DEVELOPMENT AND EVALUATION OF PROTOCOL FOR EARLY SCREENING FOR DIABETES IN PREGNANCY: A QUALITY IMPROVEMENT INITIATIVE

By

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The DNP Project committee for Courtney E. Carlson certifies that this is the approved version of the following DNP Project:

Development and Evaluation of Protocol for Early Screening for Diabetes in Pregnancy: A Quality Improvement Initiative

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Abstract

Diabetes Mellitus is a dangerous condition known to cause adverse effects to both mother and fetus. Rates of diabetes are increasing worldwide. Research indicates that undiagnosed pre-existing, or overt, diabetes may increase poor outcomes in pregnancy; therefore, new recommendations from healthcare organizations endorse first-trimester screening for undiagnosed pre-existing diabetes in at-risk patients.

Diabetes screening during pregnancy has long-been studied, and universal screening for gestational diabetes between 24 and 28 weeks gestation is endorsed by all major healthcare organizations. However, until recently, little research explored pre-existing diabetes and related effects on pregnancy.

In 2018, the American College of Obstetricians and Gynecologists released new recommendations regarding screening at-risk patients in the first trimester of pregnancy. However, many providers have not yet begun to implement this testing.

This project chronicles the development and evaluation of a protocol designed to identify and screen at-risk patients in the High-Risk Obstetrics clinic in an academic medical center located in a Midwestern city. After a review of the current literature, an evidence-based protocol for screening for overt diabetes in early pregnancy was developed. An inter-professional expert panel evaluated the protocol using the REDCap system, and the results were analyzed using qualitative and quantitative methods.

Upon review and analysis, much of the evaluation results were positive, but some areas for improvement were clear. Evaluation was broken down by theme, to identify patterns in results. This information was then employed in developing a second, and final, draft of the Protocol.

The response of a multi-professional provider review team supports adoption of this protocol; therefore, after making recommended alterations in format and content, this protocol will be considered for introduction in the High-Risk Obstetrics Clinic detailed in this document. Indicated follow-up study should include determining the early diagnosis rates of diabetes in pregnancy, as well as a cost analysis of the available methods of testing in early pregnancy.

Keywords: *diabetes, prenatal care, screening, protocol, diabetes in pregnancy, overt diabetes*

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Introduction

Diabetes Mellitus (DM) is a dangerous health condition with rates of diagnosis increasing worldwide. Defined as the inability to use insulin effectively, (Centers for Disease Control [CDC], 2017), DM leads to elevated glucose levels in the blood. This condition is risky and may lead to fatal complications if not treated appropriately. DM is also very threatening to both mother and fetus during the pregnancy (Metzger, Gabbe, & Persson, 2010). Under the umbrella diagnosis of DM, there are multiple subcategories, all with different physiologic processes, including gestational diabetes (GDM), Type I diabetes (DMI), and Type II diabetes (DMII). Any untreated or under-treated form of diabetes may have adverse and lasting effects on the health of a pregnancy (Amylidi, Mosimann, Stettler, Fiedler, Surbek & Raio, 2015; Mission, Catov, Deihl, Feghali, & Scifres, 2017).

Problem & Significance

During pregnancy, untreated DM has been shown to cause poor outcomes for both mother and fetus, including fetal and neonatal morbidities such as macrosomia (large body-size), glycemic instability after delivery, and neonatal death. Maternal complications include increased risk of pre-eclampsia, shoulder dystocia, preterm birth, and cesarean delivery, as well as lasting non-obstetric related complications from diabetes including nephropathy, neuropathy, and retinopathy (American College of Obstetricians and Gynecologists, 2018; Hessler & Dunemn, 2017; Wong, Ross, Jalaludin, & Flack, 2012).

The American Diabetes Association (ADA, 2016) defines GDM as elevated blood glucose levels during pregnancy when the patient has never had a previous diagnosis of diabetes. In the United States, it is estimated that roughly seven percent of all pregnancies, and even up to 14 percent of pregnancies in obese patients, are affected by DM (ACOG, 2018; Fong, Sere,

Gabby, Wing, & Berkowitz, 2014). Standard screening for GDM in patients that have not been diagnosed with DM prior to pregnancy, consists of an Oral Glucose Tolerance Test (OGTT), administered to all pregnant patients, between 24 and 28- weeks of gestation, to identify patients with GDM. According to Hessler & Dunemn (2017), GDM typically does not manifest until at least the second trimester of pregnancy; therefore, if a patient is diagnosed with diabetes in the first trimester, she should be considered an overt diabetic. Overt diabetes, a term introduced by the International Association of Diabetes and Pregnancy Study Group (IADPSG), is referred to in their 2010 Consensus Panel as "prepregnancy diabetes" (Metzger et al, 2010), and established the recommendation to test for this pre-existing condition during the first prenatal visit because of the dangers associated with untreated diabetes in pregnancy. Unfortunately, many patients with overt diabetes have never received a diagnosis prior to becoming pregnant, and they may continue to have untreated glycemic elevations until standard screening is completed in the late second trimester. Organogenesis, the period of organ formation for the fetus, occurs during the first trimester, and maternal hyperglycemia (high blood sugar), during this time may lead to negative effects for the fetus. Potential complications during this time frame include congenital birth defects or even spontaneous abortion (Hughes, Moore, Gullam, Mohamed, & Rowan, 2014). In many cases, overt DM continues to be undiagnosed and untreated until the standard 24 to 28-week OGT screening test.

Diagnosing Diabetes

According to estimations from the ADA (2017), over 30.3 million Americans suffered from DM in 2015; however, one-quarter of these cases went undiagnosed. Diagnosis of DM may be made using either a Hemoglobin A1c (HbA1c), a Fasting Plasma Glucose (FPG), or an OGTT (ADA, 2018). HbA1c is a blood test which evaluates the average blood glucose level

over roughly twelve weeks, giving practitioners, an idea of the blood glucose control the patient has had in the recent past (ADA, 2014). A normal-range HbA1c is <5.7%, pre-diabetes is indicated by 5.7 – 6.4%, and a result of 6.5% or greater is diagnostic for DM (ADA 2014). A FPG, drawn when the patient has been fasting for at least eight hours, is diagnostic of DM if it is greater than or equal to 126. The OGTT is a blood glucose measured two hours after drinking a measured glucose solution. A normal reading is less than 140, prediabetes range is 140-199, and diabetes is diagnosed if the reading is 200 or greater. A provider may also check a random glucose; if it is greater than 200, the ADA states this "may indicate a diagnosis of DM" (2014). Confirmation testing using a second method is recommended when diagnosing DM.

Diagnosing Gestational Diabetes (GDM) and Overt Pre-Existing DM in Pregnancy

Standard GDM screening occurs between 24 and 28 weeks gestational age, using either the one-step or two-step OGTT. This was endorsed by the U.S. Preventive Services Task Force in 2014 and is accepted by most major professional organizations (ACOG, 2018; WHO, 2013).

Concerns have arisen that patients with undiagnosed diabetes that pre-dates the pregnancy have increased fetal exposure to hyperglycemia during the first and second trimesters, leading to increased fetal and maternal morbidity (Metzger et al, 2010). Due to increasing prevalence of diabetes in the general population, rates of overt diabetes in pregnancy have also increased. Studies demonstrate a positive correlation between prolonged fetal exposure to uncontrolled blood glucose and adverse pregnancy outcomes (Amylidi et al., 2015); therefore, there is potential benefit to screening women at-risk for overt diabetes in the first trimester of pregnancy, or even during the first prenatal visit.

