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The Effect of Continuous Glucose Monitoring on Glucose Control and Re-hospitalizations in Type II Diabetes Mellitus Patients

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Abstract

Purpose: This Program Development and Evaluation project was designed to improve the management of patients with type II diabetes mellitus through the implementation of a combined in-patient discharge protocol and outpatient continuous glucose monitoring protocol follow-up plan in a diabetes clinic following discharge from a rural-based acute facility hospitalization.

Method: This quasi-experimental project was based on Rosswurm and Larrabee's Model for Change framework. Outcome measures analyzed type II diabetes mellitus patients to assess the effects of a continuous glucose monitoring discharge protocol on pre- and post-glycemic levels, rehospitalizations, and patient (n=2) and provider knowledge (n=4) obtainment.

Results: In a comparison of average pre- and post-glycemic levels, the continuous glucose monitoring group revealed a 14% decrease compared to 4% among the non-continuous glucose monitoring group. There was a 7.3% reduction of rehospitalizations indicated from pre- and post-implementation in a sample size of two, with a rehospitalization rate of 5.5% in the study population. Based on pre- and post-survey Likert scale results, participants showed increased knowledge related to diabetic treatment, monitoring of blood glucose levels, and lifestyle measures in controlling type II diabetes mellitus. Healthcare provider participants showed increased knowledge of continuous glucose monitoring risk factors, benefits, and advantages.

Conclusion: Our findings support evidence for the use of continuous glucose monitoring in patients diagnosed with type II diabetes mellitus to improve clinical outcomes and reduce healthcare costs. This project is needed to support the more widespread use of continuous glucose monitoring, which can lead to reducing rehospitalizations, decreasing glycemic index, and improving overall patient satisfaction.

Keywords: continuous glucose monitoring, type II diabetes mellitus, glycemic index, rehospitalizations

The Effect of Continuous Glucose Monitoring on Glucose Control and Re-hospitalizations in Type II Diabetes Mellitus Patients

Diabetes mellitus is the world's fastest-growing chronic condition that contributes to more serious complications such as heart disease, stroke, kidney failure, and lower-limb amputations, than any other disease.¹ Globally between 1980 and 2014, the number of adults with diabetes increased from 108 to 422 million, which was attributed to rising obesity rates, increasing population, longer life expectancy, and rising diabetes prevalence.^{1,2} Consequently, the global prevalence of diabetes mellitus is increasing rapidly and is expected to increase to 745 million by 2045.^{1,3}

Management of diabetes in the United States (U.S.) presents several challenges: 20% of individuals with diabetes remain undiagnosed, 1.4 million new cases are diagnosed annually, and one-third of adults with diabetes are not at the general recommended A1C goal of <7%.⁴ Rehospitalizations related to diabetes mellitus account for a tremendous healthcare burden and contribute to 31% of the U.S. healthcare expenditure, or 3 trillion annually. The average hospitalization cost for a diabetic-related complication averages \$9500 and an individual with a known diagnosis of diabetes will experience medical expenses 2.3 times higher than those without diabetes.^{3,5}

The problem statement for this Doctor of Nursing Practice Program Development and Evaluation was that patients with type II diabetes mellitus (T2DM) are at-risk for rehospitalization due to poor glycemic control. A practice gap identified at a rural hospital in northeastern Arkansas revealed a lack of patient follow-up and glycemic management in T2DM patients following hospitalization due to a diabetes-related condition. Additionally, readmission rates for poor glycemic control in T2DM were noted to be at 16.7%, above the benchmark of

15.6%, and the hospital goal of 15.0%. In addition, limited provider knowledge related to evidence-based continuous glucose monitoring (CGM) has resulted in poor self-management of glycemia and high readmission rates. In previous attempts to address a 30-day high readmission rate, the facility implemented patient education provided by a diabetes registered nurse educator in newly diagnosed hospitalized T2DM patients. However, this did not fully address the issue indicating further targeted interventions were needed.

This quality improvement pilot project aimed to implement evidence-based CGM through a discharge protocol in T2DM patients and improve 30-day readmission rates and outcomes in T2DM patients aged 18 years and older. Objectives were designed to:

- Develop and implement hospital discharge protocol.
- Decrease rehospitalization rates below 15% among the study population.
- Improve patient blood glucose levels and compliance with blood glucose monitoring through the initiation of continuous glucose monitoring.
- Using Likert scale measurement, increase health provider's knowledge in care management of continuous glucose monitoring.

