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## Self-Management Education in Hispanic Women with Gestational Diabetes Mellitus (GDM)

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Laura B. Hieronymus, Student

Dr. Karen Stefaniak, Advisor

Final Practice Inquiry Project

Self-Management Education in Hispanic Women with Gestational Diabetes Mellitus (GDM)

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University of Kentucky

College of Nursing

Spring 2015

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## Dedication

I would like to dedicate this work to my family, a colleague, and to God. First off, to my husband, G. D. and our daughters, Kelly and Lindsay. Their love and support are always evident and their faith in me to accomplish whatever I set out to do is constant. To my parents, Tommy and Marguerite Bertram, who have been wonderful role models and my sisters, Carol and Nell, who provide strength with their ongoing encouragement. My family is truly the “art” of my inspiration. To my colleague, the late Patti Geil, MS, RD, MLDE, CDE, FAND, FAADE whose professional mentorship and friendship pushed me to be a not only a better nurse, diabetes educator, and author, but more importantly a better wife, mother, and person. Truly, my professional vita has your name written all over it. You always encouraged me to take “science” to the next level. Your memory will stay with me always. And finally, thanks be to God—for I can do all things in him that strengthens me.

## Acknowledgements

I want to thank Dr. Karen Stefaniak, my committee chair, for her ongoing encouragement, her thoughtful and steady leadership, and for believing in me as a doctoral nursing student. Dr. Stefaniak's smile always lifts my spirit. Thank you to Dr. Kristin Ashford for her support and innovative counsel, as well as opportunity to work within one of her clinical research initiatives. And to my clinical mentor, Dr. Karen Playforth for her interest in diabetes and pregnancy, a topic near and dear to my heart. Sincere thanks to Elizabeth Coleman, Liz Combs, María Gómez, and Ena Johnson for the interdisciplinary team approach that helped me achieve this goal. I also want to recognize Dr. Mary Rayens and Dr. Amanda Wiggins for their statistical expertise and Andrea McCubbin for assistance with these data sets for which I am duly grateful. A special thank you to Kathy Collins at the College of Nursing for keeping me poised with her excellent communication skills and also for just cheering me on. To my diabetes educator cohort of friends and my DNP study group, I so appreciate your support. And finally, thank you to all of the faculty and students at the University of Kentucky College of Nursing that I have crossed paths with. To all, I believe each and every one of you wanted me to succeed, as I do you.

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### Practice Inquiry Project Overview

Working as a diabetes educator offers substantial opportunities to engage with an interdisciplinary team to develop, implement, and evaluate individualized diabetes self-management education (DSME) strategies to improve patient outcomes. The purpose of this practice inquiry project was to develop, implement, and evaluate the effectiveness of a DSME intervention in a population of Hispanic women at risk for gestational diabetes mellitus (GDM) within a CenteringPregnancy® (CP) model of care.

GDM is a clinical class of diabetes that occurs during pregnancy (Coustan, 2013). Diabetes self-management education (DSME) is essential in women with GDM to assist with promoting optimal blood glucose control and perinatal outcomes, i.e., avoiding complications such as fetal macrosomia. The first manuscript provides an overview of GDM in Hispanic women. In these women, an ethnic group at a higher risk for GDM, it is essential to address barriers to care and literacy levels by using culturally sensitive resources and education materials. This integrative review of the literature data clearly recognizes the increased risk for GDM in Hispanic women; risk for and impact of recurrent GDM in this population; and importance of timely diagnosis, treatment, and culturally sensitive strategies to promote the optimal perinatal outcomes. These data provided support for the development of our GDM DSME intervention.

The second manuscript focuses on cultural sensitivity and the appropriateness of evidence-based GDM DSME materials for Hispanic women whose primary language is Spanish and who speak very little to no English. Discussion relative to the use of an interpreter is detailed. Important points include 1) the importance of sensitivity to cultural values; 2) recommendations for the non-Spanish speaking health care professional when using an

interpreter for oral interpretation; and 3) examples of GDM DSME materials that are public-domain, peer-reviewed, and available electronically. In addition, the use of simulation, in which diabetes educators practice using an interpreter, may improve efficiency with the DSME process.

The third manuscript describes a sub-analysis that was conducted as part of the Diabetes/Obesity arm of the STRONG START Efforts to Maximize Perinatal Outcomes in Women at Risk (EMPOWR) protocol. The GDM DSME intervention within the existing CP model of care was accomplished. An overview of the implementation/evaluation a GDM DSME intervention for Hispanic women at high risk for GDM is provided. The approach was to allow women with GDM—a high risk pregnancy—to remain in their respective CP group while being educated, monitored, and treated for GDM until delivery. Overall positive outcomes were shown for the implementation of the GDM DSME intervention; however, ongoing data with a larger patient population is still needed.

Diabetes is a complex disease state that requires optimal strategies for education and treatment. The ongoing epidemic of obesity—which includes women of childbearing age—has placed more women at risk for gestational diabetes mellitus (GDM). The Hispanic population, which is the fastest growing ethnic group in the United States (US) is estimated to increase to almost one-third of the US population by 2050 (Passel, J. S., & Cohn, D., 2008). Women of Hispanic/Latino American ethnicity are at higher risk for GDM; and if she has a history of GDM, the chances of developing the metabolic disorder with a future pregnancy are 60 to 70% (Coustan, 2013). This practice inquiry project provided an innovative intervention which combined an evidence-based DSME program with an existing CP model of prenatal care for Hispanic women who are higher risk for GDM.

Gestational Diabetes Mellitus in Hispanic Women: An Integrative Review

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Abstract

Gestational Diabetes Mellitus (GDM) is the most common medical problem that occurs during pregnancy. Women of certain ethnic groups, e.g., Hispanic/Latino American, are at higher risk for GDM. An integrative review of 13 studies dated between 2005 and 2014 was conducted. Data that discussed GDM in underserved populations, particularly Hispanic women, and the impact of less than optimal blood glucose control on perinatal outcomes—specifically macrosomia—were examined and summarized to present an interpretation of these findings. Cooper’s (1982) scientific guidelines for conducting an integrative research review were utilized as the framework for discussion. Findings support the risk of adverse pregnancy outcomes, i.e., fetal macrosomia, are associated with uncontrolled blood glucose levels during pregnancy. From these data, it is determined that optimal care for women with GDM based on recognized, high-quality guidelines and evidence-based standards of care should be a priority. It is imperative that barriers to care and literacy levels be addressed in Hispanic women with GDM. Determining strategies for medical and obstetric care, treatment, and education that are culturally sensitive is essential to avoid less than optimal perinatal outcomes such as fetal macrosomia.

*Keywords:* gestational diabetes, gestational diabetes mellitus, GDM, Hispanic, Hispanic American, blood glucose, macrosomia, fetal macrosomia, perinatal, and (assessment) outcomes

Gestational Diabetes Mellitus in Hispanic Women: An Integrative Review

**Introduction**

Experts estimate that two to 10% of women in the United States (US) will develop Gestational Diabetes Mellitus (GDM) during pregnancy. GDM is a clinical class of diabetes defined as “carbohydrate intolerance of variable severity with onset or first recognition during pregnancy” (Coustan, 2013, p. 133). Women of certain ethnic groups, including Hispanic/Latino American, are at higher risk for GDM. Once a woman has a history of GDM, she has a 60 to 70% chance of developing the metabolic disorder with a subsequent pregnancy (Coustan, 2013). Additional data suggest that weight reduction prior to a future pregnancy—especially in obese women—may reduce the risk of GDM recurrence (American Diabetes Association [ADA], 2000) and that in some women, exercise may help reduce the risk for GDM (Dye, Knox, Artal, Aubrey, & Wojtowycz, 1997).

Maternal hyperglycemia is the major independent risk factor for fetal macrosomia (Coustan, 2013). The relationship between maternal hyperglycemia and influence on neonatal outcome has been reported by Stenhouse et al. (2006) who noted that for each increase in maternal glucose concentrations of approximately 18 mg/dL, neonates were approximately 48 grams heavier at birth. This increase in birth weight was associated with an increased risk of complications in the neonatal period (Stenhouse, Wright, Hattersley, & Millward, 2006).

In the past five years, there has been much attention by medical and obstetric providers relative to the criteria for diagnosis of GDM. In 2010, the release of data from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, which was conducted in more than 23,000 pregnant women around the world, measured three plasma glucose values by oral glucose tolerance test (OGTT)—fasting, 1-hour, and 2-hour. These values were associated with

targeted primary outcomes of fetal macrosomia, fetal hyperinsulinemia, primary cesarean section, and neonatal hypoglycemia in a linear, significant manner. Similar relationships were noted with secondary outcomes that included pre-eclampsia, shoulder dystocia, and injury at birth. As a result of these HAPO data, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) assembled an expert panel that issued new recommendations for the diagnostic criteria for GDM (Metzger, 2010). The IADSPG recommended that in women without a prior history of diabetes, a 75-gram OGTT be utilized at 24 to 28 weeks of pregnancy and GDM diagnosed if one of the glucose thresholds is exceeded. This recommendation is referred to as the “one-step” strategy. Subsequently, the IADSPG one-step method was adapted by the American Diabetes Association (ADA, 2011). At that time, the US health care community expressed growing concern that the prevalence of GDM could potentially increase by 15 to 25% based on the IADSPG recommendation (Coustan, 2013). In contrast, the American College of Obstetricians and Gynecologists (ACOG) continued to recommend prior established criteria referred to as the “two-step” strategy for diagnosis of GDM (American College of Obstetrics and Gynecology [ACOG], 2011). The two-step criteria require 1) an initial screening using 50-grams of glucose at 24 to 28 weeks gestation in women not previously diagnosed with diabetes; if results are above the recommended plasma glucose threshold, then 2) a 100-gram OGTT is performed. A positive 100-gram OGTT is a diagnosis of GDM. Because of the aforementioned growing concerns relative to IADSPG diagnostic criteria, the National Institutes of Health (NIH) assembled a 15-member panel of experts in 2013—represented by obstetrics and gynecology, maternal-fetal medicine, pediatrics, diabetes research, biostatistics, and other related fields. During a consensus development conference, the NIH panel recommended continuation of the two-step approach due to the lack of clinical trial data to support the benefits of using the

one-step strategy over the two-step method (VanDorsten et al., 2013). The NIH panel concluded that use of the two-step approach and the treatment of a higher threshold of maternal hyperglycemia reduced the rates of targeted fetal complications, including neonatal macrosomia. As a result of the NIH consensus statement, the ADA modified recommendations in their Standards of Medical Care—2014, to include both the IADPSG one-step strategy (Metzger, 2010) and the NIH Consensus panel (National Institutes of Health [NIH], 2013) two-step criteria. Furthermore, the ADA recognizes that “different diagnostic criteria will identify different magnitudes of maternal hyperglycemia and maternal/fetal risk” (ADA, 2014).

Regardless of the diagnostic criteria utilized, a timely diagnosis, prompt treatment, self-management strategies, and surveillance of maternal glucose are imperative to avoid maternal hyperglycemia and fetal macrosomia in women with GDM.

### **Scope of the Review**

An integrative review of published literature was undertaken to analyze data regarding the presence of GDM and fetal macrosomia in Hispanic women. Data that discussed GDM in underserved populations, particularly Hispanic women, and the impact of less than optimal blood glucose control on perinatal outcomes, specifically macrosomia, were summarized and examined to present an interpretation of these findings. This paper utilizes a framework for integrative review with five primary stages: problem formulation; data collection; evaluation of data points; data analysis and interpretation; and presentation of results (Cooper, 1982).

### **Problem Formulation**

The objective was to review studies relative to Hispanic women with GDM that focused on perinatal outcomes, specifically macrosomia. Material reviewed was printed in English, 10 of 13 publications were dated between 2011 and 2014 (two were dated 2007 and one, 2005). All

were published in peer-reviewed journals. These data address the objective and provide support for guidance with optimal medical/obstetric care, proper treatment to avoid fetal macrosomia, and for GDM self-management education for Hispanic women with GDM.

### **Data Collection**

A search of the available literature was undertaken using the following subscription-based electronic databases: PubMed Health/US National Library of Medicine; Access Medicine, which features medical titles from updated medical libraries; and The Cochrane Library, a collection of databases, six that contain various types of high-quality, independent evidence, and a seventh that provides information about The Cochrane Collaboration an international network of various specialty groups that focus on evidence-based care. Keywords used: gestational diabetes, gestational diabetes mellitus, GDM, Hispanic, Hispanic American, blood glucose, macrosomia, fetal macrosomia, perinatal, and (assessment) outcomes, were identified search terms from Medical Subject Headings (MeSH) and common clinical terms relative to the topics of interest.

### **Evaluation of Data Points**

Thirteen studies were selected that met the objective of the review and were extensively evaluated. Several study designs were included in the review, primarily systematic review, retrospective analyses, and observational studies. In a population of pregnant women, ethical considerations may limit the number of randomized controlled trials. The review of data included study type, purpose, sample, and key findings/implications (Table 1). Based on review, the strength (Levels A, B, or C) of the evidence appeared to consistently rank higher than the quality (Levels 1, 2, or 3) of these data (Ebell et al., 2004).



### **Data Analyses and Interpretation**

Strength of the studies included available data on both non-Hispanic and Hispanic women with GDM, as well as data regarding perinatal outcomes in both groups. Eight of the studies appeared to be Level A evidence which according to Ebell et al. (2004) is consistent, good quality patient-oriented evidence. Generally these studies exhibited quality in study design, were larger-scale in nature, specific to disease orientation, utilized reputable databases, and revealed consistent findings. Of these eight studies, three were Level 1 or good quality, patient-oriented evidence versus five which were Level 2 of limited quality, patient-oriented evidence. Four studies evaluated were Level B and Level 2, or limited quality patient-oriented evidence. Lastly, one study was determined to be Level C, Level 2 that is based on other evidence which in this case was expert opinion, usual practice, disease-oriented, limited quality patient-oriented evidence (Ebell et al., 2004).

### **Presentation of Results**

From these data, several points were revealed for consideration in medical/obstetrical care, proper treatment, and education relative to Hispanic women with GDM and the potential for fetal macrosomia:

- When the IADPSG criteria for diagnosis of GDM was utilized, the number of women classified with GDM “nearly doubled” (Bodmer-Roy, Morin, Cousineau, & Rey, 2012).
- GDM is potentially increasing among US women with various racial/ethnic backgrounds, including Hispanic women (Dabelea et al., 2005; Sridhar, Ferrara, Ehrlich, Brown, & Hedderson, 2013).
- Diagnostic criteria adapted to ethnicity are not likely necessary, particularly in women with “mild” GDM (Berggren et al., 2012).

- GDM recurrence was common and appeared to be consistently associated with race/ ethnicity (C. Kim, Berger, & Chamany, 2007).
- Measurement of fetal adiposity generally correlates with fetal hyperinsulinemia associated with maternal hyperglycemia (Dupak & Trujillo, 2007).
- Maternal obesity and GDM are strongly associated with LGA and obese offspring (Bowers et al., 2013; Sridhar et al., 2013; S. Y. Kim, Sharma, & Callaghan, 2012).
- When compared to women without GDM, a lack of difference in neonatal body fat may be a result of optimal glycemic control in women with GDM (Au, Raynes-Greenow, Turner, Carberry, & Jeffery, 2013).
- Intrauterine exposure to high maternal glucose appears to be associated with greater lean mass and adiposity later among the offspring prior to puberty (Chandler-Laney, Bush, Rouse, Mancuso, & Gower, 2011).
- GDM treatment is effective in reducing adverse pregnancy outcomes, specifically macrosomia (Falavigna et al., 2012; Sridhar et al., 2013).
- Perinatal outcomes differ by race/ethnicity in women with GDM (Nguyen et al., 2012; Sridhar et al., 2013).
- Multiple barriers hindering detection and treatment of GDM must be considered and addressed in low-to-middle income women (Nielsen, de Courten, & Kapur, 2012).

