DIABETES AND NUTRITION EDUCATION FOR PREGNANT WOMEN WITH PREEXISTING DIABETES IN URBAN ALASKA: A RETROSPECTIVE QUALITY IMPROVEMENT STUDY

By

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Abstract

There has been a rise in the number of women entering pregnancy with preexisting type 1 and type 2 diabetes due to changing demographics of the obstetric population, including advanced maternal age and obesity. Uncontrolled diabetes during pregnancy is directly correlated with adverse perinatal outcomes. Educational approaches need to be taken to decrease the advancement of an intergenerational cycle of diabetes fueling the current global epidemic. This retrospective chart review aimed to evaluate the relationships between completion of education (i.e., diabetes or nutrition) and outcomes measures (i.e., glycemic control and birth outcomes) in mothers with preexisting diabetes at an urban Alaska health system for the purpose of quality improvement in clinical practice.

Education provided by a registered dietitian nutritionist and/or certified diabetes educator in accordance with the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020* improves clinical outcomes, behaviors, and quality of life. In this study, data from 78 charts were reviewed including BMI, HbA1c preconceptionally and during each trimester, pregnancy complications (i.e., preeclampsia), birth outcomes (i.e., gestational age, birth weight, cesarean delivery, shoulder dystocia, malpresentation, premature rupture of membrane, postpartum hemorrhaging, and fetal loss), demographics (i.e., age, employment status, ethnicity), and completion of diabetes education or nutrition education. The insufficient availability of outcome measures documented in medical charts and low numbers of medical record sharing among facilities limited the ability to evaluate the impact of education on glycemic control and subsequent birth outcomes in this study.

The systematic evaluation of outcomes is the backbone to demonstrating the efficacy of registered dietitian nutritionists and certified diabetes educators in helping women achieve glycemic self-management outcomes. In terms of quality improvement, more documentation is needed. Medical data needs to reflect overall care provided in order to gauge the effect of

education on glycemic control and birth outcomes. To decrease barriers of reviewing a chart, the extraction of chart data should be accomplished solely by the principal investigator. Recommendations for future outcomes studies should include collecting data on a continuum of clearly defined blood glucose levels during pregnancy to reflect the effect diabetes and nutrition education has on glycemic control and birth outcomes.

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Operational Definitions

Acceptable blood glucose level during pregnancy: According to the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020*

- Benchmark: HbA1c < 6.5%
    - Pre-prandial blood glucose 60 to 99 mg/dL
    - Fasting blood glucose < 95 mg/dL and either
    - One-hour postprandial < 140 mg/dL or
    - Two-hour postprandial < 120 mg/dL[1]

Unacceptable blood glucose level during pregnancy: According to the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020*

- HbA1c ≥ 6.5%
    - Pre-prandial blood glucose > 99 mg/dL
    - Fasting blood glucose ≥ 95 mg/dL and either
    - One-hour postprandial ≥ 140 mg/dL or
    - Two-hour postprandial ≥ 120 mg/dL[1]

Diabetes education: The process of facilitating knowledge, skills, and ability necessary for diabetes self-care to improve clinical outcomes, health status, and quality of life with the guidance of a certified diabetes educator (CDE), registered nurse, pharmacist, or other trained health professional.[2,3]

Certified diabetes educator: A health professional (i.e., registered dietitian nutritionist, registered nurse, or medical doctor) who has completed a minimum number of hours in clinical diabetes practice, passed the Certification Examination for Diabetes Educators, and has responsibilities that include the direct provision of diabetes education.[2]

Diabetes-self management education: American Diabetes Association recommended education with core content including diabetes disease process treatment options; incorporating nutritional management and physical activity into lifestyle; using medications safely for maximum therapeutic effectiveness; monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making; preventing, detecting, and treating acute and chronic complications; developing personal strategies to address psychosocial issues and concerns; and developing personal strategies to promote health and behavior change.[4]

Nutrition education: Diagnostic, therapy, and counseling services administered by a registered dietitian nutritionist (RDN) for the purpose of establishing diabetes management to promote and support healthful eating patterns, address individual nutrition needs, provide nonjudgmental messages about food choices and provide the individual with practical tools for developing healthy eating patterns.[5]

Medical nutrition therapy: Treatment of a disease or condition through the modification of nutrient or whole-food intake. An evidence-based application of nutrition care process provided by a registered dietitian nutritionist. Components of medical nutrition therapy include assessment, nutrition diagnosis, interventions (e.g., education and counseling), and monitoring with ongoing follow-up to support long-term lifestyle changes, evaluate outcomes, and modify interventions as needed.[6]

Preexisting/pregestational diabetes: A diagnosis of type 1 diabetes or type 2 diabetes prior to pregnancy, excluding gestational diabetes.

Macrosomia: Refers to growth beyond specific threshold regardless of gestational age, a fetus larger than 4000 to 4500 grams.[7]

Hemoglobin A1c (HbA1c): An integrated measure of glucose, reflecting average glycemia over approximately three months. This measure helps determine if glycemic targets have been reached and maintained. HbA1c does not measure glycemic variability or hypoglycemic events.[8]

Completion of education: Attended at least one diabetes education or nutrition education appointment during pregnancy provided by a registered dietitian nutritionist or certified diabetes educator.

Gestational hypertension:

- Systolic blood pressure $\geq$ 140 mm Hg
- Diastolic blood pressure $\geq$ 90 mm Hg or both (on two occasions at least four hours apart)
- After 20 weeks of gestation in a woman with a previously normal blood pressure
- Absence of proteinuria[9]

Mild preeclampsia

- Systolic blood pressure $\geq$ 140 mm Hg
- Diastolic blood pressure $\geq$ 90 mm Hg or both (on two occasions at least four hours apart)
- After 20 weeks of gestation in a woman with a previously normal blood pressure
- $\geq$ 300 mg/dL of protein in a 24-hour urine collection[9]

Severe preeclampsia:

- Systolic blood pressure $\geq$ 160 mm Hg
- Diastolic blood pressure $\geq$ 110 mm Hg or both (on two occasions at least four hours apart)
- After 20 weeks of gestation in a woman with a previously normal blood pressure
- $\geq$ 500 mg/dL of protein in a 24-hour urine collection[9]

Eclampsia: The convulsive manifestation of the hypertensive disorders of pregnancy. New-onset tonic-clonic, focal, or multifocal seizures in the absence of other causative conditions.[9]

Chapter 1: Introduction

There has been a rise in the number of women entering pregnancy with preexisting type 1 and type 2 diabetes due to changing demographics of the obstetric population, including advanced maternal age and obesity.[10] "If one-fifth of the 30 million type 2 sufferers in the U.S. used dietary changes to reduce HbA1c levels by 1 percent, they would not only reverse the course of their diabetes, but the healthcare system would also save at least $10 billion annually and outcomes would improve measurably."[11 p.1] Preexisting diabetes during pregnancy is correlated with adverse perinatal outcomes such as macrosomia and subsequent cesarean delivery, congenital malformation, preterm birth, stillbirth, neonatal mortality, preeclampsia, and exacerbated maternal microvascular disease.[10] Individualized educational approaches need to be utilized to promote glycemic control for women with preexisting diabetes and decrease the advancement of an intergenerational cycle of diabetes fueling the current global epidemic. Approaches to diabetes self-management should focus on modifying population-specific lifestyle behaviors which are reinforced by obtaining education and skills.[12] Problematic lifestyle behaviors of pregnant women with preexisting diabetes may include poor diet, decreased physical activity, and pharmacotherapy noncompliance. These behaviors need to be adapted to manage glycemic targets and increased complexity of insulin management. The education and skills taught should support the needs of the obstetric population affected by preexisting diabetes and recognize the metabolic changes that foster fetal development. Effective diabetes and nutrition education have been shown to improve clinical outcomes (i.e., anthropometrics, HbA1c, blood glucose, serum lipids, blood pressure) that exacerbate adverse perinatal outcomes, behaviors, quality of life, and result in cost savings.[13] Barriers to preconception education need to be identified and women need to have equal access to prenatal care.

Currently, there is no consensus of the structure of a multidisciplinary team care for pregnancy and diabetes. Prenatal care should consist of nutrition and diabetes education to help women achieve optimal glycemic control. Education helps reduce risks by glycemic goal setting, lifestyle management, and medical nutrition therapy.[14] Outcome measures (i.e., HbA1c, blood glucose levels, gestational age, birth weight, pregnancy complications) of education must be tracked regularly. Documented outcome measures support the efficacy of registered dietitian nutritionists (RDN) and certified diabetes educator (CDE), thus supporting chart review as one methodology for outcomes research.[4] The use of a retrospective quality improvement chart review also affords time-sensitive and cost-effective dissemination of outcomes to stakeholders.[13] By conducting a retrospective chart review focused on outcomes research, one can identify education processes and subsequent birth outcomes related to glycemic control during pregnancy for the purpose of quality improvement.

Research purpose:

The purpose of this project was to evaluate the birth outcomes and glycemic control of pregnant women with preexisting diabetes receiving diabetes education or nutrition education by a registered dietitian nutritionist (RDN) or certified diabetes educator (CDE) during pregnancy compared to women that do not receive education with a goal of promoting quality assurance and identifying opportunities for evaluating adherence to the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020*.

Objectives:

1. Examine relationships between completing diabetes education or nutrition education appointments and HbA1c levels amongst pregnant women with preexisting diabetes type 1 and type 2 diabetes.
2. Examine relationships between completing education and birth outcomes (i.e., gestational age, birth weight, cesarean delivery, shoulder dystocia, malpresentation, premature rupture of membrane, postpartum hemorrhaging, and fetal loss) amongst pregnant women with preexisting type 1 and type 2 diabetes.

