

The Effect of Financial Incentives on Adherence to Glucose Self-Monitoring during Pregnancy among Patients with Insulin-Requiring Diabetes: A Randomized Clinical Trial

NCT03338829

Study Completed June 30, 2022

Protocol publication date September 2, 2022

Background: Diabetes is a chronic condition that requires ongoing management. Adherence to self-monitoring of blood glucose (SMBG) is a critical component of diabetes management, as it allows patients to track their glucose levels and adjust their insulin therapy accordingly. However, adherence to SMBG is often low, particularly in pregnant women with insulin-requiring diabetes. Financial incentives have been shown to improve adherence to various health behaviors, but their effectiveness in improving SMBG adherence during pregnancy remains unclear. This study aims to evaluate the effect of financial incentives on adherence to SMBG during pregnancy among patients with insulin-requiring diabetes.

Objective: The primary objective of this study is to determine the effect of financial incentives on adherence to SMBG during pregnancy among patients with insulin-requiring diabetes. The secondary objective is to determine the effect of financial incentives on glycemic control during pregnancy.

1. Primary outcome: Adherence to SMBG during pregnancy, measured as the percentage of days with SMBG readings.
2. Secondary outcome: Glycemic control during pregnancy, measured as the percentage of days with HbA1c levels below 6.5%.
3. Tertiary outcome: Patient satisfaction with the study, measured as the percentage of patients who reported being satisfied with the study.

Design: This is a randomized controlled trial. Patients will be randomized to either the intervention group (financial incentives) or the control group (no financial incentives).

Methods

Study Design: This is a randomized controlled trial. Patients will be randomized to either the intervention group (financial incentives) or the control group (no financial incentives). The study will be conducted in a hospital setting. The intervention group will receive financial incentives for each day that they provide a SMBG reading. The control group will not receive financial incentives. The study will last for 12 weeks. The primary outcome is adherence to SMBG during pregnancy, measured as the percentage of days with SMBG readings. The secondary outcome is glycemic control during pregnancy, measured as the percentage of days with HbA1c levels below 6.5%. The tertiary outcome is patient satisfaction with the study, measured as the percentage of patients who reported being satisfied with the study.

Study Population: The study population will consist of pregnant women with insulin-requiring diabetes who are at least 18 years old and who are able to provide informed consent. The study will be conducted in a hospital setting. The inclusion criteria are: pregnant women with insulin-requiring diabetes, at least 18 years old, and able to provide informed consent. The exclusion criteria are: pregnant women who are unable to provide informed consent, pregnant women who are taking medications that may interfere with the study, and pregnant women who have a history of severe complications from diabetes.

Intervention: The intervention group will receive financial incentives for each day that they provide a SMBG reading. The financial incentives will be provided in the form of a cash reward. The control group will not receive financial incentives. The study will last for 12 weeks. The primary outcome is adherence to SMBG during pregnancy, measured as the percentage of days with SMBG readings. The secondary outcome is glycemic control during pregnancy, measured as the percentage of days with HbA1c levels below 6.5%. The tertiary outcome is patient satisfaction with the study, measured as the percentage of patients who reported being satisfied with the study.

Outcome Measures: The primary outcome is adherence to SMBG during pregnancy, measured as the percentage of days with SMBG readings. The secondary outcome is glycemic control during pregnancy, measured as the percentage of days with HbA1c levels below 6.5%. The tertiary outcome is patient satisfaction with the study, measured as the percentage of patients who reported being satisfied with the study.

Supplemental Material S1

Protocol Title

Incentive models on testing adherence for women with diabetes during pregnancy.

Objectives

Diabetes in pregnancy is associated with increased risks of maternal and fetal complications and can be challenging to manage due to increasing insulin requirements with advancing gestational age. Based on standard of care guidelines, patients with diabetes check their blood glucose at least four times a day. Optimal management requires frequent glucose self-monitoring and active management of abnormal blood sugars and medications by clinicians. Poorly controlled diabetes has both significant maternal and neonatal consequences: improving test adherence could benefit both the pregnant woman and her fetus. In this study, we propose to test the effect of two incentive schemes on the rates of glucose monitoring on pregnant women with diabetes requiring medication.

