

# **Clinic to community connections- Broader Distribution**

## **Study Protocol and Statistical Analysis Plan**

### **Principal Investigator**

Cynthia Herrick, MD, MPHS

### **Funded by**

NICHD K23HD096204

### **Confidentiality Statement:**

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# Study Personnel

## Principal Investigator

Cynthia Herrick, MD, MPHS  
Internal Medicine - Division of Endocrinology,  
Metabolism and Lipid Research  
Email: [herrickc@wustl.edu](mailto:herrickc@wustl.edu)

## Key Study Personnel:

Roxann Williams, MPH  
Internal Medicine - Division of Endocrinology,  
Metabolism and Lipid Research  
Email: [rcrenshaw@wustl.edu](mailto:rcrenshaw@wustl.edu)

## Affinia Collaborators:

Sonia Deal, RN, MSN/MHA, LNHA,  
CHCEF, PCMH CCE  
Asst Vice President of Clinical Integration  
Email: [sshanklin@affiniahealthcare.org](mailto:sshanklin@affiniahealthcare.org)

Melissa Tepe, MD, MPH  
Chief Medical Officer, ObGyn Physician  
Email: [mtepe@affiniahealthcare.org](mailto:mtepe@affiniahealthcare.org)

# Synopsis

<p><b>Primary Objective</b></p> <p>Evaluate the effectiveness of an interactive online module series to train staff involved in the care of women with gestational diabetes</p>
<p><b>Secondary Objectives (if applicable)</b></p> <p>Conduct a preliminary validation of a newly developed measure to assess self-efficacy to provide diabetes education</p> <p>Assess adoption of the modules and retention in the overall training</p>
<p><b>Study Duration</b></p> <p>Participants were able to complete the four modules at their leisure and given the opportunity to enter a drawing for a \$40 Visa gift card if they completed training within 3 months.</p>
<p><b>Study Design</b></p> <p>Prospective, single arm, pre/post training evaluation</p>
<p><b>Study Population</b></p> <p>Inclusion Criteria: Clinic staff: nurses (RN, LPN, BSN), community health workers, and others involved in maternal child health care</p> <p>Exclusion Criteria: Clinic staff: individuals not involved in maternal child health care or who do not consent to participate in study</p>
<p><b>Number of Participants</b></p> <p>100 individuals will be recruited to complete anonymous pre and post evaluations with 4 online training modules</p>
<p><b>Number of Study Sites</b></p> <p>Washington University School of Medicine will be the primary study site. Collaborators at Affinia Healthcare are involved in the development of the modules. Individuals will complete training online from the comfort of their home or workplace</p>
<p><b>Primary Outcome Variables</b></p> <p>The primary outcome is change in score on the self-efficacy to provide diabetes education scale (newly developed) before and after completing the 4 module training.</p>

**Secondary and Exploratory Outcome Variables (if applicable)**

- 1) Score change on Diabetes Knowledge test (overall and on subscores tied to content of each of 4 modules)
  - 2) Score change on 3 subscales of the Diabetes Attitudes Scale-3
    - Patient Autonomy
    - Value of Tight Control
    - Importance of Specialized Training
  - 3) Score change on Intention to Recommend Diabetes Prevention Measures Questionnaire (Newly Developed)
  - 4) Percent of individuals accessing each module and pre-and post-assessments
  - 5) Validation of Self Efficacy for Providing Diabetes Education Scale
- Correlation of baseline scale scores and General Self Efficacy Scale and Physician Teaching Motivation Questionnaire
- 6) Internal reliability statistics for all scales (Cronbach's alpha)

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# 1 - Introduction

## 1.1 Introductory Statement

Type 2 diabetes is a growing public health challenge and gestational diabetes predicts this preventable chronic disease at an early age. Half of all women with gestational diabetes will go on to develop type 2 diabetes without intervention. There are clear opportunities to intercede during and after pregnancy to prevent type 2 diabetes; however, it is difficult to operationalize these interventions in low resource settings and traditional healthcare models.

This study examines changes in self-efficacy, knowledge, attitudes and intentions among individuals who currently work with women who have pregnancies complicated by gestational diabetes, before and after completing online interactive education modules created by the research team.



