4-9-2024

Implementing Continuous Glucose Monitoring: A Quality Improvement Project

Molly Suydam
suydamm@mail.sacredheart.edu

Implementing Continuous Glucose Monitoring: A Quality Improvement Project

Molly Suydam, BSN, RN

A DNP project submitted in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

Sylvie Rosenbloom, DNP, APRN, FNP-BC, CDCES

Hilary Sullivan, DNP, APRN

Sacred Heart University Davis & Henley College of Nursing

April 9, 2024

Approval Page

This is to certify that the DNP Project Final Report by Molly Suydam, BSN, RN has been approved by the DNP Project team on (Month, Day, Year)

For the Doctor of Nursing Practice Degree

DNP Project Faculty Advisor: Sylvie Rosenbloom, DNP, APRN, FNP-BC, CDCES

Practice Mentor: Hilary Sullivan, DNP, APRN

Acknowledgements

I would like to recognize the following people who were integral in supporting my achievements and success in Sacred Heart University Davis & Henley College of Nursing, Doctor of Nursing Practice Program:

- My supportive friends and family, who have stood by me the last four years and encouraged me along the way. My immediate family including my mother, father, and sister have been absolutely wonderful and provided reassurance during my toughest moments. They have helped comfort me and instilled confidence to carry on. My best friends have cheered me on and offered a shoulder to lean on, anytime.
- Dr. Sylvie Rosenbloom, DNP, APRN, FNP-BC, CDCES as my project advisor. Her knowledge, assistance and expertise has truly allowed for my succession. The intricate attention to detail when developing my project helped me better understand what was expected of me. The support that was provided made me feel confident in my abilities to not only be an exceptional APRN, but the differences that I can make in health care.
- Hilary Sullivan, DNP, APRN as my project mentor. After spending three clinical rotations with Hilary, we developed a rapport with one another and she was more than willing to assist me with a DNP project implementation in her office. The guidance and support from her is appreciated immensely and doesn't go unnoticed.

Table of Contents

List of Tables

List of Figures

Abstract

Significance and Background: Continuous glucose monitoring (CGM) devices are beneficial for assessing blood glucose measurements throughout the day by simply waving a smartphone over the sensor that's attached to the back of a patient's arm. Patients with T2DM who check blood glucose measurements via finger-sticks, have to undergo numerous daily finger-sticks. Over time, this action can grow very cumbersome while CGM offers real-time blood glucose measurements without having to pierce the skin repeatedly. CGM use in patients with T2DM may help to improve overall blood glucose measurements.

Purpose: To trial CGM in patients with T2DM and monitor blood glucose measurements over a two-week period and determine if its use can improve blood glucose control.

Methods: The project implementation and evaluation were guided by the PDSA framework. *Plan*- Initiate CGM trial in patients with T2DM who are interested in closer monitoring of blood glucose measurements and return for a two-week follow-up. *Do*- CGM trial was presented to 48 patients with T2DM and 23 patients agreed to use it. Each patient returned for their two-week follow-up appointment. *Study*- Data on pre and post blood glucose measurements was collected. *Act*- Present to stakeholders and plan for next PSDA cycle.

Outcome: Over a 12-week period, there were 23 patients with T2DM who agreed to trial CGM out of 48 patients who were seen by the project mentor (48%). The average blood glucose pre CGM trial was 196 mg/dL and the average blood glucose measurement post CGM trial was 134 mg/dL. Thirty percent of patients who trialed CGM then went on to obtain a prescription to continue the use of CGM. There was an overall downtrend of blood glucose values after the use of CGM in patients with T2DM.

Discussion: Despite low attendance rate of CGM trial in a primary care clinic, there were downward trends in overall blood glucose measurements. The CGM sensor use over a two-week period in patients with T2DM had a positive impact on overall blood glucose control.

Keywords: *continuous glucose monitoring, type 2 diabetes, blood glucose self-checks, compliance and adherence*

Problem Identification and Evidence Review

Description of the Problem

Diabetes mellitus type 2 (T2DM) is a chronic disease highly prevalent in the American population. Factors such as diet, exercise and lifestyle behaviors have a great impact on fasting blood glucose (FBG) levels (Geng, et. al, 2023). It is important to educate individuals with T2DM on ways to better manage blood glucose to prevent complications. There are many tools and resources that primary care providers can offer patients with T2DM. However, it is the patient's sole responsibility to remain adherent and ultimately improve control of their disease.

A patient with insulin-dependent T2DM should test frequently to avoid having episodes of hypo- or hyperglycemia. This process typically involves a finger-stick and the use of a glucometer. This requires patient education and monitoring over time to ensure the patient is completing this task correctly. However, once the patient is on their own, blood glucose checks cannot be monitored as frequently in-house and can decrease adherence. Most individuals with T2DM can qualify for a home glucometer with their insurance. However, continuous glucose monitoring (CGM) is costlier and has more requirements for insurance coverage.

Individuals aged 18-64 with T2DM who have private insurance can qualify for CGM sensors allowing for instant access to blood glucose measurements with the assist of their smartphone. The CGM sensors (ie: Free Style Libre™) can offer patients a greater awareness of blood glucose levels throughout the day. Primary care providers have the ability to identify patients who would qualify for CGM covered by insurance. The use of CGM could increase patient's awareness of glucose levels and potentially lead to improved glucose control.

Patients with T2DM at primary care office located in the Northeast Region often admit to not checking their blood glucose when asked at their diabetes follow-up appointments. Some patients who take oral agents to help control their T2DM and are not insulin-dependent, merely rely on their HgbA1c levels. Not checking BG levels can lead to unawareness of hypo- or hyperglycemic episodes. Patients can have a normal or near-normal HgbA1c, but this does not tell providers if the patient is experiencing episodes of hypo- or hyperglycemia throughout the last three months. The HgbA1c does not show glucose trends.

Patients who are insulin-dependent often see an endocrinologist and usually monitor their BG levels periodically. There are several patients who have become acclimated to finger-sticks with the use of their glucometer and are not aware of CGM via Free Style Libre™. The use of CGM could offer less interference with finger-sticks for qualifying patients.

Clinical Question

In individuals age 18-64 with type 2 diabetes mellitus (P), how does continuous glucose monitoring (CGM) (I), compared to finger-stick checks (C), improve fasting blood glucose (FBG) over two-weeks (O)?

Methods for Gathering External and Internal Evidence

The following databases were researched; CINAHL, PubMed and MEDLINE. The keywords selected were continuous glucose monitoring, type 2 diabetes, blood glucose self-checks, compliance and adherence. Search results limited to English language with dates ranging from 2018-2023. Criteria used when selecting articles for rapid critical appraisal included patient outcomes, defined results of CGM and overall patient satisfaction with CGM.

