Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs Completion of Women with Gestational Diabetes Mellitus

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Abstract

Gestational diabetes mellitus (GDM) can cause adverse outcomes for the mother and fetus due to hyperglycemia. The purpose of this pilot study is to evaluate the feasibility of improving pregnant women's glucose log completion rates using a Bluetooth enabled glucose monitor and associated mobile health application and to assess their satisfaction with using mobile health technology. Methods: This project utilizes a quasi-experimental pre-post design. Over the course of 8 weeks, participants completed serum glucose logs (SGL). In phase one the participants collected logs for four weeks using their standard glucose meter followed by phase two in which the participant used a provided Bluetooth-enabled glucometer with the iGluco application for four weeks. Eligibility for this study included but was not limited to a diagnosis of GDM, English or Spanish speaking, and ownership of a smartphone capable of running the mobile health application. Data collected included demographic information, serum glucose logs, and a satisfaction survey. Results: Five participants completed the study. The average completion score was 74.82% in phase one and 81.73 in phase two (a difference of 6.91%). The iHealth glucometer was the preferred monitor with overall satisfaction of the diabetes care received. Implications: This study has the potential to help demonstrate the feasibility of improved self-management of GDM and provide the groundwork for future studies. Conclusion: The use of Bluetooth enabled glucose monitors with mobile health applications may translate to a more accurate reflection of the actual meter reading, be more efficient, and more complete

Key terms: M-Health, Gestational diabetes, Bluetooth, Self-Monitoring of Blood Glucose (SMBG), Capability, Opportunity, Motivation COM-B model, Health Belief Model (HBM).

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Introduction

Diabetes occurs when the pancreas does not produce enough insulin or the body's cells cannot metabolize glucose that is in the bloodstream despite the presence of insulin (O'Tool, 2003; World Health Organization (WHO), 2016). When either of these malfunctions occurs, glucose builds up in the bloodstream. Body structures begin to fail if this problem persists. This failure can result in blindness, renal failure, cardiovascular diseases, amputations, and even death (American Diabetes Association (ADA), 2017; Cunningham et al., 2010; WHO, 2016).

The impact of diabetes can be burdensome to anyone it affects but can be especially so for women who are pregnant. Gestational diabetes mellitus (GDM) results from the development of carbohydrate intolerance during pregnancy due to the increased stress placed on the body (American College of Obstetricians and Gynecologist (ACOG), 2017; Cunningham et al., 2010). This condition can be treated with diet or medication depending on how severe the condition becomes. GDM is one of the most common diseases to occur during pregnancy affecting an estimated nine percent of pregnant women (ACOG, 2017; Cunningham et al., 2010). GDM puts women at an increased risk for polyhydramnios, pre-eclampsia, and future diagnosis of type two diabetes, also known as overt diabetes, later in life (ACOG, 2017; ADA, 2017; WHO, 2016). The effects of diabetes on the fetus depends on whether a woman has overt diabetes or develops diabetes during pregnancy. Screening for GDM occurs during the 24th through 28th week of gestation (ACOG, 2017; Cunningham et al., 2010). Fetal anomalies, stillbirth, macrosomia, and hypoglycemia are a few of the potential risks to infants born to women with GDM (ACOG, 2017; ADA, 2017; Cunningham et al., 2010; WHO, 2016). To avoid the harmful effects of GDM

healthcare providers, seek to be successful in reducing the harm of hyperglycemia. Research indicates therapy designed to control hyperglycemia, decreases the occurrence of adverse outcomes in pregnancy making glycemic control fundamental to the successful management of GDM (ACOG, 2017; Cunningham, 2010).

Diabetes can affect women of all cultures and ethnic backgrounds with a prevalence rate estimated at around 9.2% of pregnancies (CDC, 2014). Approximately 6.8% of Caucasian/ non-Hispanic women go on to develop GDM. This percentage is in stark contrast to the 16.3% who are of Asian/Pacific Island descent, the 12.1% who are Hispanic, or the 10.5% Black/non-Hispanic who will develop GDM during pregnancy (CDC, 2014). Although overall, women who develop GDM are at a higher risk of developing type two diabetes later in life, these minority groups go on to develop diabetes at higher rates (Hunsberger, Ronsenberg, & Donatelle, 2010; Wang et al., 2012).

Patients diagnosed with GDM usually are asked to perform self-monitoring of blood glucose (SMBG) one to two hours after a meal and in the morning before eating, usually four times a day (ACOG, 2017; Cunningham et al., 2010). With each testing event, the woman records her results in a log that she will bring with her to her medical appointments. However, one study with 26 participants found that only 7.7% of the control group (n = 13) completed their glucose logs (Quinn et al., 2011).

The health and technology industries have joined together to increase the wellness and reduce the burden of chronic illnesses such as diabetes. Researchers are currently studying mobile health (m-health) around the world. There are approximately 1100 diabetic applications available with several specific to GDM (University of Florida (UF), 2017). The mobile phone diabetes applications boast many benefits such as easier tracking and reporting of serum glucose results.

These applications can record glucose logs via communication with the glucometer or through manual input. This data can then be transmitted to a Health Insurance Portability and Accountability Act (HIPPA) compliant cloud giving real-time access to the data to healthcare providers (Ming et al., 2016; UF, 2017). These applications can also record exercise, nutrition, offer education and provide a visual presentation of the glucose results and the interpretations (UF, 2017).

M-Health is a sub-category of telehealth; both use digital technology to deliver health services and education remotely (Ming et al., 2016; National Rural Health Resource Center, 2014). Mobile phones and Bluetooth enabled technology has the potential to decrease the disparities seen in diabetes (Ming et al., 2016; Stroetmann et al., 2010). According to Pew research, 77% of Americans own smartphones; this includes 72% of the African-American, and 75% of the Hispanic population (Pew, 2017). Mobile internet is granting more people access to online health information and communication with their providers (Prieger, 2015). For example, African-Americans are said to be twice as likely than Caucasians to use their smartphone devices to access m-health and healthcare information (Prieger, 2015). Enabling women to efficiently record and communicate the serum glucose logs with Bluetooth technology has great potential to decrease missing data, time spent recording data, and potentially decrease the noted disparity populations.

Theoretical Framework

Evaluation of the obstacles faced by women who receive a diagnosis of gestational diabetes mellitus during their pregnancy reveals the need for a theoretical framework that provides a dynamic pathway to sustainable interventions. The Health Belief Model (HBM) best encompasses the behavior change philosophy incorporated into a framework that was used to

design the interventions for this project. The HBM originated in the 1950's by the U.S. Public Health Services (USPHS) in response to a perplexing phenomenon. The USPHS set up free mobile tuberculosis screening only to have few people utilize the much-needed service (Edberg, 2013). Doctors Godfrey Hochbaum, Irwin Rosenstock, and Stephen Kegels researched why so few used this service and concluded that motivation was at the core of health behavior (Edberg, 2013). The HBM addresses what drives motivation. Perception of six health beliefs such as susceptibility, severity, benefits, barriers, cues to action, and self-efficacy are thought to be integral parts of motivation. (Edberg, 2013). These perceptions either promote or inhibit motivation to conduct a health behavior. The base framework for this study is the Health Belief Model. However, more was needed to design appropriate interventions. The Behavior Change Wheel (BCW) is a framework based off of 19 frameworks of behavior change. Although the BCW is too broad for this specific study design, it includes a vital instrument for designing interventions that can be implemented to drive change. The capability, opportunity, and motivation behavioral system (COM-B) model is a fundamental part of the BCW that directs the examination of what drives behaviors in addition to giving insight for removing barriers and implementing interventions (Handley et al., 2016; Michie, Atkins, &West, 2014). This study uses the HBM as the overarching umbrella framework with the COM-B model embedded to facilitate interventions that support change (see Figure 1). Ultimately, a person's capability, opportunity, and motivation are both organic and perceived. The evaluation of each behavior change considers the probability of change, sustainability, the risk/benefit of the change and the measurability. The elements of capability, opportunity, and motivation are broken down into their components and evaluated for what is required for the change to occur. This study has implemented education, training, and enablement as behavior change techniques (BCT) (see

Figure 2). The review of the literature supports the use of each BCT chosen for this project. The following is an abbreviated sample for the application of COM-B as it applies to this study.

Capability

Capability establishes the ability, either physical or psychological to perform a behavior or behavior change that is needed. A person's mental capability encompasses their knowledge, ability to remember, decision-making processes, ability to regulate behavior and their cognitive and interpersonal skills (Michie et al., 2017).The questions asked for this study to guide the design were as follows: Do the women know how to check their serum glucose? Are the women physically capable of checking serum glucose? Can the women learn how to use the serum glucose monitor and the application?

Opportunity

Opportunities provide the women the needed resources either physical, social, or both to accomplish the behavior (Michie et al., 2014). The questions asked for this study to guide the design were as follows: Do women have the needed supplies to check their serum glucose as agreed upon in their plan of care? Do the women in the study have smartphones? Do the women have time to check their glucose levels and log them as agreed?

Motivation

Motivation consists of drive, impulse, incentive or inspiration to accomplish a behavior change (Michie et al., 2014). Motivation can be automatic such as wants and needs, driven by reinforcement or emotions. It can also be reflective. Reflective motivation comes from the belief of right and wrong derived from ones professional or social identity, the perception of capability, optimism, the perception of consequences, intentions, and goals. The questions asked for this study to guide the design were as follows: Do the women believe checking serum glucose is

needed? Do women desire to check their serum glucose? What are the women's perceived barriers to checking their serum glucose as agreed upon with their providers?

Review of Literature

A literature search was conducted to find literature addressing electronic submission of glucose readings by patients to clinicians. Search engines used to find articles included PubMed, Virgo, Google Scholar, Google, Ovid Medline, Web of Science, ClinicalTrials.gov and Cochrane. Keywords or combinations thereof used to search were m-health, mobile health, telemedicine, smartphones, Bluetooth, wireless, diabetes, gestational diabetes, GDM, remote transmission, barriers, and Bluetooth enabled glucose monitor. The key phrase used in this search was Barriers to self-monitoring of serum glucose. Inclusion criteria for this literature review were the ability for the patient to remotely transmit glucose readings to clinicians, randomized control trials or meta-analysis, qualitative studies, and diabetic patients of any age. Articles excluded included pilot/feasibility studies, if they included a disease process other than diabetes, reported a protocol for an approved study or they offered no new information. A total of 37 articles were scanned for inclusion criteria. Fourteen articles were excluded due to irrelevant titles. One article did not meet keyword criteria, and 13 articles were cut because they did not meet inclusion criteria. An ancestry search yielded an additional two articles that met the inclusion criteria. Ultimately 11 were included in the review of the literature (see Figure 3).

Capability, Opportunity, and Motivation and Self-Monitoring of Blood Glucose (SMBG)

The most efficient and cost-effective way to manage diabetes and GDM is to have the patient monitor their serum glucose on a schedule agreed upon by the provider and patient (Fisher, 2007; Ong, Chua, & Ng, 2014; Ward, Stetson, & Mokshagundam, 2015). The patient then records the results of the self-tested serum glucose over time providing date and time of result in a glucose

log. This method allows the patient to see how their diet affects their serum glucose and make daily adjustments to their diet. This task is also a pathway for the provider to engage the patient in personal decision making for the patient's treatment plan. A complete and accurate serum glucose log is critical to communicating the results of each test performed. The review of the literature indicates that SMBG task completion is as low as 26% in the United States for patients diagnosed with diabetes (Fisher, 2007; Ong et al., 2014). In three separate studies with a combined total of 564 participants pain, motivation, social stigma, time, money, and emotional tie to results were barriers to successful SMBG (Ong et al., 2014; Persson, Winkvist, & Morgren, 2010; Ward et al., 2015). Other significant barriers included understanding the disease, plan of care, and testing process (Ward et al., 2015).

Education, Training, Enabling, and HgbA1c

The HgbA1c can give the provider/patient dyad an idea of how the patient managed their glucose over the last three months with one blood test. The research found on utilizing m-health in conjunction with SMBG measured the HgbA1c as an outcome measure for significance either supporting or failing to support their intervention. Interventions studied in the reviewed randomized control trials lacked a stated theoretical framework or background of any kind. The researchers were likely unaware of the fact they were attempting to make a difference by altering capability, opportunity, and motivation. Each study reviewed utilized three necessary interventions identified on the Behavior Change Wheel as education, training, and enabling (Michie et al., 2014).

A randomized control trial conducted in the UK by Farmer et al., (2005) sought to determine if telehealth support would lower the HgbA1c of patients diagnosed with type one diabetes. After nine months the study failed to detect a significant difference in HgbA1c for the intervention

group compared to the control group ($p = 0.3$). The target population had an HgbA1c higher than 8%. The total number of participants was 93. The control and intervention group were given a serum glucose monitor with a cellular phone capable of documenting their insulin, dietary, activity, and glucose logs. A Diabetes Specialist Nurse (DSN) monitored the data transmissions of the intervention group and responded by contacting the patients with concerns, solutions, and assisted the patient in establishing action plans with reasonable goals. The intervention group also had access to their information via the internet that included immediate feedback with a colorful graphic display of results for the past two weeks. Although the control group's data also transmitted to the data processing facility, the DSN was unable to access that information. The cellular phone and website gave minimal feedback other than standard of care and results in basic diary format. Results for the control group were available for the past 24 hours only. Limiting factors for this study included several instances of not being able to transmit data as needed due to technical difficulties, damages, or theft of the mobile phones.

Another study conducted in the UK by Hirst et al., (2014) had a total of 49 women diagnosed with GDM and was evaluating the satisfaction component of using Bluetooth enabled monitors. Participants volunteered to use a provided Polymap glucose meter accessory with Life Scan Ultra Easy meter. This meter featured Bluetooth technology and automatically transmitted blood glucose (BG) readings to an application on a smartphone that would further transmit via a 3 G network to a secured website at the National Health Services. A midwife or physician reviewed the transmitted information three times a day that included not only the BG reading but the diet and medication as it was input by the participant. The healthcare provider would then decide if communication with the patient was necessary. If communication or intervention was necessary, the healthcare provider phoned or messaged the patient. The participant had the option of

speaking with the healthcare provider either by phone, messaging, or in person regardless of BG readings. The Questions and Responses to the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) utilized a Likert scale. Overall, the majority of the satisfaction scores were strongly positive indicating that the use of the m-health technology was acceptable and functioned as a method of communication for results and interventions.

Istepanian et al. (2009) completed a study that took place at Thomas Addison Diabetes Unit of St. George in London UK with 137 participants. Both the intervention and control group received diabetes care and self-blood glucose monitoring education. The intervention group was given Bluetooth enabled serum glucose monitors and a cellular phone. The cellular phone reminded the patient each time a serum glucose check was due based on a personalized prearranged schedule. Clinicians based at St. George's Hospital in London, UK received and reviewed the results. The participants then received letters of treatment recommendations. The participants in the intervention group were able to use the cellular phone for free to contact the research team for needed support. The control group received standard care and did not use the cellular phones to transmit their data. The completion rate for the study was 63.5% with 56% of the intervention group not completing the study. The high attrition rate was attributed to technical difficulties but is a limitation of this study even when considering intention to treat calculations. This study found no significant difference in the HgbA1c of the intervention group compared to the control group ($p = 0.17$).

Ming et al., (2016) conducted a systematic review of RCT studies with the inclusion criteria of "any system to monitor serum glucose remotely utilizing either fixed-line phones, mobile phones, or internet-based systems." (p. 2). Articles in this analysis included pregnant women with a diagnosis of (GDM) and preexisting type 1 or 2 diabetes. Seven RCT were analyzed, six

for clinical outcomes and one for patient satisfaction. It is worth noting there was significant heterogeneity for some of the studies compared in this meta-analysis. There was a significant difference in HgbA1c between the telemedicine intervention studies that included all diabetes and the control groups in the meta-analysis ($p = 0.02$) in favor of the intervention groups. There was a significant difference in HgbA1c between the telemedicine intervention groups that included only GDM and the control groups in the meta-analysis ($p = 0.01$).

Quinn et al., (2008) evaluated 30 patients who had been diagnosed with type 2 diabetes for at least six months and were between the ages of 18 to 70 years old. All patients in this study completed a Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire, a complete medical history, and had an HgbA1c collected. The control group received a One Touch Ultra BG meter with supplies and received usual care for the management of diabetes. They were instructed to fax or call in their BG results every two weeks to their Health Care Providers (HCP) until their BG was stable or their HCPs changed their regimen. Patients randomized to the intervention group were given a Bluetooth enabled One Touch Ultra BG meter with supplies and a Nokia 6682 or 6680 cellular phone that had the WellDoc's proprietary diabetes manager software. The study staff instructed the patients on how to use the technology and what to do if it did not work. The intervention group transmitted their BG results electronically every four weeks or sooner if needed. The WellDoc's software transmitted the patient's behavior and an analysis of data with trends. The WellDoc's software would then give the patient suggestions on activities, lifestyle choices, and diet if the need for improvement were detected. After receipt of the data from the WellDoc's software, the healthcare provider would personalize feedback and treatment. The intervention group had a significantly lower HgbA1c compared to the control group ($p = 0.02$). All of the intervention group had completed logs according to protocol

compared to 7.7% of the control group with $p < 0.001$. Overall patients were satisfied with the intervention system components this was true for the physicians as well. The control group had less than half of the patients satisfied with their diabetes management with only 7.7% completing the log books per protocol. None of the physicians surveyed were satisfied with the management of diabetes by their patients. Limitations include a small sample with the loss of four participants and the fact that only five of the 15 people in the intervention group consistently used the Bluetooth feature of the glucose monitor due to technical issues.

A study by the Department of Health in England via 112 clinical sites including 513 participants (Steventon, Bardsley, Doll, Tuckey, & Newman, 2014). The inclusion criteria included over 18 years old, diagnosis of gestational diabetes, chronic obstructive pulmonary disease or heart failure. The intervention arm of the study used provided telehealth equipment as well as serum glucose monitors, blood pressure monitors, pulse oximeters, or weight scales. The patient would then take readings per an agreed upon schedule and transmit them remotely to the clinical site. Patients received feedback based on the results. Patients also could transmit questions or concerns via telehealth equipment for increased support. Patients in the control arm received usual care without specific telehealth interventions. There was a significant difference for HgbA1c in favor of the intervention group ($p = 0.013$).

Wild et al., 2016 enrolled 321 male and female patients with type 2 diabetes from 42 clinics for a study in England and Scotland. The participants were over 17 years old, had mobile phone signal access at home, and had poorly controlled with HgbA1c's above 58mmol/mol. Bluetooth enabled technology transmitted results to research nurses for the intervention group. The staff gave support for needed lifestyle and medication alterations in response to the results received by the research nurses. At the conclusion of the trial that spanned nine months, the intervention

participants were asked to follow up with their healthcare provider. The control group received usual care that included a review of their results once a year by their Family Practice physician or more often if they had poorly controlled glucose levels. There was a significantly lower HgbA1c in favor of the intervention group ($p = 0.0007$). The authors concluded that there was a clinical and statistical significance for patients that utilized the Bluetooth enabled technology for transmission of data to their healthcare providers with "as needed" support.

Wojcicki et al., 2001 conducted a study at the Clinic of Gastroenterology and Metabolic Diseases of the Medical Academy in Warsaw Poland with pregnant patients diagnosed with type 1 diabetes. The participant inclusion criteria included a diagnosis of type 1 diabetes, pregnancy less than 16 weeks, no diseases, and IQ greater than 85 on the Wechsler-Bellevue Scale for Adults and an HgbA1c less than 9.5%. This study had 30 participants. Both groups received a three-day education session in which the patient had a two-day hospitalization period and an additional training day. Participants tested their serum glucose levels six times a day after aggressive insulin treatment using the multi-injection technique. The researchers compared the glycemic control of the intervention group with the usual care group. The intervention group utilized a telematic management system that would transmit results of the patients' serum glucose levels to a healthcare member every night before going to bed. A diabetologist would retrieve and interpret the information using the DiaPreT software program and contact the patient as needed for alterations to the treatment. One weakness identified included having the same unlimited availability for support of the diabetologist by phone for the control group. Although, there was not a significant difference found in the HgbA1c levels between the usual care group and intervention group the authors found that the intervention group had significantly better glycemic control than the usual care group ($p = 0.001$). There was not a significant difference in

HgbA1c for the telematic management group compared to the usual care group ($p = 0.772$).

Conclusion

There is insufficient evidence to support the use of glucose monitors enabled to deliver data remotely to a cellular phone to lower the HgbA1c for people with diabetes. Of the seven randomized control trials reviewed that measured the effects of m-health on HgbA1c three failed to find a significant difference, and four found a significant difference, making the evidence inconsistent but in favor of the use of technology to assist in controlling HgbA1c.

Satisfaction is a fundamental element of sustainability but is not consistently addressed in the studies reviewed. Three of the articles reviewed addressed patient satisfaction, reporting more satisfaction with the use of mobile phone technology to aid in diabetes management. All of the articles studied lacked a theoretical framework in which to approach the problem. The literature search clarifies the need for more research on m-health with the gestational diabetic population.

More research is needed to evaluate the effects of utilizing these devices specifically as an aid in managing serum glucose levels. There were few randomized control trials available for review. The literature on remotely transmitting serum glucose data for patients practicing SMBG comes mostly from Europe or Canada, and the value of mobile electronic monitoring has been questioned (see Table 1). Most of the research done is on non-pregnant Type 1 or 2 diabetics with few studies on gestational diabetes.

Gestational diabetes mellitus is a burdensome disease that affects women at a vulnerable time. This literature review illuminates a gap in knowledge related to the potential of mobile health monitoring for decreasing burdens of SMBG in the GDM population.

Method

The purpose of this Doctorate of Nursing Practice Scholarly Project is to evaluate the

feasibility of using a Bluetooth-enabled glucose monitor and associated mobile health application to monitor pregnant women's glucose levels and assess their satisfaction with using mobile health technology.

Study Design

This pilot study utilizes an IRB approved quasi-experimental pre-post longitudinal design over eight weeks with a convenience sample of pregnant women diagnosed with Gestational Diabetes (GDM).

Study Question

Does use of a Bluetooth enabled serum glucose monitor in conjunction with the iGluco application improve pregnant women's glucose log completion?

Definition of Terms

Blood glucose log/ Serum glucose log: The documentation of blood glucose/ Serum glucose results in chronological order by date and time.

Completeness: The percentage of entries in the glucose log with a range between zero to 100% calculated using the actual number of recorded results divided by the expected number of recorded results.

GDM: Gestational Diabetes Mellitus: A diagnosis of diabetes that occurs after the 24th week of pregnancy that is due to the state of pregnancy.

