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EVALUATING ACCEPTABILITY, FEASIBILITY AND EFFICACY OF A DIABETES CARE SUPPORT PROGRAM FACILITATED BY CELLULAR-ENABLED GLUCOSE METERS

A Dissertation Presented

By

DANIEL JOHN AMANTE

Submitted to the Faculty of the
University of Massachusetts Graduate School of Biomedical Sciences, Worcester
in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

OCTOBER 11, 2016

CLINICAL AND POPULATION HEALTH RESEARCH

EVALUATING ACCEPTABILITY, FEASIBILITY AND EFFICACY OF A DIABETES CARE SUPPORT PROGRAM FACILITATED BY CELLULAR-ENABLED GLUCOSE METERS

A Dissertation Presented
By

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This work was undertaken in the Graduate School of Biomedical Sciences
Clinical and Population Health Research

Under the mentorship of
David Harlan, MD, Thesis Advisor

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October 11, 2016

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ABSTRACT

Background. Diabetes requires significant disease management, patient-provider communication, and interaction between patients, family members, caregivers, and care teams. Emerging patient-facing technologies, such as cellular-enabled glucose meters, can facilitate additional care support and improve diabetes self-management. This study evaluated patient acceptability, feasibility, and efficacy of a diabetes care support program facilitated by cellular-enabled glucose meters.

Methods. A two-phase study approach was taken. Get In Touch – Phase 1 (GIT-1) was a 1-month pilot involving patients with type 1 and type 2 diabetes. Get In Touch – Phase 2 (GIT-2) was a 12-month randomized controlled crossover trial involving patients with poorly-controlled type 2 diabetes. Results from GIT-1 and preliminary results from GIT-2 are presented.

Results. GIT-1 participants with type 1 (n=6) and type 2 (n=10) diabetes reported the intervention and cellular-enabled glucose meter were easy to use and useful while identifying potential areas of improvement. GIT-2 participants in both the intervention (n=60) and control (n=60) groups saw significant improvements in treatment satisfaction and A1c change, with intervention participants experiencing slightly greater improvements in each after 6 months ($p=0.09$ and $p=0.16$, respectively) compared to control participants.

Conclusions. Patients reported favorable acceptability of the intervention. Preliminary results from a randomized trial demonstrated potential of intervention to improve patient-reported and physiological health outcomes. Future studies should evaluate feasibility

and efficacy over a longer period of time, with a greater number of participants, and targeting different populations of patients with diabetes. Provider perspectives and changes in provider behavior, clinical work flow, and caregiver burden should also be assessed.

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LIST OF ABBREVIATIONS

A1c – Hemoglobin A1c

AADE - American Association of Diabetes Educators

ADA – American Diabetes Association

CDE – Certified Diabetes Educator

DCOE – Diabetes Center of Excellence

DES-SF – Diabetes Empowerment Scale – Short Form

DSME – Diabetes self-management education

DTSQ – Diabetes Treatment Satisfaction Questionnaire

DTSQc – Diabetes Treatment Satisfaction Questionnaire Change

GIT-1 – Get In Touch – Phase 1

GIT-2 – Get In Touch – Phase 2

HITECH – Health Information Technology for Economic and Clinical Health Act

LOCF – Last observation carried forward

MMAS – Morisky Medication Adherence Scale

mMOS-SS – modified Medical Outcomes Study – Social Support

NCBDE - National Certifying Board for Diabetes Educators

PAM – Patient Activation Measure

PHI – Personal Health Information

SMBG – Self-monitored blood glucose

TAM – Technology Acceptance Model

T1D – Type 1 Diabetes

T2D – Type 2 Diabetes

TAM – Technology Acceptance Model

PREFACE

Chapter II of this dissertation was presented as a poster at the Connected Health Symposium in Boston, MA on October 29-30, 2015 and is published in iProceedings as: Amante, Daniel J., et al. "Evaluating Acceptability of Cellular Glucose Meter Use in a Diabetes Care Management Program: A Qualitative Study. Iproceedings 1.1 (2015): e2.

Chapter III was presented at the American Diabetes Association's 76th Scientific Sessions in New Orleans, LA on June 10-14, 2016. The results will be expanded upon to include additional data from the second half of the Get In Touch – 2 trial and submitted for publication shortly after defense of this dissertation.

Supplementary Manuscript was published in Opinions of Endocrinology and Diabetes as: Amante, Daniel J., and Michael J. Thompson. "The promise of telecommunication tools to 'reach' the disengaged patient with diabetes."Current Opinion in Endocrinology & Diabetes and Obesity 23.2 (2016): 111-120.

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CHAPTER I

INTRODUCTION

Diabetes in the US

Diabetes is one of the most prevalent and costly chronic diseases in the United States. The American Diabetes Association (ADA) estimates that over 22 million Americans were diagnosed with either type 1 (T1D) or type 2 (T2D) diabetes in 2012. This number increased from an estimated 17.5 million in 2007.[1] If the prevalence of diabetes continues to rise at this rate, up to one-third of adults in the US could have diabetes by 2050.[2] This is particularly concerning because diabetes is associated with many other health complications including being the leading cause of kidney failure, limb amputations, and blindness, a major cause of cardiovascular disease and stroke, and the seventh leading cause of death in the US.[3] Diabetes is also becoming increasingly expensive to treat. The estimated cost of diabetes in the US was $174 billion in 2007 and $245 billion in 2012. After accounting for inflation, the 2012 cost estimate is more than $43 billion greater than the 2007 estimate.[1]

Physiology of Diabetes

In general, diabetes is a group of metabolic diseases that are characterized by elevated blood glucose levels.[4] Blood glucose levels are regulated by insulin, a hormone produced by the pancreas to convert sugar, starches and other food into energy. In T1D, accounting for only 5-10% of the diabetes population, there is an absolute deficiency of insulin secretion due to destruction of the β-cells of the pancreas.[4] In T2D, accounting for over 90% of diabetes cases, individuals usually experience insulin resistance with no or only relative deficiency of insulin secretion.[4] Resistance of insulin by important body tissues, such as the liver, muscle, adipose tissue, and

myocardium, results in both glucose overproduction and underutilization.[5] When blood glucose levels are elevated, patients experience episodes of hyperglycemia with common symptoms including shortness of breath and nausea. Long-term complications of hyperglycemia include cardiovascular disease, nerve damage, kidney failure, formation of cataracts, and problems with one's feet, bones and joints. Extended periods of hyperglycemia can lead to emergency cases of diabetic ketoacidosis or hyperglycemic hyperosmolar syndrome, both of which can lead to diabetes comas and be life threatening. Hypoglycemia occurs when blood glucose levels fall and cannot return to normal level. Hypoglycemic events can occur due to an excess of exogenous or endogenous insulin. Symptoms of hypoglycemia include confusion, irritability, lightheadedness, and nausea and if untreated, hypoglycemia can lead to seizure or diabetes coma.

Living with Diabetes

Management of diabetes is very complex, with an array of pharmacological options and lifestyle interventions that should be tailored based on the individual needs, preferences, and tolerances of each patient.[5] After a treatment plan is decided, executing the plan requires significant effort dedicated to health-related activities. The effort spent managing one's health has been referred to as 'patient work'.[6] The subsequent sections highlight particular instances of patient work that is often required of patients with diabetes, as well as their family members and caregivers, to effectively manage their diabetes.

Self-Monitoring Blood Glucose

To maintain safe glycemic levels, it is important for patients with diabetes to actively monitor their blood glucose throughout the day. The frequency and timing of self-monitoring blood glucose (SMBG) testing may vary based upon the needs of each individual but it is commonly recommended that patients, especially those with T1D or being treated with insulin, test at least 6-8 times per day.[7] Active SMBG testing allows patients to detect high or low blood glucose levels, facilitates therapeutic adjustments, educates and engages patients in disease self-management, and motivates patients towards improving their health.[8] Frequency of testing has been associated with health benefits such as improved hemoglobin A1c % (A1c) levels,[9, 10] a key indicator of blood glucose control.

Medication Administration

Many patients with diabetes take oral medications, inject insulin, or do both to help control their blood glucose levels. The Centers for Disease Control and Prevention estimates that among all adults with diabetes in 2011, over 80% took either daily oral medication or used insulin to manage their diabetes with 50% only taking oral medications, 18% only taking insulin, and 13% taking both oral medications and insulin.[11] In addition to daily adherence to prescribed medication regimens, insulin-using patients may need to adjust their insulin intake at any given point based upon their SMBG levels. Injecting an inappropriate amount of insulin can lead to dangerous episodes of hypo/hyperglycemia and additional health complications.

Behavior Modification and Data Tracking

Lifestyle changes, specifically those related to one's diet and physical activity, play major roles in the treatment and management of diabetes.[12] Just as obesity and sedentary lifestyles are independent predictors to the development of T2D, weight loss and increased physical activity have been shown to improve diabetes related health outcomes.[5, 13, 14] Tracking how blood glucose levels respond to changes in regular activities can inform patients on how best to manage their health. While education upon diagnosis is critical and takes advantage of a teachable moment, repeated delivery of counseling throughout the management of diabetes is also very important.[5] As patients learn more about their disease and the way their body reacts to certain stimuli, self-management of their health should improve.

Communication with Care Team

It is important for patients to communicate with their care team about their symptoms and experiences managing their disease. Patient-provider communication has been shown to be independently related to diabetes outcomes.[15] Sharing SMBG data gives providers valuable information regarding how best to treat their patients. The availability of SMBG data can enable care teams to help troubleshoot problems with hypo/hyperglycemia and allow them to make alterations to treatment plans accordingly. Also, as patients and providers interact more outside of their routine, episodic office visits, there are more opportunities for patients to become engaged and active participants in their healthcare decisions, which have been shown to be correlated with greater treatment satisfaction.[16]

Technology Used to Improve Diabetes Management and Ease Patient Work

Patient Portals

An electronic patient portal (portal) is an Internet-enabled personal health record tethered to a health care provider's electronic health record system.[17] The functions of a portal vary depending on the system with many portals allowing patients to access their personal health information (PHI), including lab results, medication information, and office notes. Portals can also accommodate secure messaging between patients and providers or be used by patients to request medication refills and appointments or for provider offices to send appointment and wellness reminders. Particularly relevant to patients with diabetes, portals can facilitate a way for patients to electronically collect and share data such as symptoms, logbooks (medications, diet, physical activity), or health data such as weight, blood pressure, or SMBG levels. Portals can also provide patients with access to educational resources aimed to improve patient knowledge and management skills.

The use of portals in the management of diabetes has been shown to improve clinical outcomes. In particular, diabetes management programs using patient portals have resulted in improved A1c and cholesterol levels.[18-21] Portal use with secure messaging has also been shown to reduce the utilization of clinical services,[22] improve disease management and diabetes distress,[23, 24] and is associated with increased patient activation[25] and diabetes knowledge.[23] The use of portals also offers an additional opportunity for patients and providers to connect outside of their routine face-to-face appointments. This improvement in the continuity of care delivery has potential to

improve clinical outcomes and the patient-provider relationship. Portal users report having better communication[26, 27] and improved satisfaction with their providers.[18] Portal use has also resulted in an increase in treatment regimen adjustments[28] and offers an alternative form of care for patients who are dissatisfied with the regular care they receive from their providers.[27]

Telehealth Coaching

Delivery of diabetes self-managed education (DSME) has been identified as a critical component of diabetes care.[29] Several interventions have used coaches to deliver educational and/or disease management training to patients with diabetes. Health coaching has been defined as a form of education that guides and prompts a patient to be an active participant in behavior change.[30] A recent review found that diabetes health coaching resulted in reduction of A1c levels.[31] While the benefit of using health coaches for patients with diabetes has been established, there remains potential to maximize the benefits. Health coaching sessions have historically been scheduled, in-person visits. This is good for patients to set long-term goals but may not be as convenient or helpful as providing ongoing support or support during the critical instances when patients are experiencing symptoms of their health condition. In such instances additional support from coaches using increasingly common telehealth technologies such as phone calls, instant messaging, or video conferencing, could greatly improve the accessibility, convenience, and continuity of care provided, thus increasing the benefits generated by health coaches.

Computer-Generated Support Messaging

In addition to human coaches who provide patients with valuable education and training to help manage their diabetes, technologies have been developed to deliver tailored feedback to patients. Computer programs can factor in various health data to generate, select, and deliver short motivational or educational messages that are relevant to a patients' current health status. Computer-generated feedback has resulted in improved diabetes outcomes such as lowering A1c, increasing medication adjustments, and improving patient and provider satisfaction.[18] While computer-generated support has been shown to be helpful, it is still missing the critical component of human-to-human interaction. If generic, computer-generated messages were augmented with human support, it is possible that even greater benefits could be realized.

Barriers to Technology-Based Interventions

Despite the potential benefits, the use of technology to manage diabetes is limited by several barriers. These barriers vary in type and can prevent patients, caregivers, and providers from getting started and/or sustaining use of various technologies.

Physical/Access Barriers

In order for patients to use technology to help manage their diabetes, several physical and access barriers may need to be addressed. Patients need to own the equipment. In most cases of technology-based interventions, this requires access to an Internet-enabled device. Patient access to the technology may be limited and not continuous. Uploading SMBG data to a portal, for example, has historically required

manually connecting a glucose meter with a computer. This restricts the ability to upload to occasions where a computer and connectivity are both available.

Technical Capacity Barriers

There are also technical capacity barriers that may limit the use of technology to manage diabetes. Patients need to know how to properly use the technology, such as how to connect a glucose meter to the computer and execute an upload. Even after data are uploaded, patients may not know how to interpret or utilize different functions of the technology. They also might not be aware of all the functions offered by the technology they posses or forget required log-in information.

Provider-Related Barriers

There may also be provider-related barriers that limit technology use for diabetes management. Providers may not endorse or recommend the use of electronic management tools by their patients for different reasons. They could doubt the potential benefits, have concerns that use will create uncompensated work for them, or think that they will be responsible for more data than they are able to keep up with. Studies have shown how influential a provider recommendation can be[32, 33] and that the potential of telehealth to help patients with diabetes is dependent on consistent, supportive interactions with health care providers.[34] To maximize the use of patient-facing technologies to manage their disease, providers need to be on board.

