Clinical and Financial Outcomes of a Pilot Pharmacist-Led Continuous Glucose Monitoring Clinic

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Abstract

Purpose: What are the clinical and financial outcomes of patients using a continuous glucose monitor (CGM) as part of a pilot pharmacist-led service in a Federally Qualified Health Center (FQHC)? *Methods:* This single-center, prospective cohort conducted in a FQHC from October 2022 to September 2023 was submitted to IRB for review [EXMT-P-22-F-17]. Patients were seen by a pharmacist in collaboration with an attending physician during diabetes specific visits. A total of 15 patients were seen in the pharmacist-led clinic (5 males and 10 females). While follow-up visits were scheduled in-person every 3 months to obtain a hemoglobin A1c (HbA1c), patients could also be seen in the clinic for additional visits. Reimbursement rates were analyzed to determine financial outcomes of the pharmacy service. *Results:* Pharmacists saw 15 patients for their initial CGM visits, with 8 patients returning for follow-up. The average HbA1c at the first visit was 10% ± 2.49 and decreased at the last follow-up to 8.05% ± 0.29. Time in range (TIR) was obtained for 8 patients through the CGM device or online data monitoring. The average TIR 2 weeks after the first pharmacist visit was 39.625% ± 23.19 and increased to 48.75% ± 11.41 at the completion of the project. A total of 39 visits were conducted, with a total reimbursement rate of $5,978.54. *Conclusion:* This pharmacist-led pilot CGM clinic showed improvements in clinical outcomes and provided financial reimbursement for diabetes management in addition to typical office visit revenue. Further research should focus on clinical impact of pharmacist-led continuous glucose monitor clinics in larger patient populations, as well as financial sustainability of the service in both physician clinics and FQHC's.

Keywords: pharmacist, diabetes, blood glucose, self-monitoring, glycated hemoglobin

Introduction

In the United States, there are 37.3 million people with diabetes.[1] Patients with diabetes are characterized as having either Type 1 Diabetes (insulin dependence), Type 2 Diabetes (insulin resistance), or latent autoimmune diabetes of adults (LADA-an autoimmune diabetes with worsening pancreatic beta cell function over time). When insulin or non-insulin agents that increase the risk of hypoglycemia are utilized for treatment, monitoring glucose levels is important for assessing safety and efficacy of treatment. The American Diabetes Association recommends regular blood glucose monitoring for patients taking insulin, pregnant patients, patients who have difficulty reaching target ranges, patients with hypoglycemia without warning signs, and patients with elevated ketones due to high blood glucose levels.[2] Continuous glucose monitors (CGMs) measure interstitial glucose and can provide real-time data on glycemic values and target range attainment. The data is interpreted, and therapy may be adjusted based on the information collected from CGMs. The American Diabetes Association Standards of Care 2024 guidelines recommend real-time CGM (rtCGM) or intermittently scanned CGM (isCGM) in patients with diabetes on multiple daily injections or continuous subcutaneous insulin injections, while acknowledging professional CGM devices can also be helpful when rtCGM or isCGM are not available.[3] A rtCGM provides glucose levels continuously, isCGM devices require scanning of the devices to display glucose values, and professional CGMs are clinic devices placed onto the patient in the clinic and data may be either blinded or visible to the patient.[3]

In contrast with traditional self-monitoring blood glucose with fingerstick testing, CGMs are applied once every 10 to 14 days, depending on the brand of sensor and duration of use. CGM devices provide glucose data throughout the day, allowing for a higher number of data points, insight to glycemic variabilities, response to foods and medications, as well as overall patterns of glycemic control. Utilization of CGMs has been shown to be beneficial in reduction of hemoglobin A1c (HbA1c) in patients who consistently wear the device (~0.5% for the average duration of 11.9 days).[4] A study published in patients with type 2 diabetes on non-insulin therapy also showed improvement in HbA1C in patients who utilized a CGM compared to self-monitored blood glucose over a 12-week period.[5] Because uncontrolled diabetes mellitus can lead to worsening complications and increased mortality, it has been presumed that improving HbA1C levels can prevent future medical issues, including microvascular and macrovascular complications, as well as neuropathies.[6] A study evaluating the association of patient-specific HbA1c TIR on major adverse outcomes in older adults with diabetes found that lower HbA1c TIR (0 to <20%) was associated with increased mortality compared to higher HbA1c TIR (80-100%) over an average of 5.5 years of follow-up.[7]