### **Implications for Clinical Practice**

These data clearly recognize the increased risk for GDM in Hispanic women and the importance of timely diagnosis and optimal treatment to promote the best possible perinatal outcomes. Data also identified the risk for and impact of recurrent GDM in this population. Nguyen et al. (2012) discussed a potential difference in perinatal outcomes relative to

race/ethnicity, specifically that inherent sociocultural difference may have an impact on blood glucose control; chronic comorbidities may be more common in high-risk (e.g., Hispanic) women; genetic variability in GDM risk exists; and the potential barriers with access to quality, routine, prenatal care. Of note, in a study that assessed personal adjustment to the diagnosis of GDM, data show that following GDM diagnosis women undergo a period of adjustment that is largely aided by her interest in optimal pregnancy outcomes which may facilitate receptiveness to interventions that improve glycemic control during GDM and for prevention of type 2 diabetes in the future (Carolan, 2013).

### **Implications for Future Research**

Additional research studies that address GDM may help shed additional light on culture-specific needs in Hispanic women. Because of the high-risk for recurrence for GDM in this population, studies to better understand the potential for reducing this risk is of importance. Because maternal obesity and GDM are strongly associated with LGA and obesity in the offspring further research in this area is warranted. Differences in culture that may affect glycemic control relative to the quality of prenatal care and studies that continue to focus on the newer IADPSG criteria and the application of these criteria in various populations of pregnant women are necessary. Ultimately, given the variation in outcomes among ethnic groups, future research should focus on whether there are differences in the benefits that might be derived from particular types of treatment and education venues in these different cultures.

### **Conclusion**

Among women with GDM, it is established that risk of adverse pregnancy outcomes, specifically fetal macrosomia, is associated with uncontrolled blood glucose levels during pregnancy and is mediated by physiological metabolic processes during pregnancy. It is

important that health care providers work towards promoting access to medical/obstetrical care, proper treatment, and education for women with GDM to assist with moderating the causes, e.g., genetic predisposition and ethnic background, such as in the case of Hispanic women. Also that the resources for GDM care, treatment, and education exist prior to these causes. Providing optimal care for women with GDM based on recognized, high-quality guidelines and evidence-based standards of care should be a priority. Finally, it is imperative that barriers to care and literacy levels be addressed in Hispanic women with GDM and determination of the resources, including type of education necessary, to avoid less than optimal perinatal outcomes such as fetal macrosomia.

Table 1: Integrative Review: Gestational Diabetes Mellitus in Hispanic Women

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Au, C. P., Raynes-Greenow, C. H., Turner, R. M., Carberry, A. E., &amp; Jeffery, H. E. (2013). Body composition is normal in term infants born to mothers with well-controlled gestational diabetes mellitus. <i>Diabetes Care</i>, 36(3), 562–564.</p>	<p>Cross-Sectional Comparator Study</p>	<p>Describe body composition of infants of mothers with GDM compared with infants of mothers with NGT.</p>	<p>Singleton, term infants with no congenital anomalies (37–42 weeks gestation) born between September and October 2010 (n=599) at a major public teaching hospital in Sydney, Australia. Babies admitted to the neonatal intensive care unit for &gt;2 days were excluded. GDM diagnosis was based on current ADIPS criteria.</p>	<ul style="list-style-type: none"> <li>• Sixty-seven (11%) of the infants were born to women with GDM.</li> <li>• Ninety percent of women with GDM were assessed to have optimal glycemic control.</li> <li>• Neonatal BF % did not differ by maternal GDM status as compared with NGT; neonatal BF% (mean±SD) was 7.9±4.5% in infants with GDM and 9.3±4.3% in infants with NGT (<math>p=0.151</math>).</li> <li>• The lack of difference in neonatal BF % may be due to optimal maternal glycemic control in women with GDM.</li> </ul>	<p>B; 2</p>

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Berggren, E. K., Mele, L., Landon, M. B., Spong, C. Y., Ramin, S. M., ... Tolosa, J. E. (2012). Perinatal outcomes in Hispanic and non-Hispanic white women with mild gestational diabetes. <i>Obstetrics &amp; Gynecology</i>, 120(5), 1099–1104.</p>	<p>Cohort Study (Secondary Analysis)</p>	<p>Compare perinatal outcomes between self-identified Hispanic (n=1048) and non-Hispanic white (n=487) women with mild GDM or glucose intolerance.</p>	<p>Perinatal outcomes by race/ethnicity were compared for women with glucose intolerance (abnormal 50-gram 1-hour screen; normal 100-g 3-hour OGTT [n=767]); women with mild GDM assigned to usual prenatal care (n=371) and women with mild GDM assigned to treatment (n=397). Outcomes included: composite adverse perinatal outcome, gestational age at delivery, birth weight, and hypertensive disorders of pregnancy.</p>	<ul style="list-style-type: none"> <li>Individual components of some neonatal outcomes were more frequent in Hispanic neonates however most perinatal outcomes were similar between Hispanic and non-Hispanic groups.</li> <li>Among women with glucose intolerance, Hispanic women had more frequent composite outcome (37% versus 27%), adjusted=OR 1.62 (95% CI, 1.10–2.37) with more neonatal elevated C-cord peptide (19% versus 13%), adjusted OR=1.79 (95% CI, 1.04–3.08), and neonatal hypoglycemia (21% versus 13%), adjusted OR=2.04 (95% CI, 1.18–3.53).</li> <li>Outcomes were similar by race and ethnicity in women with untreated mild GDM.</li> <li>Hispanic women with treated mild GDM, had a similar composite outcome to non-Hispanic white women (35% compared with 25%), adjusted OR=1.62 (95% CI, 0.92–2.86).</li> <li>Hispanic neonates had more frequent hyperinsulinemia (21% compared with 10%), adjusted OR=2.96 (95% CI, 1.33–6.60).</li> <li>Diagnostic criteria adapted to ethnicity may not be necessary for women with mild GDM.</li> </ul>	<p>A; 2</p>
<p>Bodmer-Roy, S., Morin, L., Cousineau, J., &amp; Rey, E. (2012). Pregnancy outcomes in women with and without gestational diabetes mellitus according to the International Association of the Diabetes and Pregnancy Study Groups criteria. <i>Obstetrics &amp; Gynecology</i>, 120(4), 746–752.</p>	<p>Retrospective Observational Study</p>	<p>Compare maternal and neonatal outcomes between 1) women classified as GDM according to the IADPSG criteria; 2) not considered GDM by the CDA; and 3) women without GDM according to both criteria.</p>	<p>Retrospective chart review to compare maternal and neonatal outcomes between women with GDM according to IADPSG criteria but not by the CDA criteria (group 1; n=186) and non-diabetic women according to both criteria (group 2; n=372).</p>	<ul style="list-style-type: none"> <li>Pregnancy outcomes are similar in women without GDM, classified as normoglycemic by the CDA but had GDM according to the IADPSG criteria.</li> <li>Using the IADPSG criteria the number of women classified as GDM (27.51%) was “nearly doubled” when the CDA criteria was used, suggesting that these women did not have worse pregnancy outcomes compared with those without GDM according to both criteria.</li> <li>More randomized studies with cost-effectiveness analyses are needed before implementation of the IADPSG criteria.</li> </ul>	<p>B; 2</p>

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Bowers, K., Laughon, S.K., Kiely, M., Brite, J., Chen, Z., &amp; Zhang, C. (2013). Gestational diabetes, pre-pregnancy obesity and pregnancy weight gain to excess fetal growth: Variations by race/ethnicity. (2013). <i>Diabetologia</i>, 56, 1213–1271.</p>	<p>Retrospective Cohort Study</p>	<p>Examine the joint effects of pre-pregnancy adiposity, pregnancy weight gain, and GDM relative to excess fetal growth and to identify susceptible ethnic populations.</p>	<p>Retrospective review using data from the CSL, to examine the joint and independent effects of GDM, maternal pre-pregnancy BMI and gestational weight gain on excessive fetal growth across four race/ethnicity groups in non-Hispanic white, non-Hispanic black, Hispanic and Asian/Pacific Islander.</p>	<ul style="list-style-type: none"> <li>• GDM, pre-pregnancy obesity and excessive pregnancy weight gain were jointly associated with elevated risk of giving birth to an LGA infant and the effects varied by race.</li> <li>• The association between GDM and LGA delivery varied by category of pre-pregnancy BMI (<math>p &lt; 0.0001</math> [for interaction]), being strongest among obese women and weakest among women in the normal BMI range; the OR=2.10 (95% CI, 1.87–2.37); OR=1.77 (95% CI, 1.52–2.06); and OR=1.57 (95% CI, 1.31–1.89) for obese, overweight and normal-weight women, respectively.</li> <li>• Data suggest public health efforts aimed at preventing LGA deliveries should consider variations in racial groups when devising effective strategies.</li> <li>• These data may be pivotal in developing targeted/efficient strategies for the battle with obesity.</li> </ul>	<p>B; 2</p>
<p>Chandler-Laney, P. C., Bush, N. C., Rouse, D. J., Mancuso, M. S., &amp; Gower, B. A. (2011). Maternal glucose concentration during pregnancy predicts fat and lean mass of prepubertal offspring. <i>Diabetes Care</i>, 34, 741–745.</p>	<p>Diagnostic Case-Control Study (Children); Retrospective Analysis (Maternal)</p>	<p>Examine the relationship between maternal glucose concentrations during pregnancy and the offspring body composition.</p>	<p>Children, 5 to 10 years and their biological mothers (n=27). Maternal glucose concentration at one hour after a 50-gram oral glucose load, used to screen for GDM at 24–28 weeks gestation in a retrospective medical record review.</p>	<ul style="list-style-type: none"> <li>• Maternal glucose concentration during pregnancy was positively associated with lean mass in children (<math>p &lt; 0.05</math>) and adiposity (fat mass adjusted for lean mass; <math>p &lt; 0.05</math>).</li> <li>• Intrauterine exposure to high maternal glucose appears to be positively associated with greater lean mass and adiposity among their children prior to puberty.</li> <li>• Program development to assist with optimizing maternal glucose control during pregnancy may potentially reduce the risk for obesity among their children.</li> </ul>	<p>B; 2</p>

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Dabelea, D., Snell-Bergeon, J. K., Harsfield, C. L., Bischoff, K. J., Hamman, R. F., &amp; McDuffie, R. S. (2005). Increasing prevalence of gestational diabetes mellitus (GDM) over time and by birth cohort. <i>Diabetes Care</i>, 28(3), 579.</p>	<p>Retrospective Cohort Study</p>	<p>Examine temporal trends in GDM among diverse ethnic groups.</p>	<p>KPCO singleton pregnancies occurring between 1994 and 2002 to examine trends in GDM prevalence among women with diverse ethnic backgrounds.</p>	<ul style="list-style-type: none"> <li>• GDM prevalence is increasing; data suggest that the high rate of diabetes in pregnancy initially described among Pima Indians may also be occurring among other multiethnic populations in the U.S.</li> <li>• The prevalence of GDM increased significantly from 1994–1996 to 2000–2002 among non-Hispanic whites (1.9 to 3.4%), Hispanics (2.8 to 5.1%), African Americans (2.5 to 4.6%), and Asians (6.3 to 8.6%). Each year from 1994 to 2002, the prevalence of GDM was significantly greater among minority women than among non-Hispanic white women.</li> <li>• As many as 50% of these women developing type 2 diabetes in 5 years post-GDM.</li> </ul>	<p>A; 2</p>
<p>Dupak, J. L., &amp; Trujillo, A. L. (2007). Ultrasound surveillance in pregnancy complicated by diabetes. <i>Diabetes Spectrum</i>, 20(2), 89–93.</p>	<p>Clinical Expertise (obstetrician usual practice/literature review)</p>	<p>Evaluate the clinical relevance of ultrasonography during pregnancy complicated by diabetes for fetal surveillance, assessment of diabetes impact, guidance of diabetes treatment, and obstetric management.</p>	<p>Discussion of ultrasonography as a noninvasive, readily available method to assess and monitor the fetus, use as a guide for instituting early therapeutic management for pregnancies complicated by diabetes.</p>	<ul style="list-style-type: none"> <li>• Surveillance by ultrasound can be useful to supplement clinical evaluation of fetuses in pregnancies complicated by diabetes.</li> <li>• Measurement of the insulin-sensitive fetal fat layer and fetal abdominal circumference may better reflect the impact of diabetes on the fetus.</li> </ul>	<p>C; 3</p>



Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Falavigna, M., Schmidt, M. I., Trujillo, J., Alves, L. F., Wendland, E. R., Torloni, M. R., ...Duncan, B. B. (2012). Effectiveness of gestational diabetes treatment: A systematic review with quality of evidence assessment. <i>Diabetes Research and Clinical Practice</i>, 98(3), 396–405.</p>	<p>Systematic Review</p>	<p>Evaluate the effectiveness of GDM treatment compared to usual antenatal care in the prevention of adverse pregnancy outcomes.</p>	<p>Fourteen electronic databases and reference lists of relevant literature were searched for controlled clinical trials comparing GDM treatment to usual antenatal care. Seven trials (n=3157 women) were included.</p>	<ul style="list-style-type: none"> <li>• GDM reduces macrosomia, RR=0.47 (95% CI, 0.34–0.65); NNT=11.4 and large for gestational age birth, RR=0.57 (95% CI, 0.47–0.71); NNT=12.2.</li> <li>• GDM treatment reduces preeclampsia, RR=0.61 (95% CI, 0.46–0.81); NNT=21.0 and hypertensive disorders in pregnancy, RR=0.64 (95% CI, 0.51–0.81); NNT=18.1.</li> <li>• GDM treatment reduces shoulder dystocia, RR=0.41 (95% CI, 0.22–0.76); NNT=48.8.</li> <li>• No statistically significant reduction was seen for CS. No increase in SGA or preterm birth was found.</li> <li>• Treatment of GDM is effective in reducing macrosomia (high quality evidence), preeclampsia (moderate quality evidence) and shoulder dystocia (low quality evidence).</li> </ul>	<p>A; 1</p>
<p>Kim, C., Berger, D. K., &amp; Chamany, S. (2007). Recurrence of gestational diabetes mellitus. <i>Diabetes Care</i>, 30(5), 1314–1319.</p>	<p>Systematic Review</p>	<p>Examine rates and factors associated with recurrence of GDM among women with a history of GDM.</p>	<p>Thirteen studies – entry criteria included specified criteria for the diagnosis of GDM and rates of recurrence in subsequent pregnancies. Information also included, but was not limited to, population characteristics (e.g., race/ethnicity if reported), diagnostic criteria for GDM, average length of time between pregnancies if available, and recurrence rates of GDM in future pregnancies.</p>	<ul style="list-style-type: none"> <li>• Recurrence of GDM was common and may vary most significantly by non-Hispanic whites versus minority race/ethnicity.</li> <li>• Other risk factors, such as age, parity, BMI, oral glucose tolerance test levels, and insulin use were inconsistent in predicting recurrent GDM.</li> <li>• Interventions to reduce the risk of future GDM are important in the treatment of women with a history of GDM including the high-risk ethnic groups.</li> </ul>	<p>A; 1</p>