Addressing Barriers with Cellular-Enabled Glucose Meters

One technology with potential to address many of the barriers of using technology-based innovations is the cellular-enabled glucose meter. Cellular-enabled

glucose meters, like the In Touch meter offered by Livongo Health Inc. (Livongo, Chicago, IL), have a suite of management tools built into the machine and a touch screen interface that is designed to be user friendly. These type of meters utilize built-in cellular capability to instantly upload SMBG data to a secure portal, eliminating the physical barriers of owning a computer or connecting multiple devices. This allows patients to upload their personal health information with greater ease and frequency. Simplifying and streamlining the process of testing and uploading SMBG recordings to a secure portal could lead to increased frequency of testing and improved self-monitoring, which have been correlated with improved health outcomes.[9]

The use of cellular-enabled glucose meters to automatically upload SMBG recordings to a portal can also facilitate the unique opportunity to monitor the data in real-time. This allows care team members to provide more responsive and proactive support by communicating with patients about what is going on at that very moment. Members of the care team can provide self-management support, answer health-related questions, or direct patients to resources tailored to their specific needs at that moment. While previous studies have looked at sending generated messages in response to episodic uploading of SMBG data to a portal,[18] none have looked at in-the-moment, person-to-person support facilitated by automatic SMBG uploading by cellular-enabled glucose meters.

While physicians and nurses may not have the capacity, certified diabetes educators (CDEs) can be trained to monitor incoming data from patients and provide timely support when needed. CDEs are trained to help patients understand their treatment

plan and to direct them to reliable educational resources. CDEs can also report to the regular care team with valuable information about the health of their patients, helping them understand how to improve the care they delivery to their patients. This degree of continuous, tailored support is very unique and bridges episodic interactions typically seen between patients and their providers. In order to implement the use of cellular-enabled glucose meters into routine diabetes care, we must first evaluate the acceptability, feasibility, and efficacy of interventions utilizing them.

Specific Aims

This dissertation used mixed-methods analyses to evaluate the effects of the Livongo for Diabetes care support program and the In Touch cellular-enabled glucose meter provided by Livongo. The specific aims of this dissertation were as follows:

Aim 1: Evaluate acceptability of the Livongo for Diabetes care support program and the In Touch cellular-enabled glucose meter.

- As informed by the Technology Acceptance Model (TAM)

Aim 2: Evaluate feasibility of supplementing usual care with the Livongo for Diabetes care support program and the In Touch cellular-enabled glucose meter.

- As determined by comparison of change in patient-reported diabetes treatment satisfaction between intervention and control group participants.

Aim 3: Evaluate preliminary efficacy of the Livongo for Diabetes care support program and the In Touch cellular –enabled glucose meter.

- As determined by comparison of change in A1c between intervention and control group participants.

CHAPTER II

GET IN TOUCH - PHASE 1:

EVALUATING ACCEPTABILITY OF A DIABETES CARE SUPPORT PROGRAM FACILITATED BY CELLULAR-ENABLED GLUCOSE METERS

Abstract

Background

Connected health technologies are being used in diabetes care management and support programs to facilitate improvements in patient care. Uploading of patient SMBG recordings to electronic personal health records provides patients, providers, and caregivers with access to longitudinal data. To improve the utility of this access, SMBG data in the glucose meters should be uploaded both consistently and frequently. Unfortunately for patients who already deal with high disease management demands associated with diabetes, manually uploading SMBG recordings on a regular basis may not be practical. New types of personal glucose meters that are cellular-enabled can automate the uploading process. These cellular-enabled glucose meters eliminate the need for patients to connect to a computer or mobile device to upload SMBG data. Automatic uploading of SMBG data to a secure, cloud-based location enables diabetes care programs to provide timely and tailored support. As SMBG recordings are consistently uploaded to the cloud, computer programs can analyze the data and send back tailored feedback to the patient. Certified health professionals can monitor uploads in real-time and provide in-the-moment patient support when needed.

Despite the potential to improve diabetes management, the use of cellular-enabled glucose meters to facilitate additional care support is challenging. Although intended to be simple and easy to use, new meters can require a degree of technological skill that certain patients may not possess. Patients may also struggle to understand how best to utilize a meter's functionality, integrate the technology into existing routines, or use the

technology to interact more meaningfully with their care team. For these reasons, patient acceptability of care support programs utilizing cellular-enabled glucose meters must be evaluated before being implemented more broadly into diabetes care delivery.

Objective

To evaluate patient acceptability of a diabetes care support program facilitated by cellular-enabled glucose meters.

Methods

Patients with type 1 and type 2 diabetes received cellular-enabled glucose meters as part of a diabetes care support program in which they were enrolled. CDEs continuously monitored uploaded SMBG recordings, provided structured support to participants, and interacted with participants' medical providers as necessary. After 1 month, focus groups and semi-structured phone interviews were conducted with the participants. Audio recordings of each were transcribed verbatim and the resulting transcripts were analyzed using a constant comparative method to identify key themes. A deductive and inductive, iterative approach was taken by first generating an a priori code list based on the TAM, inductively developing additional codes within the TAM elements, and revising and refining the code list over several rounds of review.

Results

Participants with type 1 (n=6) or type 2 (n=10) diabetes all reported that the cellular-enabled glucose meter was easy to use and useful. The most favorable features of the meter were the automatic uploading of SMBG recordings, SMBG tracking and sharing tools, and tips provided through the meter. The support provided by the CDEs

through the care support program was also identified as being helpful. Identified areas of improvement included the need for training on the meter and program, improved consistency and efficiency of the meter's functional performance, and additional meter functionality.

Conclusions

All participants who finished the study reported a positive overall experience using the meter as part of the care support program. Future work should focus on long-term patient acceptability, feasibility and efficacy of using cellular-enabled glucose meters in diabetes care support programs and the subsequent effects on clinical service utilization and provider workflow.

Introduction

To prevent complications, patients with diabetes must actively manage their disease. This includes frequent interactions with their health care team, daily SMBG levels, and for many patients, adjustment and administration of insulin therapy, adherence to strict oral medication, diet, and physical activity regimens. Recently published frameworks[35] based on substantial previous research on the experience and management of chronic illness[36, 37] underscore the importance of understanding the kinds of 'work' that patients face. The demands and burden of such patient work are significant for those with chronic diseases like diabetes. Many patients do not have the skills or support to adequately satisfy them. This consequently may result in frustration and poorly controlled diabetes.

SMBG, Diabetes Care Programs and the Future Role of Technology

The practice of using personal glucose meters to self-monitor blood glucose levels among those with diabetes has become increasingly common since the introduction of the personal use glucose meter in 1981.[38] Uploading SMBG recordings from personal glucose meters into web-based patient portals accessible by patients, caregivers, and care teams has potential to improve patient activation, treatment satisfaction, and lower A1c levels.[39] Increasing the adoption and sustained use of uploading SMBG recordings over time for the general population, however, has its challenges. Identified barriers to uploading SMBG recordings include physically connecting the glucose meter to a computer or electronic device and having the technological capacity to successfully perform this task without assistance.[40] Among those who are able, many may believe

that routinely uploading is too burdensome. Automating the uploading process by using cellular-enabled glucose meters could have a significant impact on improving the use of SMBG recordings for blood glucose monitoring and management.

While uploading of SMBG recordings can improve patients' self-management of their diabetes, how the uploaded data should be used to improve diabetes care delivery still must be determined. Ideally, providers would monitor their patient's uploaded SMBG recordings and provide timely support. The amount of time required to do this, however, may not be possible for providers who have many other demands on their time. This would be particularly true with the use of cellular-enabled glucose meters that automatically upload after each testing. Using other health professionals to monitor uploaded recordings and provide appropriate and timely support has potential to improve diabetes care while limiting burden on providers. Recent studies have shown benefits of utilizing uploaded SMBG data to facilitate care support interventions led by various non-physician health care professionals including pharmacists,[41] nurses,[42] and care managers.[21]

Diabetes care programs exist to help patients improve their disease management.[19] Goals of diabetes management include improving care by facilitating communication between patients and their health care team and increasing patient self-management skills. In some cases, these programs have shown to improve A1c, blood pressure, and cholesterol levels.[19, 43-45] Other studies have shown no effect.[46] Hospital systems are using emerging technological innovations to assist in diabetes care support programs. Two examples of these technologies include advanced glucose meters

and web-based personal health records, often referred to as patient portals. Both of these technologies can support improved management and sharing of patient-generated data and delivery of tailored feedback from health care teams. This improvement in the continuity and patient-centeredness of care has potential to improve both clinical outcomes and the patient-provider relationship. Patients who use patient portals report better communication [26, 27] and increased satisfaction with their providers.[18] Portal use increases treatment regimen adjustment frequency.[28]

Addressing Challenges to Innovation in Technology Use

Despite potential benefits, patient adoption and use of new and innovative technologies to manage diabetes is not without barriers. A systematic review on the barriers of adopting and utilizing patient portals found that in addition to being unaware of a portal and its functions, many patients with diabetes cannot access the technology or do not possess the technological skills required to use it effectively.[40] This suggests additional efforts to both increase access to technologies and to simplify the technological processes required may be needed to adequately support certain patients. In the case of diabetes management, the use of cellular-enabled glucose meters can potentially help address some of the established barriers to technology use.

Cellular-enabled glucose meters can automate the process of uploading SMBG recordings, facilitate improved communication and continuous support from care teams, and provide patients with a suite of tools typically accessed through a patient portal. By uploading SMBG recordings to a secure portal automatically after a patient tests their blood glucose, cellular-enabled glucose meters alleviate the need for patients to manually

connect a meter to a computer or wireless device for upload. After the SMBG data is uploaded to a secure portal, patients and their designated health care team and caregivers can access these recordings in real-time. This allows for improved tracking and the potential for provision of timely support. Modern glucose meters are also equipped with various tools to assist patients with the self-management of their diabetes. These tools can include tailored messages and tips delivered through the meter after testing, personalized logbooks, built-in activity trackers, and ways to communicate and share patient-generated data with their care team and formal or informal caregivers. Cellular-enabled glucose meters also reduce the need for patients to use a computer or mobile device to log onto their portal as many of the portal tools are incorporated into the meter's functionality. This could be of great benefit to those who don't own a computer or don't have the skills to effectively operate one.

Study Aim

The aim of this study was to evaluate the acceptability of a diabetes care support program facilitated by cellular-enabled glucose meters. We used the TAM to guide this evaluation.

Methods

We conducted an acceptability study in which we sought to recruit 20 patients with either T1D or T2D to enroll for one month in a diabetes care support program facilitated by cellular-enabled glucose meters.

Sampling and Recruitment

A convenience sample of twenty-one patients with either type 1 or type 2 diabetes was recruited at the UMass Medical Diabetes Center of Excellence (DCOE). The DCOE combines basic science, translational research, and clinical care and serves as an integral component of UMass Memorial healthcare network. The DCOE is located in Worcester, MA and actively serves over 7,000 adults with diabetes. Research assistants recruited patients in the waiting room of the clinic during routine appointments. Participants were required to be able to speak English. Eligible patients were shown the In Touch meter and described the Livongo for Diabetes care support program. Interested patients signed consent forms and provided their contact information. Recruitment took place from 5/23/14 to 6/6/14. Providers of patients enrolled were notified of their participation.

Description of Intervention

Upon providing informed consent, enrolled participants were mailed an In Touch cellular-enabled glucose meter to use for 30 days and a one month's supply of testing strips, lances, and lancets. They were also mailed instructions on how to self-enroll in the Livongo for Diabetes care support program, an accredited program by the AADE Diabetes Education Accreditation Program. The program included both scheduled and in-the-moment support provided by CDEs certified through the National Certifying Board for Diabetes Educators (NCBDE). If participants did not successfully self-enroll after 1 week from study enrollment, they received a follow-up phone call from study staff to assist in the self-enrollment process. All meter equipment and services from the care support program were provided by Livongo. The cellular-enabled glucose meter

automatically uploaded all glucose recordings to Livongo's secure patient portal. Automated messages including helpful hints designed to assist participants in managing their diabetes, such as "Your BG is within range. Learning to eat what is right for your body is key to managing your Diabetes", were sent directly to the meter after each testing. These messages were developed using the American Association of Diabetes Educators (AADE) National Standards for DSME curriculum.[47] An algorithm selectively picked each message based on participant-provided data and the uploaded SMBG recordings. Other features of the meter included the ability to tag each recording with important contextual information about when it was taken (before meal, after meal, neither) and how they were feeling at the time, tracking SMBG recordings with an electronic log book, and a built-in activity tracker. The meter also allowed participants to share their SMBG data with anyone they designated as part of their care team (including their endocrinologist, primary care provider, caregiver, or family member) via text message, e-mail, or fax.

As part of the diabetes care support program, CDEs employed by Livongo monitored all SMBG recordings flagged for being dangerously high or low. The CDEs called participants the first time their blood glucose recording was above 250 mg/dL and greater than 400 mg/dL thereafter. The CDEs would also call participants if their SMBG recordings were below 40 mg/dL at any time during the study period. If an uploaded recording generated an alert for being too high or low, a CDE would contact the participant within 3 minutes of receiving the notification. The CDEs also provided support through scheduled coaching sessions over the phone and emails, as requested by

participants. All coaching sessions were based on the AADE's 7 self-care behaviors.[48] While CDEs did not give participants medical advice or make changes to their care plans, they could educate and answer diabetes-specific questions ranging from nutrition to lifestyle changes and contacted the participants' providers if they believed the uploaded SMBG recordings or conversations with the participants warranted clinical attention.

In cases of technical support issues, participants were directed to call Livongo's technical support staff. All SMBG recordings uploaded to Livongo's portal were sent to the DCOE every Friday evening through encrypted email to the study's Principal Investigator, who reviewed and manually added the SMBG recordings to each participant's electronic medical record as a note.

Framework

As is the case with any new technology, degree of utilization often determines extent of benefits achieved. According to the TAM (Figure 2.1), utilization of a new technology is determined by a person's behavioral intention.[49] This behavioral intention, also called acceptability of the technology, is directly influenced by two factors; the perceived ease of use and usefulness. Perceived ease of use can also directly affect perceived usefulness while both can be affected by other external factors. In the context of this intervention, how easy patients believe the meter is to utilize will have an effect on how useful they believe it is. If patients don't believe the meter is both easy to use and useful, they most likely will not use it. The same logic can be applied to the diabetes care support program. Patients need to believe it is both easy or convenient to participants in the program, and also useful, in order for the patients to utilize the services

provided. To determine the acceptability of using cellular-enabled glucose meters to facilitate diabetes care support programs, it is important to establish how easy to use and how useful patients think the technology and program are.