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Federally Qualified Health Centers (FQHCs) provide healthcare for patients qualifying for reimbursement under Medicare and Medicaid Prospective Payment Systems, as well as patients who are uninsured.[8] Upon completion of a CGM visit, as well as data interpretation, the services may be billed for by a provider; however, the different billing codes have variability in what types of providers can bill for each. While pharmacists are not typically recognized as providers who can bill for services in FQHCs, pharmacists do have the clinical skillset to help providers interpret this data, provide education to patients using the devices, as well as help with the application of devices. There are several published studies which investigate pharmacist-driven CGM services in patients with diabetes in various settings. A systematic review published in the included 11 studies of pharmacist-driven CGM services in the community and ambulatory care settings.[9] This review highlighted barriers to initiating pharmacist-driven clinical services exist, including educational and financial incentives; however, there was an association with improved time in range (TIR) and reduction in HbA1c in the ambulatory care settings.[9] In addition to the potential for improved clinical and financial outcomes, CGM data-sharing platforms allow remote access of data, which allows for decreased need for in-person follow-up visits and increased utilization of telemedicine visits–potentially being easier for patients to access healthcare providers.

Current procedural terminology (CPT) codes are used when billing for CGM services—specifically 95249, 95250 and 95251 for CGM usage, as well as 99213 and 99214 for established patient office visits. The CPT codes for CGM usage may be billed for in addition to the established patient office visit using a modifier -25, allowing for additional reimbursement for services provided. While in most settings the 95249 and 95250 codes may be billed for by a pharmacist, 95251 codes can generally only be billed for by physicians and midlevel providers, such as nurse practitioners and physician assistants.[10] In settings where pharmacists can't bill for certain codes or services (such as an FQHC and/or when using a 95251 code), co-shared appointments with recognized providers such as a physician may be necessary. A study done in 2008 assessed average reimbursements of CGMs and found Medicare reimbursements to range from $145-180 when utilizing codes 95250 and 95251.[11] Analyzing the financial outcomes of such services is important to assess the long-term feasibility of CGM clinics. While 95249 is only used for CGM startup and training once per patients' lifetime, 95250 may be used for placement of the Professional CGM and downloading data once per month. 95251 is used for CGM data interpretation and may be utilized for telemedicine or in-person visits once per month. Evaluating the financial and clinical benefits of pharmacist-led CGM programs may help contribute to increasing reimbursement rates, provide financial justification and support to pharmacist roles in primary care, as well as fill a gap in quality metrics and outcomes within FQHCs or settings with a similar patient population.

Methods

Patients and Setting

This was a single-center prospective cohort conducted in a Federally Qualified Health Center and submitted to IRB for review [EXMT-P-22-F-17]. The purpose of this project was to assess the clinical outcomes and financial reimbursement of a pharmacist-led CGM clinic. All patients (≥ 18 years of age) at the clinic on a continuous glucose monitor, excluding those followed by endocrinology, had the opportunity to receive care through the pilot CGM clinic. After an initial retrospective chart review of all patients in the clinic who were currently utilizing or had ever utilized a CGM device, patients were contacted to start receiving care in the CGM clinic. Inclusion criteria were patients who were currently utilizing CGM devices, patients who at some point utilized a CGM device, or patients who were referred to begin a CGM, with no exceptions to brand of CGM device. Exclusion criteria were patients being followed by endocrinology or who were less than 18 years of age. Patients meeting the criteria were contacted to determine their interest in receiving care through the pharmacist-led CGM service, and a patient appointment was made by the clinical pharmacist. New patients were also referred by their primary care physician for the pharmacy clinical service if they started a CGM device. Subjects in the study attended an initial in-person visit for education and training on the CGM. If the patient had previous experience with the CGM device, their knowledge and comfort level of device usage was assessed by evaluating set-up of the device, demonstrating how to scan CGM sensors, as well as appropriate goals for time in range.