Many organizations, including ACOG, the ADA, and the IADPSG have implemented recommendations for early screening of patients classified as at-risk for overt diabetes (Mission

et al, 2017; ACOG 2018). General recommendations for at-risk patients are those who are overweight or obese, defined as Body Mass Index (BMI) of greater-than or equal-to 25, and other genetics, lifestyle, and personal medical-history based criteria (See Figure One). Future research is needed to determine the most appropriate diagnostic test for diabetes in pregnancy; currently HbA1c, FPG, and OGTT are all acceptable options (ADA, 2014).

Screening Strategy or Detecting Pregestational Diabetes or Early Gestational Diabetes Mellitus

Consider testing in all women who are overweight or obese (ie, have a body mass index greater than 25 or greater than 23 in Asian Americans) and have one or more of the following additional risk factors:

- Physical inactivity
- First-degree relative with diabetes
- High-risk race or ethnicity (eg, African American, Latino, Native American, Asian American, Pacific Islander)
- Have previously given birth to an infant weighing 4,000g (approximately 9 lb) or more
- Previous gestational diabetes mellitus
- Hypertension (140/90 mm Hg or on therapy for hypertension)
- High-density lipoprotein cholesterol level less than 35 mg/dL (0.90 mmol/L), a triglyceride level greater than 250 mg/dL (2.82 mmol/L)
- Women with polycystic ovarian syndrome
- A1c greater than or equal to 5.7%, impaired glucose tolerance, or impaired fasting glucose on previous testing
- Other clinical conditions associated with insulin resistance (eg, prepregnancy body mass index greater than 40 kg/m², acanthosis nigricans)
- History of cardiovascular disease

Figure 1. ACOG Recommendations for screening in early pregnancy, adapted from the American Diabetes Association Classification and Diagnosis of Diabetes (2017).

Optimally, testing is performed at the first prenatal visit; however, if this is not feasible, it should be completed before the end of the first trimester, to avoid complications of hyperglycemia during organogenesis (Amylidi et al., 2015). If the patient is not diagnosed with DM based on the first-trimester screening, she should complete the recommended standard OGTT between 24 and 28-weeks of gestation (Metzger et al., 2010).

Adherence to Practice Guidelines

National organizations have adopted recommendations to screen women at-risk for undiagnosed overt DM in early pregnancy; however, not all providers have implemented this practice. Instead, many providers continue to rely on the standard 24-to 28-week OGTT, thereby losing the benefit of early diagnosis and treatment of overt DM. A recent study from *Obstetrics & Gynecology* (Mission et al, 2017), found that rates of early screening for diabetes in at-risk patients are relatively low. Of more than 11,000 women in the study, only 1,420 patients received early screening. BMI classification of overweight or obesity is one criterion for pre-gestational screening: 73.2% of women in this study were classified as obese or overweight, and less than 13% of participants were screened prior to 24 weeks gestation. The authors discuss these missed opportunities for early diagnosis and they explore possible reasons for lack of testing.

Multiple studies have determined the significance of testing an early HbA1c in pregnancy to explore implications for maternal and fetal health. Hughes et al. (2014) studied the use of HbA1c in early pregnancy after identifying the increased rates of congenital anomalies and perinatal mortality in undiagnosed pre-gestational diabetics. These findings indicate that a first trimester HbA1c screening test with a cutoff of 5.9% was sufficient to identify all women who would eventually be diagnosed with GDM using the standard OGTT.

In 2015, Rowan, Budden, Ivanova, Hughes, and Sadler found that women diagnosed by the HbA1c earlier in pregnancy had lower rates of pre-eclampsia and a lower risk of pre-term birth than women diagnosed after 24 weeks of gestation. A third study found that a baseline first trimester HbA1c of greater-than 5.9% positively correlated with an increased risk of fetal macrosomia, cesarean delivery, and hypertensive disorder in the pregnancy (Sweeting, Ross,

Hyett, Molyneaux, Tan, Cosentino, Harding, & Wong, 2017). Each of these studies found that early screening with HbA1c has benefits to the outcome of the pregnancy. The studies also determined that timing was important: earlier identification of diabetes was associated with lower risks of adverse outcomes to the pregnancy.

Purpose & Aim

The aim of this quality improvement Doctor of Nursing Practice project was to assist providers in identification and screening of pregnant patients at-risk for pre-existing overt diabetes, and examined the development and evaluation of a protocol for early identification and screening of these patients in a High-Risk Obstetric (HROB) clinic setting. The "First Trimester Screening Protocol for Overt Diabetes" was developed using current literature and evidence-based practice. The goal for this project was to answer the following question: will the use of the "First Trimester Screening Protocol for Overt Diabetes" tool improve provision of prenatal care? The project began with a review of the current literature, followed by development and evaluation of the protocol tool by a multi-professional panel of expert providers using the AGREE II tool. Finally, after analysis of evaluations was completed, modifications and recommendations for use of the protocol in clinical practice were then discussed.

Review of the Literature

A review of current research and literature regarding the use of HbA1c in early pregnancy was conducted using PubMed. Search terms included "pre-existing diabetes in pregnancy", "HbA1c in early pregnancy", "first trimester diabetes screening", "early GDM screening", and "pre-gestational diabetes screening." Results were screened by title. Inclusion criteria consisted of English-language articles available in full-text, from peer-reviewed journals, published within the last six years. Abstracts were reviewed and those deemed relevant to the

desired topic were included. The reference lists from the final articles were evaluated, and one landmark article which was consistently cited, the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) Study (Lowe, et al, 2012), was included. The addition of this study brought the total to nine relevant articles for review of evidence regarding the use of diabetes screening in early pregnancy.

Extensive research has been conducted on the use of screening tests in early pregnancy over the past six years, and much of this research has centered around two main themes. These are the use of HbA1c in pregnancies less than 24 weeks gestation to predict future diagnosis of GDM, and the use of HbA1c to predict severity of adverse outcomes in the affected pregnancy. This literature review examined the similarities, differences, and recommendations associated with current evidence regarding the use of HbA1c in pregnancy.

HbA1c as Diagnostic Screening for GDM

Four studies evaluate the effectiveness of early HbA1c leading to the diagnosis of GDM, and the results are mixed (Amylidi, et al., 2015; Benaiges, et al., 2017; Fong, et al., 2014; Osmudson, et al., 2016). In each study, a HbA1c was drawn in early pregnancy; the results were then compared to the standard OGTT screening collected between 24 and 28 weeks gestation. Benaiges, et al. (2017) determined that the HbA1c drawn in the first trimester using a cutoff of 4.8% was not sensitive or specific enough to accurately predict a diagnosis of GDM later in pregnancy. Increasing the cutoff to 5.6%, the number associated with a diagnosis of pre-diabetes in non-pregnant patients, was associated with a decrease in the positive predictive value. However, it was determined that implementation of the one-step HbA1c test would have multiple benefits to the patient compared to OGTT, including cost-savings, decreased time spent testing, and less delay in diagnosis. HbA1c is a one-step test, compared to the standard two-step OGTT,

which involves a one-hour screening then a three-hour diagnostic test. This large study (n=1158) with a diverse population, was conducted in one clinic setting; however, limitations include a large loss to follow-up, and a lack of information regarding pregnancy outcomes. Another large study (Osmudson, et al., 2016) reports similar findings while using the same cutoff criteria of 5.6%, to predict future development of GDM. This retrospective cohort study determined a low sensitivity of 13% in the first trimester HbA1c predicting GDM, compared to OGTT results.

Two studies determined a positive correlation between an elevated HbA1c in the first trimester and the development of GDM. (Amylidi, et al., 2015; Fong, et al., 2014). In their observational, retrospective cohort study, Amylidi, et al. studied 208 patients from one clinic, who were considered at-risk for overt DM due to one of the following criteria: BMI > 30 kg/m², a first-degree family member suffering from DM, polycystic ovarian syndrome, a personal history of GDM in pregnancy, delivery of an infant >4500 grams, or being of the "at-risk ethnicities," including African, Latino, Asian, or Pacific Islander. An HbA1c was drawn at the first prenatal visit. All patients were then given a "one-step" 75-gram, two-hour OGTT between 24 to 28 weeks gestation. HbA1c values of the women who developed GDM were found to be significantly higher than those who did not have elevated OGTT results. Notably, in women with HbA1c between 5.7% and 6.4% (pre-diabetes range), there was a statistically significant increase in the prevalence of GDM.