## **2 - Background**

### **2.1 Background/prevalence of research topic**

GDM is an important public health problem as a diagnosis of GDM increases risks for mother and baby during pregnancy and delivery and increases the lifetime risk of maternal T2DM by 7 fold. Counseling on nutrition, physical activity, and modest weight gain to meet blood sugar targets is the cornerstone of GDM management during pregnancy. However, many Federally Qualified Health Centers, which serve as safety-net providers in under-resourced communities are not able to maintain certified diabetes educators and nutritionists on staff. Hence, many women do not receive structured diabetes self-management and nutrition education. The postpartum period is a high-risk transition of care; insurance coverage and health care providers often change, childcare responsibilities increase, and glucose abnormalities persist in a significant proportion of women with GDM after pregnancy. Despite professional guideline recommendations, there are substantial barriers to providing adequate medical nutrition therapy and diabetes self-management education to women with GDM, particularly during the pregnancy to postpartum transition. Clinic staff can be trained with modules covering the core principles of diabetes management during pregnancy and diabetes prevention for the future. As such, this study sought to evaluate such training provided in an online forum.

## **3 - Rationale/Significance**

### **3.1 Problem Statement**

Despite professional guideline recommendations, there are substantial barriers to providing adequate medical nutrition therapy and diabetes self-management education to women with GDM, particularly during the pregnancy to postpartum transition.

### **3.2 Purpose of Study/Potential Impact**

Clinic staff can be trained with modules covering the core principles of diabetes management during pregnancy and diabetes prevention for the future. The purpose of this study was to evaluate the effectiveness of this online training.

### **3.3 Risk and Benefits**

#### **3.3.1 Risks**

Risks of our study are minimal. Participation in the study is anonymous. Individuals who wish to be entered into the drawing for Visa gift card provide identifiers including social security number but this information is not linked to survey information.

#### **3.3.2 Potential Benefits**

Participants in the intervention will receive education and support which may improve their ability to take care of women with GDM and prevent future type 2 diabetes.

There are many potential benefits to the population of low-income women with GDM, healthcare providers and society in terms of knowledge to be gained. The online modules can be adapted to various education settings in the future.

## **4 - Study Objectives**

### **4.1 Hypothesis**

Our central hypothesis is that completing online interactive training modules on GDM will result in improved self-efficacy for providing diabetes education, improved GDM knowledge, improved attitudes toward patient autonomy, the value of tight control, and the need for specialized training, and increased intentions to recommend diabetes prevention measures.

### **4.2 Primary Objective**

Evaluate the effectiveness of an interactive online module series to train staff involved in the care of women with gestational diabetes.

### **4.3 Secondary Objectives (if applicable)**

Conduct a preliminary validation of a newly developed measure to assess self-efficacy to provide diabetes education

Assess adoption of the modules and retention in the overall training

## 5 - Study Design

### 5.1 General Design Description

All healthcare professionals will undergo the same procedures. After reading the instructions/what to expect page, participants will first create a personal ID code that will allow their responses to be linked, but protect their identity. Next, they will decide if they would like to participate in the research study. If they elect to participate in the research, they will complete questionnaires related to GDM knowledge, both general self-efficacy and self-efficacy to provide diabetes education, teaching motivation, intention to recommend postpartum diabetes screening, and diabetes attitudes. They will also complete a demographics questionnaire. Next, all participants will complete an approximately 4-hour online GDM training at their leisure. The online training will be composed of 4 modules covering the following topics: 1) GDM Disease and Diagnosis, 2) Practical nutrition and exercise for women with GDM, 3) Blood sugar monitoring and medication for women with GDM, 4) Future Diabetes - risk, screening, and prevention.

At the conclusion of module one, participants should be able to 1) Define gestational diabetes (GDM) & how it is diagnosed in the United States. 2) Compare changes in blood sugar control during normal pregnancy and GDM 3) Identify risk factors for GDM 4) Summarize the consequences for uncontrolled GDM for mom & baby. At the conclusion of module two, participants should be able to 1) define recommendations for weight gain during pregnancy 2) describe types of nutrients and examples of each 3) apply strategies for meal planning including cost concerns 4) design alternative plans for different dietary preferences 5) explain exercise recommendations during pregnancy 6) create a patient-centered trimester-specific physical activity plan. At the conclusion of module three, participants should be able to 1) describe blood sugar monitoring recommendations and goals in women with GDM, 2) Identify the risks and common symptoms of hypoglycemia and determine the appropriate treatment for these events, 3) Explain GDM treatment options including recommended medications. At the conclusion of module four, participants should be able to 1) Assess patients' risk of future diabetes mellitus, 2) describe current postpartum diabetes screening recommendations, 3) construct a patient-centered plan to minimize risks of future diabetes mellitus. Each module will feature questions within the module to engage with the participant and conclude with a post-test module specific knowledge assessment/review. The research team will collect all responses to these questions to assess the effectiveness of the modules. Information sources for the development of these modules include guidelines from the American Diabetes Association, Academy of Nutrition and Dietetics, American College of Obstetricians and Gynecologists, USDA Center for Nutrition Policy and Promotion, and primary literature.