Data and Statistics

Patients were scheduled a follow-up visit via telemedicine or in-person each month during the project, with an in-person visit required every 3 months for collection of an HbA1c. A total of 15 patients were seen in the pharmacist-led clinic (5 males and 10 females). The following information was also obtained for each patient: demographics, past medical history, HbA1c, average blood glucose, brand of device, CGM specific measures (time in range, very high, high, low, very low, and % variability of blood glucose). Patients' medications were adjusted at follow-up visits to help patients reach their glycemic targets. Billing information and reimbursement rates were also collected and analyzed to determine financial sustainability of the pharmacy service. Codes 95249, 95250 and 95251 were utilized for CGM usage, and were added on to billing codes for established office visits. Codes 99213 and 99214 were used for established patient office visits. Average reimbursement rates for each billing code were estimated using the physician fee schedule payment estimates for Alabama. The CGM visits were conducted by a pharmacist in collaboration with a supervising physician to allow for billing code utilization and reimbursement.

All records containing private health information (PHI) were encrypted, password protected, and only available for access at

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the clinic. Patients were de-identified, and the clinical and financial data was stored via a password-protected Microsoft Excel. All investigators had access to the de-identified information outside of the clinic. The data found was analyzed using descriptive statistics.

Results

A total of 15 patients were enrolled in this pharmacist-led pilot continuous glucose monitor clinic from October 2022 until September 2023. Of the 15 patients, 10 were female (67%) and 5 were male (33%) with an average age of 55.6 ± 16.2 years old. Primary insurance payors included Medicare (47%), Medicaid (6%), and commercial insurance (47%). The baseline characteristics of all the patients can be seen in Table 1.

The average HbA1c of the 15 patients was 10% ± 2.49 at the first pharmacist-run CGM visit. Of the 15 patients, 8 patients returned for a follow-up visit, and 7 patients only had an initial visit during the project. The returning 8 patients had an average of 3 follow-up visits during the project, which were both in-person and via telehealth. Only 6 patients received a follow-up HbA1c during the time frame of the project. The average HbA1c of these 6 patients at the last follow-up was 8.05% ± 0.29 (a decrease by 1.95%- see Figure 1). The average time between the baseline HbA1c and final follow-up was 5.67 months. Of the 15 patients, 8 patients had continuous glucose monitor data for TIR. The remaining 7 patients did not have shared data due to infrequent scanning and/or incompatible smartphone devices. The average TIR 2 weeks after the first pharmacist visit was 39.625% ± 23.19, which increased to 48.75% ± 11.41 at the completion of the project (an increase by 9.125%-Figure 2). During a total of 39 visits with the patients, the pharmacists were able to make medication interventions based on interpretations of CGM data. Throughout the visits, the pharmacists made a total of 31 medication adjustments between the patients (see Figure 3).

Of the 39 visits, 10 visits included the add-on billing code 95249, and 24 visits included the add-on billing code 95251. The average reimbursement for continuous glucose monitor initiation and startup (95249) is $53.97 per visit, and the average reimbursement for interpretation of data (95251) is $33.07 per visit.[9] Additionally, each visit also utilized codes 99213 and 99214 for average reimbursements of $84.67 and $120.09 per visit.[9] One visit utilized the billing code 99496 for a high complexity face-to-face visit within 7 days of hospital discharge, which provided $258.84 on average per visit.[9] With the utilization of these billing codes and the physician fee schedule payment estimates in Alabama, the estimated total reimbursement for the 39 visits was $5,978.54, with $1,333.38 being directly from CGM codes.