Search Results

The Rapid Critical Appraisal Tool was used on each selected article (Melnyk & Fineout-Overholt, 2019). See Appendix A for RCA tool. The seven selected articles for the DNP project were identified into levels of evidence ranging from IV-V. Appendix B demonstrates level of evidence. An Outcomes Synthesis table is demonstrated in Appendix C. An evidence summary table Appendix E includes details of each article that was appraised via RCA.

Evidence Appraisal Summary, Synthesis, and Recommendations

The American Diabetes Association supports the use of CGM as it can provide significant benefits for those with T2DM (ADA, 2024). Evidence suggests that with proper instruction on usage of CGM, patient satisfaction towards CGM will outweigh the use of self-monitoring blood glucose checks, therefore increasing adherence (Zheng, et. al, 2020). Evidence also suggests that the usage of CGM can have a positive impact on not only BG, but can also improve HgbA1c, blood pressure, and BMI. (Shrivastav, et. al, 2018). Recommendations based on the evidence include having CGM daily over a set time-period, as opposed to intermittent use, for more consistent results (Janapala, et. al, 2019). Individuals who qualify for CGM via insurance may be more apt to utilize this tool if covered by insurance (Wright, et. al, 2021). This family-primary care clinic can implement a CGM protocol for patients with T2DM and private insurance to help improve control of T2DM.

The outcome synthesis table as noted in Appendix D, displays the positive relationship between lifestyle changes and decreased HgbA1c in patients using CGM. Of the seven articles, five identified this relationship (Cuevas, et. al 2022; Janapala, et. al, 2019; Shrivastav et. al, 2018; Wright, et. al, 2021; Zheng, et. al 2020). Of the seven articles retrieved, six of them identified overall improved patient satisfaction with the use of CGM (Cuevas, et. al 2022; Janapala, et. al 2019; Kruger & Anderson, 2021; Oser, et. al, 2021; Shrivastav et. al, 2018; Zheng, et. al 2020).

Project Plan

Project Goals

1. Develop and pilot a CGM trial for patients aged 18-64 years with T2DM over a two-week period.
2. Increase the number of prescribed CGM for patients with T2DM after a two-week follow-up following their CGM trial.

Framework

The Plan-Do-Study-Act (PDSA) model uses four stages when implementing a change in a process. The different stages allow for each step to be broken down in detail and then evaluate the outcome. Should the implementation process be undesirable, the PDSA model allows for revisions as needed. The PDSA model is an appropriate framework for this DNP project to allow for revisions as needed when initiating the implementation process.

Context

The setting of this DNP project is a privately owned family primary-care office. Patients attend this primary care office for annual physical examinations, mental health, women's health

and addiction services. The population of the DNP project includes individuals aged 18-64 years of age with T2DM.

Project Team and Roles

Table 1. displays the QI project team members and their roles.

Table 1. Project Team and their Roles

Person	Role
Molly Suydam DNP Student	Project Manager
Hilary Sullivan	Project Mentor, APRN
Sylvie Rosenbloom	DNP Project advisor

Key Stakeholders, Staff, and Buy-in

Key stakeholders identified for this project include the medical director, project mentor who is a nurse practitioner, and patients of the primary care practice. Staff members are crucial to the success of this QI project. Key staff members responsible for implementing this QI project include the nurse practitioner and front desk. Communication between the two will help ease the implementation of this project. Increased patient awareness and interest towards CGM will enhance staff buy-in. The nurse practitioner and front desk staff have agreed to aid with the implementation of this QI project.

Descriptions of the Practice Change

The PDSA framework describes the practice change that took place during this QI implementation. Each phase allowed for this DNP student to better prepare before beginning the project. The PDSA framework also allows for the DNP student to go back and see the original plan and what factors to change going forward.

Plan Phase

This DNP student met with the DNP project mentor to create a patient consent form explaining the purpose of this project. See Appendix E for patient consent form. Final approval was obtained in November 2023. See Appendix F for data collection worksheet. Project goal #1 was addressed in this phase.

Do Phase

In this phase, all patients with T2DM seen by the project mentor were asked if they were interested in piloting a CGM trial for two weeks, regardless of insurance. These patients were routinely performing finger-sticks to check their blood glucose. The process began with reviewing blood glucose measurements with the patient, asking about their regimen for monitoring blood glucose and presenting information regarding CGM. The DNP student explained the purpose, risks and benefits of CGM to the patient. If they were interested in a two-week trial, the consent form was presented for the patient to sign. The CGM was synced to their smartphones in the office, which took roughly five minutes for set up. Each initial BG measurement was recorded into a flowsheet (See Appendix F). The patients agreed to a two-week follow up and would utilize the CGM throughout the day with their smartphones. At the two-week follow up, patients would retrieve information on the smart phone application, showing trends of their BG. A BG measurement was recorded in the office at the two-week follow up and recorded into a flowsheet. No personal patient identifiers were collected.

Study Phase

The DNP student collaborated with the project mentor in offering CGM to all patients with T2DM that were seen during the implementation period. The project mentor was prepared to discuss CGM with patients scheduled during the implementation period. Samples of CGM

were readily available for use in the primary care office for patients who were interested. Weekly visits were made by the DNP student to evaluate if CGM was being offered to all patients with T2DM seen by the project mentor during the implementation period or if patient load was too heavy.

Act Phase

The DNP student addressed and revised the implementation process based on the data collected in the first PDSA cycle.

Evaluation

Project evaluation was assessed by measuring the percentage of patients who agreed to trial CGM that have T2DM. The DNP student identified the total number of patients who qualified for CGM trial, as well as the total number of patients who accepted.

Barriers to Implementation and Sustainability with Mitigation Plan

A barrier to implementation was the limited insurance coverage for the CGM sensor that led patients astray. Out-of-pocket price for CGM sensors is costly and doesn't fit the budget for those patients who declined to trial the sensor. Another barrier to implementation is the unwillingness to change regimen and try something new. Some patients stated that the current regimen was working well for them and they were uninterested at this time.

Table 2. Project Timeline

Phase	Description	Date
Phase 1	**Problem Identification and Evidence Review** **PICO Question**	**6/30/2023**
	Evidence Search	**7/31/2023**

	Evidence Appraisal	
Phase 2	**Project Goals**	**7/21/2023**
	Framework	**8/21/2023**
	DNP Project Proposal	**10/15/2023**
	IRB Submission	**11/03/2023**
Phase 3	**Implement Project**	**11/15/2023**
Phase 4	**Analysis**	**2/10/2024**
Phase 5	**DNP Final Paper/Presentation** **Dissemination**	**4/15/2024** **5/01/2024**

Resources/Budget

Table 3. displays the estimated costs for this DNP QI project.