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
<p>Kim, S. Y., Sharma, A. J., &amp; Callaghan, W. M. (2012). Gestational diabetes and childhood obesity: what is the link? <i>Current Opinion in Obstetrics and Gynecology</i>, 24(6), 376–381.</p>	<p>Systematic Review</p>	<p>Examine the role of prepregnancy obesity in the relationship between GDM and childhood obesity.</p>	<p>Seven studies – all differentiate between preexisting diabetes mellitus and gestational diabetes mellitus; six studies examine the role of maternal obesity; one study does not adjust for maternal obesity.</p>	<ul style="list-style-type: none"> <li>• A positive association between maternal GDM and offspring overweight/obesity appears to be attenuated significantly after adjustment for prepregnancy BMI.</li> <li>• Maternal obesity and GDM are strongly associated with offspring obesity; attention to prepregnancy obesity should be further explored.</li> <li>• The broader group of maternal obesity subjects, which often included women with GDM, may have a greater public health implication for overweight and obese children.</li> </ul>	<p>A; 1</p>
<p>Nguyen, B. T., Cheng, Y. W., Snowden, J. M., Esakoff, T. F., Frias, A. E., &amp; Caughey, A. B. (2012). The effect of race/ethnicity on adverse perinatal outcomes among patients with gestational diabetes mellitus. <i>American Journal of Obstetrics &amp; Gynecology</i>, 207(4), 322 e321–326.</p>	<p>Retrospective Cohort Study</p>	<p>Determine racial/ethnic differences in perinatal outcomes among women with GDM.</p>	<p>Singleton births among women with gestational diabetes mellitus in California from 2006 (n=32,193), using Vital Statistics Birth and Death Certificate and Patient Discharge Data. Data were divided by race/ethnicity. Multivariable logistic regression was used to analyze associations between race/ethnicity and adverse outcomes that were controlled for potential confounders.</p>	<ul style="list-style-type: none"> <li>• In Women with GDM, perinatal outcomes differ by race/ethnicity.</li> <li>• Inherent sociocultural differences; chronic comorbidities; genetic variability in GDM risk; and access to quality, routine prenatal care may impact blood glucose control.</li> <li>• Compared with women in other races, Hispanic women had higher odds of LGA, adjusted OR=0.84 (95% CI, 0.74–0.94) and macrosomia, adjusted OR=0.90 (95% CI, 0.83–0.97).</li> <li>• Clinically relevant implications include: <ul style="list-style-type: none"> <li>○ While GDM is more prevalent among Asian and Hispanic women, it appears that black women had poorer perinatal outcomes.</li> <li>○ Efforts should be directed toward preconception counseling, evaluation for comorbidities, early OGTTs and monitoring of blood pressure in high risk groups.</li> <li>○ Socio-cultural differences that may influence blood glucose control and prenatal care may embody areas for future research.</li> <li>○ It may be appropriate to focus future research on racial/ethnic variations in benefits derived from various types of GDM treatment.</li> </ul> </li> </ul>	<p>A; 2</p>

Reference	Study Design	Purpose	Sample	Key Findings	Level of Evidence <sup>1</sup>
Nielsen, K. K., de Courten, M., & Kapur, A. (2012). Health system and societal barriers for gestational diabetes mellitus (GDM) services - lessons from World Diabetes Foundation supported GDM projects. <i>BMC International Health and Human Rights</i> , 12, 3–10.	Qualitative Study	Investigate societal and health system barriers that hinder detection and treatment of GDM in LMIC.	Eleven project partners from 8 LMIC qualified to participate; ten partners participated in the study questionnaire and interview.	<ul style="list-style-type: none"> <li>Multiple barriers must be considered and addressed in order to provide effective GDM services to improve maternal health in LMIC.</li> <li>Identification of barriers in the LMIC is important to the success of the GDM care, education, and training to hopefully improve maternal health in LMIC.</li> </ul>	A; 2
Sridhar, S. B., Ferrara, A., Ehrlich, S. F., Brown, S. D., & Hedderson, M. M. (2013). Risk of large-for-gestational-age newborns in women with gestational diabetes by race and ethnicity and body mass index categories. <i>Obstetrics &amp; Gynecology</i> , 121(6), 1255–1262.	Retrospective Cohort Study	Compare the prevalence of LGA newborns across categories of BMI in five ethnic groups.	Women with GDM who delivered a live newborn at KPNC between 1995–2006 (n=7468). Racial/ethnic groups were non-Hispanic white, African American, Hispanic, Asian, and Filipina. BMI was classified using WHO international guidelines. Logistic regression was used to determine LGA by BMI and race/ethnicity.	<ul style="list-style-type: none"> <li>Prevalence of LGA newborns was highest in African American women (25.1%); intermediate among Hispanic (17.3%), non-Hispanic white (16.4%), and Filipina (15.3%) women; and lowest in Asians (13.9%).</li> <li>The highest risk of LGA was in women with Class II obesity in most racial/ethnic groups.</li> </ul>	A; 2
<p>GDM=Gestational Diabetes Mellitus; NGT=Normal Glucose Tolerance; ADIPS=Australasian Diabetes In Pregnancy Society; BF=Body Fat; SD=Standard Deviation; OGTT=Oral Glucose Tolerance Test; OR=Odds Ratio; CI=Confidence Interval; CDA=Canadian Diabetes Association; IADPSG=The International Association of the Diabetes and Pregnancy Study Groups; BMI=Body Mass Index; LGA=Large-for-Gestational-Age; CSL=Consortium on Safe Labor; KPNC=Kaiser Permanente of Colorado; RR=Risk Reduction; CS=Caesarean Section; SGA=Small for Gestational Age; NNT=Number Needed to Treat; LMIC= Low- and Middle-Income Countries; KPNC=Kaiser Permanente of Northern California; WHO=World Health Organization.</p> <p><sup>1</sup>Ebell, M. H., et al. (2004). Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. <i>American Family Physician</i>, 69(3), 548–556.</p>					

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Educating Spanish Speaking Women with Gestational Diabetes Mellitus

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Abstract

Experts predict that the Hispanic population will increase from 14% in 2005 to 29% in 2050. Diabetes educators must be prepared for exponential growth in a population that is at higher risk for diabetes. Women of Hispanic/Latino American ethnicity are at higher risk for GDM and subsequently Type 2 diabetes. Diabetes self-management education (DSME) is essential in women with GDM to assist with promoting optimal perinatal outcomes. DSME in small group settings with peers of the same culture may be beneficial. In high risk ethnic groups, it is imperative that barriers to care and literacy levels are addressed (Nielsen, de Courten, & Kapur, 2012) by using culturally sensitive resources and education materials. By doing so, we can hope to influence motivation in a positive way to promote optimal outcomes for pregnancy in our Hispanic patients with GDM.

*Keywords:* gestational diabetes, GDM, education, training, Hispanic, Latino, macrosomia

Educating Spanish Speaking Women with Gestational Diabetes Mellitus

**Introduction**

Experts from the Pew Research Center predict that the Hispanic population—the fastest growing ethnic group in the United States (US)—will increase from 14% in 2005 to 29% in 2050 (Passel, J. S., & Cohn, D., 2008). Diabetes educators must be prepared for exponential growth in a population that is at higher risk for diabetes. Women of Hispanic/Latino American ethnicity are at higher risk for Gestational Diabetes Mellitus (GDM), a clinical class of diabetes defined as “carbohydrate intolerance of variable severity with onset or first recognition during pregnancy” (Coustan, 2013, p. 133). In addition, a woman with a history of GDM has a 60 to 70% chance of developing the metabolic disorder with a future pregnancy (Coustan, 2013). Diabetes self-management education (DSME) is essential in women with GDM to assist with promoting optimal perinatal outcomes and avoiding complications such as fetal macrosomia. In high risk ethnic groups, it is imperative that barriers to care and literacy levels are addressed (Nielsen, de Courten, & Kapur, 2012) by using culturally sensitive resources and education materials.

**Gestational Diabetes Mellitus Self-Management Education**

CenteringPregnancy<sup>®</sup> (CP) is an innovative, multifaceted model that provides prenatal care in a small group setting. The framework integrates three key components of prenatal care: health assessment, education, and support services. A CP curriculum with standard topics is utilized. A goal of CP is to develop a support network with fellow group members and create a sense of empowerment to make healthy behavior choices (Centering<sup>®</sup> Healthcare Institute [CHI], 2015).

Group-based methods of DSME have been shown effective in improving glycemic control (Deakin, T. A., McShane, C. E., Cade, J. E., & Williams, R., 2005). DSME for patients

with GDM should be evidence-based using guidelines such as the American Association of Diabetes Educator's (AADE) Diabetes Education Accreditation Program (2015) and/or the American Diabetes Association's (ADA) National Standards for Diabetes Education and Support (2013). Both of these organizations' accreditation programs are recognized by the majority of third-party payers for DSME billing.

Recognizing that Hispanic women are at higher risk for GDM, we sought to implement a AADE7-friendly curriculum for DSME as an adjunct to our CP model for Hispanic women that speak little to no English (Table 1). Diabetes educators, a registered nurse (RN) and registered dietitian (RD), were non-Spanish speaking. The program objectives included the introduction of the availability of DSME by a diabetes educator to all patients entering the CP program at the first session. This initial interaction utilizes the CP patient notebook content relative to the risk factors for GDM as well as general nutrition and exercise during pregnancy. Emphasis is placed on the progressive insulin resistance that begins around the 16<sup>th</sup> week of pregnancy and the timing for GDM screening at a later date. If diagnosed with GDM, the woman continues to meet with the broader CP group with DSME provided by the diabetes educators before or after the general CP session. The RD provides medical nutrition therapy, which is recognized as the cornerstone of treatment for diabetes management, including women with GDM (Morris & Wylie-Rosett, 2010; Reader, 2007). Composition of the meal plan encouraged complex carbohydrates, monounsaturated and polyunsaturated fats, and foods high in fiber in an effort to minimize postprandial glucose excursions. Utilizing this dietary prescription, normoglycemia is maintained in 75 to 80% of women with GDM (Coustan, 2013). Additionally, a source of protein was recommended with each meal and snack. Promotion of exercise and physical activity is based on the American College of Obstetricians and Gynecologists (2011) guidelines

for safe exercise during pregnancy and stressed as an integral factor for optimal glycemic control. Self-monitoring of blood glucose (SMBG) training using a blood glucose monitor with the Spanish-language feature is provided. Surveillance of SMBG is captured via the patient's recorded values as well as by data download. The diabetes educator reviews results at each visit with the patient's obstetric health care provider. Other AADE7 self-care behaviors for women with GDM are incorporated within the CP model as the sessions progress (Table 1).

### **Cultural Sensitivity**

The importance of sensitivity to the cultural values of “simpatia (kindness), “personalismo (relationship), respeto (respect), and modestia (modesty)” in the Latino population is described by Juckett (2013, p.48). He suggests the following key clinical recommendations that may be adapted when educating Hispanic women with GDM:

- Culturally competent care may improve treatment adherence/health outcomes.
- Assess alternative supplements/treatments commonly used by the Latino community by asking the patient and determine appropriateness and if possible, incorporate into obstetric care (if not, explain to the patient).
- Utilize the “teach back” technique, asking the patient to repeat instructions or demonstrate learning, to assure she understands her education and training.
- Encourage patient participation which may motivate her to become involved in her care.

Sensitivity to Hispanic culture allows appreciation for the woman's diversity and cultural values. Allowing extra time and utilizing appropriate resources is essential to assure she gets the DSME information needed.

### Use of an Interpreter

According to the US Census Bureau report “Language Use in the United States: 2011” (Ryan, 2013), approximately 44% of Spanish Americans self-reported their English speaking ability as “less than very well” (Figure 1). In 2014, approximately 6% of AADE members reported Spanish as a primary or secondary language. Thus, in many cases, an interpreter will be required for Spanish-speaking patients for DSME. Educating non-English speaking patients in a group setting may maximize the use of an interpreter. An interpreter translates *orally* from one language to another. The interpreter should be proficient in both languages (e.g., English and Spanish) (Gonzalez, A., Rotberg, B., & Sanchez, S., 2012). Diabetes educators should work with certified interpreters to assure that diabetes education is delivered as intended. Most health care systems have policies in place that are specific to the use of an interpreter. Public academic institutions generally have access to resources within their respective state cabinet to certify interpreters. The National Board of Certification for Medical Interpreters (2015) offers a standardized certification process for credentialing medical interpreters that is available in six languages, including Spanish. Regardless of the certification process, it is important that such parameters are in place. Additionally, diabetes educators should consider the following recommendations when working with an interpreter:

- Clarify with the interpreter the objectives for the discussion prior to the education session.
- The interpreter is not a diabetes educator and should only interpret your words.
- Use quality DSME materials, avoiding medical jargon and slang.
- Focus on the patient as opposed to the interpreter.
- Direct conversation to and maintain eye contact with the patient (as first person).
- Use short, meaningful sentences, pausing for interpretation.

- Only include discussion that you mean to be interpreted.
- Avoid interrupting the interpreter.
- Wait for patient feedback to be interpreted and respond accordingly.
- Cue the interpreter when DSME is completed.

It is not appropriate for a patient's family member or friend to interpret as health information may be misunderstood and inappropriately conveyed to the patient (Juckett, 2013). Even if diabetes educators are familiar with the Spanish language, it is always fundamental to utilize a certified interpreter when working with Spanish speaking patients. If a co-worker happens to be fluent in Spanish but not certified as an interpreter, they should not be utilized (Gonzalez et al., 2012; Hesler, 2015). A simulation in which you and your coworker(s) practice using an interpreter may be helpful. Using simulation prior to seeing the patients, we found our efficiency with the DSME process was improved. Diabetes Educators should be proactive in improving skills in the provision of cross-cultural health care which may include training in cultural and linguistic competencies.

### **Patient-Friendly Education Materials**

Peer reviewed Spanish teaching tools are valuable resources for your DSME curriculum. Evidence-based, culturally sensitive DSME materials developed by experts that complement AADE and/or ADA accreditation program guidelines are ideal (Table 2). If translation of English to Spanish *written* materials is needed, a translator that is certified in written interpretation should be utilized. Individuals may be certified in one form (oral or written) of interpretation or both (National Board of Certification for Medical Interpreters, 2015).

### **Conclusion**

Diabetes educators should individualize DSME with sensitivity to the Hispanic culture and values as well as remain conscious of the morals, standards, and principles that may affect overall diabetes care. DSME in small group settings with peers of the same culture may be beneficial. Quality teaching tools are essential to support DSME. Diabetes educators should be familiar with the resources for oral interpretation and written translation in the health care setting. By doing so, it is more likely to influence motivation in a positive way to promote optimal outcomes for pregnancy in our Hispanic patients with GDM.

