Clinical Inquiry Project Proposal: Evaluation of the Implementation of the IADPSG Gestational Diabetes Screening Criteria in the Nurse-Midwifery Faculty Practice at Oregon Health & Science University

Sally Hersh

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I. Introduction: The Clinical Problem

I. A. Description of the Problem

Maternity care providers are witnessing an increase in the number of obese pregnant women and the associated rise in the prevalence of gestational diabetes mellitus (GDM) (Marshall, 2012). Almost two-thirds of women in the United States are overweight or obese (Flegal, Carroll, Ogden, & Curtin, 2010). Data from the 2007-2008 National Health and Nutrition Examination Survey (NHANES) revealed an age-related prevalence rate of obesity among adult women of 35.5%, noting a range of 33% for non-Hispanic white women to 49.6% for non-Hispanic black women (Flegal, et al., 2010). Obese women, who are known to enter pregnancy with increased insulin resistance, have a two to three times increased odds ratio of developing GDM (Gibson et al., 2012). Maternal obesity and GDM are independently associated with adverse outcomes for mother and baby (Catalano et al., 2012). Pregnant, obese women have an increased risk of preeclampsia, abnormal fetal growth, stillbirth, and cesarean birth (N. E. Marshall, Guild, Cheng, Caughey, & Halloran, 2012). Offspring born to women with GDM have higher birth weights. In addition, children of women with fasting and daily hyperglycemia are at risk for becoming overweight during adolescence (Tzanetakou, Mikhailidis, & Perrea, 2011). Gabbe et al. (2012) urge maternity care providers to assume a substantial role in assisting women to improve their families' health during and after the birth of their babies.

With the Oregon Health & Science University (OHSU) Department of Obstetrics and Gynecology's July 1, 2012 adoption of an international consensus panel's (IADPSG Consensus Panel, 2010) GDM screening criteria, it is expected that the number of OHSU patients diagnosed

with gestational diabetes will rise (ADA, 2012b). There is interest in designing care and research to support the recommendations for diet and exercise that form the foundation of diabetes care. However, clinicians and researchers perceive barriers in their ability to capture data and assess the impact of the change in GDM screening criteria on the OHSU pregnant population. The **purpose of this project** is to describe the implementation of the IADPSG GDM screening criteria in the OHSU system and select obstetrical outcomes of pregnant women diagnosed with gestational diabetes by the IADPSG criteria while enrolled for nurse-midwifery care at OHSU between June 1, 2012 and February 28, 2013.

I. B. Review of Literature

Gestational diabetes mellitus (GDM) is a condition of carbohydrate intolerance that develops during pregnancy (American Diabetes Association (ADA), 2012a) and is a common complication that affects 2%-10% of all pregnancies (Centers for Disease Control (CDC) and Prevention, 2011; Gabbe, Landon, WarrenBoulton, & Fradkin, 2012). Insulin resistance is increased in the third trimester by 40-60% over pre-pregnancy levels (Gibson, Waters, & Catalano, 2012). Gestational diabetes develops when the pancreatic beta cells do not function sufficiently to maintain normal blood glucose levels in the presence of the increasing insulin resistance of pregnancy (Gibson et al., 2012). Most cases of GDM resolve after delivery (ADA, 2012a), however 5-10% of women are found to have diabetes mellitus (DM) when tested postpartum (CDC, 2011). Women with a prior history of GDM have a sevenfold increased risk of developing type-2 diabetes mellitus (T2DM) (Gabbe et al., 2012). Approximately 50% of women with GDM will develop T2DM in the first 10 years after pregnancy (Gabbe et al., 2012). It is recommended that women with GDM be tested at 6-12 weeks postpartum, with periodic testing throughout their lifetime if the initial results are negative (Gabbe et al., 2012). Women with prior GDM have an elevated risk for cardiovascular disease later in life (Gabbe et al., 2012). In addition, the offspring of women with GDM have an increased risk for obesity and T2DM (Gabbe et al., 2012). Maternal glucose moves freely to the fetus, but insulin does not. The fetus must increase its own insulin production in order to manage this hyperglycemic state. Excess fetal insulin production leads to macrosomia due to either a direct insulin growth effect or fat deposition (Pridjian & Benjamin, 2010). Females exposed to maternal hyperglycemia while *in utero* are at risk for developing GDM during their own subsequent pregnancies (Petry, 2010). Petry (2010) comments that this metabolic programming during gestational exposure to hyperglycemia illustrates a trans-generational effect that may contribute to the anticipated rise in the worldwide prevalence of T2DM in the context of the increasing obesity prevalence rate.

Controversy exists concerning the diagnostic criteria for GDM as well as the degree of adverse pregnancy outcomes associated with the diagnosis. Testing criteria for the diagnosis of GDM were first developed over four decades ago and, with minor variation, are still in current use (International Association of Diabetes and Pregnancy Study Groups (IADPSG) Consensus Panel, 2010; Landon et al., 2009). These criteria consist of a two-step process. When the initial screening test (50-gram 1-hour glucose loading test) is failed, it is followed by a diagnostic 100-gram 3-hour oral glucose tolerance test. Original thresholds for diagnosis were based on the risk of future development of DM and were not intended to reduce potential adverse pregnancy outcomes (ISDPSG Consensus Panel, 2010; Landon et al., 2009). Women who begin pregnancy with pre-existing DM are at known risk for poor perinatal outcomes (ISDPSG Consensus Panel, 2010). Recent studies have attempted to clarify the clinical significance of diabetes that develops during pregnancy (Catalano et al., 2012; Crowther et al., 2005; ISDPSG Consensus Panel et al., 2010; Landon et al., 2009).

Two randomized controlled trials (RCT) explored the benefit of treatment of mild GDM (Crowther et al., 2005; Landon et al., 2009). Crowther et al. (2005) found that women with mild GDM who were randomized to treatment (n=490) consisting of dietary advice, blood glucose monitoring, and insulin therapy if needed for glucose control, had statistically reduced adverse perinatal outcomes including fetal or neonatal death, bone fracture, shoulder dystocia, and nerve palsy. The rate of maternal induction of labor and neonatal admission to the intensive care unit was higher in the experimental group but the cesarean birth rate was not different between groups. In addition, women in the treatment group had lower rates of postpartum depression and higher quality of life scores at three months postpartum.

Landon et al. (2009) randomized 958 women with mild GDM in a multi-center, blinded trial. Treatment consisted of nutritional counseling/diet therapy and insulin if needed for adequate glucose control. There was no difference between groups in the primary outcomes of perinatal mortality and neonatal sequelae from maternal hyperglycemia (hypoglycemia, hyperbilitrubinemia, hyperinsulinemia, birth trauma). The mean birth weight, neonatal fat mass, and large-for-gestational age (4000 g or greater) were significantly lower in the treatment group. Induction of labor was similar between groups, but the treatment group had a lower cesarean birth rate as well as lower frequencies of shoulder dystocia, preeclampsia, and gestational hypertension. Body mass index and weight gain from enrollment to delivery were lower for women in the treatment group.

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study examined the clinical associations of maternal glucose levels lower than values diagnostic for GDM (HAPO, 2008;

Catalano et al., 2012). The sentinel ten-year study was a prospective, blinded, international, multi-center trial that enrolled over 25,000 pregnant women. The researchers demonstrated a continuous positive relationship between increasing levels of maternal glycemia and the primary outcomes of birth: weight > 90th percentile, primary cesarean delivery, clinical neonatal hypoglycemia, and cord C-peptide > 90th percentile. In addition, similar trends were noted for the secondary outcomes of birth: preeclampsia, shoulder dystocia/birth injury, preterm birth, neonatal hyperbilirubinemia, and neonatal intensive care. Of particular significance was the continuous graded relationship found between increasing maternal glucose levels and the frequency of primary and secondary outcomes in women who did not meet diagnostic criteria for diabetes. The results of the HAPO study are considered to be generalizable at the global level, as the results were consistent between international research centers (IADPSG Consensus Panel, 2010).

The conclusions from two well-designed RCTs (Crowther et al., 2005; Landon et al., 2009) and one robust, multicenter, international observational study (HAPO, 2008) have calmed the debate about the benefits of treatment of mild GDM. However, controversy over screening criteria for diagnosis of GDM persists. In 2010, the IADPSG Consensus Panel released a report recommending a simplified, one-step 75-gram two-hour screening test for the diagnosis and classification of diabetes in pregnancy, with the intention of international standardization of the screening process (IADPSG Consensus Panel, 2010). The expert panel relied heavily upon the findings of the HAPO study (HAPO, 2008) when weighing screening options and used glucose thresholds associated with a 1.75-fold increased risk of having a large-for-gestational infant based on the HAPO data.

Expert groups have varied opinions about the IADPSG GDM diagnostic criteria. The U.S. Preventive Services Task Force concluded that current evidence inadequately addresses the risks and benefits of screening for GDM (U.S. Preventive Services Task Force, 2008). In their 2011 Committee Opinion statement, the American College of Obstetricians and Gynecologists did not recommend transitioning to the IADPSG screening criteria (American College of Obstetricians and Gynecologists, 2011); however, the American Diabetes Association recommends use of the IADPS criteria (ADA, 2012b; Gabbe et al, 2012). The Canadian Diabetes Association applies higher glucose level thresholds for GDM diagnosis than the IADPSG recommendations. These higher thresholds are consistent with a 2-fold increased risk for a large-for-gestational infant based on HAPO findings, which provides for a relatively lower prevalence rate (Ryan, 2012). If widespread adoption of the IADPSG criteria occurs, some experts project a substantial increase in the rates of diagnosis of GDM to as high as 18% of all pregnancies (CDC, 2011; Gabbe et al., 2012; IADPSG Consensus Panel, 2010). One Canadian physician comments, "With the stroke of a consensus pen, nearly one-fifth of pregnant women--more than double the current incidence in Canada—would be labeled as having gestational diabetes..." if the IADPSG criteria were adopted (Ryan, 2012). The consequences related to total therapeutic costs, as well as psychosocial and lifestyle ramifications for patients, have not been fully evaluated (Kargiannis et al., 2010). The ADA acknowledges concerns about the increased medicalization of pregnancy associated with this projected rise in GDM diagnosis; however, given the rising levels of obesity and type 2 diabetes worldwide, the ADA stresses that there is potential value in recognizing underlying risk and addressing health behaviors during pregnancy (ADA, 2012b).