After the training is complete, patients who elected to participate in the research, will repeat the GDM knowledge, self-efficacy to provide diabetes education, intention and diabetes attitudes assessments.

Items for each survey will be selected from previously validated measures and/or created by the PI. Items will be selected at the PI's discretion. All surveys and responses will be housed on Qualtrics. Participants will enter/create their unique personal ID before both survey sessions and before each education module. Participants may elect to complete the education training, but decline the option to participate in research.

If both the pre-assessment surveys and the post-assessment surveys are completed within 3 months, participants will be eligible to provide their information to be entered to win a \$40 Visa gift card. This identifiable information will only be collected to adhere to WashU institutional tax guidelines. This information will be collected using REDCap and will be stored separately from the research data.

### **5.1.1 Study Date Range and Duration**

Recruitment will start approximately June 1, 2020 and continue until 100 participants are recruited.

Primary outcome completion anticipated: August 2022

Secondary outcome completion anticipated: August 2022

### **5.1.2 Number of Study Sites**

Washington University School of Medicine will be the primary study site. Individuals will complete the modules online in the comfort of their homes/workplaces.

## **5.2 Outcome Variables**

### **5.2.1 Primary Outcome Variables**

The primary outcome is change in score on the self-efficacy to provide diabetes education questionnaire before and after completing the 4 module training. This was a newly developed measure

### **5.2.2 Secondary and Exploratory Outcome Variables (if applicable)**

- 1) Score change on Diabetes Knowledge test (overall and on subscores tied to content of each of 4 modules)
- 2) Score change on 3 subscales of the Diabetes Attitudes Scale-3
  - Patient Autonomy
  - Value of Tight Control
  - Importance of Specialized Training
- 3) Score change on Intention to Recommend Diabetes Prevention Measures Questionnaire (Newly Developed)
- 4) Percent of individuals accessing each module and pre-and post assessments
- 5) Validation of Self Efficacy for Providing Diabetes Education Scale
  - Correlation of baseline scale scores and General Self Efficacy Scale and Physician Teaching Motivation Questionnaire
- 6) Internal reliability statistics for all scales (Cronbach's alpha)

### **5.3 Study Population**

#### **5.3.1 Number of Participants**

100 participants will be recruited for the study.

#### **5.3.2 Eligibility Criteria/Vulnerable Populations**

Inclusion Criteria:

Clinic staff: nurses (RN, LPN, BSN), community health workers, and others involved in maternal child health care

Exclusion Criteria:

Clinic staff: individuals not involved in maternal child health care or who do not consent to participate in study

## 6 - Methods

### 6.1 Intervention

#### 6.1.1 Description of Intervention

Individuals will be provided with a link to 4 online training modules. Each module consists of a 45–60-minute video presentation with interactive illustrative patient cases and integrated knowledge assessment with feedback. Each module contained 4 to 9 example patient cases that addressed particular key points. Questions about these cases are embedded in the flow of module information and participants must answer these questions to progress. At the end of each module, 5-6 questions to assess knowledge are presented. After each question, the correct answer is provided with explanation

Module #	Topic		Learning objectives
1	GDM Disease, Diagnosis and Complications		<p>Define gestational diabetes (GDM) &amp; how it is diagnosed in the United States.</p> <p>Compare changes in blood sugar control during normal pregnancy and GDM.</p> <p>Identify risk factors for GDM.</p> <p>Summarize the consequences for uncontrolled GDM for mom &amp; baby.</p>
2	Nutrition and Physical Activity Management		<p>Define recommendations for weight gain during pregnancy.</p> <p>Describe types of nutrients and examples of each.</p> <p>Apply strategies for meal planning including cost concerns.</p> <p>Design alternative plans for different dietary preferences.</p> <p>Explain exercise recommendations during pregnancy.</p> <p>Create a patient-centered trimester-specific physical activity plan.</p>
3	Monitoring, Medications, and Avoiding Hypoglycemia		<p>Describe blood sugar monitoring recommendations and goals in women with GDM.</p>

			<p>Identify the risks and common symptoms of hypoglycemia and determine appropriate treatment for these events.</p> <p>Explain GDM treatment options including recommended medications.</p>
4	Future Diabetes Risk and Prevention		<p>Assess patient's risk of future diabetes mellitus.</p> <p>Describe current postpartum diabetes screening recommendations.</p> <p>Construct a patient-centered plan to minimize risks of future diabetes mellitus.</p>



### **6.1.2 Method of Assignment/Randomization**

Individuals were sequentially enrolled in a single study arm. There was no randomization.