Table 1. AADE7 Topic Content as an Adjunct to the CenteringPregnancy® Model: Patients at Risk for GDM and With GDM

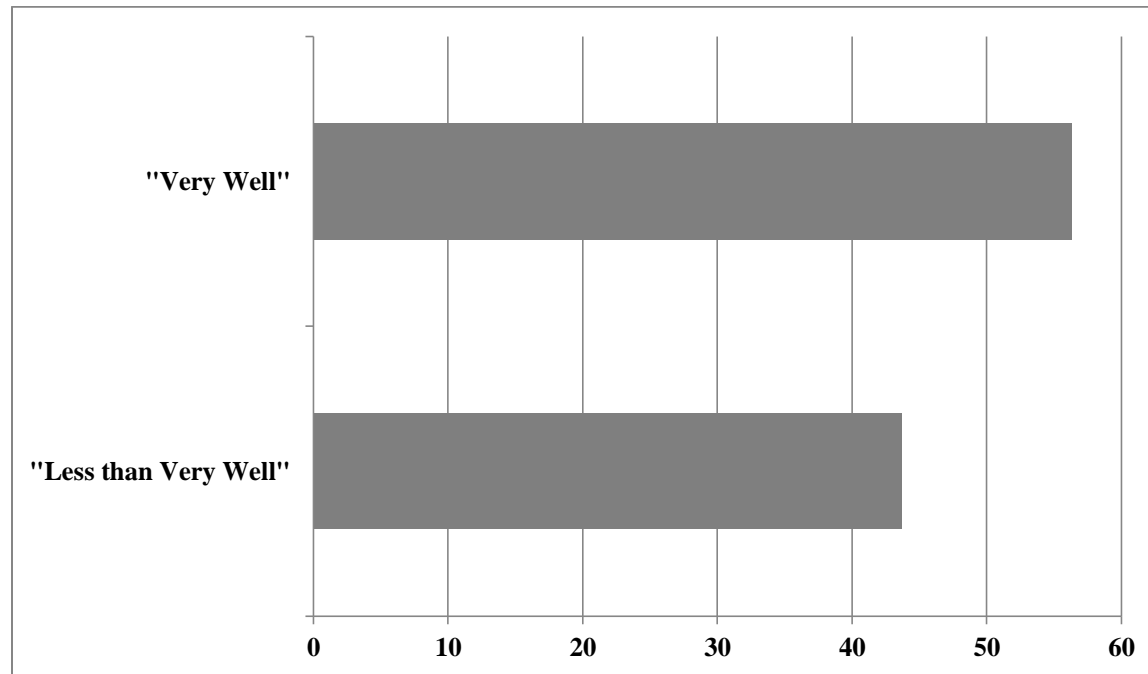
Session	Centering Topics <sup>1</sup>	At Risk for GDM/GDM Topics <sup>2</sup>
1 (16 weeks)	Intro to Centering Nutrition Weight	<i>Reducing Risks</i> (Risk factors for GDM) <i>Healthy Eating</i> (Food diary; nutrition facts label; fast food/healthier choices) <i>Being Active</i> (Physical activity during pregnancy)
2 (20 weeks)	Body Changes Common Discomforts HANDS	
3 (24 weeks)	Relaxation Dental Breastfeeding	Screening for GDM [Two-step Method: 50-gram glucola]
4 (28 weeks)	Contraception Domestic Violence Preterm Labor	<i>Healthy Eating</i> (GDM meal plan – MNT) <i>Being Active</i> (Role in blood glucose control) <i>Monitoring</i> (SMBG)
5 (30 weeks)	Birth Center Tour	<i>Monitoring/Problem Solving</i> (Upload/review of SMBG records)
6 (32 weeks)	Labor and Delivery When to go to Hospital Pain Relief Options Preeclampsia	<i>Reducing Risks</i> (Labor and delivery/GDM) <i>Monitoring/Problem Solving</i> (Upload/review of SMBG records)
7 (34 weeks)	Infant Care Car Seat/Crib Safety	<i>Monitoring/Problem Solving</i> (U/S/fetal weight; upload/review of SMBG records)
8 (36 weeks)	Postpartum Emotional Adjustments Postpartum Care Breastfeeding	<i>Healthy Coping</i> (Breastfeeding after delivery/GDM) <i>Reducing Risks</i> (GDM with subsequent pregnancies; Type 2 risk) <i>Monitoring/Problem Solving</i> (Upload/review of SMBG records)
9 (38 weeks)	Newborn Safety Preparing for Labor Stages of Labor Video	<i>Monitoring/Problem Solving</i> (Upload/review of SMBG records)
10 (40 weeks)		<i>Reducing Risks</i> (GDM with future pregnancies; Type 2 risk) <i>Monitoring</i> (Postpartum Screening; Upload/review of SMBG records) <i>Taking Medication/Reducing Risks</i> <sup>3</sup> (Prescribed drug; hypoglycemia)

GDM=gestational diabetes mellitus; MNT=medical nutrition therapy; HANDS=Health Access Nurturing Development Services; RD=registered dietitian; RN=registered nurse; SMBG=self-monitoring of blood glucose; U/S=ultrasonography

<sup>1</sup>All patients enter the program prior to 20-weeks gestation; <sup>2</sup>*Italicized* topics are AADE7™ self-care behaviors; <sup>3</sup>*Taking Medications/Reducing Risks* may be used at any time point if medication therapy is a necessary part of treatment.



Figure 1. Percent English-Speaking Ability reported within the United States Spanish\* Population in 2011



\*Spanish includes Spanish, Spanish Creole, and Ladino;

Source: U.S. Census Bureau (2011). Language use in the United States: 2011. Retrieved from:

<http://www.census.gov/prod/2013pubs/acs-22.pdf>

Table 2. Select Teaching Tools\* for Spanish-Speaking Women with Gestational Diabetes Mellitus

Content	Spanish	English
“Gestational Diabetes – What you need to know” <sup>1</sup>	<a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/#Spanish">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/#Spanish</a>	<a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a>
“What I need to know about Gestational Diabetes” <sup>1</sup>	<a href="http://www.diabetes.niddk.nih.gov/spanish/pubs/gestational_ez/index.aspx">http://www.diabetes.niddk.nih.gov/spanish/pubs/gestational_ez/index.aspx</a>	<a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>
“Learn how to read food labels” <sup>1</sup>	<a href="http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf">http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf</a>	<a href="http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf">http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf</a>
“My plate for Gestational Diabetes” <sup>2</sup>	<a href="http://www.cdph.ca.gov/programs/NutritionandPhysicalActivity/Documents/MO-NUPA-MyPlateforGestationalDiabetes-Spanish.pdf">http://www.cdph.ca.gov/programs/NutritionandPhysicalActivity/Documents/MO-NUPA-MyPlateforGestationalDiabetes-Spanish.pdf</a>	<a href="http://www.cdph.ca.gov/programs/NutritionandPhysicalActivity/Documents/MO-NUPA-MyPlateforGestationalDiabetes.pdf">http://www.cdph.ca.gov/programs/NutritionandPhysicalActivity/Documents/MO-NUPA-MyPlateforGestationalDiabetes.pdf</a>
“Exercise during pregnancy” <sup>3</sup>	<a href="http://www.acog.org/Patients/Search-Patient-Education-Pamphlets-Spanish/Files/El-ejercicio-durante-el-embarazo">http://www.acog.org/Patients/Search-Patient-Education-Pamphlets-Spanish/Files/El-ejercicio-durante-el-embarazo</a>	<a href="http://www.acog.org/Patients/FAQs/Exercise-During-Pregnancy">http://www.acog.org/Patients/FAQs/Exercise-During-Pregnancy</a>
“Daily records” <sup>2</sup>	<a href="https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf">https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf</a>	<a href="https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf">https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf</a>
“What I need to know about diabetes medicines” <sup>1</sup>	<a href="http://www.diabetes.niddk.nih.gov/spanish/pubs/medicines_ez/index.aspx">http://www.diabetes.niddk.nih.gov/spanish/pubs/medicines_ez/index.aspx</a>	<a href="http://www.diabetes.niddk.nih.gov/spanish/pubs/medicines_ez/index.aspx">http://www.diabetes.niddk.nih.gov/spanish/pubs/medicines_ez/index.aspx</a>
“Take action now to prevent diabetes later” <sup>1</sup>	<a href="http://ndep.nih.gov/am-i-at-risk/gdm/take-action-es.aspx">http://ndep.nih.gov/am-i-at-risk/gdm/take-action-es.aspx</a>	<a href="http://ndep.nih.gov/am-i-at-risk/gdm/take-action.aspx">http://ndep.nih.gov/am-i-at-risk/gdm/take-action.aspx</a>

\*All materials accessed March 2015;

<sup>1</sup>National Diabetes Education Program, National Institutes of Health; <sup>2</sup>California Diabetes and Pregnancy Program (CDAPP) Sweet Success; <sup>3</sup>American College of Obstetricians and Gynecologists.

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Evaluation of a Gestational Diabetes Mellitus Education Intervention

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Abstract

**Aim:** To develop, implement, and evaluate a diabetes self-management education (DSME) intervention for patients with Gestational Diabetes Mellitus (GDM) within the existing CenteringPregnancy<sup>®</sup> (CP) model of care. The approach was to allow women with GDM—considered a high risk pregnancy—to remain in their respective CP group while being educated, monitored, and treated for GDM until delivery.

**Intervention:** Development and implementation of a GDM DSME program utilizing an interdisciplinary team that included a registered dietitian (RD) and a registered nurse, certified diabetes educator (RN, CDE).

**Design:** Descriptive, correlational study design

**Setting:** A university-affiliated high risk prenatal clinic, directed by Maternal-Fetal Medicine

**Participants:** Hispanic women enrolled in the Diabetes/Obesity arm of the Efforts to Maximize Perinatal Outcomes in Women at Risk (EMPOWR) CP program.

**Main Outcome Measures:** Neonatal birth weights, mode of delivery, and weeks gestation at delivery were compared for women with GDM and women without GDM within the intervention group and the control group, respectively. Data were also analyzed between groups (intervention group versus control group). Overall patient satisfaction rates were evaluated in the DSME intervention group.

**Results:** The small sample size limited the interpretation of clinical findings into practice. Between groups, there was no significant difference with respect to demographic and clinical variables at baseline or at delivery. Overall, women were satisfied with the CP experience and would recommend this method of prenatal care to other women.

**Conclusion:** Development and implementation of a DSME curriculum aligned with the CP model was attained. Due to the small number of patients diagnosed with GDM in the education intervention group, more data are needed to evaluate the effect of DSME within this setting on outcomes, such as neonatal birth weight.

Evaluation of a Gestational Diabetes Mellitus Education Intervention

**Introduction**

The risk of adverse pregnancy outcomes among women with Gestational Diabetes Mellitus (GDM) is caused by uncontrolled blood glucose levels during pregnancy. Experts estimate that two to 10% of women in the United States (US) will develop GDM. GDM, a clinical class of diabetes that is diagnosed during pregnancy (Centers for Disease Control [CDC], 2015) is one of the most common medical complications of pregnancy. Women who have a history of GDM have a 60 to 70% chance of developing the metabolic disorder with a subsequent pregnancy (Coustan, 2013). Women of certain ethnic groups (e.g., Hispanic/Latino American) are at higher risk for recurrent GDM as well as Type 2 diabetes in the future (Agency for Healthcare Research and Quality [AHRQ], 2012).

In women with GDM, progressive insulin resistance occurs due to increased placental hormone secretion and weight gain exceeding the capacity of the beta-cell to respond resulting in maternal hyperglycemia. GDM typically occurs around the 24<sup>th</sup> to 28<sup>th</sup> week of pregnancy (American College of Obstetricians and Gynecologists [ACOG], 2013) with maternal hyperglycemia the major independent risk factor for fetal macrosomia (Coustan, 2013). Stenhouse et al. (2006) reported the relationship between maternal hyperglycemia and influence on neonatal outcome. The authors noted that for each increase in maternal glucose concentration of approximately 18 mg/dL, neonates were approximately 48 grams heavier at birth. This increase in birth weight was associated with an increased risk of complications in the neonatal period. A systematic review by Horvath et al. (2010) reported that women who received specific treatment for GDM (i.e., improvement in blood glucose control and specialized obstetric care) had fewer macrosomic babies or babies with a birthweight at or above the 90<sup>th</sup> percentile.



Furthermore, Kim et al. (2012) described a positive association between maternal GDM and offspring overweight/obesity.

Among women with GDM, it is well established that risk of adverse pregnancy outcomes—specifically fetal macrosomia—is associated with less than optimal blood glucose control during pregnancy. It is important that health care providers promote access to medical/obstetrical care, proper treatment, and GDM diabetes self-management education (DSME). Optimal DSME for women with GDM based on recognized, evidence-based education guidelines (American Association of Diabetes Educators [AADE], 2015) and standards of care (Haas et al., 2013) should be a priority. Barriers to care and literacy levels must be addressed in Hispanic women with GDM (Nielsen, de Courten, & Kapur, 2012). Culturally sensitive resources and education materials should be utilized to assist with promoting optimal perinatal outcomes and avoiding complications (e.g. fetal macrosomia).

Our aim was to develop, implement, and evaluate a GDM education intervention, i.e. DSME intervention, within the existing CP model which is prenatal care in a small group setting using three components: health assessment, education, and support services (Massey, Rising, & Ickovics, 2006). An increasing number of Hispanic women who are at high risk for GDM are referred to our CP program. In fact, Hispanic women make-up almost 40% of the patients enrolled in this program at the university-affiliated high-risk prenatal clinic, directed by Maternal-Fetal Medicine (J. Barnett, personal communication, February 18, 2014).

### **Intervention Framework**

The W.K. Kellogg Foundation Logic Model Guide (2004) is a tool to use in program planning, implementation, and dissemination of program results and defines a logic model as “a systematic and visual way to present and share your understanding of the relationships among

the resources to operate your program, the activities you plan, and the changes or results you hope to achieve” (p. 1). According to this guide, there are three approaches to logic models—the Theory Approach; the Outcomes Approach, and the Activities Approach. In the initial development of a program intervention, all three of these approaches add value. The program development process benefits from 1) comprehensive “big picture” planning as in the theory approach; 2) the identification of outcomes that are beneficial to the health of the particular target population or the outcomes approach; as well as 3) determination of elements that are needed for proper implementation of a program or intervention, i.e., the activities approach.

### **Intervention**

Of the three approaches previously mentioned, the optimal approach for development of a GDM DSME intervention is the outcomes model. Outcomes are generally measurable clinical entities that can provide information that reflects a particular population and potentially the benefit(s) of the program. A gap analysis identified the need for ongoing, cost-effective, culturally sensitive materials for GDM DSME that aligned with the CP program topics. The primary team of stakeholders (NP, CNM, RN-interpreter, and RD) evaluated the DSME materials for use in the CP setting. Primary materials identified for use by the RN, CDE were from National Diabetes Information Clearinghouse (NDIC) (2014) and are public domain, expert-reviewed, available in both English and Spanish, and cost-effective (free). Materials from the NDIC were printed to match the topic of discussion. All patients in the group received “at risk for” GDM information. See Appendix A for the full DSME curriculum as aligned with the CP topics. In addition, resources for downloading patient blood glucose monitors were needed. The RN, CDE worked with the university information technology department to add software programs for two Spanish-friendly blood glucose monitors. Therefore, blood glucose monitors were downloaded

with each CP visit. For a detailed description of program/intervention implementation, program/intervention results, evaluation planning, and establishing indicators, refer to Appendix B (Table B1; Figure B2; Table B3; and Table B4, respectively).

### **EMPOWR Study Analysis**

This study was approved by the University of Kentucky Institutional Review Board (UK IRB). The analysis employed a descriptive, correlational study design. All data were de-identified prior to analysis/reporting and maintained on a password-protected computer in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Data were collected and stored based on current UK IRB guidelines for data-mining.