Literature Review

An electronic search of scholarly databases, CINAHL Complete and MEDLINE Complete, was conducted. Additional searches were conducted via UpToDate and the Centers for Disease Control and Prevention (CDC). The review of current literature focused on diabetes management, continuous glucose monitoring, and glycemic control. The evidence reviewed was then implemented into the discharge protocol and CGM implementation.

Continuous Glucose Monitoring

Effective T2DM management strategies require lifestyle modifications and consistent glycemic monitoring by the patient and provider.^{6,7} The American Diabetes Association (ADA) denotes that diagnosed T2DM individuals frequently do not comply with lifestyle modifications, such as diet control, physical activity, and pharmacological treatment.⁸ In addition, individuals with “insulin-treated” T2DM often experience poor outcomes with HbA1C, hypoglycemia, frequent hospitalizations, and associated costs due to inconsistent glycemic monitoring.^{7,8}

Evidence supports the utilization of CGM technology to better control a patient’s glycemic index, as well as reduce diabetes mellitus-related hospitalizations.^{9,10,11} Optimal glycemic control results in preventing acute and chronic complications, disability, and premature mortality.¹² When compared to self-monitoring of blood glucose, the CGM technology uses a sensor to measure interstitial glucose levels throughout the day and provides both pharmacological and non-pharmacological guided treatment. The CGM also produces a personal daily glycemic report and provides education to assist the patient with the relationship that exists between self-care, adherence to medications, diet, physical activity, and glycemic control. As a result of CGM use, patients avoid frequent finger sticks and achieve significant reductions in glycated hemoglobin, caloric intake, and overall body weight.^{5,11,12}

CGM Education

Education of professionals, as well as patients, should be conducted to ensure successful implementation and outcomes of CGM technology.^{13,14} The CGM functions through a sensor that is inserted into the subcutaneous tissue, which transmits to a receiver and can be worn for 14 days, the life of the sensor.¹⁴ There is no calibration necessary, and at the end of 14 days, the patient should be prepared to change out sensors. Patients and providers should be educated that

the back of the upper arm is the preferred sensor site, at least one inch away from an insulin injection site.

Discharge Protocol

The best evidence supports a comprehensive discharge protocol that includes patient education, a standardized referral plan, and post-discharge follow-up and education.^{10,15,16} Continuous glucose monitoring protocol should be implemented during a diabetes-related inpatient hospitalization to target high variability of glycemic levels which often result in hospitalizations. Ossai and Wickramasingh analyzed 17,933 diabetes patients with 30-day unplanned readmission rates and discovered a rate of 14-21% due to diabetes-related comorbidities, which reinforces the need for enhanced mitigation of glycemic variability that requires improved discharge management and home-based interventions.¹⁵

Methodology

Design

This project used a quasi-experimental design with an aim to decrease rates of re-hospitalizations by improving glycemic levels in T2DM patients through the implementation of a discharge follow-up protocol and outpatient continuous glucose monitoring. The framework was supported by Rosswurm and Larrabee's Model for Change, which focuses on the improvement of patient outcomes and measurements of change following an intervention.¹⁷ The framework guided the implementation of the evidence-based CGM discharge protocol in patients with T2DM to improve glycemic levels and reduce rehospitalizations. The framework's six steps were utilized throughout the project phases to implement an evidence-based practice approach to improving patient outcomes.

Setting

The project was conducted at an inpatient acute care hospital and outpatient diabetes clinic located in rural northeastern Arkansas which serves primarily a rural population. Inpatient participant recruitment included medical-surgical and intensive-care unit patients hospitalized with complications due to a T2DM-related condition. Outpatient follow-up and evaluation were conducted during a one-week post-hospital discharge in a private room located within the hospital diabetes education clinic.

Study Population

The project participants consisted of adult patients aged 18 years and older admitted as an inpatient to the acute care hospital for a T2DM-related condition. Inclusion criteria consisted of patients aged 18 years and older, inpatient admission due to a T2DM-related condition, proficiency with the English language, and available transportation to the weekly diabetes clinic follow-up appointments. Exclusion criteria pertained to patients younger than 18 years old, non-English speaking, non-diabetes related condition, and lack of transportation or available driver. The two participants that received the CGM device were both males, aged 43 and 47, currently utilizing insulin as their form of diabetes management.

Recruitment strategies

After ensuring inclusion and exclusion criteria as described above, consent was obtained prior to discharge. Once identified in the electronic health record, patients meeting inclusion criteria were assessed to participate in the project. Patients were presented with education related to CGM glycemic benefits and were provided an opportunity to view a CGM sensor from the Abbott Freestyle Libre 2. Patients requiring a longer hospitalization were followed on a weekly basis until discharge approached. Recruitment included a convenience sampling approach.