### **6.1.3 Selection of Instruments/Outcome Measures**

See attached survey code book for reliability and validity statistics and references

## **6.2 Assessments**

### **6.2.1 Efficacy**

See attached surveys

### **6.2.2 Safety/Pregnancy-related policy**

There are no specific safety concerns in this study as this is an education intervention for healthcare staff, not patients.

#### **6.2.2.1 Adverse Events Definition and Reporting**

Individuals will be given contact information for study personnel to contact if there were concerns about training material or the study

## **6.3 Study Procedures**

### **6.3.1 Study Schedule**

Pre-test → Module 1 → Module 2 → Module 3 → Module 4 → Post-test

Individuals must complete pre and post tests and access all modules within 3 months to be eligible for Visa gift card drawing

### **6.3.2 Informed Consent**

A consent information sheet will be provided and individuals will be asked to confirm or decline participation in the research study. No written consent is required for this exempt study.

### **6.3.3 Screening**

Individuals will be allowed to participate if they self-identify as individuals involved in the care of women during gestational diabetes pregnancy.

### **6.3.4 Recruitment, Enrollment and Retention**

Modules are hosted online. Information about the availability of the modules will be distributed via email through multiple professional organizations to reach clinical staff providing care for women with GDM. Contacts at the following organizations will be emailed with a brief information form including a link to the modules: Nurse Family Partnership, MU Extension, St. Louis Regional Health Commission, St. Louis Integrated Health Network, Association of Women's Health, Obstetrics and Neonatal Nurses, National Association of Community Health Workers, National Association of Community Health Centers, Missouri Nurses Association, Generate Health, the Missouri Diabetes Shared Learning Network, Missouri Primary Care Association, American Public Health Association, and St. Louis community college community health worker and nurse training programs. Modules are eligible for nursing continuing education credits (1 credit per completed module) through Washington University. Information about the study with optional pre- and post-training assessments will be provided on the home page for the modules. Individuals will be asked if they agreed to participate in the study with a single question prior to completion of the

pre assessment. Individuals who complete the pre-assessment will receive a code to enter the first module and then a different code at the end of each module to enter the next module, and finally the post-assessment. The codes will be used to ensure individuals access all modules prior to completion of the post-assessment. Individuals completing modules within 3 months are eligible for drawing for a \$40 Visa gift card.

## **6.4 Statistical Method**

### **6.4.1 Statistical Design**

We plan a pre-post analysis of individual's scores on multiple continuous measures. For normally distributed data, a paired T test is planned. For non-normally distributed data, a Wilcoxon paired signed rank test is planned.

### **6.4.2 Sample Size Considerations**

This was a pilot study and no a prior sample size calculation was completed.

### **6.4.3 Planned Analyses**

#### **6.4.3.1 Primary Analyses**

For the primary outcome, we will compare scores on the self-efficacy for providing diabetes education before and after training among the individuals that complete the training.

#### **6.4.3.2 Secondary Objectives Analyses**

For GDM knowledge scores, we will compare scores before and after training for the overall diabetes knowledge test and for each of the subscales associated with the content of the 4 modules among the individuals that complete the training.

For Diabetes Attitudes scales, we will compare scores before and after training on each of 3 subscales (patient autonomy, value of tight control, importance of specialized training) among the individuals that complete the training.

For Intention to Recommend Diabetes Prevention Measures, we will compare scores before and after training among the individuals that complete the training.

To provide preliminary validation for the new self-efficacy scale, we will report correlations between the self-efficacy for providing diabetes education measure and the General Self Efficacy Scale and Patient Teaching Motivation Questionnaire. We will also report internal reliability statistics (Cronbach's alpha) for the self-efficacy for providing diabetes scale, Diabetes attitudes scale subscales, and Intention to Recommend Diabetes Prevention Measures.

We will report the number of individuals who complete the pretest, access each of the training modules, and complete the post test.