Fong, et al., (2014), was an early contributor to the idea of HbA1c benefit in early pregnancy, completing the test at the first prenatal visit in all participants regardless of risk factors for DM. They found that nearly one-third of patients in the pre-diabetes group (HbA1c of 5.7% to 6.4% in the first trimester) developed GDM compared to 8.7% who had an HbA1c <5.7%. This significant correlation is associated with the recommendation that patients with an

early HbA1c within the pre-diabetic range must have closer evaluation regarding the development of GDM and possible intervention with screening as early as possible in pregnancy.

HbA1c to Determine Adverse Outcomes in Pregnancy

Mother and fetus are both at risk in pregnancies complicated by GDM or undiagnosed overt diabetes (ACOG, 2018). Four major studies in the previous six years have evaluated the risks, including the landmark study investigating the use of HbA1c in pregnancy, (Hughes, et al., 2014; Lowe, et al., 2012; Rowan, et al., 2014; Sweeting, et al., 2017) including the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) Study by from 2012. This study evaluated the effect of various glycemic excursions on the outcome of pregnancy in patients affected by DM. Over 23,000 women were included in this study, and results indicate that in patients with impaired insulin resistance, rates of birthweight greater-than the 90th percentile, primary cesarean delivery rates, and preterm delivery rates are all higher than in non-affected pregnancies.

Hughes, et al., (2014) also investigated outcomes of pregnancies complicated by DM, and determined that an HbA1c between 5.9% and 6.4% prior to twenty weeks gestation was associated with poor outcomes including an increased risk of congenital anomalies, shoulder dystocia with delivery, pre-eclampsia affecting pregnancy, and perinatal death. The authors determine that testing HbA1c is beneficial, cost-efficient, and easier on the patient than OGTT screening.

One observational study by Rowan, et al., (2015), compares the outcomes of three patient groups: those with HbA1c between 5.9% and 6.4% diagnosed earlier than 24 weeks gestation, those with the same HbA1c range diagnosed after 24 weeks gestation, and those diagnosed prior to 33 weeks gestation with an HbA1c less than 5.9%. Across the board, those with the higher

range HbA1c results had worse outcomes, with statistically significant increased rates of pre-eclampsia, preterm birth, and admission to the Neonatal Intensive Care Unit (NICU). The authors determine that earlier treatment of GDM significantly reduces the risk of certain morbidities associated with diabetes in pregnancy.

Finally, Sweeting, et al. (2017) recently published a study investigating the optimal level of HbA1c between 24 and 28 weeks gestation to avoid poor outcomes, including fetal macrosomia (birthweight greater than 4000 grams), large-for-gestational age (LGA), or small-for gestational-age (SGA), which are defined as greater than the 90th percentile and less than the 10th percentile of expected body weight, respectively. Also studied were admission rates to the NICU, respiratory distress syndrome in the neonate, fetal hypoglycemia, preterm delivery, cesarean section rates, and hypertensive disorders such as pre-eclampsia. The authors determined that an HbA1c greater than 5.9% was associated with an increased risk of LGA, macrosomia, cesarean section, and hypertensive disorders. Interestingly, low HbA1c was also associated with neonatal complications, such as SGA infants and hypoglycemia.

HbA1c testing in pregnancy is beneficial for many reasons, including, but not limited to, convenience of the test and decreased invasiveness compared to the OGTT. One study investigated and concluded that HbA1c is an accepted tool in pregnancy, useful for evaluating maternal glycemic control both prior to, and during the pregnancy (Hughes, Rowan, & Florkowski, 2016). An euglycemic state has been shown by many studies to correlate with increased rates of healthy pregnancies; therefore, the literature supports the basis for this project (Hughes, et al., 2014; Rowan, et al., 2015; Sweeting, et al., 2017).

A gap exists in the literature regarding diagnosis of overt diabetes in early pregnancy; thus, there is a need for further research on this topic. However, there have historically been concerns associated with the use of the HbA1c test during pregnancy to determine overt DM.

Historically Cautious Use of HbA1c in Pregnancy

Hemoglobin A1c, also known as glycosylated hemoglobin, measures the amount of glucose attached to hemoglobin circulating in the body (Medline Plus, 2018). In the past, the accuracy of the HbA1c in pregnancy has been questioned, due to the physiologic changes of pregnancy, including increased blood volume which causes hemodilution, and an increased rate of red blood cell turnover (ADA, 2015). Due to these physiological changes, HbA1c historically was not used during pregnancy; recent studies investigating the use of this test to diagnose women with overt DM in the first trimester of pregnancy have become more common. Confidence in the HbA1c test during pregnancy has increased over the past ten years. However, caution is required when introducing a protocol implementing HbA1c as a screening tool for use in pregnancy. Many studies have investigated the effectiveness for diagnosing DM in pregnancy based on a standardized cutoff HbA1c level of 6.5%. Associations with later diagnosis of GDM in the literature range from 4.8% to 6.5% in the first trimester HbA1c. It is important to determine the acceptable ranges prior to implementation of this protocol for screening use in the HROB clinic.

Summary

A major gap in the literature is the use of HbA1c in early pregnancy to detect previously undiagnosed overt DM. There is a large population of pregnant patients with the potential for undiagnosed overt DM, which may cause adverse outcomes as the pregnancy progresses. These patients have an increased risk of poor pregnancy outcomes, as revealed by multiple studies cited

above. Therefore, it is important to diagnose and treat DM as early in the pregnancy as possible. Future research on this topic is needed to further clarify the most appropriate diagnostic cutoffs and treatment procedures with overt diabetes screening in pregnancy.

Project Details

Theoretical Framework

A modified SWOT Analysis was the model that drove this project (See Figure Two). SWOT, which stands for Strengths, Weaknesses, Opportunities, and Threats, is a method to analyze the positive and negative aspects that affect change in any institution (Swysen, Lousbergh, Deneckere, & Vanhaecht, 2012). This was modified because, typically, a SWOT Analysis would be conducted using a large group to evaluate. This project was developed with only the input from the author and faculty members.

	Helpful	Harmful
Internal	Strengths	Weaknesses
External	Opportunities	Threats

Figure 2. Pictorial display of the strengths, weaknesses, opportunities, and threats included in a SWOT Analysis. Adapted from Swysen et al, 2012.

Strengths. Strengths of the development of this project far outweigh the weaknesses and threats. Three main strengths are included in this summary. The first strength is that this protocol offered a clear definition of patients considered "at risk." By distributing a facility-approved protocol, providers are likely to become more familiar with the risk-factors, and are more likely to order early pregnancy screening for pre-existing diabetes affecting pregnancies. Consistency of care is the second strength that this project would provide, if implemented. The protocol will serve as instructions in how to manage at-risk patients: which lab tests to order, at what gestational age, and what follow-up is appropriate. By clearly defining the steps providers should take, patients will be provided consistent, evidence-based care and screening will be carried out according to evidence-based practice.

Finally, the third strength afforded by this protocol is buy-in from multi-professional providers. Currently in the HROB clinic, there are only Maternal Fetal Medicine Specialist (MFM) attending physicians and Fellows providing patient care. Within this limited group, there is disagreement on appropriate management of these at-risk patients. By promoting a protocol for standard of care and soliciting feedback from multi-professional providers, this project accomplishes the goal of providing standardized care with buy-in from all providers involved in this HROB clinic.