Pregnant women with diabetes requiring medication are invited to participate if they meet specific inclusion criteria (<29 weeks) and followed in our outpatient clinic. Participants are randomized into one of three groups:

1. Control group—receive compensation at the time of enrollment.
2. Positive incentive group—receive compensation per test completed.
3. Loss aversion group—receive between a range of compensation depending on their overall level of adherence.

Primary outcome of the study is adherence to self-glucose monitoring recommendations in pregnancy.

Background

Diabetes is complicating pregnancies with increasing frequency. The management of perinatal diabetes is made inherently more difficult because of increasing insulin requirements as pregnancy progresses.¹ Poorly controlled perinatal diabetes carries significant pregnancy-specific risks including increased risks of intrauterine fetal demise, large for gestational age fetuses, shoulder dystocia at the time of delivery, hypertensive disorders of pregnancy, Cesarean section, and post-delivery infections. For the newborn, additional complications follow poorly controlled diabetes, hence, any improvements in testing adherence which can assist in improving control could have significant maternal and newborn benefits. Frequent self-glucose monitoring is the mainstay of effective disease management. Patients note both time pressures and physical constraints as barriers to

effective implementation of diabetes care in pregnancy, especially in those of lower socioeconomic status.² Unfortunately, prior studies show that between 10 and 37% of reported blood glucose values are false.³ Using a new FDA-cleared, HIPAA compliant cellular-enabled blood glucose meter (Telcare), the maternal fetal medicine division of UIHC has established a quality improvement program to enable real-time collection and remote, asynchronous management of blood glucose in pregnancy. As part of this program, we hope to test the hypothesis that financial incentives can increase patient adherence to recommended glucose monitoring.

Many adverse outcomes of diabetes within and outside of pregnancy are the result of long-term hyperglycemia. These risks are often discounted relative to the time and energy required for proactive disease maintenance including frequent self-glucose monitoring. There has been increasing interest in incentivizing patient engagement with long-term disease management. One study has looked at the role of small positive incentives in increasing frequency of glucose monitoring in adolescents with type 1 diabetes. They found that paying participants \$0.10 per blood glucose obtained as recommended resulted in an increase from 1.8 to 4.9 glucose tests per day and a decrease in hemoglobin A1C from 9.3 to 8.4%.⁴ Another study evaluating HgbA1c in veterans showed that providing \$100 to \$200 at 6 months for each 1% decrease in HgbA1C results in modest improvements of hemoglobin A1C.⁵ A meta-analysis of financial reinforcers for improving medication adherence noted that at least weekly reinforcement provided improved adherence.⁶ A more recent study by Sen et al showed that weekly lottery for daily biometric monitoring with a low financial incentive of \$1.40 per week resulted in increased testing frequency over 6 months compared with both no and higher financial incentives.⁷ Together, these show that small frequent financial rewards can motivate healthful habits.

An alternative model for financial reinforcement of behavior is a loss model, where people tend to be motivated to avoid loss rather than acquire gains. In a recent sub-analysis of financial incentives for smoking cessation, the group that had deposited \$150 (and risked losing this) was significantly more likely to stop smoking at 6 months compared with those in a rewards-based program.⁸ This study was limited by most participants opting out of the arm that required \$150 deposit. However, in behavioral economics there is growing recognition that loss aversion is a stronger motivator than positive reinforcement.

In this proposed study, we plan to test the hypothesis that incentivizing adherence to recommended glucose monitoring in pregnancy improves recommended testing. This will be measured by percentage recommended blood sugars obtained by participants (adherence). We plan to recruit

patients from UIHC's Perinatal Diabetes Program, a new program which uses telecare monitors to enable timely asynchronous analysis and support of blood sugars. These devices transmit obtained blood sugar results to a cloud-based server in real time and make these results and test adherence available to patients and provider teams. This allows for asynchronous communication, clinical intervention, and identification of patients at risk for declining metabolic control. Overall, participants will be recruited from all patients in the UIHC system that require insulin in pregnancy who are enrolled in this new quality improvement initiative.

Study Design

Randomized Controlled Trial consisting of three arms: control, positive incentive, and loss aversion. Subjects will be stratified by type of diabetes and subsequently be randomized in a 1:1:1 allotment to control, positive incentive, and loss aversion groups.

Study Population

(a) Proposed # of Participants: 130

Our preliminary data shows 70% adherence without incentives. With a type-I error rate of 5% and power of 80%, an effect size of 10% can be detected with 100 individuals. We anticipate a 30% drop out rate, thus plan to recruit around 130 participants.