#### **6.4.3.3 Analysis of Subject Characteristics**

Descriptive statistics

Age mean (SD)

Race/ethnicity (n/%)

Education (n/%)

Specialty (n/%)

#### **6.4.4 Other**

##### **6.4.4.1 Subsets and Covariates**

Will compare baseline statistics on individuals who complete and do not complete training

##### **6.4.4.2 Handling of Missing Data**

Individuals who do not complete the post assessment will not be included in the pre-post score comparison.

## 7 - Trial Administration

### 7.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

This study will be conducted in accordance with the ethical principles that have their origin with the Declaration of Helsinki.

#### Protection of Human Subjects

- **Risks to Human Subjects:**

##### *1a) Human Subjects Involvement, Characteristics and Design:*

Eligible participants will be recruited for prospective data collection. Human subject involvement is essential in testing the proposed intervention. We will recruit 100 participants who self-report that they care for women who have gestational diabetes.

##### *1b) Study Procedures, Materials, and Potential Risks*

We will collect data from survey measures before and after module collection. Individual progress through pre and post assessments and all 4 assessments will be tracked by a self-generated anonymous identifier.

Risks of our study are minimal. Any identifiers collected for reimbursement of participants will be collected and stored separately in a REDCap database and is not linked to study answers.

- **Adequacy of Protection against Risks:**

##### *2a) Informed Consent and Assent:*

Participants will read a brief consent information sheet and then indicate if they would like to participate in the study with a yes or no answer.

##### *2b) Protections against Risks:*

Data are stored securely and collected anonymously.

##### *2c) Vulnerable Subjects*

This study does not recruit participants from vulnerable groups

- **Potential Benefits to Participants:**

Participants in the intervention arm will receive education and support which may improve their ability to take care of women with GDM and prevent future type 2 diabetes. There is no direct benefit for participants in the usual care arm.

- **Importance of Knowledge to be Gained:**

There are many potential benefits to the population of low-income women with GDM, healthcare providers and society in terms of knowledge to be gained. The online modules can be adapted to various education settings in the future.

### **Inclusion Plans for Women and Minorities:**

Individuals will be recruited with an attempt to have representation across gender and race and ethnicity. Given that we will be recruiting individuals involved in maternal-child healthcare, we anticipate that the majority of the sample will be female based on the composition of this workforce.

### **Inclusion Plans for Children:**

All individuals in the study will be at least 18 years of age as these must be individuals who are employed to care for women with GDM.

## **7.2 Institutional Review Board (IRB) Review**

This study will be approved by the Washington University institutional review board. This IRB reviews studies annually or as often as the research team submits modifications.

## **7.3 Subject Confidentiality**

Data will be stored in REDCap and Qualtrics with study identifiers only. There will be no link between identifiers collected for compensation and self-generated identifier for the study.

## **7.4 Deviations/Unanticipated Problems**

Adverse events will be reported to the IRB in the required time frame through submission of an adverse event reporting form.

## **7.5 Data Collection**

Data will be collected in the following ways

- 1) Qualtrics survey forms: participants will complete at baseline and after completion of online modules
- 2) Retention will be tracked by having individuals enter a self-generated identifier for the pre and post assessments and prior to entering each module.

## **7.6 Data Quality Assurance**

Data will be reviewed by the study coordinator on a quarterly basis to assess completeness and protocol adherence.

## **7.7 Study Records**

Regulatory: Incentive log, Delegation log, Team member HRPO and GCP training and certification, IRB approval memo, Protocol, Qualtrics surveys, Data collected by CME office on entry/completion of interactive questions in modules

## **7.8 Access to Source**

Data needed to provide compensation will be stored in a secure REDCap database. Survey answers will be stored by study ID in Qualtrics.

## **7.9 Data or Specimen Storage/Security**

Data will be stored in REDCap and Qualtrics and exported into SPSS for analysis.

#### **7.10 Retention of Records**

Records will be retained for 7 years after the completion of the study. They will be destroyed in a HIPAA compliant manner under the supervision of the principal investigator at that time. Any records that need to be moved will be done under the supervision of the principal investigator.

#### **7.11 Study Monitoring**

The team will conduct internal audits quarterly for quality assurance and reporting purposes.

