Official Title:	Effect of Continuous Glucose Monitoring Following Hospital Discharge of Patients With Type 2 Diabetes
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SPECIFIC AIMS

Diabetes is present in at least 25% of hospitalized patients and is associated with a myriad of adverse outcomes, including longer length of stay, higher mortality, and increased costs.[1] Hospitalization provides an opportunity to intervene with strategies to improve glycemic control within the context of a patient centered approach, as whether or not the admission is directly a result of diabetes, patients may perceive an association and be motivated to address it. However, substantial barriers exist to achieving that end after discharge, including the use of complex medication regimens (which typically include insulin) [2] and need for glucose self-monitoring. Other obstacles that are common among hospitalized patients include comorbid physical and mental health conditions and disparities in social determinants of health.[3,4,5] While a multi-modal approach is critical,[6] the lack of glucose monitoring data is one of the most glaring rate limiting steps, often limited by discomfort, inconvenience, or costs. Even when patients are performing self-care behaviors regularly, there is limited capacity to communicate data to health care providers and receive feedback in a timely manner.[7] The typical patient driven strategy relies upon high levels of patient engagement as opposed to a coordinated approach that can efficiently assess glucose levels at a population level.[8] To date, most population health strategies are centered on A1c, but A1c often does not directly inform treatment decisions, particularly in insulin-requiring patients.[9] In addition, a shorter time interval than that afforded by A1c is needed to assess glucose control post-discharge, as changes in medication, oral intake, physical activity, and illness related factors can result in significant changes in glucose levels and insulin requirements.[10,11]

Recent advances in continuous glucose monitoring (CGM) technology including greater accuracy, longer wear time, and no need for calibration, have led to an increase in use.[12] Randomized controlled trials of modern devices demonstrate improvement in A1c, time target range, hypoglycemia and patient reported outcomes in persons with type 2 diabetes (T2D).[13,14,15] Moreover, real-world evidence demonstrates a reduction in A1c, diabetes distress, and hypoglycemia, and high ease of use.[16] Other real world evidence found an association between near-continuous CGM and reduced hospitalizations and acute diabetes complications.[17,18] Among older adults, treatment satisfaction and use was high, and associated with improvement in glucose control.[19,20] However CGM is underutilized for most patients with T2D due to a variety of factors, including costs and coverage issues, time constraints imposed by implementation and use, and complexity of obtaining and interpreting data.[12,21] In addition, there limited studies addressing optimal strategies for implementation in busy clinics. In this study we evaluate a remote CGM program utilizing Dexcom G6 CGM for recently hospitalized patients with T2D.

Aim 1: Determine the efficacy of CGM following hospital discharge among patients with T2D. We will record change in glucose metrics from discharge to 12 weeks follow-up, including % time in range 70-180 mg/dl (TIR), % time below 70 mg/dl, 54 mg/dl, and above 180 mg/dl (TAR), severe (level 3) hypoglycemic events, mean glucose, coefficient of variation, and A1c. **We will assess the primary objective by testing the relationship between CGM use (including prior inpatient use) and either change in glucose metrics or individualized % of TIR**.

Aim 2: Evaluate the utility of CGM use and impact of remote monitoring dashboard among. recently hospitalized patients with T2D. A dashboard will identify patients not meeting personalized % TIR, triggering customized reports and decision support to be communicated to the patient and the usual diabetes provider. We will assess the proportion of patients with successfully transmitted data as well as change in insulin dose. A survey to the usual diabetes provider will assess usability of reports and decision support.

Aim 3: Evaluate patient reported outcomes among patients with T2D using CGM following hospital discharge. Outcomes will include treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire, Benefits of CGM/Burdens of CGM), self-management and psychosocial measures (Diabetes Distress Scale). We will assess whether % CGM wear time, prior inpatient use of CGM, or change in glucose metrics are associated with patient reported outcomes.

Exploratory Aim 1: Assess whether CGM wear time or glucose control is associated with readmission and outpatient visits.

Exploratory Aim 2: Assess whether participants maintain use of CGM and glucose metrics up to 6 months of use following discharge.

SIGNIFICANCE

Diabetes is present in at least 25% of hospitalized patients and is associated with increased costs and hospital readmission.[22] While diabetes is not usually the primary reason for admission, the hospital setting offers an opportunity to identify vulnerable populations and implement interventions to improve diabetes care after discharge. In fact, despite the availability of a growing number of diabetes therapies and technologies, the proportion of patients achieving personalized A1c targets has not changed in the past decade.[23] Moreover, there are considerable disparities across demographic and socioeconomic groups.[23,24]

Unfortunately, effective hospital discharge programs for patients with diabetes are understudied.[25,26,27] In a Society of Hospital Medicine Survey, only one fourth of hospitals were supported with written protocols to standardize medication, education, equipment, and follow-up instructions for hospitalized patients with diabetes.[28] During hospitalization, expert guidelines generally recommend discontinuation of pre-admission therapies in favor of an insulin regimen that contains basal, prandial, and correction components.[29,30] In addition, patients receiving insulin prior to admission often undergo an adjustment in dose due to changes in oral intake or illness related factors, and the type of insulin may differ due to restrictions in hospital formularies. In patients on noninsulin based regimens who are not achieving glycemic goals, intensification to insulin therapy at discharge may be required. These changes in therapy that occur during hospitalization can magnify treatment gaps in the transition from hospital to home. In particular, patients who are initiating or intensifying insulin therapy have the most to benefit in terms of glycemic control.[5,31]

Patients with diabetes are particularly vulnerable to transitions of care for a variety of reasons, including high complexity of therapy, differences in dosing and administration in the hospital compared to home, inconsistent or inadequate education in the hospital setting, differences in patient and provider expectations, and insufficient resources and access to post-discharge care.[32,33] Disruption of insulin therapy following hospitalization is associated with higher A1c, shorter survival, and increased readmissions and medical costs.[34] Thus, effective discharge programs play an important role in diabetes outcomes.

Outpatient care has shifted toward population based or value based care models, in which patients at highest risk receive greater intensity of care.[35] High risk patients include those who have been recently hospitalized or who have an elevated A1c, and both criteria align with incentives for reimbursement. Most electronic medical records (EMR)s provide a dashboard for tracking A1c. However, A1c is often not actionable for a variety of reasons, including recent changes in therapy that are not reflected by A1c, and conditions such as anemia that affect the accuracy of A1c measurement.[9] In insulin-requiring patients, A1c as a measure of mean glucose does not reflect the within day or between day variations in glucose levels. Thus, self-monitored blood glucose (SMBG) data are needed to inform adjustments in therapy. Unfortunately SMBG is often not performed at an optimal frequency to be able to appreciate glucose patterns,[36] SMBG cannot warn patients of actual or impending hyperglycemia or hypoglycemia,[37,38] and there is not an efficient method for communicating data to healthcare providers.[39] Therefore additional strategies are needed to optimize population health approaches while at the same time emphasizing a patient centered approach.[40]

INNOVATION

Unlike A1c or even SMBG, continuous glucose monitoring (CGM) facilitates the identification of daily glucose patterns which can directly inform treatment decisions or lifestyle changes. CGM also improves the recognition of hyperglycemia and hypoglycemia. However, CGM is not widely available, even in patients who qualify based upon professional society guidelines,[41,42,43] in part due to stringent criteria set forth by payers, but also due to the need to be attached to a device, skin allergies, difficulty with adhesion, concerns about accuracy and need for patient training.[44] Moreover the sheer amount of data to be processed can be overwhelming for patients and prescribers, and there are challenges posed by the amount of time and effort required to transmit and interpret CGM data.[45]