Glucometer: A handheld device used by the patient to analyze a blood droplet for blood glucose concentration.

HgbA1c: Hemoglobin that has glucose attached can be measured and will give a result in the form of a percent with normal values between four and six percent (O'Tool, 2003). This value indicates a person's glucose control over the last three-month period.

iGluco: A diabetes health application sponsored by the Apple brand that syncs with the iHealth glucose monitor via Bluetooth technology.

iHealth glucose monitor: The BG5 glucose monitor manufactured by the Apple brand.

Recommended Range: UVA protocol states the fasting values should be within 60-95mg/dL. Two-hour postprandial values should be within 90-140 mg/dL (see Appendix A).

Phase One: Four weeks of standard paper serum glucose logs with a standard monitor.

Phase Two: Four weeks following phase one in which the participant utilized the provided Bluetooth enabled iHealth glucose monitor to record their serum glucose on an iGluco smartphone application.

SGL: Serum Glucose Log for this study will mean any annotation of an individual participants serum glucose level over a period of time as agreed upon between the participant and their provider.

SMBG: Self-monitoring of Blood Glucose is the act of executing an agreed upon regimen for monitoring and treating one's serum glucose levels.

Setting

This pilot study took place at a Maternal-Fetal Medicine Clinic located in a mid-Atlantic tertiary care center. The clinic serves approximately 278 women diagnosed with GDM a year (CDR, 2016). There are Maternal-Fetal Medicine physicians, certified nurse midwives, women's health nurse practitioners, and a registered dietician proficient at caring for women who have high-risk pregnancies such as type 1, type 2, or GDM on staff at this clinic. Staff offer genetic counseling and perform ultrasounds, antenatal screening, and diagnostic procedures. The clinic director granted permission to utilize the clinic for this study (see Appendix B).

Sample

This study recruited a convenience sample from the Maternal-Fetal Medicine Clinic over a three-month period. Eligibility for this study included women who are at least 18 years old, competent for consent, English or Spanish speaking, diagnosed with gestational diabetes, have access to a smartphone capable of running the mobile health application and were willing to download the application. Women between the gestational age of 24 weeks to 32 weeks were considered eligible for recruitment. Exclusion criteria included women that did not meet the eligibility criteria or had knowledge that their delivery was going to occur before completion of both phases, or they already possessed a Bluetooth-enabled glucometer. Women were not approached for recruitment if determined by their provider that their pregnancy status was too high risk

Measures

Measures include a demographic information log and completed glucose logs collected over an 8-week period as seen in Figure four and Table two. The primary outcome measure of this pilot study is glucose log completeness measured on a scale of zero to 100%. The glucose logs annotate each glucose result, if the patient is diet controlled or taking medications, and if data transcription comes from the study coordinator or participant. Demographic data were collected to provide information about the population that agreed to participate in the study. The demographic data include education level, cultural/ethnic/racial identity, primary language, gestational age, and type of diabetes control (see Table 2). A satisfaction survey adapted from the RAND Health PSQ-18 satisfaction survey to reflect diabetes care retrieved from https://www.rand.org/health/surveys_tools/psq.html was used to measure satisfaction with the diabetes care received during the study (see Appendix C). This survey provides 18 questions with scores for each question ranging from one to five. There is an additional open-

ended question included asking the participants to disclose the glucometer they liked best during the study and their rationale. RAND Health provides the scoring instructions for the survey (see Appendix C).

Procedures

The clinical research coordinator, registered dietician, and healthcare staff assisted in the recruitment of patients. Figure 5 illustrates the procedural flow of the study. A clinic nurse or registered dietician asked the patient at the time of their regularly scheduled appointment if they were interested in speaking with the primary investigator of the proposed study. A trifold pamphlet in English explaining the study was also made available. If the patient was interested, the primary study coordinator discussed in detail the proposed study offering them a copy of the consent for preview (see Appendix D). The primary study coordinator's contact information is available on the patient recruitment trifold (see Appendix E). Because participants were being asked to provide a full eight weeks of serum glucose logs no patients were solicited for recruitment past 32 weeks gestation. Patients were also made aware that they must consent before 32 weeks of pregnancy. The primary study coordinator consented each participant. Consent forms were available in English and Spanish. The primary researcher was at the clinic for each participant's appointment. The hospital's electronic record system provided the appointment times for the participants.

Each participant was instructed to provide four weeks of serum glucose logs per usual care with their non-Bluetooth enabled glucometers for phase one. If the participant was currently completing glucose logs, the participant had the option to provide their existing glucose logs. After a total of four weeks of glucose, logs had been collected for phase one; the participant moved to the intervention stage (phase two) of the study.

Each participant received an iHealth Bluetooth-enabled glucometer with supplies enough to complete four weeks of serum glucose monitoring and training on how to use it by the primary investigator for phase 2 of the study (see Figure 5). The study coordinator offered assistance downloading the iGluco application along with training to utilize the glucometer with the application. A demonstration and written instructions for printing the glucose log from the application was given with instruction how to view the iHealth iGluco support web page at https://ihealthlabs.com/support/glucometer/wireless-smart-gluco-monitoring-system/. Each woman was given the contact information to customer service for the device and application in the event of questions. Participants were instructed to bring a printed version of their glucose logs with them to the clinic. If a participant did not bring a printed copy of the serum glucose log to the appointment, the primary investigator transcribed verbatim the available data onto a data collection sheet. The participants kept the iHealth glucometers at the conclusion of the study. At the end of the serum glucose log collection, each participant completed a diabetes care satisfaction survey. The RAND Health PSQ-18 satisfaction survey has been adapted to reflect diabetes care received. One additional open-ended question was added to the survey to assess the participants preferred glucometer and the rationale. According to Rand Health, this survey takes three to four minutes to complete.

Protection of Human Subjects

This project was reviewed by the University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR) and approved. This population is considered a vulnerable population. However, GDM is unique to pregnancy, and it is critical that pregnant women be represented in the literature to decrease the existing disparities in diabetes care. The patients' treatment plans were not affected by the use of a particular glucometer or method of recording

the resulting values. Data collected was de-identified at the point of collection. At no time did the researcher use personal identification of the patient for documentation. Each participant was assigned a unique study identification (ID) number. The patients' assigned study (ID) numbers were annotated in their logs. The locked storage container remained in the office of the primary researcher available to only the primary researcher and co-researchers. The files will be destroyed at the time indicated by the University of Virginia's DNP program. This study was approved by the IRB residing for UVA. Any secondary analysis of the data will require an institution-specific IRB approval (see Appendix F).

Data Analysis

Descriptive statistics were used to summarize the data collected. The data was analyzed SPSS v. 24. Glucose log completeness was calculated using the total number of actual entries divided by the total number of required entries. The data from this study include the number of women who consented to participate, education level, primary languages, the number of women on medication or diet only control, average completion score for usual care phase, and average completion score for the intervention phase. The number of participants that did not bring their logs but brought their smartphones or glucometer for transcription and the number of patients that dropped out of the study prior to completion of eight weeks of glucose logs along with the overall mean satisfaction score calculated from the completed individual surveys is reported.

Results

Sample

During the recruitment period, 17 women had a diagnosis of GDM. Of these 17 women, four did not meet eligibility due to speaking a language other than English or Spanish, or the women's condition made delivery uncertain. Two patients were unavailable due to repeatedly

missed appointments. Three women declined to be in the study due to technology concerns (see Table 3). Eight participants enrolled and were consented to be in this study. Five participants completed both phases with surveys resulting in a 37.5% attrition rate.

The participants ranged in age from 27 to 43 years old. The majority of participants were Caucasian-non-Hispanic (80%) or Black/non-Hispanic (20%). Education varied with 20% four-year degree, and 40% some college, 20% technical college, and 20% high school education. Everyone who consented to be in the study spoke English. Mean gestational age at entry into the study was 29.6 weeks. Two of five participants (40%) used nutrition therapy alone, and three of five (60%) used insulin and nutrition therapy for their GDM. See Table 4 for more detailed demographic information about the participants in this study.

Glucose log completion

In phase one (standard monitor and paper logs) the average completion score of the five remaining participants was 74.82% (see Figure 6). In phase 2 (iHealth/iGluco) the average completion score was 81.73%, an improvement of 6.91% (see Figure 7). Three of the remaining participants increased their completeness rates, and two participants experienced a decrease (see Figures 8 and 9). A sign test was used to calculate the significance of three out of the five participant scores increasing between the two phases. This test resulted in no significant difference between the two phases for the number of participants increasing their completeness score compared to the number of participants decreasing their score with $p = 1.00$. During phase two 55% of the time, the participants depended on the study coordinator to transcribe their glucose logs from the iGluco application.

Satisfaction

Each participant surveyed indicated the iHealth was their preferred monitor. Two participants (40%) felt the iHealth monitor was easier to use; another felt it was less work, the remaining two participants expressed it was a better monitor, and more accurate than their phase one monitor. This phenomenon will be examined further in the discussion. The PSQ-18 survey results indicated overall satisfaction with the diabetes care received with an overall score of 29.25 out of 35 possible and an average score of 4.4 out of five for general satisfaction (see Table 5)

Discussion

An overall increase of 6.91% from 74.82 to 81.73 in the blood glucose log completeness indicates that although technology such as Bluetooth-enabled monitors and diabetes health applications may not completely solve the issue of incomplete glucose logs, their use may improve completion rates. Improving glucose log completion enables better communication between healthcare providers and patients allowing for more appropriate treatment plans. These treatment plans can lead to a decrease in serum glucose levels (Selvan Thukral, Dutta, Ghosh, and Chowdhury, 2017). Ming et al., (2016) conducted a systematic review of RCT's utilizing telehealth studies that included Bluetooth-enabled monitors showing a significant difference in HgbA1c between the telemedicine intervention groups and the control groups (standard care) in the meta-analysis ($p = 0.01$). Another study utilizing transmitting technology by the Department of Health in England included 513 participants found a significant difference for HgbA1c in favor of the intervention group ($p = 0.013$) (Steventon, Bardsley, Doll, Tuckey, & Newman, 2014).

The Health Belief Model and motivational behavior change theories used in the design of this study suggested that the perception of capability, opportunity, and motivation would predict the participant's ability to change health behavior. To boost the capability, each participant received

education on the benefit of SMBG, the use of each serum glucose monitor used in the study, and the application. They received written instructions and verbal instructions on printing or uploading their results into the patient portal. None of the patients desired to use the print feature. Two of the study participants stated they did not have a personal printer. Healthcare providers provided reinforcement education at each visit regarding the benefit of glucose control. The dietician trained the participants on the phase one non-Bluetooth monitor provided by the patient's insurance or self while the primary researcher gave training and offered set up of the iHealth monitor and application for phase two of the study. To further boost opportunity and motivation, each participant received an iHealth monitor and the supplies needed for monitoring their glucose levels during the second stage at no cost to them. However, the monitor given in phase two is currently not covered by any form of health insurance nor are the needed supplies. The company stated the pricing for the monitors and supplies is less than the industry average with this in mind. Figure 10 gives a break down of pricing for the monitors given in phase two.

The design of the study was intended to educate and allow patients to have access to the study coordinator if they needed further assistance. However, none of the five patients were willing to allow the researcher to load the application onto her smartphone at the time of study consent. Each participant stated she knew how and would install the application upon returning home. One participant, during the time she would have started phase two, lost her phone and replaced it with another smartphone. She stated she was unable to load the application on to her new phone. She was unwilling to troubleshoot the iGluco application resulting in her exiting the study during phase two. Another patient dropped from the study during phase two due to being unable to negotiate the iGluco application after the iHealth monitor, and the iGluco application was set up for her with a repeat education session and demonstration.

Every participant stated that the iHealth monitor was their preferred monitor and expressed satisfaction with their diabetes care. The stated reasons for preferring the iHealth monitor, such as “it was easier to use” and “it was less work,” indicate that the patient appreciated the decrease in work needed to collect and document blood glucose levels. It may be that the women who remained in the study had a higher comfort level with the technology than those who cited technical difficulties as their reason for dropping out of the study. Hirst et al. (2014) conducted a randomized control trial for Bluetooth enabled glucose monitor usage with a GDM population. They found that overall participants were strongly positive about their care and the use m-health technology as part of their treatment regimen. In this study, one participant entered the study with eagerness to participate. She seemed fascinated by the use of this technology to aid her with this diagnosis. This participant desired to use all of the application’s features to make life with diabetes less cumbersome. Of the three participants that experienced technical difficulties, one continued with the study. She stated her iHealth monitor would not stay connected to her phone iGluco application. After replacing the monitor, follow-up revealed the problem was solved. She went on to declare the iHealth monitor as her preferred monitor.

The average glucose log completion rate in this study improved to 81.73% with the iHealth monitor. The United States has an overall completion rate of 26% making one finding in this study worth mentioning (Fisher, 2007; Ong et al., 2017). The completeness score of one participant did decrease. However, this is likely because the iHealth monitor was a more exact representation of her completion of serum glucose monitoring task than were the written logs from phase one. The patient's phone provided the information for phase two of this study. At the time of collection, her completeness score was 66%. She presented with a hand-written log that was 100% complete for all dates after her provider asked for a written log. This researcher

confirmed by revisiting her results synched to her phone iGluco application from her iHealth glucose monitor that she had completed 66% of the serum glucose collection for her log. Therefore, it is possible that she had not accurately annotated her results in phase one. Selvan et al. 2017 conducted a study looking specifically at the affect serum glucose logs had on glycemic outcomes. They classified the data as accurate, erroneous, omitted, fabricated, or other such as lost, or malfunctioning equipment. The results of this study indicated that the most common type of error in the participant's glucose readings were omissions followed by fabrication. The study had a follow-up period of 44 months. Findings indicated that the participants that had accurate data on their glucose logs were consistently and significantly lower with their HbA1c levels. This finding supports the belief that blood glucose logs are an important tool for management of blood glucose, further supporting the need to integrate more accurate methods of collecting serum glucose log data.

National data suggests that minority women are at a higher risk for GDM than Caucasian/non-Hispanic women (CDC, 2014). It is important to include these women in studies that concern GDM to gain useful insight into the SMBG habits of these women. A better representation of the women with the diagnosis of GDM will lead to better evidence to support these women with this diagnosis. At the very least including them in studies such as this one would provide better evidence to assist them with the completion of their blood glucose logs. To increase recruitment of more minority populations, an understanding of the lens through which these women view the healthcare system they are negotiating is needed. Of the women who declined, all were considered to be of minority status, and all expressed the effort required to learn the technology and report to a study coordinator were more than they had to offer. The short answer given for abstaining from the study was the technology, but during the discussions,

it was apparent the issues preventing them from participating were more multifaceted than that. Anecdotally, the current political atmosphere in the USA may have influenced their trust of the healthcare system and influenced their willingness to wirelessly sync their health data to a smartphone. Future suggestions for recruitment of the populations most affected by GDM include getting approval to recruit participants that speak the prominent languages in the geographic area that is being studied and increase the number of study coordinators that represent the demographic up for recruitment. It is crucial that the individual understand the cultures they are recruiting to be able to discern and potentially negotiate a better perception of time and benefit.

The purpose of this study was to evaluate the feasibility of improving pregnant women's glucose log completion rates using a Bluetooth enabled glucose monitor and associated mobile health application and to assess their satisfaction with using mobile health technology. Therefore, an acknowledgment that technical issues using and understanding the equipment is imperative. Technology proficiency and subsequent difficulty the participants experienced demonstrated an effect on their willingness to accept the technology and their interest to use it. Even though each of the women approached had a smartphone, this did not necessarily mean they were proficient in using the application features (Farmer et al. 2005; Istepanian et al. 2009; Quinn et al. 2008). The attrition rate of this study was 37.5%, of which 25% was attributable to technical difficulties experienced by the participants. Also, three women who declined did so because of the belief they would experience technical difficulties. Istepanian et al. (2009) completed a study in London UK with 137 participants. The intervention group was given Bluetooth-enabled serum glucose monitors and a cellular phone. The completion rate for the study was 63.5% with 56% of the intervention group not completing the study. The result of the UK study indicated there was

no significant difference between the control group and those using the Bluetooth technology. Istepanian et al. stated that technical issues might have been contributory to the high attrition rate for their study (2009). Quinn et al., (2008) evaluated 30 patients with the diagnosis of type 2 diabetes. The control group had only 7.7% completing the log books per protocol. Limitations included the fact that only five of the 15 people in the intervention group consistently used the Bluetooth feature of the glucose monitor due to technical issues. A randomized control trial conducted in the UK by Farmer et al., (2005) also suffered from technical difficulties, damages, or theft of the mobile phones. Preventing theft or damage to personal equipment used for monitoring blood glucose levels is not a reasonable goal. However, decreasing the possibility of technical difficulties by increasing technology literacy through better education and training on health assistive technology and their accompanying applications is not only reasonable but should be expected by the consumer and the provider (Cohron, 2015).

The use of technology in healthcare raises the issue of the "digital divide" which some believe may create a more profound disparity in healthcare based on the “haves and have-nots” when it comes to connectivity and access to technology-based health applications and patient portals. The majority of studies indicate that smartphones have lessened the digital divide gap regarding connectivity and access to healthcare information (Bartikowski, Laroche, Jamal, & Yang, 2018; Prieger, 2015). Smartphone devices often augment disease education and self-monitoring of many diagnoses such as diabetes. Studies have indicated that people with mobile connectivity are more likely than persons with fixed connectivity to search for healthcare information on the Internet (Prieger, 2015). Sung et al., 2016 conducted a study in Korea that included 10,872 observations evaluating how smartphones affected the digital divide for groups categorized by age, education, occupation, and income. Sung et al. noted a significant decrease

in the digital divide for many of the categories.

In this study, all potential participants had access to a smartphone or android device. However, there were several who declined to participate due to perceived or experienced technical difficulties. There are a variety of barriers to the use of technology in healthcare including lack of motivation, pain, social stigma, time, emotional tie to results, or technology literacy (Ong et al., 2014; Persson, Winkvist, & Morgren, 2010; Ward et al., 2015; Cohron, 2015). Eric Topal (2012) also points out privacy issues; not everyone wants to be constantly connected and monitored, with all of their personal information recorded. These points must be kept in mind when operationalizing any new technology like this into the clinical setting.

Suggestions for Further Research

Further research is needed to test the use of Bluetooth technology with the GDM population. A randomized controlled trial with a larger sample size would be needed to fully evaluate this new technologies effectiveness. To include a more diverse study population, non-English speaking staff and study coordinators that understand the various cultures should be involved. Although respect of the patient's time is essential, the researcher should insist patients in the intervention arm allow for set up prior and competency demonstration before leaving with the monitor. Fully funded monitors and supplies should be supplied for both the control and intervention group. All persons involved in the care of the study population should receive education about the study and the devices. Finally, a champion is needed to integrate full potential of the device, and its health applications such as the included cloud feature so the providers or nurses can access the results directly, eliminating the need for patients to have printers or write down results.

Strengths and Weaknesses

This study has the potential to demonstrate the feasibility of improved self-management of GDM and provide the groundwork for future studies with larger populations. The use of Bluetooth-enabled glucose monitors with mobile health applications to aid in efficient and complete SMBG management may translate to a decrease in adverse outcomes.

However, this was a pilot study, with a small convenience sample and a pre-post study design. Maturation, selection bias, and attrition are all threats to internal validity with the pre-post study design. This design does not control for the natural progression of the participant's knowledge and experience with glucose log completion. Each patient received continued encouragement with each visit to complete their glucose logs per standard of care. A selection bias may occur if the patients opted for participation due to a desire to receive an iHealth glucometer and supplies. It is important to acknowledge that 80% of the participants that completed the study started in phase two after providing previous glucose logs, and 100% of the participants that dropped out of the study started in phase one indicating that eight weeks may have been too long for participation. Social desirability bias may also affect the completion rates of the participants as they may improve their written log completion whether it be fact-based values or not, due to the desire to please the provider or researcher. The small sample and pilot study design inherently limit external validity outside of this clinic setting.

Nursing Implications

The accuracy of patient serum glucose logs allows for better clinical decision making and management. Accessible and user-friendly options encourage the continuation of treatment plans. Patient satisfaction leads to higher likelihood of task completion and or continuation. The use of Bluetooth monitors that sync directly to health applications allows the patient and provider to interact with complete information when utilizing the technology as intended.

The clinical implications of this study lie in the nurse's ability to understand what tools are available/accessible to the patient and how to assist the patient in using them to their advantage. The review of the literature indicates that GDM presents unique challenges to women on many levels, especially SMBG task such as blood glucose logs. Giving the patient a readily available toolkit may reduce the burden and stress while capitalizing on capability, opportunity, and motivation as behavior change agents. The findings from this project have the potential to guide nursing to take better advantage of contemporary technologies that patients already use, such as cellular phones, as well as tested diabetic health applications to improve the management of GDM and decrease the adverse outcomes associated with it.

Products of the Scholarly Project

This project was designed to provide insight into methods to improving SMBG. Information collected during this project will guide further research in the arena of SMBG. A goal of this Scholarly project is to add to the body of knowledge seeking to improve outcomes for women with gestational diabetes. A manuscript describing the pilot study results will be submitted to the *Journal of Midwifery and Women's Health* for consideration of publication (see Appendix G). This study also has the potential for presentation as a poster at a conference. A copy of this report will be submitted to the MFM clinical director, iHealth, and clinicaltrials.gov.

Conclusion

This pilot study documented that women diagnosed with GDM have the potential to improve their glucose log completion rates through the use of Bluetooth technology and diabetic healthcare applications. Women are willing to try the technology and are, according to some studies, satisfied with its uses. However, this study also highlighted the need to explore what creates motivation and desire to complete glucose logs. Suggestions to improve future study

design are included.

The ultimate goal of SMBG is to decrease adverse outcomes for pregnancies diagnosed with GDM. The use of Bluetooth-enabled glucose monitors with mobile health applications may translate to a more accurate reflection of the actual meter reading, be more efficient, and more complete. The improvement on accuracy, efficiency, and completeness can provide the pathway needed for the improved patient to provider communication allowing for more precise and collaborative management of this diagnosis and subsequently lessen the incidence of morbidity and mortality associated with GDM.

References

American College of Obstetricians and Gynecologists. (2017). *Practice bulletin: Gestational diabetes mellitus.* (No. 180). ACOG.

American Diabetes Association. (2017). Standards of medical care in diabetes 2017. *The Journal of Clinical and Applied Research Education, 40(Supplement 1)* doi: 10.2337/dc17-S001

Bartikowski, B., Laroche, M., Jamal, A., & Yang, Z. (2018). The type-of-internet-access digital divide and the well-being of ethnic minority and majority consumers: A multi-country investigation. *Journal of Business Research, 82*, 373-380.