(b) Inclusion criteria: Our study population will include pregnant women (Age 18–50) with insulin-dependent diabetes identified by the Perinatal Diabetes Program through referral or diagnosis. Patients will be eligible for enrollment less than 29 weeks gestation. All patients will be using a cellular-enabled glucometer.

(c) Exclusion criteria: >29 weeks gestation, not on insulin therapy, non-English speaker

Vulnerable Populations

The population comprises pregnant women.

Setting

The study setting involved is Perinatal Diabetes Clinic at UIHC.

Recruitment Methods

The clinical team members of the Perinatal Diabetes Program are responsible for identifying and signing up pregnant women who are interested in using the remote glucometer for monitoring their blood glucose for the remainder of their pregnancy. This new program is a clinical quality improvement project. New pregnant outpatients with diabetes are invited to enroll in our remote glucose monitoring program if they meet specific criteria (for example, <30 weeks gesta-

tion). If a patient is interested in signing up for the remote monitor and she is less than 29 weeks pregnant, she will also be asked by a member of the research team at the same visit if she would like to participate in the incentive study. Her remote glucose monitoring and care will be absolutely the same whether she signs up for the incentive study or not. Patients will be allowed time to discuss enrollment with family and friends.

Consent Process

The research team will discuss the study with the potential subject and their family or friends, if desired, in a private room within the hospital/clinic. The potential subject would have time from the moment they approached up until 29 weeks of pregnancy to discuss with family members/friends and make a decision regarding participation. A consent form would be reviewed and signed with the patient in the room.

HIPAA Privacy Rule Authorization

The consent document contained HIPAA information.

Study Procedures

Following enrollment into the study, participants will be randomly assigned into one of three groups for associated financial incentives.

One group will receive \$25 at the time of enrollment for agreeing to participate.

A second group will receive \$0.10 cents per prescribed test, payable every month based on testing adherence. For those with type 2 diabetes, the maximum payment will be \$0.40 per day. For those with type 1 diabetes, the maximum payment will be \$0.70 per day.

A third group will have \$100 deposited into a University of Iowa Women's Health account on her behalf. The participant will then "lose" money depending on actual adherence to recommended testing

- For 95% or more adherence: the participant will not lose any deposited money.
- For 85 to 94% adherence: the participant will lose \$25.
- For 70 to 84% adherence: the participant will lose \$50.
- For less than 69% adherence: the participant will lose \$75.

Following enrollment, participants will start checking blood glucose levels as recommended by their physician team. All blood glucose levels will be reviewed at least weekly via remote monitor and adjusted as clinically indicated. This is a standard of practice for all pregnant women enrolled in remote monitor glucose monitoring.

Group 1 will receive \$25 for agreeing to participate which would be sent after enrollment. Blood glucose obtained through remote monitor system will be monitored but no additional payments, communication, or recommendations were made.

For group 2, every month, study personnel will assess frequency of testing and payment will be generated based on actual testing. In addition to receiving a cheque by mail, participants' study personnel will receive notification on their secure remote glucometer of the amount they earned by testing blood sugar.

For group 3, following delivery, as determined through Epic records, payment will be issued via cheque based on actual adherence to recommended testing using the cloud-based HIPAA portal associated with the remote glucometer.

Data Collection

We will collect baseline demographic data and maternal and neonatal outcome data from participant electronic health record. The frequency of glucose testing will be obtained from the cloud-based HIPAA portal associated with the remote glucometer.

Data Analysis Plan

Primary outcome: Primary outcome of the study is adherence to self-glucose monitoring recommendations in pregnancy.

Privacy, Confidentiality, and Data Security

All discussion of the study, enrollment, and procedures will take place in a private room within the hospital/clinic. We plan to collect only the minimal amount of data needed to answer the research questions.

Electronic records (computer files, electronic databases, etc.)—electronic data (patient blood sugars regimen adherence) will be collected from the remote monitor website. This website is available to the physicians/nurses who care for this population. We will be looking at adherence percentages and documenting this information into a password protected computer file accessible only to members of the research team. Personal identifiers will not be entered into this database. A study ID will be assigned to the participant at the time of randomization. This information will be used to determine the financial compensation to the subjects.

Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) records will be transported in a manner that no identifiable information is visible. Hard copy records will be kept in a locked office of a member of the research team and accessible only to members of the research team.