3. Examine relationships between HbA1c during each trimester to demographics (i.e., ethnicity and employment status), pregnancy risks (i.e., BMI, age, chronic hypertension, multiparity) and outcome variables (i.e., pregnancy complications)

Research question:

Is the completion of diabetes education or nutrition education among pregnant women with preexisting diabetes at an urban Alaska health system associated with the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020* recommendations for glycemic control?

Subquestion:

1. How does data from this sample compare to previous research?

Chapter 2: Literature Review

Search terms used for the literature review included: preexisting diabetes, type 1 diabetes, type 2 diabetes, pregestational diabetes, pregnancy, birth outcomes (i.e., congenital malformations, macrosomia, preterm birth, shoulder dystocia, malpresentation, premature rupture of membrane, postpartum hemorrhaging, cesarean delivery), pregnancy complications (i.e., preeclampsia), prenatal education, diabetes education, diabetes self-management education, nutrition education, and medical nutrition therapy. Selected literature was published between 2008 and 2020 and found through PubMed and Google Scholar.

Pregestational Diabetes and Pregnancy

During pregnancy, all women enter a diabetogenic state in which postprandial glucose levels are elevated and insulin sensitivity is decreased due to the presence of growth factors, placenta hormones, and cytokines.[15] This diabetogenic state begins during the second trimester and insulin resistance peaks during the third trimester. During the second trimester when women become more insulin resistant, insulin needs may change on a weekly basis. Physiological changes that occur during pregnancy are essential for sufficient nutrition and growth of the fetus. Changes include increased hepatic glucose production in the fasting state and maternal peripheral insulin resistance, which increases glucose supply and availability to the fetus.[16]

Women with type 2 diabetes are more likely to achieve euglycemia with treatment, compared to women with type 1 diabetes.[17] For women with type 1 diabetes, this feat is more challenging and needs to be balanced with risks of hypoglycemia.[17] Insulin therapies need to be safe, individualized, and adapted to women's needs as they progress through pregnancy. This is especially important during delivery as women are increasingly sensitive to insulin and insulin needs drop to 50 to 90% of prepregnancy needs.[18] For women with preexisting diabetes, these changes during pregnancy equate to fluctuating glucose levels and the need for nonjudgmental and positively focused care provided by qualified health care professionals.[1]

Maternal glucose metabolism adapts during pregnancy in order to provide a continuous supply of glucose to the fetus. These metabolic changes coupled with preexisting diabetes affect placenta growth kinetics and contribute to the fetus developing hyperinsulinemia.[16] Fetal hyperinsulinemia increases the glucose gradient across the placenta and consequently the glucose flux to the fetus in an effort to decrease fetal glycemia. The gradient is greatest when maternal hyperglycemia and fetal hyperinsulinemia coexist, but fetal hyperinsulinemia favors the high gradient even when maternal blood glucose is normal.[16] To prevent the development of fetal hyperinsulinemia, maternal glycemic control needs to be established early in pregnancy.[16]

Hyperglycemia in early pregnancy coupled with taking potentially teratogenic diabetes medication leads to adverse fetal outcomes.[19] Maternal fasting blood glucose measured at nine to ten weeks gestation is directly correlated with risk for a large for gestational age birth.[16] Around 14 weeks gestation, maternal hyperglycemia induces fetal hyperinsulinemia, accelerated growth, and excess adiposity which may result in macrosomia.[20] Macrosomia occurs due to increased transport of maternal glucose and amino acids to the fetus which results in excessive fetal insulin. Excessive insulin and maternal substrates promote excessive fetal growth. Obese and overweight mothers have a two-fold increased risk of delivering a macrosomic infant.[21] An observational retrospective study by Cyagnek, et. al., indicated that there is a linear relationship between third trimester hemoglobin A1c (HbA1c) and macrosomia risk in HbA1c range from 4.5 to 7.0%.[22] Macrosomia occurs in 27 to 62% of infants of diabetic mothers and is associated with increased rate of operative delivery, birth trauma, fetal loss, and neonatal hypoglycemia.[20] Macrosomic infants of diabetic mothers also have increased hospital admissions during the neonatal period for hypoglycemia, jaundice, respiratory distress and asphyxia.[23] Macrosomia is also associated with increased incidence of shoulder dystocia, brachial plexus injury, and malpresentation.[24] Macrosomic infants are at an increased risk of for long-term complications such as obesity and insulin resistance.[25] Glycemic control is necessary through the entire pregnancy to prevent diabetic fetopathy (e.g., macrosomia).[16]

Pregestational Diabetes and Pregnancy Outcomes

Poorly managed diabetes mellitus during pregnancy is associated with poor fetal health outcomes.[26] Lack of glycemic control during fetal organogenesis which occurs during the first few weeks of pregnancy is correlated with spontaneous abortion and congenital malformations.[20] A study by Zhao, et. al., revealed that hyperglycemia during pregnancy induces the development of hyperglycemia in the embryo before the onset of insulin production which affects the expression of genes involved in cell proliferation, cytoskeleton, and energy metabolism.[27] Maternal diabetes is highly associated with congenital malformations of the cardiovascular and neural systems due to some genes being differentially regulated by hyperglycemia.[27] Congenital malformations that are often reported include neural-tube and heart defects, kidney dysgenesis and the caudal regression syndrome.[27] Neurodevelopmental outcomes effected by preexisting diabetes during pregnancy include lower long-term cognitive function and poor academic performance, higher risk of autism and attention deficit/hyperactivity disorder.[18] Diabetes in pregnancy also increases the risk of the infant developing obesity or type 2 diabetes later in life.[28] The long-term developmental programming in the infant caused by diabetes during pregnancy may also lead to adverse cardiometabolic profiles and greater risk of hospital admissions, medication, and mortality.[18,29] Uncontrolled diabetes during pregnancy increases the risk of the infant developing infections as a result of cesarean delivery.[29] Preexisting diabetes during pregnancy is also associated with the premature rupture of membranes (PROMs) in which the amniotic membrane ruptures before 37 weeks gestation. Complications of PROMs include intra-amniotic infection, placental disruption, fetal distress, fetal restrictive deformities, pulmonary hypoplasia, preterm birth, and fetal or newborn loss.[30]

Maternal complications related to lack of glycemic control during pregnancy include progression of retinopathy and nephropathy, preeclampsia, and preterm labor.[20] Type 2 diabetes during pregnancy is associated with higher risk of perinatal mortality and type 1 diabetes is associated with higher rates of diabetic ketoacidosis and cesarean delivery.[18]

Obesity is common among women with preexisting diabetes. One third of pregnant women are reported to be overweight or obese, which increases with age.[24] Obesity during pregnancy is associated with greater congenital malformations, especially cardiac defects.[18] Research indicates that the coexistence of obesity and diabetes increases the likelihood of adverse maternal and fetal outcomes.[24] High prepregnancy BMI levels are correlated with preterm births and large for gestational age preterm infants.[24] Obesity and macrosomic fetus rates increase cesarean delivery rates. Gestational weight gain increases the incidence of adverse pregnancy outcomes.[24] Women that are obese are more likely to have hypertension, hyperlipidemia, and obstructive sleep apnea (OSA). OSA is linked to higher rates of gestational hypertension, preeclampsia, preterm birth, and greater need for neonatal intensive care units. OSA is also associated with worse glycemic profiles and insulin resistance. Pregnant women with chronic hypertension and diabetes have higher risk of pregnancy loss, preterm delivery, and low birth weight.[18] Adverse postpartum outcomes are associated with elevated HbA1c levels before pregnancy and early pregnancy.[29] Women with comorbidities, such as hypertension or obesity, would benefit from individualized care to reduce the risk of adverse pregnancy outcomes.[18]

Women with preexisting diabetes are at an increased risk of developing preeclampsia, gestational hypertension, and polyhydramnios.[24] Risk factors for preeclampsia among women with preexisting diabetes include nulliparity, advanced maternal age, previous preeclampsia, hypertension, a longer duration of diabetes, microalbuminuria, nephropathy and retinopathy, and poor glycemic control.[31] Most pregnant women with preexisting diabetes require an increase in insulin dosage with advanced gestation, but a proportion of women require a reduction in insulin requirements during late pregnancy. This decrease in insulin requirements is associated with preeclampsia, small for gestational age, and increased admission to the neonatal intensive care unit. Falling insulin requirements are considered to be a marker of fetal placental compromise, prompting hospital admission and potential risk of early delivery. An imbalance of placental biomarkers such as proangiogenic factors, placental growth factor

(PlGF), and antiangiogenic factors, such as soluble fms-like tyrosine kinase 1 (sFlt-1) are used to predict and diagnose obstetric complications associated with placental dysfunction. In women with falling insulin requirements, the sFlt-1/PlGF ratio was higher regardless of factors that have previously been shown to lower PlGF levels, including maternal age, BMI, ethnicity, nulliparity, and smoking status indicating placental dysfunction. Women with preeclampsia had even higher sFlt-1/PlGF ratio at 25 and 36 weeks.[32]

Pregestational Diabetes and Prepregnancy Care

Although rates of unintended pregnancies have decreased in past years, nearly half of all pregnancies in the US are unplanned.[18] Many women do not seek preconception care and planning for diabetes due to certain maternal characteristics including poor health literacy, tobacco use, being unmarried, lower family income, and poor relationships with providers.[18] Studies indicate that glycemic control early in pregnancy is integral due to fetal organogenesis.[18] Research also indicates that the maternal metabolic environment affects fetal growth as early as prepregnancy, through modification of oocyte metabolism.[16] Women that do not participate in prepregnancy planning place their offspring at greater risk for developing congenital anomalies associated with uncontrolled diabetes.[18] Elevations of HbA1c in early pregnancy are directly proportional to increased risk of diabetes embryopathy including anencephaly, microcephaly, congenital heart disease, renal anomalies, and caudal regression.[14] Prepregnancy care is associated with improved glycemic control early in pregnancy and subsequent decreased risk of adverse outcomes. Prepregnancy care results in reduced risk of spontaneous abortion, adverse pregnancy outcomes, and premature delivery (before 34 weeks' gestation).[21] A lack of prepregnancy care is associated with higher rates of macrosomia and congenital malformations among women with pregestational diabetes.[15] Common challenges of diabetes management include lack of knowledge among women and health care providers and limited access to prepregnancy diabetes care.[15]

Women with diabetes should be educated at the onset of diabetes or during puberty about the risks of unplanned pregnancy and diabetes.[18] Prepregnancy care results in improved HbA1cs, reduced glycemic variability, and decreased hypoglycemic events and improved awareness.[33] Glycemic assessment at the end of the first trimester does not adequately represent glycemic control at the time of organogenesis, emphasizing the importance of early assessment amongst women with preexisting diabetes.[21] In a recent study that explored women's experiences and perceptions of pregnancy-related diabetes management and support systems facilitating their self-management, most women reported lack of support and empathetic engagement from their health care team.[34] Education and support that is provided by a registered dietitian nutritionist (RDN) or certified diabetes educator (CDE) during perinatal care may initiate positive behavior change and optimize glycemic control, which can have improved outcomes of pregnancy, childbirth, and early parenting.