Data Collection Instruments

A background questionnaire, focus group guide, and semi-structured interview guide were developed by the research team. The focus group and semi-structured interview guides were nearly identical and designed to elicit data on concepts related to patient acceptability, as described by the TAM. Additionally, the guides included questions to identify areas of improvement, evaluate overall experience, determine whether they would continue in the care program if covered by their insurance, if they were willing to pay out-of-pocket for the services they received, and if yes, how much they believed was a reasonable cost. The questionnaire consisted of demographic questions.

Data Collection Procedures

Participants were invited to come back to the DCOE 1 month after study enrollment for a focus group. Participants unable to attend a focus group were called to complete a semi-structured interview and the questionnaire over the phone. Three focus groups took place between June 24, 2014 and July 9, 2014. Each focus group had between 4-5 participants (Group 1: n=4, Group 2: n=4, Group 3: n=5) and were facilitated by author DA. One of the DCOE endocrinologists involved in the study also attended each focus group to observe and provide medical insight when necessary. Some of the study participants in the session were patients of the endocrinologist attending the

session. Three phone interviews conducted by DA occurred between July 16, 2014 and July 25, 2014. Each participant received a $25 gift card and a parking voucher (if attended a focus group). All study procedures were approved by the UMMS Institutional Review Board.

Data Processing and Analysis

Audio recordings of the focus groups and the phone interviews were recorded and transcribed verbatim. The data from the transcripts were coded by the author of this paper using Microsoft Excel (version 7) and analyzed using a constant comparative method to identify key themes in the data.[50]

Results

Of the 21 consented participants, two participants did not successfully complete enrollment and were thus withdrawn from the study population. Of the remaining 19 participants, 13 attended a focus group, 3 completed a phone interview, and 3 were lost to follow-up. Demographics of the 16 participants (6 T1D, 10 T2D) who completed the study are shown in Table 2.1. The majority of patients were between 40 and 70 years old, had at least a high school education, and had Internet access at their homes. Key findings of the study are summarized in Table 2.2 and described below.

Perceived Ease of Use

All participants (n=16) reported that the meter was easy to use when checking their blood glucose. The majority of participants (n=12) reported that the cellular-enabled glucose meters significantly eased the process of uploading their SMBG recordings. Several participants also described the touch screen interface as being well-designed and

intuitive (n=7). With regards to the diabetes care support program, some participants appreciated the convenience of interacting with a CDE through their preferred method of communication, either by telephone, email or through the meter (n= 6).

Perceived Usefulness

Participants identified several functions of the meter they found useful. The automatic uploading of the SMBG levels was identified as being particularly helpful among those who previously uploaded through a computer manually (n=2) and those who only uploaded during their clinical appointments (n=10). *"I like the upload feature because I never uploaded anything before because I thought it was too much of a hassle so, I like that part."* (60 year old, male, T2D) The automatic uploading also cultivated an "internal competition" within some of the participants (n= 4) as they acknowledged wanting to improve their blood glucose levels because they knew a CDE was monitoring their recordings, thus holding them more accountable. *"I think the reason for that may be that I am competitive and I know it's uploaded and looked at by people."* (65 year old, male, T2D)

Several other features of the meter were identified as being helpful, including the ability to add context with tags about meals, medications, and how they were feeling when they tested their blood glucose. Participants (n=10) also appreciated the helpful tips that automatically displayed on the meter after testing. *"I like the tips that were on there after the blood sugar recording came out. I've never seen that before and I like it."* (51 year old, female, T2D) The ability to track their recordings through the trends function was also identified as being useful (n=8). *"That's another thing that I liked. You can go*

back and look at everything, and it will show you what it was on a certain day." (51 year old, female, T2D) One participant found the sharing of SMBG functionality to be especially helpful. Using the "MyFamily TEAM" function on the meter, his mother received a text message containing his SMBG results after each testing. The participant acknowledged that this reduced the amount of time they spent talking about his routine diabetes management and that his mother appreciated receiving the notifications for each result, allowing her to monitor her son's SMBG readings from afar.

> *"One feature that I really did appreciate and I think much more so because I am new to this is there's a feature that whenever your blood sugar is above a certain level or below a certain level it can send a message to not just the staff but I had my mom who has been in town receive a message so, she actually set the message so that when it was below 100 or above 101, so she got all of them."* (19 year old, male, T1D)

All participants reported that additional support provided by the CDE coaches monitoring their SMBG recordings was, or would be in the case of those who didn't interact with the CDE, very helpful. While the degree of interaction with the CDEs varied, several participants (n=7) acknowledged a feeling of reassurance that resulted from the additional layer of support available to them through the program. One participant, a male who had recently become a widow, stated that knowing someone else was watching over him filled a void created when his wife passed away.

> *"The one feature I really like about it is that I am recently widowed so I live alone and like you said if your blood sugar goes low, there is somewhere there calling*

me to make sure you are ok, and if you need help or whatever, so I really like that feature." (63 year old, male, T1D)

One participant reported that after disclosing to the CDE his difficulties maintaining an appropriate diet when his wife was out of town, the CDE provided him with healthy recipes that he was able to make for himself.

"She said your levels are good but would you like to talk to me? and I said yea. And we got on the phone and talked for quite a bit of time about my diet and what would be good stuff for me to have that I'm not eating and she sent me an email, a whole menu for the last 2 weeks." (65 year old, male, T2D)

Other participants had frequent interactions with the CDEs and relied on them for up to daily support.

"The first time she actually she called me because the first time I got my meter my sugar was 237 and instead of hitting I was fine, I was stressed and she was on the other end of the phone, trying to find out why. Basically, we then started communicating with emails back and forth with diet suggestions and what to cut out, what not to do, what to try and change and to this day she said after this is done, if you need it ask. Just email me." (41 year old, female, T1D)

There were several occurrences reported where a CDE contacted a participant in response to a concerning SMBG level to provide support and education (n=10). In one case, a participant stated that her low sugar level caused a state of confusion that was alleviated after a CDE called and reminded her to drink juice.

"My blood sugars were running low, they were extremely low, and they contacted me. And I thought their advice was good. They kind of walked me through, if your insulin level is low you get mentally confused, and by them contacting me, it kept my focus and I did better than what I would have on my own." (68 year old, female, T2D)

Another example of care intervention occurred when a CDE called a participant in response to a dangerously high glucose level and realized the participant was in a state of confusion. The CDE contacted the participant's provider, who called the patient and directed her to come to the clinic to receive attention. When asked about the urgent attention she received during a phone interview, the participant acknowledged that the care she received was initiated by the CDE and stated that she would have probably waited a few days to receive care during her scheduled appointment."*Yeah my sugars were very high so the doctor got the message and told me to come in. So I went in, they gave me treatment and it regulated my sugar."* (68 year old, female, T2D)

External Factors

Several factors external to the meter and program influenced the participants' perceived ease of use and usefulness. Primarily, the technological literacy of participants prevented some from attempting to utilize certain functions. One participant knew that his SMBG recordings were being sent to a CDE but was unsure how they were being automatically uploaded after each time he tested. *"I really don't understand the whole uploading process so I'm sorry."* (71 year old, male, T2D)

Other participants, who identified as being technologically adept, were satisfied with the meter's functional performance but offered potential improvements, including adding functionality for the meter to pair with insulin pumps, wireless internet compatibility for supplemental connectivity in areas with poor cellular reception, and improved SMBG tagging to allow for more detailed and customizable data with which to tag each recording.

> "*Maybe you can add a few things to the notes instead of being limited to pushing buttons. Like it said I feel fine, not feeling well, stuff like that but maybe add something other than "other", so you can type in how you feel in your own words."* (53 year old, male, T1D)

Another common theme identified was that a lack of free time hampered the amount of effort participants were able to spend "playing around" with the meter or reading through the user manual. A few participants expressed regret that they did not utilize the meter and program to their full capabilities and thought an additional brief tutorial or training that described the different functions and features would be helpful (n=4).

> *"I think there were things on here that I could have utilized better if I had known more about it. So I think just to be educated on the meter a little bit would have been beneficial."* (51 year old, male, T2D)

Overall Experience and Value

When asked to evaluate their overall experience using the meter and participating in the program, every participant replied that their overall experience was positive and that they would recommend the meter and program to a friend or family member.

> *"I like that there is a coach on the other end if something goes wrong, and the test strips are the perfect size, you don't have to sit there and fight to get them out. And it's just nice that I don't have to plug a tiny little meter into my computer."*
>
> (41 year old, female, T1D)

The majority of participants (n=14) also said they would like to continue using the meter and would stay in the program if it was provided by their health insurance. When asked if they would pay out of pocket to continue receiving the services, which included unlimited test strips, several said they would if the price was comparable to what they currently pay out of pocket for test strips. This value ranged from $20 to $50 per month.

Discussion.

This pilot study demonstrated that patients with diabetes are interested in participating in a CDE-delivered diabetes care support program facilitated by cellular-enabled glucose meters. Among the participants who completed the study, most reported that the support program and cellular-enabled meter were both easy to understand and useful in the management of their diabetes.

Patient acceptability has been demonstrated by evaluating perceived ease of use and usefulness. If a patient thinks something useful, and it is easy to use, there is a greater chance the patient will use that tool to manage their health. Prominent evaluation frameworks[51] posit that the impact of an intervention is a product of its reach and

effectiveness. Without high patient acceptability, the reach of an intervention will be low. This would be particularly true if the perceived effectiveness of the intervention is also low. Our study found that overall acceptability of a diabetes care support intervention facilitated by cellular-enabled glucose meters was very high. This suggests that this type of intervention may be an important component of a multi-faceted care delivery program for patients with diabetes.

Potential for benefits such as improved patient treatment satisfaction, communication between patients and their care team, and the continuity and coordination of care delivery were also observed in this pilot study. During the study, patients were provided with additional tools to manage their diabetes and CDE support. Study participants acknowledged that both the support program and the cellular-glucose meter were very helpful. Providing patients with useful tools and support to help manage their diabetes can have a great effect on overall treatment satisfaction. Treatment satisfaction has been shown to be associated with diabetes-related outcomes.[52] The CDEs from the support program also provided an opportunity for additional and improved communication between the participants and their care team. The effects of patient-provider communication on physiological, behavioral, and overall health status outcomes for patients with chronic diseases are well established.[53] Furthermore, there were instances where the CDEs served as a bridge of interaction between the patient participants and their specialty care team. This included specific instances where the CDEs recommended providers to follow-up with certain participants who had uploaded dangerously high or low blood glucose levels. This additional coordination between

CDEs resulted in participants visiting the clinic in order to receive medical attention or to have their medications and insulin doses adjusted. By doing so, some participants possibly averted a future visit to the emergency room, suggesting that this care support program could also have cost-saving implications. The largest expenditure component of the estimated $245 billion total yearly cost of diagnosed diabetes is hospital inpatient care.[1] The extent to which this type of intervention can improve patient-centric, clinical, and economic outcomes is worthy of further investigation.

As we evaluated patient acceptability of both a support program and a glucose meter, we found that it is important to consider the variation in skills and capacities across the targeted patient populations. While the majority of participants reported that both were easy to use and useful, there were still differences in the degree of difficulty reported by the participants. Some reported that they experienced a little difficulty understanding how to best utilize all functionality presented to them while others simultaneously reported that the technology may have been too simple or that not enough functionality was provided. While we did not intentionally sample to highlight such differences, this demonstrates the wide range of skills and expectations patients have for using technological interventions to manage their health and the importance of considering variation in skills and capacities in future work.

Strengths and Limitations

This pilot study offers several strengths. We were able to recruit our targeted cohort in a short timeframe, which demonstrated the appeal of the intervention to patients with diabetes. We were also able to collect feedback from the majority of participants and

used an established framework to guide our qualitative evaluation of patient acceptability. There were also limitations of this study. The study population was predominantly white and well-educated. This is particularly concerning when studying acceptability to technology because this population may have greater exposure to technology and their experiences may not be representative of the general population. All subjects were also receiving care at a specialty diabetes center of excellence by endocrinologists. It will be important to evaluate acceptability in a larger, more diverse study population over a longer time period. We also sought feedback from patients with both type 1 and type 2 diabetes but due to scheduling conflicts within the study group we were unable to separate patients into groups exclusive to their type of diabetes. The endocrinologist who sat in on focus groups was the clinician of a small number of the patients participating in the focus group. The extent to which this affected the reporting of participants is unknown. Also, a few participants did not enroll or did not return for a focus group and could not be reached for a telephone interview. This loss of participant feedback is an important limitation to consider when evaluating patient acceptability because lack of participation may be associated with decreased acceptability of the technology and program. Qualitative coding was also only conducted by 1 coder. While the framework used to guide this study was chosen intentionally for its simplicity, other frameworks such as the Unified Theory of Acceptance and Use of Technology (UTAUT),[54] may have highlighted additional factors contributing to patient acceptability, such as social influences, that are important to consider. Lastly, the SMBG data uploaded to the patient portal required manual transfer into the DCOE electronic health record. We collected no

specific data on this process so we are unable to confirm that this data transfer method would be feasible on a larger scale.

Conclusion

The data from this qualitative study showed a high level of patient acceptability to a diabetes support program facilitated by cellular-enabled glucose meters, as determined by patient-reported perceived ease of use and usefulness of the intervention. In addition to being easy to use and useful, examples of effectiveness of the intervention were described by participants. While overall satisfaction with the technology was high across all participants, a range of comfort and ability to utilize all functionality and /or desire for additional functionality still existed.