Recently studies have demonstrated the role of a multidisciplinary virtual diabetes specialty clinic (including an escalation protocol involving health coaches, certified educators, and board certified endocrinologist) to facilitate selective CGM use and increase access to specialty services and was associated with an improvement in A1c and patient satisfaction.[46,47] However, this requires integration of workflow and personnel that are external to the primary team and health systems. The Dexcom MOBILE clinical trial assessed whether persons with T2D requiring basal but not prandial insulin who are randomized to CGM improved glucose

control (including A1c, TIR, hypoglycemia) compared to SMBG, and overall high treatment satisfaction.[15] This trial is using a pragmatic design in which the endocrinologist role is advisory to the primary care team. However, there are few data demonstrating the utility of CGM implementation in more heterogeneous populations, and no data demonstrating effective use in patients who have been recently hospitalized, a particularly vulnerable subgroup. In this study, we will implement a remote CGM monitoring strategy in recently hospitalized insulin-requiring patients with T2D. **It is hypothesized that implementation of remote glucose monitoring utilizing automated data sharing, a remote dashboard individualized patient time in range metrics, and study guided device set-up and decision support would facilitate ongoing patient engagement with the care team, improve glucose control, and improve patient reported outcomes.** This approach will set the stage for future study to further integrate CGM within clinical practice.

APPROACH

Investigative Team

Dr. Dungan and colleagues have been successfully conducting inpatient diabetes research studies for the past 8 years through collaboration with clinical and research staff at multiple levels, including administration, quality improvement, nursing, physician, physician extender, and pharmacy interactions.

- Kathleen Dungan, MD, MPH, Professor, Division of Endocrinology, Diabetes & Metabolism, (PI)
- Eileen Faulds, PhD, RN, FNP-BC, CDCES, Assistant Professor, OSU College of Nursing (Co-I)
- Elizabeth Buschur, MD, Assistant Professor, Division of Endocrinology, Diabetes & Metabolism (Co-I)
- Kathleen Wyne, MD, PhD, Professor, Division of Endocrinology, Diabetes & Metabolism (Co-I)
- Cara Harris, DNP, APRN-CNP,CDCES Division of Endocrinology, Diabetes & Metabolism (Co-I)
- Jing Peng, PhD, Statistician, (Co-I)
- Sarah MacEwan, PhD, Assistant Professor, General Internal Medicine (Co-I)

Preliminary Data

Hospital Discharge Study

This was a randomized study of hospitalized insulin-requiring patients with T2D and A1c >8.5%. All subjects received study-supplied insulin glargine 300 U/mL (Gla-300). The intervention consisted of an electronic discharge order set (DOS) and periodic phone calls from the study nurse. The primary outcome was change in A1c from baseline to 24 weeks following discharge.

Table 1. Baseline Characteristics, Hospital Discharge Study

	Overall *N=158*	Enhanced Standard Care *(N=76)*	Discharge Order Set *(N=82)*
Age (years)	51.7 (10.2)	51.4 (10.5)	52 (10.1)
Male	68 (43.0)	33 (43.3)	35 (42.7)
White[1,2]	74 (46.8)	34 (44.7)	40 (48.8)
Hispanic	3 (1.9)	1 (1.3)	2 (2.4)
Diabetes duration (years)	11 (7, 20)	14 (7, 20)	10 (6, 15)
Body mass index (kg/m^2)	38.2 (9.5)	38.1 (8.7)	38.4 (10.1)
Estimated Glomerular Filtration Rate			
>60	109 (69.0)	51 (67.1)	58 (70.7)
30-60	39 (24.7)	21 (27.6)	18 (22.0)
<30	107 (6.3)	4 (5.3)	6 (7.43)
Education			
Less than high school	15 (9.5)	10 (13.2)	5 (6.1)
High school or equivalent	118 (74.7)	55 (72.4)	63 (76.8)
Bachelor's degree	25 (15.8)	11 (14.5)	14 (17.1)
Insurance			
None	11 (7.0)	7 (9.2)	4 (4.9)
Private	52 (32.9)	22 (29.0)	30 (36.7)
Medicare	35 (22.1)	18 (23.7)	17 (20.7)
Medicaid	60 (38.0)	29 (38.2)	31 (37.8)
Diabetes Consult	62 (39.2)	26 (34.2)	36 (43.9)
Discharge medications			
Basal insulin	41 (30, 75)	50 (30, 74)	41 (30, 78.7)
Bolus insulin	123 (79)	63 (79)	60 (80)
Metformin	56 (36.1)	26 (34.7)	30 (37.5)
Sulfonylurea/glinide	6 (3.8)	3 (4.0)	3 (3.8)
SGLT2-inhibitor	5 (3.2)	5 (6.7)	0 (0.0)
DPP-4 inhibitor	10 (6.5)	6 (8)	4 (5)
GLP-1 receptor agonist	24 (15.5)	14 (18.7)	10 (12.5)

Results: The study was stopped early due to feasibility concerns during the pandemic. A total of 158 subjects were enrolled (DOS=82, ESC=76, Table 1). The DOS group had a greater frequency of new prescriptions for bolus insulin and testing supplies but no difference in order clarity. A1c was available in 27 subjects in each arm at 12 weeks, and 20 and 21 subjects in the DOS and ESC arms, respectively at 24 weeks. The adjusted difference in change in A1c (DOS-ESC) was -0.5 ± 0.4% at 12 weeks (adjusted p-value 0.20) and -0.7 ± 0.4% at 24 weeks (adjusted p-value 0.09). Achievement of individualized A1c target was greater in the DOS group at 12 weeks but not 24 weeks, after the intensity of follow-up had decreased, underscoring the need for ongoing high frequency care.[26] In post-hoc analysis, functional health literacy,

inpatient diabetes consultation and endocrinology follow-up were associated with clinically relevant reduction in A1c (Figure 1). This is not unexpected as glucose control is typically not the primary reason for hospitalization and post-discharge care is more likely to focus on other issues. Thus additional discharge support would be needed to facilitate ongoing glucose management efforts.

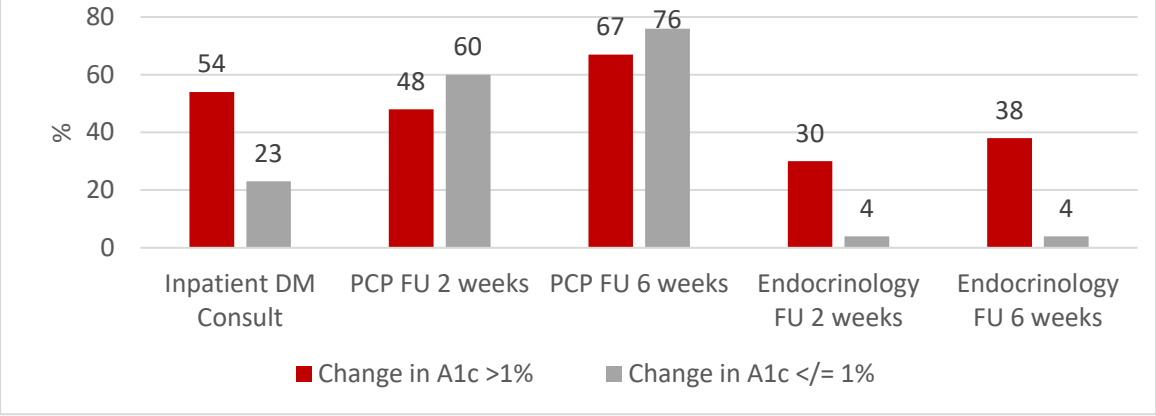

Figure 1. A1c reduction by specialty care

Post-discharge healthcare utilization did not differ between groups. While the mean insulin dose did not differ between groups, patients in the DOS group were significantly more likely to have any change in insulin dose by 12 weeks. While patients in the DOS group received instructions for basal insulin self-titration, most patients had not made self-adjustments by the initial 2 week visit, suggesting the need for close early hospital follow-up.