Management of Pregestational Diabetes

Pregnant women with preexisting diabetes that face greater social deprivation are less likely to achieve glycemic control.[19] Social determinants of health may dictate the level of lifestyle change women adhere to, further complicating the type of education that is needed.[35] Social determinants of health are the conditions in the environment in which people exist that affect their health, functioning, and quality of life. These may include quality of education, employment status, access to health services, cultural demands, and social support which all influence the management of diabetes during pregnancy.[36] Evidence indicates that epigenetic processes are main contributors by which environmental stimuli activate disease promoting pathways.[37] Racial and ethnic disparities exist among women with pregestational diabetes. Higher rates of pregestational diabetes occur among Black, Hispanic, and Alaska Native/American Indian women and lower rates in non-Hispanic, White, and Asian women.[38] The outcomes of current diabetes and nutrition education interventions need to be examined to promote improved quality of care and birth outcomes for all pregnant women with preexisting diabetes. Diabetes education provided by RDNs or CDEs is the foundation to help women with diabetes navigate the multitude of daily self-management decisions and perform complex care activities. Studies have shown that care provided by a multidisciplinary team from preconception through pregnancy is associated with improved diabetes and pregnancy outcomes.[14] For women with preexisting diabetes, preconception care is an opportunity to review diabetes management, adjust medications, and manage comorbidities.[39] The assessment of prepregnancy care by Newman, et. al., included optimizing glycemic control, folic acid use, and smoking cessation to improve pregnancy outcomes among women with pregestational diabetes.[40] The goals of the American Diabetes Association (ADA) are to improve the patient experience of care and education, to improve the health of individuals and populations, and to reduce diabetes-associated per capita health care costs.[2] It is the responsibility of the health care community to provide quality care that mobilizes efforts to address barriers and explore resources for diabetes and nutrition education in order to meet the needs of pregnant women with preexisting diabetes.[2]

A full spectrum of modifiable risk factors are associated with preexisting diabetes including optimization of blood glucose levels and supported lifestyle changes.[40,41] Glycemic targets are stricter during pregnancy and women need to be assisted in establishing food plans with an ideal insulin to carbohydrate ratio to avoid hyperglycemia or hypoglycemia.[14] Nutrition education focuses on key factors that are common among healthful eating patterns including emphasizing non-starchy vegetables, minimizing added sugars and refined grains, and choosing whole foods over highly processed foods to the extent possible.[6] The American College of Obstetrics and Gynecology recommends self-monitoring of blood glucose using fingerstick glucose values recorded in glucose logs. Glucose logs are commonly reviewed at least every one to two weeks during the first two trimesters and weekly after 24 to 28 weeks of gestation in order to adapt the treatment regimen to fluctuating insulin needs.[38] Fasting, pre-prandial, and postprandial monitoring of blood glucose is recommended to achieve glycemic control. The ADA recommendations for blood glucose levels are listed in the Operational Terms section of this paper. Individualized treatment goals may need to be established if women are not able to safely reach recommended targets. Frequent titration of insulin is common during pregnancy because of the changes in insulin resistance, underscoring the importance of frequent self-monitoring. Research is limited regarding the efficacy of using metformin and glyburide, making insulin therapy the optimal choice.[14] RDNs and CDEs play a vital role in helping women manage glycemic control.[4] Glycemic control is variable during pregnancy and research is limited regarding optimal targets for fasting and postprandial glycemia.[14] ADA defined targets should be individualized for women at risk of hypoglycemia.[14] Women with type 1 diabetes are more likely to experience hypoglycemia due to an altered counterregulatory response which decrease hypoglycemia awareness during pregnancy.[14] Women are also at risk for ketoacidosis due to the ketogenic state of pregnancy from increased maternal metabolic needs and fetal demands.[14] Education provided by RDNs and CDE includes a specific carbohydrate to insulin ratio to prevent hypoglycemia and hyperglycemia during pregnancy.[14]

Women may need regular counseling sessions to not only help manage the changes in insulin resistance but also to establish and maintain weight management goals during pregnancy.[14] Recommended weight gain during pregnancy for overweight women is 15 to 25 pounds and for obese women is 10 to 20 pounds. The ADA states that there is no optimal weight gain versus weight maintenance in women with a BMI > 35 kg/m^2.[14] Developing healthy eating patterns perinatally help decrease diabetes comorbidity risks.

The American Heart Association recognizes preeclampsia as a risk factor for future cardiovascular disease and stroke in women.[42] Maternal risk factors for preeclampsia include prepregnancy obesity, advanced maternal age, black race, and chronic hypertension.[42] Women that are preeclamptic during pregnancy and have preexisting diabetes are at higher risk of microvascular complications later in life.[42] Pathophysiology of preeclampsia is elusive but it has been hypothesized that women who develop preeclampsia are more insulin resistant prior to pregnancy.[42] There are different stages of high blood pressure during pregnancy: gestational hypertension, mild preeclampsia, severe preeclampsia, and eclampsia (see Operational Definitions). Medical nutrition therapy (MNT) and diabetes self-management education (DSME) improve glycemic control and hypertension through individualized lifestyle interventions. Diabetes nutrition education includes developing an eating plan designed to optimize blood glucose trends, blood pressure, and lipid profiles which decreases markers of cardiovascular disease and hypertension.[6] Diet modifications may include a DASH-style diet (Dietary Approached to Stop Hypertension), increasing fiber, and decreasing saturated fat and cholesterol.[6] Poor glycemic control and insulin resistance are risk factors for preeclampsia. Research is limited regarding the role that MNT plays in the prevalence of preeclampsia during pregnancy. Diabetes counseling provided by a RDN or CDE should include an explanation of the maternal and fetal risks associated with pregnancy and ways to reduce risk.

Providers need to be empathetic and supportive with their approaches.[14] Numerous reports have identified the negative psychological impact on pregnant women with preexisting diabetes due to the demanding glucose management regimen from preconception to birth.[34] Women with preexisting diabetes during pregnancy experience greater levels of stress, anxiety, and worry related to the difficulty of comanaging diabetes and pregnancy.[34] Through a retrospective quality improvement study, existing data that reflects current practices and operational approaches to diabetes and nutrition education can be extracted and disseminated to foster quality improvement initiatives and explore the efficacy of RDNs and CDEs.[13]

Quality Improvement of Pregestational Diabetes Education

This retrospective chart review focused on diabetes education and nutrition education provided by an urban Alaska health system and the subsequent birth outcomes of women with preexisting diabetes related to perinatal glycemia, pregnancy risks, and potential confounding factors to drive quality improvement. Annually in the United States, approximately 0.9% of the 4 million births are complicated by preexisting diabetes.[18] The Pregnancy Risk Assessment

Monitoring System 2009 to 2010 found that only 53% of women with preexisting diabetes received preconception care before pregnancy.[39] Although the rate of diabetes among women of childbearing age in Alaska is lower than the national average (7.6% versus 8.3%), it is steadily rising every year, increasing the cost of healthcare as well as the burden on the family.[43] The Indian Health Services Diabetes Care and Outcomes Audit indicated that in 2014, 54% of female Alaska Native people statewide seen at any IHS facility had diabetes.[44] The Centers for Disease Control and Prevention reported that from 2000 to 2010 the percentage of preexisting type 1 and type 2 diabetes amongst women aged 18 to 44 has increased 37% in the U.S.[45] It is indisputable that there is a need for focused perinatal diabetes and nutrition education. All women with pregestational diabetes need to receive individualized education to develop appropriate diabetes self-management skills and knowledge during pregnancy, which promotes positive birth outcomes and ultimately improves the health of our next generation. By completing a retrospective chart review with a focus on outcomes research for the purposes of quality improvement, the effectiveness of diabetes or nutrition education during pregnancy can be evaluated and possibly improved.