Figure 2.1. The Technology Acceptance Model

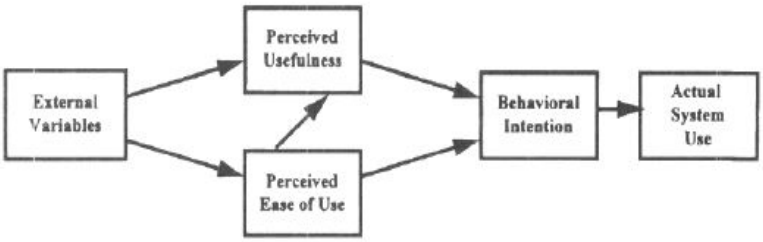

Table 2.1. Demographic characteristics of GIT-1 participants.	
	Total n = 16
Age (years), n (%)	
18-39	1 (6.3)
40-49	4 (25.0)
50-59	4 (25.0)
60-69	6 (37.5)
70+	1 (6.3)
Gender, n (%) male	10 (62.5)
DM Type, n (%) Type 1	6 (37.5)
Time since DM Diagnosis, mean (sd) years	12.9 (10.4)
Education, n (%)	
HS Grad	5 (31.3)
Some College	4 (25.0)
College Grad	4 (25.0)
Some Post Grad	3 (18.7)
Internet Access at Home, n (%)	15 (93.8)
Internet Use, n (%)	
Once a week or less	2 (12.5)
Several times a week	2 (12.5)
Every Day	4 (25.0)
Several times a day	8 (50.0)

Table 2.2. Key Findings of GIT-1		
Cellular-Enabled Glucose Meter		
Themes	**Findings**	**Exemplar quotations**
Ease of Use	Identified as easy to use: • the meter (in general) • testing process similar to other meters previously used • well-designed touch screen interface • automatic uploading after testing	Testing Process: "I really enjoyed using the meter, I mean it's so easy. And the amount of blood you need to test is really minimal." Touch Screen Interface: "I loved the interface, it was great. The keys were big, it was good and easy to see." Automatic Uploading: "For the most part, when I had a good cellular connection, the uploads worked seamlessly"
Usefulness	Identified as useful: • automatic uploading of the SMBG recordings • ability to tag details about meals, medications, and how they were feeling when they tested • helpful hint messages sent after testing • sharing results with family members • trends function	SMBG Tags: "I like the fact that it gave you a bunch of options of how you are feeling so you can decide which is the best option to check off. And then it gives you the option of telling where it was, was it before dinner, after dinner, and same with the rest of the day." Tips/Encouragement Messages: "I liked that every time after you uploaded a blood sugar it would send a message, you know "you're in range… you're low… you should monitor for signs of low blood sugar" " Sharing SMGB Recordings: "One feature that I really did appreciate, and I think much more so because I am new to this, is that whenever your blood sugar is above a certain level or below a certain level it can send a message to, not just the staff, but I had my mom receive a message" Trends Function: "I felt competitive. I wanted my trends to go down so my readings went a lot lower than they did with my old meter."
Areas of Improvement	Identified areas of improvement: • ability to pair with insulin pumps • improved cellular reception • wifi compatibility • additional SMBG tagging options • brief tutorial to describe functions	Insulin Pump capabilities: "The only other thing I would like to see is it communicate with my pump" Wifi connectivity: "So maybe adding like a wifi connectivity into this would be helpful in the

	of meter • improved functional performance of meter to reduce screen freezes and time required to test blood • enhanced reminder features • better travel cases provided	next generation" Customizable SMBG tags: "Maybe you can add a few things to the notes instead of being limited to pushing buttons like it said I feel fine, not feeling well, stuff like that, maybe add something other than "other", so you can almost type in" Improved Functional Performance: "I think the meter itself could be faster." Enhanced reminder functionality: "I'd say the only improvement I would make would be on the reminders. One of my old meters would sound off at a certain time, when it's off. This one doesn't do that. It only sounds off when the meter is on." Training of all features: "I think there were things on here that I could have utilized better if I had known more about it. So I think just to be educated on the meter a little bit would have been beneficial."
External Factors	Additional factors identified as impactful: • technological illiteracy prevented patients from utilizing full functionality • lack of free time prevented participants to explore functionality	Technological Literacy: "I'm sure there is more that I could have done with the meter then I did just because I was confused about it. Not because the meter was confusing, I was confused."
Diabetes Care Support Program		
Themes	**Findings**	**Exemplar quotations**
Ease of Use	Identified as easy to use: • interacting with CDE coach through preferred method of communication	Interaction with CDE coach via preferred method: "I'm on the go all the time and it's just easier to get it if I'm not right in the middle of something. She would email me and then I would respond and then she would respond to me later, so we were able to interact that way. I just feel it was easier that way because of my schedule."
Usefulness	Identified as useful:	Reassurance from CDE coach monitoring: "Oh

	• Continuous monitoring of SMBG recordings by CDE coaches • In-the-moment support provided by CDE coach • CDE coaching sessions and provision of diabetes-related education • CDE coach interacting with provider • Portal dashboard to monitor SMBG trends	it felt great, knowing that someone was on the other end keeping an eye on what I have done and how bad or good I've done. In-the-moment Support from CDE coach: "My blood sugars were running extremely low and they contacted me. And I thought their advice was good. They kind of walked me through it. If your insulin level is low you get mentally confused, and by them contacting me, it kept my focus and I did better than I would have on my own." Education from CDE coach: "She would call and tell me what to do and how to go about it. She would put things on my email address and different things I should do or try to do to bring my counts down." CDE coach as bridge to care team: "It was a couple weeks there when in the mornings I was having a lot of low readings. They contacted me and we talked. They ended up calling my doctor and discussed it with him and he called me to change something on my pump to rectify it and it was taken care of right away, rather than waiting to see him again in 3 or 4 months or so"
Areas of Improvement	Identified areas of improvement: • brief tutorial to describe features of program	Program tutorial: "I think, a tutorial might help, might be useful."
External Factors	Additional factors identified as impactful: • lack of free time prevented participants to explore all features of the program	Time restrictions: "I think there might have been a place on the website where it said would you be interested in hearing from a coach so I pressed that button and they sent me a couple of emails trying to schedule a time but I've just been busy so that never actually happened"

CHAPTER III

GET IN TOUCH – PHASE 2 PRELIMINARY RESULTS: EVALUATING FEASIBILITY AND EFFICACY OF A DIABETES CARE SUPPORT PROGRAM FACILITATED BY CELLULAR ENABLED GLUCOSE METERS

Abstract

Background

Patients with poorly-controlled type 2 diabetes (T2D) often struggle with the management of their diabetes. Technological interventions can help these patients by providing them with easily accessible tools and timely support from health care professionals.

Aims

The aims of the Get In Touch – Phase 2 (GIT-2) study were to evaluate feasibility and efficacy of a diabetes care support intervention facilitated by cellular-enabled glucose meters in adults with poorly-controlled T2D.

Methods

GIT-2 was a 12-month randomized crossover trial involving adults receiving care at a diabetes specialty clinic with two Hemoglobin A1c % (A1c) levels greater than 8.0 in the previous 12 months. Enrolled participants were randomized to receive the intervention or usual care for the first 6 months of the study, followed by a crossover of treatment groups for the final 6 months of the study. The intervention included enrollment in a diabetes care support program run by Certified Diabetes Educators (CDEs) and facilitated by cellular-enabled glucose meters. The cellular-enabled glucose meters automatically upload self-monitored blood glucose (SMBG) recordings to a secure patient portal, allowing intervention CDEs to monitor and provide support when uploaded SMBG recordings are flagged as being high or low. Questionnaire data were collected at baseline and 6 and 12 months post enrollment. A1c labs were recorded at

enrollment and 3, 6, 9, and 12 months post enrollment. Aims 2 and 3 of this dissertation examine results from the first half of GIT-2 (from study enrollment up to treatment crossover at 6 months post enrollment).

Results

This study population (n=120) of patients with T2D was on average 56.7 years old and 52.5% were women. Mean baseline A1c levels were 10.3 (SD=1.4) for the intervention group (n=60) and 10.0 (SD=1.4) for the control group (n=60).

The predicted mean change in diabetes treatment satisfaction was 2.3 points greater for the intervention group compared to the control group (p=0.09). Intervention participants experienced greater improvement in A1c of 0.41 from baseline to 3-months (p=0.12) and 0.38 from baseline to 6-months (p=0.16) compared to control group participants.

Discussion

Improvement in treatment satisfaction and A1c were seen by both groups, but showed signal of greater improvement for those participants receiving the intervention. The diabetes support program facilitated by cellular-enabled glucose meters displayed potential to improve diabetes-specific outcomes in this study. Significant improvements seen by patients of both groups suggest that increased engagement with their clinical team, as was required by the study protocol, can result in improved diabetes health outcomes. Future studies should look at the long-term effects of technological interventions that support both in-the-moment and scheduled support provided by care teams.

Background

The American Diabetes Association estimates over 29 million Americans had diabetes in 2012 with 1.4 million new diagnosed cases every year. Diabetes is the 7th leading cause of death and cost over $245 billion to treat in the US in 2012.[55] Patients with poorly-controlled diabetes, as indicated by an increased A1c, have even higher morbidity and mortality[56] and greater cost to treat.[57] To address the growing diabetes crisis, additional support should be provided to those experiencing difficulty with the management of their disease.

Patients with poorly-controlled diabetes struggle with their health management demands. To address these demands requires a significant degree of 'patient work'.[6] The work required for patients with diabetes to manage their health includes daily medications, self-monitoring of blood glucose levels, and administration of insulin. Effective management of diabetes can also require active carbohydrate counting, physical activity tracking, and responsive insulin bolus administration. Regular and frequent interaction with the patient's care team is also an important element of the management process. Diabetes care should be responsive to the patient's health status and work demands but also proactive in attempting to improve patient self-management skills, disease knowledge, and engagement with their health maintenance.

To help patients with poorly-controlled diabetes, additional support, education, training, and tools should be provided to help manage their health. Previously successful diabetes programs have used technology to improve the support for patients with poorly-controlled diabetes.[39, 58-62] These programs help by providing diabetes education,

self-management training, disease counseling, coaching, and additional support. Some programs provide support by having patients track PHI, such as blood glucose levels, and share it with members of their health care team. This allows the health care team to review detailed historical information and respond accordingly, depending on their role in the care team. Example of this response could include adjusting their treatment or medications plans, providing tailored education and counseling, or triaging to an appropriate care team member for additional follow-up depending on whether the care team member is a physician, nurse, pharmacist, CDE, or other health professional.

Previously, collection of PHI by patients was usually completed with hand-written logs. Sharing of that data occurred only during in-person encounters. Electronic logs, particularly those built into personal health records offered by a health care provider (also referred to as patient portals), allow patients to upload and share PHI data over the Internet. Data uploaded into patient portals are increasingly being made accessible to providers through patient portals tethered with electronic health record systems. This presents the opportunity for care teams to provide tailored support based upon data made available without requiring in-person encounters with patients.

Using PHI data uploaded by patients to tailor and improve diabetes care faces several barriers, both by patients and health care teams. On the patient side, they could lack the technical ability or the physical hardware (ie – computers) to execute a data upload. Patients may also lack the motivation or available time required to upload and share PHI. These barriers are specifically true for patients with diabetes, as uploading SMBG data from personal glucose meters has historically required plugging the device

into a computer and manually executing an upload. Cellular-enabled glucose meters eliminate several barriers by automatically uploading SMBG recordings immediately upon being taken. This allows for SMBG data to be made accessible to patients, their care team, and caregivers without creating any additional patient work to execute the upload.

In addition to easing patient work burden, automatic SMBG uploading also allows presents the opportunity for additional support to be provided in response to the uploaded data. A major provider-facing barrier for this service is the effort required to monitor and react to PHI data uploaded in real-time. While health care systems may not have the resources to pay physicians or nurses to monitor uploaded SMBG data in real-time, other health professionals, such as CDEs, may be a more affordable option. CDEs can provide responsive support and tailored education to patients after they test and upload SMBG recordings flagged as being high or low and serve as a bridge connecting the episodic encounters between patients and their usual care teams. This type of real-time, diabetes care support, provided by CDEs and facilitated by the automatic uploading of SMBG data by cellular-enabled glucose meters, has yet to be evaluated in a clinical setting of patients with poorly-controlled T2D.

Aims

The objective of this study was to conduct a preliminary evaluation of the feasibility and efficacy of the GIT-2 study. GIT-2 was a 12 month, randomized controlled crossover trial involving 120 participants with poorly-controlled T2D. In this paper, we evaluated preliminary data collected during the first half of GIT-2 (from enrollment to

treatment crossover). The goal of Aim 2 was to evaluate the feasibility of the intervention by examining change in patient-reported diabetes treatment satisfaction. The goal of Aim 3 was to look at efficacy of the intervention by evaluating change in A1c from baseline to the 3-month and 6-month follow-up periods.

Methods

Setting, Sampling and Recruitment

Patients with type 2 diabetes were recruited at the University of Massachusetts DCOE. The goal of the DCOE is to provide care to people with diabetes by coordinating a collaborative network to deliver comprehensive, patient-centered, high quality treatment. The DCOE is located in Worcester, MA and actively serves over 7,000 adults with diabetes.

Inclusion criteria included the ability to speak English and having T2D with two consecutive A1c recordings greater than 8.0 over the previous 12 months at the time of recruitment. Patients were excluded if they were cognitively impaired, pregnant, or prisoners. Daily assessment of inclusion criteria for all patients scheduled for routine appointments at the DCOE was conducted. Eligible patients were approached in the waiting room by research assistants to explain the details of the study. To enroll in the study, interested participants signed the study consent forms, had a baseline A1c lab drawn, and completed a baseline survey. Recruitment of participants took place from 4/1/2015 to 7/9/2015.

Randomization

A randomization table was created prior to the start of recruitment using the RAND function in Microsoft Excel (2007) to equally allocate 120 participants to the treatment groups. Study staff not involved with recruitment created enrollment folders for each participant based upon the randomization table. Study staff members responsible for recruitment were blinded to treatment group designation from study enrollment through baseline survey administration. The only difference between treatment group enrollment folders was the intervention-designated folders contained an additional question and information about the intervention on the last page of the baseline survey. For participants randomized to the intervention group, the last baseline survey item asked if they would like to schedule a tutorial to provide more information about the program and instructions on how to use the cellular-enabled glucose meter. If answered yes, study staff scheduled a time to call the participant approximately 7 days later, after the expected delivery of a start-up package in the mail containing the cellular-enabled glucose meter and necessary meter materials such as testing strips and lances.