#### **7.12 Data Safety Monitoring Plan**

The intervention will be provided in addition to standard of care. We will not be administering medication through the study and the study protocol will not change clinical decision making. I do not anticipate adverse events or circumstances related to study procedures that would pose a safety hazard to participants. The PI, members of the research team and the WUSM Human Research Protections Office will monitor the study for safety. In the unlikely event of an adverse event, the PI, in collaboration with relevant personnel, will take the appropriate action and report the event to the Human Subjects Research Protections Office (HRPO). While we do not anticipate any circumstances will arise that would compromise the safety of participants, should such an event occur, it will be reported to the PI immediately and research will be suspended until appropriate procedures are in place to allow the continuation of the study.

#### **7.13 Study Modification**

Study modifications will be submitted to the IRB when the need for changes arise. Changes to the protocol will only be implemented after appropriate IRB approval is received.

#### **7.14 Study Discontinuation**

The study will be discontinued if enrollment targets are not reached by 2 years or if there are adverse events directly attributed to the interaction between the patient and the community health worker.

#### **7.15 Study Completion**

Completion of the primary outcome collection is anticipated to be 8/2022

#### **7.16 Conflict of Interest Policy**

The study team members have no financial conflicts of interest with this study. Any conflicts of interest that arise during the conduct of the study will be reported to the IRB immediately.

#### **7.17 Funding Source**

This study is funded by NICHD K23HD096214

#### **7.18 Publication Plan**

There are no requirements for review prior to publication from the funders. The PI is primarily responsible for publishing study results.

# Appendix

## Pre- and post-assessment surveys

**\*GSES and PTMQ to be used to assess convergent validity of the SEPDE and only administered in the pre-assessment**

### General Self-Efficacy Scale (GSE)

Items: 10

Scoring:

	Not at all true	Hardly true	Moderately true	Exactly true
All questions	1	2	3	4

Questions:

1. I can always manage to solve difficult problems if I try hard enough
2. If someone opposes me, I can find the means and ways to get what I want
3. It is easy for me to stick to my aims and accomplish my goals.
4. I am confident that I could deal efficiently with unexpected events.
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.
6. I can solve most problems if I invest the necessary effort.
7. I can remain calm when facing difficulties because I can rely on my coping abilities.
8. When I am confronted with a problem, I can usually find several solutions.
9. If I am in trouble, I can usually think of a solution
10. I can usually handle whatever comes my way.

### Physician Teaching Motivation Questionnaire (PTMQ)

Items: 4

Scoring: Answers on a Likert scale from 0 to 4. Zero represents “does not apply at all” and 4 represents “fully applies” for all questions.

Note: word “unit” changed to “opportunity” in question 1 to better reflect experience of our participants.

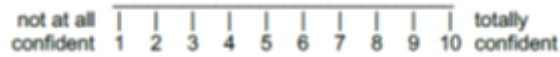
Questions:

1. I look forward to my next teaching opportunity most of the time.
2. I enjoy my teaching most of the time.
3. During my teaching, I am completely in my element.
4. Teaching enriches my job.

### Self-Efficacy for Providing Diabetes Education (SEPDE)

Items: 15

Scoring: Please select a whole number that represents your degree of confidence with each of the statements below. Response scale:



#### Statements related to specific components of diabetes education:

##### I feel confident that I can...

1. Teach a woman how to check her blood sugar.
2. Talk to women about healthy culturally relevant food choices and alternatives.
3. Help women change their diet from unhealthy food choices to healthy food choices.
4. Help women plan meals to keep their blood sugar in a good range.
5. Help a woman find an exercise she can do safely during pregnancy.
6. Recognize when a woman's blood sugars are too high and she needs to speak to the doctor.
7. Recognize low blood sugar symptoms and tell a woman how to treat this effectively without over treating.
8. Tell a woman what steps she can take to prevent diabetes after pregnancy.
9. Describe diabetes screening recommendations after a pregnancy with gestational diabetes.

#### Statements related to overall ability in teaching:

##### I feel confident that I ....

10. Can ask for the support I need to provide high quality education to patients with gestational diabetes.
11. Am able to identify and address challenges that may make providing diabetes education difficult.
12. Can try out different ways to overcome learning challenges and help the patient understand, even when a patient struggles with the concepts I am teaching.
13. Am as good as others with my level of training at teaching patients about their gestational diabetes.
14. Can set realistic goals with my patients to reach their blood sugar targets (for example, I can help a patient recognize that drinking soda raises blood sugar and set a goal to substitute soda with another non-caloric drink).
15. Can help my patients make a plan to meet their diabetes care goals.

Scoring: Calculate mean score from all components (and mean score of subscales if load on more than one factor).