In summary, forty years after the development of the first set of criteria on the topic, the absence of universally accepted screening criteria for GDM persists (Karagiannis 2010). Despite

the hopes that the IADPSG consensus panel's recommendations would create uniformity among clinical and research centers, conflicting guidelines remain in place and contribute to the high variability and limitations in generalizability of research on this topic (Karagiannis 2010). On the national level, a National Institutes of Health Consensus Development Conference on diagnosis of GDM scheduled for October 2012, although highly anticipated, was postponed until March 2013 due to hazardous weather caused by Hurricane Sandy. Whether the conclusions of this panel will lead to uniformity of criteria, even in the United States, remains to be seen.

Specific Aims of Clinical Inquiry Project

The specific aims of the clinical inquiry project are:

- **Aim 1.** To describe the demographic characteristics of nurse-midwifery patients who were diagnosed with gestational diabetes or gestational hyperglycemia using the screening criteria adopted by the Oregon Health & Science University (OHSU) Department of Obstetrics and Gynecology on July 1, 2012.
- **Aim 2.** To describe select antepartum process measures of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013.
- **Aim 3.** To describe select maternal and neonatal outcomes of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013.
- **Aim 4.** To report on select indicators of increased utilization of resources related to the diagnosis of gestational diabetes or gestational hyperglycemia by patients who met the inclusion criteria.

II. Approach to the Conduct of the Project

A. Setting and Care Practices

Maternity patients have a variety of provider options at OHSU. The nurse-midwifery faculty practice, the generalist obstetrics practice, and the obstetrics and gynecology residency practice provide care through the OHSU Center for Women's Health. The outpatient Perinatal Center, staffed by maternal-fetal medicine (MFM) physicians, obstetric fellows, and obstetric and gynecology residents, specializes in the care of women with high-risk pregnancies. It is located in the Physician's Pavilion. The generalist, MFM, and residency groups are all administered and funded through the OHSU Department of Obstetrics and Gynecology. The nurse-midwifery faculty practice is administered and funded through the OHSU School of Nursing as part of the academic graduate nurse-midwifery program. Nurse-midwifery practice guidelines are reviewed every two years and signed off with the Obstetrics Chief, the Nurse-Midwifery Academic Program Director, and the Nurse-Midwifery Practice Manager. Based on the current OHSU nurse-midwifery practice guidelines, women diagnosed with GDM are typically managed with diet and exercise (A1GDM) unless they require pharmacologic therapy (A2GDM). In that case, most women transfer to the Perinatal Diabetes Clinic, where the care is provided by the MFM practice.

In standard prenatal care, an initial visit includes a thorough history and physical examination as well as assessment of risk factors. If the patient has risk factors for diabetes, she is encouraged to undergo screening as soon as possible in early pregnancy. If the screening is normal, she is re-screened between 24 and 28 weeks of pregnancy. If the patient does not have risk factors for diabetes, she is scheduled for a screening test for GDM at 24-28 weeks of pregnancy. If her screening result is abnormal in either early pregnancy or at 24-28 weeks

gestation, the patient is notified of her diagnosis and scheduled with a dietician appointment. The dietician provides individualized education on diet and glucose monitoring. The patient is instructed on counting carbohydrates and testing her capillary blood glucose (CBG) four times daily, which includes a fasting level and one-hour post-prandial levels after breakfast, lunch, and dinner. Subsequent separate appointments are held one to two weeks later with the dietician and the nurse-midwife. If the majority of the CBG values (greater than 80%) are within normal limits during the first two weeks of therapy, the patient continues to manage her glucose with diet and exercise. Phone calls to the dietician or nurse to clarify medication or diet management and glucose values are common in the initial phase of care and eventually diminish as the patient's glucoses reach clinical goals. However, if the patient has more than 20% abnormal values despite her best efforts with diet and exercise, medication in the form of oral diabetic agents or insulin may be started. If medication is required to maintain good glycemic control, the patient is transferred to the OHSU Pregnancy Diabetes Clinic for physician management throughout the rest of the pregnancy and inpatient labor care is provided by the OB resident physicians and attending physicians in the labor and delivery unit at OHSU.

B. Driving Forces

Effective July1 2012, the OHSU Department of Obstetrics and Gynecology implemented new screening criteria for GDM based on the recommendations of the IADPSG Consensus Panel (ISDPSG Consensus Panel, 2010). The screening algorithm is included in the Appendix. The former two-step process, which included a one-hour glucose tolerance test followed by a threehour glucose tolerance test for those who failed the first screen, was abandoned and the capability to place these orders was removed from the electronic health record effective mid-June 2012. The order set was replaced with a two-hour glucose tolerance test, which includes a fasting blood glucose followed by a 75-gram oral glucose load with subsequent testing at one and two hour intervals. If one or more levels are abnormal, a diagnosis if GDM is made. It was expected that the prevalence rate of GDM would increase with the implementation of new screening criteria at OHSU. Both the midwifery practice and the providers in the OHSU Perinatal Diabetes Clinic have expressed substantial interest in gathering data on population effects of the new GDM screening criteria on OHSU patients and health care system.

C. Constraining Forces

The EPIC electronic health record (EHR) was funded and implemented by OHSU administrators without broad financial or workforce support for creation of documentation that would make data collection or analysis simple and efficient. At this time, there is no efficient way to capture the midwifery patients who have been diagnosed with gestational diabetes since June 1, 2012. For a clinical practice to plan a change in the electronic health record that would allow for data collection, funding from departmental or research sources is required. This is a large barrier that is furthered by the relatively slow process of making such a change once funding has been secured. The workforce dedicated to implementing such changes is stretched and each particular project is undertaken based on its prioritization on the EPIC optimization calendar.

A portion of the clinical inquiry project will involve meeting with EPIC resource team members, health information technology staff, and the midwifery practice billing and coding specialist in order to discover how to obtain patient screening data and outcomes from the EHR. A list of all midwifery patients who have been diagnosed with GDM has been maintained by the midwifery clinic nurse since the inception of the new criteria. This information will be used to verify the patients included in this project. IRB approval will be sought for using data collected in the course of clinical care to address the aims of this clinical inquiry project.

D. Participants and Population

Inclusion and Exclusion Criteria

All patients who have been diagnosed with GDM based on the IADPSG criteria by the OHSU nurse-midwifery practice between June 1, 2012 and February 28, 2013 will be included. Eligible patients who have transferred into the midwifery practice with current GDM diagnosis or who have transferred out of the OHSU system prior to the birth will be excluded. Women under the age of 18 will be excluded.

Size of Population

At this time, it is challenging to calculate a specific number of patient records that will be accessed. The prevalence of GDM varies from population to population. The GDM prevalence rate among OHSU midwifery patients prior to the adoption of the new GDM screening criteria is unknown. Approximately 25 patients from the Center for Women's Health midwifery clinic give birth per month. All patients are screened unless they decline screening or have received screening from a previous provider and subsequently transferred into the midwifery practice. If the prevalence rate for GDM under the new criteria is approximately 10 to 15%, 2 to 4 (2.5 to 3.75) patients per month would be diagnosed. It is anticipated that approximately 40 to 50 maternal electronic health records will be reviewed. In addition, a corresponding number of infant electronic health records, which are linked with the maternal record, will be reviewed for neonatal outcomes.

Protection of the Participants

This project will consist of abstraction of data from the electronic health record of all patients enrolled in the OHSU nurse-midwifery practice that have been diagnosed with gestational diabetes ore gestational hyperglycemia according to the IADPSG criteria between June 1, 2012 and February 28, 2013. Data will be abstracted from the electronic health record using an acrostic in lieu of names (eg., Subject #1). The master list matching the acrostic with the patient name will be stored in an encrypted, secure file in the Nurse-midwifery clinic. The list of names and acrostics will be kept secure and totally apart from the abstracted clinical de-identified data. Only de-identified data collected as part of the normal clinical processes in the OHSU nurse-midwifery practice will be abstracted from the electronic health records and used for analysis. Health Insurance Portability and Accountability Act (HIPAA) protected patient data will not be obtained and a waiver for HIPPA authorization will be submitted.

E. Intervention or Implementation Procedures (does not apply)

F. Measure and Outcomes

Based on the specific aims of the clinical inquiry project, the data collection sources, as well as the processes and procedures for each aim will be described. Included in this description will be the measures used to operationalize key clinical variables relevant to each aim.

Aim 1.: To describe the demographic characteristics of nurse-midwifery patients who were diagnosed with gestational diabetes or gestational hyperglycemia using the screening criteria adopted by the Oregon Health & Science University (OHSU) Department of Obstetrics and Gynecology on July 1, 2012.

<u>Processes and Procedures.</u> Patients who meet the inclusion criteria will be identified by searching the EPIC database for all OHSU midwifery patients undergoing GDM screening

between June 1, 2012 and Feb 28, 2013. Non-pregnant patients will be excluded unless they are within 3 months postpartum and have been previously identified as screened for GDM using the IADSPG criteria during the select time frame. Patients will be sorted based on gestational age at the time of screening. Patients who have undergone screening more than once (early pregnancy and 24-28 weeks gestation) will then be identified.

<u>Sources and Measures.</u> The following **demographic data** will be collected to provide a clear description of the characteristics of all of the patients diagnosed with GDM by the OHSU nurse-midwifery practice between June 1, 2012 and February 28, 2013.