Weaknesses. Two potential weaknesses have been identified, which may occur during the implementation of this project. The first weakness is a lack of feedback from providers asked to evaluate the protocol. Many of these providers are extremely busy, and it was difficult to obtain the necessary feedback from everyone. To overcome this potential set-back, a large panel of multi-professional providers was included. Feedback was requested from multiple

providers involved with the department, to get feedback that encompasses all professions involved with this patient population.

The second potential weakness in this project setup is the process for protocol implementation at the hospital system with which this HROB clinic is affiliated. There is an implementation process including a review board, which is time-consuming and limits approval to some suggested protocols. There is the possibility that, even after implementing changes and suggestions from the evaluation panel, this protocol is unfit for acceptance through the hospital system.

Opportunities. Multiple opportunities exist in executing this project. These opportunities include providing the best, evidence-based care for patients; the opportunity to improve pregnancy outcomes with improved identification of those at-risk; standardized care across the professional continuum; and heightening the level of care provided. If this protocol is well-regarded, it could be the impetus to continue to examine protocols and other projects to investigate, update, and encourage changes in standard of care for these high-risk patients.

Threats. Threats include the potential that providers or physicians in the management team of the HROB clinic will not support the implementation of this protocol. The hospital-system may determine this protocol is unacceptable, and the providers, may, even after implementation, decide they do not wish to begin screening for diabetes in early pregnancy. Patients' lack of ability to pay for testing is another such threat which may limit the scope of this implementation. A sizeable portion of patients in the HROB clinic are self-pay or uninsured, and many of these patients may see diabetes screening as optional or unnecessary. Many other patients receive state-funded insurance, which may not cover testing screening tests early in pregnancy. This is a severe limitation which poses a threat to the implementation of this project.

Midwifery Model of Care

The Midwifery Model of Care is a second theoretical model driving the development of this project. Midwives are experts in the care of normal, healthy women. According to the American College of Nurse-Midwives (2018), the Midwifery Model includes striving to provide responsible, equal care to all people, allowing for self-care and involvement of family members. The model promotes compassion, individualized, evidence-based care, therapeutic use of human presence, and skillful communication. The belief is that the lifecycle of the woman should be treated as a normal event, with watchful waiting if it is a normal process; however, the use of consultation, collaboration, and referral to the healthcare team members is encouraged if appropriate, to provide optimal care. Formal education, lifelong learning, research, and ethical, competent midwifery care are valued. They are committed to improving the health of women and their families worldwide.

This model drives the development of this project, because many women desire prenatal care from a Certified Nurse-Midwife during their pregnancies. If these patients suffer from undiagnosed overt diabetes prior to becoming pregnant, they are not appropriate to be managed solely by Nurse-Midwives and should be referred for consultation or collaboration with a physician. This protocol will help to determine the most appropriate provider to assure safe care to mother and fetus.

Project Design, Rationale, & Assumptions

This quality improvement project aimed to develop and evaluate the "First Trimester Screening Protocol for Overt Diabetes", which has potential to impact the HROB Clinic and its' effectiveness in diagnosing overt diabetes in the first trimester of pregnancy. This project is warranted, as recent recommendations from many healthcare organizations is to perform diabetes

testing in the first trimester of pregnancy for at-risk patients. According to the ADA (2017), roughly one-quarter of patients who suffer from diabetes are unaware of their illness. Therefore, it is reasonable to conclude that some proportion of patients currently receiving prenatal care in this clinic also suffer from undiagnosed pre-existing diabetes, which could negatively affect their pregnancy. The author's assumption is that providers in this setting are unaware of the new recommendations for early screening of at-risk patients, and they are not ordering testing during the first trimester for patients who meet the necessary criteria. By implementing a protocol for screening all at-risk patients in the first trimester, providers in this clinic will become more aware of the factors qualifying these patients as at-risk, and these providers will be more likely to proceed with appropriate screening. Therefore, the working hypothesis is that the providers will find this protocol to be a useful and beneficial tool, which will improve the care provided to patients.

Quality Improvement Designation

Prior to evaluation by expert providers, a Quality Improvement Determination Request (Appendix #B) was submitted to the Human Subjects Committee at the University of Kansas Medical Center. This application was accepted and approved prior to proceeding with distribution of the protocol proposal and evaluation form.

Setting

The setting for this study was from a small, High-Risk Obstetrics clinic in a large, urban, midwestern hospital system. Roughly 80 patients are seen weekly by six Maternal Fetal Medicine Attending physicians and four Fellows. On average, ten patients per week are seen in their first trimester of pregnancy. The patient population is roughly 50% Hispanic and 50% Caucasian, and patients are either referred in from outside providers for high-risk pregnancy

conditions of mother or fetus, or patients self-refer for a history of medical conditions complicating pregnancy. Now, first-trimester diabetes screening is not routinely used to identify pre-existing diabetes, although many patients do meet the suggested at-risk criteria for screening. The rates of positive screening for GDM during the standard 24- to 28-week OGTT are high; therefore, it is plausible to believe that some of these at-risk patients have pre-existing diabetes which may cause adverse effects to the pregnancy and the future health of the patient and fetus.

Methodology

Development of the Protocol

By identifying at-risk patients and standardizing the use of an early screening test in pregnancy, there is the potential for great benefit to both mother and fetus. Early diagnosis and treatment of diabetes in pregnancy may decrease adverse outcomes related to long-term untreated hyperglycemia during pregnancy.

In 2018, ACOG released Practice Bulletin #180, which revolves around the care of patients with gestational and overt diabetes. The recommendation to screen for undiagnosed overt diabetes early in pregnancy has been around since 2010, when the IADPSG released "Recommendations on the diagnosis and classification of hyperglycemia in pregnancy." This practice recommendations details many of the concerns associated with untreated diabetes in pregnancy. These recommendations from multiple healthcare associations, combined with rapidly increasing rates of DM around the world, led to the idea for a development of a protocol to identify and screen at-risk patients in this clinic setting. The first draft of this protocol, entitled "First Trimester Screening Protocol for Overt Diabetes" is located in Appendix A. This protocol was developed specifically for use in the HROB clinic, using recommendations from ACOG (2018), the IADPSG (2010), and the ADA (2015), in an attempt to identify patients

appropriate for early screening in pregnancy. The working hypothesis is that this will improve the delivery of prenatal care and treatment of previously undiagnosed pre-existing diabetes in pregnancy.

Evaluation of the Protocol

A survey, along with the "First Trimester Screening Protocol for Overt Diabetes", was distributed to an expert panel of multi-professional providers affiliated with the HROB clinic to ascertain the expert panel's evaluation of the protocol. The survey was based on the Appraisal of Guidelines for Research and Evaluation (AGREE) II tool (See Appendix B). This tool is devised of seven domains and 30 items and uses a Likert scale to calculate a quantitative score to evaluate an appraisal. The seven domains include "Scope of Practice", "Stakeholder Involvement", "Rigor of Development", "Clarity of Presentation", "Editorial Independence", and a final domain that requests an overall quality rating of the protocol. Finally, the survey concludes with four open-ended questions eliciting responses to the protocol. The responses to this section were used to evaluate strengths, concerns, and recommendations for modifications, as well as suggestions for implementation of the protocol into practice. The last query requests the role of the respondent in the HROB clinic. The AGREE II tool was developed specifically for use in evaluating Clinical Practice Guidelines. This tool has been used in numerous clinical studies and has proven benefits of reliability and validity (Cruz, Fahim, & Moore, 2015).

The expert panel consisted of a multi-professional team. The HROB clinic this protocol is intended for currently only employs MFM physicians as providers; however, all potential types of care providers affiliated with the clinic were asked for feedback on the protocol. The expert panel included: MFM attending physicians and MFM Fellows, the Obstetrician/Gynecologist (Ob-Gyn) physician Chair of the Women's Health Department at the Hospital System, Certified

Nurse-Midwives from clinics in the hospital system, Ob-Gyn resident physicians, and Registered Nurses from the HROB clinic. By including a multi-professional panel, evaluation feedback ensures that this protocol encompasses knowledge and evidence-based practice from across the care continuum.