Data Collection

Upon study enrollment, all participants had a study-specific A1c lab drawn at the UMass Memorial Ambulatory Care Center. Participants were scheduled to return at 3, 6, 9 and 12 months ±1 week post-study enrollment for quarterly A1c follow-up labs. Participants completed a baseline, 6-month, and 12-month survey. All surveys were completed by pen and paper. Participants were asked to complete the survey at the clinic. Participants were allowed to finish baseline surveys at home and mail them back, when

necessary. Data from the surveys were collected and managed using REDCap electronic data capture tools hosted at University of Massachusetts Medical School.[63]

Primary Outcomes

Aim 2: Evaluating feasibility by change in Diabetes Treatment Satisfaction.

Change in patient-reported diabetes treatment satisfaction was the primary outcome used to assess feasibility of the intervention. Diabetes treatment satisfaction has been shown to be associated with positive diabetes outcomes.[52] To measure participant satisfaction with their diabetes treatment, the Diabetes Treatment Satisfaction Questionnaire (DTSQ) was administered at each survey.[64] The DTSQ is an 8-item survey that asks patients to rate their satisfaction from 1 (very dissatisfied) to 6 (very satisfied) on the following areas of their diabetes care: satisfaction with current treatment, feeling their blood sugars are unacceptably high recently, feeling their blood sugars are unacceptably low recently, how convenient their treatment is, how flexible their treatment is, how satisfied they are with the understanding of diabetes, how likely they are to recommend their treatment, and how satisfied they are to continue with the present form of treatment. To evaluate change in satisfaction attributable to the intervention, the Diabetes Treatment Satisfaction Questionnaire Change (DTSQc) was included in the 6-month follow-up and 12-month final surveys. The DTSQc is an 8-item survey that asks the extent to which participants experienced change in satisfaction over the course of the previous 6 months with responses ranging from much less satisfied now (-3) to much more satisfied now (3). The DTSQc, used in conjunction with the DTSQ, overcomes potential of ceiling effects encountered when only the status measure is used, allowing for interventions to show

greater value than possible with only the DTSQ measure being administered. To score the DTSQ and DTSQc, items 1, 4, 5, 6, 7 and 8 are added together for each scale. Item 2 (perceived frequency of hyperglycemia) and item 3 (perceived frequency of hypoglycemia) are treated individually in data analyses.[64]

Aim 3: Evaluating efficacy by change in A1c. Change in A1c was the primary outcome used to assess physiological efficacy of the intervention. A1c provides an estimate of blood sugar control over the previous 2-3 months and is the test of choice for the chronic management of diabetes.[65] A1c change was evaluated by comparing the mean changes in A1c from baseline to the 3 and 6-month follow-up visits between treatment groups.

Covariates

Additional patient-reported covariates were collected in order to evaluate success of randomization by looking at baseline differences between treatment groups, to explore potential for mediation of intervention effects, and to conduct future exploratory secondary analyses. Included measures were selected to measure diabetes empowerment, patient activation, medication adherence, and social support and are described in greater detail below.

Diabetes Empowerment. The Diabetes Empowerment Scale – Short Form (DES-SF) is an 8 item self-report questionnaire created as a short form version of the original 36-item Diabetes Empowerment Scale (DES). The DES-SF has shown to be a valid and reliable measure of diabetes-related psychosocial self-efficacy.[66] Responses for each

item of the scale are on a Likert scale ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). A total score is calculated by averaging the scores of all the completed items.

Patient Activation. The Patient Activation Measure (PAM)-6 is a short-form of the original PAM-22 measure. It assesses patient knowledge, skill, and confidence for self-management by asking patients on a scale from Disagree Strongly to Agree Strongly their level of agreement with a set of statements about the management of their health.[67] A summary score is calculated using a custom scoring sheet provided by Insignia Health (Portland, OR).

Medication Adherence. The Morisky Medication Adherence Scale (MMAS)-8 was used to assess medication adherence.[68] The MMAS-8 is an 8 item scale measuring medication adherence with scores ranging from 0 to 8. The first 7 items are yes/no questions where yes=1, no=0 in items 1-4, 6-7 and yes=0, no=1 for item 5. Item 8 is a five-point likert scale ranging in values from 0-4, which is then divided by 4 to standardize the item's score to a maximum of 1 point. A total score of 0 indicates high adherence, 1-2 indicates medium adherence, and 3-8 indicates low adherence.

Social Support. The 8-item modified Medical Outcome Study Social Support (mMOS-SS) survey was used to assess social support. The mMOS-SS is a valid and reliable survey to measure social support in 2 subscales, emotional and instrumental social support.[69] A higher score indicates more support. To obtain a score for each subscale, the average of the scores for each item in the subscale is calculated. The overall support index is calculated by taking the average of all the 8 items and transform to a 0-100 scale

by the following formula: dividing (observed score-minimum possible score) by the (maximum possible score –minimum possible score) and multiplying by 100.

Description of Intervention

All participants randomized to the intervention group received an In Touch cellular-enabled glucose meter and were enrolled in the Livongo for Diabetes program[70] for 6 months. The meter, testing supplies, and enrollment in the diabetes care program were provided by Livongo free of charge.

The cellular-enabled glucose meter automatically uploaded all glucose recordings to a secure patient portal. Messages including feedback and tips designed to assist participants manage their diabetes were sent directly to the meter after each testing. These messages were developed using the American AADE National Standards for DSME curriculum. An algorithm selectively picked each message based on participant-provided data and the uploaded SMBG recordings. Other features of the meter included tagging SMBG recordings with important contextual information (before meal, after meal, neither, and how they were feeling at the time), tracking SMBG recordings with an electronic log book, and a built-in activity tracker. The meter also allowed participants to share SMBG data with anyone they designate as part of their care team (including their endocrinologist, primary care provider, caregiver, or family member) via text message, e-mail, or fax.

The Livongo for Diabetes care program is an accredited program by the AADE Diabetes Education Accreditation Program. The program includes both scheduled and in-the-moment support provided by CDEs certified through the National Certifying Board

for Diabetes Educators (NCBDE). The CDEs monitored all flagged SMBG recordings 24 hours a day and called participants the first time an uploaded blood glucose recording was above 250 mg/dL and greater than 400 mg/dL thereafter. The CDEs would also call participants if their SMBG recordings were below 40 mg/dL at any time during the study period. If an uploaded recording generated an alert for being too high or low, a CDE would contact the participant within 3 minutes of receiving the notification. After any call from the CDEs, participants were allowed to change the high or low threshold that would prompt a call. The CDEs also provided support through scheduled coaching sessions delivered over the phone and via email, as requested by participants. All coaching sessions were based on the AADE's 7 self-care behaviors; healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and health coping.[48] While CDEs did not give participants medical advice or make changes to their care plans, they could answer diabetes-specific questions including topics such as nutrition and lifestyle changes and contact participants' providers if they believed uploaded SMBG recordings or conversations with participants warranted intervention from the participants' care teams.

Sample Size Estimation

The primary physiological outcome of this study was change in A1c. We anticipated the distribution of change in A1c from baseline to 6-months would approximate a normal distribution, allowing for the use of a standard t test to examine differences in mean A1c change between treatment groups. Assuming a 1.0 % difference in mean A1c change between treatment groups and a 1.5 SD in A1c change for both

groups, we needed 48 participants per group for 90% power at the p=0.05 level. Assuming a 10% drop out, 53 participants were required. A conservative approach was taken and resulted in the recruitment of 60 participants per treatment group. Sample size calculations were performed using SAMPSI command in Stata software version 13.1 (StataCorp, College Station, TX).

Analytic Plan

Bivariate comparisons of baseline characteristics between treatment groups using independent samples t tests for continuous variables were conducted to evaluate success of randomization. Baseline characteristics of the participants who failed to return for the quarterly A1c labs and follow-up surveys were compared against those who adhered to protocol by using independent samples t tests.

The primary outcome used to evaluate intervention feasibility was patient-reported diabetes treatment satisfaction. Paired-samples t tests were used to evaluate treatment satisfaction change within each treatment group. Independent samples t tests were used to examine differences in treatment satisfaction change between treatment groups. Linear regression models were also used to estimate the relationship between the intervention and change in treatment satisfaction. The crude regression model contained only the treatment group and change in treatment satisfaction variables. A second model was then constructed including patient demographic characteristics and patient reported covariates that had a $p<0.20$ difference between treatment groups in baseline bivariate comparisons. Demographic characteristics included age, sex, race, income, education and

use of the Internet. Patient-reported covariates included were patient activation, diabetes empowerment, and social support.

The primary physiological outcome used to evaluate efficacy of the intervention was change in A1c. Differences in A1c recordings from baseline to 3 and 6 months were examined using paired samples t tests to evaluate change within each treatment group. Independent samples t tests were used to examine change in A1c between treatment groups. Intention-to-treat versions of these analyses were conducted using the last observation carried forward (LOCF) data imputation method. The effects of the intervention on A1c change over time were analyzed using repeated measures, mixed-effects linear regression models. The primary model contained a group variable, a time variable (0, 3 months, 6 months), and a treatment-by-time interaction variable as independent variables. A secondary model also contained demographic characteristics, including age, sex, race, income, education, and use of the internet, and the patient-reported covariates that differed between groups at baseline under the $p<0.20$ level. Patient-reported covariates included in the model were patient activation, diabetes empowerment, and social support. All statistical analyses were conducted using Stata software version 13.1 (StataCorp, College Station, TX).

Results

Of 195 eligible patients approached for recruitment, 123 (63%) expressed interest in participating (Figure 3.1). Three participants failed to successfully complete the enrollment process. Of the 120 participants enrolled, 119 completed the initial survey (intervention n=59, control n=60) (Figure 3.1). We evaluated the success of

randomization by comparing baseline A1c, diabetes treatment satisfaction, demographic characteristics and patient-reported covariates between treatment groups (Table 3.1). Mean baseline A1c levels were 10.3 (SD=1.4) for the intervention group and 10.0 (SD=1.4) for the control group. Out of a highest possible score of 36, intervention group participants reported a mean treatment satisfaction score of 29.6 (SD=5.4) compared to 28.4 (SD=5.2) for control group participants. Age at enrollment ranged from 23 to 84 years old with an average age of 56.7 years. The study population was 52.5% women and 66.6% white. No differences in patient-reported medication adherence were seen at baseline between treatment groups while participants in the intervention group reported slightly higher diabetes empowerment (p=0.07) and patient activation (p=0.10) and slightly lower social support (p=0.16) compared to participants in the control group (Table 3.1).

Of the original 120 study participants enrolled, 92 (76.7%) completed the 6 month follow-up survey, 99 (82.5%) returned for the scheduled 3-month A1c lab and 96 (80.0%) returned for the 6-month A1c lab. Those who did not return for follow-up visits had significantly higher baseline A1c than those who returned for the scheduled A1c labs within both groups (Table 3.2). Among those who did not return for a follow-up A1c lab, the number of participants, mean baseline treatment satisfaction, and mean baseline A1c did not differ between the intervention and the control groups (Table 3.2).

Of the 60 participants who received the intervention, 26 (43%) requested and received a phone tutorial at the start of the study. Actual use of the meter varied within the group, with 27 (45%) participants using the meter on average more than once per

day, 26 (43%) participants using the meter on average less than once per day, and 7 (12%) participants not using the meter at all. Among the participants who used the meter, 23 were called at least once in response to their uploaded SMBG recordings with 20 participants receiving support from a CDE. Of the 20 participants who interacted with the CDEs, 11 scheduled at least one additional coaching session.

Change in Diabetes Treatment Satisfaction.

Among participants completing the 6-month follow-up survey, intervention group participants reported an improved mean treatment satisfaction change score of 12.9 (SD=5.6). This was in comparison to an improved mean treatment satisfaction score of 10.7 (SD 6.6) for the control group (p=0.09). At the individual item level, 3 items of the DTSQc showed greater improvement in the intervention group compared to the control group. They were: satisfaction with current treatment (p=0.07), how convenient their treatment is (p=0.02), and how satisfied they were with their understanding of diabetes (p=0.04) (Table 3.3).

Results from the multivariable linear regression models with change in treatment satisfaction as the dependent variable are shown in Table 3.4. In the primary model, intervention group participants showed a 2.3 unit greater improvement in diabetes treatment satisfaction score compared to control group participants (p=0.09). After accounting for age, sex, education, race, income use of internet, patient activation, diabetes empowerment, and social support, intervention group participants reported a 2.5 unit higher treatment satisfaction change score than the control group (p=0.08).

Change in Hemoglobin A1c.

Mean A1c for the intervention group were 10.3 (SD=1.4) at baseline (n=60), 8.8 (SD=1.1) at 3 months (n=48) and 8.9 (SD=1.0) at 6 months (n=47). Mean A1c for the control group were 10.0 (SD=1.4) at baseline (n=60), 8.9 (SD=1.4) at 3 months (n=51) and 9.0 (SD=1.5) at 6 months (n= 49). Mean A1c improvement at 3 months was 1.3 (95% CI: 0.8-1.7)) for the intervention group compared to 0.9 (95% CI: 0.5-1.3) for the control group (p=0.22) and at 6 months was 1.1 (95% CI: 0.7-1.6) for intervention group compared to 0.7 (95% CI: 0.3-1.1) for control group (p=0.14) (Table 3.5). Intent-to-treat analyses using LOCF imputation showed the change in A1c from baseline to 3 months was 1.0 (95% CI: 0.6-1.6) for intervention group participants compared to 0.75 (95% CI: 0.4-1.1) for control group participants (p=0.34). Mean change from baseline to 6 months was 0.9 (95% CI: 0.6-1.3) for the intervention group compared to 0.7 (95% CI: 0.4-1.0) for the control group (p=0.46).

A repeated measures mixed-effects linear regression model containing the treatment group, time, and treatment-by-time interaction as independent variables and A1c at baseline, 3 months, and 6 months as dependent outcomes showed that participants in both groups improved from baseline to 3-months ($p<0.001$) and maintained that improvement at 6-months ($p<0.001$). A1c was an estimated 0.41 greater improvement for Intervention group participants at 3 months and 0.38 greater improvement at 6 months compared to control group participants (p=0.12 and p=0.16, respectively) (Table 3.6). After accounting for demographic characteristics (age, sex, race, income, education, and internet use) and patient reported covariates (patient activation, diabetes empowerment,

and social support), intervention group participants had an estimated 0.45 greater improvement in A1c compared to the control group at the 3-month time point (p=0.12). This estimated difference in A1c improvement between the intervention and control group participants was 0.56 at the 6-month follow-up time point with intervention group participants seeing greater improvement (p=0.05) (Table 3.6).