Chapter 3: Methods

After receiving University of Alaska Anchorage and Swedish Institutional Review Board approval (Appendix A), a retrospective chart review focused on outcomes research was conducted at an urban Alaska health system for the purposes of quality improvement. Inclusion criteria included: females of childbearing age, type 1 or type 2 diabetes diagnosis prior to pregnancy, and patient at an urban Alaska health system. Exclusion criteria included gestational diabetes diagnosis and nonpregnant women. Eighty-five medical records of previously pregnant women were reviewed. Medical charts were reviewed for all women that had pregestational diabetes from 2017 to 2019 and gave birth at an urban Alaska health system. The urban Alaska health system includes an inpatient hospital, neuroscience center, outpatient diabetes and nutrition center, urgent care facilities, extended care facility, family medical center, behavioral health facility, maternal-fetal medicine clinic, palliative care clinic, laboratory services, pediatric clinics, palliative care clinic, rehabilitation center, and a pulmonology and sleep clinic. Data collected included completion of diabetes education, completion of nutrition education, demographics (age, ethnicity, gravida para, employment status), type of diabetes, duration of diabetes diagnosis, BMI, patient health history (chronic hypertension), blood sugar levels for each trimester, HbA1c for each trimester, birth outcomes (gestational age, birth weight, mode of delivery, shoulder dystocia, malpresentation, premature rupture of membrane, postpartum hemorrhage, fetal loss), and pregnancy complications (preeclampsia) (Appendix B). Completion of diabetes or nutrition education was identified as yes or no based on documentation in the education portion of the medical record. Health system staff extracted data and provided it to the principal investigator. All personal health information was de-identified and coded at the point of extraction and kept on a password protected computer. Data was stored on password protected computer until the conclusion of the research project, at which point it will be destroyed. Outcome measures included HbA1c during each trimester (if available) and resultant birth outcomes.

For this project it was assumed that measures of HbA1c during the first trimester indicate prepregnancy glycemia which is a surrogate marker for diabetes control prior to conception related to the completion of preconception education. Diabetes and nutrition education were assumed to be provided by a RDN or CDE. Data regarding which trimester diabetes education and nutrition education was completed was not included in this research project. It is also unknown whether all women received referrals for diabetes education or nutrition education. No assumptions were made regarding blood sugar levels due to the variability of acceptable fasting levels compared to postprandial levels.

Analysis

Demographic assessment

All statistical analyses were performed using SPSS software, version 26.[46] Some variables were excluded due to lack of availability in medical charts. Excluded variables included preconception care, blood glucose values, number of missed appointments, medication, educational attainment, and income. Of the 85 charts reviewed, 78 charts were included in the analysis. Five charts were excluded due to women having gestational diabetes and not preexisting diabetes, one chart was for an infant, and one was excluded for confidentiality reasons. Once data was compiled into a table (Appendix B), descriptive statistics were computed for continuous and categorical variables. Continuous variables included age, BMI, duration of diabetes, preconception HbA1c, HbA1c during each trimester, blood glucose during each trimester, and gravida para. Categorical data included health history (chronic hypertension), diabetes type, employment status, ethnicity, birth outcomes (birth weight, gestational age, cesarean delivery, shoulder dystocia, malpresentation, premature rupture of membrane, postpartum hemorrhaging, and fetal loss), pregnancy complications (preeclampsia), diabetes education, nutrition education. Continuous variables including age-related pregnancy risk, BMI-related pregnancy risk, and multiparity were also categorized as categorical variables in order to run chi-square contingency tables.

Relationships between variables

To examine relationships for all objectives in this project, Chi square test for association was completed for multiple variables. Chi square compared the association between education (diabetes or nutrition) and outcomes measures (birth outcomes and HbA1c preconception and during each trimester). This analysis compared observed frequencies of education (diabetes or nutrition) with what was expected if there was no association between variables being measured. Data was coded in preparation for Chi square. Acceptable blood glucose was defined using the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020* recommendation of HbA1c < 6.5%, which accounts for preconception and perinatal targets.[14] Women were divided into two categories (yes/no) depending on if they had any of the following birth outcomes: shoulder dystocia, premature rupture of membrane, postpartum hemorrhage, malpresentation, or fetal loss. Other outcomes include preterm birth (yes/no), cesarean section (yes/no) completion of diabetes education (yes/no), completion of nutrition education (yes/no), and macrosomic infants (yes/no). Pregnancy complications, such as high blood pressure during pregnancy was categorized as yes/no in preparation for Chi square. High blood pressure during pregnancy included gestational hypertension, mild preeclampsia, and eclampsia and severe preeclampsia. Age was coded as yes/no for age-related pregnancy risk (greater than 35 years old). Similarly, prepregnancy BMIs were categorized as yes/no for BMI-related pregnancy risk (greater than 23.9 kg/m^2). Chronic hypertension and multiparity were also coded as a pregnancy risks as yes/no. Demographic data coded to included White (yes/no) and employed (yes/no).

Chapter 4: Results

Sample Demographics

The mean age of the sample was 31 years old (S.D. $\pm$ 5.5) and the mean BMI of the sample was 31 kg/m^2 (S.D. $\pm$ 8.6) (Table 1). More women had type 2 diabetes (64.1%, n = 50) than type 1 diabetes (35.9%, n = 28) and the mean duration of diabetes diagnosis was 10 years (S.D. $\pm$ 9.0) (Table 2). The HbA1c levels during preconception were 8.2% (S.D. $\pm$ 1.9), first trimester was 7.8% (S.D. $\pm$ 1.6), second trimester was 7.5% (S.D. $\pm$ 1.9), and HbA1c in the third trimester was 7.0% (S.D. $\pm$ 1.1). Blood glucose levels were also collected for each trimester, during the first trimester the mean blood glucose level was 200 mg/dL (S.D. $\pm$ 86.7), second trimester 132 mg/dL (S.D. $\pm$ 64.4), and third trimester 140 mg/dL (S.D. $\pm$ 74.0). Descriptive statistics also indicated that 30.8% (n = 24) of women had chronic hypertension. The mean number of previous pregnancies within the sample was 3 (S.D. $\pm$ 2.0) and the mean number of previous births was 1.0 (S.D. $\pm$ 2.0). Pregnancy complications included eclampsia and severe preeclampsia (12.8%, n = 10), mild preeclampsia (6.4%, n = 4), and gestational hypertension (5.1%, n = 4). In terms of birth outcomes, more women had a cesarean delivery (60.3%, n = 47) than a vaginal delivery (39.7%, n = 31). Most women gave birth during weeks 37 to 38 (43.6%, n = 34) and weeks 34 to 36 (38.5%, n = 30). Sample preterm births included 5.1% (n = 4) during weeks 28 to 33, 3.8% (n = 3) during weeks 24 to 27, and 1.3% (n = 1) at less than 24 weeks. Within the sample 26.9% (n = 21) of the infants were born macrosomic (weighing greater than 4000 grams at birth). The remaining sample gave birth to infants weighing 3500 to 3999 grams (25.6%, n = 20), 3000 to 3499 grams (24.4%, n = 19), 2500 to 2999 grams (10.3%, n = 8), 2000 to 2499 grams (2.6%, n = 2), 1500 to 1999 grams (2.6%, n = 2), and less than 1500 grams (3.8%, n = 3). Additional birth outcomes included premature rupture of membranes (10.3%, n = 8), shoulder dystocia (6.4%, n = 5), malpresentation (3.8%, n = 3), fetal loss (3.8%, n = 3), and postpartum hemorrhaging (2.6%, n = 2). Nutrition education was provided to 73.1% (n = 57) and diabetes education was provided to 74.4% (n = 58) of the sample.

Possible confounding factors related to not completing nutrition and diabetes education and subsequent glycemic and birth outcomes were also analyzed. Within the sample, 55.4% (n = 41) were employed. Results indicated that 50% (n = 37) of the sample were White, 23% (n = 17) were Native Hawaiian/Pacific Islander, 13.5% (n = 10) were Asian, 6.8% (n = 5) were Black, and 6.8% (n = 5) were Hispanic (Table 1 and Table 2). Educational attainment and income information were not available in the medical charts

Table 1. Sample Demographics – Continuous Data

Continuous data	Mean ± standard deviation	n	Minimum	Maximum
Age (y)	31.3 ± 5.5	78	19	42
Body mass index (kg/m^2)	34.9 ± 8.8	74	22	59
Duration of DM	10.8 ± 9.0	41	1	31
HbA1c, preconception (%)	8.2 ± 1.9	18	6.1	14.1
HbA1c, 1st trimester (%)	7.8 ± 1.6	38	5.4	11.0
HbA1c, 2nd trimester (%)	7.5 ± 1.9	27	5.0	12.2
HbA1c, 3rd trimester (%)	7.0 ± 1.1	24	5.1	9.7
Blood glucose, 1st trimester (mg/dL)	200 ± 86.7	6	100	301
Blood glucose, 2nd trimester (mg/dL)	132 ± 64.4	17	77	303
Blood glucose, 3rd trimester (mg/dL)	140 ± 74.0	52	71	408
Gravida	3.0 ± 2.0	73	1	12
Para	1.0 ± 2.0	73	0	10

Table 2. Sample Demographics – Categorical Data

Categorical Data	n (%)
Diabetes type	
Type 1	28 (35.9)
Type 2	50 (64.1)
Health hx	
Chronic hypertension	24 (30.8)
No chronic hypertension	54 (69.2)
Employment status	
Employed	41 (52.6)
Unemployed	33 (42.3)
Ethnicity	
White	37 (47.4)
Black	5 (6.4)
Asian	10 (12.8)
Hispanic	5 (6.4)
Native Hawaiian or Pacific Islander	17 (21.8)
Mode of delivery	
Vaginal	31 (39.7)
C-section	47 (60.3)
High blood pressure during pregnancy	59 (75.6)
None noted	4 (5.1)
Gestational hypertension	5 (6.4)
Mild preeclampsia	10 (12.8)
Eclampsia and severe preeclampsia	
Gestational age (weeks)	
< 24	1 (1.3)
24-27	3 (3.8)
28-33	4 (5.1)
34-36	30 (38.5)
37-38	34 (43.6)
39-40	6 (7.7)

Table 2. Continued.