## **Diabetes Attitude Scale (DAS)**

Items: 20

Scoring: Answers on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree) for all questions. 20 question and 3 subscales were selected. Calculated mean score for each subscale.

### **Questions focused on patient autonomy:**

In general I believe that...

1. The important decisions regarding daily diabetes care should be made by the person with diabetes.
2. Health care professionals should help patients make informed choices about their care plans.
3. People with diabetes should have the final say in setting their blood glucose goals.
4. The person with diabetes is the most important member of the diabetes care team.
5. People with diabetes should learn a lot about the disease so that they can be in charge of their own diabetes care.
6. What the patient does has more effect on the outcome of diabetes care than anything a health professional does.
7. People with diabetes have a right to decide how hard they will work to control their blood sugar.
8. People with diabetes have the right not to take good care of their diabetes.

### **Questions focused on value of tight control:**

In general I believe that...

9. There is not much use in trying to have good blood sugar control because the complications of diabetes will happen anyway.
10. Keeping the blood sugar close to normal can help to prevent the complications of diabetes.
11. Almost everyone with diabetes should do whatever it takes to keep their blood sugar close to normal.
12. Low blood sugar reactions make tight control too risky for most people.
13. People who have gestational diabetes will probably not get much payoff from tight control of their blood sugars.
14. Tight control is too much work.
15. Tight control of blood sugar makes sense only for people with type 1 diabetes.

### **Questions focused on need for special training:**

In general I believe that...

16. Health care professionals who treat people with diabetes should be trained to communicate well with their patients.
17. Health care professionals should be taught how daily diabetes care affects patients' lives.
18. It is important for the nurses and dietitians who teach people with diabetes to learn counseling skills.
19. Health care professionals should learn how to set goals with patients, not just tell them what to do.
20. To do a good job, diabetes educators should learn a lot about being teachers.

## Gestational diabetes knowledge questions

Items: 23

Score: Ratio total correct/total number.

Correct answers are highlighted.

23 questions total, subdivided by topic area:

Questions 1-5: Disease and complications knowledge

Questions 6-11: Weight, nutrition and physical activity knowledge

Questions 12-18: Medication and monitoring knowledge

Questions 17-23: Future risk and screening knowledge

1. Gestational diabetes occurs because:
  - 1) The body develops antibodies to the cells in the pancreas that make insulin (A)
  - 2) The placenta makes hormones that make the mother resistant to insulin
  - 3) The mother's pancreas can't make enough insulin
  - 4) B&C
2. Gestational diabetes is diagnosed in the US by:
  - 1) The HbA1C test
  - 2) A 3-hour 100 g oral glucose tolerance test with 2 or more abnormal values
  - 3) A 1 hour 50 g glucose challenge test
  - 4) Finger stick blood glucose testing
  - 5) A 2-hour 75g oral glucose tolerance test with 2 or more abnormal values
3. All of the following are possible complications from poorly controlled gestational diabetes except:
  - 1) Preterm labor
  - 2) Low blood sugar for infant at birth
  - 3) Placenta previa
  - 4) C section
  - 5) Large for gestational age infant
4. Which of the following are risk factors for gestational diabetes?
  - 1) Maternal age
  - 2) Hispanic ethnicity
  - 3) Maternal obesity
  - 4) All of the above
5. What is a good estimate of how common gestational diabetes is in the US?
  - 1) 2%
  - 2) 7%
  - 3) 15%
  - 4) 25%

6. If a woman starts pregnancy with a BMI over 30, how much weight should she gain if she is having one baby?
- 1) 28-40 lbs
  - 2) 25-35 lbs
  - 3) 15-25 lbs
  - 4) 11-20 lbs
7. How many extra calories does a woman need during the 1st trimester?
- 1) None
  - 2) 200
  - 3) 400
  - 4) 500
8. When choosing a vegetable, which of the following would have the least amount of carbohydrates?
- 1) Corn
  - 2) Winter Squash
  - 3) Spinach
  - 4) Carrots
  - 5) Peas
9. When choosing a fruit, which of the following would have the least amount of carbohydrates?
- 1) Blackberries
  - 2) Grapes
  - 3) Banana
  - 4) Apple
  - 5) Dried apricot
10. Which of the following meals would be the best choice for lunch for a woman with gestational diabetes?
- 1) Pizza and sweet tea
  - 2) Ham and cheese sandwich with an apple
  - 3) Baked potato with butter, sour cream, cheese, and bacon
  - 4) Peanut butter and jelly sandwich with Sugar free pudding
  - 5) Hard-boiled egg and string cheese
11. What exercise is considered safe during pregnancy?
- 1) Walking
  - 2) Low impact aerobics
  - 3) Weight lifting
  - 4) Roller skating
  - 5) A&B