- Age will be abstracted from the medical record and recorded for each patient. This data will then also be sorted into age ranges using the following three categories: ages 18-25, ages 25-34, and age 35 and above. These categories represent identified stratification of risk, with women at or above age 25 considered to be at higher risk for GDM and women age 35 and over to be at the highest risk for GDM (Pridjian 2010).
- Race and ethnicity will be noted and recorded if available in the medical record. Certain racial and ethnic groups have higher rates of diabetes and GDM (South East Asian, Hispanic, African American) (Pridjian 2010). In the records for the practice, race and ethnicity are self-identified characteristics that patients may report on intake into the practice. U.S. Census categories will be used and, for ethnicity, include identification of Hispanic, Spanish or Latino origin. For race, the categories will include:
 - o White
 - o Black, African American
 - o American Indian, Alaska Native
 - o Asian

- o Native Hawaiians or other Pacific Islander
- \circ Two or more races
- **Gravidity and parity** data will be collected. Categories will include women who have never carried a full-term pregnancy and those who have had at least one birth. Women with a history of previous cesarean or previous vaginal birth after cesarean will be identified.
- Socioeconomic status is difficult to measure with data from the electronic medical record as the patients are not asked to provide income levels at intake and these are not recorded in the chart. Instead of a direct measure of socioeconomic status, the type of insurance for each patient will be identified. Since patients will not be approached for this project, the ability to gain information about income levels will not be possible and the type of insurance has been a proxy for socioeconomic status in the practice. Categories will include private insurance, public assistance insurance, military insurance, and self-pay. Gestational diabetes has been associated with lower income levels (Lega, Ross, Zhong, & Dasgupta, 2011).
- Educational level will be assessed by recording the highest level of education attained through chart review. In a recent Canadian study, the association between GDM and education level was inconclusive (Lega, et al. (2011); however, Californian women with GDM and a lower level of educational attainment were more likely to have macrosomic infants at birth (Chung, Voss, Caughey, Wing, Henderson, & Major, 2006). Some experts comment that educational level could account for some of the variation seen in health outcomes of women with GDM due to disparate levels of health literacy and the complexity of the medical regimen required for proper care and treatment (Goldman &

Smith, 2002). Education level will be captured from the chart according to the following categories:

- Primary school graduate
- Some high school
- High school graduate or equivalency exam
- Some college
- o College graduate
- o Graduate degree

The following **process measures, maternal, and neonatal outcomes** data will be collected to provide a detailed description of when and how women who met the inclusion criteria were screened, their screening results, and pregnancy, birth, and neonatal outcomes.

Aim 2.: To describe select antepartum process measures of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013.

Antepartum Process Measures

• The number of times each patient has been screened during pregnancy will be collected. Most women will have been screened once between 24 and 28 weeks of gestation. Those with risk factors will have been screened in early pregnancy (less than 13 weeks) unless they declined. If the first screening test was normal in early pregnancy, the patients should have been re-screened between 24 and 28 weeks of gestation. If the early screening test was abnormal, they will have received a diagnosis of GDM at that time and will not have been re-tested later in pregnancy.

- Presence of risk factors at screening will be obtained from the medical record by
 reviewing the patient's history, family history, history and physical documentation,
 progress notes, and problem list. The current OHSU GDM screening algorithm is listed
 in Appendix 1. According to the algorithm, risk factors that warrant early screening are:
 BMI greater than or equal to 30, non-Caucasian, first degree relative with diabetes,
 multiple gestation, glucosuria, personal history of gestational diabetes, pre-diabetes
 unexplained stillbirth, fetal malformation, infant with macrosomia (birth weight
 greater than 4000 gm) or medical co-morbidities (polycystic ovarian syndrome,
 hypertension, hyperlipidemia).
- The gestational age at the time of screening (percentage identified early versus standard screening at 24-28 weeks) will be collected from the laboratory data and dating sections of the medical record. As noted above, early screening is recommended for women with risk factors. Insulin resistance reaches its highest level in the early third trimester (Pridjian & Benjamin, 2010) and the majority of the women will have been screened between 24 and 28 weeks gestation.
- The type of screening test and results (FBS, HgbA1c, 2 hour GTT) will be identified from the patient's medical record through review of the laboratory section. In addition, progress notes will be reviewed to clarify the way the results were applied to form the diagnosis of GDM.
 - FBS or HgbA1c. In early pregnancy and if risk factors are present, the patient may have been screened with a fasting blood glucose test (FBS) and/or a hemoglobin A1c (HgbA1c) (Appendix 1). The fasting blood glucose is performed after an eight-hour fast and examines the patient's current glycemic

state when fasting in early pregnancy. The HgbA1c provides an average of blood glucose control over the previous six to twelve weeks. The nurse-midwifery practice made a decision to screen with both tests in order to discriminate between the two test results. If the patient requests confirmation, a two-hour 75-gm glucose tolerance test (GTT) will be performed. According to the OHSU GDM screening algorithm (Appendix 1), if the fasting blood glucose is between 92 and 125 mg/dl, then a working diagnosis of gestational diabetes is given. If the HgbA1c result is between 5.7 and 6.4%, then a 2-hour 75-gm (GTT) is provided and if abnormal, would result in a diagnosis of GDM. With a HgbA1c result in this range, the consideration that the patient may have begun pregnancy with T2DM would be entertained. Her management would not be changed for the pregnancy, but the likelihood that she may require medication to manage her blood glucose levels may be elevated and the importance of screening at 6-12 weeks postpartum would be paramount. There is controversy among OHSU physicians and midwives about the type of test and threshold for diagnosis when patients meet the criteria for early screening. The new OHSU algorithm represents a significant departure from the previous screening criteria, in which patients with risk factors were given a two-step screening and diagnosis process. As discussed earlier, if the one-hour GTT was abnormal, a diagnosis of GDM was not made unless the three-hour GTT was failed by achieving two out of four abnormal values. In the current algorithm, a patient will be diagnosed with GDM if a single test-- the fasting blood glucose-- is abnormal. There is concern that by setting this fasting blood glucose threshold so low (which, as explained above, is

based on a calculation of risk for large-for-gestational infants based on HAPO data), the number of women diagnosed with GDM, possibly in a very mild form, will substantially rise. In anticipation of fielding concerns and complaints from patients, the midwifery practice decided to offer a confirmatory 2-hour 75-gm (GTT) for patients who have borderline abnormal fasting blood glucose results.

- Results of 2-hour 75-gm GTT. Based on the current OHSU algorithm for GDM screening, the 2-hour 75-gm GTT is the only option for testing for GDM between 24 and 28 weeks gestation. (As noted above, it is also offered if the patient's early Hgb A1c meets a specific range in early pregnancy). If one or more values are abnormal, a diagnosis of GDM is made.
- The degree of abnormality of the glucose results will be collected and sorted. Controversy over the threshold set by the IADPSG study panel has led some experts to suggest alternative criteria that would lead to fewer women with very borderline glucose results being diagnosed with GDM (Kalter-Leibovici et al., 2012; Ryan, 2012). Fasting blood glucose results and 2-hour 75-gm GTT results will be categorized into two groups: those that fall within the IADPSG criteria (1.75-fold increased risk of large-forgestational age infant) and those that fall within the Canadian criteria (2-fold increased risk of large-for-gestational age infant).
- The type of gestational diabetes will be categorized for each patient as A1GDM or A2GDM. The categorization of diagnosis will be obtained by reviewing the progress notes and problem list. Patients with A1GDM are able to maintain adequate glycemic control through diet and exercise. When medication is required for glycemic control, the

current OHSU nurse-midwifery practice is to transfer patients with A2GDM for physician management for the rest of the pregnancy and birth.

Aim 3.: To describe select maternal and neonatal outcomes of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013.

Maternal Outcome Measures

- Mode of delivery: vaginal, operative vaginal, or cesarean. The delivery note of the medical record will be reviewed to identify whether the birth was vaginal or abdominal. Women with GDM have an elevated risk for cesarean birth, particularly if the infant birth weight is elevated. Cesarean birth is often included as a primary or secondary outcome in GDM research (Crowther et al., 2005; HAPO, 2008; Landon et al., (2009). Spontaneous or assisted (vacuum or forceps) birth will be noted.
- Induction of labor for GDM and/or insulin administration during labor. The admission and progress notes of the inpatient medical record will be reviewed to determine whether patients were induced for GDM and if they required insulin intravenously during labor or postpartum. OHSU nurse-midwifery patients with excellent glucose control and A1GDM are not routinely tested for hyperglycemia during labor or postpartum. As they approach their due dates, they are managed similarly to women without A1GDM. They do not have an elevated risk of stillbirth compared to women without GDM (Pridjian & Benjamin, 2010). Women with A1GDM are not hungry during active labor and hydrate with water or dilute fruit juice or sports drinks. Patients

with A2GDM who have been transferred for physician management at OHSU are routinely induced at 39 weeks of gestation due to their elevated risk of stillbirth (Rosenstein, Cheng, Snowden, Nicholson, Doss, & Caughey (2012). They are more likely to have hyperglycemia and therefore their capillary blood glucose levels are tested periodically throughout labor. At OHSU, patients with A2GDM are started on intravenous insulin if they meet criteria for hyperglycemia (usually greater than 125 mg/dl). After the birth, insulin is stopped and the fasting blood glucose is checked in the first postpartum day. Unless the patient has previously undiagnosed T2DM, the glucose level is usually normal immediately postpartum following the birth of the placenta (Pridjian & Benjamin, 2010).

• **Results of 2-hour 75-gm GTT postpartum**. All women with GDM should be screened for diabetes at 6-12 weeks postpartum, as five to 10 percent will be found to have T2DM (CDC, 2011). The results of the 2-hour 75 gm GTT, consisting of a fasting blood glucose and blood glucose level at 2 hours post 75-gm glucose load, will be identified in the medical record and the number and percentage of women who test positive for T2DM will be noted.

Neonatal Outcome Measures

Neonatal outcomes will be determined by identification of the infant birth weight, immediate neonatal injury, admission to the neonatal intensive care unit, and neonatal hypoglycemia will be obtained by reviewing the medical record of the patient and of her infant.

 Macrosomia, birth injury, shoulder dystocia, and neonatal hypoglycemia are common outcomes measured in GDM research (Crowther et al., 2005; HAPO, 2008; Landon et al., 2009). Macrosomia (birth weight over 4000 gm) is commonly found among the offspring of women with GDM in poor glucose control (Pridjian & Benjamin, 2010). Birth injury, such as nerve palsy, is more common. With the increased fetal fat deposition in the shoulders in macrosomic infants of mothers with diabetes, there is a risk that the anterior shoulder will be wedged anteriorly behind the maternal pubic bone after the head is born (Petry, 2010). Special maneuvers must be undertaken to release the shoulder and accomplish delivery of the infant. If several maneuvers are needed, the delay in the delivery may lead to neonatal injury or complications. Infants of mothers with poorly controlled GDM have a higher rate of neonatal hypoglycemia as they adjust to the withdrawal of the maternal hyperglycemia after birth (Petry, 2010). Admission to the neonatal intensive care unit is necessary for evaluation and treatment of birth injury or hypoglycemia as OHSU does not have a regular or intermediate care nursery for newborns.