Categorical Data	n (%)
Birth weight (grams)	
< 1500	3 (3.8)
1500-1999	2 (2.6)
2000-2499	2 (2.6)
2500-2999	8 (10.3)
3000-3499	19 (24.4)
3500-3999	20 (25.6)
≥ 4000 [a]	21 (26.9)
Birth outcomes	
None noted	56 (71.8)
Shoulder dystocia	5 (6.4)
Postpartum hemorrhage	2 (2.6)
PROM [b]	8 (10.3)
Shoulder dystocia/PROM	1 (1.3)
Malpresentation	3 (3.8)
Fetal loss	3 (3.8)
Diabetes education	
Completed	58 (74.4)
Incomplete	20 (25.6)
Nutrition education	
Completed	57 (73.1)
Incomplete	21 (26.9)

[a] Macrosomic
[b] Premature rupture of membrane

Demographic Comparison

To compare data to previous research, a medical chart review by Newman, et. al., was evaluated. Newman et. al., retrospectively analyzed data from 2015 to 2017 and compared outcomes to data from 2010 to 2014 to assess if improvements related to preconception care were maintained in subsequent years. The study included women with pregestational diabetes and examined glycemic targets and neonatal outcomes. This study included similar variables to the current study including age, BMI, HbA1c during each trimester, macrosomia, preterm births, and shoulder dystocia. Demographic characteristics from each study were compared to one another (Table 3).[40]

Table 3. Demographic Comparison

	Urban Alaska chart review (n = 78)	Newman, et. al., 2010-2014 (n = 228)	Newman, et. al., 2015-2017 (n = 98)
Age (y)	31.3 $\pm$ 5.5	33 + 5.1	33.6 + 5.1
Body mass index (kg/m^2)	34.9 $\pm$ 8.8	29.6 $\pm$ 6.5	27.09 + 6.24
Education completion	58 (74.4%) DE [a] 57 (73.1%) NE [b]	112 (49%)	34 (35%)
HbA1c, 1st trimester (%)	7.8 $\pm$ 1.6 (n = 38)	7.3 $\pm$ 2.5[c] 6.7 $\pm$ 2.6	7.0 $\pm$ 3.1 6.1 $\pm$ 2.7
HbA1c, 2nd trimester (%)	7.5 $\pm$ 1.9 (n = 27)	6.4 $\pm$ 2.3 6.0 $\pm$ 2.3	6.4 $\pm$ 3.0 5.5 $\pm$ 2.6
HbA1c, 3rd trimester (%)	7.0 $\pm$ 1.1 (n = 24)	6.4 $\pm$ 2.3 6.0 $\pm$ 2.3	6.4 $\pm$ 2.9 5.5 $\pm$ 3.0
Delivery < 34 wks (%)	7 (12.8%)	42 (21%)	11 (11.2%)
Shoulder dystocia	5 (6.4%)	3 (1%)	1 (1%)
Macrosomia (%)	21 (28%)	53 (23%)	22 (22%)

[a] DE: Diabetes education
[b] NE: Nutrition education
[c] Type 1 diabetes followed by type 2 diabetes

Relationships Between Variables

For one analysis the Chi square assumptions were not met. Due to missing information in the medical charts, the unmet assumption violated the 'minimum expected cell frequency', which should be five or greater. The remaining Chi square tests that met the assumptions are depicted in Table 4. The only significant association found is between acceptable HbA1cs in the second trimester and White women ($p = 0.013$). Significance was determined as a p value of less than 0.05.

Table 4. Chi Square Results

Variable 1	Variable 2	Pearson Chi square	*p* value
Diabetes education, completed	Birth outcomes[a]	0.136	0.712
Ethnicity, non-White	Unacceptable HbA1c, 2nd trimester[b]	6.238	0.013[c]
Nutrition education, completed	Birth outcomes	0.002	0.965
Chronic hypertension	Unacceptable HbA1c, 2nd trimester	2.734	0.098
Preterm birth[d]	Unacceptable HbA1c, 2nd trimester	2.054	0.152

[a] Birth outcomes in this analysis include: shoulder dystocia, PROMs, postpartum hemorrhage, malpresentation, and fetal loss
[b] Unacceptable HbA1c is > 6.5%
[c] Significant value is < 0.05
[d] Infant born < 34 weeks old

Chapter 5: Discussion

Diabetes during pregnancy is associated with increased risk of maternal and neonatal complications and constitutes a significant medical, social, and financial issue.[22] By examining current practices in relation to the American Diabetes Association Management of Diabetes in Pregnancy: *Standards of Medical Care in Diabetes – 2020* and subsequent pregnancy outcomes, institutions can drive quality improvement for future practices in healthcare.[13] Improving current practices related to management of pregestational diabetes in pregnancy will help combat diabetic fetopathy and the intergenerational cycle of diabetes that increases health care costs and familial hardship.[12]

Evaluation of Glycemic Control Outcomes

The evaluation of outcome measures is an integral part of establishing the efficacy of RDNs and CDEs. These measures reflect the effect that current diabetes and nutrition education have on glycemic control during pregnancy. In addition to outcome measures being documented, it is necessary to record the measures of glycemic control that most accurately reflect fluctuating perinatal glycemia. The present study utilized HbA1c as a biomarker for glycemic control. Research has reported that individualized RDN-administered MNT accounts for statistically significant HbA1c reductions of 0.9% to 1.9% and the added benefit of DSME results in HbA1c reductions exceeding 2.0%.[4] Marincic, et. al., indicated that patients with HbA1c > 7% have been reported to exhibit total health care costs that are 32% higher than those with sustained HbA1c in the target range.[4] Despite acceptable HbA1c levels during pregnancy, the risk of macrosomia remains high in women with type 1 diabetes. This may suggest inadequacy of HbA1c as a solitary outcome measure because it misses significant episodes of hyperglycemia.[22] The ADA suggests that HbA1c represents a consolidated measure of glucose, reporting a broad view of what blood sugars have been over a period of two to three months. This measure does not capture postprandial hyperglycemia which drives macrosomia.[14] Furthermore, research has suggested that there is a physiological fall in HbA1c in pregnancy, which may be due to increasing erythrocyte production rate, reduced glucose affinity, and a shortened erythrocyte life span.[8] This retrospective quality improvement chart review at an urban Alaska health system found limited retrospective data regarding perinatal glycemia for women entering the health system at the time of birth. It is impossible to correlate birth outcomes with perinatal glycemia if outcome measures are unavailable. Efficacy of RDNs and CDEs depends on adequate documentation of interventions and resultant clinical measures.

In comparison to HbA1c, pre- and postprandial blood glucose monitoring provide immediate feedback of glucose excursions which guide insulin adjustments. Fasting and pre-prandial glucose values may be more relevant to adverse pregnancy outcomes.[17] In this retrospective quality improvement study, glucose values available in medical charts were not specified as fasting, preprandial, or postprandial. It was not possible to relate glycemic excursions with birth outcomes when the most prevalent variable defining “acceptable” blood glucose was HbA1c. Future research should focus on evaluating a continuum of blood glucose levels to help understand the relationship between perinatal glycemic control and birth outcomes among women with preexisting diabetes during pregnancy. A continuum of blood glucose levels, as would be available through continuous glucose monitoring (CGM) technologies, also aids in identifying periods during pregnancy where education and support provided by a RDN and/or CDE may be most useful. The ADA states that using a CGM-reported mean glucose is superior to the use of estimated HbA1c given the changes in HbA1c that occur in pregnancy.[2]

Sample Demographics

The results of this study align with current research indicating changing demographics of the obstetric population. The mean age of mothers in the United States at first birth is 26.9 years.[47] National Vital Statistics data shows that of the 0.9% of pregnant women with preexisting diabetes, a higher percentage of women were greater than 40 years old compared to the urban

Alaska health system review mean age of 31.3 ± 5.5 years and Newman, et. al.'s mean age of 33 ± 5.1 years.[48]

Obesity is often associated with type 2 diabetes and is becoming more prevalent in type 1 diabetes.[6,14] Excessive weight gain during pregnancy is associated with increased risk of adverse pregnancy outcomes in subsequent pregnancies.[14] The majority of patients in the urban Alaska health system sample and Newman, et. al., sample were obese, according to mean BMI ranges 27.09 kg/m^2 to 34.9 kg/m^2. If appropriate, prepregnancy care should include risk assessment of obesity and lifestyle interventions to prevent or treat obesity.[14]

Diabetic embryopathy is associated with HbA1c elevations during the first ten weeks of pregnancy. The ADA recommends that women achieve a HbA1c < 6.5% before conception due to its association with the lowest risk of preeclampsia, macrosomia, and congenital anomalies.[14] The rates of macrosomia and shoulder dystocia were lower in the Newman, et. al., study than were observed in this study. It is possible that the timing of preconception education and universal access to medical care in Ireland, the origin of the Newman, et. al., data, had a more positive effect on birth outcomes.

Maternal and fetal risks are greater in women with preexisting diabetes due to the degree of hyperglycemia, chronic complications, and comorbidities. The urban Alaska health system and Newman, et. al., review had varying HbA1c levels, possibly related to timing of education completion. The HbA1c levels were the more elevated in the urban Alaska health system review compared to Newman et. al., review. Uncontrolled glycemia is associated with adverse birth outcomes. The urban Alaska health system had a higher percentage of preterm births compared to Newman, et. al. In the urban Alaska health system chart review, the relationship between preterm births and unacceptable HbA1c in the second trimester was statistically non-significant (p = .152). Women can be educated on ADA recommendations for glycemic control and receive subsequent individualized interventions provided by a RDN or CDE to decrease pregnancy risks. The urban Alaska health system review included several other birth outcomes that may be affected by diabetes education or nutrition education and perinatal glycemia including malpresentation, premature rupture of membrane, postpartum hemorrhaging, and fetal loss.