Table 3. Resources/Budget

Expense	**Cost**	**Running Total**
Freestyle Libre™ Sample	$0.00	$0.00
Patient Consent Forms	Staples Professional Print $0.20/page in black & white Letter (8.5” x 11”) 30 copies printed	$6.00
Poster board	Professional Printing $45	$51.00

Dissemination Plan

The dissemination plan included a QI poster board presentation held at Sacred Heart University, an abstract and an executive summary. The poster board presentation included data in the forms of charts and tables reflecting data collected. Information was relayed to the nurse

practitioner and medical director at the primary care office where the DNP project took place via PowerPoint presentation.

Ethical Review

The DNP project was implemented at private family practice office in CT. All information collected was aggregate data and no personal identifiers were recorded. Patients could decline participation (ie. Free Style Libre ^{TM}). There was no IRB process for this medical office. This project was reviewed by the SHU IRB and given an exempt status (IRB# 231106B) See Appendix G and H.

Project Implementation

Implementation for this project began in November 2023 and was conducted for 12 weeks. There was efficient communication between the DNP student and the DNP project mentor regarding the project at the start of the implementation. The project mentor had begun having discussions with prospective patients about CGM and sample CGM sensors were available during the implementation period.

When a patient with T2DM came to the office, they were checked in by the front desk staff and brought to the examination room by a medical assistant. The project mentor, an advanced practice registered nurse (APRN), then examined the patient and introduced the topic of CGM and how it is related to T2DM. The information and benefits regarding CGM were given to the patient and explained that CGM offers real-time blood glucose measurements by simply waving their smartphone over a sensor that is applied to the back of their arm. The APRN presented a sample of CGM to the patient. The sensor application process was explained to the patient and information regarding the life of the sensor (14 days) was provided. The patient was educated to discard the sensor if it became unattached before the 14 days. The patient was

educated that the CGM sensor syncs with their smartphone, so all data can be viewed by the project mentor. The patient was then educated that a two-week follow-up appointment would be made in order to review blood glucose measurements and discuss results.

Once a patient expressed interest in the FreeStyle Libre™ CGM sensor, consent was obtained and the consent form was signed. The sensor was then set up in the office before the patient left. Every patient interested in the CGM sensor had a smartphone and was able to download the FreeStyle Libre™ application. The sensor was synced to their phone at that visit and BG monitoring began. Setting up the sensor and smartphone application took in total no more than five minutes. The initial blood glucose reading was recorded. The front desk then made a two-week follow up appointment for the patient either in the office or via telehealth. The two-week blood glucose reading was recorded at the follow-up visit.

Evaluation/Results

Data retrieval was completed by the DNP student and project mentor. Data was collected over a 12-week period. Not all patients with T2DM who saw the APRN had appointments during the implementation period. This limited the project data to only those who were seen in office during this time. Some patients with T2DM were content with the regimen they currently had and did not want to make changes. Some were interested in doing the trial CGM but were told up front that insurance wouldn't cover this long-term if they decided to continue after the two-week trial period and ultimately decided against it. Those who decided to trial CGM were informed that there was a chance the CGM sensor may become detached before the two-week follow-up. During the implementation period, no one experienced the CGM sensor becoming detached throughout the two-week trial.

Out-of- pocket CGM cost was a deterrent for some patients who were initially interested in trialing the CGM. Private or commercial insurance will help with coverage of CGM with a copay averaging $40/month. This does not include patients with Medicare, Medicaid, or uninsured (FreeStyle Libre, 2023). Medicare coverage has requirements that include an official diagnosis of diabetes, insulin-treated or at risk for hypoglycemic events (FreeStyle Libre, 2023). Veterans may also qualify for coverage of CGM with specific qualifications. However, out-of-pocket price for one FreeStyle LibreTM sensor ranges from $130-$160 according to multiple pharmacy websites (GoodRx, 2024). There are coupons available via GoodRxTM that can help aid in cost reduction. Considering the CGM sensors have a two-week life period, this would require purchasing two sensors per month. Until CGM is more widely covered, patients may be unable to afford this.

Process Measures

The intervention that was implemented was trialing a CGM sensor for two weeks in patients that have T2DM. Of the 48 patients seen by the APRN, 23 agreed to trial the CGM sensor. All 23 patients returned for the two-week follow-up visit. Data collected included initial BG measurement and BG measurements two weeks after CGM trial. See Figure 1. for data collection.

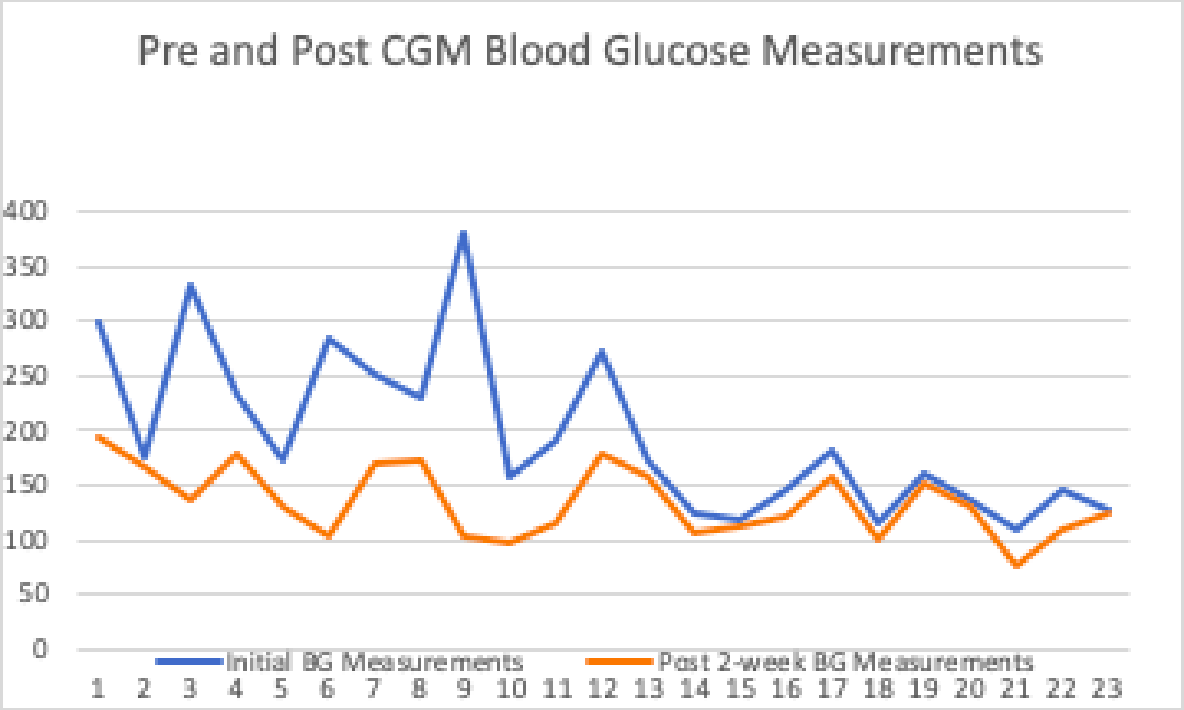
Figure 1. CGM Data Collection

CGM Data Collection				
Total # T2DM patients seen by Hilary	**Total # patients agree to Trial**	**Total # of prescriptions**	**Initial BG Measurements**	**Post 2-week BG Measurements**
48	23	7	298	195
			177	166
			333	136
			232	178
			172	129
			283	103
			250	170
			230	173
			380	102
			157	98
			192	115
			271	178
			174	158
			123	107
			118	111
			144	120
			182	158
			115	100
			160	152
			137	129
			108	76
			145	110
			128	124
		AVERAGE:	**196**	**134**

