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Integration of Blood Glucose Monitoring into Electronic Health Records

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Sponsor:

Site of Investigation: Inova Health Systems Primary Care (MyChart)

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1. Introduction

1.1 Specific Aims

This study aims to test methods of increasing adoption and integration of blood glucose monitoring into electronic medical records, and to measure the impact of widescale adoption on health status of patients with diabetes. To investigate determinants of adoption, the research will combine and test doctor and patient focused approaches to encouraging patient use of blood glucose flow sheets through the online patient portal, MyChart. Adoption will be measured on both the extensive and intensive margin: the number of patients who enter data into the flowsheets at all during the study period, and the mean number of entries per patient during the study period. Conditional on statistically significant increases in adoption, the study will examine corresponding intent-to-treat effects on patient health, and consider possible mechanisms through which health indicators improve or do not improve.

1.2 Hypotheses

1.2.1 Interfacing with primary care practices to encourage physicians to implement default online orders of blood glucose flowsheets and informational messaging for all patients with diabetes will increase patient adoption (as defined above).

1.2.2. Additional reminder messaging to patients that (1) emphasizes the value of tracking blood glucose data to the patient OR (2) emphasize the value of tracking blood glucose data to the doctor OR (3) informs patient of their selection for a chance to receive an award conditional on tracking will increase adoption relative to no reminder messaging.

1.2.3 Promotion of adoption of electronic blood glucose tracking through the means described above will result in the following intent-to-treat effects:

(a) reduction in patient A1c
(b) increases in frequency of doctor-patient interaction
(c) changes to treatment plan path

1.2.4 Reminder messaging treatments that induce more intensive use of flowsheets will lead patients to experience larger effects as described in 1.2.3.

1.2.5 Entries of blood glucose data will be predictive of A1c on average and will lower over the study period.

1.3 Background and Significance

The percentage of the US population with diagnosed diabetes increased from 4% to over 7% from 1999 to 2014 (CDC 2016), with nearly $1 in $5 of health care dollars spent caring for people with diabetes (ADA 2013). There is substantial evidence that improved average blood sugar control (as measured by

A1c levels) is associated with significant decreases in the probability of complications from diabetes (ADA 2016). Commercially insured patients with type II diabetes who lower their A1c, blood pressure and lipid levels, experience significant reductions in total medical costs (Fitch et al 2013). Recent research also suggests that reduction in blood glucose variability is associated with reduced risk of complications and mortality independently of average blood glucose/A1c (Cavalot et al. 2006) (Sorkin et al. 2005).

For patients who are insulin-dependent, self monitoring of blood glucose (SMBG) is a critical aspect of disease management and regulation of blood glucose levels and variability. A landmark randomized controlled trial comparing intensive insulin therapy guided by frequent blood glucose monitoring to conventional insulin treatment. Intensive therapy delayed the onset and slowed the progression of diabetic retinopathy, nephropathy and neuropathy in patients with IDDM (Diabetes Control and Complications Trial Research Group 1993).

However, for non-insulin dependent type 2 diabetics, there has been some debate over the value of self tracking. The ASIA randomized controlled trial of 689 patients over a period of 24 weeks found that patients assigned to perform 6 SMGB measurements per week had a statistically significant 0.3 reduction in A1c (ITT) after 6 months (Guerci et al 2001). However, the DiGem randomized trial found that SMGB without additional training had no effect on A1c after 1 year (Simon et al 2008). A Cochrane meta-analysis of 12 randomized controlled trials evaluating SMBG found a statistically significant mean reductions in A1c of 0.3 for studies with 6 month follow-up (effect sizes in individual studies ranged from .07 to .69), but no statistically significant change in A1c for studies with a 12 month follow up (Malanda et al 2012). However, the review was criticized for including few studies with 12 month follow-up (two, one of which had only 22 subjects). A more recent meta-study was updated to include the latest RCTs, finding a somewhat larger statistically significant reduction in A1c at 6 month follow-up (-.36), and a statistically significant reduction in A1c at 12 month follow-up (-.28) (Zhu et al 2016).