Chronic hypertension and comorbidities are more prevalent among women with type 2 diabetes and pregnancy loss is more prevalent in the third trimester. Diabetes in pregnancy is associated with an increased risk of preeclampsia.[42] In the urban Alaska health system chart review most women did not have preeclampsia but 30.8% (n = 24) had chronic hypertension. The relationship between chronic hypertension and unacceptable HbA1c during the second trimester were statistically nonsignificant ($p = 0.098$) in the urban Alaska health system chart review. Major risk factors for preeclampsia include prepregnancy obesity, advanced maternal age, black race, and chronic hypertension.[42] Diabetes education or nutrition education provided by an RDN or CDE should focus on managing comorbidities such as blood pressure.

Several variables (i.e., ethnicity, mode of delivery, and gravida para) included in the chart review were later determined to be incomplete or outside the scope of this research project. The urban Alaska chart review revealed that most women that visited the health system were White followed by Native Hawaiian or Pacific Islander, Asian, Black and Hispanic. Email correspondence with the urban Alaska health system staff revealed that most Alaska Native women typically attended a different hospital, but it was suggested that they could have been included in one of the aforementioned ethnicity groups. Of note, pregestational diabetes is most prevalent among American Indian/Alaska Native women in the U.S.[48] Delivery method was decided to be irrelevant due to the multitude of possible implications for cesarean delivery (i.e., prolonged labor, abnormal fetal positioning, cord prolapse).[49] Although gravida para was included in this chart review and multiparous women have a greater need for close glucose control due to parity being correlated with increased insulin needs, this is outside of the scope of RDNs and CDEs.

Diabetes Education and Nutrition Education

In the urban Alaska health system chart review 74.4% (n = 58) of women received diabetes education and 73.1% (n = 57) received nutrition education. However, it is not clear whether the other patients received a referral for education or when during pregnancy education was completed. Preconception education occurred among 35% (n = 34) to 49% (n = 112) in the Newman, et. al review. Timing of education and preconception planning may influence glycemia during pregnancy. Women that live in greater social deprivation are less likely to have access to perinatal resources, which may have affected completion of education.[19]

Many women included in the retrospective chart review were only admitted to the health system to give birth. It was unknown whether women received preconception or prenatal nutrition and diabetes education because their charts only included what was accomplished within the urban Alaska health system. Assumptions can be made about barriers to completing nutrition and diabetes education based on previous research exploring the experiences and perceptions of pregnant women with preexisting diabetes. Many women reported anxiety related to the prospect that they could be responsible for their babies being diagnosed with diabetes at birth or later in life. The feelings of anxiety, guilt, panic, stress, and selfishness associated with discussing the risks and management of diabetes could result in women not attending education appointments. Simultaneously managing pregnancy and diabetes takes an emotional toll on women; they need to be empowered with support, encouragement, and knowledge to successfully navigate pregnancy complicated by preexisting diabetes.[34]

The relationships between the completion of nutrition education and birth outcomes (p = 0.965) and diabetes education and birth outcomes (p = 0.712) were statistically non-significant. Birth outcomes included shoulder dystocia, malpresentation, PROMs, postpartum hemorrhage, and fetal loss. The most common birth outcomes associated with uncontrolled pregestational diabetes are congenital malformations and spontaneous abortion. These common birth outcomes are correlated with a lack of glycemic control during fetal organogenesis which occurs during the first few weeks of pregnancy.[20] Prepregnancy care would have the biggest impact on preventing congenital malformations and spontaneous abortion. It is unknown which trimester diabetes education or nutrition education was completed in the urban Alaska health system chart review.

Data collected regarding educational attainment and ethnicity support the need for individualized care focusing on cultural backgrounds, food availability, personal preferences, health literacy and numeracy, and the socioeconomic setting in which people live.[6] In the urban Alaska health system chart review, a non-White ethnicity was associated with unacceptable HbA1c in the second trimester ($p = 0.013$). Evaluating barriers to diabetes education or nutrition education may help promote initiatives focusing on increasing access and acceptability.

Outcome measures are an essential part of tracking success of educational programs and supporting the efficacy of RDNs and CDEs. Women with pregestational diabetes are at increased risk of adverse pregnancy outcomes. Nutrition education and diabetes education needs to be individualized and appropriately documented to help promote healthy pregnancies and drive quality improvement. Outcome measures for this project could not be determined due to lack of comprehensive data available. Documentation of outcomes measures is needed to distinguish associations between ADA approved education and birth outcomes before quality improvement recommendations can be made.

Strengths and Limitations

A strength of conducting this retrospective chart review is that the sample of pregnant women with preexisting diabetes was not affected. All data were collected after women had given birth and this review had no effect on their pregnancy or well-being. An additional strength of this retrospective quality improvement study was that best practices were used when compared to previous research. Reviews by Newman, et. al., and Marincic, et. al., used similar outcome measures to assess the success of diabetes and nutrition education during pregnancy.[13,40]

There were several limitations of this study. A main limitation of this project's chart review was that the principal investigator depended on health system staff to extract data. Another limitation was that medical professionals provided varying levels data into the medical charts of their patients, making consistency of data collection difficult. Data (perinatal glycemia) was also limited because many women included in this review only visited the urban health system to give birth. This resulted in an inadequate amount of blood glucose datapoints. Medical charts seldomly included confounding factors to receiving care (i.e., income, educational attainment, ethnicity). Recording confounding factors are essential for identifying health disparities to help guide future interventions.[39] Confounding factors are also important to identify because they alter data during analysis. Women with pregestational diabetes with greater social deprivation are less likely to achieve glycemic control due to a decreased ability to achieve and maintain lifestyle changes.[19,35] In the chart review, it could not be deciphered whether education appointments were made and subsequently missed or whether all women received a diabetes or nutrition education referral. The number of diabetes or nutrition education appointments women completed was also unknown. During data extraction, it was not verified if education was provided by a RDN or CDE. It is important to note that information missing from medical charts does not necessarily mean information was not gathered during the assessment or intervention. Lastly, the effects of poor glycemic control early in pregnancy were lacking in this review because spontaneous abortions and fetal malformations were not included in data collection.

Outcome measures included in this retrospective quality improvement chart review were limited. Blood glucose was not used in the analysis due to data lacking specificity of when measures were taken (i.e., fasting, pre-prandial, postprandial). The American Diabetes Association (ADA) and the American College of Obstetricians and Gynecologists (ACOG) indicate that HbA1c is useful but it should be used as a secondary measure of glycemic control in pregnancy, after self-monitoring blood glucose.[14,38] The ADA also specifies that self-monitoring blood glucose targeting pre- and postprandial recommendations remains the superior methodology.[14] HbA1c, although not ideal, provided a biomarker of glycemic control over a two to three month period which was helpful in assessing prepregnancy and perinatal glycemia.

The most significant barrier of this project was unavailable data in medical charts, making it difficult to analyze relationships between variables. Without documentation of outcome measures, the impact of education is unknown and the role that RDNs and CDEs play in diabetes management during pregnancy is unsubstantiated. The objectives of this research project aimed to examine the relationship between the completion of ADA approved diabetes or nutrition education with perinatal glycemia and birth outcomes and that could not be completed.

Chapter 6: Conclusion and Recommendations

Diabetes self-management education (DSME) provided by a RDN and/or CDE has been shown to improve clinical outcomes (i.e., weight, BMI, HbA1c, and blood lipids), behaviors (i.e., self-monitoring blood glucose), and quality of life.[50] DSME includes individualized medical nutrition therapy (MNT) in conjunction with pharmacotherapy, increased physical activity to promote weight loss or insulin sensitivity, and ongoing support and counseling based on level of behavior change.[50] Despite the beneficial outcomes, many women with diabetes do not plan their pregnancies and receive diabetes and nutrition education.[21] The uncovered cost of MNT and DSME provided by RDNs and CDEs limits education programs and decreases access to ADA recommended *Standards of Medical Care*.[14] The inconsistent documentation of outcome measures or medical record sharing amongst facilities limits the ability to examine completion of ADA recommended education with glycemic control and subsequent pregnancy outcomes. Affordable access is integral to remedy the intergenerational cycle of diabetes related to poorly managed perinatal glycemia. By assessing outcomes, more funding and staff should be appropriated to provide the necessary education and instill diabetes self-management efficacy. This will ultimately improve birth outcomes and decrease costs associated with diabetes management.[2] Diabetes is a chronic disease and necessitates regular follow-up appointments, especially during pregnancy when insulin resistance is inconsistent.[4]

Future quality improvement studies should closely investigate aspects of perinatal education and subsequent outcome measures. Specific recommendations for future research include collecting a continuum of clearly defined blood glucose levels throughout pregnancy and include the use of continuous glucose monitoring technology to better understand glycemia during pregnancy in women with pregestational diabetes and subsequent birth outcomes. Secondly, a repository of information is needed to further demonstrate the efficacy of the RDN and the CDE and the nutrition education and diabetes education they provide to pregnant women with pregestational diabetes. The effect of diabetes and nutrition education provided to women with preexisting diabetes could be more accurately analyzed if outpatient clinic charts were included in the chart review or if medical records were consistently shared between facilities. To eliminate barriers associated with data extraction, future retrospective chart reviews should be performed solely by the principal investigator after receiving training on the electronic health record system, if possible.