Outcome Measures

Forty eight percent of patients with T2DM agreed to trial the CGM. The average BG measurement at the start of implementation was 196 mg/dL compared to the average BG measurement of 134 mg/dL following the two-week CGM trial. See Figure 2 for pre and post CGM BG measurements. The impact the intervention of CGM sensors demonstrated an overall downtrend in BG after two weeks of having the CGM sensor applied. Of these 23 patients, 30% of patients qualified for insurance coverage. These are the only patients who sought out a prescription for CGM.

Figure 2. Pre and Post CGM Blood Glucose Measurements



Return on Investment

Overall, roughly half of the patients seen by the nurse practitioner that have T2DM decided to trial the CGM sensor. There was an overall improvement in BG over the two-week CGM trial period. Patients felt more engaged in self-management of T2DM and seeing an improvement in BG measurements. Patient self-management is critical in improving chronic disease outcome. Having better disease control can decrease risk of other complications associated with T2DM (DCCT, 1987).

Key Lessons Learned

A key lesson learned is that some patients were very comfortable with their current routine. Some patients have had HgbA1c levels in the target region and didn't feel that it was necessary to implement a change in the regimen. These patients have made changes to their diet and lifestyle behaviors and have had success with keeping their diabetes controlled. While

attaching a CGM sensor in non-invasive, having a CGM sensor attached to their arm was not something that all patients were interested in.

Lastly, this DNP project may have had an increase in data if all providers were included in the implementation of CGM. There are two other nurse practitioners at this primary care office who also see patients with T2DM. If the other nurse practitioners were included in the implementation period, there may have been more patients interested in trialing CGM which would have produced more data.

Sustainability

Engaging the entire staff to increase awareness and conversations regarding CGM would also increase usage of CGM in patients with T2DM. Having CGM samples and informational brochures about these readily available in the examination rooms could help increase awareness. However, since CGM isn't fully covered by all insurances, it may present as a barrier for patients to trial.

References

American Diabetes Association, 2022. A study of access to continuous glucose monitors *by* ... https://www2.diabetes.org/sites/default/files/2022-10/ADA-CGM-Utilization-White-Paper-Oct-2022.pdf

Cuevas, H., Heitkemper, E., & Haque, B. (2022). Relationships among perception of cognitive function, diabetes self-management, and glucose variability in older adults: A mixed methods study. *Research in Gerontological Nursing*, *15*(4), 203–212. https://doi.org/10.3928/19404921-20220609-02

GoodRx (2024). Freestyle Libre prices, coupons & savings tips. https://www.goodrx.com/freestyle-libre

Geng, T., Zhu, K., Lu, Q., Wan, Z., Chen, X., Liu, L., Pan, A., & Liu, G. (2023). Healthy lifestyle behaviors, mediating biomarkers, and risk of microvascular complications among individuals with type 2 diabetes: A cohort study. *PLOS Medicine*, *20*(1). https://doi.org/10.1371/journal.pmed.1004135

Janapala, R. N., Jayaraj, J. S., Fathima, N., Kashif, T., Usman, N., Dasari, A., Jahan, N., & Sachmechi, I. (2019). Continuous glucose monitoring versus self-monitoring of blood glucose in type 2 diabetes mellitus: A systematic review with meta-analysis. *Cureus*. https://doi.org/10.7759/cureus.5634

Kruger, D. F., & Anderson, J. E. (2021). Continuous Glucose Monitoring (CGM) is a tool, not a reward: Unjustified insurance coverage criteria limit access to CGM. *Diabetes Technology & Therapeutics*, *23*(S3). https://doi.org/10.1089/dia.2021.0193

Oser, T. K., Litchman, M. L., Allen, N. A., Kwan, B. M., Fisher, L., Jortberg, B. T., Polonsky, W. H., & Oser, S. M. (2021). Personal continuous glucose monitoring use among adults with type 2 diabetes: Clinical efficacy and economic impacts. *Current Diabetes Reports*, *21*(11). https://doi.org/10.1007/s11892-021-01408-1

Shrivastav, M., Gibson, W., Shrivastav, R., Elzea, K., Khambatta, C., Sonawane, R., Sierra, J. A., & Vigersky, R. (2018). Type 2 diabetes management in primary care: The role of retrospective, professional continuous glucose monitoring. *Diabetes Spectrum*, 31(3), 279–287. https://doi.org/10.2337/ds17-0024

Wright, E. E., & Subramanian, S. (2021). Evolving use of continuous glucose monitoring beyond intensive insulin treatment. *Diabetes Technology & Therapeutics*, 23(S3). https://doi.org/10.1089/dia.2021.0191

Zheng, M., Luo, Y., Lin, W., Khoja, A., He, Q., Yang, S., Zhao, X., & Hu, P. (2020). Comparing effects of continuous glucose monitoring systems (CGMS) and self-monitoring of blood glucose (SMBG) amongst adults with type 2 diabetes mellitus: A systematic review protocol. *Systematic Reviews*, *9*(1). https://doi.org/10.1186/s13643-020-01386-7

Appendix A. RCA Tool

RAPID CRITICAL APPRAISAL OF A MIXED METHODS STUDY

Project Title: Continuous Glucose Monitoring in Type 2 Diabetics

Date: 06/07/2023

Appraiser's Name: Molly Suydam

PICO(T) Question: In adults ages 18-65 with type 2 diabetes (p), how does continuous glucose monitoring (I) ocmpared to ACHS finger sticks(C) improve fasting blood glucose in two weeks?

Article Citation (in APA 6th ed format): Cuevas, H., Heitkemper, E., & Haque, B. (2022). Relationships among perception of cognitive function, diabetes self-management, and glucose variability in older adults: A mixed methods study. Research in Gerontological Nursing, 15(4), 203–212. https://doi.org/10.3928/19404921-20220609-02

Indicate the level of the study you are appraising: Mixed methods study

Recommendation for article inclusion in your body of evidence to answer your question: This study has information and data explaining the benefits of CGM in patients with T2DM, while also investigaitng self-reports from questionnaires regarding awareness of physiological changes and self-management.