The EMPOWR program offers pregnant women an evidence-based model of group prenatal care developed by Centering<sup>®</sup> Healthcare Institute, a nonprofit organization. Women who participate in CP group prenatal care have been reported to have improved birth outcomes when compared to women who receive traditional prenatal care (Ickovics et al., 2007; Grady & Bloom, 2004). The DSME intervention was developed and implemented to educate Hispanic women with GDM to obtain/ attain optimal glycemic control during pregnancy and prevent macrosomia. Three questions served as the premise for data collection and evaluation of the GDM DSME intervention component:

1. What are the delivery outcomes, i.e., neonatal birth weight, method of delivery, and weeks gestation for the patients in the DSME intervention- and the control- groups for women with and without GDM?
2. What are the delivery outcomes, i.e., neonatal birth weight, method of delivery, and weeks of gestation when compared between groups (DSME intervention group versus the control group)?

3. How satisfied is each patient in the intervention group with the facilitative nature of the program and the program topics?

The GDM DSME intervention is consistent with the EMPOWR protocol Diabetes/Obesity arm; evidence-based interventions throughout prenatal care which includes but is not limited to: 1) baseline intensive review of nutrition in pregnancy with emphasis on individual-appropriate weight gain goals; 2) discussion of dietary recommendations/restrictions; 3) detailed educational materials presented in group individual sessions with a Certified Diabetes Educator (CDE); 4) intensive review of glycemic control with individualized recommendations for dietary/activity alterations to improve profile; and 5) discussion of potential complications associated with diabetes/obesity during pregnancy, delivery and other lifetime risks (AADE, 2015; Haas et al., 2013).

As part of the EMPOWR protocol, each patient signed an IRB approved informed consent (Appendix C) to enter the CP program. Using the CP curriculum, all patients in the intervention group received basic education from a RN, CDE on risk factors for GDM, general nutrition, and safe exercise based on the ACOG recommendations (2011). Only the women in the group diagnosed with GDM received the full DSME intervention with counseling by the RD for medical nutrition therapy (MNT) and the RN, CDE. For women diagnosed with GDM, topics such as nutrition, exercise, breastfeeding, labor and delivery, as well as post-partum care, were further discussed relative to GDM. Self-monitoring of blood glucose (SMBG) records were downloaded at each session and discussed. The DSME curriculum content for patients at risk for GDM and with GDM in the CP model aligned with the American Diabetes Association's (ADA) National Standards for Diabetes Self-Management Education and Support (Table 1). The RD and RN, CDE documented all patient interaction in the electronic health record (EHR)

interdisciplinary DSME note and/or the GDM Education Record (Appendix D) which was scanned and placed in the EHR. The number of sessions attended was tracked.

## **Methods**

### **Study Setting**

Participants receiving services at a university-affiliated high-risk prenatal clinic, directed by Maternal-Fetal Medicine were included in the study. The prenatal clinic provides care for women who are pregnant with a condition that puts the mother, fetus, or both at a higher than normal risk for pregnancy-related complications. Women who are likely to have a high-risk pregnancy include those who have pre-existing diabetes or GDM and/or those that have had any complications in previous pregnancies such as pre-eclampsia, GDM, or preterm labor and/or delivery. There are four obstetricians/perinatologists who specialize in high-risk maternal/fetal medicine and serve as resources for the clinic. An advanced practice registered nurse, certified nurse midwife (APRN, CNM) provides prenatal care and is a trained facilitator for the CP program patients. The nurse-interpreter spoke fluent English and Spanish, is certified as an *oral* interpreter, and is also a trained facilitator for the CP program.

### **Study Population**

The EMPOWR program provides specialized CP care for Medicaid or Medicaid-eligible patients. The program offers a total of ten prenatal care sessions in a small group setting, once monthly for three months and then twice monthly for the remainder of the pregnancy. CP group size in the study analysis ranged from five to nine women. Patients are required to enroll prior to 20-weeks gestation. GDM is typically diagnosed between 24 to 28 weeks (ACOG, 2013); therefore, the DSME intervention will target Hispanic women enrolled in program who are at higher risk for GDM. All Hispanic women were referred to the “high risk for GDM” CP group.

Inclusion criteria included patients who: 1) were <20 weeks pregnant upon entering the group (necessary for entry to the CP program); 2) signed consent to participate in the CP program; 3) are of Hispanic descent; and 4) attended  $\geq 5$  of the 10 CP sessions. Women diagnosed with GDM were to remain in the respective CP group with the DSME intervention provided before or after the respective CP group session. Hispanic women in the program spoke Spanish as a primary language; therefore, an interpreter certified in *oral* interpretation was present during all patient-provider interactions, including DSME.

Hispanic women who are smokers were excluded from this evaluation due to the association with low birth weight infants (Hinkle et al., 2014). Smoking status was interpreted based on a NicAlert™ reading (Health4u, 2015). A level three ( $\geq 100$  ng/mL) or higher in the urine indicated a positive test for the use of tobacco products. One patient in the control group with a level three NicAlert reading was excluded from this analysis; no women in the intervention group were confirmed as tobacco users.

Within either group there was the possibility that there would be Hispanic women who would be diagnosed with GDM, as well as Hispanic women who did not develop the metabolic disorder.

### **Data Collection**

Data were collected via retrospective chart review and REDCap—a secure HIPAA compliant standardized software tool and customized programming to support data management activities (REDCap™, 2015) for the EMPOWR protocol. Neonatal birth weight data, mode of delivery, and weeks gestation at delivery were collected. The months of enrollment for the three CP groups that were the control group (2013) versus the three CP groups that made up the intervention group (2014) were identical. Baseline data were collected for all women entering

the program (Table 2). Only those women who completed at least five of the 10 sessions (50%) by the time of delivery were retained for analysis.

Patient satisfaction data were collected for the intervention group utilizing the Spanish-version of the evaluation tool “CenteringPregnancy Evaluation”, an approved instrument for use in health care systems participating in the CP model program (Appendix E). The GDM DSME intervention was evaluated as part of the core/educational content. Patient satisfaction data for the intervention group was self-reported and were collected at either session #7, #8, #9, or #10. One patient completed the form over the telephone by replying to the evaluation questions via the interpreter.

### **Outcomes Measures**

Neonatal birth weight, mode of delivery, and weeks gestation at delivery were compared for women with GDM and women without GDM within the intervention group and the control group, respectively. Neonatal birthweight was reported in grams; mode of delivery was characterized as cesarean section versus spontaneous vaginal delivery; and gestational age in weeks from estimated date of delivery. A macrosomic neonate was defined as greater than 4000 grams (Gregory, Henry, Ramicone, Chan, & Platt, 1998; Zamorski & Biggs, 2001). These data were also analyzed between groups (intervention group versus control group). Patient satisfaction rates were evaluated in the intervention group. Patient satisfaction was evaluated with 12 topics of discussion as “not helpful”, “somewhat helpful”, “very helpful”, or “not discussed” among women who received the intervention. Four questions regarding the group setting dynamics and preparation for labor and delivery were assessed with ratings of “disagree”, “not sure”, and “agree”. And, finally, measurement of overall experience with the CP group care setting were assessed with a one to five scale rating with one being the worst and five being the

best. Patients were also invited to add comments. Comments written in Spanish were translated by an interpreter certified in *written* interpretation.

### **Statistical Analysis**

Descriptive statistics, including means and standard deviations or frequency distributions, as appropriate, were used to summarize study variables. For between group comparisons (intervention/control), a two-sample t-test analysis evaluated differences in maternal age, maternal BMI, maternal weeks gestation at birth, and neonatal birth weight. Due to small sample sizes, Fisher's Exact Test was used to determine associations between group (intervention/control) and partnered status, history of GDM/macrosomia, and mode of delivery. Frequency distributions were used to summarize patient satisfaction. Significance was set at  $p < .05$  for all results. SPSS version 22.0 (SPSS Corp., Chicago, IL) was used for analysis.

### **Study Results**

A total of 40 patients were evaluated in this analysis; in the control group ( $n=25$ ) and in the DSME intervention group ( $n=15$ ). Data are presented in Table 2 for select variables (baseline and at delivery) for both women with and without GDM, in the control- and the DSME intervention- groups, respectively. Between groups, the mean age in the control group was  $28.2 \pm 6.0$  years compared with  $26.6 \pm 5.6$  years in the DSME-intervention group. The mean BMI was  $26.8 \pm 4.2$  kg/m<sup>2</sup> in the control group versus  $25.6 \pm 3.3$  kg/m<sup>2</sup> in the DSME-intervention group. Maternal weeks gestation at delivery were  $39.0 \pm 1.2$  and  $38.0 \pm 4.4$  for the control- and the DSME intervention- groups, respectively. Mean infant birth weight in the control group was  $3244.3 \pm 591.8$  grams versus the  $3105.4 \pm 790.9$  grams in the DSME intervention group. Overall mean values for the control group were slightly higher for these four variables; however, there were no significant differences between groups. There was no significant difference with respect



to history of GDM with a previous pregnancy ( $p<.99$ ); married/partner status ( $p=.27$ ); and mode of delivery (vaginal versus cesarean) ( $p=.34$ ) between the control group and the DSME intervention group. Because there was only one woman in the DMSE intervention group diagnosed with GDM, we were not able to assess the effect of the DSME intervention on outcomes such as birth weight and mode of delivery.

Patient satisfaction was assessed in the DSME intervention group. Eight of 11 (73%) participants who attended five or more CP sessions completed the voluntary CP evaluation tool. Ten participants self-reported these data by completing the form at session #7, #8, #9, or #10. One participant completed the form post-delivery via interview with the nurse-interpreter. Eighty-six percent of responses indicated the discussion topics (Appendix E, p. 1) “very helpful”. Ninety-three percent of the time participants agreed that they liked prenatal group format; were comfortable with their prenatal assessments in the group setting, and felt prepared for labor, birth, and parenting. On a scale of one to five for overall CP group care, with five being the best, 87.5% (7/8) of women selected a five and 12.5% (1/8) selected a four (Appendix E, p. 2). Generally, women were pleased with the overall CP experience and would recommend this method of prenatal care to other women.

### **Discussion**

Pregnancies complicated by diabetes are considered high-risk. Diabetes in pregnancy is divided in to two categories: 1) pre-existing diabetes in women who become pregnant; and 2) development of diabetes during pregnancy, described as GDM. In either category, if the diabetes is untreated the risk of maternal and fetal morbidity and mortality is significantly increased (Coustan, 2013). Data are widely available that support the interdisciplinary team approach to diabetes care, education, and support which includes an RD, a RN, and/or pharmacist (Brown,

1999; Deakin, McShane, Cade, & Williams, 2005; Emerson, 2006; Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003; Norris, Lau, Smith, Schmidt, & Engelgau, 2002; Renders et al., 2001). The National Standards for Diabetes Education and Support recognize the importance of DSME in women with GDM (Haas et al., 2012).

The interdisciplinary team, which included an APRN, CNM; RN, CDE; RD; and an RN who is a certified interpreter were focused on providing care for women in the CP program at high risk for GDM. Additionally, a team of obstetricians/perinatologists who specialize in high-risk maternal/fetal medicine were available as expert resources for patient care. All patients in the intervention group received education relative to the risk factors for GDM, and general nutrition and exercise in pregnancy that included carbohydrate awareness and the metabolic benefits of timing exercise post meal. A question to consider in a future study might be whether education focused on risks for GDM, nutrition, and exercise pre-GDM screening lowers the rate of diagnosis in Hispanic women at higher risk for GDM.

The interdisciplinary partnership with a faculty member in the division of dietetics and human nutrition, offered expertise in clinical dietetics and outpatient nutrition services, weight management counseling, and DSME. A potential for ongoing MNT services exists as graduate student RDs will be offered clinical rotations through the CP program model.

The increasing growth of the Hispanic population is seen within our prenatal clinic. Additionally, GDM is potentially increasing among US women with various racial/ethnic backgrounds, including Hispanic women (Dabelea et al., 2005; Sridhar, Ferrara, Ehrlich, Brown, & Hedderon, 2013). The US Census Bureau recently reports that approximately 44% of Spanish Americans self-reported their English speaking ability as “less than very well” (Ryan,

2013). Thus, due to the higher risk for GDM in Hispanic women, consideration to employing a diabetes educator that speaks fluent Spanish is a valid one.

### **Limitations of the Study**

This analysis was a pilot study to establish the effect of an evidence-based GDM DSME intervention on neonatal birth weight in a CP model setting. Data were also assessed for any differences in birth method and weeks gestation at delivery. For the pilot study, the GDM DSME intervention was limited to enrollees in three CP groups. All patients were screened for GDM; however, only one patient was diagnosed in the intervention group compared with five in the control group. Because a small sample in a single prenatal clinic is being used, these findings cannot be generalized beyond this sample. Ongoing assessment is necessary to further evaluate the effectiveness of the DSME intervention in a CP model setting.

### **Conclusions**

A DSME education intervention for Hispanic women with GDM that is aligned with the CP model was attained. The pilot provided process data for use of a culturally-sensitive GDM DSME curriculum in the CP model setting. Evaluation of the program indicated this model may provide the potential for streamlined care, the possibility of added resources—such as an RD for MNT, and supported the benefits of an interdisciplinary approach to prenatal care. Due to the small number of patients diagnosed with GDM in the education intervention group, more data are needed to evaluate the effect of DSME within this setting on clinical outcomes, such as neonatal birth weight.

The project described was supported by Funding Opportunity Number CMS-1D1-12-001 from the Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation.

The contents provided are solely the responsibility of the authors and do not necessarily represent the official views of HHS or any of its agencies.

Table 1. Diabetes Curriculum Content Based on the American Diabetes Association’s National Standards for Diabetes Self-Management Education and Support<sup>1</sup>: Patients at Risk for GDM and GDM in a CenteringPregnancy<sup>®</sup> Model

Session Number (Weeks gestation)	CenteringPregnancy Curriculum <sup>2</sup>	At Risk for GDM/GDM Curriculum <sup>3</sup>
1 (16 weeks)	Intro to Centering Nutrition Weight	<i>Disease Process</i> (GDM risk factors) <i>Nutrition/Lifestyle</i> (Food diary; nutrition facts label; fast food/healthier choices) <i>Physical Activity/Lifestyle</i> (Physical activity in pregnancy)
2 (20 weeks)	Body Changes Common Discomforts HANDS	
3 (24 weeks)	Relaxation Dental Breastfeeding	<i>Monitoring/Interpreting Blood Glucose</i> Screening for GDM [50-gram glucola]
4 (28 weeks)	Contraception Domestic Violence Preterm Labor	<i>Nutrition/Lifestyle</i> (MNT) <i>Physical Activity/Lifestyle</i> (Effect on BG) <i>Monitoring Blood Glucose</i> (SMBG)
5 (30 weeks)	Birth Center Tour	<i>Monitoring/Interpreting Blood Glucose</i> (Upload/review of SMBG records)
6 (32 weeks)	Labor and Delivery When to go to Hospital Pain Relief Options Preeclampsia	<i>Reducing Risks</i> (Labor and delivery/GDM) <i>Monitoring/Interpreting Blood Glucose</i> (Upload/review of SMBG records)
7 (34 weeks)	Infant Care Car Seat/Crib Safety	<i>Monitoring/Interpreting Blood Glucose</i> (Upload/review of SMBG records) <i>Monitoring/Interpreting Other Parameters</i> (U/S/fetal weight)
8 (36 weeks)	Postpartum Emotional Adjustments Postpartum Care Breastfeeding	<i>Personal Strategies to Promote Health</i> (Breastfeeding after delivery/GDM) <i>Personal Strategies to Promote Health</i> (GDM with future pregnancies; Type 2 risk) <i>Monitoring/Interpreting Blood Glucose</i> (Upload/review of SMBG records)
9 (38 weeks)	Newborn Safety Preparing for Labor Stages of Labor Video	<i>Monitoring/Interpreting Blood Glucose</i> (Upload/review of SMBG records)
10 (40 weeks)		<i>Disease Process/Psychosocial Issues</i> (GDM with future pregnancies; Type 2 risk) <i>Monitoring/Interpreting Blood Glucose</i> (PP Screening; Upload/review of SMBG records) <i>Using Medications/Prevention of Acute Complications</i> <sup>4</sup> (Prescribed drug; hypoglycemia)

<sup>1</sup>American Diabetes Association (2013). *Standard #6*; <sup>2</sup>All patients enter the program prior to 20-weeks gestation; <sup>3</sup>*Italicized* topics are ADA curriculum friendly; <sup>4</sup>*Using Medication/s/Prevention of Acute Complications* may be used at any time point if medication therapy is a necessary part of treatment.