Center For Disease Control. (2014). *Diabetes report card 2014.* (). Atlanta GA: Center for Disease Control and Prevention. Retrieved from http://www.cdc.gov/diabetes/library/reports/congress.html

Cohron, M. (2015). The continuing digital divide in the United States. *Serials Librarian, 69*(1), 77-86. doi: 10.1080/0361526X.2015.1036195

Cunningham, G., Williams, W., Leveno, K., Bloom, S., Hauth, J., Rouse, D., . . . Eugene Neff Memorial Fund. (2010). In Twickler D., Wendel G. (Eds.), *Williams obstetrics* (23rd ed ed.). New York: McGraw-Hill Medical.

Edberg, M. (2013). Individual health behavior theories. In R. Riegelman (Ed.), *Essentials of health behavior: Social and behavioral theory in public health* (2nd ed., pp. 37). Washington DC: Jones and Bartlett Learning.

Farmer, A. J., Gibson, O. J., Dudley, C., Bryden, K., Hayton, P. M., Tarassenko, L., & Neil, A. (2005). A randomized controlled trial of the effect of real-time telemedicine support on glycemic control in young adults with type 1 diabetes (ISRCTN 46889446). *Diabetes Care, 28*(11), 2697-2702. doi: 10.2337/diacare.28.11.2697

Fisher, W. (2007). Barriers and behaviors in blood glucose monitoring. *US Endocrine Disease,* 51-53. doi: 10.17925/USE.2007.00.2.51

Handley, M. A., Harleman, E., Gonzalez-Mendez, E., Stotland, N. E., Althavale, P., Fisher, L., . . . Rios, C. (2016). Applying the COM-B model to creation of an IT-enabled health coaching and resource linkage program for low-income latina moms with recent gestational diabetes: The STAR MAMA program. *Implementation Science, 11*, 1-15. doi: 10.1186/s13012-016-0426-2

Hirst, J. E., Loerup, L., Mackillop, L., Farmer, A., Kenworthy, Y., Bartlett, K., . . . Levy, J. C. (2016). Digital blood glucose monitoring could provide new objective assessments of blood glucose control in women with gestational diabetes. *Diabetic Medicine, 33*(11), 1598-1599. doi: 10.1111/dme.13035

Hunsberger, M., Author, Rosenberg, K. D., Author, Donatelle, R. J., Author, Göteborgs Universitet, Sahlgrenska Akademin, Institutionen För Medicin, Avdelningen För Samhällsmedicin Och Folkhälsa, Publisher, & the University of Gothenburg, Sahlgrenska Academy, Institute of Medicine, Department of Public Health and Community Medicine, Publisher. (2010). Racial/ethnic disparities in gestational diabetes mellitus: Findings from a population-based survey. *Women's Health Issues: Official Publication of the Jacobs Institute of Women's Health, 20*(5), 323-328. doi: 10.1016/j.whi.2010.06.003

Istepanian, R. S. H., Zitouni, K., Harry, D., Moutosammy, N., Sungoor, A., Tang, B., & Earle, K. A. (2009). Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes. *Journal of Telemedicine and Telecare, 15*(3), 125-128. doi: 10.1258/jtt.2009.003006 Retrieved from http://journals.sagepub.com/doi/abs/10.1258/jtt.2009.003006

Michie, S., Atkins, D. L., & West, R. (2014). *The behavior change wheel A guide to designing interventions*. Great Britain: Silverback Publishing.

Ming, W. K., Mackillop, L. H., Farmer, A. J., Loerup, L., Bartlett, K., Levy, J. C., . . . Hirst, J. E. (2016). Telemedicine technologies for diabetes in pregnancy: A systematic review and meta-analysis. *Journal of Medical Internet Research, 18*(11), e290. doi:10.2196/jmir.6556. v18i11e290 [pii]

National Rural Health Resource Center. (2014). Start-up and resource guide version 1.1. Retrieved from https://www.ruralcenter.org/network-ta/resources/telehealth-start-and-resource-guide

Ong, W. M., Chua, S. S., & Ng, C. J. (2014). Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: A qualitative study. *Patient Preference and Adherence, 8*, 237-246. doi: 10.2147/PPA.S57567

O'Tool, M. (Ed.). (2003). *Miller-Kane encyclopedia & dictionary of medicine, nursing, & allied health* (7th ed.). Pennsylvania: Como, Darlene.

Persson, M., Winkvist, A., & Mogren, I. (2010). 'From stun to gradual balance'– Women's experiences of living with gestational diabetes mellitus. *Scandinavian Journal of Caring Sciences, 24*(3), 454-462.

Pew, R. C. (2017). Mobile fact sheet. Retrieved from http://www.pewinternet.org/fact-sheet/mobile/

Prieger, J. (2015). The broadband digital divide and the benefits of mobile broadband for minorities. *Journal of Economic Inequality, 13*(3), 373-400. doi: 10.1007/s10888-015-9296-0

Quinn, C. C., Shardell, M. D., Terrin, M. L., Barr, E. A., Ballew, S. H., & Gruber-Baldini, A. L.

(2011). Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care, 34*(9), 1934-1942. doi: 10.2337/dc11-0366

RAND Health. (2017). Patient satisfaction survey: PSQ-18 questionnaire. Retrieved from https://www.rand.org/health/surveys_tools/psq.html

Selvan, C., Thukral, A., Dutta, D., Ghosh, S., & Chowdhury, S. (2017). Impact of self-monitoring of blood glucose log reliability on long-term glycemic outcomes in children with type 1 diabetes. *Indian Journal of Endocrinology & Metabolism, 21*(3), 382-386. doi: 10.4103/ijem.IJEM_342_16

Steventon, A., Bardsley, M., Doll, H., Tuckey, E., & Newman, S. P. (2014). Effect of telehealth on glycaemic control: Analysis of patients with type 2 diabetes in the whole systems demonstrator cluster randomized trial. *BMC Health Services Research, 14*(1), 334. doi: 10.1186/1472-6963-14-334 Retrieved from http://dx.doi.org/10.1186/1472-6963-14-334

Stroetmann, K., Kubitschke, L., Robinson, S., Stroetmann, V., Cullen, K., & McDaid, D. (2010). *How can telehealth help in the provision of integrated care?* (Policy Brief No. 13). Denmark: World Health Organization. Retrieved from http://www.euro.who.int/__data/assets/pdf_file/0011/120998/E94265.pdf

Sung, W. (2016). A study of the digital divide in the current phase of the information age: The moderating effect of smartphones. *Information Polity: The International Journal of Government & Democracy in the Information Age, 21*(3), 291-306. doi: 10.3233/IP-160398

The University of Florida. (2017). Mhealth. Retrieved from http://diabetes.ufl.edu/patient-care/my-diabetes/diabetes-resources/diabetes-apps/

The University of Virginia. (n.d). Clinical data repository [de-identified data file and code book]. Retrieved from Retrieved from https://cdr.virginia.edu/ on (February 17, 2017)

Topol, E. (2012). *The creative destruction of medicine: How the digital revolution will create better health care* [Kindle Fire version]. New York, NY: Basic Books.

Wang, Y., Chen, L., Horswell, R., Xiao, K., Besse, J., Johnson, J., . . . Hu, G. (2012). Racial differences in the association between gestational diabetes mellitus and risk of type 2 diabetes. *Journal of Women's Health (15409996), 21*(6), 628-633.

Ward, J. E. F., Stetson, B. A., & Mokshagundam, S. P. L. (2015). Patient perspectives on self-monitoring of blood glucose: Perceived recommendations, behaviors and barriers in a clinic sample of adults with type 2 diabetes. *Journal of Diabetes & Metabolic Disorders, 14*(1), 1-7. doi: 10.1186/s40200-015-0172-z

Wild, S. H., Hanley, J., Lewis, S. C., McKnight, J. A., McCloughan, L. B., Padfield, P. L., . . . McKinstry, B. (2016). Correction: Supported telemonitoring and glycemic control in people with type 2 diabetes: The telescot diabetes pragmatic multicenter randomized controlled trial. *PLoS Medicine, 13*(10), e1002163. doi:10.1371/journal.pmed.1002163.

Wojcicki, J. M., Ladyzynski, P., Krzymien, J., Jozwicka, E., Blachowicz, J., Janczewska, E., . . . Karnafel, W. (2001). What we can really expect from telemedicine in intensive diabetes treatment: Results from a 3-year study on type 1 pregnant diabetic women. *Diabetes Technology & Therapeutics, 3*(4), 581-589. doi: 10.1089/15209150152811207

World Health Organization. (2016). *Global report on diabetes.* (Health). France: World Health Organization. Retrieved from http://www.who.int/diabetes/publications/grd-2016/en/

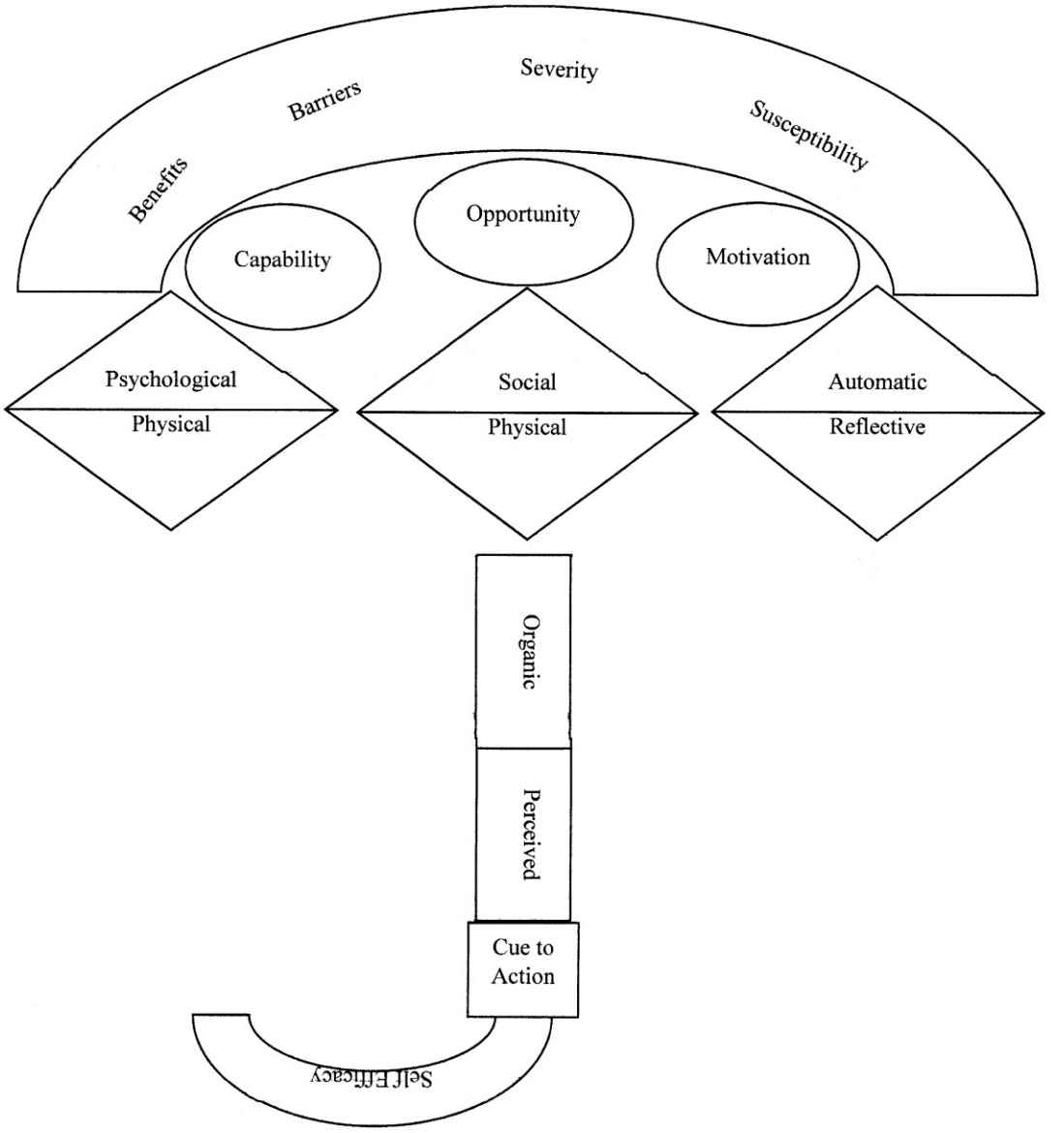

Figure 1. Health Belief Model integration with COM-B model

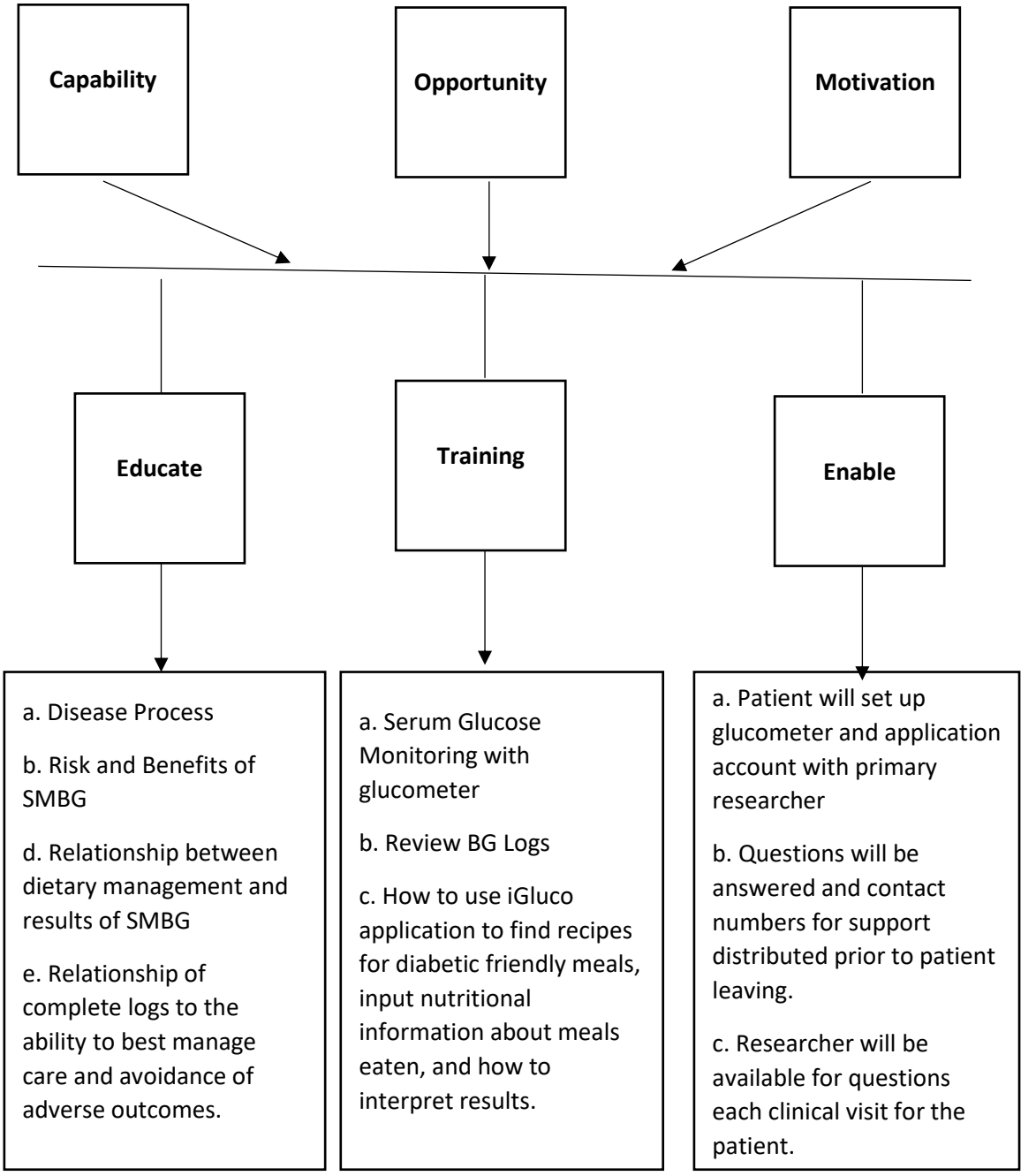

***Figure* 2.** COM-B Model with interventions for pilot study

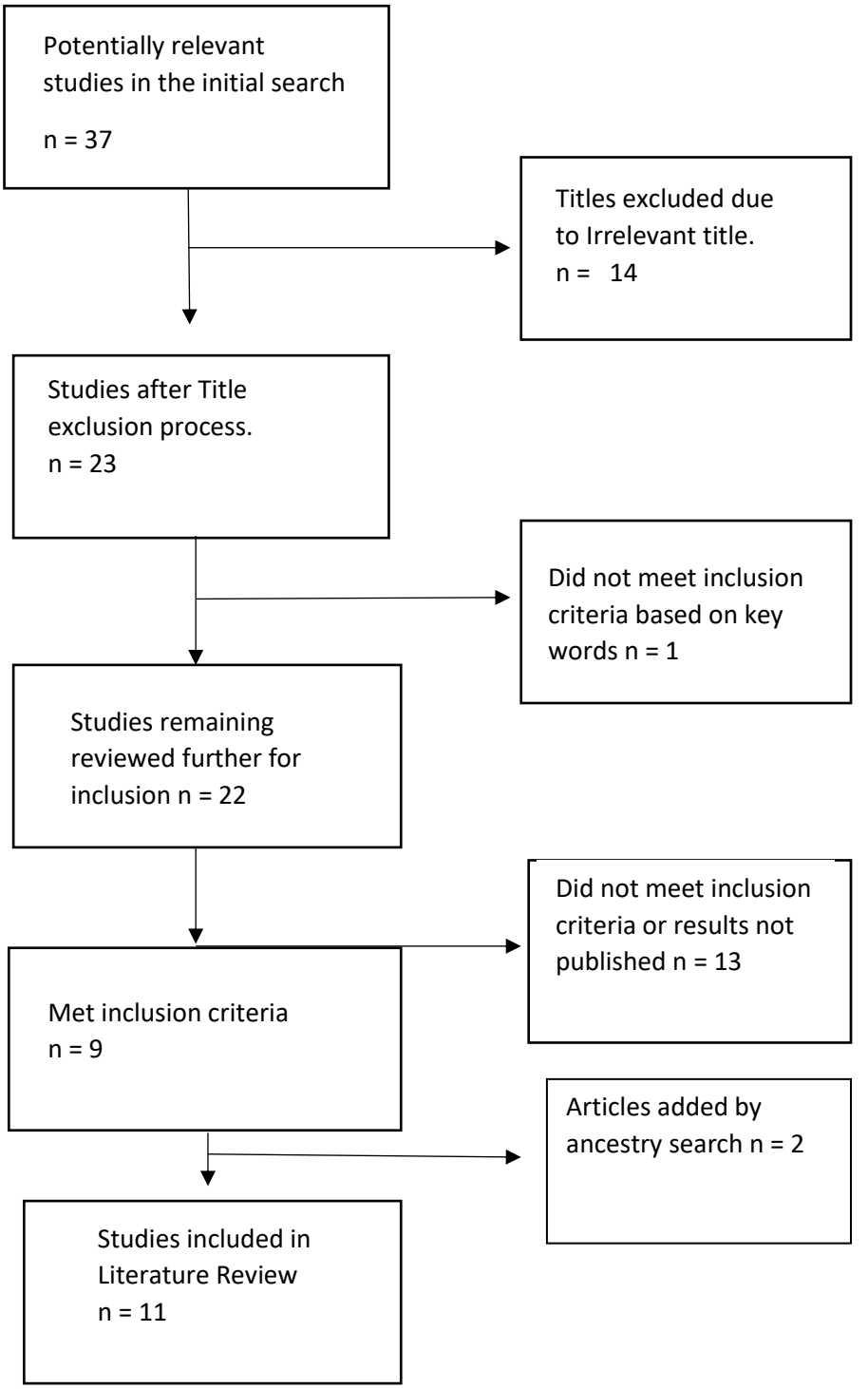

***Figure* 3**. Literature Review Flow Chart

Patient Study ID	Diet Only Y/N	Medication Y/N	Gestational Age	Completeness Score Was log present? Y/N
Date	Fasting	2 hr PP Breakfast	2 hr PP Lunch	2 hr PP Dinner