Discussion

This pilot project shows that a pharmacist-led CGM clinic may have a positive impact on clinical and financial outcomes within a FQHC. Pharmacists play a role in identifying which patients can utilize CGMs, as well as with the education, training and access of devices when working in collaboration with providers. Throughout this project, pharmacists assisted in making medication interventions as necessary, including dosage adjustments, medication discontinuation and medication initiation (Figure 3). These interventions helped lead to the improved clinical outcomes measured throughout the project. Financially, pharmacists in this study were able to make an impact by providing billable services, which were not billed for previously. While some patients may have already been on continuous glucose monitors prior to the pharmacist-led clinic, the billing codes for continuous glucose monitor initiation, education, and interpretation were not being added on to the primary visit billing code. When utilizing both codes, the financial reimbursements increased for services being provided. The 39 visits performed by the pharmacists in collaboration with providers equated to $5,978.54. Having this pharmacist-led clinic provided the additional reimbursement previously not utilized, as well as the expansion of the service to patients identified to need further glycemic management. The additional reimbursement could justify the ambulatory care pharmacists' role in CGM clinical services within FQHCs or other clinics with similar patient populations.

This project had some limitations. First, access to CGMs is limited based on insurance plans and financial burden to the patients. Without an insurance plan that provided coverage or meeting qualifications for patient assistance, patients must pay cash price for their device–limiting the use of the devices to many patients. Commercial insurance coverage of the devices, as well as copays, vary based on the insurance payor. At the start of the project, Medicare covered CGMs for patients who required at least three insulin injections per day. Medicare has since increased their coverage of CGMs to patients who are insulin treated or have problematic hypoglycemia—meaning recurrent level 2 hypoglycemic events (blood glucose <54 mg/dL) or history of a level 3 hypoglycemic event (altered physical or mental status) requiring treatment.[12] This could increase the number of qualifying patients in future studies, since more patients will be able to access CGMs. Alabama Medicaid covers CGMs for patients with type 1 diabetes mellitus who are less than 21 years old, or patients with gestational diabetes.[13] Unless these qualifications were met, the overall number of patients qualifying for coverage of the devices was limited. This contributed to fewer patients being able to participate than originally planned.

Another limitation was the cancellation and no-show rate throughout the project. There were more than 10 appointments which were canceled, or the patient did not show up for; therefore, a small number of patients were included in this project. The patients who cancelled or did not show up to an appointment did not provide specific details as to why they needed to cancel. Ideally, the allowance for telemedicine visits

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would have alleviated some of the burden of traveling to clinic; however, this project did require the in-person HbA1c check for follow-up, and some patients did not come back during the time frame of the project for this lab result. In addition to the need for follow-up visit for labs, the patients' CGM data needed to be shared via a compatible device and required correct scanning of the sensor. There were 7 patients who had issues data sharing, also contributing to a smaller number of patients included. Within FQHCs and other settings with similar patient populations, social determinants of health can affect health and quality-of-life outcomes. In this study, social determinants of health such as economic stability and ability to afford medications, proximity to the clinic and transportation issues, as well as access to smartphone devices, internet, and e-mail setup could have had an impact on patients' access to the CGM service.

These challenges all led to a small sample size for the project. The results showed improvements in clinical outcomes and financial reimbursements; however, a larger study within a FQHC or other outpatient settings with a similar patient population needs to be done to determine the clinical significance of this service. The American Diabetes Association Standards of Care 2024 guidelines support the use of CGMs and recognize the correlation of time in range with HbA1c and potential complications from diabetes mellitus.[3] Furthermore, the guidelines acknowledge the increasing use of CGMs and metrics like TIR and glucose management indicator as a way to monitor patients via remote access.[3] With insurance payors like Medicare becoming more inclusive on the eligibility criteria for CGM coverage, the use of these devices will likely see an increased demand. Pharmacists can have a role in this process as demand increases by providing education at initiation, interpreting data at follow-up appointments, and making interventions to medication regimens over time.

Conclusion

This pharmacist-led pilot CGM clinic led to improved clinical outcomes related to diabetes mellitus, including hemoglobin A1c reduction as well as increased time in range, and increased financial reimbursements for the clinic. Further studies with a larger sample size are needed to determine the clinical impact of CGM usage as well as financial sustainability of a pharmacist-led CGM clinic in a FQHC or other primary care settings.

Treatment of Human Subjects: IRB exemption granted (EXMT-P-22-F-17).

Conflicts of Interest: The authors declare no conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patients, and royalties.

Disclaimer: The statements, opinions, and data contained in all publications are those of the authors.