Conclusions: An electronic DOS resulted in more complete discharge prescriptions for insulin and related supplies but there is an opportunity to improve the clarity of instructions. Endocrinology follow-up was associated with better A1c reductions.

Predictors of Readmission in Patients with Poorly Controlled Diabetes

Among hospitalized patients with an A1c >9%, fewer patients who were readmitted at 30 days had a diabetes education consultation than those with no readmission (32 vs. 44%, p<0.0001, Table 2).[48] This relationship persisted (OR 0.68, 95% CI 0.52-0.89, p=0.006) after adjusting for demographics, income, marital status, physician consultation, insurance, length of stay, need for critical care, A1c, and year of admission. While attenuated, the relationship persisted for 180 day readmissions. Readmissions were more common than previously reported (30% at one year vs. 32% at 6 months in this study).[29] Thus, we have identified a higher risk population than previously recognized.

Table 2. Predictors of 30-day Hospital Readmission

	Readmitted N=293	Not Readmitted N=2028	P-value^
Age	52 (14.9)	51 (14.4)	0.38
Male	138 (47%)	1075 (53%)	0.06
Caucasian	163 (56%)	1090 (54%)	0.57
Married	94 (32%)	682 (34%)	0.64
HbA1c	10.8 (9.7-12.3)	11 (9.9-12.6)	0.05
Income	34,559 (29,573-41,713)	35,006 (30,716-43,216)	0.17
Physician consult	140 (48%)	922 (45%)	0.49
Education consult	93 (32%)	900 (44%)	**<0.0001**
Hyperglycemic emergency	17 (5.8)	145 (7.2)	0.46
Non-surgical service	215 (81%)	1615 (86%)	**0.04**

Data are reported as number (%) for binomial variables and mean (standard deviation) or median (interquartile range) for normally and non-normally distributed variables respectively. ^P-value obtained from unpaired t-test, Wilcoxon Rank-Sum, and Fisher's Exact Test for variables with normal, non-normal, and binomial distributions respectively.

Hospital Discharge Program for Patients with Poorly Controlled Diabetes

This pilot program incorporated individualized education with phone follow-up at one week following discharge and then monthly follow-up (N=77, 58 with T2D, 19 with T1D).[2] A1c was reduced 1.5% overall (p=0.04) but was limited to patients with T2D. Both patients who were newly diagnosed (−4.5 ± 3.8%, p =0.02, n = 7) and patients with established diabetes (−1.5 ± 2.1, P =0.0002, n = 34), had a significant A1c reduction (p =0.08, between groups). In multivariable analysis, independent predictors of reduction in A1c included older age, higher body mass index, shorter duration of diabetes, higher baseline A1c, insulin naïve at admission, and education prior to the day of hospital discharge. In this sample, patients who were discharged new to insulin,

new to basal insulin, or new to bolus insulin had significant A1c reductions.

Of this sample, functional health literacy was limited (median score 4/5, IQR 3-5), but Diabetes Empowerment Score (DES) was relatively high (median 36, IQR 34-38). The literacy score predicted patients who were ultimately discharged with flexible mealtime insulin dosing using carbohydrate counting (median literacy score 5 [4-5] vs. 3 [1-4], p =0.001) and thus may be an effective screening tool for targeting patients for appropriate modalities and intensity of therapy.[8] Hospital follow-up was associated with higher income as well as higher DES.

Application to proposed study: The data indicate that an intensive yet individualized education and discharge support is expected to improve glucose control in patients with T2D post-discharge. The current proposal will address the concern about long-term patient engagement through a more intensive model utilizing remote glucose monitoring, usual diabetes care provider communication, and decision support.

Study Design: In this 12 week prospective observational cohort study, hospitalized insulin-requiring patients with T2D and A1c >8.0% will receive Dexcom transmitter and sensors with application of one sensor prior to discharge. Patients will complete surveys assessing patient reported outcomes prior to CGM use and following completion of the study. CGM data will be captured by patient smartphone app and analyzed. A patient dashboard will be used to assess whether personalized CGM targets are met. This will trigger reports/ decision support to be sent to the patient provider. The initial observational cohort study design will be followed by an extension phase of 12 weeks in which data on use and glucose control will be collected but no further reports will be communicated to providers.

Study Population: Hospitalized patients (age ≥18 years) with T2D (A1c >8.0%) who are receiving basal insulin (at least 10 unit per day) and are able to provide informed consent will be approached (Table 3). Patients must have access to smart phone technology (compatible with Clarity App) and be willing to allow investigators to access CGM data following discharge. Known pregnancy will be excluded but pregnancy testing will not be performed due to no added risk.

Table 3. Enrollment Criteria

Inclusion Criteria	Exclusion Criteria
Age ≥18 years	Type 1 DM
Type 2 Diabetes	Inability to consent
Basal insulin use >10 units per day	Pregnancy
Hemoglobin A1c >8.0% (within the previous 3 month)	Prisoners
Smart phone compatible with Clarity App	Discharge to skilled nursing facility

Recruitment: Patients will be identified through daily screening of the endocrinology consults placed by inpatient medical and surgical services throughout the institution, as well as daily screening of inpatient non-ICU services. An efficient system is already in place for screening patients for inpatient diabetes studies. Each morning, the research assistant screens services through the EMR, initially filtering by insulin use and then A1c. Permission will be obtained from the attending physician of the admitting inpatient service to contact the patient. Current annual inpatient diabetes physician and educator consults at OSU main and OSU East are roughly 3000 per year, but there are approximately 13,000 admissions with a diagnosis code for diabetes each year. Approximately 1000 admissions per year have an A1c >9%.

Enrollment

Enrollment is expected at a rate of approximately 2 patients per week with the last patient enrolled within 12 months to allow completion and analysis of all data within 2 years. The study and all study-related documents will be approved by the OSU IRB. Written informed consent will be obtained.

Retention

Patients will be contacted at pre-arranged times, with up to 3 attempts during the week of the encounter. In the event of failure to contact, a letter/email will be sent and staff will then reach out to the patient designated secondary contacts. The medical records will be monitored at OSU and queries to the patient's designated

primary care physician will be made up to 12 weeks following enrollment. Incentives will be provided for completing the follow-up A1c at the 12 week visit.

Procedures

Study procedures are summarized in Table 5.