Patient consent was obtained from a total of 16 participants from November 1, 2022, to February 2nd, 2023.

Intervention

The CGM discharge protocol was specifically designed for patients admitted due to diabetes-related conditions to a medical-surgical or intensive-care unit. The CGM protocol consisted of two phases, a discharge CGM protocol implemented while inpatient, and a follow-up appointment for outpatient CGM implementation (See Table 1). Each patient received preliminary patient discharge education and a one-week diabetes education follow-up appointment provided by the investigator and diabetes nurse educator. Continuous glucose monitoring through a sensor placed subcutaneously was implemented by the investigator at the one-week post-discharge follow-up appointment. Three additional outpatient follow-up appointments were scheduled to provide ongoing patient education and monitoring of the 30-day CGM implementation time period. Weekly follow-up meetings in person and by email were conducted among nurses, providers, and administrators within the hospital.

Table 1. Project Intervention Components

Referral Discharge Protocol	CGM Protocol
<ul style="list-style-type: none"> • Standardized referral appointment scheduled within one-week post-discharge at the hospital outpatient diabetes clinic. • Standardized patient discharge education which included glycemic management and CGM. 	<ul style="list-style-type: none"> • Follow-up appointment at the outpatient diabetes clinic with investigator and diabetes nurse educator. • Initial blood glucose level obtained. • CGM implemented for a 30-day period. • Education provided on CGM technology overview, initial CGM application, risks, costs, troubleshooting, and when to contact the diabetes clinic or provider. • Three, one-week follow-up appointments scheduled. • Final blood glucose level obtained.

-
- Referral to PCP for sustainability.
-

Anticipated barriers included the patient cost of sixty dollars monthly, adherence to CGM protocol, and attending follow-up appointments. Unanticipated barriers included cell phone incompatibility with CGM application, limited pharmaceutical CGM reader supply for sensor compatibility, and support from primary care physicians. The Plan-Do-Study-Act was utilized to address deviations from the implementation plan.

Study Measures

The project operational definitions consisted of a project population of adults aged 18 years and older and T2DM as A1C greater than 6.5% (48 mmol/mol) or random plasma glucose more than 200 mg/dL.⁴ Continuous glucose monitoring was specified as an Abbott™ freestyle CGM device. Type II diabetes risk factors were defined as a first-degree relative with diabetes, women who delivered a baby over nine pounds, diagnosis of hypertension with a blood pressure exceeding 140/90 mmHg, diagnosis of polycystic ovarian syndrome, history of gestational diabetes mellitus, or acanthosis nigricans.

The outcome measures were as follows:

- Reduction of average pre- and post-implementation glycemic levels by 5% among CGM participants.
- Increased diabetic educational attainment among participants and healthcare providers via pre- and post-surveys.
- Decrease rehospitalization rates by 15% among the project population.

Process measures addressed the percentage of T2DM patients electing to participate in CGM implementation through the discharge protocol. Adherence to the discharge protocol was evaluated according to the percentage of patients meeting inclusion and exclusion criteria. The

percentage of patients that adhered to one-week follow-up appointments was compared to the baseline follow-up rate. In addition, the percentage of patients that complied with CGM intervention was evaluated on a weekly basis.

Balancing measures addressed the percentage of provider and patient satisfaction in the program measured by a post-survey. Additionally, budgets were measured by a cost analysis to compare pre-implementation to post-implementation of the CGM discharge protocol.