Aim 4.: To report on select indicators of increased utilization of resources related to the diagnosis of gestational diabetes or gestational hyperglycemia by patients who met the inclusion criteria.

Assessment of the utilization of resources will be undertaken by collecting data from the progress notes and encounters on the following items listed below. Non-diabetic, low-risk pregnant women do not self-monitor blood glucose, may be encouraged to participate in a reduced number of scheduled prenatal visits, do not receive antenatal fetal well-being testing until they pass 41 weeks of pregnancy, and are commonly managed independently by the OHSU nurse-midwives. In contrast, women with a diagnosis of GDM undergo a

rigorous and specific medical regimen, with increased frequency of contact and visits with the medical system.

- **Blood glucose monitoring** and maintenance of the daily logbook is part of the self-care activities of women with GDM. Most women monitor their glucose four times per day. It is possible that women who are diagnosed with GDM at the borderline of glucose thresholds and who immediately demonstrate excellent glucose control may be advised that they can reduce the number of times per day that they check their capillary blood glucose. The number of patients who maintained four times daily monitoring and the number of patients who transitioned to less than four times daily monitoring will be recorded.
- The **number of prenatal visits** will be counted by reviewing the encounters in the chart review section of the medical record. For a low risk pregnancy, the typical range of prenatal visits is between nine and thirteen. In addition to counting the total number of prenatal visits, percentages for the following categories of visit frequency will be noted: 0 to 6 visits, 7 to 13 visits, more than 13 visits.
- The number of phone calls or personal health record emails to the practice or dietician regarding glucose control or GDM and the number of visits to the dietician will be counted by reviewing the encounters in the chart review section of the medical record. Just after diagnosis, women with GDM typically have an initial and follow-up visit with the dietician. As noted above, it is common that women call in with questions related to diet and glucose control early after diagnosis. This usually wanes as they adjust. Non-diabetic, healthy low risk pregnant women do not receive referrals to a

dietician; in fact, most insurance companies do not cover the cost of such visits without a diagnosis of GDM or obesity.

- Referrals to a physician for consultation or transfer of care will be identified through the progress notes of the medical record. The nurse-midwives at OHSU consult the maternal fetal medicine specialist by phone or refers the patient for consultation when glucose control is inadequate and medication is being considered. In the OHSU nursemidwifery practice, independent management of the uncomplicated patient with A1GDM is the norm.
- Procedures driven by the GDM diagnosis, such as antenatal fetal assessment (nonstress test, amniotic fluid index) prior to 41 weeks will be identified through procedure notes of the electronic health record. As noted above, the risk of stillbirth increases in women with GDM but does not appear to be increased in the patient with A1GDM (Pridjian & Benjamin, 2010). At OHSU, antenatal fetal assessment is routinely advised for women with A2GDM. Typically, weekly non-stress tests are initiated at 32 weeks. Twice weekly non-stress tests and once weekly amniotic fluid index testing (accomplished through 2 visits weekly) are started at 36 weeks of gestation with the intention of discerning early signs of fetal/placental compromise and prevention of stillbirth.

G. Data Analysis

The plan for the data analysis will be described per each aim of the project.

Aim 1.: To describe the demographic characteristics of nurse-midwifery patients who were diagnosed with gestational diabetes or gestational hyperglycemia using the screening criteria adopted by the Oregon Health & Science University (OHSU) Department of Obstetrics and Gynecology on July 1, 2012. (Conversion to the one step screening with a 2-hour GTT actually took place mid-June, 2012).

First, the demographic profile of the women meeting inclusion criteria will be examined.

Demographic Data

A summary of the demographic data will be presented in a table and selected data will be presented in pie or bar charts. Age categories consisting of 18-24 years old, 25 -34 years old, and 35 years old and above will tabulated by frequency and mean. The percentage of each race (white, black/African American, American Indian/Alaska native, Asian, native Hawaiians/other Pacific Islander, two or more races and each ethnic category (Hispanic or Latino or non-Hispanic or Latino) will be presented. Percentages of gravidity/parity, insurance status, and highest educational level attained by the patient will be presented.

Aim 2.: To describe select antepartum process measures of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational

hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013. Second, the frequency and distribution of the following categories of antepartum process variables will be described in tables and figures. An analysis of the frequency of tests and subsets of tests by trimester will be completed. The analysis will help us describe the variance in practice patterns among the nurse-midwives as this new criteria was implemented.

Antepartum Process Measures

Second, the frequency and distribution of the following categories of antepartum process variables will be described in tables and figures. An analysis of the frequency of tests and subsets of tests by trimester will be completed This analysis will help us describe the variance in practice patterns among the nurse-midwives as this new criteria was implemented.

Antepartum Process Measures

- Presence of risk factors at screening (percentage of the total number of screenings)
 - BMI greater than or equal to 30
 - Non-Caucasian
 - First degree relative with diabetes mellitus
 - Multiple gestation
 - o Glucosuria
 - Personal history of:
 - gestational diabetes
 - pre-diabetes
 - unexplained stillbirth
 - fetal malformation
 - infant with macrosomia (birth weight greater than 4000 gm)
 - medical co-morbidities (polycystic ovarian syndrome, hypertension, hyperlipidemia)
- Number of times screened during pregnancy (percentage of the total number of screenings)
- Gestational age at the time of screening at the time of diagnosis (percentage identified early versus standard screening at 24-28 weeks)
- Type of screening test used: FBS, HgbA1c, 2 hour GTT (percentage)

- Percentages of fasting blood glucose results and 2-hour 75-gm GTT results will be based on categorization into two groups: those that fall within the IADPSG criteria (1.75-fold increased risk of large-for-gestational age infant) and those that fall within the Canadian criteria (2-fold increased risk of large-for-gestational age infant).
- Categorization of type of GDM:
 - Number of patients with A1GDM, A2GDM (percentage)
 - Type of GDM and association with the portion of the screening test that was abnormal (fasting versus one-hour or two-hour postprandial)

Aim 3.: To describe select maternal and neonatal outcomes of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28, 2013.

Third, the frequency and distribution of the following categories of maternal and neonatal outcome variables will be described in tables and figures.

Maternal and Neonatal Outcomes

- Mode of delivery (vaginal, operative vaginal, cesarean) (percentage)
- Insulin requirement during labor (percentage)
- Induction of labor (percentage)
- 6-12 week PP screening (percentage): the number screened and the number diagnosed with T2DM
- Macrosomia (percentage by type of GDM)
 - Birth weight between 4000 and 4499 gm
 - Birth weight between 4500 and 4999 gm
 - Birth weight greater than 5000 gm

- Shoulder dystocia (percentage by type of GDM)
- Neonatal injury at birth (percentage by type of injury)
- Neonatal hypoglycemia in the first 24 hours of life (percentage)

Aim 4.: To report on select indicators of increased utilization of resources related to the diagnosis of gestational diabetes or gestational hyperglycemia by patients who met the inclusion criteria.

Fourth, the frequency and distribution of the following categories of resource utilization variables will be described in tables and figures.

Indicators of Increased Resource Utilization

- Blood glucose monitoring and maintenance of log:
 - Number of patients who maintained four times daily monitoring and number of patients who transitioned to less than four times daily monitoring (presented in percentages).
- Number of prenatal outpatient visits presented in percentages
 - Number of patients with 0-6 prenatal visits
 - Number of patients with 7-13 prenatal visits
 - Number of patients with greater than 13 prenatal visits
- Number of phone calls or personal health record emails to the practice or dietician regarding glucose control or GDM
- Number of visits to the dietician
- Referral to physician for consultation or transfer of care
 - Added procedures related to GDM diagnosis, such as antenatal fetal assessment (non-stress test, amniotic fluid index) prior to 40 weeks.

Implementation and Outcome Evaluation

The specific aims of the clinical inquiry project are:

Aim 1. To describe the demographic characteristics of nurse-midwifery patients who were diagnosed with gestational diabetes or gestational hyperglycemia using the screening criteria adopted by the Oregon Health & Science University (OHSU)
Department of Obstetrics and Gynecology on July 1, 2012. (Conversion to the one-step screening/diagnostic testing with a 2-hour GTT actually took place mid-June, 2012).

The demographic characteristics of the sample are presented in Table 1. The study population consisted of 33 women diagnosed with GDM using the OHSU hyperglycemia diagnostic guidelines between June 1, 2012 and February 28, 2013. Eighty-eight percent were over the age of 25. All women had insurance. The education level was documented in 82% of the sample, with 73% educated beyond high school. Thirty-two (97%) women in the sample were Caucasian. Three of the 33 women were Caucasian and Hispanic. Non-Caucasian race is included as a risk factor in the OHSU GDM diagnostic criteria; Hispanic, Latino, or Spanish origin is not. Therefore, these 3 women did not meet criteria for early screening unless they had other risk factors. Thirty-four percent of the patients had pre-pregnancy BMIs above 30, which is a risk factor for GDM. Thirty-six percent of the sample had normal pre-pregnancy BMIs.

Aim 2. To describe select antepartum process measures of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and February 28,

2013. (Conversion to the one-step screening/diagnostic testing with a 2-hour GTT actually took place mid-June, 2012).