Discussion

Feasibility and efficacy of a diabetes support intervention facilitated by cellular-enabled glucose meters were assessed in a population of patients with poorly controlled type 2 diabetes. Significant improvements in diabetes treatment satisfaction and reductions of A1c were seen within both control and intervention groups with improvement in treatment satisfaction greater for intervention participants. In per-protocol analyses, participants in the intervention group showed trends towards greater improvement in A1c compared to participants in the control group. Repeated measures mixed-effects model showed greater improvement of A1c from baseline to each of the follow-up time points for intervention group participants compared to the control group participants, albeit not at the $p<0.05$ statistical significant level. These results demonstrate the feasibility and potential efficacy of the intervention.

Similar interventions targeting patients with poorly-controlled diabetes have also shown potential to improve health outcomes for this increasingly prevalent and costly patient population.[18, 39, 58-62, 71, 72] Unique to this study is the in-the-moment support provided in response to low or high SMBG recordings uploaded instantly by cellular-enabled glucose meters. By contacting patients immediately after their

dangerously high or low blood glucose test results are taken, care teams can offer timely support when patients may need it most. They can also take advantage of a teachable moment to provide education and disease management training. Teachable moments have been described as times when patients are receptive to counseling, education, and discussions of lifestyle patterns, risk factors, or compliance.[73] During these teachable moments, care team members can help patients identify the reasons why their blood glucose is suboptimal at that time and advise on how best to prevent it from happening in the future.

In this population of poorly-controlled T2D patients, we saw improvements in treatment satisfaction and A1c in both intervention and control groups. In addition to an observer effect bias, the increased amount of interactions between patients and care team members, as the study protocol required both groups to return for quarterly A1c labs and follow-up surveys(with reminder calls preceding each), could also result in positive outcomes. Previous studies have also found that patients with diabetes who fail to show for routine appointments have worse health outcomes, lower SMBG rates, and greater medication non-adherence.[74-76] This is supported by our finding that patients from both groups who failed to return for the follow-up visits had higher baseline A1c levels. Future studies should plan additional intervention activities to engage these patients who are at risk for being lost to follow-up. A possible solution would be to add a structured, scheduled coaching session component to encourage participation in the study while providing an additional opportunity to deliver diabetes self-management education. Similar program have shown to successfully improve health outcomes in this

population.[77] An alternative approach would be to involve caregivers in the intervention. In addition to encouraging their patients to engage in the study, providing caregivers access to patient's uploaded SMBG recordings can improve the quality of support they are able to provide and reduce caregiver burden. The effects of this intervention on caregiver support and burden were not investigated in this study but should be considered in future work.

There were several strengths and limitations of this study. Strengths included recruiting an inflated sample size that adequately accounted for participant drop out allowing for power to detect a clinically meaningful difference in A1c change between groups to be retained. Other strengths included the collection of both physiological outcomes (A1c) and patient-reported outcomes (diabetes treatment satisfaction). The collection of patient-reported demographics and diabetes-specific covariates were also strengths of the study. Limitations of this study included the relatively short time frame of receiving the intervention (6 months) and the duration of diabetes per participant was not collected. These limitations are especially important considering the primary outcome, change in A1c, is a measurement for glucose instability over an extended period of time. Other limitations were that participants who failed to return for follow-up visits had higher baseline A1c levels than those who did return. This suggests additional efforts must be done to engage patients with very poorly-controlled diabetes.

This intervention resulted in improved treatment satisfaction and health outcomes that approached being significantly greater than the improvements seen by the control group, demonstrating feasibility and efficacy potential. Next, we will analyze post-

crossover effects for each group in order to evaluate intervention maintenance among intervention participants and intervention effects among the participants who first served as controls. Future studies should consider including a scheduled coaching component, involve the caregivers of patients, and invest additional efforts to engage sicker patients who are more likely to drop out of study activities.

Figure 3.1. Get In Touch – Phase 2 Study Overview

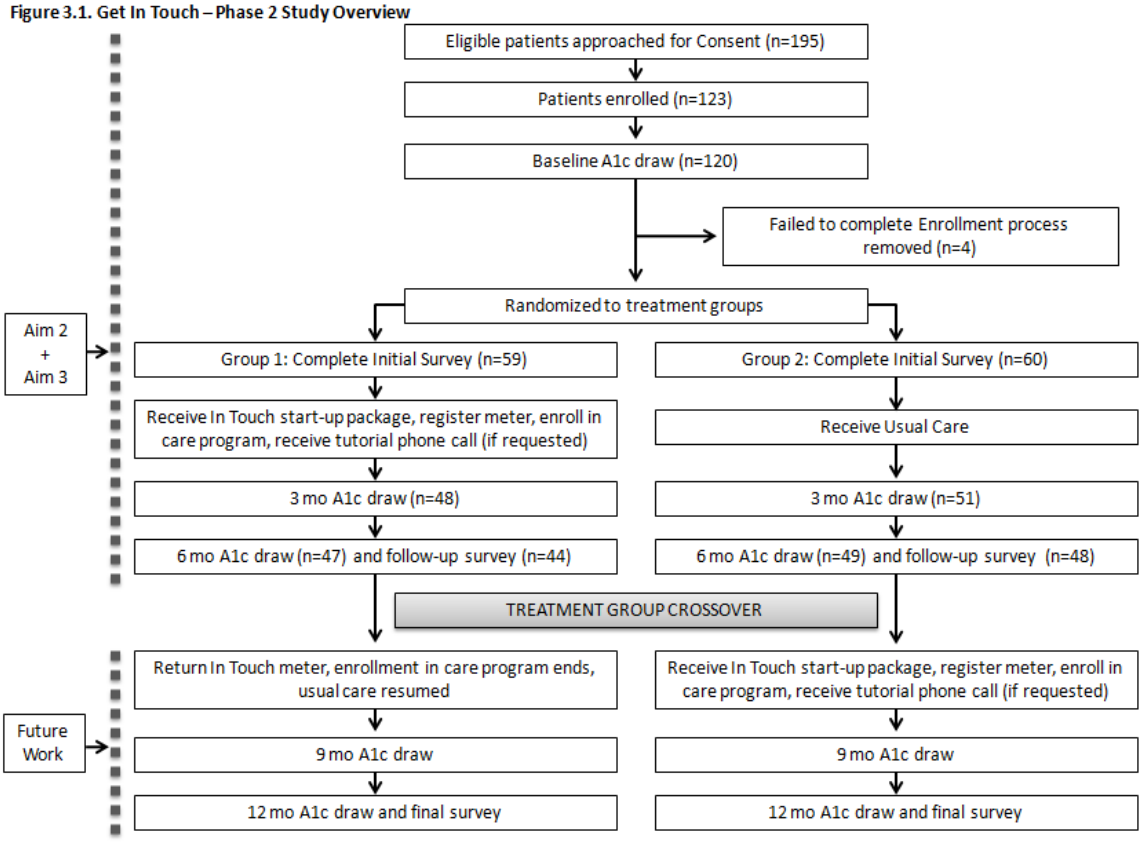

Table 3.1. GIT-2 Study Population Demographics			
Characteristics	**Intervention n=59***	**Control n=60**	**p**
Age, mean(SD)	56.1 (11.1)	57.4 (12.1)	0.55
Age Categories, (%)			
18-40	8.3	6.7	
40-65	71.7	65.0	0.56
65+	20.0	28.3	
Gender, (%)			0.36
Women	56.7	48.3	
Race, (%)			
White	61.6	71.7	
Black	10.0	5.0	
Hispanic Latino	18.3	15.0	0.75
Native/Alaskan American	1.7	0.0	
More than 1 race	3.3	3.3	
Not Reported	5.0	5.0	
Education, (%)			
<High School Grad	15.0	11.7	
High School Grad	30.0	28.3	
Post High School Trade	10.0	8.3	0.80
1-3 years College	23.3	26.7	
College Grad	18.3	21.7	
Not Reported	3.3	3.3	
Household Income, (%)			
<20k	40.0	36.7	
20-50k	18.3	23.3	
50-100k	16.7	18.3	0.78
>100k	18.3	11.7	
Not Reported	6.7	10.0	
Internet Access, (%)			
No	15.0	18.3	
Yes	83.3	78.3	0.73
Not Reported	1.7	3.3	
Internet User, (%)			
No	28.3	33.3	
Yes	68.3	63.3	0.84
Not Reported	3.3	3.3	
A1c %, mean (SD)*	10.3 (1.4)	10.0 (1.4)	0.21
Treatment satisfaction, mean (SD)	29.6 (5.3)	28.4 (5.2)	0.24
Diabetes empowerment, mean (SD)	4.0 (0.6)	3.8 (0.7)	0.07
Patient activation, mean (SD)	58.6 (13.4)	55.0 (10.0)	0.10
Medication adherence, mean (SD)	2.8 (1.9)	3.1 (1.9)	0.24
Social support, mean (SD)	26.1 (8.5)	28.5 (8.8)	0.16

*n=60 in Intervention Group for baseline A1c %

Table 3.2. Baseline characteristics. Participants returned for 6-month follow-up per-protocol vs. those who did not return, by group							
	Intervention group			**Control group**			**Did Not Complete IV vs. Control p**
	Completed 6-month	**Did Not Complete 6-month**	**p**	**Completed 6-month**	**Did Not Complete 6-month**	**p**	
	n=40	n=16		n=44	n=15		
Treatment Satisfaction, mean (SD)	29.3 (5.6)	30.2 (4.8)	0.58	28.2 (5.3)	29.1 (4.9)	0.56	0.53
	n=47	n=13		n=49	n=11		
A1c, mean (SD)	10.1 (1.2)	11.1 (1.6)	0.01	9.7 (1.1)	11.3 (2.0)	<0.001	0.88

Table 3.3. Change in Diabetes Treatment Satisfaction, by group						
	Intervention group		**Control group**		**Intervention-Control**	
	n	**Mean (SD)**	**n**	**Mean (SD)**	**Difference**	**p**
Baseline DTSQ	56	29.6 (5.4)	59	28.4 (5.2)	1.2	0.24
6 Months DTSQ	41	31.1 (3.9)	45	29.4 (4.8)	1.7	0.07
Change at 6 Months, Overall DTSQc	41	12.9 (5.6)	46	10.6 (6.6)	2.3	0.09
Change at 6 Months, Individual DTSQc Items						
Satisfaction with current treatment	42	2.2 (1.1)	48	1.7 (1.2)	0.46	0.07
Felt blood sugars unacceptably high recently	41	0.93 (1.8)	48	1.1 (1.7)	-0.16	0.67
Felt blood sugars unacceptably low recently	42	-0.38 (1.6)	48	-0.38 (1.8)	0.00	0.99
How convenient treatment is	42	2.2 (0.8)	47	1.5 (1.4)	0.61	0.02
How flexible treatment is	41	2.0 (1.3)	48	1.6 (1.4)	0.41	0.15
How satisfied with understanding of diabetes	42	2.3 (1.0)	48	1.7 (1.5)	0.56	0.04
How likely to recommend treatment	42	2.1 (1.3)	47	2.0 (1.3)	0.12	0.66
How satisfied to continue with present form of treatment	42	2.2 (1.2)	48	1.9 (1.3)	0.34	0.20

Table 3.4. Linear regression results predicting change in Diabetes Treatment Satisfaction			
Variable	**Coefficient**	**SE**	**p**
Intervention			
Crude	2.3	1.3	0.09
Full model*	2.5	1.4	0.08

*Accounts for age, gender, education, race, income, internet use, diabetes empowerment, patient activation, and social support

Table 3.5. Change in A1c, by group						
	Intervention group		**Control Group**		**Intervention - Control**	
A1c % Results	**n**	**Mean (SD)**	**n**	**Mean %**	**Difference**	**P***
Baseline, mean (SD)	60	10.3 (1.4)	60	10.0 (1.4)	0.32	0.21
3 month						
Per-protocol, mean (SD)	48	8.8 (1.1)	51	8.9 (1.4)	-0.14	0.59
Intention to treat, mean(SD)	60	9.3 (1.5)	60	9.2 (1.7)	0.08	0.80
Change from Baseline to 3 month						
Per-protocol, mean (95 % CI)	48	-1.3 (0.81-1.69)[a]	51	-0.88 (0.47-1.30)[a]	0.37	0.22
Intention to treat, mean (95% CI)	60	-1.0 (0.63-1.37)[a]	60	-0.75 (0.39-1.11)[a]	0.25	0.34
6 month						
Per-protocol, mean (SD)	47	8.9 (1.0)	49	9.0 (1.5)	-0.05	0.86
Intention to treat, mean(SD)	60	9.4 (1.5)	60	9.2 (1.8)	0.14	0.64
Change from Baseline to 6 month						
Per-protocol, mean (95% CI)	47	-1.1 (0.69-1.57)[a]	49	-0.71 (0.34-1.08)[a]	0.42	0.14
Intention to treat, mean (95% CI)	60	-0.91 (0.55-1.3)[a]	60	-0.73 (0.40-1.06)[a]	0.18	0.46

* independent-samples t test

[a] paired sample t test, significant at p<0.001 level

Table 3.6. A1c Repeated Measures Mixed Effects Regression Results, Empty and Full Model						
	Crude Model			**Full Model***		
Variable	**Beta Coefficient**	**SE**	**p**	**Beta Coefficient**	**SE**	**p**
Treatment						
Control (ref)						
Intervention	0.32	0.25	0.20	0.27	0.25	0.28
Time						
Baseline (ref)						
3-mo visit	-0.97	0.19	<0.001	-1.02	0.21	<0.001
6-mo visit	-0.87	0.19	<0.001	-0.84	0.21	<0.001
Treatment x Time						
Intervention, 3-mo	-0.41	0.26	0.12	-0.45	0.29	0.12
Intervention, 6-mo	-0.38	0.27	0.16	-0.56	0.29	0.05

*Accounts for age, sex, race, education, income, internet use, diabetes empowerment, patient activation, social support

CHAPTER IV

CONCLUSIONS AND DISCUSSION

The overall purpose of this dissertation was to evaluate the acceptability, feasibility, and preliminary efficacy of a diabetes care support program provided by CDEs and facilitated by cellular-enabled glucose meters. To accomplish these aims, we conducted a multi-phase study at the University of Massachusetts Medical School DCOE. The first phase was a 1-month acceptability pilot involving patients with T1D and T2D. The second phase was a 12-month randomized crossover trial involving patients with poorly-controlled T2D. Preliminary results at the 6-month time point are reported in this dissertation.