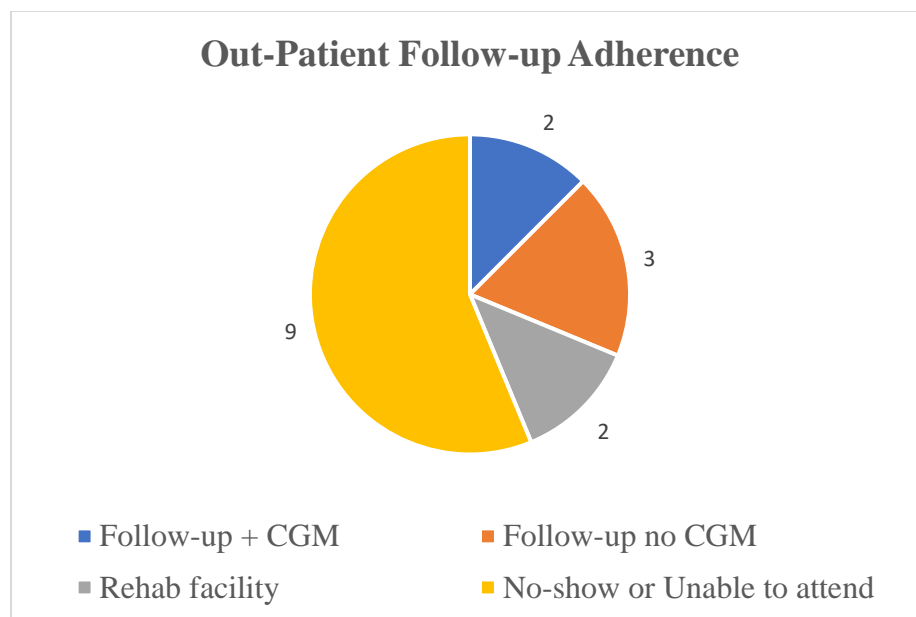
Ethical Considerations

Institutional Review Board (IRB) approval was obtained on November 1st, 2022. Continuous glucose monitoring samples were provided by Abbott Pharmaceuticals, and no financial relationship or conflict of interest was identified with Abbott Pharmaceuticals. No direct funding sources contributed to the project resources.

Results

A cohort of 41 patients meeting inclusion criteria was assessed in the hospital between November 1st, 2022, through January 25, 2023. Consent from a total of 16 hospitalized patients (39%) was obtained to participate. Two participants (12.5%) were compliant with the CGM discharge protocol 30-day implementation plan with a follow-up rate of 36%, excluding those that went to rehabilitation. See Figure 1.

Figure 1. Out-Patient Follow-up Adherence



Outcome Measures

Due to the small sample size, simple statistics measures of frequency and percent change were used to compare pre and post-glycemic levels. The CGM group, which included two patients revealed a 14% pre-post glycemic level decrease compared to 4% pre-post glycemic level decrease among the non-CGM group. Average pre-hospital glycemic levels for CGM participants were 322 mg/dL, while post-hospital glycemic averages decreased to 276.5 mg/dL. Average pre-hospital glycemic levels for non-CGM participants were 178.3 mg/dL and post-hospital glycemic averages were slightly decreased to 171 mg/dL (Table 2).

Table 2. Pre/post Glycemic Averages

Pre/Hospital Average	CGM Participants (mg/dL)	Non CGM participants (mg/dL)
Pt 1	349	205
Pt 2	295	130
Pt 3		200
Total	644	535
Average	322	178.33

Post/Out of Hospital Average	CGM Participants (mg/dL)	Non CGM participants (mg/dL)

Pt 1	270	198
Pt 2	283	105
Pt 3		210
Total	553	513
Average	276.5	171
	45.50	7.33
Percent change	14%	4%

Pre- and post-patient participant survey data were analyzed using descriptive statistics due to the small sample size. Question scoring was completed on a Likert scale from 1-5. Based on the results, participants showed increased knowledge related to diabetic treatment, monitoring of blood glucose levels, and lifestyle measures in controlling T2DM. High participant satisfaction was noted for all aspects of CGM and the project with a response of 5, on a Likert scale of 1-5, on all satisfaction-related questions. (See Table 3).

Table 3. Participant Pre-Post Survey Results

Survey Questions:	Pre-Survey Response Average (n=2)	Post-Survey Response Average (n=2)
How would you rate your knowledge of diabetic treatment therapies?	Mean 1.00 (Unknowledgeable)	Mean 4.00 (Very knowledgeable)
How important do you rate lifestyle measures (i.e., exercise, diet) in controlling your type II diabetes mellitus?	Mean 3.50 (Slightly-Extremely important)	Mean 4.00 (Very important)
What is your knowledge of monitoring blood glucose levels with the continuous glucose monitor?	Mean 1.00 (Unknowledgeable)	Mean 4.00 (Very knowledgeable)

Pre- and post-provider knowledge survey data were analyzed using descriptive statistics due to the small sample size. Based on the results, participants showed increased knowledge in all CGM-related questions. Healthcare provider participants showed increased knowledge of CGM risk factors, benefits, and advantages. All post-survey mean response rates were noted to

be moderate to very knowledgeable indicating that knowledge was gained following the educational intervention (See Table 4).

Table 4. Provider Pre-Post Survey Results

Survey Questions:	Pre-Survey Response Average (n=4)	Post-Survey Response Average (n=4)
How would you rate your knowledge of continuous glucose monitoring (CGM)	Mean 2.67 (Moderately knowledgeable)	Mean 3.50 (Moderately-Very knowledgeable)
How would you rate your knowledge of CGM risk factors?	Mean 2.33 (Not knowledgeable at all-Moderately knowledgeable)	Mean 3.50 (Moderately-Very knowledgeable)
How would you rate your knowledge of the benefits of CGM?	Mean 0	Mean 3.67 (Moderately-Very knowledgeable)
How would you rate your knowledge of CGM advantages?	Mean 0	Mean 4.00 (Very knowledgeable)

*Question scoring was completed on a Likert scale from 1-5.