The OHSU diagnostic guidelines for gestational hyperglycemia, adopted July 1, 2012, are presented in the Appendix. Data on women with risk factors, gestational age at screening, type of testing, diagnostic category, and mode of delivery is shown in Tables 2 and 3. All women without risk factors (N=18) were screened a single time at more than 23 weeks gestation. This was consistent with the recommendations of the OHSU guidelines. Fifteen of 33 (46%) patients presented for nurse-midwifery care with risk factors for GDM and thus, met the criteria for early screening. Two of these patients transferred care to the midwifery practice after 20 weeks and were tested after 23 weeks. The remainder (n=13) was tested at less than 17 weeks. In accordance with the OHSU guidelines, the midwifery practice planned to screen all women with risk factors who were less than 13 weeks with both a HgbA1c test and a fasting blood glucose test. As can be seen in Tables 2 and 3, despite this practice decision, a variety of screening tests over a range of gestational ages were used in women with risk factors. Seven of the 15 women (47%) with risk factors were diagnosed with A2GDM; each of them had more than one risk factor. Of these women, only two had normal testing in early pregnancy and were subsequently diagnosed at 27 and 28 weeks gestation; the remainder of the women was diagnosed at less than 17 weeks gestation. Two women with A2GDM had no risk factors and were diagnosed at 27 and 28 weeks gestation.

Data on diagnostic testing using the 75-gm 2-hour GTT, the diagnostic category of GDM, and infant birth weights is presented in Tables 4a, 4b, and 5. A total of 6 women with gestational age less than 17 weeks were diagnosed with GDM based on abnormal 75-gm 2-hr glucose testing. Of these women, 5 had abnormal fasting blood glucoses. Two of these

women also had abnormal one and two hour post-glucose load results. Of twenty-three women diagnosed at greater than 23 weeks of gestation, 13 had abnormal fasting blood glucoses. Five of the 13 had an abnormal post-glucose load test and 2 had abnormal values for all three levels (fasting, and one and two hour post-glucose loads). An abnormal result of the one hour post-glucose load was more common than abnormal results with the two hour post-glucose loads, but slightly less common than abnormal fasting blood glucose.

Five out of the 29 women (17%) tested with the 2-hour GTT failed the test by a single abnormal fasting result of 92-94 mg/dL by the IADPSG thresholds (corresponding to the HAPO 1.75 odds ratio for neonatal outcomes of birth weight, cord C-peptide, and percentage of body fat). These women would not have been diagnosed with GDM based on Canadian GDM diagnostic criteria (corresponding to the HAPO 2.00 odds ratio for neonatal outcomes of birth weight, cord C-peptide, and percentage of body fat). Of note, 2 of these 5 (40%) women were diagnosed with A2GDM. One of them had a GDM risk factor of BMI greater than 30, but was not tested by an outside provider in early pregnancy. She transferred to the nurse-midwifery practice at 22 weeks and was diagnosed with A1GDM at 27 weeks. She did not bring her log routinely to antepartum visits but had significant numbers of elevated glucose levels when she did supply the CBG data, thus warranting transfer of care to the pregnancy diabetes clinic for medication management. She did not comply with glucose monitoring and did not start on medication prior to her induction of labor at 39 weeks. She was classified as non-compliant A2GDM. She had a repeat CD for fetal intolerance of labor. The baby weighed 3345 grams. The second woman was a 36 year-old multiparous woman with no GDM risk factors. She was unable to control her fasting blood glucose with diet and

lifestyle management and was placed on insulin. She had an induction of labor and vaginal birth of a baby who weighed 3480 grams.

Four of the 29 women (14%) tested with the 2-hour GTT failed either the one or two hour test according to the IADPSG thresholds. These 4 women, all diagnosed with A1GDM, would not have been diagnosed with GDM based on the Canadian criteria. Thus, 9 of the 29 women (31%) failed the 2 hour GTT by one single value and would not have been diagnosed with GDM based on less stringent criteria. Although patient satisfaction and reaction to the GDM screening process was not included in this data collection, notes were kept in the raw data collection sheet when it was noted in the medical record that the patient either had a difficult time accepting the diagnosis or independently altered the CBG collection frequency. Roughly a third of the sample questioned the diagnosis or initiated an alternative CBG testing frequency.

Approximately two-thirds of the sample was diagnosed with A1GDM (67%) and one third was diagnosed with A2GDM. Women with A2GDM require medication to control their blood glucose. Patients with A2GDM are typically transferred out of the OHSU nursemidwifery practice to the maternal fetal medicine service. An exception was made for one woman who strenuously argued against transfer of care. The midwives co-managed her antepartum care with the maternal fetal medicine specialist and she was prescribed oral medication for glucose management. She was managed by the midwives in labor and had a normal vaginal delivery of a baby with a normal birth weight.

Aim 3. To describe select maternal and neonatal outcomes of all patients enrolled in the OHSU nurse-midwifery practice diagnosed with gestational diabetes or gestational hyperglycemia by the IADPSG criteria between June 1, 2012 and

February 28, 2013. (Conversion to the one-step screening/diagnostic testing with a 2-hour GTT actually took place mid-June, 2012).

Data on diagnostic testing of women with risk factors, the diagnostic category of GDM, mode of delivery, provider during labor, and infant birth weight is presented in Tables 3 and 6. Out of 28 patients who had delivered by the time of the data analysis on April 17, 2013, 29% (n=8) were induced for GDM related indications and one person required insulin during labor. Twenty-seven deliveries occurred between 37 to 42 weeks of gestation. The single preterm delivery at 36 weeks gestation was not attributed to a gestational diabetes-related condition (preterm premature rupture of the membranes). The mean gestational age was 39.6 weeks gestation (SD=1.04).

Thirty-two percent (*n*=9) of the 28 women who have given birth were planning a trial of labor after cesarean delivery; of these 9 women, 5 had successful VBACs. Out of the 28 women who have delivered thus far, 4 had primary CDs and 4 had repeat CDs after laboring. Two of the four primary CDs were scheduled, one for a known breech presentation and the other due to suspected macrosomia in a mother with a past history of macrosomia and shoulder dystocia. The two other primary CDs were for fetal intolerance of the first stage of labor and second stage arrest of descent. Two of the four repeat CDs were due to first stage arrest of labor and second stage arrest of descent; two others were for fetal intolerance of labor in the first stage. There was a 21.4 % unscheduled CD rate (6 out of 28 women). Of these 6 women, 4 (67%) CDs were among women who labored with a past history of CD.

Ten of the fifteen women who had risk factors for GDM have delivery information (one moved out of state and four have not yet delivered). Among these ten women, there was a 40% CD rate and 50% successful VBAC rate. Five of the six women who had unscheduled

cesareans had pre-pregnancy BMIs greater than 25; of these, three women had BMIs greater than or equal to 30 (ranging from 30 to 40). Two of these 3 women had CDs for second stage arrest, one of which was a repeat CD. The other woman had a repeat CD for fetal intolerance of the first stage of labor. Of the two women with CDs who had BMIs between 25 and 29, one CD was for first stage arrest; the other was for fetal intolerance of labor.

Of the women who had reached at least 6 weeks postpartum by the time of the data analysis, eighteen women had returned for a 6 weeks postpartum visit; 4 had not. Out of these 22 women, 68% (n=15) were not tested despite clinical guidelines recommending postpartum testing for T2DM. Some of the providers did not order postpartum testing; others ordered it, but the patients did not comply with testing. Of those who were compliant with testing, 27% (n=6) tested normal, and 5 percent (n=1) had an abnormal test.

The mean infant birth weight was 3,552g (*SD*=477g). Six of the 28 infants (21%) had birth weights greater than or equal to 4000g, with the heaviest infant weighing 4500g born by scheduled cesarean for suspected macrosomia. Birth weights of all neonates according to maternal GDM screening and diagnostic criteria are listed in Table 5. There were no cases of shoulder dystocia or birth injuries and no instances of neonatal hypoglycemia at the first capillary blood glucose test. All Apgar scores were 7 or above at 5 minutes. There were no neonatal intensive care admissions or separation of the mother and baby dyads for GDM related conditions. One baby was admitted to the neonatal intensive care unit for antibiotic prophylaxis due to maternal intra-amniotic infection; the blood cultures were normal and the baby was reunited with the mother on the mother-baby unit during the maternal hospital stay.

Aim 4. To report on select indicators of increased utilization of resources related to the diagnosis of gestational diabetes or gestational hyperglycemia by patients who met the inclusion criteria.

Of twenty-eight women who had delivered by the time of data analysis on April 17, 2013, 4 did not maintain the daily log as recommended, and 6 did not bring the log consistently to their visits. There were no patients who had less than 7 prenatal visits during the duration of their pregnancy. Eleven women had between 7 and 12 prenatal visits (39%); 17 patients had 13 or more prenatal visits (61%). Seven patients made fewer than 3 phone calls or medical record email messages related to diabetes issues. Twenty-one patients made greater than or equal to 3 phone calls or email messages regarding diabetes issues. The total range of number of messages by phone or email was 0 to 11. Three patients declined to meet with the dietitian, a standard part of treatment for women newly diagnosed with GDM. Thirteen patients made at least one visit to the dietician; 12 patients made more than one visit to the dietician. The range of dietician visits was 0 to 7. Eleven patients (33%) were transferred out of the midwifery practice because of requiring medication to manage GDM. As noted above, one of these patients was co-managed with the physicians. About half (15 of 28 delivered) of the women underwent GDM-related antenatal procedures, such as ultrasounds for fetal growth or fetal well-being tests

DISCUSSION

The objective of GDM screening is to identify women at significant risk for adverse pregnancy outcomes and apply evidence-based interventions (Kalter-Leibovici, et al, 2012). Langer, Umans, and Miodovnik (2013) comment on the current state of GDM diagnostic methodology: "The diagnosis and management of GDM continues to be a focus of academic deliberation and practical uncertainty" (p. 179). One of the major goals of the panel that developed the IADPSG GDM diagnostic criteria was to reduce practice variation, thereby improving care and outcomes through uniformity of diagnosis (Reece & Moore, 2013). A descriptive summary of the patient characteristics, outcomes, and resource utilization among OHSU nurse-midwifery patients screened with the IADPSG criteria reveals significant practice variation in the application of the testing protocol and in the degree of acceptance and compliance by patients. The use of the IADPSG criteria substantially increased the prevalence rate in this midwifery population. Maternal diagnosis and outcomes varied by degree of risk factors. Neonatal outcomes were overwhelmingly normal. Utilization of resources was predictably high among women with GDM.