Table 5. Study Procedures and Visits

Phase of Study	**Phase 1**					**Phase 2 (Extension)**		
Visit number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Time of Visit (week)	Screen/ consent	1-2	4	8	12	16	20	24
Type of visit	🧍	☎	🧍	☎	🧍	☎	☎	🧍
Informed consent/contact team	x							
Provide study CGM supplies and training	x		x	x				
Set up Clarity account. Document sharecode in EMR	x							
Establish targets from Dashboard	x							
Communication to usual DM provider	x	x	x	x	x			
Usual care provider Instructions for prescribing CGM/CMN				x				
Demographics/Socioeconomic	x							
Diabetes history	x							
Hospitalization history	x							
MSPSS scale	x							
eHEALS score	x							
SNS3	x							
DTSQ (original plus change at screen and week 12)					x			
DDS	x				x			
BenCGM, BurCGM					x			
Additional patient questions		x	x	x	x			x
Patient barriers								x
Ascertain health care utilization		x	x	x	x	x	x	x
Record CGM data		x	x	x	x			x
Adverse events		x	x	x	x	x	x	x
Insulin/DM medication use		x	x	x	x	x	x	x
A1c	x				x			x
Usual Provider Survey					x			

CMN=certificate of medical necessity, MSPSS=Multidimensional Scale of Perceived Social Support, eHEALS=eHealth Literacy Scale Diabetes, DTSQ=Diabetes Treatment Satisfaction Questionnaire, BenCGM=Benefit of CGM score, BurCGM=Burdens of CGM score, DDS=Diabetes Distress Scale, SNS3=Subjective Numeracy Scale-3. In-Person clinic visits will be conducted at either Outpatient Care East or McCampbell Hall. Telephone visits may be converted to in-person visits as needed.

Initial Assessment: Trained interviewers will perform initial data collection.

- Contact information, including email address, best times to reach the patient, contact information for 2 additional individuals, and primary care provider (PCP).
- Demographics, medical, social history
- Multidimensional Scale of Perceived Social Support (MSPSS): Social support is an environmental factor that is associated with readmissions[49], determines behavior in SCT and influences self-efficacy[50] and will be measured using the MPSS.[51]
- Electronic health literacy: Baseline perceived eHealth literacy will be measured by the eHealth Literacy Scale (eHEALS), in which a score of 28 was used as the cut-off for high or low ehealth literacy.[52] The scale is comprised of 8 items on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree).
- Subjective Numeracy Scale-3 (SNS-3): The SNS-3 is a validated 3-item version of the longer SNS that was found to be reliable and valid to be used as a measure of subjective numeracy.[53]

- Comorbidity is key determinant of readmission; it is measured with the Charlson comorbidity index.[54]
- Discharge medications: The complexity of the discharge regimen will be assessed as number of injections per day, use of basal, prandial, and premix insulin, total units of insulin per day, basal dose, and other diabetes medications by treatment class.

Intervention:
Device use: Participants will wear the Dexcom G6 CGM throughout the study. All patients will receive education from trained personnel in its use according to manufacturer instructions. Target ranges will be set up as 70-180 mg/dl. Patient alerts will be customized, but generally <70 mg/dl for hypoglycemia and >200 mg/dl (surgical patients) or 300 mg/dl (nonsurgical patients).

Device Connections, Alerts, and Dashboard: Data will be obtained using the Clarity app which will be set up on the patient smartphone. A sharecode will be set up for 1 year and documented in the patient's electronic medical record. The patient will also be linked directly to the study Clarity account. Subjects not meeting % time in range metrics over the previous 14 days will be identified (Table 4).

Table 4. Target Metrics

Population*	% TAR	% TIR	% TBR
Hypoglycemia risk, eGFR <30 ml/min/1.73m^2, >age 65	50	50	1
Otherwise healthy or recent surgery (within 2 weeks or wound infection)*	25	70	4
*Goal % of time in target range (70-180 mg/dl) may shift categories depending on predominant clinical characteristics. TAR=time above range (>180 mg/dl), TIR-time in range (70-180 mg/dl), TBR=time below range (< 70 mg/dl)			

Discharge: Patients will also receive basic survival skills education (regarding glucose targets, consistent carbohydrate meals, basal insulin titration). The discharge regimen and all prescriptions and clinical follow-up will be determined by the primary team with input from the diabetes consult service if requested. All patients will receive standard discharge instructions using the EMR as per usual practice. Hospital discharge is coordinated by the primary team and patient care resource manager who arranges follow-up prior to discharge. A discharge summary is sent to the primary provider per routine practice.

Communication with Usual Care Providers:
- **Enrollment** Providers (up to 2 providers per patient, primary care and endocrinologist, up to 200 providers total) will be notified of initial patient enrollment in the study using a standardized letter containing the patient's Clarity sharecode and instructions for accessing Clarity.
    - **Inclusion/exclusion criteria:** The patient's usual care provider (primary care or endocrinologist) will be identified from the electronic medical record and via patient self-report. Providers will be invited to anonymously respond to the survey via an electronic communication (Inbox message, email, or letter with a URL link—in case of external provider).
- **Week 1, 2, 4, 8, and 12:**
    - **Patients NOT meeting targets:** At 1-2, 4, 8, and 12 weeks, the study team will:
        - Provide advice to the patient on basal insulin titration.
        - Counsel patient on therapeutic lifestyle changes
        - Provide a letter with a summary of the CGM interpretation and counseling provided to the patient as well as any additional advice to the usual diabetes care provider using a standardized template. The letter will include a copy of the Ambulatory Glucose Profile and the Glucose Overlay from the previous 14 days.
    - **Patients meeting targets:** a summary letter with Ambulatory Glucose Profile will be sent to usual care providers at weeks 1-2, 4, 8, and 12.
- **Week 8:** In preparation for transitioning patient to the extension phase of the study, the usual care provider will be sent instructions for prescribing the CGM device, including a pre-filled certificate of medical necessity, if applicable.

Follow-up Encounters: Patients will be contacted 1-2 weeks after discharge to confirm CGM use and address any concerns. If needed, this visit can be converted to in-person if additional supplies and/or training is needed. Thereafter, in-person visits are only required for the completion of A1c and patient reported outcomes surveys and other visits can be completed via telephone call. Dexcom supplies will be shipped directly to patients monthly or can be picked up by the patient. CGM data will be reviewed on Clarity and sent to the usual diabetes care provider after every visit as noted above. Diabetes medications and healthcare utilization will also be reviewed at each visit. At the 12 week visit, patients will complete patient-reported outcomes surveys and A1c.

Study Completion
Participants will receive an order to complete the A1c at 12 weeks via point-of care assay. They will be asked to complete additional surveys (Table 5). The study team will complete the 12 week visit and send a final communication to the healthcare provider with a summary of the visit, notice of study completion with study extension phase, the patient's Clarity sharecode, and CGM report.

Study Extension*:* Patients will transition to standard of care observational extension phase of the study in order to ascertain whether patients continue use of CGM through their usual care provider. General instructions will be provided to the patient and provider based upon the patient's payer (including use of durable medical equipment company or pharmacy). We will assess device use, glucose metrics, medication adjustments, healthcare utilization, and A1c.