The outcome measure included an assessment of rehospitalization rates with the goal to decrease rehospitalization rates at or below 15% among the project population. A total of 559 records were analyzed of patients admitted and readmitted due to a T2DM complication during the period of 08/01/22 to 03/15/23. The rehospitalization rate from the pre-implementation period compared to the post-implementation period revealed a 7.3% decrease in the rehospitalization rate. An odds ratio was conducted to determine if there was a statistically significant difference in the odds that a rehospitalization would occur post-implementation of the protocol compared to the odds that a rehospitalization would occur prior to the implementation. This was shown to be statistically significant at a p-value =0.046 with an odds ratio of 0.3953 and a 95% CI of 0.1585-0.9857. (See Table 5).

Table 5. Rehospitalization Rates

Pre 08/01/22 to 10/31/22 rehospitalizations	During implementation 11/01/22 to 01/25/23 rehospitalizations	Post-implementation 01/26/23 to 03/15/23 rehospitalizations
28/218 = 12.8%	20/209=9.6%	6/109=5.5%

Process Measures

Two participants were compliant with the CGM discharge protocol 30-day implementation plan with a follow-up rate of 36% excluding those that went to rehabilitation. Three participants attended the initial outpatient diabetes appointment for CGM implementation but experienced personal cell phone incompatibility with CGM technology. Nine participants were unable to attend the initial outpatient diabetes appointment. Through the Plan-Do-Study-Act, contact with the CGM representative was made to address cell phone incompatibility. It was discovered that an alternative CGM reader could not be obtained through durable medical equipment (DME) companies, which required several weeks of processing should the patient not afford the \$65 out-of-pocket pharmacy expense.

Balancing Measures

Based on the results, participants showed increased knowledge in all CGM-related questions. High participant satisfaction was noted for all aspects of CGM and the project. Healthcare provider participants showed increased knowledge of CGM risk factors, benefits, and advantages. All post-survey means response rates were noted to be moderate to very knowledgeable indicating that knowledge was gained following the educational intervention. A cost analysis indicated an additional outpatient diabetes clinic registered nurse educator will be required to promote sustainability with the increased rate of outpatient clinic visits. This will result in an additional annual cost of approximately \$65,000.

Discussion

Type II diabetes mellitus has created a global healthcare concern on account of significantly increasing numbers, and extensive evidence supports the implementation of CGM

and a standardized discharge protocol.^{9,10,11} Our project outcomes were congruent with the proposed CGM discharge protocol association with decreased rehospitalizations, improved glycemic index, and enhanced patient and provider education in individuals diagnosed with T2DM. A key strength of our analyses revealed no cohort rehospitalizations and an overall pre and post-30-day CGM implementation glycemic index decrease of 14% in CGM participants compared to 4% among the non-CGM group. In addition, participants demonstrated increased knowledge of diabetic treatment, monitoring of blood glucose levels, and lifestyle measures to control T2DM. Likewise, providers showed an increased knowledge of CGM risk factors, benefits, and advantages. High participant satisfaction was noted for all aspects of CGM and the project.

Limitations

This project could have benefitted from a longer duration to increase enrollment and cohort size, as the small sample size could have limited that data power, but the significant of clinical findings remain positive. A notable limitation of the project affecting cohort size involved CGM technology incompatibility with participants' cell phones. Continuous glucose monitoring readers may be obtained through processing with a specific DME company over the course of several weeks to overcome incompatibility, or through the patient out-of-pocket expense of \$65 at a local pharmacy.

Conclusion

This small pilot project has the potential to expand to populations in both rural, underserved, and urban settings to improve patient outcomes by reducing glycemic levels and rehospitalizations. Our findings support evidence for the use of CGM in patients diagnosed with T2DM to improve clinical outcomes and reduce healthcare costs in rural northeastern Arkansas.

This project is needed to support more widespread use of CGM, which can lead to reducing rehospitalizations, decreasing glycemic index, and improving overall patient satisfaction, with potential for widespread implications. The project noted only a 12.5% participation rate, which supports difficulty with patient adherence to diabetes mellitus care management recommendations. The project will contribute to sustainability following the dissemination of CGM discharge protocol project results to the clinical site as well as other healthcare facilities. In addition, it will impact provider and patient practice through dissemination in *The Journal for Nurse Practitioners* and the University of Arkansas.

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