Potential sources of variation in effects of SMBG on A1c for insulin-naive patients across these studies include the characteristics of the patient population, differences in involvement of physicians and training/education provided to patients, as well as heterogeneity in adherence by patients. Much larger effects were found for newly diagnosed patients in comparison to those with a diagnosis greater than 1 year (-0.54 vs -.28 change in A1c). Some of the studies finding no effect of SMBG included mostly patient populations with already well-controlled A1c. Both meta-studies pooled interventions with different levels of guidance and structure to glucose testing.

Two key factors in enhancing the effectiveness of SMBG seem to be patient adherence and physician involvement (Clark 2007). In one study, structured SMBG was compared to enhanced standard care for 483 poorly controlled insulin-naive type 2 diabetics (Polonsky 2011). Analysis revealed much larger effects for patients who adhered to the intervention (-0.5 A1c change). Additionally, patients in both the treatment and control group of this intervention were assigned to quarterly office visits, with structured SMBG patients instructed to bring their readings to consult with their physician. Availability of this data encouraged primary care physicians to treat glycemia earlier, more frequently, and more effectively. Significantly more patients assigned to structured SMBG group received recommendations for a

treatment change as compared with control subjects. These findings highlight the key role that physician engagement with SMBG data plays in its effectiveness.

Nearly all randomized controlled trials of SMBG have had patients monitor their glucose using either pen and paper or store the information on the monitoring device itself to be brought to an office visit for physician viewing. As emphasized above, physicians play an important role in interpreting blood glucose trends, but likely do not have access to this patient generated data between office visits. Though technology to electronically transmit blood glucose readings is available, it is not widely used as a standard practice of care. The TELEDIAB-1 study piloted the Diabeo system (a smartphone coupled to a website) which incorporated automated advice on the insulin doses required; and remote monitoring by teleconsultation. Use of the system improved A1c by 0.9% vs controls in patients with chronic, poorly controlled type 1 diabetes (Charpentier et al 2011). However, there are few examples of integration of such technologies into Electronic Medical Records systems in a manner that would allow for wide-scale use. One study demonstrated the feasibility of automatically sending data from continuous glucose monitors to EMR patient portals for physician viewing, but did not test the impact of this on patient outcomes (Kumar et al 2016). To our knowledge, there is no randomized trial or prior research testing the causal effects of integrating of data from patient self blood glucose monitoring into EMRs on a wide-scale.

Inova patients can track their blood glucose electronically through MyChart, allowing physicians to view their data in real time and be notified if results are out of range. More recently, functionality has been developed to connect Apple's HealthKit to MyChart, such that patients with compatible glucometers can link them to their smartphones, which can in turn be linked to MyChart to automatically transfer glucometer readings to the EHR. This update streamlines the tracking process for patients with compatible devices. Despite these capabilities however, few doctors and patients at Inova use MyChart's blood glucose flowsheets. In order for patients to use the flowsheets, their physician must place an order through the EMR, and this initial step is rarely taken.

Recent research suggests that that informational frictions are a key barrier to updating convention across medical practices (Chan 2016). Anecdotal evidence supports that many physicians at Inova are not aware of blood glucose tracking features in MyChart or how to set up tracking. This study will seek to test an intervention to inform physicians of the tracking capabilities, and give guidance for placing bulk glucose flowsheet orders for all patients with diabetes. This aspect of the intervention is intended to remove barriers to physician action, setting a default such that patients have access to the tracking feature.

However, SMBG is most effective when patients track regularly. Many of the studies discussed above show a correlation between adherence and reduction in A1c. This study will also test the effect of reminder messaging on patient use of the flowsheets. One version of messaging will emphasize physician engagement and monitoring of flowsheet entries. Previous research has shown doctor patient communication is predictive of adherence (Friedman et al 2008). Patients may feel more accountability and value to tracking if they anticipate their physicians will be looking at their results. Additionally, as part of this design, some patients will be given a chance to receive a gift card if they fill out the flowsheets, intended to provide compensation for time spent setting up and learning how to use the

tracking features. Past research in other contexts has shown higher adherence to patient driven behaviors when such compensation is provided (Roski et al 2003).

