.78	4.81	4.81
Median		5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
Mode		5	5	5	5	5	5	5	5
Std. Deviation		.000	.164	.329	.000	.534	.479	.518	.518
Std. Error of Skewness		.388	.388	.388	.388	.388	.388	.388	.388
Minimum		5	4	3	5	3	3	3	3
Maximum		5	5	5	5	5	5	5	5
Skewness			-6.083	-6.083		-2.498	-2.203	-2.794	-2.794

Implications - Practice

- New guidelines being utilized to an exent
  - Rate of screening prior to 20 weeks gestation was only 57%
- Potential causes for the delay in screening
- GDM class was proven to be beneficial to the participants, but the actual long term effectiveness of the class is unknown

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Implications – Future Research

- Additional research to fully optimize the screening process for GDM
  - 57% screening prior to 20 weeks
  - Physician trends and/or limitations for delay
- GDM classes
  - Follow these women from the initial GDM screening throughout the pregnancy and even the delivery
  - Evaluate overall blood sugar management and fetal outcomes
  - Research could continue long term to evaluate the probability of women with GDM and/or the macrosomia/LGA neonates developing type 2 diabetes mellitus in the future

Strengths

- Consistency among the educators. CDEs are trained and certified in diabetes education and therefore maintain the required knowledge to present the GDM classes.
- Study population of 35 participants was larger than the originally proposed sample size of 30.
- An accidental strength of the project was due to the delay in implementation as it provided the physicians approximately a year to adjust to the new screening guidelines prior to the project being implemented and screenings for GDM being measured

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Limitations

- Study population is a convenience sample.
- Study population size was small even though larger than initially proposed
- Length of the project
- Timing of the class with regards to weeks gestation

Recommendations for Limitations

- Larger study sample
- Study sample obtain through method other than one of convenience
- Longer time frame for study
- Women to attend GDM class during first trimester

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Analysis

- As scholar
  - Gained vast knowledge in screening, treating, and providing education for GDM
  - Gained awareness and knowledge of the many complications both mother and child may be subjected to as a result of poorly controlled blood sugars.
- As practitioner
  - Outpatient population challenges
- As project developer –
  - Project development is challenging and vigorous
  - An educational experience that can be obtained in any other format
  - Better understanding and appreciation of the various steps necessary to conduct a quality study

Conclusion

- Project outcomes were proven
  - 57% women screened for GDM prior to 20 weeks gestation
  - 16.3 point increase from pretest to posttest results
- Beyond the scope of this DNP project, the ultimate goal was to reduce complications associated with GDM
- Cesarean section rates decreased from 37.4% in 2013 to 35.4% in 2014
  - January through April 2015 34.3%
- Macrosomia decreased from 11.6% in 2013 to 10% in 2014
- LGA rates increased from 27.7% in 2013 to 28.3% in 2014
- Infant hypoglycemia has also decreased from 18 in 2013 to 14 in 2014
  - 7 NICU admissions in 2013 to 5 in 2014

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Recommendations

- Continue to screen for GDM in first trimester
- Meet with obstetric providers to discuss current screening rate
  - Why and how to improve?
- Continue with early referral for GDM education
  - Stress importance of early attendance to patient
- Continue to monitor LGA and macrosomia
  - Add cesarean section, infant hypoglycemia, and NICU admissions due to infant hypoglycemia
  - May also consider adding other complications such as shoulder dystocia, hypertension, prematurity, and preeclampsia

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