Analysis

Data analysis for this proposal consisted of a quantitative analysis of the Likert scale-guided evaluation questions using the AGREE II tool, utilizing the REDCap system. Qualitative analysis was then performed for responses to the open-ended questions. Recommendations were considered regarding proposed revisions to the protocol and in determining suggestions for implementation of the tool into practice.

Results

Study data were collected and managed using REDCap electronic data capture tools hosted at Kansas University Medical Center (Harris, Taylor, Thielke, Payne, Gonzalez, & Conde, 2009). Through this survey management system, the evaluation tool was emailed to 14 individuals involved in providing care in the HROB clinic, including two MFM attending physicians, three MFM Fellow physicians, three Obstetrics and Gynecology resident physicians, two Certified Nurse-Midwives, three Registered Nurses, and one Ob-Gyn attending physician, who is the Chair of the Women's Health Department for the Hospital System. Of fourteen surveys sent, ten responses were received, for a 71% response rate and there was at least one response from each of the professions included in the survey; however, one of the Ob-Gyn resident physicians marked herself as an Ob-Gyn attending.

The AGREE II Instrument is broken down into seven domains with a final section eliciting feedback and recommendations through open-ended questions. The first seven domains

are graded on a Likert-scale with responses of 1 to 7, with the following responses: 1=Strongly Disagree, 2=Disagree, 3=Partially Disagree, 4= Neutral, 5= Partially Agree, 6=Agree, and 7=Strongly Agree.

Each of the seven domains which utilized the Likert-scale was evaluated with mean average scores of 5 or 6, indicating "Agree" or "Strongly Agree". Figure 3 details the mean average responses for the first seven domains in the evaluation tool for the First Trimester Screening Protocol for Overt Diabetes. Details of each Domain topics, individual questions, and mean average results are discussed below. In parenthesis after each question is the individual question mean average.

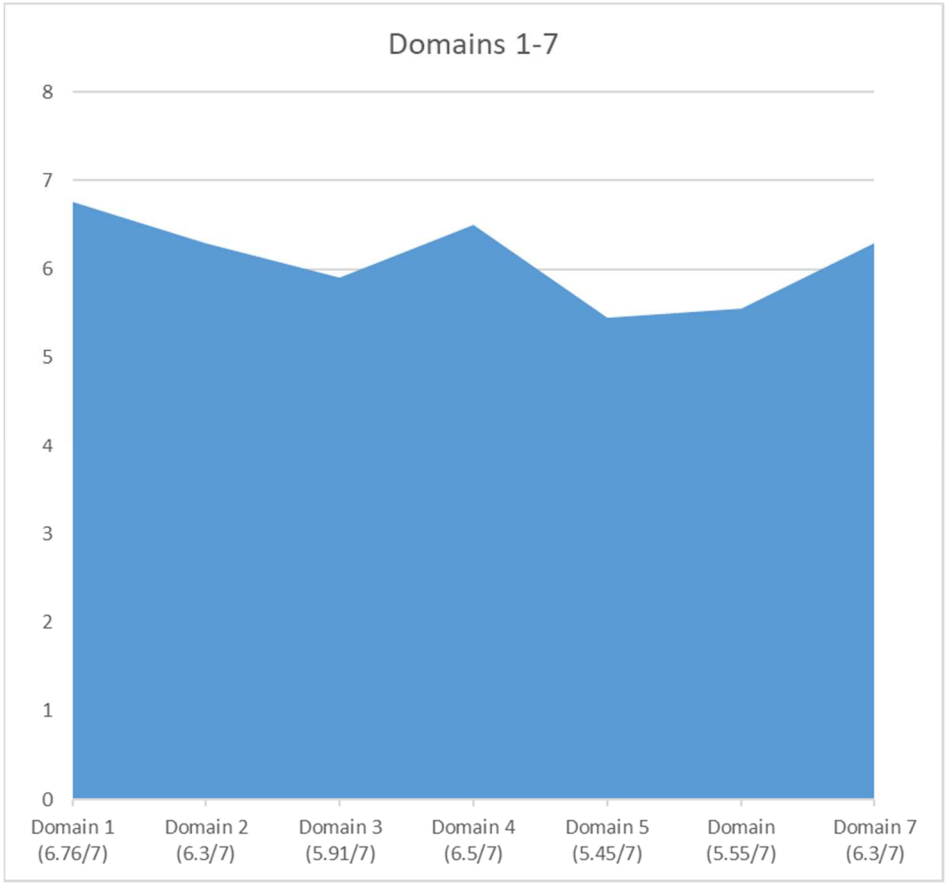

Figure 3. Mean scores for domains One through Seven of the AGREE II Evaluation tool sent to a multi-professional panel of experts.

Domain One: Scope of Practice

Domain One received an average rating of 6.76 out of 7. The three questions included in this domain are, "1. The overall objectives of the protocol are specifically described" (6.7), "2. The health questions covered by the protocol are specifically described" (6.7), and "3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described" (6.9).

Domain Two: Stakeholder Involvement

Consisting of three questions, Domain Two collected a mean average of 6.3 out of 7. Domain Two questions consisted of "4. The protocol involves individuals from all relevant professional groups" (6.6), "5. The views and preferences of the target population (patients, public, etc.) have been sought" (5.7), and "6. The target users of the protocol are clearly defined" (6.6).

Domain Three: Rigor of Development

The evaluations of Domain Three elicited more variability than any other domain. The eight questions had individual mean averages ranging between 4.9 (question 14) and 6.6 (question 12), with an overall mean average of 5.91. These questions included, "7. Systematic methods were used to search for criteria" (6.0), "8. The criteria for selecting the evidence are clearly defined" (5.8), "9. The strengths and limitations of the body of evidence are clearly described" (5.6), "10. The methods for formulating the recommendations are clearly defined" (5.4), "11. The health benefits, side effects, and risks have been considered in formulating the recommendations" (6.5), "12. There is an explicit link between the recommendations and the supporting evidence" (6.6), "13. The guideline has been externally reviewed by the experts prior to its' publication" (6.5), "14. A procedure for updating the protocol is provided" (4.9).

Domain Four: Clarity of Presentation

Domain four is entitled, "Clarity of Presentation." The average for the group of three questions in Domain four was 6.5, and the individual questions were "15. The recommendations are specific and unambiguous" (6.9), "16. The different options for management of the condition or health issue are clearly presented" (5.8), and "17. Key recommendations are easily identifiable" (6.8).

Domain Five: Applicability

Domain Five encompassed four questions. The questions are, "18. The protocol describes facilitators and barriers to its application" (5.4), "19. The protocol provides advice and/or tools on how the recommendations can be put into practice" (6.2), "20. The potential resource implications of applying the recommendations have been considered" (5.1), and "21. The protocol presents monitoring and/or auditing criteria" (5.1). The domain average was 5.45/7.

Domain Six: Editorial Independence

Two questions make up Domain Six, which garnered a mean average rating of 5.55/7. These questions include, "22. The views of the funding body have not influenced the content of the guideline" (6.1), and "23. Competing interests of the guideline members have been recorded and addressed" (5.0).

Domain Seven: Overall Quality

Domain 7, which asks for an overall quality rating of this protocol, received a score of 6.3, and each of the ten participants indicated they would recommend this guideline for use in the HROB clinic.

Open-Ended Questions

Question 26 asks for free-text, open-ended recommendations for any changes to be made to the protocol. Recommendations range widely, and encompass including a flow-diagram for increased visual comprehension of protocol use to including alternative management processes, as well as "I would not change anything." Of ten respondents, five provided answers. Please see Figure 2 for a complete list of responses to Question 26.