This research will address two key questions related to integration of blood glucose tracking data into EHRs in a large health system. First, effective use of this new technology requires doctors and patients to update the production process, which may be stalled by inertia or lack of knowledge about the new feature. This study will examine methods for encouraging adoption of the new technology. Additionally, it is not known how systematic, widespread use of blood glucose data by providers through an EHR will impact patient health. These questions will be addressed using a clustered randomized design to test patient and provider focused interventions which encourage uptake of blood glucose tracking through the EHR. This encouragement design will also allow for testing effects on patient health, as measured by A1c test results.

1.4 Preliminary Studies

Season Majors is the MyChart (Patient Portal) Manager at Inova Health System. In her role she is responsible for the management of the portal as well as for increasing patient engagement and use. Season has worked with the portal since 2013 and has coordinated the implementation of multiple features within the portal to allow patients to better manage their care along with their care team. Her nursing experience has helped her to better understand the needs of the patients as well as the clinical aspects of care that can be enhanced through portal usage.

Dr, Christopher Connolly is Board Certified in Internal Medicine and is currently the EPIC Certified Physician Builder for the Inova Health System- Inova Medical Group (IMG). He has served as the Clinical Informatics Chief Medical Information Officer from 2008-2016 for Medical Group and Urgent Care. He completed a Research Fellowship at New York Medical College and has been in practice for 11 years.

Dr. Mary Ann Friesen is the Nursing Research and Evidence Based Practice Coordinator for Inova and chair of the Inova Health System Nursing Research and Evidence Based Council she also serves on the Institutional Review Board. In her role she coordinates research efforts across the system and has served as Principal Investigator for various studies focused on nursing, patient- centered care, and communication. Dr. Friesen has presented at numerous professional conferences and published in various journals. Dr. Friesen is a Certified Professional in Healthcare Quality (CPHQ). In 2016 she received the Distinguished Alumni Award for George Mason University College of Health and Human Services.

Allyson Barnett is a PhD student at UC Berkeley studying health economics and current Associate Fellow with the GSA Office of Evaluation Sciences. She has extensive experience conducting data analysis on large administrative datasets as a research analyst, and designing randomized field trials. She is currently authoring another paper on the effects of health IT on preventative care, leveraging a large insurer claims database and detailed IT login data. She is also working with the Center for Medicare and Medicaid

Services to design a randomized experiment testing updated versions of a notice sent out to low income Part D beneficiaries.

Nuole Chen is a PhD student studying International Relations in the Department of Political Science at the University of Illinois at Urbana-Champaign and current Associate Fellow with the GSA Office of Evaluation Sciences.

2. Study Design and Subject Selection

2.1 Study Type

Cluster randomized encouragement design.

2.2 Setting/Location

Research will be conducted through the MyChart electronic medical records system with patients of Inova Health Systems primary care offices (27 locations). Half of the 27 primary care offices will be randomly selected to receive treatment, but outcome data (existing electronic medical records data) will be analyzed for the entire study population.

2.3 Duration of Study

Primary care practices identified in the treatment group will be encouraged to place bulk orders for electronic glucose flowsheets over a period of two weeks. Patients will be actively encouraged to use flowsheets for 12 weeks following the administration period. Outcome data will be collected for a total of 38 weeks:

(a) 12 weeks retrospective at baseline
(b) 2 week administration period
(c) 12 week implementation period
(d) 12 week follow up period

2.4 Number of Subjects

Estimated intake over study duration: 9,000 (only half selected for treatment group). ; Maximum number of subjects: 15,000.

2.5 Study Population

Non-pregnant adult patients of Inova physicians at primary care sites other than Ashburn II Primary Care, Lake Ridge Primary Care and Springfield Primary Care with a current diabetes mellitus diagnosis and active MyChart account at time of treatment administration will be included in the study. There will be no gender, age, racial or ethnic exclusions of adult patients, and study population is expected to match the

distribution of diabetic patient characteristics in Inova health system. Patients will not be formally recruited for participation in the study. The intervention involves practice-level promotion of an existing feature of Inova's MyChart: electronic blood glucose flowsheets. Promotion of this feature will not be formally mandated by the study design. All communications and interactions included in the study will take place electronically through MyChart.