***Figure* 4**. Example of Excel glucose annotation back-up log

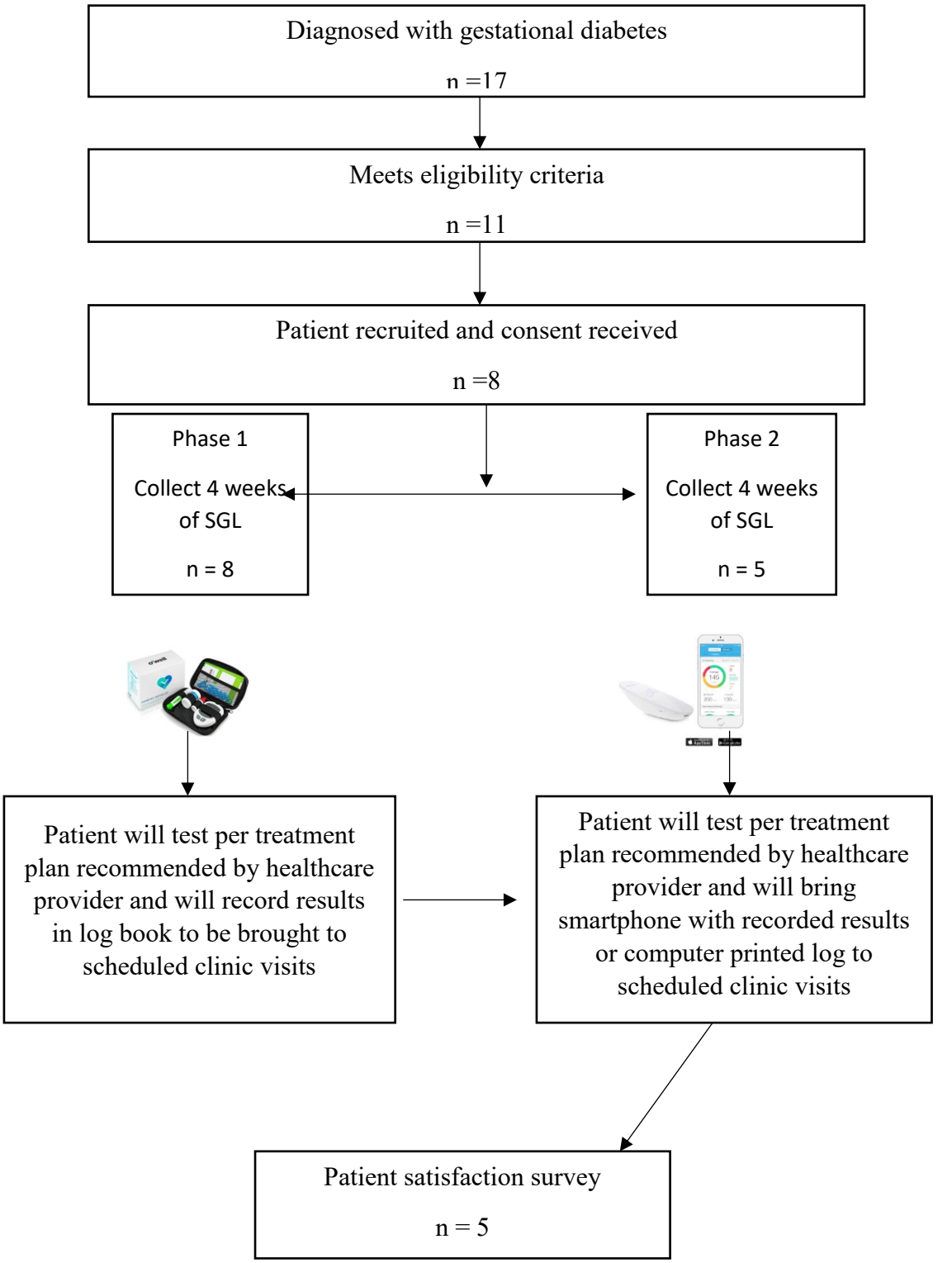

***Figure* 5**. Procedure Flow Chart. Adapted from (Mackillop et al., 2016)

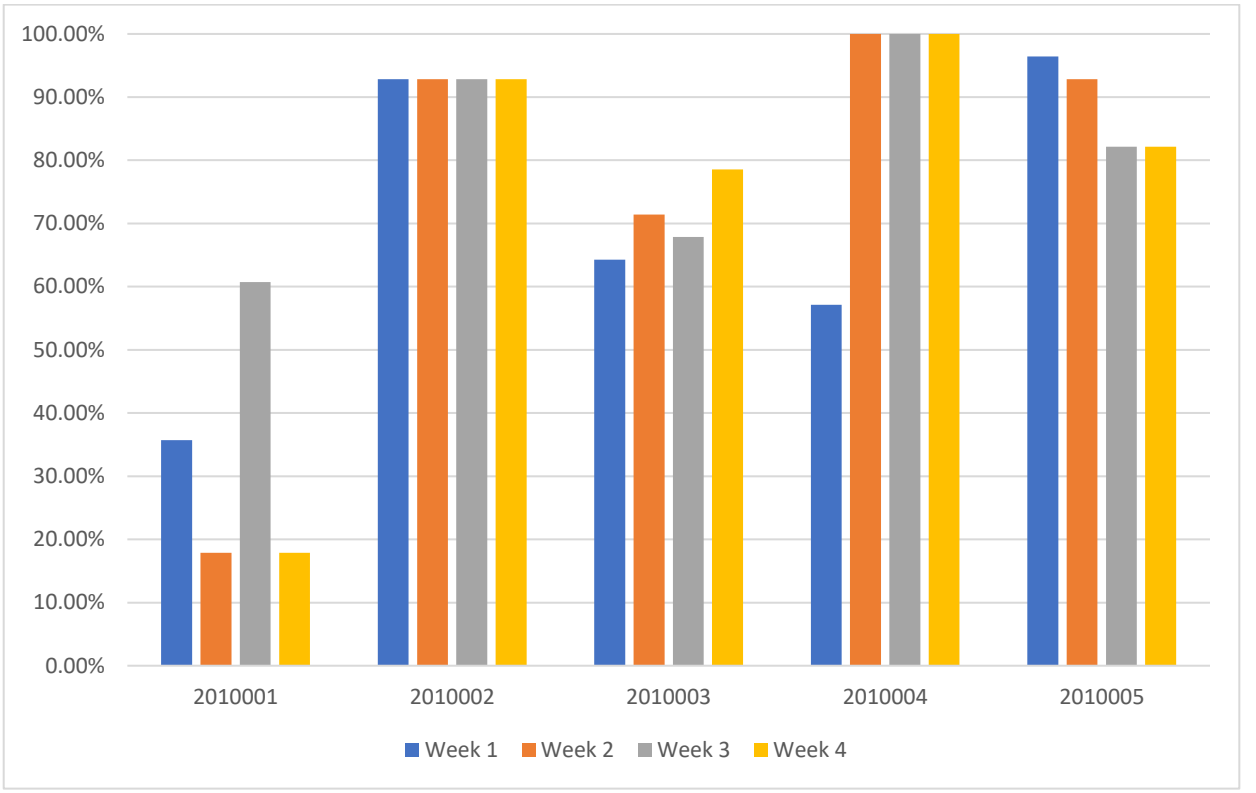

***Figure* 6.** Participant completion rates phase 1

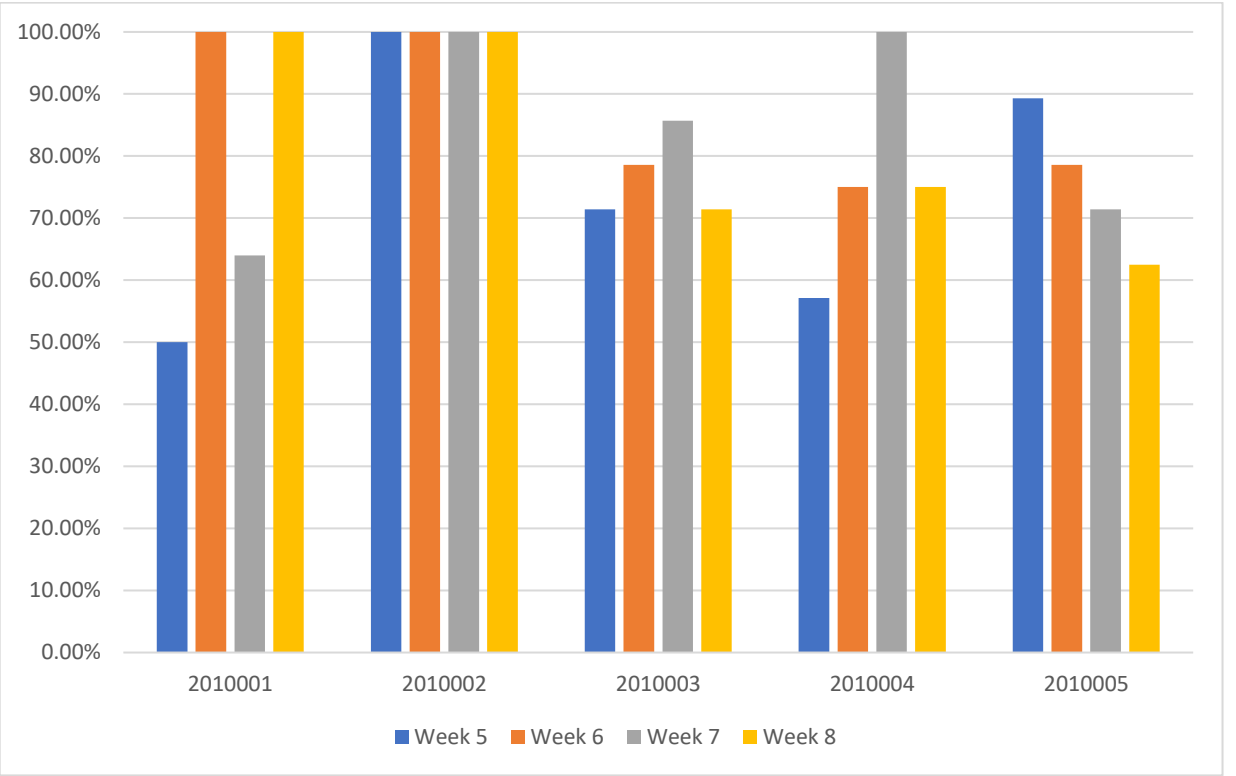

***Figure* 7**. Participant completion rates phase 2

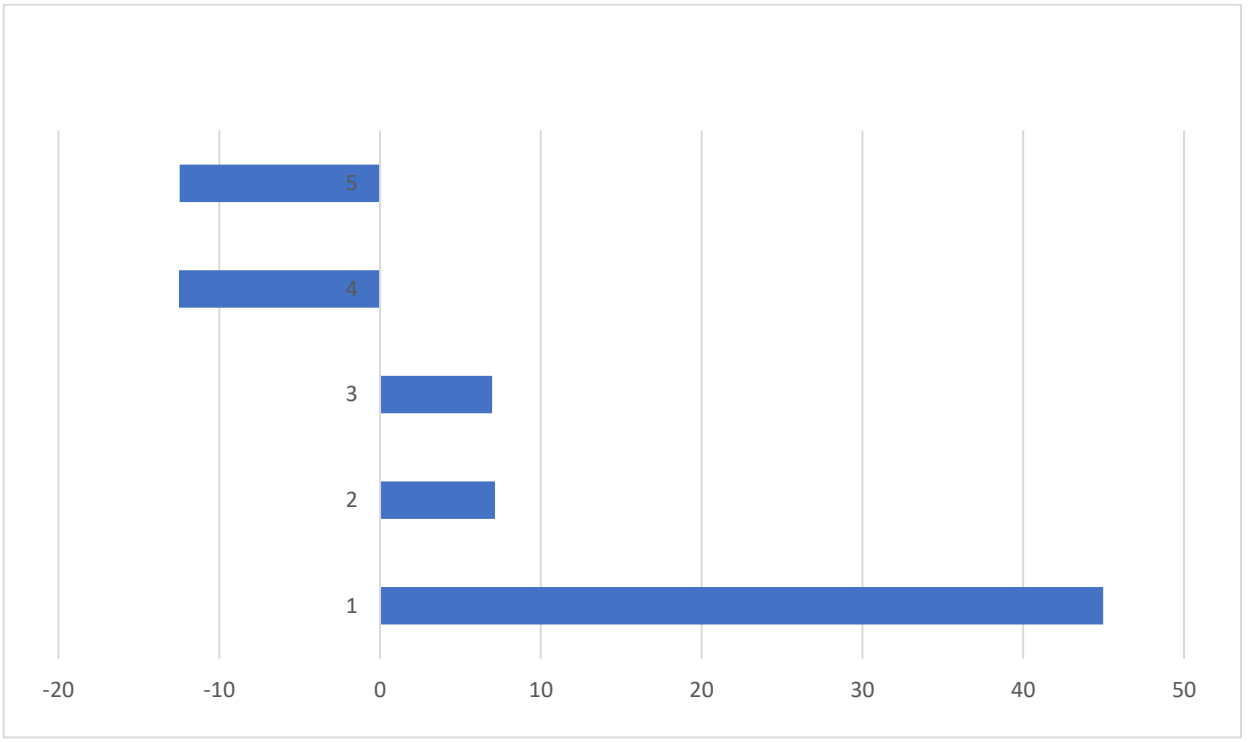

***Figure* 8.** Percentage of increase/decrease from phase 1 and 2.

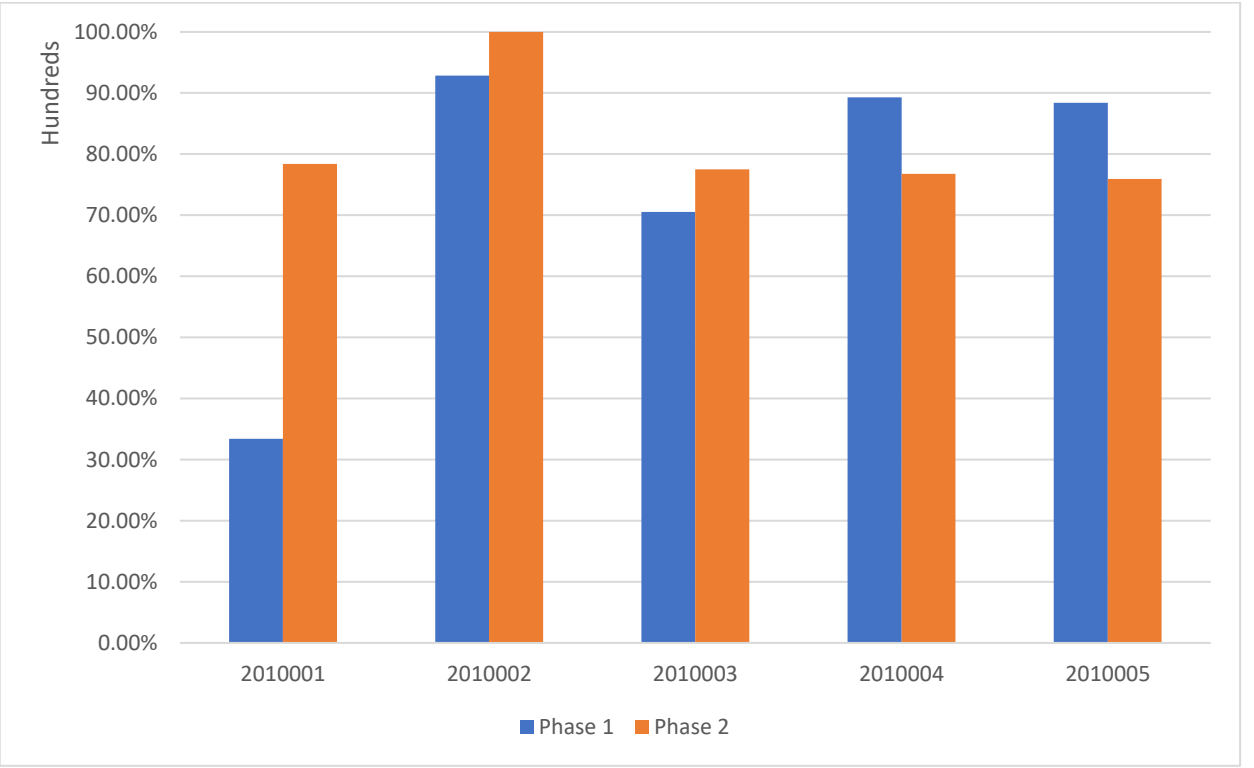

***Figure* 9**. Completion rates compared.

Starter bundle: $64.99 (Every Day Pricing)

Includes:

100 strips ($12.50)

100 Lancets ($ 4.99)

Lancing device

Glucometer ($29.99)

Control solution ($7.00)

Case

Charging system

**Not covered through insurance available at

Amazon, Best Buy, Target, Walmart, Meijer

Retrieved from: https://duckduckgo.com/?q=ihealth+products&atb=v84-3__&iax=images&ia=images

https://ihealthlabs.com/glucometer/wireless-smart-gluco-monitoring-system/bundle

***Figure* 10.** Starter bundle with everyday pricing Illustration.

Table 1

Table of Evidence for Diabetes SMBG and M-health.

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
Farmer et al., (2005)	The study was conducted in Oxford UK with males and females who were insulin dependent type 1 diabetics ages 18-30. n = 93	RCT	The control and intervention group were given a blood glucose monitor with a cellular phone capability of documenting their insulin, dietary, activity, and glucose logs. This information was remotely transmitted for both groups to a data processing facility. A Diabetes Specialist Nurse (DSN) monitored the data transmissions and responded by contacting the patients with concerns, solutions, and assisted the patient in establishing action plans with reasonable goals. The intervention group also had access to their personal information via the internet. However, the standard of care was given to this group.	One limitation of the study was the 94 incidences of not being able to transmit data as needed due to technical difficulties, damages, or theft of the mobile phones provided. There was a 12.9% attrition total. Data calculated on intention to treat basis. An unpaired *t*-test was used to compare the HgbA1c differences between groups. There was not a significant difference in HgbA1c between the control group and the intervention group at the nine-month mark [CI -0.2 – 07], (p = 0.3).
Hirst et al., (2014)	This study was conducted at Oxford University Hospitals NHS Trust, Oxford, the UK with 52 women starting the study and 49 finishing. The	Satisfaction of Pilot study	Participants volunteered to use a provided Polymap glucose meter accessory with Life Scan Ultra Easy meter. This meter was equipped with Bluetooth technology and	The Questions and Responses to the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire(OMDTSQ) were given on a Likert scale. There were nine questions, and

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	women were diagnosed with Gestational Diabetes. The article mentions women in the study at delivery are either diet controlled, using metformin, insulin, or both metformin and insulin.		automatically transmitted blood glucose (BG) readings to an application on a smartphone that would further transmit via a 3 G network to a secured website at the National Health Services. The transmitted information that included not only the BG reading but the diet and medication as well was reviewed by a diabetes midwife or physician three times a day. The healthcare provider would them decide if communication with the patient was necessary. The participant had the option of speaking with the healthcare provider either by phone, messaging, or in person regardless of BG readings. Fasting, pre, and 2-hour postprandial BG readings taken daily with a target of 4.0 to 6.0mmol/l. Women were allowed to reduce to reduce readings to 3 days if readings were within the target levels.	responses ranged from -3 to +3. Negative three strongly disagreed, zero was neutral, and + 3was strongly agreed. The Internal consistency of the Cronbach's alpha score was 0.89. Overall the majority of the satisfaction scores were strongly positive indicating that the use of the m-health technology was acceptable and functioned as a method of communication for results and interventions for Postprandial Blood glucose. Limitations were the number of patients enrolled and no control to compare results too.
Istepanian et al., (2009)	The study took place at Thomas Addison Diabetes	RCT	Diabetes care and self-blood glucose monitoring education	The completion rate for the study was 63.5% with 56% of

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	Unit of St. George in London UK. The inclusion criteria for the patients included patients that were ambulatory, and over 18 years old with exclusions made for physically unable to complete study task, pregnancy, high mortality illness, and no consent. n = 137.		was given to both the intervention and control group. The intervention group was given Bluetooth enabled serum glucose monitors and a cellular phone. The cellular phone reminded the patient each time a serum glucose check was due based on a personalized prearranged schedule. Clinicians based at St. George's Hospital in London UK received and reviewed the results. Treatment recommendations were then given to the patients via letters. The control group received standard care and did not use the cellular phones to transmit their data.	the intervention group not completing the study. The high attrition rate was contributed to technical difficulties but is clearly a limitation of this study even when considering an intention to treat calculations. The results were calculated on an intention to treat basis. There was no significant difference in the HgbA1c for the intervention group as compared to the control group ($p = 0.17$).
Ming et al., (2016)	Any pregnant women with a diagnosis of gestational diabetes mellitus (GDM) were eligible for enrollment. Seven RCT were analyzed, six for clinical outcomes and 1 for patient satisfaction.	Systematic Review Meta-Analysis of RCT	This study was a review of RCT studies with the inclusion criteria of "any system to monitor blood glucose remotely utilizing either fixed-line phones, mobile phones, or Internet-based systems." (p. 2)	The Random Effects Model was used for the I^2 with greater than 50% representing high heterogeneity. It is worth noting that two of the meta-analysis ran in this review had an I^2 above 96%, and 2 had an I^2 above 58% indicating that there was significant heterogeneity for some of the studies compared. There was a

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
				significant difference in HgbA1c between the telemedicine intervention studies that included all diabetes and the control groups in the meta-analysis ($p = 0.02$) in favor of the intervention groups. There was a significant difference in HgbA1c between the telemedicine intervention groups that included only GDM and the control groups in the meta-analysis ($p = 0.01$). Reject the null hypothesis.
Ong et al. (2014)	The study was completed at a primary care center at the University Malaya Medical Centre in Malaysia. Participants were eligible if they were over 21 years old, had a diagnosis of type 2 diabetes, and were prescribed insulin. The participants had to speak English, Malay, or Cantonese. Exclusion criteria included type 1 diabetes, gestational diabetes, or inability to communicate in the	Qualitative	The purpose of this study was to explore the barriers type to insulin diabetics faced in performing SMBG. The interviews lasted 16-41 minutes and were recorded then transcribed verbatim. Interviews were conducted until saturation of themes occurred. Analyzes of the themes that evolved from the detailed and purposeful interviewing were completed.	Pain, motivation, social stigma, time, money, and emotional tie to results were barriers discovered in studies examining obstacles to successful SBGM. The researchers concluded that more research with a larger sample was needed. The ultimate takeaway for providers involved healthcare providers becoming familiar with each patient's particular barriers and addressing them on an individualized scale.

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	languages mentioned above.			
Persson, Winkvist, & Mogren. (2009)	The study took place in Sweden at local health care centers. Swedish speaking women Diagnosed with gestational diabetes were recruited for the study. n = 10.	Cross-sectional Qualitative study	The women were interviewed in an open and semi-structured format while being tape recorded. The interviews lasted from 28-84 minutes. The Grounded Theory approach was taken to analyze the data gathered from the interviews. The aim of the study was to establish what the women experienced and how they felt after being diagnosed with gestational diabetes as well as how they adjusted to the change in lifestyle	A core category developed from the interviews that incorporated the expressed experiences of the women was coined "From stun to gradual balance" (p. 456). The influence the diagnosis had on the women's lives formed nine other categories" Stuck by lightning, Having a personal responsibility, Being under surveillance, Struggling for protection, Feeling socially apart, Being Sufficiently supported, Changing the self-image, Adapting to a new situation, and Waiting for the "Moment of truth""(p. 456). The more experienced the women had with gestational diabetes, the less she felt the negative effects of the lifestyle. The authors concluded
Quinn, Clough, Minor, Lender, Okafor, & Gruber-Baldini, (2008)	The patients for this study had been diagnosed with type 2 diabetes for at least six months and were between the ages of 18 to 70 years old. Both male and female were enrolled.	RCT	All patients in this study completed a Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire, a complete medical history, and had an HgbA1c collected. The control group received a	The intervention group had a significantly lower HgbA1c compared to the control group with p around 0.02. 100% of the intervention group had completed logs according to protocol compared to 7.7% of

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	However, 65% of the participants were female, and 62% were African American. The participants HgbA1c was required to be above 7.5% with a stable therapeutic plan in place for at least three months before enrollment. n = 26		One Touch Ultra BG meter with supplies. They were instructed to fax or call in their BG results every two weeks to their HCP's until their BF was stable or their HCP's changed their regimen. They were given usual care for the management of diabetes. Patients randomized to the intervention group were given a Bluetooth enabled One Touch Ultra BG meter with supplies and a Nokia 6682 or 6680 cellular phone that had the WellDoc's proprietary Diabetes Manager software. The patients were instructed how to use the technology and what to do if it did not work. The intervention group transmitted their BG results electronically every four weeks or if needed sooner. The patient's behavior and an analysis of data with trends were automatically transmitted by the WellDoc's software. The WellDoc's software would then give the patient suggestions on activates lifestyle choices, and	the control group with $p < 0.001$. Overall patients were satisfied with the intervention system components this was true for the physicians as well. The control group had less than half of the patients satisfied with their diabetes management with only 8% completing the log books per protocol. None of the physicians surveyed were satisfied with the management of diabetes by their patients. Limitations include small sample and the fact that only 5 of the 15 people in the control group consistently used the Bluetooth feature of the glucose monitor due to technical issues.