Respondent	Response
1	Making a flow diagram would organize the information for how screening should proceed in a better manner. I wasn't sure where the information for the results part of the protocol came from - I can understand that the recommendations for whom to screen comes from the ACOG practice bulletin but I didn't think they had these screening guidelines.
2	None
3	what the proposed effect of these guidelines
4	None
5	None
6	The evidence or background information used to formulate an expert opinion regarding the proposed protocol need to be better defined and stated in the protocol. Why should we sue a Hgb1c of 5.7%? Why a FBG of 126? I know why but does the general public? Need to provide monitoring/auditing processes that will be utilized during the study. Describe alternative management options (i.e. current standard of care vs your protocol)
7	None
8	In the one page document attached, I did not see if the target population had been included, what kind of search method had been used, how the foundational evidence had been selected, the plan for updating, what facilitators or barriers had been identified, the potential resource implication considerations, effects of funding bodies and what competing interests may be. These items were not explicit to the reader in the one page protocol but certainly may have been considered in its writing.
9	I thought it was well thought out and would not change anything.
10	None

Figure 4. Responses to Question 26 from Evaluation of *First Trimester Screening Protocol for Overt Diabetes*. Study data were collected and managed using REDCap electronic data capture tools hosted at Kansas University Medical Center, 2019.

Question 27 requested the multi-professional panel to describe what they liked about the protocol. Responses include, "I think this is an important topic and the proposal addresses the concern well"; "It narrows first trimester screening to those at risk instead of everyone which tends to be what is being done now"; "easy to follow, clear and concise"; "Short, yet detailed and direct"; "Outlines specific inclusion criteria and concrete plans of action based on HgbA1c and FBG values"; "Clear-evidence based Improved/earlier detection"; "Short and to the point. Easy

to follow. Concise evidence for the protocol."; and "That it is a practical and useful tool for treating and evaluating our patients."

Potential barriers are identified in Question 28. The multi-professional panel provided the following responses: "I think the interpretation of whom to screen will be very subjective and may be prone to variations based on provider practice. Providing definitions of 'sedentary lifestyle' via a patient questionnaire or other means might decrease this variability"; "Patient compliance, otherwise none clinically"; "Getting providers to recognize the key risk factors that would result in a HgbA1c and FBG performed"; "Getting fasting sugars, returning for multiple draws", and "Late entry to care will be a barrier. What is done if they arrive to care between 12 and 22 weeks?".

Question 29 requests any other comments related to the protocol. One comment was, "I thought it was clearly explained and very user friendly."

Finally, Question 30 uses a numeric scale to indicate the professional role of the survey respondent. According to these responses, two Certified Nurse-Midwives, two Maternal Fetal Medicine Fellow physicians, one Maternal Fetal Medicine attending physician, three Registered Nurses, and two Ob-Gyn physicians (one resident physician, one attending physician) weighed in on the protocol.

Discussion

The reaction to the "First Trimester Screening Protocol for Overt Diabetes" was overwhelmingly positive, across the multi-professional responses. Some excellent recommendations for alterations and additions were proposed by respondents, and these were each considered.

Domains one, two, and four all received average results greater than six, indicating agreement that the protocol has clearly defined objectives and the health information and proposed population is appropriately geared toward all involved care providers with insight into the patient population; the protocol also presents specific, clear recommendations for management options and easily identifies key portions of patient care.

Domain three, "Rigor of Development," elicited more variability than any other domain. The eight questions had individual mean average results ranging between 4.9 (question 14, regarding a procedure for updating the protocol is provided), and 6.6 (question 12, there is an explicit link between the recommendations and the supporting evidence). These lower scores are easily explained, in that most of the questions in this domain were not addressed through the initial version of the protocol, which was sent for evaluation; for example, the systematic search methods used to search for evidence were not incorporated into the protocol, the criteria for selecting evidence are not clearly described, and a procedure for updating the protocol was not included. These are items that will improve the credibility of the protocol as well as increase the buy-in from the multi-professional providers, should the protocol be recommended for use in the HROB clinic. Therefore, revisions to the protocol were made, and the information described in Domain three was included in the final version of the protocol (see Appendix C for revised protocol).

Domains five and six, "Applicability" and "Editorial Independence," both scored in the five to-six range, indicating values of "Somewhat Agree" on the Likert scale. This indicates that the providers believe that the protocol has the potential for beneficial implications to patient care. Initiation of the protocol in the HROB clinic has been considered, and that the protocol has not

been influenced by outside forces or companies which may serve to benefit from adapting the protocol.

Domain seven requested the overall quality rating to be assessed by the respondents. The mean rating of 6.3 out of seven indicates approval of the quality of the protocol. Each of the ten respondents stated that they would recommend the protocol for use. The feedback and recommendations given from the evaluation tool were used to make changes to the protocol; after these changes were made, the final product will be recommended for use as a patient care protocol in the HROB clinic.

Barriers to Implementation

Some barriers discussed throughout the evaluation responses, and others, addressed above, continue to be barriers to implementation of this protocol in the HROB clinic. The first barrier is the possibility that patients may be unable to pay for the screening test. Many patients seen in this clinic are uninsured and pay out of pocket for all testing. Other patients have state-funded insurance, or even insurance through private companies, which may not cover HbA1c as a screening test, regardless of risk factors.

Patient compliance is an on-going problem in the HROB clinic, and another barrier to implementation of the protocol to screen for diabetes in early pregnancy. Irregular prenatal care, skipping recommended lab tests, and refusing to follow through with recommendations for care are common in this patient population. Patients may refuse the early testing, or question the implementation of this new protocol if they are returning for a subsequent pregnancy.

Recognition of risk factors for pre-existing diabetes is another barrier to successful implementation of this protocol. This barrier can be overcome by providing education for multi-professional providers on recognizing key risk factors for diabetes, and alerting providers of the

importance of screening in early pregnancy, starting at the initial prenatal visit. By including the multi-professional team, it becomes an expectation throughout the continuum of providers, instead of falling onto the physician or nurse-midwife to screen each patient. Including the nurses and medical assistants in the education allows these members of the care team to assert their knowledge of the patients and suggest those appropriate for early screening.

Changes to the Protocol

As discussed above, the responses to the evaluation were accounted for, and revisions were made to the initial protocol (See Appendix C). The updated protocol includes a streamlined flow diagram to clarify the process, as was suggested by Respondent #1. Reference was made to the sources of the recommendations for whom to screen, as well as clarifications to definitions and cutoff thresholds for the HgbA1c and FBS values. As evidenced during the literature review, HgbA1c was historically not believed to be accurate during pregnancy, and this early screening test for pre-existing diabetes affecting pregnancy is a new recommendation. Previous studies focused on linking elevated HbA1c with the future development of GDM and associations between elevated HgbA1c and adverse outcomes in pregnancy. Therefore, information regarding studies suggesting these values for diagnostic use during pregnancy were cited in the protocol. This portion of the protocol will need review and possibly revision in the future, should recommendations for cutoffs be released with ongoing research. The suggestion for annual review of literature regarding diagnosis of DM in pregnancy was included in the revised protocol.

The desired effect of the proposal, alternative management options and current practice, were also included in the second version of the protocol. Search criteria for the literature review was included to make the protocol more robust. The proposed effect of the protocol was

included to clarify the goal for improved patient care and outcomes. By including this information, the rigor of the protocol will improve. Providers using this protocol, throughout the care continuum, will be aware of the recommendations and evidence base which guided this protocol and dictate best practice for patient care.

Education for patients was another addition to the revised protocol. Patient education is an important component of treating diabetes in pregnancy and preventing lasting adverse outcomes from hyperglycemia to the patient and her fetus. By setting a standard for education regarding treatment, providers will have a standard protocol to follow regarding patient education.