Physicians will exclude from initial bulk flow sheet orders any individual patients whom they identify as having contraindications for tracking of blood glucose.

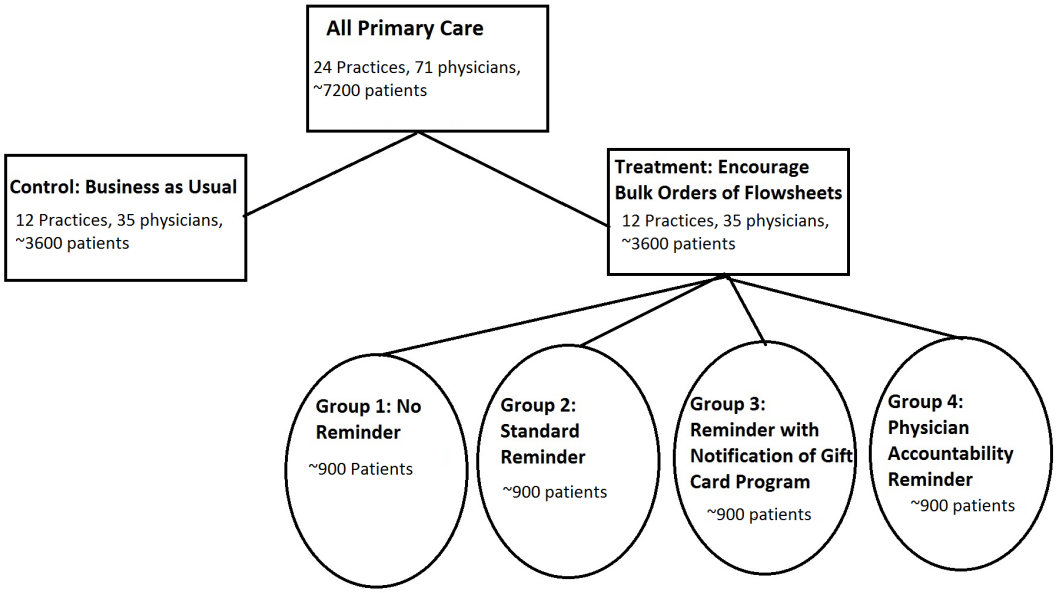
2.6 Recruitment

Patients will not be formally recruited for participation in the study. The intervention involves practice-level promotion of an existing feach of Inova's MyChart: electronic blood glucose flowsheets. Promotion of this feature does not represent a change in standard of care, and will not be formally mandated by the study design.

3. Study Methods and Procedures

3.1 Study Treatment/Intervention

The focus of the study treatment will be to encourage adoption of the blood glucose monitoring feature of MyChart by patients with diabetes and their providers. Currently, providers must place an order to allow patients to enter their blood glucose into the online system. If patients enter data, providers are then able to view these readings through the patient portal. This feature is currently available, but awareness and utilization are low. The sections describe intervention design, which will promote adoption.



3.1.1 PRACTICE LEVEL PROMOTION

Providers in the randomly selected group of treatment primary care practices will be encouraged to batch order blood glucose flowsheets for all patients with diabetes with active MyChart accounts. The research team will contact physicians and practice managers with an explanation of the initiative and instructions for completing batch orders and viewing entries through the system. The practice will be advised to complete filling orders over a two week administration period, after which the implementation period will begin. A batch order will trigger two forms of alerts sent to providers, according to the default settings for electronic glucose flowsheets:

1. A bi-weekly report received of values that the patient has entered, or a notification that the patient has not entered data during the interval.
2. A notification when patient entered values are out of range (the patient also gets a notification that their doctor will see this value) according to the following current settings:

Notification Setting	Current Default
Pre-Meal Range (entry outside range=alert)	60-180 mg/dl
Post-Meal Range	100-240 mg/dl
Nighttime Range	60-300 mg/dl

Patients will automatically be notified when the flowsheet has been ordered for them. Additionally, providers will be given text for a secure smart-text message to send to all patients receiving the flowsheets, instructing them to enter data for the study period. The secure message will also provide them with information on how to enter data, and on the benefits of tracking blood glucose. Draft text of this message is included below:

Dear [Patient],
You may have seen that there is a new electronic form available for you to enter your blood glucose results in the MyChart portal. Keeping track of your blood glucose can help you manage your diabetes and reduce your chances for developing complications like heart disease, kidney damage and eye damage. As part of a new Inova program to help patients with diabetes get healthy, I would like you to try entering the results of your home blood glucose tests on MyChart for the next 3 months, through [Date]. Please let me know if you have any questions.
Sincerely,
[Practitioner]

<u>WHAT TO DO NEXT</u>

*1. **Get help**: If you need help learning how to measure your blood glucose or getting testing supplies, you can contact [Practice Contact].*

*2. **Learn how:** See [insert link to instructions/screenshots] to learn how to use the electronic blood glucose flowsheets on MyChart*
*3. **Link your devices**: You don't need to have special equipment to use the flowsheets, but if you have an Apple/iOS device and compatible glucometer, you can set up automatic data transfer. This will pull the results of your glucose tests into MyChart automatically, making it even easier to track. See [insert link to instructions] for help setting this up, and for a list of compatible devices.*
*4. **Track your blood glucose**: For the next 3 months, try to enter at least 6 measurements total per week, spread out over a few different days. However, don't be discouraged if you miss a day-- even tracking occasionally could be beneficial to your health.*

Note: If you've never tested your blood glucose before, get in touch with [Practice Contact] to make sure you have all the materials and instructions you need, and to confirm that testing is right for you. Patients who think they might be pregnant should also be sure to talk to a physician before starting any new tracking regime.

3.1.2 INDIVIDUAL LEVEL REMINDERS

After the initial two-week roll-out/administration period, follow-up emails will be sent out by the research team to patients at treatment practices whose doctors have placed blood glucose flowsheet orders. Patients will be assigned at the individual level to one of four reminder treatment conditions, which will be administered by the research team. The number of reminder conditions may be reduced (to 2 or 3 instead of 4) depending on the rate of flowsheet orders by physicians to preserve statistical power. Assignment to any of these treatments will not preclude or provide guidelines for other communication between providers and patients (e.g. providers are free to send out their own reminders or messaging regardless of patient assignment to treatment group). The four reminder treatment conditions are described below:

(1) **No additional reminders from research group**

(2) **Standard secure message reminder, addressed from Inova Medical Group, sent every two weeks during 12 week implementation period. Draft text below:**

Dear [Patient],
Don't forget to track your blood glucose through MyChart! Keeping track of your blood glucose can help you manage your diabetes and reduce your chances for developing complications like heart disease, kidney damage and eye damage.
Sincerely,
Inova Medical Group

(3) **Secure message reminder with chance to receive gift card, addressed from Inova, sent every two weeks during 12 week implementation period. Draft text below:**
Dear [Patient],
You have been chosen for a special program to help you get started tracking your blood glucose through MyChart. For each day that you track your blood glucose on MyChart through [DATE], you will be

entered to receive one of fifty $50 gift cards to Amazon. You'll be sent a secure message through MyChart after [DATE] if you've been selected to receive a gift card. Keeping track of your blood glucose can help you manage your diabetes and reduce your chances for developing complications like heart disease, kidney damage and eye damage.
Sincerely,
Inova Medical Group

(4) **Secure message reminder, addressed from primary care doctor, sent every two weeks during 12 week implementation period. Draft text below:**
Dear [Patient],
Don't forget to track your blood glucose through MyChart! Viewing your results helps me to respond if they are out of range, and improve your diabetes treatment to help you stay healthy. We will talk about your results at your next office visit. Keeping track of your blood glucose can help you manage your diabetes and reduce your chances for developing complications like heart disease, kidney damage and eye damage.
Sincerely,
[Practitioner]

3.2 Control Group

The control group will be randomly selected half of the 27 primary care practices, and will receive no encouragement of adoption. However, this group will not be explicitly discouraged from making flowsheet orders.