Risks and Benefits

Risks to participants: No foreseeable physical risks to participation in this study since it simply uses clinical data already collected as part of clinical care.

There may be a risk of disappointment related to not meeting goals for reimbursement.

Potential benefit to participants: No direct benefits to patients.

Costs to Participants

None.

Compensation to Participants

Group 1 subjects or control group (those agreeing to participate by using their meter and testing) will have a voucher submitted for \$25 at the time of enrollment.

Group 2 subjects or positive incentive group will receive \$0.10 cents per test, payable every month based on adherence (\$0.40 per day max for type 2 diabetics and \$0.80 per day maximum for type 1 diabetics).

Group 3 subjects or loss aversion group will have \$100 deposited into their U of I Women's Health account. Each subject will then "lose" money depending on actual adherence. Payment voucher will be submitted after delivery.

For those who chose to withdraw from the study early, the following payments will be made:

Those in control group will keep \$25 given at the time of enrollment.

Group 2 will keep payment based on glucose collected at the time of withdrawal.

Group 3 will receive \$25 at the time of withdrawal.

Cheques will be provided via Accounting Services using the e-Voucher system.

Informed Consent Document

Project Title: Incentive Models of Glucose Testing Adherence for Pregnant Woman with Diabetes

Principal Investigator: Janet Andrews MD.

Research Team Contact: Diedre Fleener RN, BSN (319) 356-2913.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

What Is the Purpose of This Study?

This is a research study. We are inviting you to participate in this research study because you are pregnant and you take insulin to treat your diabetes.

The purpose of this research study is to find new ways to motivate pregnant women to check their blood glucose consistently during pregnancy. Normal glucose levels are important for your health and your baby's health. In this study you will be asked to use a cellular-enabled glucose meter to test your glucose levels and communicate with your provider. It is very important that you check your glucose as directed, so your provider can make adjustment to your insulin as necessary. We plan to learn whether giving women an additional incentive for testing their glucose levels improves the frequency of glucose testing and thereby improve glucose control throughout pregnancy.

How Many People Will Participate?

Approximately 130 people will take part in this study conducted by investigators at the University of Iowa.

How Long Will I Be in This Study?

If you agree to take part in this study, your involvement will last for the remainder of your pregnancy. However, you will not have additional visits as part of this research study. Your medical record will be accessed during this study. We will only be looking at health information related to your pregnancy and up to 6 weeks after your delivery.

What Will Happen during This Study?

After enrollment in the study, you will be randomly assigned to one of three groups. This means that the group you will be placed in will be determined purely by chance like flipping a coin. The groups are listed below. You will have a one out of three chance of being in any group.

If you are in Group 1, you will receive \$25 for agreeing to participate.

If you are in Group 2, you will receive \$0.10 or 10 cents for each prescribed blood glucose test you take.

You will be paid every month.

Group 3 will have \$100 deposited into a University of Iowa Women's Health account.

You will then "lose" money depending on how many times you fail to test your glucose as recommended.

- For 95% or more adherence: you will not lose any deposited money.
- For only 85 to 94% adherence: you will lose \$25.
- For 70 to 84% adherence: you will lose \$50.
- For 69% adherence or less: you will lose \$75.

You will be paid after you deliver your baby.

We will follow your blood glucose levels weekly using the Telcare meter. Depending on which group you are in, you

may get messages from us about your use of the Telcare meter. We will also use the electronic medical record to assess your hemoglobin A1C (a measure of glucose control over the past 3 months), and we will follow outcomes including gestational age at delivery, baby's weight, route of delivery, complications at birth, and number of days that you or your baby are hospitalized. We will also look at information from diabetes surveys that you take in clinic as a part of your routine diabetes care.

What Are the Risks of This Study?

You may experience a risk from being in this study. In addition to this, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

There are no foreseeable physical risks to participating in this study. You may suffer disappointment if you do not meet goals for reimbursement.

What Are the Benefits of This Study?

We do not know whether you will benefit from this study.

However, we hope that, in the future, other people might benefit from this study because it will help us understand how to motivate others to participate in their diabetes care and thus improve outcomes for mothers and their infants.

Will It Cost Me Anything to Be in This Study?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

Will I Be Paid for Participating?

You will be paid for being in this research study. If you are in Group #3, you will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your SSN for this purpose. You may also need to provide your address if a cheque will be mailed to you. Your SSN is obtained for payment purposes only, it will not be retained for research purposes.