GENERAL DESCRIPTION OF STUDY

1. **Purpose of study, including research question(s) or hypotheses:** The purpose of this study is to examine relationships between adults with T2DM and glucose variability via quesitonairres, CGM or self-management.

2. **Design/Method:** The mixed methods deisgn incorporates the use of online questionnaires, CGM reports and interviews. Questionnaires included perceived cognitive dysfuntion, execitive functioning scale, diabetes self-management and CGM data. Interviews involved examination of self-management use which lasted 30-45 minutes and composed of 5 open-ended questions. Data analysis incorporated SPSS version 25 for quantitative analyses.

3. **Sample:** 30 adults ages 60-72 with at least two years of being diagnosed with T2DM and using CGM were sampled. The sample was diverse with hispanic, non-hispanic, and african-american individuals. Recruitment took place over 5 months. Informed consent was obtained.

4. **Setting:** Endocrinology clinic in Texas from september 2019-Januaray 2020

5. **Data Collection methods:** Questionnaires, interviews, CGM data using SPSS version 25

QUALITY OF STUDY

General Questions

1. **What different methods or approaches were used in the study?**

☒Yes ☐No ☐Unknown

Core Component:	Supplemental Component:
☒Qualitative	☐Qualitative
☐Quantitative	☒Quantitative

Comments: Most of the data collected was via personal feedback. After these questionnaires and interviews were conducted, CGM data was used for quantitative analysis.

Important Note:
Please complete the appropriate rapid critical appraisal form for each component (e.g. RCT, Descriptive, Qualitative study) before you answer the questions below about this mixed methods study.

Validity: Are the results of this study valid?

2. **Was the qualitative component(s) of the study well developed?**

☒Yes ☐No ☐Unknown

- **Strength of the qualitative component(s):** More verstaile: allows for a variety of feedback
- **Level of the qualitative component(s):** level 3: non-experimental
- **Quality of the qualitative component(s):** ☐high ☒medium ☐low

3. **Was the quantitative component(s) of the study well developed?** ☒Yes ☐No ☐ Unknown

   - **Strength of the quantitative component(s):** important facts from numerical data, more accurate and reliable
   - **Level of the quantitative component(s):** Interval : data can be categorized, ranked and evenly spaced
   - **Quality of the quantitative component(s):** ☒high ☐medium ☐low

4. **Were the two components used to created joined, comprehensive results or discussion?** ☒Yes ☐No ☐Unknown

Comments: Results from both qualitative and quantitative findings were discussed in separate sections and joined as a whole in the conclusion.

5. **What statistical analysis methods were used?**
   - **Were the statistical analysis methods clearly described?** ☒Yes ☐No ☐ Unknown
   - **Were the statistical analysis methods appropriate?** ☒Yes ☐No ☐ Unknown
     Comments: Click here to enter text.

6. **What were the main mixed results of the study?** There seems to be a direct correlation between glucose variability and perceived cognitive function/memory. The benefits of CGM arise when persistence and education is provided. Improved self-management could lead to better glucose control.

7. **What were the main results of the study?**
   - **Statistical significance (*p* value)** <0.01
   - **Confidence interval and/or standard deviation** SD for memory contentment (0.465), SD for memory ability (0.255), SD for executive function (-0.085). SD for diet (0.256), SD for glucose testing (0.114), SD with years with diabetes (0.170)
   - **How precise was the intervention/treatment?** ☒Narrow ☐Wide
   - **Effect size** n/a, no control group to measure

8. **Were the results clinically significant?** ☒ Yes ☐No ☐ Unknown
   - **Were the following reported: NNT, NNH, OR, RR?** ☐Yes ☒No
     Comments: Click here to enter text.
9. **Was the date range of the cited literature current?** ☒ Yes ☐No ☐ Unknown
   - **What date ranges were included?** 2017**to** 2023
     - **If older literature was included, why was it included?** Click here to enter text.

Applicability/generalizability: Can I apply these valid, important results?

10. **Can the results be applied to my population of interest?** ☒Yes ☐No ☐ Unknown
    - **Is the treatment feasible in my care setting?** ☒Yes ☐No
    - **Do the outcomes apply to my population of interest?** ☒Yes ☐No
    - **Are the likely benefits worth the potential harm and costs?** ☒Yes ☐No
    - **Were the subjects/participants in the study similar to my population of interest?** ☒Yes ☐No
    - **Were all clinically important outcomes considered?** ☒Yes ☐No
      Comments: In my clinical setting, I will be collecting data on adults with type 2 diabetes using CGM.

11. **Will you include the article/study in your practice decision to make a difference in outcomes?**

    ☒Yes ☐No ☐Unknown

    - **If yes, why would you do this and how would you do this?** This study shows that use of CGM can improve not only self-awareness of BG but also influence diet and exercise decisions.
    - **If no, why would you not include the results to make a difference?** Click here to enter text.

STRENGTH OF STUDY

Level of Study: ☐I ☐ II ☐ III ☐ IV ☒ V ☐ VI ☐ VII

Quality of study: ☐ High ☒ Medium ☐ Low

STRENGTH = LEVEL + QUALITY

What is the strength of the study? The strength of the study is that it involes both qualitative and quantitave data that can be further researched.

What is your recommendation for article inclusion in the body of evidence to answer your question? Click here to enter text.

☒Include this article in the body of evidence (place this article's information on the evaluation & synthesis tables)

☐Do NOT include this article in the body of evidence

Additional comments: Click here to enter text.

Appendix B. Levels of Evidence

Article	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Level 1: Systematic review or meta-analysis of all relevant RCT							
Level II: Randomized Control Trial							
Level III: Controlled trial without randomization							
Level IV: Case-control or Cohort Studies	**X**			**X**			
Level V: Systematic review of descriptive and qualitative studies		**X**	**X**		**X**	**X**	**X**
Level VI: Qualitative or Descriptive Study, EBP, QI							
Level VII: Expert Opinion							

Legend: X indicates level of evidence of the associated article

Appendix C. Outcomes Synthesis of CGM use

Outcomes	**1**	**2**	**3**	**4**	**5**	**6**	**7**
HgbA1c	**NE**	↓	↓	↓	↓	**NE**	↓
Lifestyle Changes	↑	**NE**	↑	↑	↑	↑	**NE**
Patient Satisfaction	↑	↑	**NE**	↑	↑	↑	↑

Legend: NE = not evaluated

↓ = Decrease in HgbA1c with CGM

↑ = Increased lifestyle changes and satisfaction with CGM.

Appendix D. Evidence Summary Table

Evidence Summary Table

PICO Question: In individuals age 18-64 with type 2 diabetes mellitus (P), how does continuous glucose monitoring (CGM) (I), compared to finger-stick checks (C), improve fasting blood glucose (FBG) over two-weeks (O)?