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
			diet if the need for improvement was detected. After receipt of the data from the WellDoc's software, the healthcare provider would personalize feedback and treatment.	
Stevenson et al. (2014)	This study was conducted by the Department of Health in England via 112 clinical sites. The inclusion criteria included over 18 years old, diagnosis of gestational diabetes, chronic obstructive pulmonary disease or heart failure. Patients were excluded from the study if they were unable to understand or participate in the requirements of the study. n = 513.	RCT/ pragmatic	The intervention arm of the study was provided with telehealth equipment as well as serum glucose monitors, blood pressure monitors, pulse oximeters, or weight scales. The patient would then take readings per an agreed upon schedule and transmit them remotely to the clinical site. Patients received feedback based on the results. Patients also had the ability to transmit questions or concerns via telehealth equipment for increased support. Patients in the control arm received usual care without specific telehealth interventions	There were two specific limitations to this trial. They relied on HgbA1c's that were collected based on of patient need or provider request versus trial protocol potentially increasing average HgbA1c result. The second limitation may have been selection bias due to cluster sampling. There was a significant difference for HgbA1c in favor of the intervention group [CI 0.4 mmol/mol – 4.2 mmol/mol (p = 0.013).
Ward, Stetson, & Mokshagundam., (2015)	Patient with Type 2 Diabetes was recruited from a hospital-based outpatient diabetes clinic located in Indiana. Inclusion criteria included	Cross-sectional design	The participant's height, weight, and HgbA1c was extracted from the patients' medical chart. Patient answered questions from the Personal Diabetes	Several statistical analyses were run. The statistical test included two and three-way ANOVA, *T*-test, and Chi-square, Spearman's Rho and Kruskal-Wallis H-test

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	21-90 years of age and literate in the English language. Excluded were patients with the diagnosis of Type 1 diabetes, cognitively or mentally impaired. n = 589.		Questionnaire (PDQ). The completion of this questionnaire was accomplished either at the clinic or by mail. Increasing understanding of how the patient perceives SMBG, eliciting recommendations, defining barriers, and becoming familiar with patient SMBG practices was the stated aim of this study	analyzed with Mann–Whitney U post hoc testing using the Holm correction. The patient's had an accurate grasp of their glucose control with p values less than 0.001 ($p < .001$). The patient's avoided a question pertaining to SMBG behaviors, 50.3% of the participants left this item blank. Participants that tested more frequently reported higher barrier scores. Young females had higher barrier ratings at $p = .001$ for age and $p = .021$ for gender. The participant's perception of being busy was associated with this phenomenon. BMI was significantly lower for older women participating in SMBG at least once per week. Having a target range for SMBG made a significant difference when compared to not having one or not knowing if one had been established ($p = .18$) The authors concluded SMBG could be effective if the patient knows and understands their target blood glucose value.
Wild et al., (2016)	Male and female patients	RCT	Baseline information was	Adjustments were made for

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	with type 2 diabetes from 42 clinics England and Scotland. The participants were over 17 years old, had mobile phone signal access at home, and were poorly controlled with HgbA1c above 58mmol/mol. Patients with severe range blood pressure greater than 210/135 mmHg, complex renal disease, complicated cardiac, or other high mortality illnesses within last six months, and inability to perform study requirements were excluded from the study. n = 321		collected on all participants. Bluetooth enabled technology transmitted results to research nurses for the intervention group. Support for needed lifestyle and medication alterations were given in response to the results received by the research nurses. At the conclusion of the trial that lasted nine months, the intervention participants were asked to follow up with their healthcare provider. The control group received usual care that included a review of their results once a year by their Family Practice physician or more often if they were poorly controlled.	baseline HgbA1c and analysis of covariance to minimize strata. Also, the intra-cluster correlation was used to examine clustering by practice. The authors mention potential limitations as the inability to blind patients and providers, lack of representative subjects, and uncertainty about the length of the effect or how long the intervention should be. The attrition rate was 11.2%. There was a significantly lower HgbA1c in favor of the intervention group [CI 2.38 – 8.81 mmol/mol] ($p = 0.0007$).
Wojcicki et al., (2001)	This study was conducted at the Clinic of Gastroenterology and Metabolic Diseases of the Medical Academy in Warsaw Poland with pregnant patients diagnosed with type 1 diabetes. The participant inclusion criteria included a dx of type 1 diabetes,	RCT	A three-day education session was given to both groups in which the patient had a two-day hospitalization period and an additional training day. Six Blood glucose measurements were taken per day with an aggressive insulin treatment using the multi-injection technique. The researchers compared the	One weakness identified included having the same unlimited availability for support of the diabetologist by phone for the control group. Although, there was not a significant difference found in the HgbA1c levels between the control and intervention group the intervention group had significantly better glycemic

Study Citation	Subjects and setting	Design	Intervention and Comparison	Outcome
	pregnancy less than 16 weeks, no diseases, and IQ greater than 85 on the Wechsler-Bellevue Scale for Adults and an HgbA1c less than 9.5%. n = 30		glycemic control of the intervention group with the usual care group. The intervention group utilized the telematic management system that would transmit results of the patients' blood glucose levels to a healthcare member every night before going to be A diabetologist would retrieve and interpret the information using the DiaPreT software program and contact the patient as needed for alterations to the treatment.	control than the control group (p = 0.001). The Mean Blood Glucose (MBG) was more tightly controlled in the intervention group and was overall slightly lower than the control group. There was not a significant difference in the MBG between the intervention group and the control group (p = 0.581). There was not a significant difference in HgbA1c for the telematic management group compared to the control group (p = .772).

Table 2. Participant Demographic Collection Log

ID	GDM	Smartphone	Over 18	English Speaking	Consented	Phase Entered	GA/Approach	Education	Ethnic ID	Meds
20100003	yes	iphone	yes	yes	yes	2	31w3d	T/College	C/NH	Insulin
20100004	yes	Android	yes	yes	yes	2	29w6d	11th	B/NH	Diet
20100001	Yes	iphone	Yes	Yes	yes	2	32w1d	S/College	C/NH	Insulin
20100002	Yes	iphone	yes	yes	Yes	2	31w2d	BS	C/NH	Diet
20100005	Yes	iphone	Yes	Yes	yes	1	25w4d	S/College	C/NH	Insulin
20100006*	Yes	Android	Yes	yes	yes	1	30w5d	Nurse	Tanzania/NB	Oral
20100008*	yes	Android	yes	yes	No	1	31w6d	N/Available	B/NH	Oral
20100007*	yes	iphone	yes	yes	yes	1	27w5d	N/Available	H/PI	Oral

Note. * Participants dropped out of the study in phase 2.

Table 3.

Demographic Characteristics of GDM Patients not in Study

	Mean (SD)	**(%)**
Gestational Age at identification for potential recruitment	29.20 (2.94) *	
Race /Ethnicity		
White, non-Hispanic		25.00
African American/Black, non-Hispanic		25.00
Hispanic/Latino		25.00
Other		25.00
Primary Spoken Language		
English		33.33
Spanish		25.00
Korean		25.00
Unknown		33.33

Note. n =12. * Missing data for two patients.

Table 4

Demographic characteristics of the Sample

	Mean (SD)	**(%)**
Age at study entry (years)	34.2 (6.1)	
Gestational Age at entry of Study	29.6 (2.8)	
Education		
4-year Degree		20.0
Technical College		20.0
Some College		40.0
High School		20.0
Race /Ethnicity		
White, non-Hispanic		80.0
African American/Black, non-Hispanic		20.0
Primary Spoken Language		
English		100.0
Smartphone type		
iphone		80.0
Android		20.0
Phase entered study		
Phase 1		20.0
Phase 2		80.0
GDM control treatment		
Diet		40.0
Insulin		60.0

Note. n =5.

Table 5

PSQ Survey Results

ID	General Satisfaction	Technical Quality	Interpersonal	Communication	Financial	Time	Accessibility	Why	Total
2010001	5	4.75	5	4.5	2	5	4.75	easier to use	31
2010002	4.5	3.75	5	4.5	5	4	4	more accurate	30.75
2010003	4.5	4.5	4.5	3.5	3.5	3.5	4	less work	28
2010004	4.5	4.5	4.5	4.5	4.5	4	4.5	better	31
2010005	3.5	3.75	4	3	4	3.5	3.75	easier to use	25.5
Average	4.4	4.25	4.6	4	3.8	4	4.2		29.25

Appendix A

Diabetes in Pregnancy Clinical Practice Guideline Continued

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TITLE:
DIABETES IN PREGNANCY CLINICAL PRACTICE GUIDELINE

PURPOSE:
This clinical practice guideline has been developed by the Women's Place Clinical Practice Committee. It is intended to provide guidance for the evaluation and management of glucose intolerance during pregnancy, but not to dictate a single standard of or approach to care. As always, appropriate clinical judgment should be applied to the care of individual patients.

PATIENT POPULATION:
Define the patient population for whom the guideline or protocol is intended. Check appropriate box(s):
□ Adult Acute Care
□ Ambulatory Care

TABLE OF CONTENTS:
For guidelines that are lengthy or have multiple appendices, it is helpful to include a table of contents with hyperlinks to the appropriate place in the document.

DEFINITIONS:
A. Gestational Diabetes Mellitus (GDM): Carbohydrate intolerance that begins or is first recognized during pregnancy.
B. Pre-gestational Diabetes Mellitus (PGDM): Carbohydrate intolerance, regardless of etiology, known to exist prior to pregnancy. When glucose intolerance is newly diagnosed in pregnancy at less than 20 weeks, the suspicion for PGDM is high. Regardless of early diagnosis, most patients with glucose intolerance diagnosed during pregnancy should have the diagnosis confirmed 6-8 weeks after delivery.
1. Type 1 Diabetes Mellitus: Diabetes typically of abrupt onset during the first two decades of life due to destruction of pancreatic β-cells resulting in insulin deficiency. When appropriate, the diagnosis may be confirmed by detecting very low levels of C-peptide in serum. Symptoms prior to diagnosis may include polydipsia, polyuria, polyphagia, and weight loss, and is characterized by low plasma insulin levels and susceptibility to ketoacidosis. Managed with insulin therapy and dietary regulation.
2. Type 2 Diabetes Mellitus: Diabetes mellitus of gradual onset typically in the third decade of life or later and often but not invariably associated with obesity. There is a strong familial pattern of Type 2 diabetes. Management will include dietary regulation, exercise, and glucose-lowering therapy with either oral hyperglycemic agents or insulin.

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Both forms of pre-gestational diabetes are susceptible to end-organ complications, and screening should be implemented as described below. The degree of glucose control around the time of conception has an important relationship to the risk for miscarriage and congenital anomalies.

PATIENT ASSESSMENT/DOCUMENTATION:

Risk Assessment at initiation of prenatal care: Is the patient at average or increased risk?
Women without an established diagnosis of pre-gestational diabetes should be assessed at their initial prenatal visit to determine their risk profile both for gestational diabetes and undiagnosed pre-gestational diabetes. Women can be assessed as either average risk or high risk and have appropriate screening implemented. (The American Diabetes Association has endorsed a series of screening factors which would characterize a woman as low risk for gestational diabetes; the recommended practice of the University of Virginia Women's Service Line is to screen all pregnant women without a history of PGDM for gestational diabetes, with early screening for those at highest risk.)

Risk Factors:
Women may be identified at entry to prenatal care as high risk for Type 2 diabetes (or early GDM) based on historical risk factors. Screening at entry to prenatal care should be considered in the following clinical scenarios:
1. BMI ≥ 40, with or without additional risk factors
2. BMI ≥ 25 (23 if Asian) with one or more of the following risk factors:
a. First degree relative with diabetes
b. High risk race or ethnicity: African-American, Latina, Native American, Asian-Pacific Islander
c. Previous gestational diabetes
d. Previous birth of a child > 4000 grams
e. Hypertension: BP > 140/90 or taking antihypertensive medication
f. Abnormal lipids: HDL < 35 mg/dL or triglycerides > 250 mg/Dl
g. Polycystic ovarian syndrome
h. Hemoglobin A1C ≥ 5.7% on prior testing
i. History of cardiovascular disease
j. Other stigmata of insulin resistance, eg acanthosis nigricans
k. Prior stillbirth, or birth of a child with birth defects (if not assessed for diabetes at time of occurrence).

Screening:
A. High Risk: Individuals with major risk factors should be evaluated for glucose intolerance at entry to prenatal care. Screening options include the following tests:
1. Hemoglobin (A1c ≥ 6.5% = abnormal) – reliable before 20 weeks
2. Fasting plasma (glucose ≥ 126 mg/dL = abnormal)
3. 1-hour, 50 gram oral glucose challenge test (glucose > 140 mg/dL = abnormal)
An abnormal result in early pregnancy of any of the above tests is strongly suggestive of pre-gestational DM. Further evaluation and prenatal care should proceed as described in Section IV. The ultimate category of diabetes will be determined at the time of postpartum testing. A normal result on any of the tests above indicates that this patient does not have DM at the time the test is performed. If clinical suspicion for pre-gestational diabetes is high, she may be re-tested in 2-4 weeks. Otherwise, she should undergo screening between 24 and 26 weeks as described in the next section.

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B. Average Risk:
1. Screening is performed between 24 and 28 weeks, at the time of a routinely scheduled visit for women at average risk, as well as those who were deemed at high risk but had normal results at initial screening. Timing the screening test between 24 and 26 weeks is ideal to allow adequate time for follow-up after abnormal results.
2. The screening test is a 50-gram one-hour glucose challenge test. A 2-hour fast preceding ingestion may improve test performance. The patient should be instructed to drink the 50-gram glucose solution within 5 minutes and to report to the Clinical Lab to obtain a venous plasma glucose one hour later.
3. Screening results and response:
a. One-hour plasma glucose ≤ 140 mg/dL – this constitutes a negative screen for gestational diabetes. Unless new risk factors develop as the pregnancy progresses, no further screening is recommended.
b. One-hour plasma glucose between 141 and 190 mg/dL – abnormal glucose screen. These patients should be scheduled as soon as possible for a diagnostic 3-hour, 100-gram glucose tolerance test, as described below in C.
c. One-hour plasma glucose > 190 mg/dL – reports in the literature and our own experience indicate that women with a glucose screening result of > 190 mg/dL have a high likelihood of being diagnosed with gestational diabetes (having an abnormal 3 hour GTT). It is our practice to initiate gestational diabetes treatment as outlined below in Section V.
4. Other centers have endorsed lower screening thresholds including 135 mg/dL and 130 mg/dL. Choosing a screening threshold represents a compromise between adequate sensitivity and avoidance of excessive false-positives.

C. Diagnostic Testing:
Women with a one-hour glucose challenge test result between 141 and 190 mg/dL should undergo a 3-hour 100-gram fasting oral glucose tolerance test as soon as possible. In the days preceding the test, the patient should be instructed to follow a normal diet, which should include approximately 175 grams of healthy carbohydrates daily (see attached diet examples, Appendix A).
1. Place an order in Epic for LAB6009, or Glucose Tolerance, 3 Hour (Gestational) GTT.
2. After an overnight fast of 8-12 hours, the patient should report to the Clinical Lab.
3. Fasting plasma glucose is obtained prior of the administration of the 100-gram glucose load. Fasting hyperglycemia is defined as a fasting plasma glucose ≥ 126 mg/dL. If this threshold is exceeded, the glucose tolerance test is not administered, and the patient is presumed to have a diagnosis of GDM.
4. If the fasting plasma glucose is < 126 mg/dL, the patient ingests an oral solution containing 100 grams of glucose within 5 minutes. Plasma samples are drawn at one, two and three hours after ingestion of the solution.
5. The University of Virginia Women's Service Line utilizes the thresholds defined by Carpenter and Coustan for the diagnosis of gestational diabetes. If two or more of the thresholds given below are met or exceeded, gestational diabetes is diagnosed.
a. Fasting plasma glucose – ≥ 95 mg/dL.
b. One-hour plasma glucose – ≥ 180 mg/dL.
c. Two-hour plasma glucose - ≥ 155 mg/dL.
d. Three-hour plasma glucose – ≥ 140 mg/dL.
6. Women with one value exceeding the above thresholds are not considered to have gestational diabetes. In general, they do not require additional screening. However, those for whom a clinical concern for glucose intolerance remains elevated, particularly if they had one abnormal value on the three-hour glucose tolerance test, may be re-tested in 2-4 weeks as clinically indicated.

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TREATMENT/DOCUMENTATION:

I. **Pre-gestational Diabetes:**

A. Women with pre-gestational diabetes mellitus should receive preconception counseling regarding optimization of their diabetes management and health status. Preconception counseling will be centered upon:

- optimizing diabetes control to a hemoglobin A1c of < 6.5%;
- assessment for and management of end-organ complications;
- discontinuation of medications contraindicated in pregnancy prior to conception;
- achievement of optimal weight;
- discontinuation of tobacco, alcohol and drugs of abuse.

As many women conceive without having preconception counseling, such issues need to be addressed as soon as possible after a pregnancy is confirmed. In addition to routine prenatal labs, appropriate screening tests include:

1. assessment of diabetes control: in addition to reviewing any blood glucose records the patient has brought with her, obtain a hemoglobin A1c to assess baseline diabetes control;
2. assessment for diabetic nephropathy: obtain a spot urine sample for protein-to-creatinine ratio with a normal value being ≤ 0.30. A 24-hour urine protein collection is not required unless recommended by Nephrology. Endocrinology may also recommend a urine microalbumin.
3. ophthalmology assessment: schedule a dilated eye exam unless she has had one within the last 12 months;
4. assessment of cardiovascular health: Consider obtaining a baseline cardiovascular health assessment (either an EKG or echocardiogram) in women whose review of systems or past medical history suggests an increased likelihood of underlying cardiovascular disease, in those with a strong family history of cardiovascular disease, in those women with particularly longstanding or uncontrolled diabetes, and in those with documented microvascular disease;
5. thyroid assessment: obtain thyroid function testing with TSH and free T4 for women with type 1 diabetes.

The fetus of the mother with pre-existing diabetes is at increased risk for congenital abnormalities. Appropriate screening includes:

6. women with diabetes are candidates for genetic screening as are all pregnant women; their diabetes status should be stated on the laboratory request forms in order for the laboratory to perform appropriate adjustments;
7. a maternal serum alpha fetoprotein at 16 weeks is recommended as early screening for open neural tube defects;
8. a detailed fetal anatomic survey should be ordered at 18-20 weeks to assess for congenital anomalies. A 16 week baseline scan can be considered if the msAFP is elevated or if the patient is considered at high risk for anomalies due to elevated peri-conception Hgb A1C > 8.5%.
9. a fetal echocardiogram should be performed at 20 weeks due to the increased risk of congenital heart disease in infants of diabetic mothers.

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10. Maternal diabetes is a risk factor for delayed lactogenesis stage II. Breastfeeding has been shown to decrease the risk of mothers with GDM going on to develop Type II DM. Expectant mothers should be referred to the UVA Breastfeeding Medicine program to schedule a prenatal consultation.

II. Treatment:

In all pregnant women with diabetes, regardless of the form, the principal goal of treatment is to achieve euglycemia. The most common way to assess glycemic control, and that which is most validated in pregnancy, is frequent home blood glucose monitoring with targeted therapy of hyperglycemia. In women with pre-existing diabetes, periodic assessment with hemoglobin A1c may be a useful adjunct.

A. If she does not already have one, arrangements should be made for the patient to obtain a glucometer and appropriate testing supplies and to receive instruction on how to use these effectively.

1. Women with diabetes in pregnancy should test their blood sugar four times a day, fasting and two hours after each meal. The goals for appropriate control are:

a. Fasting: 60 – 95 mg/dL

b. Two-hour postprandial: 90 – 120 mg/dL

c. Some programs endorse the use of one-hour postprandial blood glucose measurements; the goal for adequate glycemic control is 100 – 140 mg/dL

d. On recommendation by Endocrinology, patients with Type 1 diabetes may perform pre-meal rather than post-meal blood glucose testing. Ideal pre-meal (non-fasting) blood glucose is 100-120 mg/dL.

B. Medical Nutrition Therapy:

Medical nutrition therapy is a mainstay of the appropriate treatment of patients with gestational diabetes in pregnancy. The most effective way to implement is by a nutrition consult. Common recommendations include:

1. a diet composed of 1,800 - 2,200 calories per day, frequently divided into three meals and three snacks;
2. consistent avoidance of concentrated sweets;
3. 20% of total daily calories derived from protein;
4. 30-40% of daily caloric intake derived from fats with an emphasis on unsaturated fats;
5. the remaining 40-50% of the total caloric intake should be derived from complex carbohydrates including starches and whole grains high in fiber;
6. periodic follow-up with nutritionist throughout pregnancy is often helpful in reinforcing medical nutrition therapy, trouble-shooting episodes of hypo- or hyperglycemia, and re-educating women who are not adherent to the prescribed diet.

C. Glucose Lowering Therapy:

The traditional mainstay of medical treatment for diabetes during pregnancy is insulin. Recently, evidence has become available that in selected patients the use of oral hypoglycemic agents may achieve a similar level of glycemic control to treatment with insulin. Pharmacologic therapy may be initiated immediately after the diagnosis of gestational diabetes for significant hyperglycemia, or after a period of 1-2 weeks of

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medical nutrition therapy and exercise without achieving the goals of control, defined as no more than one-third of values exceeding the goals outlined above.

1. Insulin
   Subcutaneous injection (usually a combination of intermediate or long-acting insulin and short acting insulin) or continuous subcutaneous infusion (for Type 1 diabetes)
2. Glyburide/sulfonylureas
   Glyburide, a second-generation sulfonylurea, provides superior glycemic control when compared to placebo, but does not result in a reduction in birth weight. When compared to insulin, has been shown to provide similar glucose control, but is associated with higher mean birth weight, risk of macrosomia, and risk of neonatal hypoglycemia. Cord serum analyses showed no detectable glyburide in the infants. Up to 20% of women will not achieve ideal glycemic control with glyburide, and will need to be switched to insulin therapy. Glyburide may be an option for management when women have very mild hyperglycemia, are unwilling to take insulin, or are unable to tolerate the side effects of metformin.
3. Metformin
   Metformin, a biguanide that acts to inhibit hepatic gluconeogenesis as well as to stimulate glucose uptake in peripheral tissues, is used widely for management of type 2 diabetes in pregnancy and has been evaluated for the treatment of gestational diabetes. Up to 60% of women who use metformin for GDM will ultimately require insulin to achieve glycemic control. However, when compared to glyburide, metformin appears superior, with less maternal weight gain, lower mean birth weight, and lower risk of macrosomia/LGA.