Provider survey: At 12 weeks, Clinicians will be contacted via email to participate in a web-based survey. Participants provided electronic informed consent prior to taking the survey. The survey is anticipated to take approximately 15 minutes. An incentive in the form of a $20.00 Amazon gift card will be electronically distributed to providers who complete the survey. Survey elements will include:

- Practice characteristics: provider type, years in practice, practice setting, specialty, characteristics (percentage of patients with diabetes, familiarity of CGM use [5-point scale], frequency of interpreting CGM reports).
- Utility of CGM reports to make adjustments to therapy. There is no validated survey specifically assessing utility of CGM reports for clinicians. The Sustainability Use Survey (SUS), a 10-item questionnaire, is widely used for measuring perceived usability of a system.[55] The SUS-2 is the best combination of SUS items that predict an SUS score with high accuracy; therefore, the 2 items were included in the provider survey in lieu of using the full SUS to enable benchmarking of usability and minimize provider burden. The 2 items used in the CAS are: 1) *I thought the CGM report was easy to use,* and 2), *I found the CGM report was cumbersome to use*. These questions map to SUS 03 and SUS 08, respectively, and when analyzed together are known as the SUS-2. The questions are analyzed based upon a 5-point Likert scale. Benchmarking SUS scores: SUS-2 scores and individual item scores have been compared against a large dataset of ~500 published studies of SUS data. The average raw SUS score (at the 50th percentile) is 68.
- Additional questions will include (5-point likert scale)
    - *I found the Ambulatory Glucose Profile to be helpful for assessing glucose control*
    - *I found the Ambulatory Glucose Profile to be helpful for making adjustments to therapy*
    - *I found the report recommendations to be helpful for making adjustments to therapy*
- Whether the provider or care team logged onto Clarity.

Patient Reported Outcomes*:* Patient reported outcomes will be collected at baseline (satisfaction, distress) and/or after 3 months of Dexcom use (Table 4).

- Treatment Satisfaction: The Diabetes Treatment Satisfaction Questionnaire (status version, DTSQs) has 8 items, measuring treatment satisfaction and perceived frequency of hyperglycemia and hypoglycemia.[56] DTSQs evaluates satisfaction with the diabetes treatment regimen over past weeks (in this case 12 weeks) and is composed of eight items, six of which are summed into a single score on a 7-point scale, ranging from very satisfied to very dissatisfied. DTSQ measures overall satisfaction, convenience, flexibility, understanding of diabetes, willingness to recommend current treatment to others, and willingness to continue the current treatment. The remaining two items are treated individually and explore the perceived frequency of hyperglycemic and hypoglycemic episodes. For these two items, low scores represent good BG control. The DTSQ change (DTSQc) version was

developed to overcome potential ceiling effects (i.e. respondents scoring maximum or near maximum satisfaction at baseline can show little or no improvement at follow-up).[57] The DTSQc compares the experience of the current treatment with the experience of the treatment before initiation of the study. Scores range from +3 ("much more satisfied now") to 23 ("much less satisfied now"), with 0 (midpoint) representing no change. Higher scores on the DTSQ total score indicate higher treatment satisfaction, and lower scores indicate lower treatment satisfaction. Studies of flash glucose monitoring demonstrated improvements in DTSQ scores in patients with T2D.[13,58]

- Benefit of CGM (BenCGM) and Burdens of CGM (BurCGM). Each questionnaire contains 8 items and was originally validated in a sample of 431 adolescents with type 1 diabetes.[59] In a large sample of 1334 adults with type 1 diabetes, CGM CGM users perceived more benefits and less burden compared to those who were not using CGM, though older users (above age 50) had higher mean BurCGM scores, and users above age 65 reported more worry and more difficulty understanding CGM information than younger users.[60] Both questionnaires showed high internal consistency (Cronbach's α of 0.89 for BenCGM, and 0.87 for BurCGM) and reliability. Previous measures of glucose monitoring satisfaction were lengthy, or omit major themes specific to CGM. Possible limitations include a high mean score for BenCGM, indicating possible ceiling effect limiting the ability to detect improvement over time and conversely, a low mean BurCGM score, reducing the ability to detect further worsening of the score.
- Diabetes Distress: The Dexcom G6 was associated with reductions in diabetes distress, a quality of life measure, in a recent observational study[17] using the Diabetes Distress Scale (DDS; 17-item scale; 4 subscales; higher scores indicate greater distress).[61] Answers to each item are based on a 6-point Likert scale, rated from 1 (''not a problem'') to 6 (''a very serious problem'') for the past month. Subscales evaluate emotional burden (five items), regimen distress (five items), interpersonal distress (three items), and physician distress (four items). The total mean score is calculated and a score of <2.0 is considered as "little or no distress," 2.0-2.9 as "moderate distress," and ≥3.0 as ''high distress.'' This copyrighted scale is available free of charge to non-profit institutions for use in clinical care and research. In contrast, the Problem Areas in Diabetes (PAID), was not significantly affected in a recent study. [17]
- Additional Questions: In addition we will ask the patient whether they have made a change to their basal insulin, diet, or activity in the past 7 days in response to CGM data (Yes/No) and whether the usual care provider reviewed CGM data. At the end of the extension phase, we will ask the patient about important barriers to ongoing use (1-5 Likert scale).

Data Collection and Management:
The database used for this study is REDCap, which is a secure web-based application for building and managing data. It is designed specifically for clinical research and administered by the OSU Center for Clinical and Translational Research. Permission for data access or entry will be granted or revoked at a level that is appropriate for each individual involved in the study. Following verification, data will be locked. Data and data labels can be downloaded selectively (for interim progress reports) or in entirety (end of study) directly from REDCap in SAS or Excel format.

Baseline Data:

- Demographics: gender, race/ethnicity, age, marital status, education, employment, insurance, marital status, contact information
- History: diabetes duration, tobacco use, microvascular/macrovascular complications, heart failure, conditions requiring anticoagulation (thromboembolism, atrial fibrillation), hypertension, hyperlipidemia, liver disease, hypoglycemia awareness, reason for hospital admission
- Medications: pre-admission, discharge, and follow-up insulin use and total daily dose, insulin type, other glucose-lowering medications, steroid use, anticoagulants, antiplatelets
- Exam: weight, height, BMI
- Surveys: MPSSS, eHEALS, SNS-3
- Labwork: eGFR, A1c, glucose level on admission and discharge
- Patient reported outcomes: DTSQs, DDS
- Additional patient questions about CGM use
- CGM target (Table 4)

Visit 1, 2, 3:

- Glucose data: detailed below
- Communication: to usual care provider (summary only, summary with advice)
- Diabetes medications, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Additional patient questions about CGM use
- Healthcare Utilization: PCP visit, education visit, endocrinology visit, hospital readmission, emergency visit
- CGM target (Table 4)

Visit 4:

- Glucose data: detailed below
- Communication: to usual care provider (summary only, summary with advice)
- Diabetes medications: non-insulin medication use by class, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Healthcare Utilization: PCP visit, education visit, endocrinology visit, hospital readmission, emergency visit
- Patient reported outcomes: DTSQs, DTSQc, DDS, BenCGM, BurCGM
- Additional patient questions about CGM use
- A1c
- CGM target (Table 4)

Visit 5, 6

- Glucose data: detailed below

Visit 7

- Glucose data: detailed below
- Diabetes medications: non-insulin medication use by class, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Healthcare Utilization: PCP visit, education visit, endocrinology visit, hospital readmission, emergency visit
- A1c
- Additional patient questions about CGM use, barriers to use

Glucose data: A minimum of 14 consecutive days with 70-80% of data overall is recommended for analysis.[62]