12. What is the initial recommendation for blood sugar monitoring frequency during pregnancy with gestational diabetes?
- 1) Once a day at bedtime
  - 2) Once a day in the morning
  - 3) Fasting and 1 or 2 hours after each meal
  - 4) Twice a day before breakfast and dinner
  - 5) Before each meal and at bedtime
13. If a woman with gestational diabetes requiring insulin has a normal blood sugar before a meal and is planning to eat a sandwich, she would need to take rapid acting insulin
- 1) True
  - 2) False
14. Which of the following medication(s) are not first line to treat gestational diabetes?
- 1) Metformin
  - 2) Glyburide
  - 3) Insulin
  - 4) A and B
  - 5) A and C
15. Which times of day are her blood sugars too high?
- 1) Fasting in the morning
  - 2) 1 hour post breakfast
  - 3) 1 hour post dinner
  - 4) A&C
  - 5) B&C
16. What insulin(s) are best to give as a rapid acting insulin with a meal that has carbohydrates?
- 1) NPH (Humulin R or Novolin N)
  - 2) Regular (Humulin R or Novolin R)
  - 3) Glargine (Lantus, Basaglar, or Toujeo)
  - 4) Lispro (Humalog, Admelog)
  - 5) A and C
17. What symptoms might indicate that someone's blood sugar is low?
- 1) Sweating
  - 2) Vomiting
  - 3) Confusion
  - 4) Abdominal pain
  - 5) A&C
18. If a woman's blood sugar is 59, what should she be told to do first?

- 1) Call the doctor
  - 2) Drink a 20 oz soda and check blood sugar in an hour
  - 3) Drink 4 oz of juice and check blood sugar in 15 minutes
  - 4) Eat a bowl of ice cream and check blood sugar before next meal
19. What percentage of women with gestational diabetes may go on to develop type 2 diabetes?
- 1) 10%
  - 2) 30%
  - 3) 50%
  - 4) 90%
20. Sam had gestational diabetes in her recent pregnancy and is now 2 weeks postpartum. What should she be told about getting screened for type 2 diabetes?
- 1) If they checked her blood sugar in the hospital and it was normal, she doesn't need further testing.
  - 2) She should have a 2-hour oral glucose tolerance test at 4-12 weeks and a hemoglobin A1C every 1-3 years life long
  - 3) She should have a hemoglobin A1C now and every 1-3 years life long
  - 4) She should have a 2-hour oral glucose tolerance test 4-12 weeks postpartum and if this is normal, she doesn't need further testing.
21. Anna's blood sugar was 152 mg/dl 2 hours after drinking 75g glucose at 6 weeks postpartum (this is consistent with impaired glucose tolerance or pre-diabetes). How often should she be screened for diabetes going forward?
- 1) Every 6 months
  - 2) Every 1 year
  - 3) Every 3 years
  - 4) Every 5 years
22. Metformin was as effective as lifestyle change at preventing diabetes among women who had gestational diabetes.
- 1) True
  - 2) False
23. Which of the following would not be helpful in making lifestyle change to prevent diabetes?
- 1) Increase non-starchy vegetable consumption
  - 2) Stop drinking soda and drink juice instead
  - 3) Limit portion sizes
  - 4) Increase moderate physical activity
  - 5) Eat whole grains instead of refined grains

## Intentions for Diabetes Prevention

Items: 8

Scoring: Please rate the following statements on a scale of 1 (very unlikely) to 5 (very likely).

	Very unlikely	Somewhat unlikely	Neutral	Somewhat likely	Very likely
All questions	1	2	3	4	5

How likely are you to recommend that women with a history of gestational diabetes ...

1. Receive a diabetes screening test in the first 3 months after delivery
2. Receive a diabetes screening test at least every 3 years
3. Receive a diabetes screening test early (1<sup>st</sup> trimester) in the next pregnancy
4. Breastfeed, if able, for at least a little while after delivery
5. Breastfeed, if able, for more than 6 months after delivery
6. Continue the diet recommendations for gestational diabetes after pregnancy
7. Continue to get 150 minutes of moderate physical activity per week after pregnancy
8. Try to get back to their pre-pregnancy weight by one year postpartum