GDM=Gestational Diabetes Mellitus; MNT=Medical Nutrition Therapy; HANDS=Health Access Nurturing Development Services; RD=Registered Dietitian; RN=Registered Nurse  
SMBG=Self-Monitoring of Blood Glucose; U/S=Ultrasonography; PP=Postpartum; ADA=American Diabetes Association

Table 2. Select Demographic and Clinical Variables for Hispanic Women With and Without GDM in the DSME Intervention- and Control- Groups of the CenteringPregnancy® Model

DEMOGRAPHIC & CLINICAL VARIABLES*	Control Group <i>n</i> =25		DSME Intervention Group <i>n</i> =15	
	With GDM <sup>1</sup> <i>n</i> =5	Without GDM <i>n</i> =20	With GDM <sup>1</sup> <i>n</i> =1	Without GDM <i>n</i> =14
<b><i>Baseline</i></b>				
Age (years)	28.2±6.7	28.2±6.0	27.0	26.6±5.8
BMI (kg/m <sup>2</sup> )	29.96±6.37	26.07±3.22	32.8	25.56±3.33
Married/Partner (%)	75	25	100	38
Prior history GDM/Macrosomia (%)	20	0	0	7
<b><i>Delivery</i></b>				
Gestation (weeks)	38.3±1.0	39.1±1.2	40.1	37.60±4.62
Infant birthweight (g)	3280.0±934.7	3236.4±527.3	3540.0	3062.0±819.71
C-section (%)	25	11	0	22

<sup>1</sup>Diagnosis per ACOG two-step method for screening and diagnosis;  
\*Numbers may vary due to missing data; data are expressed in mean±standard deviation unless otherwise specified;  
GDM=Gestational Diabetes Mellitus; BMI=Body Mass Index; C-section=Cesarean section; Section; g=grams

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### Practice Inquiry Report Conclusion

GDM is a metabolic disorder that occurs in pregnancy. Untreated GDM significantly increases the risk of maternal and fetal morbidity and mortality. National Standards for Diabetes Education and Support recognize the importance of DSME in women with GDM. Three manuscripts support the development, implementation, and evaluation of an innovative GDM DSME program in an existing CP model setting.

The opportunity to share learnings is an additional priority of this practice inquiry project. The second manuscript has been solicited for *AADE in Practice*, a peer-reviewed journal of the AADE. This manuscript will be coauthored by members of the project interdisciplinary team, Liz Combs, MS, RD, EdD-Candidate and María Gómez, DrPH, MPH. Team members have contributed to the learning process as well as provided careful review of the manuscript. The manuscript will be formatted with respect to “Manuscript Submission Guidelines” (Appendix F) and submitted to the journal in June 2015. Discussion with Chief Editor for ADA’s *Diabetes Spectrum* peer-reviewed journal resulted in an interest to publish the third manuscript. Coauthors include Elizabeth Coleman, APRN, CNM and Liz Marshall, MS, RD, EdD-Candidate, members of the interdisciplinary team; Kristin Ashford, PhD, APRN, Primary Investigator for the Efforts to Maximize Perinatal Outcomes in Women at Risk (EMPOWR) study; and Amanda Wiggins, PhD for her statistical expertise. Each has contributed to project implementation and/or evaluation, as well as provided careful review of the manuscript. This manuscript will be formatted with respect to the journal “Instructions for Author” guidelines (Appendix F) and submitted to the journal in 2015.

As a result of this Project, an evidence-based DSME curriculum is in place that aligns with the CP model. All components are available in Spanish and English and may be accessed

electronically. Moving forward, this innovative program will succeed with organizational support and the continued resources as needed to implement the GDM DSME intervention in the CP program setting.

Appendix A. At Risk for Gestational Diabetes Mellitus (GDM) and GDM Topics Aligned with CenteringPregnancy® Sessions

Session	Centering Topic	Diabetes Topic	Diabetes Resources/Materials
1 (16 weeks)	Intro to Centering Nutrition Weight	<b>At Risk for GDM [50-gram Glucola Screening]</b> <b>AADE7™ "Healthy Eating"</b> 1) GDM Risk Factors 2) Select Materials/ Food Diary 3) Total Carbohydrate/ Nutrition Facts Label 4) Fast Food (Healthier Choices)	1) Use <b>select handouts</b> including those from listed web resources for GDM risk factors (both available in Spanish) [CenteringPregnancy Notebook: page 9] <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a> 2) <b>Health Nutrition Concepts</b> (CenteringPregnancy Notebook: pages 6-13) 3) <b>Carbohydrate Awareness; Label Reading for Carbohydrate Content of Foods</b> (Nutrition Facts Label [English and Spanish]) <a href="http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf">http://ndep.nih.gov/media/learn-food-labels-bw-508.pdf</a> ) 4) <b>Select information</b> fast food nutrition facts (how to access Fast Food info via web)
2 (20 weeks)	Body Changes Common Discomforts HANDS	<b>At Risk for GDM AADE7™ "Being Active"</b> 1) Physical Activity in Pregnancy	1) Use <b>select handouts</b> from listed web resources for GDM risk factors and Physical Activity; <u>The American College of Obstetricians and Gynecologists. Exercise during Pregnancy. [English (2011) and Spanish (2014)].</u> <a href="http://www.acog.org/Patients/FAQs/Exercise-During-Pregnancy">http://www.acog.org/Patients/FAQs/Exercise-During-Pregnancy</a> <a href="http://www.acog.org/Patients/Search-Patient-Education-Pamphlets-Spanish/Files/El-ejercicio-durante-el-embarazo">http://www.acog.org/Patients/Search-Patient-Education-Pamphlets-Spanish/Files/El-ejercicio-durante-el-embarazo</a>
3 (24 weeks)	Relaxation Dental Breastfeeding	<b>At Risk for GDM [50-gram Glucola Screening]</b>	

Session	Centering Topic	Diabetes Topic	Diabetes Resources/Materials
4 (28 weeks)	Contraception Domestic Violence Preterm Labor	<b>GDM [Glucola Screening] Diagnosed with GDM</b> <b>AADE7™ "Healthy Eating"</b> 1) GDM Meal Plan <b>AADE7™ "Being Active"</b> 2) Role in Blood Glucose Control <b>AADE7™ "Monitoring"</b> 3) Instruct on Self-Monitoring of Blood Glucose (SMBG)	1) "Planning Health Meals" AADE Favorably Reviewed/NovoNordisk] (detail GDM meal plan); Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a> 2) Use select handouts from listed web resources for GDM (above) 3) SMBG with appropriate meter* / consider Spanish settings *Based on insurance coverage; set-up with meter for download English and Spanish SMBG records: <a href="https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf">https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf</a> <a href="https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf">https://www.cdappsweetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf</a>
5 (30 weeks)	Birth Center Tour	<b>GDM</b> <b>AADE7™ "Monitoring"</b> 1) Review of SMBG records; discussion of ongoing surveillance	1) Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>
6 (32 weeks)	Labor and Delivery When to go to Hospital Pain Relief Options Preeclampsia	<b>GDM</b> <b>AADE7™ "Reducing Risks"</b> 1) Labor & delivery (GDM) <b>AADE7™ "Monitoring"</b> 2) Review of SMBG records; discussion of ongoing surveillance	1) Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>

Session	Centering Topic	Diabetes Topic	Diabetes Resources/Materials
7 (34 weeks)	Infant Care Car Seat/Crib Safety	<b>GDM</b> <b>AADE7™ "Healthy Coping"</b> 1) Discussion on ongoing blood glucose control 2) Ultrasound monitoring / baby's weight <b>AADE7™ "Monitoring"</b> 3) Review of SMBG records; discussion of ongoing surveillance	1) Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>
8 (36 weeks)	Postpartum Emotional Adjustments Postpartum Care Breastfeeding	<b>GDM</b> <b>AADE7™ "Healthy Coping"</b> 1) Postpartum GDM with future pregnancies; Risk for Type 2 <b>Diabetes; Breastfeeding</b> <b>AADE7™ "Monitoring"</b> 2) Review of SMBG records; discussion of ongoing surveillance	1) Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>
9 (38 weeks)	Newborn Safety Preparing for Labor Stages of Labor Video	<b>GDM</b> <b>AADE7™ "Monitoring"</b> 1) Review of SMBG records; discussion of ongoing surveillance	1) Use select handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish) <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational_ES/</a> <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/gestational/index.aspx</a>

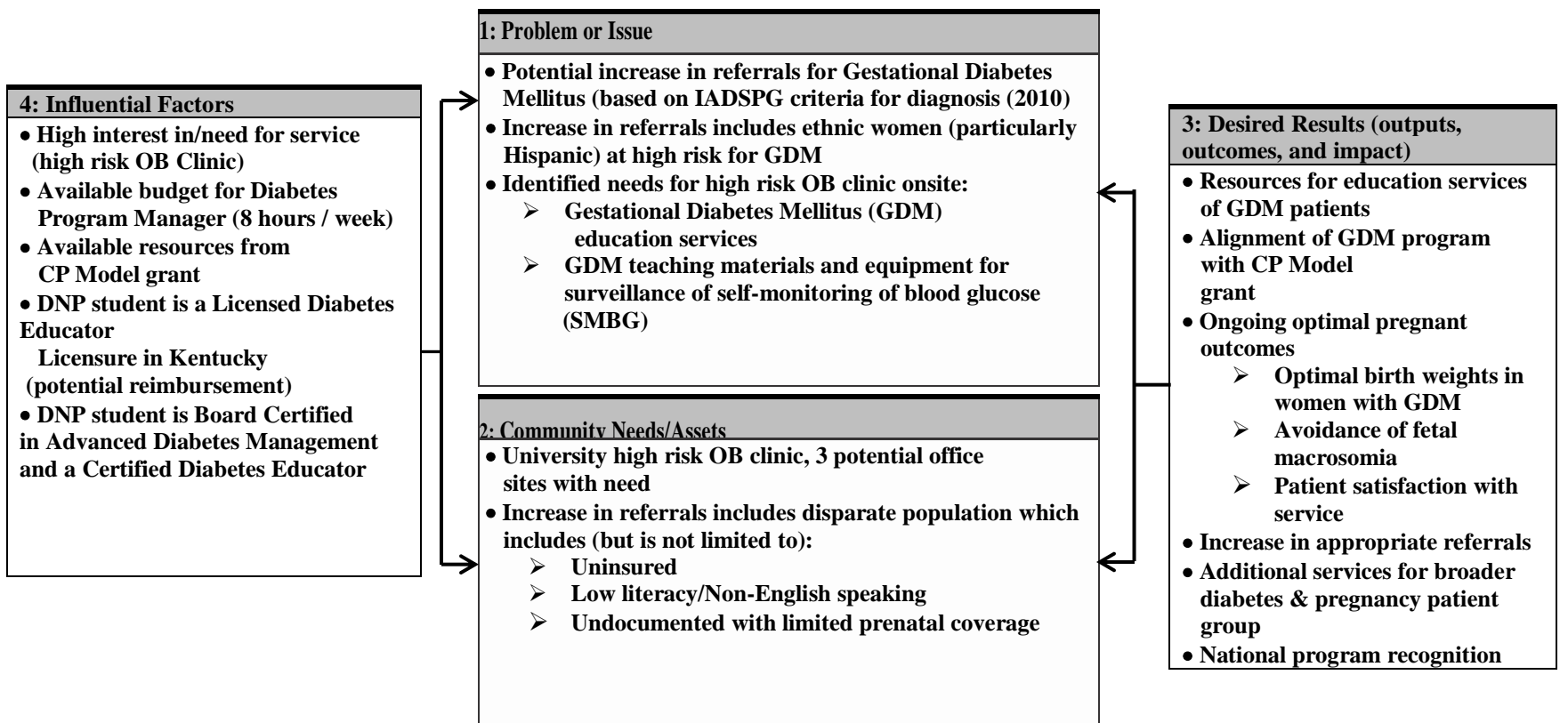
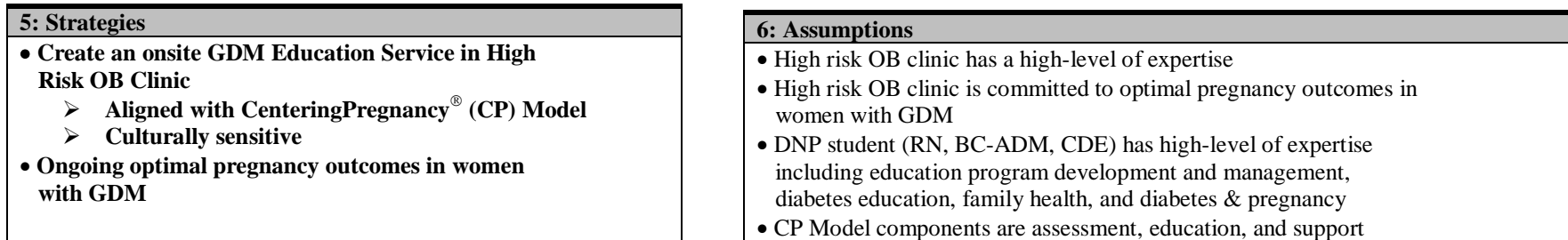
Session	Centering Topic	Diabetes Topic	Diabetes Resources/Materials
10 (40 weeks)		<b>GDM [as needed]</b> <b>AADE7™ "Taking Medication"</b> 1) If prescribed 2) Hypoglycemia <b>AADE7™ "Reducing Risks"</b> 3) Prevention of Type 2	Other materials [ <i>use as needed</i> ]: 1) Use select (medication) handouts from listed web resources for GDM; "Gestational Diabetes" Roche (all available in Spanish); Hypoglycemia information available with both <a href="http://www.diabetes.niddk.nih.gov/dm/pubs/medicines_ez/index.aspx">http://www.diabetes.niddk.nih.gov/dm/pubs/medicines_ez/index.aspx</a> 2) "Small Steps. Big Rewards. Your GAME PLAN to Prevent Type 2 Diabetes: Information for Patients", includes an activity tracker and a fat and calorie counter (available in Spanish) <a href="http://ndep.nih.gov/publications/PublicationDetail.aspx?PubId=71">http://ndep.nih.gov/publications/PublicationDetail.aspx?PubId=71</a>

Appendix B/Table B1. Logic Model Development: Program Development/Implementation of a GDM Education Intervention at a University Maternal-Fetal Medicine Service