- Coefficient of variation (CV) is calculated as the standard deviation/mean glucose and is the preferred measure of glucose variability.
- % Time in target range (TIR) 70-180 mg/dl
- Hyperglycemia
  - Time spent >180 mg/dl (TAR)
  - Time spent >300 mg/dl
- Hypoglycemia
  - Time spent <54 mg/dl
  - Time spent <70 mg/dl (TBR)
- Additional Measures
  - Mean sensor glucose
  - % time of CGM data
  - Sensor Failures

Usual care providers: usual care providers will complete a 12 item questionnaire which will include

- provider type
- years in practice

- practice setting
- specialty
- % of patients with diabetes (5-level category)
- familiarity with CGM (5-point Likert)
- frequency of CGM interpretation (4 level category)
- 5-item Likert scale:
    - SUS-2 (ease of use, cumbersome to use)
    - CGM report helpful in assessing glucose control
    - ambulatory glucose profile helpful for making adjustment in therapy
    - report recommendations helpful for making adjustments to therapy
- Whether Clarity website was accessed

Endpoints:

*Aim 1***:**

Primary

- Change % TIR 70-180 mg/dl from baseline (week 2) to 12 weeks

Secondary

- Change in % of patients meeting individualized TIR (Table 3)
- Change % TAR, TBR, % time <54 mg/dl, mean glucose, CV from baseline to 12 weeks
- Change in A1c from baseline to 12 weeks

Aim 2:

Primary

- % CGM wear time at 12 weeks

Secondary

- % of patients with % wear time >70% at 12 weeks.
- Reason for CGM wear <70% (loss to follow-up, issue with mobile phone, sensor/transmitter loss or damage, adverse sensor event, patient preference [state reason], other
- % with transmitted data at 12 weeks
- % with dashboard driven summary, dashboard driven advice sent to usual care provider by 12 weeks
- Change in basal insulin dose from discharge to 12 weeks
- Usual Care Provider usability: SUS-2 (ease of use, cumbersome to use), CGM report helpful in assessing glucose control, ambulatory glucose profile helpful for making adjustment in therapy, report recommendations helpful for making adjustments to therapy, whether Clarity website was accessed.
- % of usual care providers reporting review of data

Aim 3:

Primary:

- Change in DTSQ scores from baseline to 12 weeks

Secondary:

- Change in DDS from baseline to 12 weeks
- Patient reported outcomes (DTSQ, DDS, BenCGM, BurCGM).

Endpoints for Exploratory Aim 1:

- healthcare utilization (clinic visits, education visit, hospital readmission, emergency visit)

Endpoints for Exploratory Aim 2 (Extension Phase): By 18 months (the end of the last 90 day visit), we anticipate that a subset of patients (75%) will have at least 12 additional weeks of data following the primary endpoint at 12 weeks. We will assess the following metrics among users and compare to nonusers:

- Change in % CGM wear from 12 weeks to 24 weeks
- Change in glucose metrics from 12 weeks to 24 weeks.
- Change in insulin dose from 12 weeks to 24 weeks.
- Patient reported barriers to continued CGM use (5-point Likert from not important at all to very important, unless otherwise noted):
    - Cost/coverage concerns (if important or very important, then answer the following)

        - Insurance did not cover CGM (yes/no)
        - Insurance partially covered CGM but co-pay was too high (yes/no)
        - Usual care provider would not prescribe CGM (yes/no)
    - Too much hassle to order/obtain CGM
    - Too many alarms
    - Having device attached to the body/lack of privacy
    - Do not understand what to do with the information
    - Unreliable/does not work
    - Discomfort/pain
    - Too time-consuming
    - Interferes with sleep
- Healthcare utilization (PCP visit, education visit, endocrinology visit, hospital readmission, emergency visit)

Sample Size
We anticipate enrollment of 120 patients over a 1 year period with 20% drop-out. The following data support this sample size.

Aim 1:
- %TIR: Beck et al reported time in target 70-180 mg/dl per day increased from median 802 (IQR 604-974) to 937 (664-1083) minutes from baseline to 12 weeks. This is commensurate with a % TIR of 55.7% and 65.1% respectively.[14] In a study of 25 older patients with either type 1 or type 2 diabetes (N=25) who wore the Dexcom G4 for 4 weeks, the % TIR increased from 66.3 (SEM 2.6) to 76.9% (SEM 3.0), the TBR decreased from 9.6 (SEM 2.1) to 5.2 (SEM 1.1)%, the TAR decreased from 23.9 (SEM 3.0) to 17.9 (3.1), and the CV decreased from 37.3 (SEM 2.3) to 32.9 (SEM 1.3).[19] In the MOBILE study, the % time in target range was 59%.[15] Thus, we estimate a sample size of 80 will yield 99% power to detect a 15% difference from a hypothesized mean of 60% TIR, a standard deviation of 15 and significance level of 0.05.
- % Individualized TIR: In the LANDMARK study, a total of 47% of subjects met the target of 70% TIR. In this study we will use individualized target time in range (Table 3) and thus anticipate a greater proportion of participants (60%) meeting the individualized % TIR.[16]
- A1c: In the real-world LANDMARK study, A1c fell from 8.5 +/-2.2% to 7.1 +/- 1.1% in 66 patients with T2D at 12 weeks following Dexcom G6 CGM initiation.[16] Beck et al reported the A1c decreased from 8.5% to 7.5 (IQR 7.4-7.7), a reduction of 1.0 (IQR -1.2 to -0.8).[14] In the MOBILE study, the A1c decreased 1.3 (1.0)% in the CGM group and -0.7 (0.9%) in the control group.[15] Thus, a sample size of 80 will yield 98% power to detect a 0.4% difference from a hypothesized mean 0.7% reduction in A1c, assuming a standard deviation of 0.9%, and significance level of 0.05.

Aim 2:
- % Wear time: In a randomized study using the Dexcom G4 system (a 7 day sensor), the % of possible CGM readings (excluding 2 hours after each new sensor insertion) was mean 92 (SD 15), median 97 (IQR 92-99) at week 12 of use, or approximately 92% wear time.[14] In the MOBILE study, the median wear time was 6.3 (IQR 5.4, 6.7).[15] We would anticipate a lower wear time with the current study due to differences in the study population. Thus, a sample size of 80 will yield 99% power to detect a 1 day difference from a more modest hypothesized mean 6.3 days of wear time, a standard deviation of 0.96, and significance level of 0.05.

Aim 3:
- DTSQ: In the LANDMARK study, 94% of participants with T2D were satisfied or very satisfied (Question 1 of the DTSQ). In a randomized study of 101 patients with T2D using the Freestyle Libre Flash glucose monitor (an intermittently scanned glucose monitoring device), mean (SD) DTSQc score per subject for each question was 2.47 (0.77) with CGM vs. 2.18 (0.83) in the control group (P = 0.053). Thus, we would anticipate a change in DTSQc that is proportional.[13]
- DDS: In the LANDMARK study, the DDS decreased from 2.67 (SD 0.65) to 1.85 (0.65) from baseline to 12 weeks. We would anticipate a similar change in DDS score.
- BenCGM, BurCGM: In a large study of patients with type 1 diabetes, there was a significant difference in BenCGM (4.48 vs. 4.19, p<0.001) and BurCGM (1.69 vs. 2.35, p<0.001) among CGM users vs. non-

users, respectively. Thus, we anticipate that both scores will be associated with CGM wear time in the present study.