However, education is also crucial for providers. The author strongly suggests a mandatory in-service regarding introduction of this protocol to all providers prior to implementation of the protocol into practice. By receiving education regarding early identification of diabetes affecting pregnancy, providers will identify at-risk patients, and they will also be more prepared to offer solutions in evaluating and treating the patient effectively throughout pregnancy.

Conclusions

Worldwide, rates of DM are increasing rapidly, and this condition is extremely dangerous for both mother and fetus during pregnancy. Diagnosis and treatment of DM early in pregnancy are imperative in preventing adverse health outcomes. Recent literature has led to recommendations for early screening for pre-existing diabetes from most major healthcare organizations (ACOG, 2018; ADA, 2014; Metzger et al, 2010); however, implementation of this screening process has not been occurring as recommended (Mission et al, 2017). The purpose of this project was to develop a clear, concise protocol designed to identify patients appropriate for

screening as well as to streamline the screening process; the hypothesis is that this protocol will improve the delivery of care by allowing early identification and treatment of patients afflicted by overt diabetes which pre-dates the pregnancy.

A review of the literature revealed themes in research regarding HbA1c and later development of GDM and adverse outcomes to the pregnancy, but more information is needed regarding HgbA1c and the diagnosis of overt diabetes in pregnancy. The "First Trimester Screening Protocol for Overt Diabetes" was developed, and a multi-professional expert panel was asked to review and evaluate the protocol using the AGREE II tool on the REDCap system. Ten of fourteen panel members responded. Overwhelmingly, the providers, including Certified Nurse-Midwives, Ob-Gyn Physicians, Maternal-Fetal-Medicine Specialists, and Registered Nurses, stated that they would recommend this guideline for use. Feedback from the evaluations was analyzed, and the protocol was altered to include suggestions from the expert panel as well as background information to support providers in identifying and screening all patients at-risk for pre-existing DM in pregnancy.

The revised "First Trimester Screening Protocol for Overt Diabetes" is a tool that allows all providers to quickly assess patients' risk factors, and screen for DM in the first trimester. Early treatment for hyperglycemia is important in decreasing adverse outcomes to the pregnancy (Amylidi et al., 2015). The hypothesis remains, that improving identification methods for early screening will lead to improved prenatal care and better outcomes. This protocol is a relevant and useful tool in the HROB clinic, and the recommendation is to begin the process to officially introduce this protocol into practice. This protocol is a valuable tool in any prenatal practice setting, because it allows identification of at risk patients as early as the first prenatal visit, by any provider: Certified Nurse-Midwife or physician, thus allowing for care coordination that is

appropriate for the patient. Implementation of the "First Trimester Screening Protocol for Overt Diabetes", will allow for earlier identification and care that is necessary in pregnancy affected by pre-existing overt diabetes.

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Appendix A – First Trimester Screening Protocol for Overt Diabetes

PROTOCOL

FIRST TRIMESTER SCREENING PROTOCOL FOR OVERT DIABETES

According to reports from the CDC, rates of Diabetes Mellitus, a dangerous health condition, are rapidly increasing; almost 34% of the total U.S. population were found to suffer from diabetes or pre-diabetes in 2017 (2018). Many patients of childbearing age may be afflicted by these conditions prior to becoming pregnant, which may lead to complications for both mother and fetus.

During pregnancy, unrecognized or untreated diabetes has been linked to poor outcomes, including spontaneous abortion, congenital anomalies, and increased rates of pre-eclampsia, preterm birth, and neonatal hypoglycemia (Hessler & Dunenm, 2017; Wong et al, 2012). Studies demonstrate a positive correlation between prolonged fetal exposure to uncontrolled blood glucose and adverse pregnancy outcomes (Amylidi et al, 2015). Therefore, diagnosis and treatment as early in the pregnancy as possible is optimal to decrease maternal and fetal morbidities. This protocol aims to identify patients considered at-risk for first trimester screening, according to ACOG (2018).

Proposal: Identify "at-risk" patients for first trimester screening. Patient must be in the first trimester and have a BMI ≥ 25, and at least one of the following factors:

1. Sedentary Lifestyle
2. First Degree Relative with DM
3. Of African American, Latino, Asian American, Pacific Islander, or Native American Heritage
4. Previous delivery of infant ≥ 4000 grams
5. Hypertension
6. Hypercholesterolemia
7. PCOS
8. Previous HbA1c ≥5.7
9. Other clinical findings suggestive of insulin resistance (Acanthosis Nigricans, Glucosuria)
10. Cardiovascular disease

If patient meets the above criteria, screen using one of the following methods:

1. Hemoglobin A1c (HbA1c)
2. Fasting Blood Glucose (FBG)

Results

1. Patient with HbA1c < 5.7% for FBG < 92 will undergo standard OGTT between 24- 28 weeks gestation
2. Patient with HbA1c between 5.7% - 6.4% will have FBG drawn
3. Patient with FBG between 92-125 should receive counseling and treatment for GDM immediately. Test at 6 weeks postpartum for DMII.

Appendix B – AGREE II Evaluation Tool

Domain One

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

1. The overall objectives of the protocol are specifically described.
2. The health questions covered by the protocol are specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Domain Two

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

4. The protocol involves individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the protocol are clearly defined.

Domain Three

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by the experts prior to its' publication.
14. A procedure for updating the protocol is provided.

Domain Four

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

Domain Five

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

18. The protocol described facilitators and barriers to its' application.
19. The protocol provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The protocol presents monitoring and/or auditing criteria.

Domain Six

Score: 7= Strongly Agree, 6= Agree, 5= Somewhat Agree, 4= Neutral, 3= Somewhat Disagree 2= Disagree, 1= Strongly Disagree

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of the guideline members have been recorded and addressed.

Domain Seven

24. Rate the overall quality of this guideline.
    Scale of 1 (lowest possible quality) to 7 (highest possible quality)
25. I would recommend this guideline for use:
    (Yes / Yes with Edits / No)

Recommendations - Free Text

26. What changes would you like to see in this protocol?
27. What did you like about this protocol?
28. What barriers do you see with implementation of the protocol?
29. Please leave any other comments related to this protocol here.
30. Please indicate your professional role in the care of women in labor, delivery, recovery, and postpartum.

Appendix C – Revised First Trimester Screening Protocol for Overt Diabetes

PROTOCOL

FIRST TRIMESTER SCREENING PROTOCOL FOR OVERT DIABETES

According to reports from the CDC, rates of Diabetes Mellitus, a dangerous health condition, are rapidly increasing; almost 34% of the total U.S. population were found to suffer from diabetes or pre-diabetes in 2017 (2018). Many patients of childbearing age may be afflicted by these conditions prior to becoming pregnant, which may lead to complications for both mother and fetus.

During pregnancy, unrecognized or untreated diabetes has been linked to poor outcomes, including spontaneous abortion, congenital anomalies, and increased rates of pre-eclampsia, preterm birth, and neonatal hypoglycemia (Hessler & Dunenm, 2017; Wong et al, 2012). Studies demonstrate a positive correlation between prolonged fetal exposure to uncontrolled blood glucose and adverse pregnancy outcomes (Amylidi et al, 2015). Therefore, diagnosis and treatment as early in the pregnancy as possible is optimal to decrease maternal and fetal morbidities. This protocol aims to identify patients considered at-risk for first trimester screening, according to ACOG (2018).

Proposal: Identify "at-risk" patients appropriate for first trimester screening.

Proposed Effect: Protocol for identification of patients at-risk for pre-existing diabetes in the first trimester will enhance opportunity for early screening, identification, and treatment of diabetes in pregnancy, thereby improving provision of prenatal care and decreasing adverse outcomes to mother and fetus.