The data from this study was insufficient to complete the planned analysis due to the previously mentioned limitations. Quality improvement reviews of medical treatment, such as perinatal nutrition and diabetes education, are reliant on medical documentation. Marincic, et. al., states “documenting patient outcomes is a first step in establishing the efficacy of RDN interventions.”[4, p. 450] Evaluating the efficacy of RDN and CDE services relies on accurate charting of baseline data and outcome measures. The documentation of outcome measures provides the basis for the reimbursement of DSME and MNT, directs policy initiatives, and improves access and affordability of perinatal care provided by a multidisciplinary team in which RDNs and CDEs play an essential role.[4]

More research is needed to support the efficacy of RDNs and CDEs in providing diabetes self-management education and medical nutrition therapy to women with pregestational diabetes. Currently there is no consensus on the structure of prenatal multidisciplinary care teams for pregestational diabetes and there is minimal evidence pertaining to the impact various methods of healthcare delivery have on pregnancy outcomes. Appropriate outcome measures need to be documented following care provided by a RDN or CDE to help promote the role they play as part of a prenatal multidisciplinary care team.

Dietetics and Nutrition Practice Implications

Registered dietitian nutritionists (RDNs) and certified diabetes educators (CDEs) continue to establish the expertise they bring as part of the interprofessional healthcare team. It is important to be proactive in the care provided to female patients preconceptionally and perinatally. RDNs and CDEs need to promote health literacy and prepare women to have successful perinatal outcomes. During pregnancy, optimal glycemia reduces the risk of obstetric and neonatal complications.[34] Population specific programs should be created and promoted to improve access to prenatal care. Preconception programs should help women with preexisting diabetes feel empowered and positive about their pregnancy experience, while also providing information about any potential risks and support for managing those risks.[34] Poorly managed diabetes during pregnancy carries considerable risk to the mother and infant as well as unnecessary burden on health care services and society.[41]

The valuable role that RDNs and CDEs play in promoting glycemic control during pregnancy is best supported by outcome measures being documented and analyzed. The analysis of variables leading to positive birth outcomes promote the development of affordable and accessible perinatal programs, ultimately improving the health of the next generation and promoting the efficacy of RDNS and CDEs.

References

1. American Diabetes Association. 13. Management of diabetes in pregnancy: *Standards of medical care* in diabetes. *Diabetes Care*. 2019;42(1):S165-S172. https://doi.org/10.2337/dc19-S014

2. Powers MA, Bardsley J, Cypress M, et. al. Diabetes self-management education and support: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *The Diabetes EDUCATOR*. 2017;43(1):40-53. doi: 10.1177/0145721716689694

3. Powers MA, Bardsley J, Cypress M, et. al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care*. 2015;38(7):1372-1382. https://doi.org/10.2337/dc15-0730

4. Marincic PZ, Salazar MV, Hardin A, et. al. Diabetes self-management education and medical nutrition therapy: a multisite study documenting the efficacy of registered dietitian nutritionist interventions in the management of glycemic control and diabetic dyslipidemia through retrospective chart review. *Journal of the Academy of Nutrition and Dietetics*. 2018:1-15. https://doi.org/10.1016/j.jand.2018.06.303

5. American Diabetes Association. 5. Lifestyle management: *Standards of medical care in diabetes*. *Diabetes Care*. 2019;42(1):S46-S60. https://doi.org/10.2337/dc19-S005

6. Evert AB, Dennison M, Gardner CD, et. al. Nutrition therapy for adults with diabetes or prediabetes: a consensus report. *Diabetes Care*. 2019;42(5):731-754. https://doi.org/10.2337/dci19-0014

7. Abramowicz JS, Ahn JT. Fetal macrosomia. UpToDate. https://www.uptodate.com/contents/fetal-macrosomia#H4. Published October 11, 2019. Accessed January 23, 2020.

8. American Diabetes Association. 6. Glycemic targets: Standards of medical care 2020. *Diabetes Care*. 2020;43(1):S66-S76. https://doi.org/10.2337/dc20-S006

9. American College of Obstetricians and Gynecologists. Practice bulletin 202: Gestational hypertension and preeclampsia. *Obstetrics and Gynecology*. 2019;133(1):e1-e25. https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Obstetrics/Gestational-Hypertension-and-Preeclampsia. Accessed March 12, 2020.

10. Allnutt KJ, Allan CA, Brown J. Early pregnancy screening for identification of undiagnosed pre-existing diabetes to improve maternal and infant health. Cochrane Database of Systematic Reviews. 2015;4. doi: 10.1002/14651858.CD011601.

11. Lagasse J. How reversing diabetes cost to drive savings impact is viable. *Healthcare Finance*. Accessed November 2, 2018. Retrieved from https://www.healthcarefinancenews.com/news/how-reversing-diabetes-cost-drive-

savings-impact-viable

12. Rollo ME, Aguiar EJ, Williams RL, et. al. eHealthy technologies to support nutrition and physical activity behaviors in diabetes self-management. *Diabetes Metab Syndr Obes*. 2016;9:381-390. doi: 10.2147/DMSO.S95247

13. Marincic PZ, Hardin A, Salazar MV, et. al. Diabetes self-management education and medical nutrition therapy improve patient outcomes: a pilot study documenting the efficacy of registered dietitian nutritionist interventions through retrospective chart review. *Journal of the Academy of Nutrition and Dietetics*. 2017;117(8):1254-1264. doi: 10.1016/j.jand.2018.06.303

14. American Diabetes Association. Management of diabetes during pregnancy: *Standards of medical care* in diabetes 2020. *Diabetes Care*. 2020;43(1):S183-S192. https://doi.org/10.2337/dc20-S014

15. Yehuda, I. Implementation of preconception care for women with diabetes. *Diabetes Spectrum*. 2016;29(2): 105-114. https://doi.org/10.2337/diaspect.29.2.105

16. Desoye G, Nolan CJ. The fetal glucose steal: an underappreciated phenomenon in diabetic pregnancy. *Diabetologia*. 2016;59:1089-1094. doi: 10.1007/s00125-016-3931-6

17. Maresh MJA, Holmes VA, Patterson CC et al. Glycemic targets in the second and third trimester of pregnancy for women with type 1 diabetes. *Diabetes Care*. 2015;38(1):34-42. https://doi.org/10.2337/dc14-1755

18. Alexopoulos AS, Blair R, Peters AL. Management of preexisting diabetes in pregnancy: a review. *The Journal of the American Medical Association.* 2019;321(18):1811-1819. https://doi-org.proxy.consortiumlibrary.org/10.1001/jama.2019.498

19. Murphy HR, Bell R, Dornhorst A, Forde R, Lewis-Barned N. Pregnancy in diabetes: challenges and opportunities for improving pregnancy outcomes. *Diab Med*. 2018;35(3):292-299. https://doi-org.proxy.consortiumlibrary.org/10.1111/dme.13579

20. Kitzmiller JL, Block JM, Brown FM, et. al. Managing preexisting diabetes for pregnancy. *Diabetes Care*. 2008;31(5):1060-1079. https://doi.org/10.2337/dc08-9020

21. Buschur E, Stetson B, Barbour LA. Feingold KR, Anawalt B, Boyce A, et. al., editors. Diabetes in pregnancy. South Dartmouth, MA: MDText.com, Inc. https://www.ncbi.nlm.nih.gov/books/NBK279010/. Accessed February 22, 2020.

22. Cyganek K, Skupien J, Katra B, et. al. Risk of macrosomia remains glucose-dependent in a cohort of women with pregestational type 1 diabetes and good glycemic control. *Endocrine*. 2017;55:447-445. doi: 10.1007/s12020-016-1134-z

23. Lloreda-Garcia JM, Sevilla-Denia S, Rodriguez-Sanchez A, et. al. Perinatal outcome of macrosomic infants born to diabetic versus non-diabetic mothers. *Endocrinologia y Nutricion*. 2016;63(8):409-413. https://doi.org/10.1016/j.endoen.2016.09.011

24. Timur BB, Timur H, Tokmak A, Isik H, Eyi EGY. The influence of maternal obesity on pregnancy complications and neonatal outcomes in diabetic and nondiabetic women.

Geburtshilfe Frauenheilkd. 2018;78(4):400–406. doi: 10.1055/a-0589-2833

25. Abramowicz JS, Ahn JT. Fetal macrosomia. UpToDate. https://www.uptodate.com/contents/fetal-macrosomia#H4. Published October 11, 2019. Accessed January 23, 2020.

26. Ryswyk EV, Middleton P, Shute E, Hague W, Crowther C. Women's views and knowledge regarding healthcare seeking for gestational diabetes in the postpartum period: a systematic review of qualitative/survey studies. *Diabetes Research and Clinical Practice*. 2015;110:109-122. http://dx.doi.org/10.1016/j.diabres.2015.09.010

27. Zhao J, Hakvoort TB, Willemsen AM, et. al. Effect of hyperglycemia on gene expression during early organogenesis in Mice. *PLoS One*. 2016;11(7):1-22. doi: 10.1371/journal.pone.0158035

28. Earle S, Tariq A, Komaromy C, et. al. Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring update of preconception care. *Healthy technology assessment*. 2017;21(14):1-130. doi: 10.3310/hta21140

29. Knorr S, Stockholm K, Vlachova Z, et. al. Multisystem morbidity and mortality in offspring of women with type 1 diabetes (the EPICOM Study): a register-based prospective cohort study. *Diabetes Care*. 2015;38(5):821-826. https://doi.org/10.2337/dc14-2907

30. Kari A, Sahhaf F, Abbasalizadeh F. Maternal, fetal, and neonatal outcomes in mothers with diabetes mellitus or gestational diabetes that complicated with preterm prematurerupture of the membrane (PPROM). *International Journal of Women's Health and Reproduction Sciences*. 2017;5(1):66-71. doi: 10.15296/ijwhr.2017.12

31. Weisgerber TL, Mudd LM. Preeclampsia and diabetes. *Current Diabetes Reports.*2015;15(9):1-10. https://doi-org.proxy.consortiumlibrary.org/10.1007/s11892-015-0579-4