Analysis

Descriptive statistics will summarize the sample characteristics and distribution of each variable. Data will be screened for normality, outliers, and homogeneity. Continuous variables with normal distribution will be reported as mean (standard deviation) while non-normal distribution will be reported as median (interquartile range). Binary variables will be reported as number (percentage). Change over time in continuous variables will be reported as paired t-test or nonparametric test as appropriate. Difference of proportions between groups for binary variables is tested by Fisher's test (two groups) or chi-square test (three or more groups). Statistical significance will be determined at p-value of <0.05.

For Aim 1, linear regression can be used for checking the relationship between %CGM wear time and change in glucose metrics. Appropriate transformation may be needed if the residual plots show obvious violation of linear regression assumptions. Logistic regression can be used for checking the association between % CGM wear time and % meeting individualized TIR or change in % of patients who meet their individualized TIR. For choosing the predictors of change in TIR from baseline to 12 weeks, we can first include a subset of the exploratory variables depending on the descriptive statistics and clinical context. If necessary, further variable selection (stepwise selection) can be conducted to make the analysis reliable. In addition, we will assess baseline predictors of glucose metrics.

For Aim 3, for checking the association between % CGM wear time and patient reported outcomes, we use linear regression and test the model assumptions by residual plots. We will do screening based on baseline imbalance and clinical context, and then do variable selection to get predictors for these scores. In addition, we will assess baseline predictors of patient reported outcomes.

Potential Limitations & Proposed Solutions

Limitations of the study relate to the potential loss to follow-up. From our preliminary data, we have determined that even the addition of a single specially trained student improved successful telephone contacts substantially. Therefore, within the context of a specifically dedicated study staff and the other enhancements, it is anticipated that further improvement in successful telephone contacts can be achieved. Furthermore, a large percentage of individuals in the pilot studies are followed in the OSU health system, simplifying the access to follow-up data at 24 weeks.

Work Plan and Timeline

The overall project is anticipated to last 2 years (Table 10). The first 3 months will involve project start-up activities, including development of the REDCap database, regulatory submission, and training study staff. Study recruitment and enrollment will commence during the second quarter of the first study year and is anticipated to last 12 months to achieve the final enrolled sample. The final visit is expected at 18 months. Data gathering activities are scheduled to take 3 additional months. Data processing activities will commence at the start of data gathering and continue through the 15 months. The last quarter of Study Year 2 will be spent preparing reports and manuscripts. It is anticipated that 1 poster and 1 manuscript will be generated from this work. The publication plan includes the following:

- Poster: preliminary efficacy/safety data (end of year 1)
- Manuscript 1: Efficacy/safety data, patient reported outcomes
- Manuscript 2: Population health dashboard, provider surveys, extension data

Activities	Year 1				Year 2			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start-up procedures	X							
Recruit & enroll sample		X	X	X	X			
Follow-up visits			X	X	X	X		
Data analysis							X	
Prepare reports & manuscripts								X

Summary and Future Directions

For the hospitalized patient, multiple factors collude to impede successful transitions in care in the current fragmented health system. Diabetes provides a suitable framework for chronic disease management in general due to its complexity regarding therapies, self-care, and multiple comorbidities. This proposal seeks to redefine the role of diabetes management throughout the continuum of care. Future applications would include multi-center studies and studies to determine the efficacy of the individual components as well as comparative effectiveness across different devices.

HUMAN SUBJECTS

A. Protection of Human Subjects

A.1 Risk to human subjects

A.1.a Human Subjects involvement, characteristics, and design

This is a nonrandomized observational study of the use of real-time CGM and a remote CGM dashboard to direct intensity of care in recently hospitalized patients with T2D not at goal A1c. The outcomes include % CGM wear time, % of patients with transmitted data, insulin dose changes, usual provider feedback, glycemic control (CGM data, A1c), patient reported outcomes, and long-term use. Specific medical concerns will be forwarded to the usual diabetes provider, who will receive updates regarding CGM data based upon the population dashboard at baseline and up to once monthly. Patient reported outcomes will be assessed at baseline and 3 months. A1c will be collected at baseline, 3 months, and 6 months. CGM data, insulin data, and healthcare utilization will be assessed at baseline and monthly up to 6 months.

The sample is obtained from hospitals from a single academic medical center. The main campus hospital consists of University hospital, Ross Heart Hospital, and Brain and Spine hospitals and has a referral base from central and southern Ohio as well as a diverse array of medical and surgical patients. OSU East is a community hospital that serves a large percentage of local, often indigent patients. A total of 120 participants are planned, approximately 80% from the main hospital. Data will be entered into REDCap from both sites online. Completed informed consent and questionnaires will be scanned into this system as well. The OSU EMR has the capability of designating the patient is enrolled in a research study in order to improve communication between providers and patients.

Based upon preliminary data, we found that approximately 30% were of African American race. We are enrolling a wide age range, 25-75, in order to achieve optimal external validity. Participants are anticipated to be sick and have other comorbidities (in our pilot data, 70% were admitted for a problem that was not directly related to diabetes). However, all participants will be free-living in the community and have a phone. Due to bias introduced by additional support staff at institutions such as nursing homes and rehabilitation centers, these participants will be excluded. Participants who are unable to provide consent in English will be excluded as this number is very small and educational materials from the manufacturer are not available. Other vulnerable populations, such as prisoners will be excluded. Pregnant individuals will be excluded since the A1c is not as reliable, glucose targets differ, and because such individuals have different motivations and follow-up already in place.

Permission will be obtained from the attending physician of the admitting inpatient service prior to approaching participants for enrollment. The frequency of follow-up is felt to be adequate to establish reasonable endpoints for reinforcement of behavior and capture a realistic window for readmission.

The patient's usual care provider (primary care or endocrinologist) will be identified from the electronic medical record and via patient self-report. Providers will be invited to anonymously respond to the survey via an electronic communication (Inbox message, email, or letter with a URL link—in case of external provider). Up to 2 providers per patient, primary care and endocrinologist, up to 200 providers total will be contacted.

A.1.b. Sources of Materials

Baseline Data:

- Contact information, including email address and best times to reach the patient, contact information for two emergency contacts, and contact information of the patient's usual diabetes care provider
- Demographics: gender, race/ethnicity, age, marital status, employment, contact information, discharge location

- History: diabetes duration, tobacco use, microvascular/macrovascular complications, heart failure, conditions requiring anticoagulation (thromboembolism, atrial fibrillation), hypertension, hyperlipidemia, liver disease, hypoglycemia awareness, reason for hospital admission
- Medications: pre-admission, discharge, and follow-up insulin use and total daily dose, insulin type, other glucose-lowering medications, steroid use, anticoagulants, antiplatelets
- Exam: weight, height, BMI
- Labwork: eGFR, A1c, glucose level on admission and discharge
- Patient reported outcomes: DTSQ, DDS
- CGM target (Table 3)

Visit 1, 2, 3:
- Glucose data: detailed below
- Communication: to usual care provider (summary only, summary with advice)
- Diabetes medications, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Healthcare Utilization: PCP visit, endocrinology visit, hospital readmission, emergency visit
- CGM target (Table 3)