RESOURCES	ACTIVITIES	OUTPUTS	SHORT- & LONG-TERM OUTCOMES	IMPACT
<p>In order to accomplish our set of activities we will need the following:</p>	<p>In order to address our problem or asset we will accomplish the following activities:</p>	<p>We expect that once accomplished these activities will produce the following evidence or service delivery:</p>	<p>We expect that if accomplished these activities will lead to the following changes in 1–3 then 4–6 years:</p>	<p>We expect that if accomplished these activities will lead to the following changes in 7–10 years:</p>
<ul style="list-style-type: none"> <li>○ Site location(s) for GDM education</li> <li>○ Initial Core Committee of Stakeholders</li> <li>○ Additional Stakeholders (identified by Core Committee)</li> <li>○ Diabetes Educator funding</li> <li>○ Clinic needs:               <ul style="list-style-type: none"> <li>● Equipment</li> <li>● Job descriptions</li> </ul> </li> <li>○ Addendum to CenteringPregnancy® (CP) IRB Application (GDM)</li> <li>○ Diabetes Educator orientation</li> </ul>	<ul style="list-style-type: none"> <li>○ 8-hour week (Diabetes Educator FTE)</li> <li>○ Confirmation of site(s) for GDM education (for both 1:1 and group)</li> <li>○ Resources for Education (English and Spanish)</li> <li>○ Interpreter training on GDM materials</li> <li>○ Evaluation plan created (per stakeholders)</li> </ul>	<ul style="list-style-type: none"> <li>○ Number of GDM patients referred to high risk OB clinic annually</li> <li>○ Number (%) of Hispanic GDM patients</li> <li>○ Number (average) of patients enrolled in Centering Pregnancy program (versus not)</li> <li>○ Number of GDM patient high risk prenatal visits</li> <li>○ Volume of GDM patients per resources</li> <li>○ Collection of data relative to pregnancy outcomes in GDM patients (for both 1:1 and group settings)</li> <li>○ Completion of patient Satisfaction Surveys</li> </ul>	<ul style="list-style-type: none"> <li>○ Adequacy of clinical space</li> <li>○ Adequacy of resources available to see GDM patients</li> <li>○ Positive receipt of CP Model of care</li> <li>○ Ongoing optimal pregnancy outcomes in GDM patients</li> <li>○ Additional services for the broader diabetes &amp; pregnancy group</li> <li>○ Increase in appropriate referrals</li> <li>○ National program recognition</li> </ul>	<ul style="list-style-type: none"> <li>○ Decrease in number of less than optimal GDM pregnancy outcomes (e.g., macrosomic neonates)</li> <li>○ Growth in program</li> <li>○ (Ongoing) National program recognition</li> </ul>



Appendix B/Figure B2. Describing Program/Intervention Results—GDM Education Intervention at a University Maternal-Fetal Medicine Service



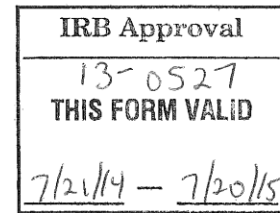
Appendix B/Table B3. Logic Model Development: Evaluation Planning for a GDM Education Intervention at a University Maternal-Fetal Medicine Service

Evaluation Focus Area	Audience	Question	Use
Relationships	Staff	How has the staff embraced the GDM education program?	Program improvements/promotion
		Was all staff appropriately trained regarding GDM education program?	Program improvements & planning
		What was the impact of training?	Program improvements & planning
	Patients	Is GDM treatment/education plan being carried out?	Program improvements & planning
		Is the program completed (do patients stay in/finish the program)?	Program improvements & planning
	Administrative	Has the broader medical community embraced the education program?	Evaluation/program promotion
Education Program	Staff	What available clinic space is confirmed for use with the GDM educational program?	Program improvements & planning
		Is identified space for education program adequate (for 1:1 and group)?	Program improvements & planning
		Are referrals to program appropriate?	Program improvements & planning
		Is SMBG software in place to download meters?	Evaluation/program improvements & planning
	Patients	Are GDM educational materials available (i.e. from the National Institutes of Health [NIH]) optimal for use with this program?	Evaluation/program improvements & planning
		Are these materials available in Spanish?	Evaluation/program improvements & planning
		Are adequate SMBG supplies available?	Evaluation/program improvements & planning
		Are SMBG supplies Spanish-friendly?	Evaluation/program improvements & planning
		Are patients completing the program?	Annual report/program improvements
Program Outcomes	Staff	Are program outcomes being met?	Annual report/program improvements
		What are maternal / fetal outcomes (specifically maternal glycemic control and neonatal birth weight)?	Annual report/program improvements
	Administrative	Are patients satisfied with the program?	Annual report/program improvements
		Are program outcomes being met?	Annual report/program improvements

Appendix B/Table B4. Logic Model Development: Establishing Indicators in a GDM Education Intervention at a University Maternal-Fetal Medicine Service

Focus Area	Question	Indicators	Technical Assistance Needed
Relationships	How has the staff embraced the GDM education program?	<ul style="list-style-type: none"> <li>• Staff meeting</li> <li>• Solicitation of staff feedback</li> </ul>	Staff survey/feedback
	Is GDM treatment/education plan being carried out?	<ul style="list-style-type: none"> <li>• Chart review</li> <li>• SMBG records</li> </ul>	SMBG software for downloads/patient reporting
Education Program	Is the program completed (do patients stay in/finish the program)?	<ul style="list-style-type: none"> <li>• Chart review</li> <li>• Patient feedback</li> </ul>	Patient satisfaction surveys
	Has the broader medical community embraced the education program?	<ul style="list-style-type: none"> <li>• Patient referrals</li> </ul>	Medical community feedback
	Is identified space for education program adequate (for 1:1 and group)?	<ul style="list-style-type: none"> <li>• Patient feedback</li> <li>• Patient referrals</li> </ul>	Patient satisfaction surveys Review of available space
	Are referrals to program appropriate?	<ul style="list-style-type: none"> <li>• Patient feedback</li> <li>• Solicitation of staff feedback</li> </ul>	Patient satisfaction surveys Tracking patient database
	Are GDM educational materials (English/Spanish) optimal for use with this program?	<ul style="list-style-type: none"> <li>• Patient feedback</li> <li>• SMBG records</li> </ul>	Patient satisfaction surveys SMBG software
	Are adequate SMBG supplies (English/Spanish) available?	<ul style="list-style-type: none"> <li>• Patient feedback</li> <li>• SMBG records</li> </ul>	Patient satisfaction surveys SMBG software
	Are patients completing the program?	<ul style="list-style-type: none"> <li>• Chart review</li> <li>• Patient feedback</li> </ul>	Chart review
Program Outcomes	What are maternal / fetal outcomes (specifically maternal glycemic control and neonatal birth weight)? Rate of Cesarean Section?	<ul style="list-style-type: none"> <li>• Chart review</li> </ul>	Chart review Research database
	Are patients satisfied with the program?	<ul style="list-style-type: none"> <li>• Patient feedback</li> </ul>	Patient satisfaction surveys

Appendix C. Consent/Parent Permission to Participate in a Research Study: STRONG START  
EMPOWR: Efforts to Maximize Perinatal Outcomes in Women at Risk



Consent/Parent Permission to Participate in a Research Study  
STRONG START EMPOWR: Efforts to Maximize Perinatal Outcomes in Women at Risk

WHY ARE YOU/YOUR DAUGHTER BEING INVITED TO TAKE PART IN THIS RESEARCH?

You/ your daughter are being invited to take part in a research study about receiving group prenatal care during your pregnancy in a small group setting of 8-10 pregnant women. The group prenatal care, known as CenteringPregnancy® will include everything you receive in traditional prenatal care, including individual check-ups, without having to spend time in a waiting room. In addition, you will receive additional education on childbirth, breastfeeding, and caring for your newborn. At the end of your prenatal appointments, you will also discuss how to avoid or stop behaviors that may put you at risk for preterm birth. This additional time to talk about risk behaviors is called EMPOWR (Effort to Maximize Perinatal Outcomes in Women-at-Risk). The CenteringPregnancy/EMPOWR group care will also provide a unique opportunity of interactive care allowing you to take part in discussions about your pregnancy with women with similar risk factors. You/your daughter are being invited to take part in this research study because you are pregnant, less than 20 weeks gestation, and are eligible for Medicaid assistance. If you/ your daughter volunteer to take part in this study, you/your daughter will be one of about 1600 women at the University of Kentucky prenatal clinics to do so.

WHO IS DOING THE STUDY?

The providers in charge of this study are Kristin Ashford, ARNP, PhD of UK College of Nursing, and John O'Brien, MD of UK Department of OBGYN Maternal Fetal Medicine. There will be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn how meeting in a small group of 8-10 pregnant women (along with a healthcare provider and group facilitator) for prenatal care, will improve your pregnancy experience and the outcome of your pregnancy. The group prenatal care appointments will share topics of pregnancy that are of importance specifically to the women in your group. For example if you feel stressed, the group will talk about ways to deal with stress every day to help you have a healthy pregnancy.

ARE THERE REASONS WHY YOU/ YOUR DAUGHTER SHOULD NOT TAKE PART IN THIS STUDY?

In order to participate in this study you/your daughter must be: pregnant and less than 20 weeks gestation; eligible for Medicaid assistance; able to read and write English or Spanish; and at least 16 years old. Non-English speaking women will have an interpreter available during the group prenatal care appointments.



WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research will take place at the University of Kentucky prenatal clinics (Polk Dalton Clinic and UK Good Samaritan), Women's Care of the Bluegrass (Frankfort, KY), and Baptist Health Inc. (Madisonville, KY). You/your daughter will need to attend the group prenatal appointments as scheduled 10 times throughout your pregnancy. You will still have one on one time with a healthcare provider during the 10 group prenatal care appointments. Each appointment will last approximately 120 minutes. You will be asked to complete a brief, 20 minute survey during today's visit and again at the eighth group prenatal care appointment. We will invite you to complete a 14 question satisfaction survey at your post-partum visit (after you delivery your baby).

WHAT WILL YOU/YOUR DAUGHTER BE ASKED TO DO?

You/ your daughter will have the same number of visits and testing/screening procedures as you would have if you did not participate in this study. This group prenatal care called EMPOWR & CenteringPregnancy will include everything you receive in traditional prenatal care, PLUS additional education and time to share and learn with a small group of other pregnant women. You will be placed in a prenatal group that is based on a risk factor that can affect your pregnancy. The groups are: 1) Hispanic ethnicity, 2) high stress, 3) diabetes/risk for diabetes, 4) tobacco use, substance abuse, or 5) a medical risk factor (i.e., previous preterm birth). Each group prenatal care appointment will be held during a prescheduled appointment time and will be with the same small group of 8-10 pregnant women, a healthcare provider, and your group facilitator. Visits will be conducted using traditional CenteringPregnancy® model of care, which is a nationally recognized curriculum for learning about your pregnancy.

Group care appointments will be divided into 3 parts (a flexible breakdown of appointment is listed below):

- First 45 minutes:
  - Participants will arrive, check-in, complete personal assessments (weight, blood pressure, etc.) at Centering group location
  - Participants will meet with providers individually (5 min each)
- Next 45-60 minutes:
  - Facilitators (and co-facilitators) will then follow CenteringPregnancy® curriculum for prenatal education
- Final 10-15 minutes:
  - EMPOWR Principles: Time will be dedicated to discussing specific EMPOWR group risk factors and strategies to decrease or eliminate these risk factors (i.e. stress, tobacco use)

During today's visit, and again at the eighth prenatal group care appointment, you will be asked to complete a brief, 20 minute survey on an iPad, laptop computer, or a paper version. The survey will ask questions related to your psychosocial health (anxiety, stress, and depression), perceived support, and general health and well-being (sleep, diet, exercise). All surveys and study samples are identified by a code number (not your name) and are confidential.

We will also collect a urine sample from all participants to measure the level of cotinine in your urine. This measurement will show whether you have smoked cigarettes in the last 1-2 days. If you are a confirmed *non-smoker*, measured by the level of cotinine in your urine at the first prenatal visit, you will only provide this one urine sample for the study. If you are a confirmed *smoker*, we will collect one additional urine sample during the study.



Visit	What is Expected	Risks
First OB Screening appointment	<ul style="list-style-type: none"> <li>• Survey</li> <li>• Urine sample</li> </ul>	Minimal discomfort
CenteringPregnancy/EMPOWR Group prenatal care Prenatal Appointments 1-10	<ul style="list-style-type: none"> <li>• Meet with assigned group for prenatal care as scheduled</li> <li>• Schedule 20 week Prematurity Prevention visit</li> <li>• Appointment 8 – survey</li> <li>• 28-32 weeks gestation– urine sample for confirmed smokers</li> </ul>	Minimal discomfort
Postpartum (after delivery)	<ul style="list-style-type: none"> <li>• Satisfaction survey</li> </ul>	

You may be invited to participate in a Focus Group during the course of this study. A Focus Group is a small group of participants invited for approximately 2 hours to share your opinions, beliefs, attitudes, and perceptions of the EMPOWR CenteringPregnancy program. You may be offered compensation for participating in the Focus Group. The Focus Group will be conducted by Master's or PhD level trained researchers from the evaluation team who will moderate the discussion, using data collection methods and instruments that have been approved for research evaluation. As a participant in a focus group, topic areas include how you chose your prenatal care provider; what type of information you learn/discuss during your prenatal care visits; your perceptions of the EMPOWR CenteringPregnancy program; experiences with birth and postpartum care; health coverage after pregnancy; and comparisons to previous prenatal care experiences. You may be contacted to participate in a Focus Group by a UK research Team member or by a member of the team selected to evaluate the study. Participation in the Focus Group is optional and does not affect your participation in the EMPOWR study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks to the participant are minimal. The only known risks are breach of confidentiality, and possible emotional discomfort associated with completing the survey. There is always the possibility that you/your daughter may experience a previously unknown risk or side effect while participating in this study.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. You/your daughter's willingness to take part however may, in the future, help doctors better understand how group prenatal care may improve pregnancy outcomes.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you/your daughter decide to take part in the study, it should be because you/your daughter want to volunteer. You/your daughter will not lose any benefits or rights that you/your daughter would normally have if you/your daughter choose not to volunteer. You/your daughter can stop at any time during the study and still keep the benefits and rights you/your daughter had before volunteering. If you/your daughter decide not to take part in this study, you/your daughter decision will have no effect on the quality of medical care receive

IF YOU/YOUR DAUGHTER DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?



If you/your daughter do not want to be in the study, there are no other choices except not to take part in the study. No therapy is provided as part of the study.

WHAT WILL IT COST YOU/YOUR DAUGHTER TO PARTICIPATE?

There is no cost to participate in this study. You/ your daughter's insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you/ your daughter will receive during this study that you would normally receive for the pregnancy. These are costs that are considered medically reasonable and necessary and will be part of the care you/your daughter receive if you do not take part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep all research records private that identify you/your daughter to the extent allowed by the law. You/your daughter's information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You/your daughter will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your/your daughter name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you/your daughter gave us information, or what that information is. We will use a code number, and not you/your daughter's name on all your specimens and you/your daughter's survey. We will keep all participant records in a locked cabinet in the College of Nursing.