III. Antepartum Testing:

Antepartum testing of fetal well-being is indicated in pregnancies complicated by diabetes due to the increased risk of adverse fetal outcomes related to placental insufficiency and hyperglycemia. The timing of onset and frequency of testing is determined by the assessed risk for poor fetal outcome.

Estimation of fetal size is a component of antenatal testing of well-being. Women with diabetes mellitus are predisposed to have babies who are large for gestational age, and this risk is increased in the setting of uncontrolled diabetes, pre-gestational obesity, and excess gestational weight gain. Conversely, women with diabetes complicated by microvascular disease or co-existing hypertension are at increased risk for having babies who are small for gestational age.

For the purposes of the recommendations below, "controlled" is defined as >70% of blood glucose values at or below goal and with normal fetal growth and amniotic fluid volume by ultrasound.

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Diabetes in Pregnancy Clinical Practice Guideline Continued

University of Virginia Medical Center

Condition	GA to initiate serial growth sonograms	GA to initiate antenatal testing	Modality of antenatal testing	Frequency (per week)	Delivery timing
Pre-gestational diabetes (controlled on diet or oral medications only)	30	34	NST	1x	≥ 39.0
Pre-gestational diabetes (requiring any insulin regimen)	28-30	32-34	NST	2x	Per MFM recommendation
Gestational diabetes (controlled on diet only)	36	40	NST	1x	≥ 39.0
Gestational diabetes (controlled on oral medications)	36	34	NST	1x	39-40
Gestational diabetes (requiring any insulin regimen)	30	32-34	NST	2x	Per MFM recommendation

IV. Timing / Route of Delivery:

The timing of delivery selected represents a balance of fetal maturity and potential for spontaneous labor with the fetal risks associated with the development of placental insufficiency. A target for delivery may be established at the onset of prenatal care or the time of diagnosis of GDM, and then modified as the pregnancy progresses.

A. **Gestational Diabetes, diet controlled**, no comorbidities and no evidence of hydramnios or LGA – may be allowed to await spontaneous labor until 41 weeks in the setting of normal antenatal testing.

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Appendix A

Diabetes in Pregnancy Clinical Practice Guideline

University of Virginia Medical Center

B. **Gestational Diabetes, well-controlled on insulin or oral treatment** – delivery between 39 and 40 weeks is appropriate, so long as antenatal testing remains normal until that time.
C. **Gestational diabetes, uncontrolled or with history of IUFD** – Consider delivery between 37 and 39 weeks, with specific timing based on timing of prior demise, degree of diabetes control, and presence of other risk factors.
D. **Pre-gestational Diabetes, well-controlled, <10 years' duration, no other risk factors** – deliver at 39-40 weeks so long as antenatal testing remains normal.
E. **Pre-gestational Diabetes, uncontrolled OR >10 years' duration OR presence of other risk factors OR history of IUFD** - Consider delivery between 37 and 39 weeks, with specific timing based on timing of prior demise, degree of diabetes control, and presence of other risk factors.
F. **Patients with Pre-gestational Diabetes or GDM** should be counseled regarding the risks of birth injury when the projected EFW is ≥ 4,500 grams and be presented the option of cesarean delivery without a trial of labor. Women with GDM should have their care regarding route of delivery individualized when the EFW is between 4000 and 4500 grams. (Using a threshold of 4500 grams, it is estimated that it would be necessary to perform 588 cesarean deliveries to prevent one permanent brachial plexus injury.) For lesser fetal weights, additional factors such as the patient's past delivery history, clinical pelvimetry, and the progress of labor may be helpful to consider in determining mode of delivery.

V. Post-partum testing

Women who have been diagnosed with gestational diabetes are at increased risk for overt diabetes after delivery. In general, they should have some blood glucose assessments in the hospital before discharge, particularly if they were taking an oral hypoglycemic agent or insulin, to be certain that they do not need ongoing treatment. Women who were treated for gestational diabetes should be scheduled to have a 2 hour, 75 gram oral glucose tolerance test approximately 6-8 weeks after delivery.

1. Order test code LAB6007, Glucose Tolerance, 2 Hour No 30 minute.
2. The normal ranges for values are as follows:
   a. Fasting: 60-100 mg/dL
   b. 1 Hour: <200 mg/dL
   c. 2 Hour: <140 mg/dL
3. Impaired glucose tolerance is diagnosed when the 2 hour glucose value is between 140 and 200 mg/dL
4. Diabetes mellitus is diagnosed when the fasting glucose value is > 126 mg/dL and/or the 2 hour value is > 200 mg/dL.

DISCHARGE/FOLLOW-UP/PATIENT EDUCATION AND HAND-OFF OF CARE:

After Initial Diagnosis

A patient newly diagnosed with gestational diabetes who does not require insulin may receive her home blood glucose meter, meter training and diet teaching from the dietician at the OB/GYN clinic at the Maternal Fetal Care Center. The dietician is in the

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University of Virginia Medical Center

OB/GYN clinic Tuesday and Thursday 9am – 1pm. Patients may schedule a clinic visit to see the dietician during those hours, even if they do not have an appointment with a provider. The patient may also receive her meter and education at Diabetes Education and Management (DEMP) at Fontaine Research Park. The nurse should call DEMP at 434-243-4620. The provider must enter a referral to DEMP and then DEMP will call the patient for an appointment.

Insulin

Patients requiring insulin may receive their insulin teaching at the OB/GYN clinic if a nurse is available. Patients may also receive insulin teaching by making an appointment at DEMP.

Patient Education –

The nurse should emphasize the following to all diabetic patients at regular intervals during prenatal care:

Home Glucose Testing

The patient should check her blood sugar first thing in the morning before she eats (fasting) and two hours after each meal (post-prandial) unless specifically instructed otherwise by the physician. She should follow the specific instructions she received with her meter and record her readings in the log book. If she is having trouble operating her meter, the nurse may assist or request assistance from the dietician or DEMP.

Reinforce importance of blood glucose control

When the patient receives her glucometer, she will be instructed to record her readings and bring the log book to her visits. The nurse will review the patient's log and reinforce the importance of good blood sugar control. At each visit, the nurse should emphasize:

Target blood glucose ranges – Fasting 60-95 mg/dL; two hours post-prandial 90-120 mg/dL

Good glucose control helps prevent –

- The development of preeclampsia
- Having a baby that is large for gestational age, or who is injured during the birth process (shoulder dystocia)
- Stillbirth
- Having a baby with blood sugar or breathing problems at birth
- Having too much amniotic fluid and preterm labor
- Needing a cesarean delivery.

The nurse may request a consult from the dietician on Tuesday and Thursday mornings.

Diet

- Eating meals and snacks spread throughout the day and at bedtime will help to keep blood sugar levels in the target range.
- Avoid sugar and concentrated sweets. Include a good source of protein and fiber with meals and snacks.

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Appendix A

Diabetes in Pregnancy Clinical Practice Guideline Continued

University of Virginia Medical Center

- Stay within the recommended range for weight gain during pregnancy
- Do not go on a weight reduction diet during pregnancy
- Follow the meal plan as set out by the dietician.

If the patient has multiple readings outside the target range, is having trouble with carbohydrate counting, or fails to record her blood sugars on a regular basis, arrange a consult with the dietician

Signs and Symptoms of Hyperglycemia

- More urine output than usual
- Increased thirst
- Dry skin and mouth
- Decreased appetite
- Nausea and vomiting
- Blurry vision
- Fatigue or drowsiness
- Vaginal yeast infections

Signs and Symptoms of Hypoglycemia

- Shakiness
- Anxiety, confusion and irritability
- Sweating
- Hunger
- Tingling sensation around the mouth

This information was drawn from "Pregnancy, Your Baby, and Diabetes" available on the Patient Education Repository website, document number 07002.

OUTCOME MEASURES:

- Percent of patients achieving glycemic control (hemoglobin A1C < 6.5% or achievement of stable insulin regimen)
- Percent of patients initiating antepartum testing at the appropriate gestational age
- Percent of newborns of mothers with diabetes whose birth weight is below the 90th percentile for gestational age
- Percent of mothers with diabetes initiating breastfeeding

EDUCATION PLAN:

Audience

1. **Licensed Independent Practitioners (Inpatient and Ambulatory Services)**
   OB Attending & Resident MD's, CNM's & NP's
   Family Medicine Attending & Resident MD's & NP's

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Appendix A

Diabetes in Pregnancy Clinical Practice Guideline Continued

University of Virginia Medical Center

2. **Nurses (Inpatient and Ambulatory Services)**
   Maternal Fetal Care Center (MFCC), -Northridge, Teen Clinic, FM PCC, FM Northridge Women's Services (8E, 8C, 8N)

Communication

Staff will be informed about the creation of this guideline via email (written communication) within one week of its final approval and activation/accessibility via the intranet. Additionally, it will be discussed during subsequent staff meetings to allow for Q & A.

- Communication will include how to access the guideline on the intranet for reference at the point of care.
- Review of the guideline contents will be requested.
- Medical Directors will be responsible for communication to LIP's
- Nurse Managers will be responsible for communication to the nurses.

REFERENCES:

Pre-gestational Diabetes Mellitus. American College of Obstetricians and Gynecologists, Practice Bulletin 60, March 2005.

Gestational Diabetes Mellitus. American College of Obstetricians and Gynecologists, Practice Bulletin 180, July 2017.

Landon MB, Gabbe SG. Gestational Diabetes Mellitus. *Obstet Gynecol* 2011;118:1379-93.

Carpenter MW, Coustan DR. Criteria for screening tests of gestational diabetes. *Am J Obstet Gynecol* 1982;144:768-73.

Wang P, Lu M-C, Yu C-W, Wang L-C, Yan Y-H. Influence of food intake on the predictive value of the gestational diabetes mellitus screening test. *Obstet Gynecol* 2013;121:750-8

Donovan L et al. Screening tests for gestational diabetes: A systematic review for the U.S. preventive services task force. *Ann Intern Med* 2013;159:125-22.

Balcells M, Garcia-Patterson A, Sola I, Roque M, Gich I, Corcoy R. Glibemclamide, metformin and insulin for the treatment of gestational diabetes: a systematic review and meta-analysis. *BMJ* 2015;350:h102. Doi: 10.1136/bmj.h102.

Casey BM, Duryea EL, Abbassi-Ghanavati M, et al. Glyburide in women with mild gestational diabetes. A randomized controlled trial. *Obstet Gynecol* 2015;126:303-9.

American Diabetes Association. Classification and diagnosis of diabetes. *Diabetes Care* 2017;40(Suppl 1):S11-S24.

DISCLAIMER:

Guidelines or protocols are general and cannot take into account all of the circumstances of a particular patient. Judgment regarding the propriety of using an specific procedure or guideline with a particular patient remains with the patient's physician, nurse, or other health care professional, taking into account the individual circumstances presented by the patient.

REVISION HISTORY

Date	Version	Description	Owner(s) Name, Credentials, Title	Committee Approval*	Date of Approval
082213			Christian A. Chisholm MD or TWP Medical Director		

Appendix A

Diabetes in Pregnancy Clinical Practice Guideline Continued

University of Virginia Medical Center

010617	2	3 year Review/revision	Christian A. Chisholm MD (or TWP Medical Director)		
05.26.17	2.1	Clarification of ordering test codes for 3 hour GTT and post-partum glucose testing.			
09.05.17	2.2	Update of criteria for early pregnancy screening			

***Adults-** Patient Care Committee approval is required if the guideline will be used in multiple areas or if the local area does not have a practice committee to approve the guideline. If approval is required through other committees (such as patient safety, infection control, etc.), please list those committees and dates of approval as well.

Appendix A

Diabetes in Pregnancy Clinical Practice Guideline Continued

University of Virginia Medical Center

For 3 days before to your glucose tolerance test, it is important you include an adequate amount of carbohydrate in your diet. You should eat at least 175 grams of carbohydrate each day. It is okay to eat more than 175 grams of carbohydrate each day. Do not avoid carbohydrate foods as this may affect your test. **Select at least 12 of the foods in the amounts listed below each day for the 3 days before your test**. You may eat the same food more than once. It is also important to include protein (meat, poultry, fish, eggs, cheese, etc.) and fats (butter, oils, nuts, etc.) throughout the day.

Starchy Vegetables	**Starches**	**Fruits**	**Dairy**	**Sweets**
½ cup mashed potatoes ¼ of a large baked potato (3 oz.) ½ cup sweet potato ½ cup cooked beans—black, garbanzo (chickpeas), kidney, navy, pinto, lima, white ½ cup refried beans ⅓ cup baked beans ½ cup cooked lentils ½ cup corn ½ of a large corn on the cob ½ cup peas 1 cup acorn or butternut squash	1 slice of bread 1 (6 inch across) tortilla ⅓ cup rice ⅓ cup pasta ½ cup quinoa ½ English muffin ½ hamburger bun 3 cups popcorn 4-6 crackers ½ cup oatmeal or grits ¾ cup cold cereal, unsweetened ½ cup cold cereal, sugar-coated 1 (4 inch across) pancake or waffle	1 small apple or orange 1 medium peach ¾ cup blueberries, blackberries 1 cup raspberries 1 ¼ cup strawberries 1 ¼ cup watermelon ½ large grapefruit 1 kiwi ½ cup mango ¾ cup pineapple ½ cup canned fruit ½ medium banana 1 cup honeydew or cantaloupe 15-17 small grapes 2 Tbsp. dried fruit ½ cup applesauce, unsweetened	8 oz. milk (soy or cow's) 2/3 cup plain yogurt 2/3 cup yogurt, artificially sweetened	5 vanilla wafers 3 graham cracker squares 3 gingersnap cookies ½ cup ice cream ½ cup Sherbet 1 Tbsp. jam or jelly 1 Tbsp. honey ½ cup pudding 2 small cookies 4 oz. regular soda 8 oz. sports drink

Sample Menu:

Breakfast	Lunch	Dinner	Nighttime Snack
2 slices of toast lightly buttered 1 Tbsp. jam or jelly 2 scrambled eggs 8 oz. milk	3 oz. chicken breast 1 6-inch tortilla 2/3 cup rice 1 oz. shredded cheese Shredded lettuce 2 Tbsp. reduced fat sour cream	3 oz. meat, fish or poultry 1 cup mashed potatoes ½ cup corn Small side salad 1 small apple or orange	5 crackers with low-fat cheese or 2 Tbsp. peanut butter

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*Page 14 left intentionally blank is excluded

Appendix B

Maternal Fetal Medicine Approval Letter

23 Jun 2017

Donald Dudley M.D.
Director, Maternal-Fetal Medicine
UVA Medical Center

Leslie Balcazar de Martinez
Doctoral of Nursing Practice Student
AFIT/University of Virginia
School of Nursing

Dear Dr. Donald Dudley,

I am currently an AFIT student, completing my doctorate of nursing practice (DNP) at the University of Virginia (UVA). I will be initiating a pilot study for my Scholarly Project during the Fall 2017 semester. My pilot study will be addressing the question; Does using a Bluetooth enabled serum glucose monitor in conjunction with a diabetes application improve accuracy/completeness of glucose logs for women with gestational diabetes (24-38 weeks gestation)? The purpose of this study is to improve completion rates of serum glucose logs for women diagnosed with gestational diabetes with the aim of reducing the burden placed on these women. A proposal has been drafted for IRB approval. I am writing to request your written endorsement to use the Maternal Fetal Medicine Clinic as the place of research for this pilot study. Thank you for your support. Please feel free to contact me for any questions 707-430-3070.

Sincerely,

Leslie Balcazar de Martinez CNM, WHNP BC
Doctoral of Nursing Practice Student

1st Ind, Donald Dudley M.D 22 Jun 2017

I endorse the use of the University of Virginia Maternal-Fetal Medicine Clinic for the pilot study proposed by Leslie Balcazar de Martinez with the understanding UVA Institute Review Board approval is attained.

Donald Dudley M.D.
Director Maternal-Fetal Medicine

Appendix C

Patient Satisfaction Questionaire

Patient Satisfaction Questionnaire

SHORT-FORM PATIENT SATISFACTION QUESTIONNAIRE adapted from the (PSQ-18) to reflect diabetes care retrieved from https://www.rand.org/health/surveys_tools/psq.html

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On the following pages are some things people say about medical care. Please read each one carefully, keeping in mind the medical care you are receiving now. (If you have not received care recently, think about what you would expect if you needed care today.) We are interested in your feelings, good and bad, about the medical care you have received.

How strongly do you AGREE or DISAGREE with each of the following statements?

	(Circle One Number on Each Line)				
	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. My healthcare providers are good about explaining the reason for blood glucose testing.....	1	2	3	4	5
2. I think my healthcare providers office has everything needed to provide complete diabetes care	1	2	3	4	5
3. The diabetes care I have been receiving is just about perfect	1	2	3	4	5
4. Sometimes doctors make me wonder if their diagnosis is correct.....	1	2	3	4	5
5. I feel confident that I can get the diabetes care I need without being set back financially.....	1	2	3	4	5
6. When I go to my appointments, they are careful to check everything when treating and examining me.....	1	2	3	4	5
7. I have to pay for more of my diabetes care than I can afford.....	1	2	3	4	5
8. I have easy access to the medical specialists I need.....	1	2	3	4	5

Appendix C

Patient Questionaire Continued

Patient Satisfaction Questionnaire

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How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
9. Where I get medical care, people have to wait too long for emergency treatment	1	2	3	4	5
10. Healthcare providers act too businesslike and impersonal toward me	1	2	3	4	5
11. My healthcare provider treats me in a very friendly and courteous manner	1	2	3	4	5
12. Those who provide my medical care sometimes hurry too much when they treat me	1	2	3	4	5
13. Healthcare providers sometimes ignore what I tell them	1	2	3	4	5
14. I have some doubts about the ability of the healthcare providers who treat me	1	2	3	4	5
15. Doctors usually spend plenty of time with me	1	2	3	4	5
16. I find it hard to get an appointment for medical care right away	1	2	3	4	5
17. I am dissatisfied with some things about the diabetes care I receive	1	2	3	4	5
18. I am able to get medical care whenever I need it.....	1	2	3	4	5

Appendix C

Patient Questionaire Continued

19. Which glucose meter where you most satisfied with and why?

_____

_____

_____

Figure 7. PSQ-18 adapted for diabetes care.

Appendix C

Patient Questionaire Continued

Instructions for Scoring the PSQ-18

The PSQ-18 yields separate scores for each of seven different subscales: General Satisfaction (Items 3 and 17); Technical Quality (Items 2, 4, 6, and 14); Interpersonal Manner (Items 10 and 11); Communication (Items 1 and 13); Financial Aspects (Items 5 and 7); Time Spent with Doctor (Items 12 and 15); Accessibility and Convenience (Items 8, 9, 16, and 18).

Some PSQ-18 items are worded so that agreement reflects satisfaction with medical care, whereas other items are worded so that agreement reflects dissatisfaction with medical care. All items should be scored so that high scores reflect satisfaction with medical care (see Table 1). After item scoring, items within the same subscale should be averaged together to create the 7 subscale scores (see Table 2).

We recommend that items left blank by respondents (missing data) be ignored when calculating scale scores. In other words, scale scores represent the average for all items in the scale that were answered.

Appendix C

Patient Questionaire Continued

Patient Satisfaction Questionnaire
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Table 1

Scoring Items

Item Numbers	Original Response Value	Scored Value
1, 2, 3, 5, 6, 8, 11, 15, 18	1 ---------->	5
	2 ---------->	4
	3 ---------->	3
	4 ---------->	2
	5 ---------->	1
4, 7, 9, 10, 12, 13, 14, 16, 17	1 ---------->	1
	2 ---------->	2
	3 ---------->	3
	4 ---------->	4
	5 ---------->	5

Appendix C

Patient Questionaire Continued

Table 2

Creating Scale Scores

Scale	Average These Items
General Satisfaction	3, 17
Technical Quality	2, 4, 6, 14
Interpersonal Manner	10, 11
Communication	1, 13
Financial Aspects	5, 7
Time Spent with Doctor	12, 15
Accessibility and Convenience	8, 9, 16, 18

Note. Items within each scale are averaged after scoring as shown in Table 1.

Appendix D

Patient Consent GDM #20100

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Linda Eastham (434) 591-6032 lae3g@virginia.edu Box: PO Box 800782 School of Nursing, Academic Divisions

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study. Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

iHealth Labs Inc. and Leslie Balcazar are providing the iHealth glucose meters and supplies for this study.

Why is this research being done?

The purpose of this study is to learn more about the use of a Bluetooth enabled glucose (blood sugar) monitor and cellular phone application (app) as a way to keep track of glucose values. Researchers also want to know how satisfied users are with this type of device.

You are being asked to be in this study, because you have been diagnosed with gestational diabetes (high blood sugar during pregnancy).

Up to 15 women will be enrolled in this study at UVA.

What will happen if you are in the study?

If you agree to participate in this study, you will sign this consent form before any study procedures take place. Then, the following will occur:

- **Part 1:** During the first four weeks of the study you will check your blood sugar according to your doctor's advice, using your own glucometer. We will ask you to provide a copy of the glucose log you are already bringing to your prenatal visits.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

OR

- If you have four weeks of previously recorded glucose logs available, you may give copies of those logs to the study coordinator and proceed with Part 2 the study.

Part 2: The study coordinator will educate you on the operation and use of the Bluetooth enabled glucose meter and mobile health application. This system is called iHealth.

- We will provide you with an iHealth BG5 glucose meter and the necessary supplies to test your blood sugar as recommended by your health care provider. We will assist you in downloading the app to your own cell phone. During the training session, which will last up to 30 minutes, you will set up the glucometer, download the application, and sync the glucometer with the application. You will also be shown how to print a glucose log to bring with you to your appointment. You will be asked to follow your provider's prescribed treatment plan and to attend scheduled appointments. We ask that you bring a computer printed glucose log to your appointments. If you are unable to do this, the study team can transcribe the results from your smartphone. The second half of the study, in which you use the iHealth glucometer and the app for your cellular phone, is also 4 weeks long.

- The iHealth Glucometer has complete contact information in the event you have issues with the meter or supplies. However, you may also contact the study coordinator with any questions you may have.

A satisfaction survey will be given to you at the end of your participation in this study. This will take about 10 minutes to complete.

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell your provider about any changes in your health or the way you feel.
- Ensure that you are following the plan of care that you and your provider agreed upon during your prenatal visits.
- Answer all of the study-related questions completely.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

How long will this study take?