Current Process: All patients receive standard screening: One-step, Two-hour Oral Glucose Tolerance Test (OGTT) at 28 weeks of gestation. Occasionally, patients may be screened for GDM prior to 28 weeks, however, no screening protocol is implemented.

Targeted Population: All patients in the High Risk OB Clinic who present for care in the first trimester. If patients present after the first trimester, patients should receive standard OGTT screening between 24 – 28 weeks.

Definitions:

Hemoglobin A1c (HbA1c): Measures the amount of glucose attached to circulating hemoglobin in the blood. HbA1c less than 5.7% is considered normal, and patients with a normal first-trimester HbA1c will receive standard screening for GDM at 24-28 weeks gestation. The patient with HbA1c between 5.7% - 6.4% is considered pre-diabetic, and this result in the first trimester of pregnancy warrants further investigation using a FBG, as detailed below. HbA1c of 6.5% or greater is diagnostic of Diabetes Mellitus, and patients should be educated on diabetes during pregnancy; after pregnancy, patient will be referred to Endocrinologist for continued care. (ADA, 2018; ADA, 2017; Amylidi et al., 2015; Fong et al., 2014; Hessler & Dunemn, 2017; Osmundson et al., 2016.)

Fasting Blood Glucose (FBG): Also referred to as Fasting Plasma Glucose (FPG), FBG is the amount of glucose on the blood after fasting for a minimum of eight hours (ADA, 2014). Any patient

with a FBG greater than, or equal to 126 will be diagnosed with overt diabetes. According to the International Association of Pregnancy and Diabetes WorkGroup, FBG between 92 – 125 during the first trimester of pregnancy should be considered gestational diabetes (GDM), and the patient will be educated and treated on appropriate management. This includes checking for overt diabetes 6 weeks after delivery (Metzger et al., 2009). Patients with FBG less than 92 in the first trimester of pregnancy should undergo standard GDM screening between 24-28 weeks of gestation.

Protocol:

Patient must be in the first trimester and have a BMI ≥ 25, and at least one of the following factors: (retrieved from ACOG Practice Bulletin #180: Gestational Diabetes Mellitus (2018) and American Diabetes Association Classification and Diagnosis of Diabetes (2017).)

1. Sedentary Lifestyle
2. First Degree Relative with DM
3. Of African American, Latino, Asian American, Pacific Islander, or Native American Heritage
4. Previous delivery of infant ≥ 4000 grams
5. Hypertension
6. Hypercholesterolemia
7. PCOS
8. Previous HbA1c ≥5.7
9. Other clinical findings suggestive of insulin resistance (Acanthosis Nigricans, Glucosuria)
10. Cardiovascular disease

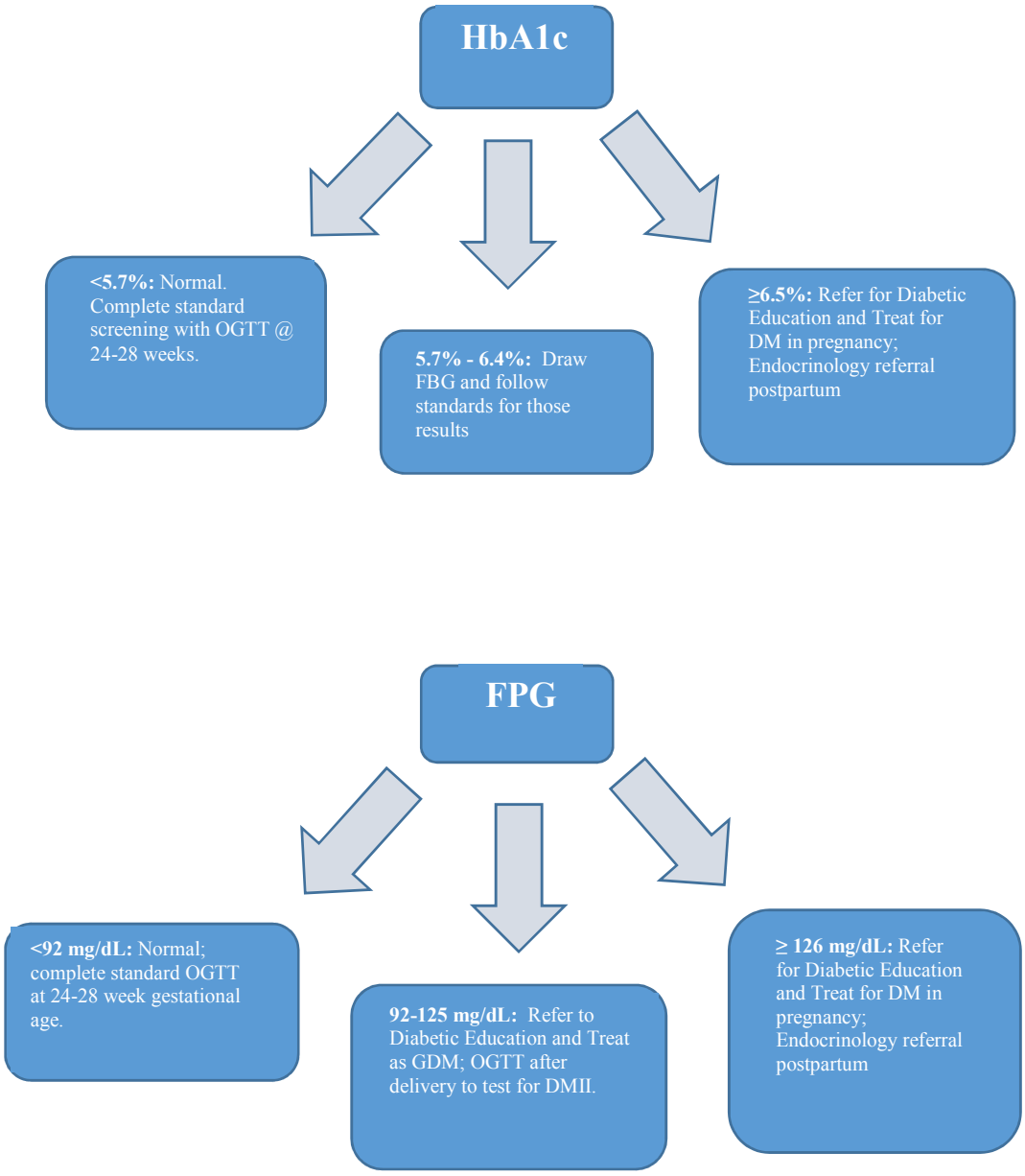
If patient meets the above criteria, screen using one of the following methods:

1. Hemoglobin A1c (HbA1c)
2. Fasting Blood Glucose (FBG)

Results

1. Patient with HbA1c < 5.7% for FBG < 92 will undergo standard OGTT between 24- 28 weeks gestation
2. Patient with HbA1c between 5.7% - 6.4% will have FBG drawn
3. Patient with FBG between 92-125 should receive counseling and treatment for GDM immediately. Test at 6 weeks postpartum for DMII.
4. Patients with HbA1c ≥ 6.5 or FBS ≥ 126 will be considered diabetic and should receive counseling and treatment immediately. Refer to endocrinology for management post-delivery.

Flow Chart for Results



Search Method: A Literature Review was conducted using PubMed with search terms "pre-existing diabetes in pregnancy", "HbA1c in early pregnancy", "first-trimester diabetes screening", "early GDM screening", and "pre-gestational diabetes screening." Inclusion criteria consisted of English-language articles available in full text, from peer-related journals, published within the last 6 years.

Monitoring Process: Development of a database is recommended, to track patients screened per this protocol, and the results of the screening. Patients will be de-identified and Medical

Record Number will be used in place of patient name. This will track the frequency of diagnosis and the early diagnosis and management of diabetes in the first trimester.

Plan for Update: Annual review of the monitoring database and current literature is recommended, to determine continued appropriateness for use of Protocol.