The OHSU nurse-midwifery practice is in the process of developing a data repository in order to benchmark care measures and answer significant clinical care questions. Based on a preliminary examination of data on women seen in the midwifery practice who received a diagnosis of GDM between January 1, 2012 and June 30, 2012, the prevalence rate of GDM was approximately 4.6%. A careful analysis indicated no overlap of June cases between cases diagnosed with the 2-step criteria and the IADPSG 1-step criteria when assessing prevalence rates. The prevalence rate was determined by estimating the number of OHSU clinic patients giving birth attended by nurse-midwives at OHSU on a monthly basis. The OHSU midwives attend about 40 births per month; of these, approximately 60% or 25 of them are derived from their own clinic population. Using this formula, the nurse-midwifery practice GDM prevalence rate over 8.5 months from June 15, 2012 to February 28, 2013 was approximately 15.6%. This estimate represents a prevalence rate that is 3 to 4 times greater than in the 6 months prior to implementing the IADPSG criteria, which is consistent with the projected increases of up to

almost 18% described in the medical literature (CDC, 2011; Gabbe et al., 2012; IADPSG Consensus Panel, 2010).

Women diagnosed with GDM were stratified in early pregnancy based on risk factors. Those with risk factors were diagnosed according to the IADPSG guidelines found in the Appendix. Forty-six percent of the women diagnosed with GDM had risk factors, with the majority having at least two factors. This group of women represents a sample of women at significant risk for development of GDM and thus may be considered separately related to outcomes. Forty-seven percent of women with risk factors (7/15 women) were diagnosed with A2GDM during the pregnancy, requiring medication and transfer of care to the physician service. Of the 10 women with risk factors who had delivered by the time of the data analysis, there was a 40% CD rate and 50% successful VBAC rate. Two of the four CDs were repeat cesareans; one for second stage arrest and the other for fetal intolerance of labor in the first stage of labor. Of the primary CDs, one was for second stage arrest and the other was scheduled due to suspected macrosomia. The 2012 total CD rate (primary and repeat) for the midwifery practice was 12.9%. Therefore, this subsample of women with risk factors, early pregnancy screening, and diagnosis of GDM at less than 17 weeks were managed by either midwives or physicians in labor, had more complicated pregnancies and a higher cesarean rate than the rest of the sample and than the practice's annual total cesarean rate. The presence in the sample of a relatively high number of women seeking vaginal birth after cesarean complicates the interpretation of the high cesarean rate.

The significance of these findings is limited by the small sample size and descriptive nature of this project. In addition, this analysis includes women who were diagnosed *in the presence of* risk factors, not women who had risk factors but never met criteria for GDM

diagnosis. The nurse-midwifery practice has not previously analyzed GDM data. Therefore, there is no capability of comparing this sample's characteristics and outcomes with those women diagnosed under a different screening model or not achieving diagnosis. The number of women with risk factors appears high for a practice considered to be a typical low-risk midwifery service; however, given the current obesity epidemic, this number may be increasingly common for midwifery practices. Among the 15 women with risk factors in the sample, 10 (67%) had pre-pregnancy BMIs greater than 30, which is consistent with recent trends in rates of obesity (Flegal et al., 2010).

A critical analysis of the use of the IADPSG criteria for early screening is not well documented in the literature and was not reviewed at the recent NIH Consensus Development Conference, Diagnosing Gestational Diabetes Mellitus (March, 2013). According to the IADPSG protocol, a HgbA1c or fasting blood sugar should be tested at less than 13 weeks gestation in women with risk factors. Depending upon whether either of these results is borderline abnormal or abnormal, the screening algorithm suggests further testing using the 75gm 2-hour GTT or assigning the patient with an immediate diagnosis. It is clear that despite a plan by the midwifery practice to obtain a HgbA1c and fasting blood glucose on women with risk factors, in actual practice, a variety of tests at less than optimal early gestational ages were employed. Based on medical record audits, the reason for this variation appears to be confusion about the exact protocol, patient resistance to the fasting state required for a FBS and the 2 hour GTT, the requirement for further testing or a longer test (such as the 2 hour GTT), and the need to return at another date to the laboratory when in a fasting state. One of the arguments in favor of the IADPSG criteria is simplification of testing (Reece and Moore, 2013). However, even if that is true for the 2 hour GTT (which is debatable, as will be discussed later), simplification of

the screening process was not the experience of the midwifery service related to the early testing protocol.

Interestingly, the combination of stratification by risk factors to early screening using hemoglobin A1c, fasting plasma glucose, 2-hour GTT, or a combination there-of appeared to correctly identify a group of women at risk for significant insulin resistance. The number of cases with specific combinations of abnormalities (eg., abnormal fasting blood glucose and normal hemoglobin A1c) was too small to make any type of correlation with outcome. Given the patient volume of this midwifery practice, a few more years of data would need to be collected in order to address this type of correlation.

Women without risk factors represent a second subset of the sample and were tested at greater than 23 weeks with a 2-hour GTT. Although the testing was easy to order and there was no confusion about what test to order, there was some dissatisfaction by patients with the new screening criteria. As noted earlier, roughly a third of the sample questioned the GDM diagnosis or initiated an alternative CBG testing frequency. It is possible that this number could be higher, as it was only collected incidentally during the retrospective chart review if the provider had mentioned patient concerns in a progress note. Multiparous women, who had been screened using the 2-step screening criteria in their previous pregnancies, expressed concern about the requirement to come in for a longer test that mandated arriving at the laboratory in a fasting state. Some women missed the normal threshold by a point or two by the IADPSG criteria and were directly diagnosed with GDM based on one slightly abnormal value. Many of these women questioned the validity of the diagnosis. To put this in a social media context, during the same time period as this data analysis, the local media presented information on the question of changing to the IADPSG criteria and the potential increase in the GDM prevalence rate. The

midwives struggled to defend the rationale for the diagnosis. Some patients expressed substantial anger and emotional upset in lengthy telephone calls or visits to the midwife or dietician. Others requested repeat testing which then confused the clinical picture and management plans. Some women independently initiated a reduction in the recommended frequency of CBG testing at home.

Concerns about labeling women with a medical diagnosis based on data that applies a 1.75 odds ratio based on neonatal outcomes are prominent in the recent medical literature (Kalter-Leibovici et al., 2012; Langer et al., 2013; Reese & Moore, 2013; Ryan, 2012). However, studies on the true emotional impact on women and protocol modifications made by providers when applying the lower diagnostic thresholds of one-step diagnosis are lacking. Two recent qualitative studies on the maternal experience of the GDM suggest that increased sensitivity and nonjudgmental communication are key elements of care for women as they adjust to self-management of GDM (Collier, Mulholland, & Williams, Mercereau, Turay, & Prue, 2011; Nolan, McCrone, & Chertok, 2011).

A legitimate question, and one that was heavily debated at the 2013 NIH Consensus Development Conference on diagnosing GDM, is whether the substantial increase in prevalence rate and the accompanying burden on women and health care systems resources is justified by improvement in outcomes. For women in this second subset, who did not present with risk factors, 16 of 23 (70%) had A1GDM. Of the 15 who have delivered, 8 (53%) had spontaneous vaginal births, 4 (27%) had VBACs, 2 ((13%) had repeat cesareans after laboring, and one (7%) had a primary CD. This is a 67% successful VBAC rate and a total vaginal birth rate (spontaneous and VBAC) of 80%. Overall, neonatal outcomes were normal with infant birth weights ranging from 2580 to 4139 grams, with just two babies weighing over 4000 grams. There were no babies with low Apgar scores at 5 minutes, shoulder dystocias, neonatal injuries, or immediate hypoglycemia. As opposed to two landmark studies (Crowther et al.2005; Landon et al., 2009) on treatment of women with mild GDM, complications among women in this sample without risk factors and with a diagnosis of A1GDM were few; short-term outcomes, such as neonatal status, were good. Primary outcomes differed between these two influential studies; both sets of authors concluded that treatment of mild GDM resulted in improved outcomes. The results of the midwifery data analysis may not be significant due to the relatively small size of the sample. In addition, the two RCTs used differing fasting thresholds of less than 95 mg/dL and less than 140 mg/dL, respectively (Crowther et al.2005; Landon et al., 2009). This makes direct comparison with samples using the IADPSG criteria difficult. There are no RCTs comparing IADPSG screened patients with a control group, although the NIH Consensus Development Panel on diagnosing GDM called for this gap in the literature to be addressed (http://prevention.nih.gov/cdp/conferences/2013/gdm/files/DraftStatement.pdf.).

Analysis of treatment regimens revealed that some midwives and patients negotiated a modified CBG routine when the overwhelming majority of the home glucose test results were normal. Kalter-Leibovici et al. (2012) analyzed data from Israeli participants in the 2008 HAPO study and compared women who tested positive for GDM based on IADPSG criteria, IADPSG criteria with a formula for risk-stratification, or based on BMI or fasting plasma glucose. The authors found that one-third of the IADPSG positive women had rates of macrosomia only slightly higher than those who screened negative with the IADPSG criteria. They postulate that some women may benefit from less intensive management that stresses lifestyle modification, which supports the customized management scheme that some of the patients in the OHSU midwifery sample employed.

One of the compelling concerns about the use of the IADPSG criteria is the application of a one-step approach for screening and diagnosis. A single 2 hour GTT value that exceeds the normal threshold by as little as one point results in a diagnosis of GDM. As seen in this midwifery sample, 9 of the 29 women (31%) failed the 2-hour GTT by one single value. These women would not have been diagnosed with GDM based on less stringent criteria. Diagnosed by the IADPSG criteria, they contributed to the increase in the GDM prevalence rate in the midwifery patient population. The majority of these women (7 out of 9 or 78%) had A1GDM. Kalter-Leibovici et al. (2012) argue that applying risk stratification formulas that are validated for the specific population may be a more efficient use of resources over universal application of the IADPSG criteria.