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Table 1. Baseline Demographics

Variable	n=15
Male	5
Female	10
Average age (years) ± SD	55.6 ± 16.2
Baseline hemoglobin A1c (%)	10
African American (%)	9 (60)
Caucasian	5 (33)
Other race	1 (7)
Medicare (%)	7 (47)
Medicaid (%)	1 (6)
Commercial insurance (%)	7 (47)
Insulin glargine	7
Insulin lispro	4
Insulin degludec	2
Insulin detemir	2
Insulin aspart	4
Farxiga	1
Jardiance	2
Trulicity	4
Ozempic	1
Metformin	5
Pioglitazone	1

Figure 1. Average Change in Hemoglobin A1c

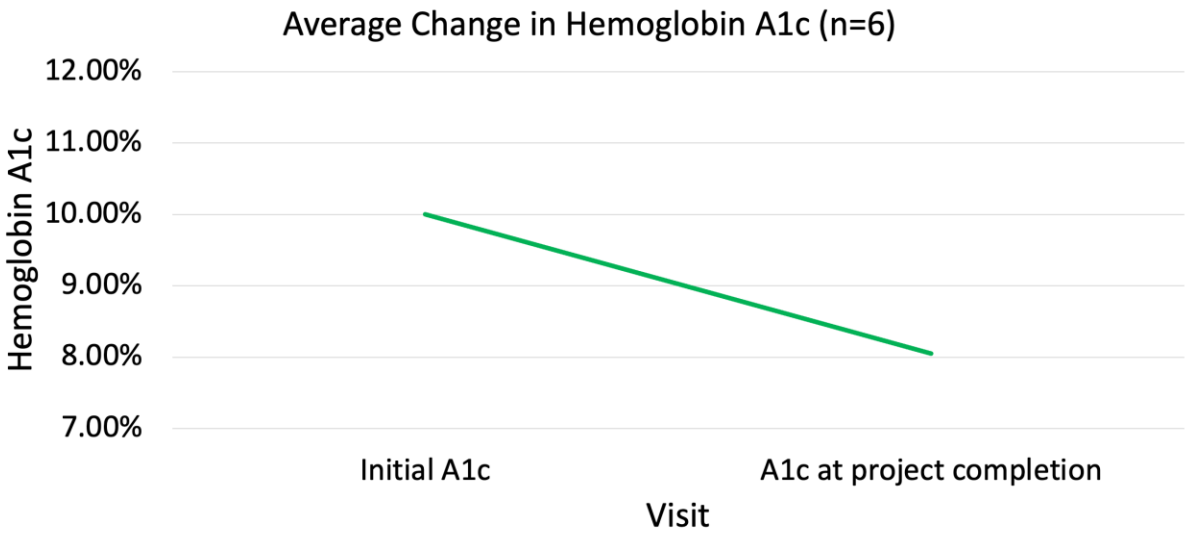

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Figure 2. Average Change in Time in Range (TIR)