In the acceptability pilot, we found that patients with both T1D and T2D were generally satisfied with the care program and reported that the cellular-enabled glucose meter was both useful and easy to use. Participants particularly liked the automatic upload feature of the meter and the additional support provided by the CDEs. Important areas identified for improvement included providing additional training and education about the functionality of the meter. In the first half of the subsequent randomized crossover trial, we saw significant improvements in treatment satisfaction and A1c results for patients in both groups, with trends towards greater improvement in the intervention group when compared to the control group.

Diabetes is a very complex disease with several patient health management demands that could benefit from innovative technological interventions.[78] Common barriers to utilizing patient-facing technology to manage diabetes include physically possessing the technology throughout the day, knowing how to operate, execute, and take advantage of different functions and services, and receiving positive endorsements from

providers who may doubt the benefits are worth the additional time, effort and uncompensated work that will be created for them.[40] We believe the Livongo for Diabetes support program and the In Touch cellular-enabled glucose meter addresses several of these barriers. By providing patients with cellular-enabled glucose meters as part of the intervention, the physical barriers of owning the equipment were addressed. The automatic upload feature of the cellular-enabled glucose meter eliminated the need to possess any additional equipment or to know how to execute a SMBG upload. The meter also had a user-friendly touch screen interface and used testing strips that were thicker and easier to handle than most strips currently available. The support program was also run by CDEs employed by Livongo, adding little additional burden on the regular clinical care team.

Among the participants who completed the follow-up protocols, overall improvements were seen for both the intervention and control group. The design of this study may have contributed to this study effect. Per study protocol, participants from both groups were scheduled to return at 3 and 6 months for A1c labs and were called to remind them of their upcoming appointments. Increased frequency of encounters between patients and providers has been shown to lead to improved health outcomes for patients with diabetes,[79, 80] suggesting that efforts to engage patients may have significant health benefits. This is especially true if interventions can tailor the support to the patients' level of activation. Patient activation has been defined as a patients' willingness and ability to take independent actions to manage their health and care.[81] Providing flexible support that addresses the varying needs and preferences of patients and then

setting reasonable goals that are achievable by the patients has shown to result in benefits among patients with both high and low patients activation.[81]

Tailoring support to meet the needs of patients is important to consider in the context of our study. To investigate the potential of the intervention, we recruited a population of patients with poorly-controlled diabetes. By selecting this specific population, the risk of successfully retaining participants in the study was heightened. This risk was demonstrated as the majority of those who failed to return for follow-up visits had significantly higher A1c levels at enrollment. As there were no differences among those who failed to be retained between treatment groups, it suggests that the intervention was equally unsuccessful at engaging these hard to reach patients as usual care was. To increase patient engagement and improve patient activation, future studies should tailor outreach and support so that it is amenable to all participants.

Support provided by the CDEs in the intervention consisted of outreach in response to high or low SMBG recordings and through coaching appointments as requested by participants. While in-the-moment support may have been valuable to patients who tested high or low with the meter and scheduled support may have assisted patients who were activated enough to seek additional help, there was minimal CDE support delivered routinely to all patients receiving the intervention. Scheduled, periodic coaching sessions using telehealth technology have been shown to improve diabetes health outcomes and lower costs by reducing the number of in person visits.[42, 62, 82] Future studies should consider implementing scheduled coaching sessions with the CDEs to complement in-the-moment and requested support provided.

A key component to delivering health education and self-management training is taking advantage of teachable moments. Teachable moments are periods when patients are particularly receptive to counseling, education, or a simple discussion of lifestyle patterns, risk factors, or compliance.[73] In our intervention, the responsive support provided by the CDEs presented opportunities to take advantage of teachable moments that occurred immediately after a concerning SMBG level was recorded as patients may be more receptive to learning about their disease as they are experiencing complications. While other participants may have not been well enough at that moment to process information or counseling, the support call still provided the opportunity to schedule future coaching sessions and to have a tailored discussion regarding their recent experience. This support could also be particularly beneficial for patients who have recently been diagnosed, switched medications, are beginning administration of insulin or adjusting their insulin dosage. These patients will experience changes in their health status that may generate questions that are best answered immediately. Receiving this timely support could be very beneficial as shown by a recent telehealth intervention that effectively helped patients reach optimal insulin dose, resulting in higher treatment satisfaction.[82]

There were several strengths and limitations to this study. Strengths included a mixed-methods approach consisting of both qualitatively evaluating the acceptability in patients with both T1D and T2D and quantitatively assessing feasibility and efficacy by conducting a randomized trial comparing the intervention to usual care received at a diabetes specialty clinic. To assess feasibility and efficacy, we used both patient reported

and physiological measures as the primary outcomes and collected data at baseline and at multiple follow-up periods. We believe the cross-over trial design was also a strength as it presented the opportunity for all participants to receive the intervention.

In addition to positive acceptability, feasibility, and efficacy of the intervention from the patient perspective, an effective intervention must also fit into the clinical work flow of a care team in order for benefits seen to be sustainable. In the case of GIT-2, data from the cellular-enabled meters flowed directly into each patient's EHR and intervention CDEs provided weekly reports on interactions with patients. Both of these intervention components were designed to improve the delivery of comprehensive, coordinated care without taxing the regular care team's resources. This was an important strength of the intervention.

A limitation of the study was the relatively small sample size who received the intervention over a limited period of time during GIT-2. This is especially limiting considering that the primary efficacy outcome, change in A1c, is a metric that averages the amount of blood glucose over a 3 month period of time. A longer time enrolled in the intervention may be required by some to see benefits in A1c. We also experienced a moderate loss of participants to follow-up, especially among those with very poorly controlled A1c levels. Because of the multiple components of the intervention, it was difficult to tease apart benefits seen due to the care support program and those resulting from using a technologically advanced glucose meter. Furthermore, there was minimal data collected on the utilization of different functions on the meter for this analysis, restricting the potential to look at the benefits each function provided.

Next we will evaluate the data from the second half (post treatment crossover) of GIT-2. It will be particularly interesting to see if the benefits seen amongst the intervention group are maintained after they no longer have access to the cellular-enabled glucose meter and CDE support. It will also be interesting to see if benefits achieved by the control group are increased even greater upon receiving the meter and access to additional CDE support. Additionally, all study participants are provided with the option to continue in the program on a subscription payment ($25/month) basis. Monitoring the patients who choose to pay for the service out of pocket may provide additional insight into the long term effects of the intervention.

SUPPLEMENTARY MANUSCRIPT:

THE PROMISE OF TELECOMMUNICATION TOOLS TO "REACH" THE DISENGAGED PATIENT WITH DIABETES.

Abstract

Purpose of Review

To discuss recent research on the use of telecommunication technologies to improve care for disengaged patients with diabetes.

Recent Findings

It is established that patients who are disengaged with their health care have worse health outcomes. Reasons for disengagement vary but could be due to difficulties accessing or affording care or not possessing the skills or tools required to manage their disease. New patient-facing technologies are being used to improve communication and coordination of care for patients with diabetes. Early results show improvements in health outcomes. Utilizing these technologies to reach patient groups susceptible for disengagement has begun to demonstrate improvement.

Summary

Research over the past year has continued to demonstrate the promise of using telecommunication tools to assist patients in the management of diabetes. While a few studies looked specifically at disengaged patients, efforts to utilize appropriate technological interventions targeting specific groups of patients are needed.

Introduction

Diabetes Mellitus is a complex, chronic condition affecting over 29 million Americans and costing over $245 billion dollars in direct and indirect costs per year for diagnosed individuals. [83] Managing diabetes is very demanding of patients. Appropriate self-management requires a significant amount of time, energy, and discipline. Patients are required to make difficult behavioral changes in their diet and exercise habits. They often need to monitor their blood glucose levels and self-administer complex medication regimens. Effective self-management of diabetes requires a high-degree of disease knowledge as patients must interpret their self-monitored blood glucose (SMBG) recordings and adjust their physical activity, diet, and medications accordingly.

The demands of self-caring for diabetes are often overwhelming for patients.[84] Frequent interactions between patients and their care teams are required to answer questions, troubleshoot new situations, and make adjustments to their medications and care plan. While frequent interaction with care teams is recommended for most patients with diabetes, actual engagement is surprising low for many patients. Patients with diabetes that are disengaged with the management of their care have higher Hemoglobin A1c (A1c), anxiety, and depression levels.[85]The cost of medical care for disengaged patients with poorly controlled diabetes is ultimately greater as they more likely to require emergency services and have worse health outcomes with more co-morbidities.[86, 87]

Reasons for disengagement

There are several potential reasons, involving both extrinsic and intrinsic factors, for patients with diabetes to become disengaged with the management of their own health.[88] Access barriers include living in rural or low-income locations, having insufficient transportation or insurance coverage, or not being able to afford to pay for clinical visits and medications. Disengaged patients may also not have time available to regularly interact with their care team because they can't afford to miss work, have trouble getting appointments that fit their schedule, or are too busy managing other personal, family, or co-morbidity obligations. Language barriers can also result in disengagement as non-English speaking patients may not understand their care plan or be able to effectively communicate with their care team.

There may also be intrinsic reasons why patients are disengaged from their care team. Patients may not possess the appropriate attitude, knowledge, or skill set to effectively self-manage. They may be embarrassed about their health status or that they did not meet goals set with their care team or believe interacting with their care team may result in undesired negative feedback. There may be a perceived lack of value of regular interactions with their care team and missing appointments with no follow-up scheduled can lead to a prolonged absence from care. Males and younger adults have particularly shown to be more at risk of disengagement.[85] Previous studies have also shown that satisfaction with treatment and relationship with providers are both associated with adherence to treatment plans.[89]

Using telecommunication technologies to engage patients

A potential solution to reach disengaged patients is to leverage emerging telecommunication technologies. This is particularly true for mobile-health (mHealth) interventions as 64% of American adults now own a smartphone.[90] Technological interventions could be particularly beneficial reaching young people as they are high users of technology while people of lower SES status and of non-white race are more likely to depend on their smartphone for Internet access.[90] As technology becomes more entwined in the everyday lives of our population, the potential for leveraging its use for health promotion, disease prevention and management rises accordingly, especially for typically hard-to-reach, vulnerable populations of patients with diabetes.

A promising technological approach to reach disengaged patients is to encourage the adoption and utilization of electronic patient portals. A patient portal is an online personal health records "tethered" with a healthcare provider's electronic health record system, allowing patients to access and contribute personal health information (PHI), communicate with their care team, and utilize various tools to manage their health.[40] Functions available through a portal vary by healthcare organization but typically include access to PHI, secure messaging with care team, online appointment scheduling and reminders, requesting prescription refills, and provision of tailored health information and education. Patient portals serve as a valuable alternative to the traditional encounter with the health care system and may be particularly helpful for patients who are disengaged due to access difficulties such as a lack of time available or living in a rural location. There were several studies in the past year that examined patient portal use and its effects

in the management of diabetes.[91-93] This should be expected as the number of providers are offering more enhanced portal features in response to the meaningful use requirement of the Health Information Technology for Economic and Clinical Health Act (HITECH).[94]

Additional telehealth interventions could be valuable for patients with access difficulties. Telehealth involves the use of audio, video, and other telecommunications technologies for the transmission of information and data relevant to the diagnosis and treatment of medical conditions, to provide health services or aid healthcare personnel at distant sites, and for health promotion and disease prevention.[95] Telehealth consultations via video, telephone, or e-messaging eliminate physical barriers of traveling to clinical appointments and can facilitate both regular and emergency consultations. Telehealth systems can also provide a means of secure transmission of patient self-management data to web-based patient portals accessible to patients, caregivers, and care teams. Access to this data improves the ability of providers to monitor patients' health status and adjust care plans and medications without requiring patients to attend clinics in person. This is in contrast to traditional in-person care that requires patients to be more engaged and show up in person. Recent interventions that involve the sharing of patient self-management data to inform telehealth consultations with nurses, pharmacists, and certified diabetes educators have all shown varying degrees of benefits.[61, 96]. Health care that requires frequent assessment, for example wound care, may be particularly suited for telehealth monitoring.[97]

Patients who report experiencing trouble accessing health care services are more likely to use technology to search for health information.[98] In addition to searching for and obtaining health information, the "Web 2.0" movement has created public and private platforms for patients to share and contribute their own health information.[99] Social media outlets such as Twitter or Facebook allow patients to access and publically post information while online social support groups and websites provide more private opportunities for patients to obtain health information and disease management support.

While the potential roles of telecommunication technology interventions in health care are numerous, in this paper we focus on their potential to reach the difficult to treat 'disengaged' patient. To do so, we highlight recent studies that evaluate telecommunication technologies in special or vulnerable populations of patients with diabetes. This includes pregnant women, Veterans, patients from rural or urban communities, and patients with poorly-controlled diabetes.

Recent Findings

The following highlighted studies were published between 2014-2015. They are separated into two categories, studies aimed to evaluate acceptability, feasibility, and preliminary efficacy of a new technological innovation to a certain group of patients or practice and studies aimed to evaluate efficacy of such interventions.

Evaluating Acceptability, Feasibility, and Preliminary Efficacy

As new technologies are introduced to patients, it is important to evaluate acceptability by both patients and their care teams, feasibility of integrating into current care patterns and preliminary efficacy. Several studies published in the past year aimed to

evaluate acceptability of new technologies. Many of these studies are qualitative in nature, limited in the number of study participants, and last for a brief duration of time. While not intended to assess long-term clinical or patient-reported efficacy, these studies serve as a critical first step in evaluating the introduction of emerging technological interventions.