Your participation in this study will last 8 weeks. The study visits will take place during your regularly scheduled appointments that are part of your prenatal care. The clinic visit in which you learn how to use the new glucometer and app may take up to 30 minutes.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

The blood glucose monitoring system used in this study has been approved by the Food and Drug Administration.

There is only a very small risk that someone might see your private information.

Risks from Completing Questionnaire

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. You may find it easier and more convenient to use the Bluetooth-enabled system to test and record your glucose results.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include continuing to use the glucometer you are currently using.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

There is no payment for participation in this study; however, you will be able to keep the iHealth glucometer and any remaining supplies when your participation in the study is complete or you are no longer in the study.

Will being in this study cost you any money?

All of the procedures in this study (training on the use of the glucometer and app, and satisfaction survey) will be provided at no cost to you or your health insurance. You will be continue to be responsible for the cost of your prenatal care, travel to come to any study visit, and any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) You do not follow instructions
d) The study is closed for administrative or other reasons

If you decide to stop being in the study, we will ask you to continue to check your blood sugar as your doctor recommends.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.
A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Dr. Linda Eastham
PO Box 800782
225 Jeanette Lancaster Way
Charlottesville, VA 22903-8703

(434) 591-6032

lae3g@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

> University of Virginia Institutional Review Board for Health Sciences Research
> PO Box 800483
> Charlottesville, Virginia 22908
> Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Appendix D

Patient Consent GDM # 20100 Continued

IRB-HSR # 20100: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.

Appendix E

GDM Patient Informational Trifold

Have You Been Diagnosed with Gestational Diabetes?

Please consider participating in a pilot study to study the effects of mobile health technology on decreasing the burden of GDM.

References

American College of Obstetricians and Gynecologists. (2017). *Practice bulletin: Gestational diabetes mellitus.* (No. 180).ACOG.

Cunningham, F. G., Williams, J. W., Leveno, K. J., Bloom, S. L., Hauth, J. C., Rouse, D. J., . . . Eugene Neff Memorial Fund. (2010). *Williams obstetrics: [Edited by] F. gary cunningham . . [et al.]* (23rd ed ed.). New York: McGraw-Hill Medical.

Ming, W. K., Mackillop, L. H., Farmer, A. J., Loerup, L., Bartlett, K., Levy, J. C., . . . Hirst, J. E. (2016). Telemedicine technologies for diabetes in pregnancy: A systematic review and meta-analysis. *Journal of Medical Internet Research, 18*(11), e290. doi:10.2196/jmir.6556. doi:v18i11e290 [pii]

National Rural Health Resource Center. (2014). Start-up and resource guide version 1.1. Retrieved from https://www.ruralcenter.org/network-ta/resources/telehealth-start-and-resource-guide

Have You Been Diagnosed with Gestational Diabetes?

Appendix E

GDM Patient Informational Trifold Continued

Gestational Diabetes Mellites (GDM)

Gestational diabetes results from the development of carbohydrate intolerance during pregnancy due to the increased stress placed on the body. Gestational diabetes mellitus (GDM) is one of the most common diseases to occur during pregnancy affecting an estimated 9% percent of pregnant women (American College of Obstetricians and Gynecologists, 2017; Cunningham et al., 2010).

Blood Glucose logs

Patients diagnosed with gestational diabetes usually are asked to perform self-monitoring of blood glucose (SMBG) one to two hours after a meal and in the morning before eating, usually four times a day (American College of Obstetricians and Gynecologist, 2017; Cunningham et al., 2010). With each testing event, the woman records her results in a log that she will bring with her to her medical appointments.

Mobile Health (m-Health) Technology

The health and technology industry have joined to increase the wellness and reduce the burden of chronic illnesses such as diabetes. M-Health is a sub-category of telehealth; both use digital technology to deliver health services and education remotely (Ming et al., 2016; National Rural Health Resource Center, 2014).The mobile phone diabetes applications boast many benefits such as easier tracking and reporting of blood glucose results. These applications can record glucose logs via communication with the glucometer or through manual input.

Purpose of Study

The purpose of this Doctorate of Nursing Practice Scholarly Project is to evaluate the feasibility of improving pregnant women's ability to effectively complete their glucose logs using a Bluetooth enabled glucose monitor and associated mobile health application

- Study Question: Does use of a Bluetooth enabled serum glucose monitor in conjunction with the iGluco application improve pregnant women's ability to completely fill out the glucose log?
- Study length 8 weeks. Ihealth glucose meter with supplies provided for second half of study. Participants keep the glucose meter when participation is complete.

Contact of Primary Investigator

Leslie Balcazar de Martinez CNM, WHNP BC
Doctor of Nursing Student at the University of Virginia
E-mail llb9uv@virginia.edu

[redacted]

Appendix F

IRB Approval Event

UVA IRB OnLine

University of Virginia
Institutional Review Board for Health Sciences Research
HIPAA Privacy Board

IRB - HSR # 20100		
Event: Approval New Protocol - Expedited	**Type:** Protocol	**Sponsor(s):** **Sponsor Protocol #:** **Principal Investigator:** Linda Eastham
Title: Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes		
Assurance: Federal Wide Assurance (FWA)#: 00006183 **IRB#00000447**		
Certification of IRB Review: The IRB-HSR/HIPAA Privacy Board abides by 21CFR50, 21CFR56, 45CFR46, 45CFR160, 45CFR164, 32CFR219 and ICH guidelines as compatible with FDA and DHHS regulations. This activity has been reviewed in accordance with these regulations.		
Event Date: 10/11/17 **Protocol Expiration Date:** 10/10/18 **Number of Subjects:** 25 **HSR Protocol Version Date:** 09/14/17 **IRB Application Date:** 09/28/17 **Data Security Plan Date:** 10/02/17		
Current Status: Open to enrollment		
Consent Version Dates: Adult Consent -- 10/03/17		
Committee Members (did not vote):		
Comments: The IRB determined the protocol met the criteria for approval per the federal regulations and was approved. It is open to enrollment. The purpose of this study is to evaluate the feasibility of improving pregnant women's glucose logs using a Bluetooth enabled glucose monitor and associated mobile health application, and to assess patient satisfaction with using this mobile health technology. The study will involve asking women with gestational diabetes to use the iHealth glucometer and its associated app to record glucose logs. There is no outside sponsor for this study. iHealth labs will provide partial funding for glucometers. N= 25 subjects Ages: greater than or equal to 18 years The following documents were submitted with this protocol: patient satisfaction survey, iHealth BG65 glucose meter manual and 510K. No additional committee approvals are required. No monetary compensation. Subjects may keep the glucometer used in this protocol; tax information will		

Appendix F

IRB Approval Event Continued

UVA IRB OnLine

not be collected.

New Medical Device application form for Clinical Engineering on file.

Approved with this protocol is the following recruitment material: brochure.

REGULATORY INFORMATION:

The IRB determined this protocol met the criteria of minimal risk.

Protocol Expedited by Category #4: Collection of data through non-invasive procedures (not involving general anesthesia or sedation) employed in clinical practice, excluding procedures involving x-rays or microwaves.

Where medical devices are employed, they must be cleared/approved for marketing.

Protocol Expedited by Category #7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Enrollment of pregnant women approved under 45CFR46.204.

This protocol has been granted a Waiver of Consent to identify potential subjects via 45CFR46.116.

This protocol has been granted a Waiver of Consent via 45CFR46.116 to contact potential subjects by direct contact by a person who is their health care provider.

Direct contact may include phone, letter, direct email or potential subject approached at UVa by a person is their health care provider.

Phone, letter or emails will be approved by the IRB-HSR prior to use.

Written consent will be obtained for this study.

The consent form signed will have a non-expired IRB-HSR approval stamp.

The device (iHealth glucometer and associated mobile app) being used in this study has FDA approval/clearance.

The FDA device regulation 21CFR812 does not apply to this protocol.

PLEASE REMEMBER:
* If an outside sponsor is providing funding or supplies, you must contact the SOM Grants and Contracts Office/ OSP regarding the need for a contract and letter of indemnification. If it is determined that either of these documents is required, participants cannot be enrolled until these documents are complete.
* You must notify the IRB of any new personnel working on the protocol PRIOR to them beginning work.
* You must obtain IRB approval prior to implementing any changes to the approved protocol or consent form except in an emergency, if necessary to safeguard the well-being of currently enrolled subjects.
* If you are obtaining consent from subjects, prisoners are not allowed to be enrolled in this study unless the IRB-HSR previously approved the enrollment of prisoners. If one of your subjects becomes a prisoner after they are enrolled in the protocol you must notify the IRB immediately.

Appendix F

IRB Approval Event Continued

UVA IRB OnLine

* You must notify the IRB-HSR office within 30 days of the closure of this study.
* Continuation of this study past the expiration date requires re-approval by the IRB-HSR.

The IRB-HSR official noted below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

Name: Margaret W. Ball, BSN, MEd, CIP Title: Member, Institutional Review Board for Health Sciences Research Phone: 434-924-9634 Fax: 434-924-2932	Name and Address of Institution: Institutional Review Board for Health Sciences Research PO Box 800483 University of Virginia Charlottesville, VA 22908
Approval: Approved by Margaret W. Ball, BSN, MEd, CIP From IP Address: 128.143.219.228	Date: 10/11/17 at 03:21 PM

Appendix F

IRB Approval Event Continued

UNIVERSITY of VIRGINIA

Office of the Vice President for Research
Institutional Review Board for Health Sciences Research

Confirmation of Training in Human Subject Protection

HSR # : 20100 **Title :** Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs of Women with Gestational Diabetes

This is a certificate confirming that the following personnel have completed University of Virginia Research Training, an on-line tutorial that reviews the core concepts for the responsible conduct of research in a way that is consistent with federal and university requirements. Following each topic summary, the investigator must correctly answer the test question before being allowed to continue. This training is required every three years.

Name	Training	Last Trained	Expires
Emily J Drake	HSR	(HSR CITI - All Researchers) 23-Mar-16	23-Mar-19
Linda A Eastham	HSR	(HSR CITI - All Researchers) 14-Aug-17	14-Aug-20
Amaya L Cotton-Caballero	HSR	(HSR CITI - All Researchers) 25-Mar-15	25-Mar-18
Leslie L Balcazar	HSR	(HSR CITI - All Researchers) 06-May-17	06-May-20

10/11/2017

Richard Stevenson, MD
Chair, Institutional Review Board for Health Sciences Research
(UVA IRB)

Date

One Morton Drive, Suite 400 * P.O. Box 800483 * Charlottesville, VA 22908-0483
434-924-2620 * Fax: 434-924-2932
www.virginia.edu/vprgs/irb/

Appendix G

Author Guidelines: Journal of Midwifery & Women's Health

Journal of Midwifery & Women's Health www.jmwh.org

Instructions for Authors

The *Journal of Midwifery & Women's Health* (*JMWH*) is the official journal of the American College of Nurse-Midwives. This peer-reviewed journal presents new research and current knowledge across a broad range of clinical and interdisciplinary topics including maternity care, gynecology, primary care for women and newborns, public health, health care policy, and global health. With a focus on evidence-based practice, *JMWH* is dedicated to improving the health care of women throughout their lifespan and promoting excellence in midwifery.

SUBMITTING A MANUSCRIPT

JMWH uses an online manuscript submission and peer review system. Please visit http://mc.manuscriptcentral.com/jmwh to submit a manuscript. A manuscript may be accepted as a submission with the understanding that: (1) it has not been published previously; (2) it is not simultaneously under consideration by any other journal; (3) the content is not fraudulent or plagiarized; (4) the material does not infringe or violate any copyright agreements or other personal or proprietary rights; and (5) all financial support for the work described in the manuscript and any conflicts of interest are disclosed. Copies of articles that are published or in press elsewhere that have any similar material (eg, data from the same dataset) should be provided at the time of submission. Authors must upload signed Author Disclosure and Copyright Transfer Agreement forms for each author. Please contact the editorial office at jmwh@acnm.org with questions about manuscript submission.

TYPES OF ARTICLES

Original Research

Original reports of research should include an introduction with study objective(s), methods, results, discussion, and conclusion. Include clinical, and policy if applicable, implications in the discussion section. For qualitative research, choose exemplar quotes judiciously. Readers should be able to clearly see the relationship between the quotes and your study findings. Length limit is 4000 words, 50 references. For pilot studies, length limit is 2500 words, 30 references.

Reports of research involving human participants must state in the methods section of the manuscript that institutional review board (IRB) or independent ethics review committee approval was obtained or an exemption was granted. The name of the IRB or ethics review committee must be included. *JMWH* may request documentation of the IRB or ethics committee approval or exemption. The methods section should also indicate how informed consent was obtained from all participants (ie, written or oral). Research in which members of the American College of Nurse-Midwives were solicited as participants must be conducted in accordance with the organization's policy regarding soliciting members for research purposes, which is available at www.acnm.org. Adherence to this policy must be noted in the methods section of the manuscript. Clinical trials started aft er May 2005 must be registered with a central registry.[1–3]

Reporting guidelines are used to improve the quality and transparency of research reports.[4] Reporting guidelines specify what information should be included in a research report. Many reporting guidelines include checklists, flow diagrams, and other resources that can be valuable for organizing a manuscript and ensuring the content is complete. Following reporting guidelines will improve your manuscript and may enhance its chances for eventual publication.

Use of the following reporting guidelines is encouraged for original research manuscripts:

- Randomized controlled trials: Consolidated Standards of Reporting Trials (CONSORT) Statement[5]
- Observational studies: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement[6]
- Nonrandomized evaluations of behavioral and public health interventions: Transparent Reporting of Evaluations with Nonrandomized Designs (TREND)[7]
- Qualitative research: Standards for Reporting Qualitative Research (SRQR)[8] and Consolidated Criteria for Reporting Qualitative Research (COREQ)[9]
- Quality improvement studies: Standards for Quality Improvement Reporting Excellence (SQUIRE)[10]
- Diagnostic accuracy studies: Standards for the Reporting of Diagnostic Accuracy Studies (STARD)[11]
- Online surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES)[12]

Wiley will post the accepted version of any manuscript authored by National Institutes for Health (NIH) grant-holders to PubMed Central upon acceptance. This accepted version will be made publicly available 12 months after publication in accordance with the NIH Public Access Policy. For further information, see http://www.wiley.com/go/nihmandate. Wiley also offers open access via OnlineOpen (http://wileyonlinelibrary.com/onlineopen). Upon payment of the OnlineOpen fee, the published version of the article will be deposited into PubMed Central, with public availability in PubMed Central and on the Journal's website immediately upon publication.

Reviews

Reviews may address, but are not limited to, clinical practice; education; health care policy; or legal, ethical, environmental, cultural, or international issues affecting women's health. Systematic reviews, integrative reviews, and meta-analyses are welcome and should follow the same format as research reports (ie, introduction, methods, results, discussion, and clinical implications). Length limit is 5000 words, 70 references.

Use of the following reporting guidelines is encouraged for systematic reviews and meta-analyses:

- Systematic reviews and meta-analyses: Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) Statement[13]
- Systematic reviews of observational studies: Meta-analysis of Observational Studies in Epidemiology (MOOSE)[14]

Brief Reports

Brief reports may include, but are not limited to, innovative practice initiatives; assessment tools, resources, or evidence-based protocols that address a specific clinical topic; instructional techniques, technologies, and programs of interest for midwifery and other health professions educators; professional affairs updates; and historical perspectives. While manuscripts may focus on an

Appendix G

IRB Approval Event Continued

individual practice or education program, the content must include broader implications and applicability. Length limit is 3000 words, 30 references.

Quality Improvement Reports

Quality improvement reports summarize the process and outcomes of systematic efforts undertaken to improve the quality and safety of health care. These manuscripts should include the following sections: introduction, process, outcomes, discussion, and conclusion. The Guidelines for Quality Improvement Reports, located at www.jmwh.org, provide an outline of suggested content for each section. Length limit is 2500 words, 30 references.

Commentaries

Controversial points of view cogently presented in the form of position papers or editorials may be submitted as commentaries. This section provides a forum for authors to express varied points of view, propose new ideas, or generate relevant debate on controversial topics. Length limit is 2000 words, 20 references.

Clinical Rounds

This column begins with a description of a case that is unusual, educational, or highlights an area in which the management is controversial, followed by a brief review of the evidence for management and/or discussion of the controversy. The Clinical Rounds Guidelines, located at www.jmwh.org, provide more detailed instructions for these manuscripts. Length limit is 3000 words, 30 references.

Share With Women

Health professionals may copy and distribute these patient education handouts without permission. The entire series is available at www.sharewithwomen.org. Please contact the editorial office with your proposed topic prior to writing a Share with Women handout.

Letters to the Editor

Letters to the Editor should be no longer than 400 words and must include a complete citation of the published work that generated the letter. All letters must be submitted via the online manuscript submission system. A letter's submission will be viewed as de facto permission for its publication. The Editorial Board reserves the right to select, edit, and condense letters for publication and to publish an author or editor response to letters.

MANUSCRIPT STYLE AND PREPARATION

JMWH has adopted the *AMA Manual of Style, 10th ed.*[15] for grammar, punctuation, and style. The *Journal of Midwifery & Women's Health Manuscript Preparation and Style Guide* contains necessary information about manuscript preparation and style specific to *JMWH* and is available at www.jmwh.org.

Manuscripts must be in English. Authors who are not fluent in English should seek assistance to ensure manuscript readability. Authors for whom English is a second language may choose to have their manuscript professionally edited before submission. A list of independent suppliers of editing services can be found at http://wileyeditingservices.com/en/. Use of an English-language editing service does not guarantee acceptance or preference for publication.

MANUSCRIPT COMPONENTS IN ORDER OF PRESENTATION

The manuscript components will be uploaded as separate files in the following order: (1) cover letter (optional); (2) title page, including author biographic sketch(es), conflict of interest disclosure, and acknowledgements; (3) blinded manuscript, including précis, abstract, keywords, Quick Points, text, references, tables, figure titles and legends, and appendices; (4) figures; and (5) supporting information. The title page and manuscript files should be uploaded as Microsoft Word files.

Title Page

A separate title page file is required to ensure that manuscripts sent for review do not include identifying author information that would prevent a blinded review. The title page includes (1) full title of manuscript with no abbreviations; (2) authors' names and credentials in the order of authorship for publication; (3) the name, mailing address, telephone and fax numbers, and e-mail address of the author to whom communications should be sent (corresponding author); (4) word count of the text (excluding précis, abstract, references, and tables); (5) author biographic sketch(es); (6) conflict of interest disclosure; and (7) acknowledgements. Choose a concise, specific manuscript title that summarizes the main idea of the manuscript, is fully explanatory, and includes terms likely to be used by readers searching for articles on the topic. The title must be able to stand alone, and the subtitle should complement or amplify the main title.

Author biographic sketch(es)

Provide a biographic sketch for each author. The biographic sketch should be 1 to 2 sentences, and include name, credentials (earned academic degrees, certification, and/or licensure), position(s), and current affiliation(s). For example, Jane Doe, CNM, MSN, is in clinical practice at Alaska Family Health & Birth Center in Fairbanks, Alaska, and a clinical instructor at the University of Alaska.

Conflict of Interest

Provide full disclosure of any conflicts of interest for all authors. If there are none, note "The author(s) has(have) no conflicts of interest to disclose."

Acknowledgements

Identify sources of financial or other support that contributed to the manuscript. Acknowledge contributors who are not included as authors. Obtain written permission from any individuals named in the acknowledgements section. *JMWH* may request the author provide documentation of permission from individuals acknowledged.

Manuscript

Précis (only required for Original Research, Review, Brief Report, and Quality Improvement Report submissions)

The précis is a description of the manuscript conclusions, which appears under the title in the Table of Contents. Describe the primary findings in 25 or fewer words that do not repeat the manuscript title. Use present tense and be specific. Tell what was found, not what was done.

Appendix G

IRB Approval Event Continued

Abstract (only required for Original Research, Review, Brief Report, Quality Improvement Report, and Clinical Rounds submissions)

The abstract is a summary paragraph that describes the manuscript. The abstract is published at the beginning of an article and is also displayed in databases, such as PubMed and CINAHL. This is the text that individuals conducting literature searches see first. The abstract invites the potential reader to read the entire article. A well-written abstract improves the likelihood of an article being read and cited. Do not include the same sentences in the abstract that are in the introduction. Do not cite references in the abstract. Further information on optimizing an abstract for search engines can be found at http://authorservices.wiley.com/bauthor/seo.asp.

Manuscripts reporting original research, systematic reviews, integrative reviews, and meta-analyses should include a structured abstract of no more than 300 words with the following headings:

Introduction: State the purpose of the study or review and why this question is important.
Methods: For original research include the study design, setting (for example, location and level of clinical care), population intervention(s), and main outcome measure. For reviews and meta-analyses identify data sources, including years searched; inclusion and exclusion criteria used to select studies; and methods for abstracting data and assessing quality and validity.
Results: State the key findings of the study or review. Include the response rate for surveys.
Discussion: Clearly state the conclusions of the study or review, including the implications for clinical practice.

Quality Improvement Report manuscripts should include a structured abstract of no more than 300 words with the following headings:

Introduction: State the issue being addressed and the purpose of the project.
Process: Describe the intervention and evaluation plan.
Outcomes: Identify the key outcomes of the intervention.
Discussion: State the conclusions of the project, including implications for clinical practice.

For Review, Brief Report, and Clinical Rounds manuscripts, include an unstructured abstract of no more than 300 words that summarizes the objective, main points, conclusions, and clinical implications.

Keywords (only required for Original Research, Review, Brief Report, Quality Improvement Report, and Clinical Rounds submissions)

Identify 3 to 10 keywords that best describe the content of the manuscript, and are search terms readers are likely to use when looking for articles on the topic. Keywords should be selected from the list of Medical Subject Headings (MeSH) used by the National Library of Medicine for indexing in PubMed. An online search tool for the MeSH vocabulary is available at http://www.nlm.nih.gov/mesh/MBrowser.html. Reviewing PubMed citations for articles with similar content is a helpful way to identify MeSH terms commonly associated with the topic.

Quick Points (only required for Original Research, Review, Brief Report, and Quality Improvement Report submissions)

Quick Points appear in a box on the second page of Original Research, Review, Brief Report, and Quality Improvement Report articles and give readers a brief synopsis of the article's key points. Provide 3 to 5 short bulleted sentences following the abstract that summarize the manuscript's significance and applicability. Specify clinical implications if possible. Other appropriate content includes what the manuscript adds to the existing literature, important findings, and policy implications. Quick Points can be direct quotations from the manuscript or new sentences, but they should not include exact sentences that are in the abstract. Quick Points provide a brief summary of the article, whereas the abstract encourages individuals conducting literature searches to read the entire article.