3.3 Randomization

Provider-side treatments will be cluster randomized at the practice level. Randomization will stratify across practices by number of diabetic patients (cluster size), and will be conducted using a random number generator at the outset of the study. Reminder messaging treatments will be assigned alphabetically by first two letters of patient last name, as it is logistically infeasible to do individual level patient messaging without sorting on an existing field in the patient's EHR . There are some concerns that ethnicity could correlate with assignment based on last name spelling, so this form of assignment is "pseudo-random". However, the patient's race/ethnicity recorded in the medical record will be controlled for in the analysis. Causal interpretation of the results of the reminder messaging portion of the experiment will thus require the assumption that grouped last name spelling is not independently related to likelihood of flowsheet adoption.

3.4 Endpoints/Outcomes Measurements

Hypothesis: Interfacing with primary care practices to encourage physicians to implement default online orders of blood glucose flowsheets and informational messaging for all patients with diabetes will increase patient adoption.

Outcome Measures: Comparison of individuals between treatment and control practices-- (a) fraction of patients entering blood glucose measurements into MyChart flowsheets during implementation period & follow-up period (dichotomous), (b) mean number of flowsheet entries during implementation period and follow-up period (c) fraction of patients for whom order is placed by doctor

Hypothesis: Additional reminder messaging to patients that (1) emphasizes the value of tracking blood glucose data to the patient OR (2) emphasize the value of tracking blood glucose data to the doctor OR (3) informs patient of their selection for a chance to receive an award conditional on tracking will increase adoption relative to no reminder messaging.
Outcome Measure: Comparison of individuals across reminder messaging assignment groups (within treatment practices)-- (a) fraction of patients entering blood glucose measurements into MyChart flowsheets during implementation period & follow-up period (dichotomous), (b) mean number of flowsheet entries during implementation period and follow-up period

Hypothesis: Promotion of adoption of electronic blood glucose tracking through the means described above will result in the following intent-to-treat effects:

(a) reduction in patient A1c

Outcome Measures: Intent to treat comparison of individuals between treatment and control practices of the following measures at the end of the intervention period and follow-up period: (1) Mean A1c (2) Quartiles of A1c using quantile regression analysis (3) fraction of patients experiencing improvement [reduction] in A1c from baseline (dichotomous) (4) fraction of patients below benchmark 7.0% A1c (dichotomous)

(b) increase in frequency of doctor-patient interaction

Outcome Measures: Intent to treat comparison of individuals between treatment and control practices of the following measures during the intervention period and follow-up period: (1) number of securing messaging (2) number of phone interactions, and (3) number of in-office appointments

(c) changes to treatment plan path

Outcome Measure: Intent to treat comparison of individuals between treatment and control practices of number of alterations to patient prescriptions/medication list during the intervention period and follow-up period

Hypothesis: Reminder messaging treatments that induce more intensive use of flowsheets will lead patients to experience larger effects as described above.

Outcome Measure: Intent to treat and treatment on the treated comparison of individuals across reminder messaging assignment groups (within treatment practices)-- reduction in A1c, increase in frequency of doctor-patient interactions, changes to treatment plan path (outcomes as described above in a-c)

Hypothesis: Entries of blood glucose data will be predictive of A1c and will lower over the study period.

Outcome Measure: Descriptive analysis of flowsheet entry values in the treatment group during the implementation and follow-up period.

3.5 Consent

A waiver of informed consent and waiver of HIPAA authorization is requested. The study is an encouragement design aiming to increase uptake of an existing service (electronic flowsheets) provided through Inova's MyChart electronic medical record system, and will not change standards of care. Patients and providers in both the treatment and control groups will have access to electronic flowsheets throughout the study unchanged from baseline. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Research could not practicably be conducted without a waiver of consent and HIPAA authorization due to the number of subjects, online nature of the experiment, and design of the study which will seek to examine outcomes for the identified population regardless of actual use of electronic flowsheets. Outcomes of the research could not practicably be studied without access to and use of protected health information. See sections on Data Storage, Risks and Confidentiality for more details.

3.6 Monitoring Subjects and Criteria for Withdrawal

Not applicable-- nature of encouragement design means that the intervention is discrete administration.

4. Statistical Considerations/Data Analysis

4.1 Sample Size

Non-pregnant adult patients of Inova primary care physicians with a current diabetes mellitus diagnosis and active MyChart account at time of treatment administration will be included in the study. The estimated number of patients is around 7200, from 71 primary care physicians across 24 selected Inova primary care practices.