Increased utilization of resources was demonstrated in the midwifery sample by the number of phone calls and medical record emails to providers and dieticians, the number of dietician visits, and the use of antenatal fetal wellbeing or growth testing. Understandably, these resources were used at a higher rate for women diagnosed with A2GDM, as they required medication management. For those with A1GDM and mild GDM, the potential benefits of identification and treatment must be weighed against the burden on patients and the health system. Black, Sacks, Xiang, & Lawrence (2013) studied the contribution of pre-pregnancy weight and gestational weight gain to fetal overgrowth. Data from this retrospective study of 9,835 women found that, in agreement with the suggestion by Kalter-Leibovici and colleagues, interventions to effectively assist with pre-conceptual weight gain and weight gain control during pregnancy may have a greater potential to reduce the risk of having an LGA infant and other adverse outcomes.

Neonatal outcomes in this retrospective cohort were remarkably uniform. All neonates, regardless of the number of maternal risk factors, type of GDM, or degree of compliance with the regimen had Apgar scores above 7 at five minutes, had no birth injuries or immediate hypoglycemia, and none were separated from their mothers for GDM related conditions. Some conditions, such as shoulder dystocia, would be expected to be identified only with much larger sample sizes. The threshold for neonatal hypoglycemia varies based on institutional protocols (Langer et al, 2013). Maternal insulin is initiated in labor for hyperglycemic women with A2GDM or T2DM to help lower the odds of neonatal hypoglycemia in the early postpartum phase. Only one mother in the sample required insulin in labor. The other women with A2GDM had normal glycemic levels in labor and therefore it would be expected that neonatal hypoglycemia would not have been discovered.

This is the first known analysis of the implementation of the IADPSG criteria in a nursemidwifery population and provides a basis for future studies. There are multiple systems and quality improvement implications to be drawn. First, the importance of participation in multidisciplinary committees during the development of important clinical guidelines cannot be over-emphasized. Despite the absence of such an invitation in this case, the development of an inquiry project examining the impact of the new guideline on midwifery practice and patients was highly useful, providing the basis for a presentation at a recent OHSU Department of Obstetrics and Gynecology Grand Rounds. As a result, there is a plan to form a new task force to reassess the use of the IADPSG criteria at OHSU. The midwifery practice was the first to raise the issue and will have representation on this task force.

Second, the midwifery practice will be evaluating aspects of GDM care based on the data from this sample of women. One potential area of improvement concerns the early recognition

of risk factors, logistics for testing, and compliance with laboratory work. Strategies to enhance early, continued, and strong counseling about nutrition, exercise, and weight gain are under consideration, as well. Alteration of the nurse-midwifery data repository to include GDM risk factors might contribute to the opportunity for a future practice improvement project that analyzes all women with risk factors. As noted earlier, the project described in this paper only included women with risk factors who achieved a diagnosis of GDM. It would inform the options for GDM screening of the OHSU midwifery patient population if there was information about the outcomes of the women who had risk factors but did not meet criteria for diagnosis.

Another area of practice improvement that was highlighted by the data is that a method for follow-up of women diagnosed with GDM beyond the 6 weeks postpartum check-up was not in place. A recent study involving Ohio nurse-midwives found suboptimal levels of postpartum testing, supporting similar findings among other groups of maternity care providers (Ko et al., 2013). Since there is a substantial risk of future development of T2DM in the GDM population, there is a high degree of stress placed on postpartum follow-up with testing and lifestyle counseling (Gabbe et al., 2012). Simmons, McElduff, McIntyre, and Elrishi (2010) comment that maternal knowledge about the increased risk of complications during pregnancy and the future risk of T2DM should enhance patient empowerment. The midwifery practice does not have a current protocol in place for continued follow-up or visits with women with GDM beyond six weeks, an area that the midwifery service plans to address. Development of the process for a meaningful hand-off to the primary care provider would contribute to truly comprehensive patient care.

A final care management issue that could be reevaluated is the decision to transfer women who have A2GDM to physician-managed care. In this sample, the rate of transfer to physician care was high; yet, there was just one case requiring insulin management in labor and there were no cases of early neonatal hypoglycemia. Historically, the potential need for insulin during labor and the recommendation for induction of labor at 39 weeks gestation due to an increased risk of stillbirth have led the OHSU midwifery service to avoid management of women with A2GDM. Now that data is available from this practice, a new discussion about transfer of care is recommended. Collaborative management of women requiring medication management of GDM is within the scope of nurse-midwifery practice provided that supportive institutional midwifery practice guidelines are in place (Avery, 2000).

A third implication of this data analysis involves the issue of sharing decisions about screening and diagnosis of GDM with our patients. Witnessing the struggle (both in person and through the medical record review) that the midwives faced in working with patients who were unhappy with GDM diagnoses based on the new screening criteria, it became evident to this writer that a fresh look at patient-centered care was in order. Shared decision-making (SDM) is a foundation of midwifery care and has been described as an ethical imperative (Politi et al., 2013). It is a collaborative process in which patients and practitioners form health decisions based on a consideration of the clinical evidence and the patient's informed preferences (Elwyn et al., 2012; Politi et al., 2013; Stigglebout et al., 2012). The risks and benefits of options are discussed, the probability and uncertainty of evidence is reviewed, and the patient's understanding is verified. Then, the patient's values and preferences are discussed, followed by selection of a decision and plan for follow-up (Makoul, G. & Clayman, M.L., 2006). Evidence from more than 80 trials suggests that SDM leads to knowledge gain by patients, enhanced confidence in decision-making, and improved patient satisfaction (Elwyn et al., 2012; Politi et al., 2013). Discussions

about examining the midwifery service's incorporation of shared decision-making into the routine of offering GDM screening are in process.

Conclusion

A descriptive summary of a nurse-midwifery practice's processes and outcomes after implementation of the IADPSG GDM diagnostic criteria reveals areas for potential change at both institutional and service levels. With the obesity epidemic and recent calls for coordinated, excellent and cost-effective care, this analysis could not be more timely. A re-examination of the institution's use of the IADPSG criteria is planned. Potential midwifery practice improvements include early detection and management of women with GDM risk factors, enhancement of shared decision-making during the process of GDM screening, and postpartum screening and follow-up. Reconsideration of the transfer of care to physicians of women with GDM should be undertaken. Future projects involving nurse-midwifery GDM practice improvement, including continued monitoring of women with risk factors and outcomes for women diagnosed with and without GDM, will be considered. Under current development is a group prenatal care curriculum for women with GDM. As well, a new interdisciplinary collaboration with the maternal fetal medicine service on a curriculum for group prenatal care for women with T2DM is under way. Finally, dissemination of information in the form of publication will raise the level of awareness of the implications and outcomes when transitioning to new GDM screening and diagnostic testing criteria.

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Demographic Characteristics of Nurse-Midwifery Patients Diagnosed with GDM by IADPSG Criteria between June 1, 2012 and February 28, 2013

Characteristic Total N=33	M (SD)	Percent
Age n=33; Range: 19 – 40 years old	31 (5.2)	
18 to 25		12
26 to 34		61
35 and over		27
Race		
White; n=32		97
Black/African American; n=0		0
American Indian/Alaska Native; n=0		0
Asian; n=0		0
Native Hawaiians/Other Pacific Islander; n=0		0
Two or more races; n=1		3
Hispanic Origin		
Hispanic, Latino, or Spanish Origin; n=3		9
Not Hispanic, Latino, or Spanish Origin; n=30		91
Insurance Status		
Private; n=20		61
Public; n=11		33
Military; n=2		6
Self-Pay; n=0		0
Highest Education Level Attained; n=33		
Primary Education; n=0		0
Some High School; n=1		3
High School Degree or GED; n=2		6
Some College; n=9		27
College Degree; n=11		33
Graduate Degree; n=4		12
Not Listed; n=6		18
Parity; n=33		
Nulliparous; n=14		42
Multiparous; n=19		58
BMI; n=33; Range 20 to 47	29(7.3)	29
Pre-Pregnancy BMI by IOM		
Less than 18.5; n=0		0
18.5 to 24.9; n=12		36
25 to 29.9; n=9		27
30 to 39.9; n=7		21
40 or over; n=5		15

Note. Not all percentages add up to 100 because of rounding.

Risk Factors and	Gestational Age	at First Screen
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Risk Factors and Gestational Age at First Screen	Percent
Presence of Risk Factor; N=33	
Yes; n=15	45
No; n=18	55
Number of Risk Factors; N=15	
1 Risk Factor; n=5	33
2 Risk Factors; n=8	53
3 or More; n=2	13
Gestational Age at First Screening; N=33	
Screening at less than 20 weeks; n=14	42
Of the total 14 screened early:	
Less than 13 weeks; n=9	64
Between 13 and 18 weeks; n=5	36
Screening at 24 weeks or greater n=19	58
Range 27 to 29 Weeks	
Type of Screening Test at First Screening; N=33	
FBS plus HgbA1c; n=5	15
FBS Range: 84 to 116	
HgbA1c: 5.3 to 6.4	
FBS; n=0	0
HgbA1c; n=4	12
Range: 5.4 to 5.6	
2 hour GTT; n=21	64
Screened before 17 weeks; n=5	
Other; n=3	9

Testing Regimen, Mode of Delivery, and Infant Birth Weight Among Nurse-Midwifery Patients Meeting Criteria for Risk Factors for GDM N=15

One risk factor	More than one	Testing at first	Type of GDM	Mode of
	risk factor	screening	diagnosis	delivery/infant
		-		birth weight
NA	BMI, Family	Abnormal FBS	A2GDM ^a	SVD
	History of DM	Normal HgbA1c		2580 gm
	5	at 14 weeks		U
NA	BMI. Family	Abnormal FBS	A1GDM	TOC out of
	History of DM	Normal HgbA1c		state: no
		At 14 weeks		information
History of GDM	NA	Abnormal 2 hour	A1GDM	SVD
		GTT at 16 weeks ^b		3720 gm
NA	BMI, Family	Abnormal 2 hour	A2GDM	PTD
	History of DM	GTT at 14 weeks		2790 gm
NA	BMI,	Abnormal	A1GDM	Primary CD
	Macrosomia,	HgbA1c at 12		without Labor
	Shoulder	weeks;		for Suspected
	Dystocia	Abnormal 2 hour		Macrosomia
		GTT at 13 weeks		4500 gm
History of	NA	Normal HgbA1c	A1GDM	SVD
Macrosomia		at 12 weeks ^c		4167 gm
		Abnormal FBS at		e
		15 weeks		
NA	BMI	Abnormal 2 hour	A1GDM	Repeat CD for
	History of PCOS	GTT at 12 weeks		Second Stage
	5			Arrest
				4082 gm
BMI	NA	Abnormal 2 hour	A1GDM	Repeat CD for
		GTT at 27 weeks ^d		FIOL/Suspected
				Abruption
				3345 gm
BMI	NA	Normal One Hour	A1GDM	VBAC
		at 9 weeks		3459 gm
		Abnormal 2 hour		_
		GTT at 28 weeks		
NA	BMI, History of	Normal 2 hour	A2GDM	VBAC
	Macrosomia	GTT at 28 weeks ^e		3600 gm
NA	BMI, Family	Abnormal FBS	A2GDM	Not yet
	History of DM	and Abnormal		delivered
		HgbA1c at 12		
		weeks		
NA	BMI, Family	Normal HgbA1c	A2GDM	Primary CD for