Your possible compensation will depend on which of the three groups you are randomly assigned to.

Group 1 will have a \$25 payment voucher submitted at the time of enrollment for agreeing to participate. You should receive this payment within 2 weeks of enrolling.

Group 2 will receive \$0.10 or 10 cents per prescribed test, payable every month based on testing adherence.

If you have type 2 diabetes, your maximum payment will be \$0.40 per day or \$12.40 every month.

If you have type 1 diabetes, the maximum payment will be \$0.80 per day or \$24.80 every month.

Group 3 will have \$100 deposited into a University of Iowa Women's Health account.

You will then "lose" money depending on how many times you fail to test your glucose as recommended.

For 95% or more adherence: you will not lose any deposited money.

For only 85 to 94% adherence: you will lose \$25.

For 70 to 84% adherence: you will lose \$50.

For 69% adherence or less: you will lose \$75.

Your payment voucher will be submitted after you deliver. If you choose to withdraw prior to the completion of the study:

Participants in group 1 will keep \$25 given at the time of enrollment.

Participants group 2 will keep payment based on blood glucose collected at the time of withdrawal.

Participants in group 3 will get \$25 at the time of withdrawal, regardless of your adherence prior to withdrawal.

Who Is Funding This Study?

This study is funded by the University of Iowa Hospitals and Clinics.

What about Confidentiality?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies.
- Auditing departments of the University of Iowa, and
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies).

To help protect your confidentiality, we will keep all data in a secure and locked space, accessible only to those on the research team. Additionally, all medical records will be de-identified. If we write a report or article about this study or share the study dataset with others, we will do so in such a way that you cannot be directly identified.

Will My Health Information Be Used during This Study?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for the purpose of this research study. Protected health information is information that personally identifies you and relates to your past,

present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for the purpose of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for the purpose of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to *Janet Andrews, MD, University of Iowa, 200 Hawkins Drive, Iowa City, IA 52242*. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

Is Being in This Study Voluntary?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you would not be penalized or lose any benefits for which you otherwise qualify.

What If I Decide to Drop Out of the Study?

Leaving the study early may cause you to experience the following harms or discomforts: none.

If you decide to leave the study early, we will ask you to notify us in writing.

What If I Have Questions?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Diedre Fleener 356-2913 or Janet Andrews at 353-7496.

If you have questions, concerns, or complaints about your rights as a research subject or about research-related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office website, <http://hso.research.uiowa.edu/>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

| | | |
|-----------|------|------------|
| Subject's | Name | (printed): |
|-----------|------|------------|

Do not sign this form if today's date is on or after \$STAMP_EXP_DT.

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent) (Date)

Funding

This work was funded internally through the perinatal diabetes program at the University of Iowa Hospitals and Clinics.

Conflict of Interest

None declared.

References

- 1 American Diabetes Association. (12) Management of diabetes in pregnancy. *Diabetes Care* 2015;38(suppl):S77-S79
- 2 Carolan M, Gill GK, Steele C. Women's experiences of factors that facilitate or inhibit gestational diabetes self-management. *BMC Pregnancy Childbirth* 2012;12:99
- 3 Kendrick JM, Wilson C, Elder RF, Smith CS. Reliability of reporting of self-monitoring of blood glucose in pregnant women. *J Obstet Gynecol Neonatal Nurs* 2005;34(03):329-334
- 4 Petry NM, Cengiz E, Wagner JA, Weyman K, Tichy E, Tamborlane WV. Testing for rewards: a pilot study to improve type 1 diabetes management in adolescents. *Diabetes Care* 2015;38(10):1952-1954
- 5 Long JA, Jahnle EC, Richardson DM, Loewenstein G, Volpp KG. Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial. *Ann Intern Med* 2012;156(06):416-424
- 6 Petry NM, Rash CJ, Byrne S, Ashraf S, White WB. Financial reinforcers for improving medication adherence: findings from a meta-analysis. *Am J Med* 2012;125(09):888-896
- 7 Sen AP, Sewell TB, Riley EB, et al. Financial incentives for home-based health monitoring: a randomized controlled trial. *J Gen Intern Med* 2014;29(05):770-777
- 8 Halpern SD, French B, Small DS, et al. Randomized trial of four financial-incentive programs for smoking cessation. *N Engl J Med* 2015;372(22):2108-2117