Power Calculations

Power calculations were performed using the "clustersampsi" command in Stata. Knowledge of available sample and estimates/assumptions of control outcome mean, variance, and intracluster correlation were used to calculate a minimum detectable effect size for the key outcomes of flowsheet adoption (extensive margin, dichotomous rate of adoption) and changes in mean A1c.

Flowsheet Adoption: Practice Level Treatment-Control Comparison
Sample Size: 7200
Number of Treatment Arms: 2
Number of Clusters: 24
Assumed Control Adoption Rate: 2%
Assumed Intra-Cluster Correlation (within practices): 0.1
Minimum Detectable Effect: **9.5 percentage point increase in flowsheet orders**

Mean HbA1c: Practice Level Treatment Control Comparison

Sample Size: 7200
Number of Treatment Arms: 2
Number of Clusters: 24
Assumed Control HbA1c Mean: 6.74
Assumed Control HbA1c Standard Deviation: 1.39
Assumed Intra-Cluster Correlation (within practices): 0.07
Assumed Baseline Correlation: 0.80
ITT Minimum Detectable Effect: **0.27 change in A1c**

Flowsheet Adoption: Individual Level Comparison between Messaging Assignment Groups in Treatment Practices
Sample Size: 3600
Number of Arms (including no reminder): 4
Assumed No Reminder Adoption Rate: 20%
Minimum Detectable Effect: **5.5 percentage point increase in use of flowsheets when compared to no reminder**

Justification
The sample size represents the entire population of Inova primary care patients with diabetes who have active MyChart accounts and are therefore able to access the blood glucose tracking feature. The minimum detectable effects resulting from power calculations above are in-line with similar studies cited in the protocol background. Metastudy reviews of the effect of self monitoring of blood glucose found a 0.33 point change in A1c.

4.2 Method of Data Analysis

All data analyzed in this study will be administrative health and use data that is collected as part of routine medical care and record keeping. EPIC has offered to build the SQL queries required to produce the outcome datasets described in this protocol. Outcomes listed in Section 3.4. will be analyzed using regression analysis, including (a) a version with no covariates, (b) a version controlling for patient age/gender, race/ethnicity, A1c at baseline, days since most recent office visit at baseline, and doctor fixed effects. A flag identifying patients who are eventual participants of "Impact of Innovative Interventions on Diabetic Adherence with Digital Sensors" (a study recently submitted to the IRB that may have limited overlap with this population) will also be included in the controls. For outcomes indicating analysis of practice level treatment and control groups, standard errors will be clustered at the practice level.

4.3 Data Storage

All data will be stored on Inova systems, and authorized collaborating researchers and personnel will access the data remotely through Citrix. A data use agreement (draft attached) will be entered into by Inova and the General Services Administration, and specified personnel from GSA will be authorized to

access the limited dataset and perform data analysis. The limited dataset accessed through Citrix will be have facial identifiers removed in accordance with the HIPAA definition of limited dataset and personnel authorized to access will agree to (i) not use or disclose the information other than as permitted by the DUA or as otherwise required by law; (ii) use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the DUA; (iii) report to Inova any use or disclosure of the information not provided for by the DUA of which the recipient becomes aware; and (iv) not to identify the information or contact the individual. Data will be fully anonymized and linkages to identifying information will be permanently destroyed three (3) years after the conclusion of the study.

5. Human Subjects Protections

5.1 Risks

The risks to participation in this study are minimal. The randomized encouragement design means that doctors will make the final determination of whether use of electronic blood glucose flow sheets is suitable for the patient. The study does not advise against or preclude the provider or patient from switching to alternative methods for self monitoring of blood glucose, or using other forms of treatment concurrently. Previous research has shown positive health effects of self monitoring of blood glucose, and it is a recommended treatment for diabetes. However, one low risk area is potential loss of privacy. The risk will be minimized by implementing an adequate plan to protect the identifiers from improper use and disclosure: a limited dataset will be created and made available to authorized researchers via remote access on Citrix. Data will be fully anonymized and linkages to identifying information will be permanently destroyed three (3) years after the conclusion of the study. Protected health information will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research project.