Text and References

All references, tables, figures, and appendices must be cited in the text of the manuscript in chronologic order.

Tables

Tables are an effective way to summarize, organize, or condense data or information. Tables should not repeat information in the text and vice versa. A table should stand independently, without requiring explanation from text. Remember that some readers only read the tables. Make sure there is adequate content for a table. If the information it contains could be reported in 1 or 2 sentences, a table is unnecessary.

Type each table on a separate page. Number tables consecutively according to when they are cited in the text. Construct tables using the table function in word processing software. The title of a table succinctly conveys the table topic without providing detailed background information or summarizing or interpreting the results. The title should completely explain the contents and be placed above the table, outside the table. Footnotes for tables should be identified with superscript lowercase letters placed in alphabetical order as each row is read from left to right starting at the top and moving to the bottom. The *JMWH Manuscript Preparation and Style Guide* contains detailed instructions for creating tables and includes examples. Additional table examples can be found in the *AMA Manual of Style*.[15]

If a table is constructed or reprinted from text or tables in another publication, the table legend must give appropriate credit to the original source. Tables that are constructed or reprinted from tables in other publications must be accompanied by written permission for their use from the copyright holder, and this permission must be acknowledged in the table legend. The legend wording depends upon the construction of and permission for the table content. A table constructed from the author's data does not need a legend. A table constructed from text found in another publication that the author has assembled into a table needs the source cited (ie, Source: Smith et al.[22]). A table constructed from a table in another publication needs permission from the original publication and a legend noting permission and the source (ie, Adapted with permission from Smith et al[22]; Jones.[25]). A table reprinted from another publication needs permission from the original publication and a legend noting permission and the source (ie, Reprinted with permission from Smith et al.[22]). Sources should be listed in numeric order of the references (eg, Smith et al[22]; Jones;[25] Alvarez.[29])

Figures

The caption for each figure should be placed on a separate page of text at the end of the manuscript. Number figures consecutively according to where they are cited in the text. The figure caption succinctly identifies and describes the figure. It should provide sufficient detail to make the figure comprehensible without reference to the text. Abbreviations and footnotes for figures should be formatted the same way these items are formatted for

Appendix G

IRB Approval Event Continued

tables. The *JMWH Manuscript Preparation and Style Guide* section on tables contains detailed instructions for abbreviations and footnotes, including examples.

If a figure is constructed or reprinted from text or figures in another publication, the figure legend must give appropriate credit to the original source. Figures that are constructed or reprinted from figures in other publications must be accompanied by written permission for their use from the copyright holder. Photographs of potentially identifiable people must be accompanied by written permission to use the photograph as a figure. Permission must be acknowledged in the figure legend. The legend wording depends upon the construction of and permission for the figure. The instructions for source and permission legend wording and order in the preceding section on tables should also be used for figures.

Appendices

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REFERENCES

1. International Committee of Medical Journal Editors. *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*. http://www.icmje.org/recommendations/. Updated December 2016. Accessed January 22, 2017.
2. DeAngelis C, Drazen JM, Frizelle FA, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *JAMA*. 2004;292(11):1363–1364. http://jama.ama-assn.org/cgi/reprint/292/11/1363.pdf. Accessed January 22, 2017.
3. ClinicalTrials.gov website. http://clinicaltrials.gov/. Accessed January 22, 2017.
4. EQUATOR Network website. http://www.equator-network.org/. Accessed January 22, 2017.
5. CONSORT Statement website. http://www.consort-statement.org/. Accessed January 22, 2017.
6. STROBE Statement website. http://www.strobe-statement.org/. Accessed January 22, 2017.
7. Centers for Disease Control and Prevention. Transparent Reporting of Evaluations with Nonrandomized Designs (TREND). http://www.cdc.gov/trendstatement/. Accessed January 22, 2017.
8. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245-1251.
9. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349-357. http://intqhc.oxfordjournals.org/content/19/6/349.long
10. SQUIRE website. http://www.squire-statement.org/. Accessed January 22, 2017.
11. STARD Statement website. http://www.stard-statement.org/. Accessed January 22, 2017.
12. Eysenbach G. Improving the quality of Web surveys: the checklist for reporting results of Internet e-surveys (CHERRIES). *J Med Internet Res*. 2004;6(3):e34. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550605/. Accessed January 22, 2017.
13. PRISMA Statement website. http://www.prisma-statement.org/. Accessed January 22, 2017.
14. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology. *JAMA*. 2000;283(15):2008–2012. http://jama.ama-assn.org/cgi/content/full/283/15/2008. Accessed January 22, 2017.
15. Iverson C, Christiansen S, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 10th ed. New York, NY: Oxford University Press; 2007.
16. Committee on Publication Ethics website. http://publicationethics.org/. Accessed January 22, 2017.
17. World Association of Medical Editors website. http://www.wame.org/. Accessed January 22, 2017.
18. Council of Science Editors website. https://www.councilscienceeditors.org/. Accessed January 22, 2017.

Appendix H

Manuscript

Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs Completion of Women with Gestational Diabetes Mellitus

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Women diagnosed with GDM have the potential to improve their glucose log completion rates through the use of Bluetooth technology and diabetic healthcare applications.

Evaluating the Feasibility of using M-Health to Improve Serum Glucose Logs Completion of Women with Gestational Diabetes Mellitus

Abstract

Gestational diabetes mellitus (GDM) can cause adverse outcomes for the mother and fetus due to hyperglycemia. The purpose of this pilot study is to evaluate the feasibility of improving pregnant women's glucose log completion rates using a Bluetooth-enabled glucose monitor and associated mobile health application and to assess their satisfaction with using mobile health technology. Methods: This project utilizes a quasi-experimental pre-post design. Over the course of 8 weeks, participants completed serum glucose logs (SGL). In phase one the participants collected logs for four weeks using their standard glucose meter followed by phase two in which the participant used a provided Bluetooth-enabled glucometer with the iGluco application for four weeks. Eligibility for this study included but was not limited to a diagnosis of GDM, English or Spanish speaking, and ownership of a smartphone capable of running the mobile health application. Data collected included demographic information, serum glucose logs, and a satisfaction survey. Results: Five participants completed the study. The average completion score was 74.82% in phase one and 81.73 in phase two (a difference of 6.91%). The iHealth glucometer was the preferred monitor with overall satisfaction of the diabetes care received. Implications: This study has the potential to help demonstrate the feasibility of improved self-management of GDM and provide the groundwork for future studies. Conclusion: The use of Bluetooth-enabled glucose monitors with mobile health applications may translate to a more accurate reflection of the actual meter reading, be more efficient, and more complete.

Key terms: M-Health, Gestational diabetes mellitus (GDM), Bluetooth, Serum glucose log (SLG), Self-Monitoring of blood glucose (SMBG).

- Self-monitoring of blood glucose (SMBG) task completion is as low as 26% in the United States for patients diagnosed with diabetes[2,3].
- Blood glucose logs are an important tool for management of diabetes, further supporting the need to integrate more accurate methods of collecting serum glucose log data
- The improvement of accuracy, efficiency, and completeness with serum glucose logs can provide the pathway needed for the improved patient to provider communication allowing for more precise and collaborative management of gestational diabetes (GDM) and subsequently may lessen the incidence of morbidity and mortality associated with it.[8]
- The clinical implications of this study lie in the nurse's ability to understand what tools are available to the patient and how to assist the patient in using them to their advantage.

Gestational diabetes mellitus (GDM) can cause adverse outcomes for the mother and fetus due to hyperglycemia.[1] The most efficient and cost-effective way to manage diabetes and GDM is to have the patient monitor their serum glucose on a schedule agreed upon by the provider and patient.[2-4] The patient then records the results of the self-tested serum glucose over time providing date and time of result in a glucose log. This method allows the patient to see how their diet affects their serum glucose and make daily adjustments to their diet and medication. This task is also a pathway for the provider to engage the patient in personal decision making for the patient's treatment plan. A complete and accurate serum glucose log is critical to communicating the results of each test performed. The review of the literature indicates that self-monitoring of blood glucose (SMBG) task completion is as low as 26% in the United States for patients diagnosed with diabetes.[2,3] In three separate studies pain, motivation, social stigma, time, money, and emotional tie to results were identified as barriers to successful SMBG.[2,4,5] Other significant barriers included understanding the disease, plan of care, and testing process.[4]

The purpose of this pilot study is to evaluate the feasibility of improving pregnant women's glucose log completion rates using a Bluetooth-enabled glucose monitor and associated mobile health (mHealth) application and to assess their satisfaction with using mobile health technology. This pilot study utilizes a quasi-experimental pre-post longitudinal design over eight weeks with a convenience sample of pregnant women diagnosed with Gestational Diabetes (GDM). This pilot study took place at a Maternal-Fetal Medicine Clinic located in a mid-Atlantic tertiary care center that serves approximately 278 women diagnosed with GDM a year.[6]

Methods

This study utilized a prospective, longitudinal quasi-experimental pre-post design in two phases. Institutional IRB approval was obtained prior to data collection. In phase one the participants collected logs for four weeks using their standard glucose meter followed by phase two in which the participant used a provided Bluetooth-enabled glucometer with the iGluco application for four weeks. Eligibility for this study included but was not limited to a diagnosis of GDM, English or Spanish speaking, and ownership of a smartphone capable of running the mobile health application. Data collected included demographic information, serum glucose logs, and a satisfaction survey.

The primary outcome measure of this pilot study was glucose log completeness measured on a scale of zero to 100%. The glucose logs annotate each glucose result, if the patient is diet controlled or taking medications, and if data transcription comes from the study coordinator or participant. Demographic data collected included education level, cultural/ethnic/racial identity, primary language, gestational age, and type of diabetes control (see Table 1). A satisfaction survey adapted from the RAND Health PSQ-18 satisfaction survey to reflect diabetes care retrieved from https://www.rand.org/health/surveys_tools/psq.html was used to measure satisfaction with the diabetes care received during the study.[7] This survey provides 18 likert scale questions with scores for each question ranging from one to five. There is an additional open-ended question included asking the participants to disclose the glucometer they liked best during the study and their rationale.

Each participant received an iHealth Bluetooth-enabled glucometer with supplies enough to complete four weeks of serum glucose monitoring and training on how to use it by the primary investigator for phase two of the study. The study coordinator offered assistance downloading the iGluco application along with training to utilize the glucometer with the application. A

demonstration and written instructions for printing the glucose log from the application was given with instruction how to view the iHealth/iGluco support web page.

Descriptive statistics were used to summarize the data collected. The data was analyzed using SPSS v. 24. Glucose log completeness was calculated using the total number of actual entries divided by the total number of required entries.

Results

Sample

During the recruitment period, 17 women had a diagnosis of GDM. Of these 17 women, four did not meet eligibility due to speaking a language other than English or Spanish, or the women's condition made delivery uncertain. Two patients were unavailable due to repeatedly missed appointments. Three women declined to be in the study due to technology concerns. Eight participants enrolled and were consented to be in this study. Five participants completed both phases with surveys resulting in a 37.5% attrition rate.

The participants ranged in age from 27 to 43 years old. The majority of participants were Caucasian-non-Hispanic (80%) or Black/non-Hispanic (20%). Education varied with 20% four-year degree, and 40% some college, 20% technical college, and 20% high school education. Everyone who consented to be in the study spoke English. Mean gestational age at entry into the study was 29.6 weeks. Two of five participants (40%) used nutrition therapy alone, and three of five (60%) used insulin and nutrition therapy for their GDM. See Table 1 for more detailed demographic information about the participants in this study.

Glucose log completion

In phase one (standard monitor and paper logs) the average completion score of the five remaining participants was 74.82% (see Figure 1). In phase two (iHealth/iGluco) the average

completion score was 81.73%, an improvement of 6.91%. A sign test was used to calculate the significance of three out of the five participant scores increasing between the two phases. This test resulted in no significant difference between the two phases for the number of participants increasing their completeness score compared to the number of participants decreasing their score with p = 1.00.

Satisfaction

Each participant surveyed indicated the iHealth was their preferred monitor. Two participants (40%) felt the iHealth monitor was easier to use; another felt it was less work, the remaining two participants expressed it was a better monitor, and more accurate than their standard monitor. The PSQ-18 survey results indicated satisfaction with the diabetes care received with an overall score of 29.25 out of 35 possible and an average score of 4.4 out of five for general satisfaction

Discussion

An overall increase of 6.91% from 74.82 to 81.73 in the blood glucose log completeness suggests that although technology such as Bluetooth-enabled monitors and diabetes health applications may not completely solve the issue of incomplete glucose logs, their use may improve completion rates. Improving glucose log completion may enable better communication between healthcare providers and patients allowing for more appropriate treatment plans. These treatment plans can lead to a decrease in serum glucose levels.[8] Ming et al. conducted a systematic review studies that included Bluetooth-enabled monitors showing a significant difference in HgbA1c between the intervention groups and the control groups (standard care) in the meta-analysis ($p = 0.01$).[9] Another study utilizing transmitting technology included 513 participants found a significant difference for HgbA1c in favor of the intervention group ($p = 0.013$).[10]

The purpose of this study was to evaluate the feasibility of improving pregnant women's glucose log completion rates using a Bluetooth-enabled glucose monitor and associated mobile health application and to assess their satisfaction with using mobile health technology. However, some technical issues using and understanding the equipment was noted. Technology proficiency and subsequent difficulty the participants experienced demonstrated an effect on their willingness to accept the technology and their interest to use it. Even though each of the women approached had a smartphone, this did not necessarily mean they were proficient in using the application features.[11-13] The attrition rate of this study was 37.5%, of which 25% was attributable to technical difficulties experienced by the participants. Also, three women who declined did so because of the belief they would experience technical difficulties.[12] Istepanian et al. completed a study with 137 participants. The intervention group was given Bluetooth-enabled serum glucose monitors and a cellular phone. The completion rate for the study was 63.5% with 56% of the intervention group not completing the study. The results of that study indicated there was no significant difference between the control group and those using the Bluetooth technology.[12] Istepanian et al. stated that technical issues might have been contributory to the high attrition rate for their study (2009).[13] Quinn and colleagues evaluated 30 patients with the diagnosis of type 2 diabetes. The control group had only 7.7% completing the log books per protocol. Limitations included the fact that only five of the 15 people in the intervention group consistently used the Bluetooth feature of the glucose monitor due to technical issues. A randomized control trial conducted in the UK by Farmer et al. also suffered from technical difficulties, damages, or theft of the mobile phones.[11] Preventing theft or damage to personal equipment used for monitoring blood glucose levels is not completely avoidable. However, decreasing the possibility of technical difficulties by increasing technology literacy through

better education and training on health assistive technology and their accompanying applications is not only reasonable but should be expected by the consumer and the provider.[14]

Further research is needed to test the use of Bluetooth technology with the GDM population. A randomized controlled trial with a larger sample size would be needed to fully evaluate the effectiveness of this technology. To include a more diverse study population, non-English speaking staff and study coordinators that understand the various cultures should be involved. Although respect for the patient's time is essential, the researcher should insist that patients in the intervention arm allow for set up and competency demonstration before leaving with the monitor. It should be noted that this was a pilot study, with a small convenience sample and a pre-post study design. Maturation, selection bias, and attrition are all threats to internal validity with this study design. This design does not control for the natural progression of the participant's knowledge and experience with glucose log completion. Each patient received continued encouragement with each visit to complete their glucose logs per standard of care. A selection bias may occur if the patients opted to participate due to a desire to receive an iHealth glucometer and supplies. Social desirability bias may also affect the completion rates of the participants as they may improve their log completion due to the desire to please the provider or researcher. The small sample and pilot study design inherently limit external validity outside of this clinic setting.

The clinical implications of this study lie in the nurse's ability to understand what tools are available/accessible to the patient and how to assist the patient in using them to their advantage. The review of the literature indicates that GDM presents unique challenges to women on many levels, especially SMBG task such as blood glucose logs. The findings from this project can help guide health care providers to take better advantage of contemporary technologies that

patients already use, such as cellular phones, as well as diabetic mHealth applications to improve the management of GDM and help decrease the adverse outcomes associated with it.

References

1. American College of Obstetricians and Gynecologists. Practice bulletin: Gestational diabetes mellitus. 2017;180.

2. Ong WM, Chua SS, Ng CJ. Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: A qualitative study. *Patient Prefer Adherence*. 2014;8:237-246. doi: 10.2147/PPA.S57567 [doi].

3. Fisher W. Barriers and behaviors in blood glucose monitoring. *US Endocrine Disease*. 2007:51-53.

4. Ward JEF, Stetson BA, Mokshagundam SPL. Patient perspectives on self-monitoring of blood glucose: Perceived recommendations, behaviors and barriers in a clinic sample of adults with type 2 diabetes. *Journal of Diabetes & Metabolic Disorders*. 2015;14(1):1-7.

5. Persson M, Winkvist A, Mogren I. 'From stun to gradual balance'– women's experiences of living with gestational diabetes mellitus. *Scand J Caring Sci*. 2010;24(3):454-462.

6. University of Virginia. Clinical data repository [de-identified data file and code book]. Retrieved from https://cdr.virginia.edu/ on (February 17, 2017). Updated n.d.

7. RAND Health. Patient satisfaction survey: PSQ-18 questionnaire. https://www.rand.org/health/surveys_tools/psq.html. Updated 2017.

8. Selvan C, Thukral A, Dutta D, Ghosh S, Chowdhury S. Impact of self-monitoring of blood glucose log reliability on long-term glycemic outcomes in children with type 1 diabetes. *Indian Journal of Endocrinology & Metabolism*. 2017;21(3):382-386.

9. Ming WK, Mackillop LH, Farmer AJ, et al. Telemedicine technologies for diabetes in pregnancy: A systematic review and meta-analysis. *J Med Internet Res*. 2016;18(11):e290. doi:10.2196/jmir.6556. doi: v18i11e290 [pii].

10. Steventon A, Bardsley M, Doll H, Tuckey E, Newman SP. Effect of telehealth on glycaemic control: Analysis of patients with type 2 diabetes in the whole systems demonstrator cluster randomised trial. *BMC Health Services Research*. 2014;14(1):334. http://dx.doi.org/10.1186/1472-6963-14-334. doi: 10.1186/1472-6963-14-334.

11. Farmer AJ, Gibson OJ, Dudley C, et al. A randomized controlled trial of the effect of real-time telemedicine support on glycemic control in young adults with type 1 diabetes (ISRCTN 46889446). *Diabetes Care*. 2005;28(11):2697-2702. doi: 10.2337/diacare.28.11.2697.

12. Istepanian RSH, Zitouni K, Harry D, et al. Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes. *J Telemed Telecare*. 2009;15(3):125-128. http://journals.sagepub.com/doi/abs/10.1258/jtt.2009.003006. doi: 10.1258/jtt.2009.003006.

13. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care*. 2011;34(9):1934-1942. doi: 0366 [pii].

14. Cohron M. The continuing digital divide in the united states. *Serials Librarian*. 2015;69(1):77-86.

Table 1

Demographic characteristics of the participants that completed the study.

	Mean (SD)	**(%)**
Age at study entry (years)	34.2 (6.1)	
Gestational Age at entry of Study	29.6 (2.8)	
Education		
4-year Degree		20.0
Technical College		20.0
Some College		40.0
High School		20.0
Race /Ethnicity		
White, non-Hispanic		80.0
African American/Black, non-Hispanic		20.0
Primary Spoken Language		
English		100.0
Smartphone type		
iphone		80.0
Android		20.0
Phase entered study		
Phase 1		20.0
Phase 2		80.0
GDM control treatment		
Diet		40.0
Insulin		60.0

Note. n =5.

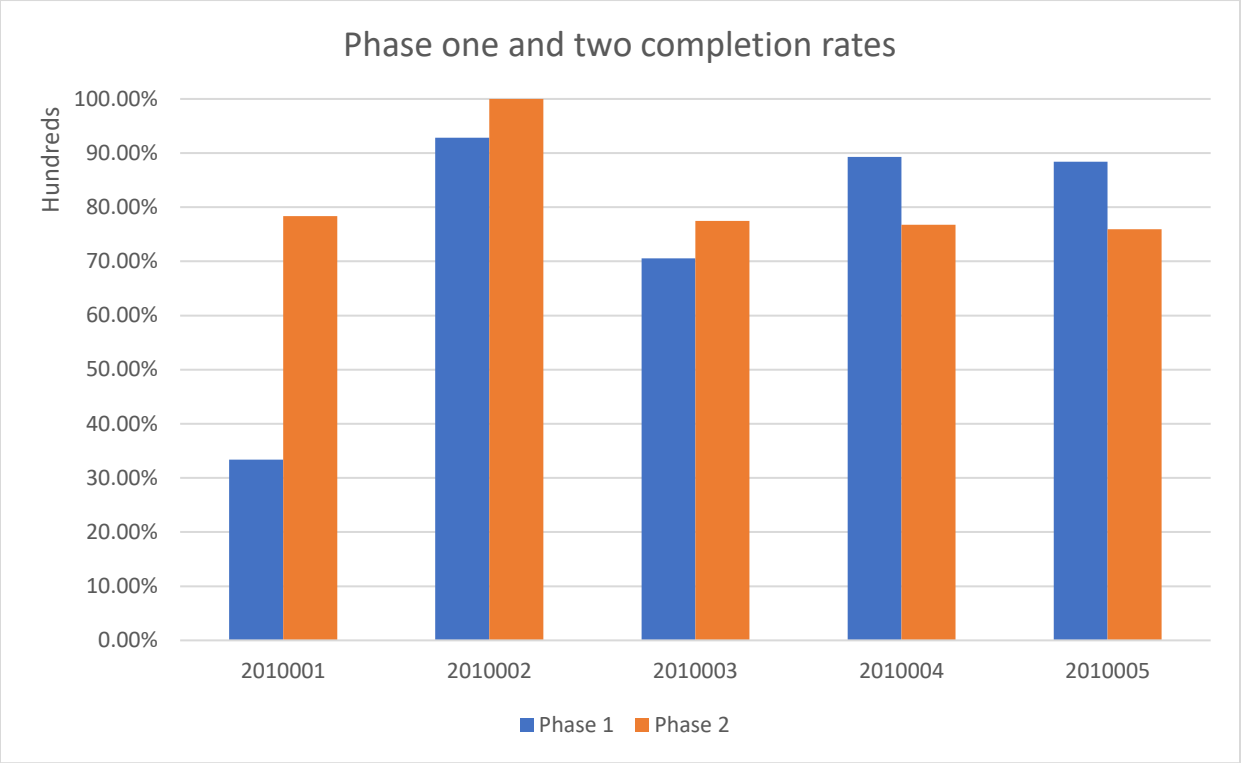

***Figure* 1**. Completion rates compared