Citation	Design/ Method	Sample/Setting	Intervention	Major Variables Studied and Their Definitions	Findings	Level of Evidence/Quality	Quality of Evidence: Critical Worth to Practice
Article 1 Cuevas, et. al, (2022). Relationships Among Perception of Cognitive Function, Diabetes Self-Management, and Glucose Variability in Older Adults	Cohort Study	Participants ranged from 60-72 years old from an endocrinology office in Texas 30 adults underwent interviews, questionnaires and CGM reports This took place from 9/2019 to 01/2020	CGM use	IV: CGM use DV: improved lifestyle changes, improved patient satisfaction	The integration of CGM in adults with T2DM improved overall awareness of glucose control and decreased levels of hypo/hyper-glycemia	Level IV: Cohort Study	CGM improved lifestyle changes which inherently decreased fasting BG, decreased episodes of hypoglycemia
Article 2 Kruger & Anderson, et. al, (2021).	Systematic Review	Adults >60 with T2DM and cost/coverage of CGM with insurance	Use of CGM and data interpretation	IV: CGM use in adults >60 with insurance coverage DV: cost of CGM and	Insurance coverage of CGM means higher likeliness of	Level V: Systematic review of descriptive and qualitative studies	CGM improves overall HbA1c, but can be costly without insurance coverage from prescription

Continuous Glucose Monitoring (CGM) Is a Tool, Not a Reward: Unjustified Insurance Coverage Criteria Limit Access to CGM				likeliness of usage	individuals using CGM		
Article 3 Wright, et. al, (2021). Evolving Use of Continuous Glucose Monitoring Beyond Intensive Insulin Treatment	Systematic Review	Recent randomized control trials reviewed resulting in decreased HbA1c due to use of CGM, decreased hospitalizations, and improved insulin management	Studies over 10 years reviewed showing impact of CGM on lifestyle modifications and weight management	IV: CGM use DV: Increased behavior modifications and awareness of weight management, decreased HbA1c	Consistent use of CGM has many glycemic benefits including improved dietary habits, increased physical activity, reduction of body weight, reduced HbA1c by 1%, $p < 0.001$	Level V: Systematic review of descriptive and qualitative studies	CGM increases awareness of behavior modifications that can help reduce BG without insulin therapy
Article 4 Shrivastav, et. al, (2018).	Case Study	Total of 4 case studies reviewed regarding	Use of CGM	IV: CGM DV: improved HbA1c, HTN, BMI, glucose	Use of CGM improved overall QoL for these	Level IV: Case study	Use of CGM can ultimately increase awareness of behavior modifications/lifestyle

Type 2 Diabetes Management in Primary Care: The Role of Retrospective, Professional Continuous Glucose Monitoring		individuals with T2DM and benefits of CGM		control, remission of DM	individuals in the case studies via reduced HbA1c, overall CV health, better control of DM without use of insulin therapy and complete remission of DMT2.		modifications that ultimately improve QoL outside of DMT2.
Article 5 Janapala, R. et. al, (2019). Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Type 2 Diabetes Mellitus	Systematic Review	Multiple studies reviewed researching use of CGM daily vs intermittently over a period of time Adults >18yo	CGM device used daily for 24 weeks CGM used every 3 days intermittently for 12 weeks	IV: CGM usage DV: reduced hypoglycemia, increased quality of life, increased patient satisfaction	Increased patient satisfaction with use of CGM, change in QOL, No measures of hypoglycemia	Level V: Systematic review of descriptive and qualitative studies	Usage of CGM increased patient satisfaction towards glucose monitoring
Article 6 Zheng et. al, (2020).	Systematic Review	Adults>18yo with T2DM	CGM vs SMBG	IV: CGM/SMBG	CGM has increased patient	Level V: Systematic review of descriptive and qualitative studies	There is an increased QoL with CGM as opposed to SMBG due to the

Comparing effects of continuous glucose monitoring systems (CGMs) and selfmonitoring of blood glucose (SMBG) amongst adults with type 2 diabetes mellitus: a systematic review protocol		RCTs between 2010 and 2020 reviewing CGM and SMBG		DV: Glucose control, body weight, hypoglycemia, QoL	satisfaction over SMBG		inconsistency of SMBG.
Article 7 Oser, T. K. et. al, (2021). Personal Continuous Glucose Monitoring Use Among Adults with Type 2 Diabetes Mellitus	Systematic Review	Multiple studies reviewed researching usage of CGM with patients utilizing insulin therapies vs non-insulin therapies	CGM device used for 12 weeks	IV: CGM usage DV: decrease in HbA1c, decreased BMI, BP, HDL	Usage of CGM decreased overall HbA1c in 12 and 24 weeks, reduction of BMI, BP, increased patient satisfaction	Level V: Systematic review of descriptive and qualitative studies	Usage of CGM improved HbA1c, decreased BMI and BP after 12 weeks and self-modifications with lifestyle changes

Appendix E. Patient Consent Form.

DR. SUSAN L. DAVIS, R.N.,
& RICHARD J. HENLEY
COLLEGE OF NURSING
Sacred Heart University

Continuous Glucose Monitoring Informed Consent Form

Patients who have been diagnosed with type 2 diabetes are encouraged to check blood sugars throughout the day, but finger-sticks can grow cumbersome over time. Continuous glucose monitoring (CGM) allows for closer blood glucose monitoring via a sensor that is self-applied on the back of the arm. This sensor requires a smartphone to sync to, and when the smartphone is waved over the sensor, blood glucose measurements are revealed in real-time.

PURPOSE

The purpose of implementing CGM in patients diagnosed with type 2 diabetes is to increase awareness of blood glucose throughout the day. CGM would allow for the cessation of finger-sticks and offer real-time blood glucose measurements. Having this knowledge may encourage individuals with type 2 diabetes to continue making lifestyle changes. These changes may include dietary modifications, exercise, and remaining adherent with type 2 diabetes recommendations.

You will be given the choice to utilize a sample CGM sensor for two-weeks, of absolutely no charge, and have the smartphone synced before leaving the office. You can choose to opt out at any time, without penalty. Should you choose with opt out, please continue checking blood sugar as you previously would. Participating or not will not impact access to medical care.

The life of the CGM sensor is two weeks, in which a follow-up appointment will be made to check in and monitor blood glucose measurements on the smartphone. If you are unable to

attend an in-person visit, a Telehealth appointment will be offered to you. If a Telehealth appointment cannot be obtained, you are more than welcome to phone the office and request a prescription, if you are interested. Please note, you are not required to sample a CCGM sensor in order to obtain a prescription. You may request a prescription at the initial visit if you wish. Should there be a smartphone malfunction at any time, please feel free to contact the office in hopes we can trouble shoot over the telephone. During this time, please continue to check your blood sugar as you previously would.