5.2 Benefits

The intervention seeks to test methods for increasing utilization of an existing feature of the MyChart EHR system. Lessons from this aspect of the study may be applied to increase awareness and utilization of other new EHR features, potentially benefiting patients and doctors indirectly.

Patients who decide to track their blood sugar through MyChart as a results of the intervention may experience increased ability to control and manage their diabetes. Because providers will be able to view and interpret blood glucose data more easily and frequently, they may be more likely to adjust and tailor treatment plans to this information. Both of these factors may lead to improved patient health indicators (specifically A1c).

5.3 Alternatives

Not applicable.

5.4 Confidentiality

To minimize the risk of loss of confidentiality, the research team will implement a plan to protect the identifiers from improper use and disclosure: a limited dataset will be created and made available only to to authorized researchers via secure remote access to Inova systems on Citrix. Data will be fully anonymized and linkages to identifying information will be permanently destroyed three (3) years after the conclusion of the study. Protected health information will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research project.

6. Subject Compensation

6.1 Costs

There are no direct costs to participants. Indirect costs to patients may include inconvenience of receiving additional secure messages. Due to encouragement of flowsheet orders by physicians in the treatment group, patients choosing not to follow their doctor's recommendation of electronic glucose tracking may feel guilt, and patients choosing to complete the online flowsheets will need to spend additional time entering their values. Amount of time spent will depend on whether they set up an automatic download of electronic readings through their smartphone, or manually enter the values via an internet-connected device. If patients choose to start tracking their blood glucose and have not already been doing so, they may face additional supply costs.

6.2 Payment

There will be no payment for participation. A subset of participants in the treatment group--one quarter of patients with diabetes in 10 randomly selected practices--will have the chance to receive one of 50 $50 gift card to Amazon.com if they choose to enter data into the flowsheet for any day during the study period (chance will be increasing in the number of days flowsheet is used). This gift card is intended as compensation to offset hassle costs of entering data into the flowsheet, and not as an incentive to participate in the study. Study personnel will follow guidelines from section 11.10 of IRC on the distribution of gift cards.

The code for online redemption of the gift card will be sent to selected recipients who remain MyChart activated at the time of distribution in a secure message through MyChart. The subject line will read Gift Card Recipient: MyChart Glucose Tracking Program. Patient replies will be disabled for this communication. We will track read-receipts after one month, but will not re-send messages or take any action based on this information. The message will read as follows:

We're pleased to let you know that you were selected to receive a $50 gift card to Amazon.com!
You were chosen for a special program through Inova to help you get started tracking your blood glucose through MyChart. For each day that you tracked your blood glucose on MyChart between May and August 2018, you were entered to receive one of fifty gift cards. You tracked, and one of your entries was randomly selected! To redeem your gift card, visit https://www.amazon.com/gc/redeem and enter [code].

7. Adverse Event Reporting

Risks from participation in this study are minimal, but one possible adverse event is breach of confidentiality. Adverse events will be reported in accordance with IRC 11.16.

8. Funding

Key Personnel Allyson Barnett has received a small J-PAL North America HCDI Project Development grant (less that $5000) to cover gift cards, and personal travel costs. The grant will be administered directly to Allyson and will not pass through the Inova grant office.

9. Conflicts of Interest

None.

10. Facilities and Equipment

Data analysis will be conducted through remote access to Inova Citrix systems. The intervention will be administered primarily through through MyChart, and will not require any additional equipment or facilities.

11. Outside Collaborators

General Services Administration, Office of Evaluation Sciences: Key Personnel will conduct data analysis for the study, see attached DUA
Department of Health and Human Services, Office of the National Coordinator for Health Information Technology: Will not have access to data or serve as investigators on the study, but is coordinating with OES to incorporate results into guidelines and informational materials
Ben Handel, UC Berkeley: Will not have access to data. Academic advising of key personnel.

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13. Appendix

Documents to be included:

- Pre-review checklist
- Collaborator agreements
- Data Use Agreement
- Financial Disclosure From
- IIA with Berkeley IRB
- Department Impact Form
- Department Facility Signature Form