32. Padmanabhan S, Lee VW, Mclean M, et. al. The association of falling insulin requirements with maternal biomarkers and placental dysfunction: a prospective study of women with preexisting diabetes during pregnancy. *Diabetes Care.* 2017;40(10):1323-1330. https://doi.org/10.2337/dc17-0391

33. Perea V, Gimenez M, Amor AJ, et. al. Prepregnancy care in women with type 1 diabetes improves HbA1c and glucose variability without worsening hypoglycemia time and awareness: glycemic variability during prepregnancy care. *Diabetes Research and Clinical Practice*. 2019;154:75-81. https://doi.org/10.1016/j.diabres.2019.06.015

34. Singh H, Ingersoll K, Gonder-Frederick L, Ritterband L. "Diabetes just tends to take over everything:" experiences of support and barriers to diabetes management for pregnancy in women with type 1 diabetes. *Diabetes Spectrum*. 2019;32(2):118-124. https://doi.org/10.2337/ds18-0035

35. Oster, RT. Diabetes in pregnancy among First Nations women in Alberta: a multiphase mixed methods approach. ProQuest Dissertation and Theses retrieved from https://search-proquest-com.proxy.consortiumlibrary.org/pqdtglobal/docview/1504616246/FAA5F1D059A24DDB

PQ/2?accountid=14473

36. Office of Disease Prevention and Health Promotion: Healthy People 2020 social determinants of health. Accessed Nov 28, 2018. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health

37. Bagby SP, Martin D, Chung ST, Rajapakse N. From the outside in: biological mechanisms linking social and environmental exposures to chronic disease and health disparities. *American Journal of Public Health*. 2019;109(1):S56-S63. https://doi.org/10.2105/AJPH.2018.304864

38. American College of Obstetricians and Gynecologists. Practice bulletin 102: Pregestational diabetes mellitus. *Obstetrics and Gynecology*. 2018;132(6):e228-e248. https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Obstetrics/pb201.pdf?dmc=1. Accessed January 25, 2020

39. Kim SY, Deputy NP, Robbins CL. Diabetes during pregnancy: surveillance, preconception care, and postpartum care. *J Womens Health (Larchmt).* 2018;27(5):536-541. doi: 10.1089/jwh.2018.7052

40. Newman C, Carmody L, Egan AM, Owens LA, Dunne F. 1429-P: A review of prepregnancy care and pregnancy outcomes in pregestational diabetes- are prior improvements in pregnancy preparation and outcomes maintained for women with pregestational diabetes? *Diabetes.* 2019;68(1). https://doi.org/10.2337/db19-1429-P

41. Earle S et al. Preconception care for women with type 1 or type 2 diabetes mellitus: a mixed-methods study exploring uptake of preconception care. *Health Technol Assess*. 2017;21(14). doi: 10.3310/hta21140

42. Weissgerber TL, Mudd LM. Preeclampsia and diabetes. *Current Diabetes Reports*. 2015;15(9):1-10. https://doi-org.proxy.consortiumlibrary.org/10.1007/s11892-015-0579-4

43. Centers for Disease Control and Prevention: National and state data. Accessed Dec 1, 2018. Retrieved from https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html

44. Alaska Native Tribal Health Consortium Epidemiology Center Health Data: Diabetes Demographics. Accessed March 15, 2020. Retrieved from http://anthctoday.org/epicenter/healthData/factsheets/Diabetes_Demographics_01_05_2017.pdf

45. Centers for Disease Control and Prevention: Diabetes during pregnancy. Accessed December 1, 2018. Retrieved from https://www.cdc.gov/reproductivehealth/maternalinfanthealth/diabetes-during-pregnancy.htm

46. IBM Corp. Released 2018. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

47. Center for Disease Control and Prevention. National Center for Health Statistics: Birth and Natality. Accessed March 3, 2020. Retrieved from

https://www.cdc.gov/nchs/fastats/births.htm

48. Deputy NP, Kim SY, Conrey EJ, Bullard KM. Prevalence and changes in preexisting diabetes and gestational diabetes among women who had a live birth — United States, 2012–2016. MMWR Morb Mortal Wkly Rep. 2018;67:1201-1207. http://dx.doi.org/10.15585/mmwr.mm6743a2

49. Mylonas I, Friese K. Indications for and risks of elective cesarean section. *Deutsches Arzteblatt International*. 2015;112(29-30):489-495. doi: 10.3238/arztebl.2015.0489

50. Early KB, Stanley K. Position of the Academy of Nutrition and Dietetics: the role of medical nutrition therapy and registered dietitian nutritionists in the prevention and treatment of prediabetes and type 2 diabetes. *Journal of the Academy of Nutrition and Dietetics.* 2018;118(2):343-353. doi: https://doi.org/10.1016/j.jand.2017.11.02

Appendix A: Research Approvals

UAA Research & Graduate Studies
UNIVERSITY of ALASKA ANCHORAGE

3211 Providence Drive
Anchorage, Alaska 99508-4614
T 907.786.1099, F 907.786.1791
www.uaa.alaska.edu/research/ric

DATE:	August 15, 2019
TO:	Audrey Anderson
FROM:	University of Alaska Anchorage IRB
PROJECT TITLE:	[1426447-1] Diabetes and nutrition education for pregnant women with preexisting diabetes in Anchorage, Alaska: a retrospective quality improvement study
SUBMISSION TYPE:	New Project
DETERMINATION:	UAA Not Engaged in Human Subjects Research
DECISION DATE:	August 13, 2019

Thank you for your submission of New Project materials for this research study. The University of Alaska Anchorage IRB has been coordinating with the Swedish IRB and has determined that, since no UAA students, staff, or faculty will have access to identifiable data about the subjects of this study, UAA is Not Engaged in Human Subjects Research and does not require UAA IRB oversight.

However, if the protocols of this project are to change such that UAA students, staff, or faculty will have access to identifiable data about the subjects, then prior to that change being implemented you must seek UAA IRB review and approval.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact the IRB Chair, Robert Boeckmann, or the UAA IRB Coordinator through IRBNet Project Mail (accessible on the left hand menu within your IRBNet project). The IRB Coordinator is also available at (907) 786-0916 or uaa_irb_coord@alaska.edu. Please include your IRBNet number and Project Title in all correspondence with this office.

Daniel Allen, CIP
IRB Coordinator
Office of Research Integrity & Compliance (ORIC)
University of Alaska Anchorage

APPROVAL OF SUBMISSION

August 16, 2019

Audre Anderson
P.O. Box 398
Girdwood, AK 99587

Dear Dr. Anderson:

On 8/14/2019, the IRB reviewed the following protocol via expedited review:

Type of Review:	Initial Study
Title of Study:	Diabetes and nutrition education for pregnant women with preexisting diabetes in Anchorage, Alaska: a retrospective quality improvement study
Investigator:	Audre Anderson
IRB ID:	STUDY2019000259
Sponsor:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Data collection tool; • Diabetes and nutrition education for pregnant women with preexisting diabetes in Anchorage, Alaska: a retrospective quality improvement study
IRB of Record:	Swedish Health Services

The IRB has approved this study effective 8/14/19. Per the federal regulations for research at 45 CFR 46.109(f)(1)(i), this minimal risk protocol does not require continuing review. **Please note** that the Principal Investigator still has the obligation to report various events to the IRB, such as unanticipated problems, deviations or non-compliance, changes to the research or study staff, or study closure. Additionally, the Principal Investigator remains responsible for monitoring HSP training and reporting conflicts of interest for study staff. You will continue to receive a notification yearly to check in with you regarding the above. That notification will not be a continuing review submission but only to check if any changes have occurred or if you are ready to close the study.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,
Allen Wyler, MD, SMC IRB Chair

APPROVAL OF SUBMISSION

March 9, 2020

Audre Anderson
audreyraye@gmail.com

Dear Audre Anderson:

On 3/3/2020, the IRB reviewed the following protocol via expedited review:

Type of Review:	Modification / Update
Title of Study:	Diabetes and nutrition education for pregnant women with preexisting diabetes in Anchorage, Alaska: a retrospective quality improvement study
Investigator:	Audre Anderson
IRB ID:	MOD2020000302
Sponsor:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Diabetes and nutrition education for pregnant women with preexisting diabetes in Anchorage, Alaska: a retrospective quality improvement study, Category: IRB Protocol
IRB of Record:	PSJH IRB

The IRB approved the most recent study modifications on 3/3/2020. As a reminder, in conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,

PSJH IRB

Appendix B: Updated Data Collection Templates

Table B-1. Assessment Information

Sample	Age	BMI	Health history (chronic hypertension)	Diabetes type	Diabetes duration	Employment status	Ethnicity	Pregnancy complications	Mode of delivery	Birth outcomes	Birth weight	Gravida para
1												
2												
3												
4												
5												
6												
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8												
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23												
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25												

Table B-2. Nutrition Education and Diabetes Education

Sample	Diabetes education ordered	Diabetes education completed	Nutrition education ordered	Nutrition education completed
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
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21				
22				
23				
24				
25				

Table B-3. Perinatal Blood Glucose and HbA1c

Sample	Preconception	1st trimester	2nd trimester	3rd trimester
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3				
4				
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10				
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Appendix C: Dissemination

Results of this retrospective quality improvement study will be disseminated to the health system in urban Alaska to aid in future staffing projections. This project could influence current diabetes education and record keeping provided at urban clinics in Alaska by addressing best practices and areas of improvement. Research findings support the need for outcome measures, specifically a blood glucose continuum, when providing MNT and DSME to pregnancy women with preexisting diabetes. Appropriate outcomes measures reinforce the efficacy of RDNs and CDEs. The final product of this research study will be an abstract submitted to the *Journal of the Academy of Nutrition and Dietetics* and the creation of a poster to submit for presentation at the Academy of Nutrition and Dietetics Food and Nutrition Conference and Expo.