Even for technologies that have previously shown to be beneficial, it is important to replicate results in different populations and settings. This is particularly true for disengaged patients for which the potential benefits of telecommunication technologies are great. Siminerio et al.[100] found that patients in rural populations receiving consultations with endocrinologists through a videoconferencing intervention reported high levels of satisfaction and improvements in patient empowerment, self-care skills, and reduction in diabetes distress. Robinson et al.[101] also evaluated the use of videoconferencing home consultations for patients with poorly controlled diabetes and found the majority of patients were satisfied with the technology. Care team members also reported satisfaction and noted advantages such as reaching patients who typically are absent from in-person visits, improved real-time treatment and management, and being able to view a patient's home setting including their food items and prescription bottles. Given et al.[102] conducted a small randomized controlled trial (RCT) pilot of patients with gestational diabetes to evaluate an intervention consisting of weekly blood pressure, weight measurement, and SMBG recordings transmitted through a telemedicine hub by patients for review by a care team member. The majority of patients receiving the intervention reported being satisfied and both patients and providers reported that the

technology was easy to use. Providers also expressed that in the future if telemedicine replace regular appointments that protected time would be necessary. Welch et al.[103] also looked at satisfaction of a 3-month telemedicine intervention primarily among African-American and Latino patients with poorly controlled diabetes at an urban community health center. The intervention consisted of a home monitoring device connected to an electronic pillbox, a Bluetooth®-enabled glucose meter and a blood pressure monitor with telehealth nurses receiving regular data alerts from the home monitoring system and calling patients at scheduled intervals. They found consistently high ratings of usability and program satisfaction from patients and providers. Additionally, they found clinically and statistically significant improvements in blood glucose control.

Evaluating efficacy

While evaluating the acceptability, feasibility, and preliminary efficacy of new technologies used to manage diabetes is a critical first step, the effects on clinical and patient-reported outcomes should also be assessed to establish efficacy. Several studies over the past year investigated the effects of using telehealth systems, videoconferencing, and mHealth interventions to improve the management of diabetes in difficult to manage or disengaged patient populations.

Telehealth systems with remote monitoring devices

Carral et al.[104] examined the effects of a telehealth system that supported web-based manual entry of SMBG values, insulin dose administration, and carbohydrates consumed followed by regular asynchronous communication with a care team compared

to usual care in a population of pregnant women. While they found no significant difference in mean A1c change during pregnancy or after delivery, patients in the telehealth group required insulin therapy less frequently and had significantly lower number of clinical visits. Since standard care for women with gestational diabetes calls for intensive glucose assessments every 1-2 weeks, the use of telehealth to reduce overall in-person visits while maintaining similar levels of glycemic control and maternal and neonatal outcomes may be particularly beneficial for those with difficulty frequently attending in-person visits.

Shane-McWhorter et al.[41] conducted a case-control study to assess the effects of a remote monitoring system to provide electronic preprogrammed feedback supplemented by pharmacist Certified Diabetes Educators (CDEs) in a predominately Hispanic population recruited from community health centers. A1c was significantly lower in the telemonitoring group (2.07% decrease vs. 0.66% decrease). They also found a positive improvement in patient-reported outcomes such as self-efficacy and diabetes and hypertension knowledge in the intervention group.

Crowley et al.[72] evaluated the use of an interactive voice response (IVR) system in a veteran population with poorly controlled diabetes. Veterans randomized to the intervention group monitored their blood glucose levels before meals and at bedtime and received daily IVR calls to report their SMBG recordings followed by regular 2-week calls from home telehealth nurses to review SMBG data, reconcile medications, assess medication adherence, and administer a diabetes self-management support module.

After 6 months, A1c had improved by 1.3% for intervention participants compare to 0.3% for usual care participants.

Nicolucci et al.[62] evaluated the use of a home telehealth system for patients with poorly-controlled diabetes to monitor body weight, blood glucose, and blood pressure values with a Bluetooth®-connected hub with educational support provided by a general practitioner. In this RCT, the telehealth group saw significant reduction in A1c levels, improvement in patient-reported quality of life, and reduction of specialist visits compared with the control group.

Videoconferencing consultations

Videoconferencing offers a potential solution for patients who are disengaged due to inability to regularly attend in-person visits. Young et al.[42] conducted an RCT to examine the effects of a nurse delivered telehealth coaching intervention for patients with diabetes living in rural communities. Intervention participants were offered nurse coaching via either telephone or videoconferencing. They found significantly higher self-efficacy scores for patients receiving the intervention compared to those in the control group. Trends towards significance were also noted for improved physical health, mental health, and satisfaction with care.

Harris et al.[105] conducted an RCT to compare the effectiveness of delivering the Behavioral Family Systems Therapy for Diabetes (BFST-D) in clinic compared to videoconferencing in a population of patients with poorly controlled Type 1 diabetes. They found statistically significant improvements in adherence and glycemic control in both groups with no significant between-group differences.

mHealth Interventions

Interventions involving mHealth have potential to reach the increasingly number of patients with cell phones. Arora et al.[71] conducted an RCT to test the effects of a 6 month text message program targeting low-income, Spanish speaking patients with poorly-controlled diabetes from an urban, public emergency room setting. Intervention participants received 2 daily text messages intended to enhance patient motivation, self-efficacy, and ability to perform diabetes self-care behaviors. They also found trends of greater improvement in A1c change, medication adherence, and reduced utilization of emergency services.

Levy et al.[82] also evaluated a mHealth intervention in an urban, low-income population. They conducted an RCT to test the effects of using text messages and phone calls to help patients reach optimal insulin dose within 12 weeks. Patients randomized to the intervention group received weekday text messages requesting their fasting blood glucose values which were monitored by a nurse who would call the patient to adjust insulin doses. They found a significantly greater proportion of patients in the intervention group reached their optimal insulin dose than patients in the control group. Patients receiving the intervention also reported higher treatment satisfaction compared to the control group.

Summary

Telecommunication technologies have shown promise of improving self-management skills and medical care for patients who are likely to be disengaged with the management of their health. Moving forward, it will be important to target specific

populations of patients and provide appropriate technology, training, support, and motivation to utilize such technologies to achieve maximum benefits. The key to maintaining engagement in such interventions appears to be continual support and interaction between patients and their care teams. It is also important to implement targeted telecommunication technology interventions that demonstrate benefits in pilot and efficacy testing into everyday practice. Ideally, telecommunication technologies should be utilized in a fashion that not only helps patients improve self-management of their disease but also to help providers deliver more efficient, coordinated, and quality health care to patients with diabetes.

Key Points

- Recent studies have shown that telecommunication technologies can improve management of diabetes.
- Highlighted studies evaluate the use of patient portals, videoconferencing, telehealth systems, and mHealth telecommunication technologies on the delivery of care and patient self-management of diabetes.
- The use of telecommunication technologies has shown to be particularly beneficial in reaching disengaged, special, or vulnerable populations of patients with diabetes.

Table S.1. Characteristics and Results of Acceptability and Feasibility Studies involving the use of telecommunication technologies in Diabetes						
1st Author, year	**Study Aim**	**Study Type**	**N**	**DM Type, Study Population**	**Telecommunication Tools**	**Main Findings**
Siminerio, 2014 [100]	To examine diabetes-related behavioral and psychosocial outcomes as well as patient satisfaction with the Telemedicine for Reach, Education, Access, and Treatment (TREAT) model.	Prospective Cohort	35	T2DM Rural Population	Videoconferencing	Patients reported high levels of satisfaction and significant improvement in empowerment, self-care, and reduction in diabetes distress
Robinson, 2015 [101]	To determine satisfaction and usability of patients and diabetes care team members with videoconferencing capabilities.	Prospective Cohort	34	T2DM Poorly controlled diabetes population	Videoconferencing	83%% of patients reported videoconferencing was as helpful as and more convenient than an office visit. 76% agreed that FaceTime was effective in improving diabetes.
Given, 2015 [102]	To determine the feasibility and acceptability of using telemedicine in the diabetes care of women with GDM and the possibility of replacing alternate diabetes review appointments with telemedicine.	RCT Pilot	50	GDM Pregnant women population	Home monitoring	Eighty-nine percent of patients were satisfied with telemedicine and would use it again. Both HCPs and patients found the equipment easy to use and were positive about using it to replace alternate diabetes review appointments in the future. Healthcare providers felt that protected time in which to perform the telemedicine review would be necessary.
Welch,	To examine the usability, satisfaction, and clinical impact	Prospective	30	T2DM	Home monitoring, Scheduled nurse	High levels of remote home monitoring device use during the intervention period,

2015 [103]	of a 3-month diabetes telehealth intervention for poorly controlled type 2 diabetes (T2D) patients.	Cohort		Urban population	coaching	high ratings of usability and program satisfaction from patients, and high ratings of provider satisfaction with the program. Clinically and statistically significant improvement in blood glucose control at 3 months.

Table S.2. Characteristics and Results of Studies evaluating telecommunication technologies in Diabetes

1st Author, year	**Study Aim**	**Study Type**	**N**	**DM Type, Study population/ setting**	**Telecommunication Tools Examined**	**Main Findings**
Carral, 2015 [104]	To examine the impact of a Web-based telemedicine system for monitoring glucose control in pregnant women with diabetes on healthcare visits, metabolic control, and pregnancy outcomes	Prospective Cohort	104	GDM, T1DM, T2DM Pregnant women population	Telehealth system with manual data entry and asynchronous communication	No significant differences in A1c level during pregnancy or after delivery, despite a significantly lower number of visits to the Gestational Diabetes Unit (3.2±2.3 vs. 5.9±2.3 visits; P<0.001), nurse educator (1.7±1.3 vs. 3.0±1.7 visits; P<0.001), and general practitioner (3.7±2.0 vs. 4.9±2.8 visits; P<0.034) in the telemedicine group.
Shane-McWhorter, 2015 [41]	To assess clinical outcomes (A1c, blood pressure, and lipids) and other measurements (disease state knowledge, adherence, and self-efficacy) associated with the use of telemonitoring devices to expand and improve chronic disease management of patients with diabetes, with or without	Case-Control	150	T2DM Majority Spanish speaking, community health center	Telehealth system with automatic or manual blood pressure and manual blood glucose and weight data entry, asynchronous communication, pharmacist coaching	Change in A1cwas significantly greater in the telehealth group compared with the usual care group (2.07% decrease vs. 0.66% decrease; P <0.001). Patient activation measure, diabetes/hypertension knowledge, and medication adherence with antihypertensives (but not diabetes medications) improved in the telehealth

	hypertension.			population	phone sessions	group.
Crowley, 2015 [72]	To evaluate a comprehensive telemedicine intervention specifically designed for delivery using existing Veterans Health Administration (VHA) clinical staffing and equipment.	RCT	50	T2DM Veteran population	Telehealth system with IVR reporting of home monitoring and scheduled nurse telephone contact	By 6 months, estimated HbA1c had improved by 1.3% for intervention participants and 0.3% for usual care. Intervention participants' diabetes self-care, systolic blood pressure, and diastolic blood pressure were improved versus usual care at 6 months
Nicolucci, 2015 [62]	To evaluate whether a home telemedicine system enabling the patient to monitor body weight, blood glucose values, and blood pressure values, associated with remote educational support and feedback to the general practitioner, can improve metabolic control and overall cardiovascular risk in individuals with type 2 diabetes mellitus, compared with usual practice.	RCT	302	T2DM Poorly controlled diabetes population	Telehealth system, remote monitoring devices, nurse coaching phone sessions	Use of the telehealth system was associated with a statistically significant reduction in A1c levels compared with the control group (estimated mean difference, 0.33±0.1; P=0.001. Significant differences in favor of the telehealth group were detected as for physical functioning (P=0.01), role limitations due to emotional problems (P=0.02), mental health (P=0.005), and mental component summary (P=0.03) scores. Lower number of specialist visits was reported in the telehealth group (incidence rate ratio, 0.72; 95% confidence interval, 0.51–1.01; P=0.06).
Young, 2014 [42]	To evaluate the benefits of nurse telehealth coaching for persons with diabetes living in rural communities through a person-centered approach using motivational interviewing (MI)	RCT	101	T1DM, T2DM Rural community	Videoconferencing with nurse coaching sessions	Significantly higher self-efficacy scores in the intervention group compared with the control group based on the DES at 9 months (4.03 versus 3.64, respectively; $p<0.05$).

	techniques			population		
Harris, 2015 [105]	To compare the relative effectiveness of two modes of delivering Behavioral Family Systems Therapy for Diabetes (BFST-D) to improve adherence and glycemic control among adolescents with type 1 diabetes with suboptimal glycemic control: face to face in clinic and Internet videoconferencing conditions.	RCT	90	T1DM Poorly controlled diabetes population	Videoconferencing	No between-group differences in treatment effects for adherence and glycemic control (P = 0.77)
Arora, 2014 [71]	To determine whether a scalable, low-cost, unidirectional, text message–based mobile health intervention (TExT-MED) improves clinical outcomes, increases healthy behaviors, and decreases ED utilization in a safety net population.	RCT	128	T2DM Emergency department setting, low-income population	mHealth intervention with text messaging	A1c level decreased by 1.05% in the TExT-MED group compared with 0.60% in the controls (Δ0.45; 95% confidence interval [CI] -0.27 to 1.17) at 6 months. Self-reported medication adherence (Morisky Medication Adherence Scale) improved from 4.5 to 5.4 in the TExT-MED group compared with a net decrease of -0.1 in the controls (Δ1.1 [95% CI 0.1 to 2.1]). Effects were larger among Spanish speakers for both medication adherence (1.1 versus -0.3; Δ1.4; 95% CI 0.2 to 2.7) and A1c (-1.2% versus -0.4%) in the TExT-MED group. The proportion of patients who used emergency services trended lower in the TExT-MED group (35.9% versus 51.6%; Δ15.7%; 95% CI 9.4% to 22%). 93.6%

						of respondents enjoyed TExT-MED and 100% would recommend to family/friends.
Levy, 2015 [82]	To evaluate if Mobile Insulin Titration Intervention (MITI) intervention using text messaging and phone calls was effective in helping patients reach their optimal insulin glargine dose within 12 weeks, assess the feasibility of the intervention within our clinic setting and patient population, collect data on the cost savings associated with the intervention, and measure patient satisfaction with the intervention.	RCT	61	T2DM Urban, low-income population	mHealth intervention with text messaging and weekly phone sessions	A significantly greater proportion of patients in the intervention arm reached their optimal insulin glargine dose than patients in the usual care arm. Patients responded to 84.3% of the SMS text messages requesting their blood glucose values. The nurse reached patients within 2 attempts or by voicemail 91% of the time. The intervention was cost saving in terms of time for patients, who were able to have their insulin titrated without multiple clinic appointments. After participating in the study, patients in the intervention arm reported higher treatment satisfaction than those in the usual care arm.

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