You should know, however, that there are some circumstances in which we may have to show your/your daughter's information to other people. For example, the law may require us to show you/your daughter information to a court or to tell authorities if you/your daughter report information about a child being abused or if you/your daughter pose a danger to yourself or someone else. Officials of the Centers for Medicare and Medicaid Services (the study Sponsor), the Urban Institute (study Evaluator), and the University of Kentucky may look at or copy pertinent portions of records that identify your child/you.

CAN YOU/YOUR DAUGHTER TAKING PART IN THE STUDY END EARLY?

If you/your daughter decide to take part in the study you/your daughter have the right to decide at any time that you/your daughter no longer want to continue. You/your daughter will not be treated differently if you/your daughter decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you/your daughter from the study if you/your daughter lose your Medicaid eligibility coverage.

ARE YOU PARTICIPATING OR CAN YOU/YOUR DAUGHTER PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You/your daughter can take part in this study if you/your daughter are currently involved in another research study. It is important to inform the person enrolling you/your daughter in this study if you/your daughter are in another research study. You/your daughter should also discuss with the investigator before you/your daughter agree to participate in another research study while you/your daughter are enrolled in this study.

WHAT HAPPENS IF YOU/YOUR DAUGHTER GET HURT OR SICK DURING THE STUDY?



If you/your daughter believe you/your daughter are hurt or if you/your daughter get sick because of something that is due to the study, you should call Dr. John O'Brien, MD at 859-257-2323 immediately. Dr. O'Brien will determine what type of treatment, if any, is best for you/your daughter at that time.

It is important for you/your daughter to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you/your daughter get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you/your daughter may lose if you/your daughter are harmed by this study.

The medical costs related to you/your daughter care and treatment because of research related harm will be your responsibility; **or** may be paid by you/your daughter's insurer if you/your daughter are insured by a health insurance company (you should ask your insurer if you have any questions regarding you/your daughter insurer's willingness to pay under these circumstances); **or** may be paid by Medicare/Medicaid if you/your daughter are covered by Medicare/Medicaid (if you have any questions regarding your coverage, you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you/your daughter may be required by you/your daughter's insurer or Medicare/Medicaid (even if you/your daughter's insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial. You/your daughter do not give up your legal rights by signing this form.

WILL YOU/YOUR DAUGHTER RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You/your child will not receive any rewards or compensation for taking part in this study, unless you are invited to participate in a Focus Group, in which compensation may be offered by the study Sponsor or Evaluator.

WHAT IF YOU/YOUR DAUGHTER HAVE QUESTIONS, SUGGESTIONS, CONCERNS OR COMPLAINTS?

Before you/your daughter decide whether to accept this invitation to take part in the study, please ask any question that might come to mind now. Later, if you/your daughter have questions, suggestions, concerns or complaints about the study, you/your daughter can contact the investigator, Kristin Ashford at (859)527-9333, or the research coordinator, Andrea McCubbin at (859)533-7941, or lead Research Facilitator Janine Barnett at (859)333-1572. If you/your daughter have any question about you/your daughter rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at (859)257-9428 or toll free at (866)400-9428. We will give you/your daughter a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT MY/MY DAUGHTER'S DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change you/your daughter willingness to stay in the study, the information will be provided to you/your daughter. You/your daughter may be asked to sign a new informed consent form if the information is provided to you/your daughter after you/your daughter have joined the study.

WHAT ELSE DO YOU/YOUR DAUGHTER NEED TO KNOW?

This study is supported by a Center for Medicare Services, Medicare and Medicaid Innovation Center research grant titled "Strong Start for Mothers and Newborns". The information collected during the group appointments and medical records reviews may lead to new products for research, diagnosis or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you/your daughter should this occur.





AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. This form describes how researchers may use your information. Please read it carefully.

Your health information will be used and/or released (disclosed) for the following research study:

EMPOWR: Efforts to Maximize Perinatal Outcomes in Women at Risk

You allow (or authorize) Kristin Ashford, APRN, PhD and her research staff at the University of Kentucky to create, access, use and release your health information for the purposes listed below.

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Mother:
  - Age, race, prenatal history, pregnancy risk factors, labor and delivery history, psychosocial and medical history, lab results, and smoking status
- Infant
  - Birthweight, gestational age, newborn assessment, lab results, and newborn complications

Your health information will be used for:

The purpose of this study is to gather information on predictors of preterm birth and assess how group prenatal care impacts birth outcomes. The study will also examine how smoking status and maternal psychosocial factors, including stress, anxiety, social support and depression can affect preterm birth. With increased knowledge about the causes of preterm birth, healthcare practitioners may develop methods to identify mothers at risk for preterm birth. One reason to share the information is to be able to conduct research and to ensure that the research meets legal, institutional or accreditation requirements.

The Researchers may use and share your health information with:

- The University of Kentucky's, Baptist Health Madisonville's, and Women's Care of the Bluegrass' (Cumberland Family Medical Group) Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky Hospital or UK representatives.
- UK College of Dentistry
- UK College of Nursing
- Other collaborating researchers
- Primary physician will be contacted if research in the course of the project learns of a medical condition that needs immediate attention
- CMMI: Center for Medicare and Medicaid Innovation (study Sponsor)
- Urban Institute (the Sponsor's contracted Evaluator)

The researchers agree to only share your health information with the people listed in this document.

SELF-MANAGEMENT EDUCATION FOR HISPANIC WOMEN WITH  
GESTATIONAL DIABETES MELLITUS (GDM)

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect you:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Kristin Ashford, APRN, PhD, CON 417, University of Kentucky College of Nursing, Lexington KY 40536-0232 to inform *her* of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

\_\_\_\_\_  
Signature of research subject or \*research  
subject's legal representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of research subject or  
\*research subject's legal representative

\_\_\_\_\_  
Representative's relationship to  
research subject

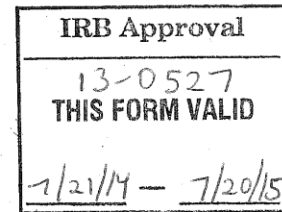
\*(If, applicable) Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

\_\_\_\_\_  
Signature of Investigator

IRB approved: 06/29/14  
7/21/14



ASSENT FORM

EMPOWR: Efforts to Maximize Perinatal Outcomes in Women at Risk

You are being invited to take part in a research study done by Kristin Ashford, ARNP, PhD and John O'Brien, MD from the University of Kentucky. Research studies are done with doctors and nurses who want to find ways of treating patients. You are invited to take part in a research study about receiving group prenatal care during your pregnancy in a small group setting of 8-10 pregnant women. The group prenatal care, known as CenteringPregnancy® will include everything you receive in traditional prenatal care, including individual check-ups, without having to spend time in a waiting room. In addition, you will receive additional education on childbirth, breastfeeding, and caring for your newborn. You are being invited to take part in this research study because you are pregnant. If you volunteer to take part in this study, you will be one of about 1600 women at the University of Kentucky prenatal clinics to do so.

You will have the same number of visits and testing/screening procedures as you would have if you did not participate in this study. Each group prenatal care appointment will be held during a prescheduled appointment time and will be with the same small group of 8-10 pregnant women, a healthcare provider, and your group facilitator.

During today's visit, and again at the eighth prenatal group care appointment, you will be asked to complete a brief, 20 minute survey. The survey will ask questions related to your psychosocial health (anxiety, stress, and depression), perceived support, and general health and well-being (sleep, diet, exercise). All surveys and study samples are identified by a code number (not your name) and are confidential.

We will also collect a urine sample from all participants to measure the level of cotinine in your urine. This measurement will show whether you have smoked cigarettes in the last 1-2 days.

In addition, you may be invited to participate in a Focus Group. This is a small group of women who will share ideas and opinions about this study. Participating in the Focus Group is optional and does not change your prenatal care during your pregnancy.

There is always the possibility that you may experience a previously unknown risk or side effect while participating in this study. Your family and your doctor and nurses will know that you are in the study. If anyone else is given information about you, they will not know your name. A number of initials will be used instead of your name.

If something makes you feel bad while you are in the study, please tell the Investigator Kristin Ashford (859-257-9333), the Lead Facilitator Janine Barnett (859-333-1572) or your parent. If you decide at any time you do not want to finish the study, you may stop whenever you want.



You can ask the Investigator Kristin Ashford (859-257-9333), the Lead Facilitator Janine Barnett (859-333-1572) or study nurses questions any time about anything in the study. You can also ask your parent(s) any questions you might have about the study.

Signing this paper means that you have read this or had *it* read to you and that you want to be in the study. If you do not want to be in the study, do not sign the paper. Being in the study is up to you, and no one will be mad if you do not sign this paper or even if you change your mind later. You agree that you have been told about this study and why it is being done and what to do.

\_\_\_\_\_  
Signature of person agreeing to be in the study

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of (authorized) person obtaining informed consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

IRB approved 5/29/2014  
*[Handwritten signature]*

Appendix D. Gestational Diabetes Mellitus Education Record



Name: _____		Gender: <input type="checkbox"/> M <input type="checkbox"/> F		Age: _____		Date: _____	
Interpreter: <input type="checkbox"/> Yes <input type="checkbox"/> No		Spanish Materials Provided: <input type="checkbox"/> Yes <input type="checkbox"/> No		Key: Pre / Post program Knowledge/Skill Level			
1. Needs Instruction   2. Needs Review/Assistance   3. Verbalizes/Demonstrates Competency   4. N/A (Not Applicable)							
At Risk for GDM		Pre-Program	Date	Date	Date	Post-Program	Comments/Education Materials
1. Describes risk factors for GDM							
2. Recognizes healthy nutrition and physical activity appropriate for pregnancy							
3. GDM Diagnosis <i>Date:</i> _____							
4. Referred for GDM education intervention at Diagnosis <input type="checkbox"/> Yes <input type="checkbox"/> No							
Diagnosis of GDM GDM education activities based on the AADE7 <sup>1</sup> self-care behaviors		Pre-Program	Date	Date	Date	Post-Program	Comments/Education Materials
5. Incorporate appropriate <b>healthy eating</b> / nutrition management for GDM							
<input type="checkbox"/> RD instruction provided <i>Date:</i> _____ <input type="checkbox"/> <b>Carbohydrate Allowances:</b> <b>Carb Grams</b> <b>Carb Choices</b> <b>Breakfast</b> Carbs:                    _____                    _____ <b>Snack #1</b> Carbs:                    _____                    _____ <b>Lunch</b> Carbs:                        _____                    _____ <b>Snack #2</b> Carbs:                    _____                    _____ <b>Supper</b> Carbs:                        _____                    _____ <b>Snack #3</b> Carbs:                    _____                    _____ *Carb(s)="Total Carbohydrate"							
6. <b>Being active</b>							
<input type="checkbox"/> "Exercise during pregnancy" booklet <sup>2</sup> provided							
7. <b>Monitoring</b>							
<input type="checkbox"/> Provided blood glucose monitor <i>Name of meter / control check result recorded</i> <input type="checkbox"/> Documentation of patient SMBG return demonstration <input type="checkbox"/> SMBG log-book provided <input type="checkbox"/> Parameters for BG control provided <input type="checkbox"/> Attained/reviewed BG records at each visit via patient log-book, meter download <sup>**</sup> , or both <i>Date(s):</i> _____ BG results within goal <sup>4</sup> at each visit discussed with patient; BG results outside of goal <sup>4</sup> at any visit, referred for medication therapy? <i>Date:</i> _____							
8. <b>Taking medication (if applicable)</b>							
<input type="checkbox"/> Medication instruction: o Glyburide o Metformin o Other: _____ <input type="checkbox"/> Return demonstration (insulin) <i>Date:</i> _____							
9. <b>Problem solving</b>							
<input type="checkbox"/> Risk for hypoglycemia <input type="checkbox"/> Verbalizes signs and symptoms of hypoglycemia <input type="checkbox"/> Identifies appropriate treatment for hypoglycemia							
10. <b>Reducing risks</b>							
<input type="checkbox"/> "Did You Have Gestational Diabetes When You Were Pregnant? What You Need to Know" booklet <sup>3</sup> provided							
11. <b>Healthy coping</b>							
<input type="checkbox"/> "What I need to know about GDM" booklet <sup>3</sup> provided (Section: How will GDM affect me?)							
Date of Delivery: _____				Infant Birth Weight/Gestational Age at Delivery: _____			
<small> <sup>1</sup>American Association of Diabetes Educators. <i>The AADE7™ self-care behaviors</i>. Retrieved from: <a href="http://www.diabeteseducator.org/ProfessionalResources/AADE7/">http://www.diabeteseducator.org/ProfessionalResources/AADE7/</a>; <sup>2</sup>The American College of Obstetricians and Gynecologists. <i>Exercise during pregnancy</i>. <a href="http://www.acog.org/~media/For%20Patients/faq119.pdf?dmc=1&amp;ts=20140310T1712163140">http://www.acog.org/~media/For%20Patients/faq119.pdf?dmc=1&amp;ts=20140310T1712163140</a>; <sup>3</sup>National Institutes of Health. <i>National Diabetes Education Program, gestational diabetes mellitus booklets (English and Spanish versions)</i>. Retrieved from: <a href="http://ndep.nih.gov/am-i-at-risk/gdm/index.aspx">http://ndep.nih.gov/am-i-at-risk/gdm/index.aspx</a>; <sup>4</sup>Coustan, D. R., (Ed) (2014). <i>Medical management of pregnancy complicated by diabetes, 5<sup>th</sup> ed.</i> Alexandria, VA: American Diabetes Association (p. 141).                      **any patients entering the CenteringPregnancy program is required to enroll prior to 20 weeks; **meter <u>must</u> be downloaded with each visit (unless patient did not bring it which should be documented; collect self-reported SMBG records, retrieved from: <a href="https://www.cdappswetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf">https://www.cdappswetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_English.pdf</a> <a href="https://www.cdappswetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf">https://www.cdappswetsuccess.org/Portals/0/Documents/Nutrition/Patient%20Diary_Daily%20Record%20Sheet_Spanish.pdf</a>)                      GDM=Gestational Diabetes Mellitus; CP=CenteringPregnancy™; AADE=American Association of Diabetes Educators; RD=Registered Dietitian; SMBG=self-monitoring of blood glucose; BG=blood glucose;                 </small>							

Appendix E. **CenteringPregnancy Evaluation**

Please give us feedback on your experience over the past months with CenteringPregnancy. Is this your first baby? \_\_\_yes \_\_\_no

**Check the column that best describes how helpful the discussions of each of these topics were for you.**

TOPIC	Not Helpful	Somewhat Helpful	Very Helpful	Not discussed
Common changes in Pregnancy				
Nutrition				
Exercise and relaxation				
Pregnancy problems				
Breastfeeding and infant feeding				
Sexuality and family planning				
Family and relationships				
Family violence and abuse				
Labor and birth				
Baby care and parenting				
Postpartum care				
Emotional changes and depression				

*Please turn over and continue on the back.*



Appendix F. American Association of Diabetes Educators, *AADE in Practice* and American Diabetes Association, *Diabetes Spectrum*: Citations/Links for Author Guidelines

American Association of Diabetes Educators (2015). *AADE in Practice: Manuscript submission*

*guidelines*. Retrieved from

<http://www.sagepub.com/journals/Journal202157/manuscriptSubmission>

American Diabetes Association (2015). *Diabetes Spectrum: Instructions for authors*. Retrieved

from <http://spectrum.diabetesjournals.org/site/misc/ifora.xhtml>



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- American Association of Diabetes Educators (2015). *Diabetes education accreditation program*. Retrieved from <http://www.diabeteseducator.org/ProfessionalResources/accred/>
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