RISKS

The CGM sensor is self-applied onto the back of an arm but may fall off before the two-week appointment. This may leave slight redness to the skin which is temporary. If the sensor should become detached from the arm, the sensor may be placed back into the original box and disposed of. Please continue to check your blood sugar is you previously would.

The area of skin will be cleansed with rubbing alcohol prior to sensor application to minimize the risk of infection at the site of the sensor. There are no risks of injury or death. There are no risks of punishment if you should choose not to utilize CGM. There are also no risks if you choose to opt out of CGM after you've started.

In the event you develop a medical concern, please contact the office immediately. If you are experiencing an emergency, please call 911 or go to the emergency room immediately

BENEFITS

Utilizing CGM can increase awareness of blood glucose measurements throughout the day which can encourage lifestyle changes such as dietary change, exercise, and remaining adherent with type 2 diabetes recommendations. There are no monetary benefits to this CGM trial period.

CONFIDENTIALITY

Your privacy is important to us. All information we obtain from you before, during and after the CGM utilization shall be kept confidential and anonymous. The information that will be recorded is the pre-CGM blood sugar measurements and post-CGM blood sugar measurements, with no personal identifiers and recorded in no specific order. This numerical data will be entered into an excel spreadsheet, only as numbers and without any personal identifiers. This data will be used towards a Doctor of Nursing Practice Project at Sacred Heart University via a presentation to monitor the trends of blood glucose measurements pre-and-post CGM use.

By filling out and signing this form, I hereby declare that I have read the information above and voluntarily participate to utilize a CGM sensor.

I understand the risks and benefits of CGM as well as my right to privacy. I also have had the opportunity to ask relative questions concerning the topic and all of which were explained to me and to my satisfaction. This information has been presented to me in writing of my primary language.

I will be provided a copy of the signed informed consent form for my own personal record.

Participant

First Name	Last Name	Date

Signature of Participant

Investigator

First Name	Last Name	Date

Signature of Investigator

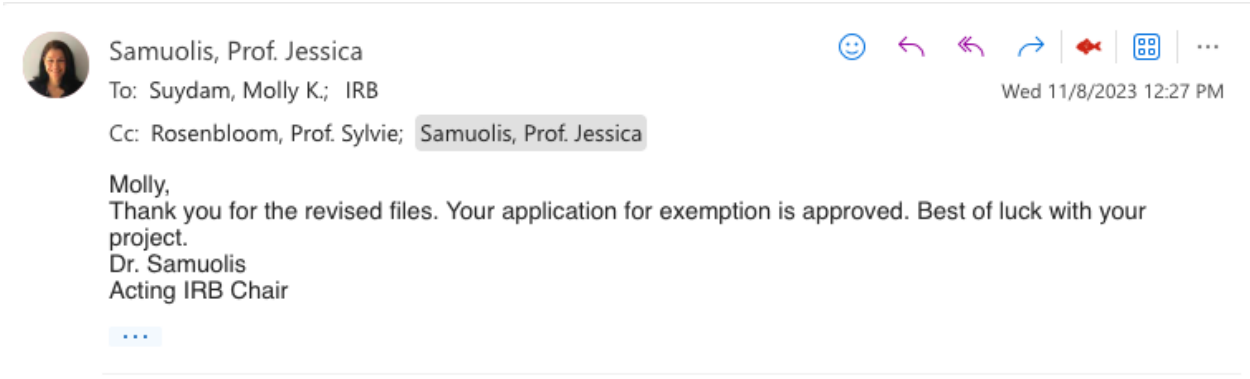
Faculty Advisor
Dr. Sylvie Rosenbloom, DNP, APRN, FNP-BC, CDCES, CME
Email: Rosenblooms@sacredheart.edu
Office: (203)-416-3932

Sacred Heart University Institutional Review Board Member
Funda Alp, Assistant Provost for Research & Sponsored Programs
Email: alpf1@sacredheart.edu
Office: (203)-396-8241

Appendix F. Data Collection Plan.

CGM Data Collection				
Total # T2DM patients seen by Hilary	Total # patients agree to Trial	Total # of prescriptions	Initial BG Measurements	Post 2-week BG Measurements

Appendix G. IRB Approval



Samuolis, Prof. Jessica

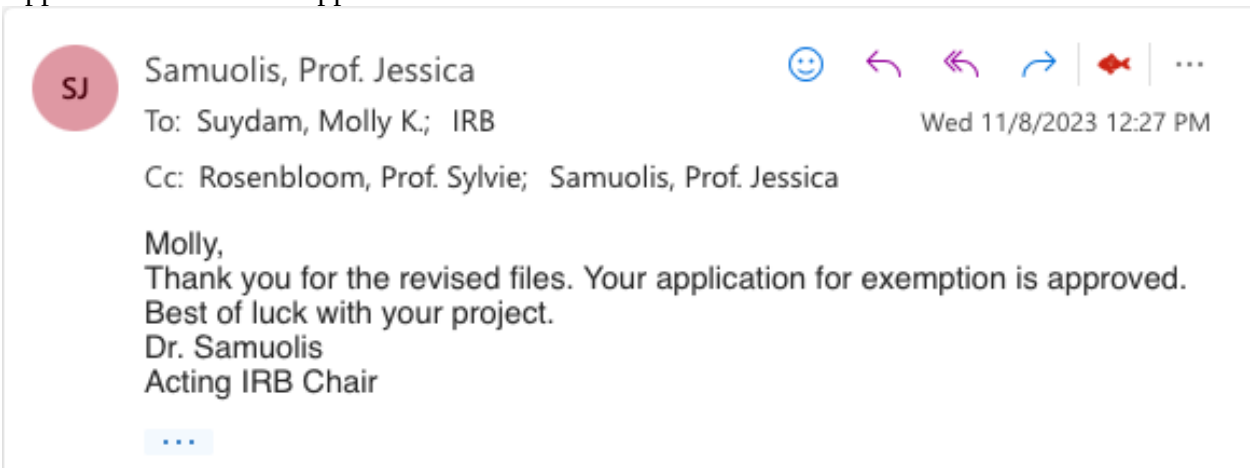
To: Suydam, Molly K.; IRB

Wed 11/8/2023 12:27 PM

Cc: Rosenbloom, Prof. Sylvie; Samuolis, Prof. Jessica

Molly,
Thank you for the revised files. Your application for exemption is approved. Best of luck with your project.
Dr. Samuolis
Acting IRB Chair

Appendix H. Letter of Approval from IRB



SJ

Samuolis, Prof. Jessica

To: Suydam, Molly K.; IRB

Wed 11/8/2023 12:27 PM

Cc: Rosenbloom, Prof. Sylvie; Samuolis, Prof. Jessica

Molly,
Thank you for the revised files. Your application for exemption is approved.
Best of luck with your project.
Dr. Samuolis
Acting IRB Chair