Visit 4:
- Glucose data: detailed below
- Communication: to usual care provider (summary only, summary with advice)
- Diabetes medications: non-insulin medication use by class, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Healthcare Utilization: PCP visit, endocrinology visit, hospital readmission, emergency visit
- Patient reported outcomes: DTSQ, BenCGM, BurCGM, DDS, SDSCA
- A1c
- CGM target (Table 3)

Visit 5, 6
- Glucose data: detailed below

Visit 7
- Glucose data: detailed below
- Diabetes medications: non-insulin medication use by class, bolus insulin use, basal insulin dose, missed doses
- Adverse events (sensor irritation, infection, bleeding)
- Healthcare Utilization: PCP visit, endocrinology visit, hospital readmission, emergency visit
- A1c

Glucose data: A minimum of 14 consecutive days with 70-80% of data overall is recommended for analysis.[61]
- Coefficient of variation (CV) is calculated as the standard deviation/mean glucose and is the preferred measure of glucose variability.
- % Time in target range (TIR) 70-180 mg/dl
- Hyperglycemia
  - Time spent >180 mg/dl (TAR)
  - Time spent >300 mg/dl
- Hypoglycemia
  - Time spent <54 mg/dl
  - Time spent <70 mg/dl (TBR)
- Additional Measures
  - Mean sensor glucose
  - % time of CGM data
  - Sensor Failures

Usual Care Provider: usual care providers will complete a 12 item questionnaire which will include the 2 item provider type, years in practice, practice setting, specialty, % of patients with diabetes, familiarity with CGM, frequency of CGM interpretation, SUS-2 (ease of use, cumbersome to use), CGM report helpful in assessing glucose control, ambulatory glucose profile helpful for making adjustment in therapy, report recommendations helpful for making adjustments to therapy, whether Clarity website was accessed.

Potential Risks

There are no physical risks that would not otherwise be anticipated, as the blood draw for A1c is considered standard of care. No specific prescriptive regimen for medications is planned and therefore this also represents standard of care. Participants undergoing interstitial glucose monitoring, while considered a standard of care practice, may experience discomfort during sensor insertion, or difficulty with sensor adhesive such as irritation, pruritus, rash, or infection. In a study of the Dexcom G4, no device related serious adverse events occurred during the study (N=158).[14] While the frequency of mild skin irritations with the Dexcom G6 have not been reported in a recent study, [63] mild reactions such as erythema, bruising, bleeding, infection have been reported with other devices, and may lead to device discontinuation.[64] Sensor accuracy may be affected by rapid changes in glucose, acute illness, theoretically resulting in over- or undertreatment of high or low glucose levels. However, studies have demonstrated that overall glucose control, including A1c, is improved and hypoglycemia risk is reduced. While the sensor is FDA approved for use up to 10 days, actual sensor life may vary. Psychological harm may be a possibility if participants neglect other aspects of self-care in favor of diabetes. However, this seems unlikely and will be averted with frequent contact and anticipated increased outpatient follow-up. No financial or legal consequences are anticipated. Breach of confidentiality is a possibility but with standard procedures for immediate entry of paper data into the secure online database, use of a study identification code on all data gathering instruments, and the use of electronic health records, this should be limited.

Usual Care Providers: the survey will pose limited risk, breach of confidentiality is very low as an anonymous electronic link will be provided.

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Potential participants will be identified during their hospitalization through screening inpatient endocrine consults as well as review of non-ICU medicine and surgery wards. A HIPAA waiver will be obtained for this purpose. The patient will be approached in private. Personnel (coordinator) will describe the purpose of the study in the same words that are used on the consent form, which states lack of participation will not otherwise influence patient care. Participants are expected to read the consent form (or have it read to them) in full and be able to explain the study purpose, risks, and procedures to the investigator before consent will be considered complete and informed. Participants that seem unsure or want to consider it further will be re-approached with their permission, after several hours or the following day or otherwise per the participant's request. The samples and study-related information will not be used and the participant will be withdrawn if the participant subsequently declines enrollment.

Usual Care Providers: providers will be contacted by electronic inbox, email (internal providers), or mail (if external to OSU) and will be invited to provide feedback. There is no obligation to proceed and individual responses will not be tracked or traceable.

Protections against risk

Participants will receive instruction for use of the glucose monitoring device, including interpretation of data, limitations of use, and recognizing and addressing sensor irritation issues.
Participants will be assigned a study number that will be the primary means of identifying patient data. A key will be kept on the secure endocrine network drive but this will only be for internal investigator use. Any personal information acquired will be entered into the secure online database (Redcap), which is password protected, and allows limited access to varying degrees. Only immediate study staff (PI, nurse, research assistants) will have access to Redcap. Other personal information (such as signed consent forms) will be

kept in the office of the PI or the study coordinator and locked when not in use. Personal data that is otherwise not recorded into the database will be destroyed immediately through appropriate confidential shredding bins. After the program is complete and the data has been analyzed, all paper data will be shredded and electronic data will be de-identified after being stored for the minimum required amount of time. Personally identifiable past medical history and study data (glucose, laboratory assessments) will be obtained from EPIC, Redcap and the chart reviews. No highly sensitive information (mental illness, HIV status, social security number) will be collected and vulnerable populations such as prisoners will not be enrolled.

Study-related adverse events will be recorded and severe adverse events will be reported to the study PI and the institutional review board. Any severe adverse events felt to be related to the study will be reported immediately to the PI and IRB. Participants may leave the study for any reason and are assured that this will not otherwise affect their care. Thus, informed consent is treated as a continual process.

Usual Care Providers: We will use an anonymous electronic link. Moreover, we will not be collecting identifiers. The information requested is not sensitive information that would be expected to lead to psychological, professional, or physical harm.

Potential Benefits of the Proposed Research to Human Subjects and Others

Participants may benefit from more intensive interaction with study staff, through improved glycemic control as well as close follow-up and anticipatory guidance. Benefits to society include improved glycemic control and hospital readmission, which may result in reduced medical costs, particularly among uninsured individuals. The risks are primarily related to breach of confidentiality and are limited, though still possible. Expert guidelines recommend glucose monitoring among insulin requiring patients using periodic finger stick glucose measurements or via continuous or semi-continuous interstitial measures (intermittently scanned glucose monitoring or CGM). CGM greatly reduces the need for fingerstick glucose monitoring and therefore minimizes discomfort related to glucose monitoring as it only needs to be replaced every 10 days. However, CGM is not widely adopted, primarily due to the expense. Moreover, CGM users have easy access to glucose values at any time and therefore are more likely to use the data to modify behaviors that affect glucose control. Thus patients may benefit from this technology as a result of participating in the study. Given the safeguards that are put in place, the potential benefits should outweigh the risks.

Usual Care Providers: Providers may obtain indirect benefit from additional support provided by the study in training patients to use CGM, assisting with obtaining and interpretation of reports, and improved glucose control among their patients.

Importance of the Knowledge to be Gained

The importance of the knowledge is in the understanding of the role of diabetes, in particular glucose control, on patient satisfaction outcomes in patients with cancer who were recently discharged from hospital. Currently, few studies have examined glucose control in this population following inpatient hospitalization. The rising epidemic of diabetes will continue to contribute significantly to the morbidity of these patients, frequently necessitating hospital care. Providing solutions to this problem is of considerable urgency. Therefore, the potential benefits outweigh the given the aforementioned risks.

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