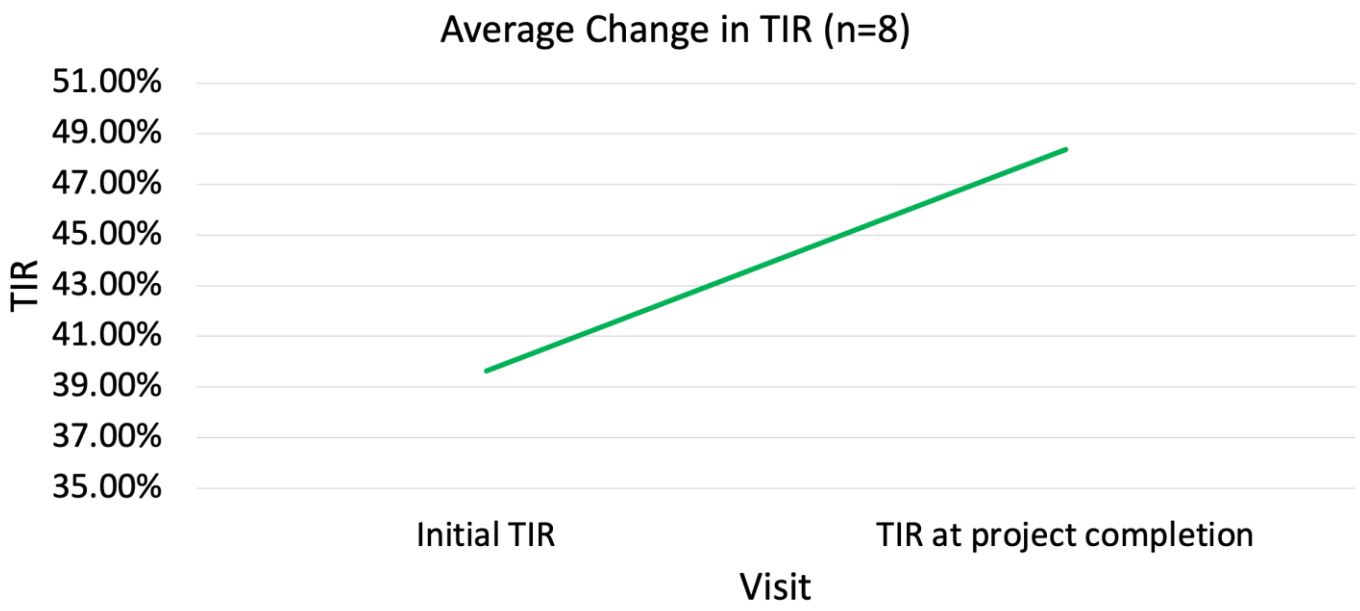
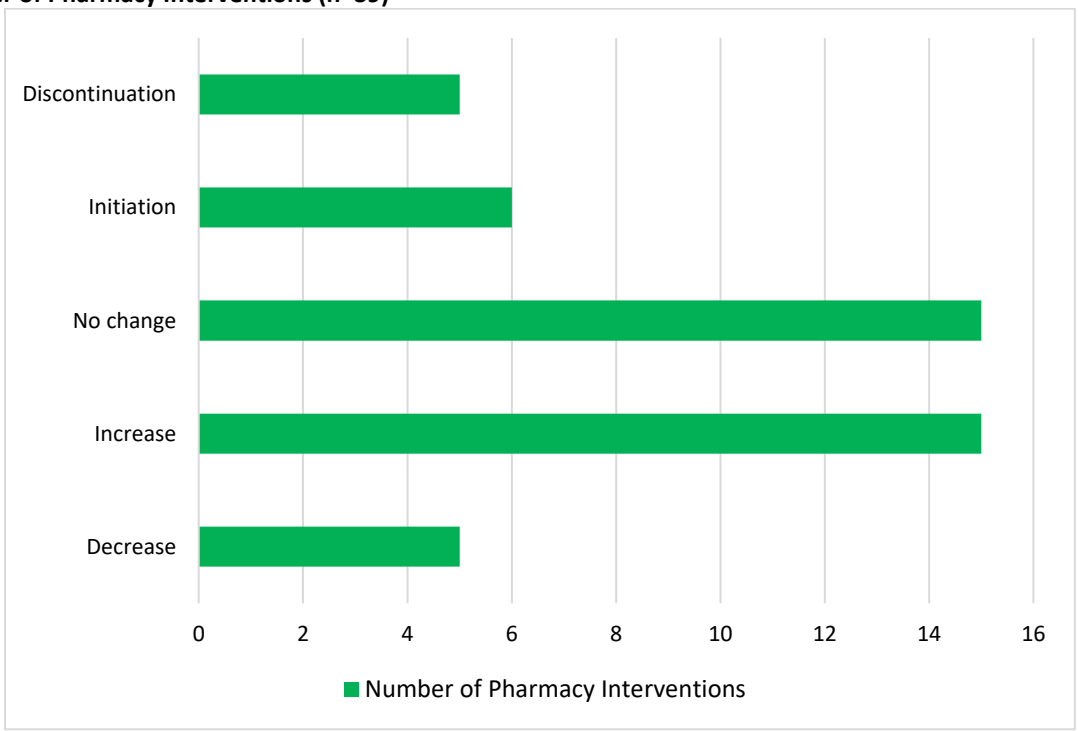


Figure 3. Number of Pharmacy Interventions (n=39)



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