Appendix I. Executive Summary

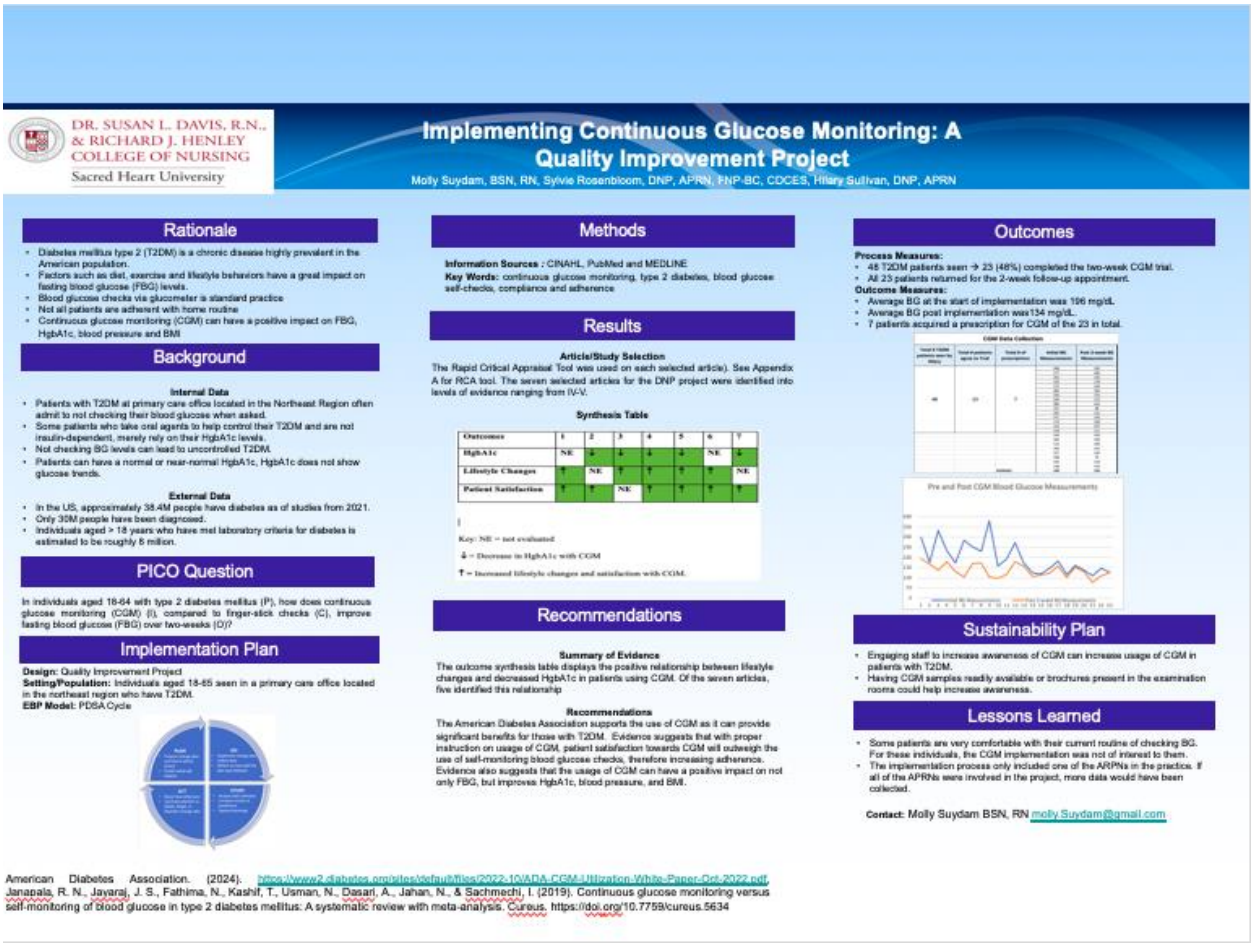
Type 2 diabetes mellitus (T2DM) has increased in prevalence and is estimated to have affected over 30 million people in the United States. Factors such as diet, exercise and lifestyle behaviors have a great impact on blood glucose levels. However, not all people with T2DM routinely check their blood sugars and therefore do not know if their diabetes is well-controlled. Continuous glucose monitoring (CGM) is a sensor that is applied to the back of a patient's arm and syncs to a smartphone to display real-time blood glucose measurements by waving the smartphone over the sensor. CGM is less cumbersome than daily finger-sticks and each sensor has a two-week battery life. The use of CGM aids to promote patient adherence of self-management of T2DM.

For this project, the Plan-Do-Study-Act method was used to provide education on the use and benefits of CGM for patients with T2DM seen at a primary care office in the northeast region of New England. In the Plan phase, a trial period for CGM was developed and a patient consent form was created. In the Do phase, patients with T2DM implemented CGM for a two-week trial period and returned to the office for a follow-up at the end of the trial to review BG data. For the Study phase, aggregate data regarding pre and post-CGM blood glucose measurements were evaluated. In the Act phase, CGM data was presented to the key stakeholders at the primary care office and recommendations were made to future PDSA cycles.

Twenty-three patients (48%) of 48 patients diagnosed with T2DM completed the two-week CGM trial. All 23 patients returned for their two-week follow-up appointment. All aggregate data was collected and recorded into an excel spreadsheet as pre- and post-CGM BG measurements. The average pre-CGM BG measurement was 196 mg/dL and the average post-CGM BG measurement was 134 mg/dL. This data demonstrates an overall decrease in BG measurements following the use of CGM. Seven patients in total obtained a prescription for CGM sensor solely because it was covered by their insurance.

Insurance coverage served as a barrier to implementation because patients were informed of the lack of coverage prior to CGM trial. Another barrier to implementation was the disinterest in changing current regimens for checking BG. Although CGM provides many benefits and is user-friendly, there were also those who did not wish to recreate a routine. However, the implementation of the CGM trial created an increased awareness across the providers and patients about the benefits of CGM for patients with T2DM. Sustainability includes having all providers at this primary care office engage in more education regarding CGM to patients with T2DM in hopes of improving overall self-management.

Appendix J. DNP Poster



American Diabetes Association. (2024). https://www2.diabetes.org/sites/default/files/2022-10/ADA-CGM-Utilization-White-Paper-Oct-2022.pdf.
Janapala, R. N., Jayaraj, J. S., Fathima, N., Kashif, T., Usman, N., Dasari, A., Jahan, N., & Sachmechi, I. (2019). Continuous glucose monitoring versus self-monitoring of blood glucose in type 2 diabetes mellitus: A systematic review with meta-analysis. Cureus. https://doi.org/10.7759/cureus.5634