One risk factor	More than one	Testing at first	Type of GDM	Mode of
	risk factor	screening	diagnosis	delivery/infant
				birth weight
	History of DM	at 13 weeks		Second Stage
		Abnormal 2 hour		Arrest
		GTT at 28 weeks		3941 gm
NA	Macrosomia	Normal HgbA1c	A2GDM	Not yet
	History of GDM	at 11 weeks		delivered
		Abnormal 2 hour		
		GTT at 27 weeks		
NA	BMI, Family	Normal FBS &	A2GDM	Not yet
	History of DM	Abnormal		delivered
		HgbA1c at 17		
		weeks		
		Declined 2 hour		
		GTT until 26		
		weeks: abnormal		
NA	BMI, Family	Abnormal 2 hour	A1GDM	Not yet
	History of DM ^f	GTT at 11 weeks		delivered

Note. BMI: Body Mass Index Greater than or equal to 30; FBS: Fasting Blood Sugar; SVD: Spontaneous Vaginal Delivery; TOC: Transfer of Care; PTD: Preterm Delivery; CD: Cesarean Delivery; FIOL: Fetal Intolerance of Labor.

^aCo-managed antepartum with MD. CNM labor and birth management.

^bOne hour glucose at 11 weeks (June, 2012) followed by normal HgbA1c; followed by 2 hour GTT incorrectly ordered as FBS and 2 hour glucose.

^c*HgbA1c* was 5.6 which is normal, but was called borderline abnormal by the CNM; thus, a FBS was ordered.

^d *TOC* to *CNMs* at 22 weeks. No earlier testing for *GDM* in pregnancy.

^eTOC to CNMs at 26 weeks. No earlier testing for GDM in pregnancy. US showed suspected macrosomia. CBGs (capillary blood glucose) 4 x daily initiated at 32 weeks and > 60% abnormal at 33 weeks; diagnosis of GDM made.

^fPatient with history of Gastric Bypass Surgery

Table 4a

Diagnostic Testing with 2 hour GTT at less than 17 Weeks	N=6
2 Hour GTT FBS result range:	
92 to 94 mg/dL	1
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant (see note)	
95 to 99 mg/dL	2
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
100 mg/dL or greater	2
Less than 92 mg/dL	1
2 Hour GTT first hour result range ^a :	
180 to 190 mg/dL	1
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant	
191 mg/dL or greater	2
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
Less than 180 mg/dL	2
2 Hour GTT second hour result range:	
153 to 161 mg/dL	1
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant	
162 mg/dL or greater	1
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
152 mg/dL or less	4

Note. Some women would have met criteria that are listed in more than one row so data in rows are not mutually exclusive.

IADPSG diagnostic thresholds are the average glucose values at which odds for birth weight $>90^{th}$ percentile, cord C-peptide $>90^{th}$ percentile, and percent of neonatal body fat $>90^{th}$ percentile reached 1.75 times the estimated odds of these outcomes at mean glucose values. IADPSG (2010) International Association of Diabetes and Pregnancy Study Groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 33(3), 676-682.

^aOne patient was tested with a 75-gram 2-hour GTT that omitted the first hour result (included only the FBS and second hour result)

Table 4b

Diagnostic Testing with 75-gram 2 hour GTT at greater than 23 Weeks

Diagnostic Testing with 2 hour GTT at greater than 23 Weeks	N=23
2 Hour GTT FBS result range:	
92 to 94 mg/dL	6
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant (see note below)	
95 to 99 mg/dL	1
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
100 mg/dL or greater	6
Less than 92 mg/dL	10
2 Hour GTT first hour result range:	
180 to 190 mg/dL	8
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant	
191 mg/dL or greater	4
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
Less than 180 mg/dL	11
2 Hour GTT second hour result range:	
153 to 161 mg/dL	2
Corresponds to HAPO results equal to a 1.75 OR Increased Risk of	
LGA infant	
162 mg/dL or greater	6
Corresponds to HAPO results equal to a 2.00 OR Increased Risk of	
LGA infant	
152 mg/dL or less	15

Note. Some women would have met criteria that are listed in more than one row so data in rows are not mutually exclusive.

IADPSG diagnostic thresholds are the average glucose values at which odds for birth weight >90th percentile, cord C-peptide > 90th percentile, and percent of neonatal body fat > 90th percentile reached 1.75 times the estimated odds of these outcomes at mean glucose values. IADPSG (2010) International Association of Diabetes and Pregnancy Study Groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 33(3), 676-682.

FBS	One hour result	Two hour result	Type of GDM	Infant birth
				weight in grams
Less than 17				
weeks				
99 ^a	^b	98	A1GDM	3720
100	133	116	A2GDM	2790
99	196	168	A1GDM ^c	4500
114	189	154	A1GDM	3130
94	162	132	A1GDM	4082
78	213	48	A1GDM	Not yet delivered
Greater than 23				
weeks $N = 23$				
93	163	125	A1GDM	3502
100	185	73	A1GDM	4315
104	161	136	A1GDM	4065
93	125	104	A1GDM	2930
78	192	180	A1GDM	3410
89	185	165	A1GDM	3274
106	166	142	A2GDM	3266
93	198	209	A1GDM	3500
99	189	144	A2GDM	3345
92	182	128	A1GDM	3610
82	180	135	A1GDM	4139
86	183	113	A1GDM	3941
81	203	139	A1GDM	3020
73	164	159	A1GDM	3204
92	125	100	A2GDM	3345
107	155	126	A1GDM	3459
90	132	132 ^d	A1GDM	3600
92	151	138	A2GDM	3480
84	168	155	A1GDM	3940
105	174	124	A2GDM	3941
80	208	193	A2GDM	Not yet delivered
79	180	163	A1GDM	3189
109	189	169		Not yet delivered
			A2GDM	

75-Gram Two-Hour GTT results, Type of GDM, and Infant Birth Weights

^a Abnormal levels (according to IADPSG criteria) are presented in bold typeface

^b 75 gram 2 hour GTT without one hour testing was ordered erroneously

^cPoor compliance with testing CBGs and presentation of log to provider

^d Normal 2 hour GTT, ultrasound with suspected macrosomia, CBG x 4 daily with > 60% abnormal at 33 weeks when diagnosis of GDM was made.

Mode of Delivery by Nurse-Midwifery Patients Diagnosed with GDM by IADPSG Criteria between June 1, 2010 and February 28, 2013. N=28

Mode of	Indication if	Type of	Gestational	Birth weight	Provider
birth	cesarean	GDM	age	in grams	during labor
SVD	NA	A2GDM	39	2580	CNM (Co-
					managed)
SVD	NA	A1GDM	37	3720	CNM
SVD	NA	A1GDM	39	3502	CNM
SVD	NA	A2GDM	36 (PPROM)	2790	MD
PRIMARY	Scheduled ^a	A1GDM	39	4500	NA
CD					
REPEAT CD	First Stage	A1GDM	41	4315	CNM
	Arrest				
REPEAT CD	Fetal	A1GDM	40	4065	CNM
	Intolerance				
	in First Stage				
PRIMARY	Scheduled,	A1GDM	39	3130	NA
CD	Breech,				
	Declined ECV				
VBAC	NA	A1GDM	40	2930	CNM
SVD	NA	A1GDM	40	3410	CNM
SVD	NA	A1GDM	40	3274	CNM
SVD	NA	A2GDM	39	3266	MD
SVD	NA	A1GDM	39	4167	CNM
REPEAT CD	Second Stage	A1GDM	41	4082	MD ^b
	Arrest				
SVD	NA	A1GDM	41	3500	CNM
SVD	NA	A2GDM	39	3345	MD
PRIMARY	Fetal	A1GDM	41	3610	
CD	Intolerance				
	in First				
	Stage ^c				
VBAC	NA	A1GDM	42	4139	CNM
SVD	NA	A1GDM	40	3941	CNM ^d
SVD	NA	A1GDM	40	3020	CNM
VBAC	NA	A1GDM	40	3204	CNM ^e
REPEAT CD	Fetal	A2GDM	39	3345	MD
	Intolerance				
	in First Stage				
VBAC	NA	A1GDM	38	3459	CNM ^f
VBAC	NA	A2GDM	39	3600	MD
SVD	NA	A2GDM	39	3480	MD

Mode of	Indication if	Type of	Gestational	Birth weight	Provider
birth	cesarean	GDM	age	in grams	during labor
SVD	NA	A1GDM	39	3940	CNM
PRIMARY	Stage 2	A2GDM	40	3941	MD
CD	Arrest				
SVD	NA	A1GDM	40	3189	CNM

Note. CD = Cesarean Delivery; ECV = external cephalic version, antenatal

^aHistory of macrosomia and shoulder dystocia with suspected macrosomia in this pregnancy ^bInduction of labor with severe hypertension at admission. MD managed induction. ^cNuchal Cord x 4

^dDiverted to CNM at another area hospital due to full capacity on Labor Unit at OHSU ^eHistory of CD x 2

^f Induction of labor for cholestasis of pregnancy

Appendix

Hyperglycemia in Pregnancy: OHSU Diagnostic Guidelines



Hyperglycemia in Pregnancy: Diagnostic Guidelines