CONTINUOUS GLUCOSE MONITORING, TYPE 2 DIABETES AND HEMOGLOBIN A1C: AN INTEGRATIVE REVIEW

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Kimberly Dawn Fairchild

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Lynchburg, VA

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[redacted]

July 30, 2021

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ABSTRACT

Continuous glucose monitors (CGMs) are used to measure a patient's glucose levels every few minutes around the clock. According to the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), CGMs are mostly used by Type 1 Diabetes Mellitus patients, but research has shown that Type 2 DM patients can benefit from them as well (Ida et al., 2019; NIDDK, 2017). Glucose levels can change over hours or days, and seeing the trends by using a CGM will help patients make more informed decisions about the food they eat and how much they exercise, and the type and amount of medication they take (NIDDK, 2021). The use of CGMs allows more control over a patient's disease process and promotes better health maintenance. The final outcome of using CGMs is lowering hemoglobin A1c levels. When glucose is monitored continuously, trends can be seen, hyperglycemic episodes, which may require a medication adjustment or an increase in exercise regimen, will be seen. This is especially beneficial for those who are hypoglycemic unaware, as food or glucose can be given to bring glucose levels to normal. Each of these adjustments keeps the glucose in the body at a more stable level, and ultimately, HbA1c levels will become lower as well.

Keywords: Type 2 diabetes, continuous glucose monitoring, hemoglobin A1c, T2DM, self-monitoring blood glucose, hypoglycemia, adults

Acknowledgments

During the writing of this integrative review, I received support that kept me from giving up when the days were long and hard. I would like to acknowledge my nursing chair, Dr. Sharon Kopis, who gave me strength, encouraged me, and prayed for me during this time. Her experience was invaluable to draw from and helped me to think more deeply by giving me feedback to push me to work harder and make me stronger through it all. I will always be grateful for her support.

I also want to thank my husband, Jim Fairchild, who has told me over and over again, "you can do this." Although he has suffered through many physical disabilities over the past few years, he has been the one to encourage me to follow my dream and to never give up. I want to tell him "thank you" from the bottom of my heart. I would never have made it to this point without you in my life.

And to my beautiful children and grandchildren (Courtney, Austin, Tyler, Caleb, Reagan, Sarah, Elaina, and Theo) who have inspired me to reach my goals, even though they probably did not know they were doing so: I want to say "I love you more than you could ever dream." Each of you is truly a gift from God, and just thinking of you at times has been my inspiration to carry on with this project.

And finally, I want to say "thank you" to the Lord Jesus Christ, who has given me the physical, mental, and spiritual strength to finish this project. The Lord is my strength and my song; He has given me victory (Exodus 15:2).

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List of Abbreviations

Continuous glucose monitor (CGM)

Hemoglobin A1c (HbA1c)

Integrative review (IR)

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

Randomized controlled trial (RCT)

Self-monitoring blood glucose (SMBG)

Time in range (TIR)

Type 1 diabetes mellitus (T1DM)

Type 2 diabetes mellitus (T2DM)

SECTION ONE: FORMULATING THE REVIEW QUESTION

Introduction

One of the greatest concerns with diabetic patients is the damage that high glucose levels can have on the blood vessels of the body, which could lead to heart disease, stroke, kidney disease, retinopathy, and neuropathy (National Institute of Diabetes and Digestive and Kidney Disease [NIDDK], 2021). The outcome of keeping blood sugar levels within normal range can be seen in evaluation of the hemoglobin A1c (HbA1c) levels. Maintaining time in range (TIR) of glucose levels by using a continuous glucose monitor (CGM) will ultimately lower HbA1c levels. The ability to see at a glance if a patient's glucose level is above range, below range, or in range will help the patient to be aware of the action needed to keep levels maintained better. The trends that can be seen with CGMs will allow patients, as well as medical personnel, to provide better care in that they can see these ranges. Using CGMs in Type 2 diabetes mellitus (T2DM) patients will allow them a better quality of life and could help them to escape the micro- and macrovascular problems that are related to glucose levels that are not well controlled. A review of numerous articles demonstrated that the use of CGMs benefits adult patients who have T2DM by lowering their HbA1c levels.

Problem Statement

This integrative review (IR) addresses the following clinical statement: In T2DM adult patients, the use of CGMs will improve the TIR of glucose levels, thus leading to a reduction of HbA1c levels.

Background

Continuous glucose monitoring is the use of a small sensor applied under the skin in the upper arm or abdomen that detects the glucose levels in the interstitial fluid (the fluid between

the cells). Most CGMs can detect the glucose levels every one to five minutes and show a trend or pattern over a 24-hour period or longer (NIDDK, 2017). Most patients who are diagnosed with T2DM check their blood sugar levels via self-monitoring blood glucose (SMBG) methods three to four times daily. Using SMBG addresses glucose levels at certain points in time, such as at meals and at bedtime. By using CGMs instead, patients and providers alike can see trends in glucose levels and make management decisions accordingly. With better management of glucose levels, HbA1c levels will be lower, thus decreasing the probability of the development of co-morbidities such kidney disease, heart disease, blindness, and neuropathy (Ida et al., 2019).

In the United States, according to the Centers for Disease Control (2019), 26 million people have a diagnosis of T2DM, and another 79 million have prediabetes. Ida et al. (2019) presents some astounding numbers from the World Health Organization, which estimated that the number of people with T2DM may increase to over 300 million by the year 2050. Arguello and Freeby (2017) stated that there have been many advances in the treatment in T2DM over the past several decades, but over half of patients are still not controlling their glucose levels, which creates more risk for further complications. It is important to know that diabetes management is not viewed in a silo, that is, it is not a disease that can be viewed as just one problem. Uncontrolled diabetes is responsible for the leading causes of blindness, kidney disease, heart disease, neuropathy, foot complications, high blood pressure, and stroke (American Diabetes Association, n.d.). The use of CGMs can help assist patients and care providers to better manage the disease, thus lowering the incidences of these other issues as well. In other words, CGMs may lead the way for prevention of secondary diseases associated with T2DM. Type 2 diabetic patients who use real-time CGMs have a way to look back and make adjustments to their lifestyle and pharmacotherapy regimen based on data (Ida et al., 2019). As mentioned earlier,

most CGMs are used by Type 1 diabetes mellitus (T1DM) patients. This brings up the question of why? Approximately 90%–95% of diabetics in the United States have T2DM, with the remainder having T1DM (Centers for Disease Control, 2019). Patients with both types of diabetes need to know their glucose levels, know their trends, keep their glucose under control, and avoid associated diabetes-related diseases. Compared to SMBG in T2DM patients, CGMs do not pose such a burden on these patients, such as the painful finger sticks that are associated with SMBG (Ida et al., 2019). Providers and patients alike need to see the importance of using CGMs as a tool for controlling the disease in both types of diabetes. For millions of patients with uncontrolled T2DM, CGMs can make a difference by facilitating better control of glucose levels, thereby decreasing the complications associated with the disease.

Defining Concepts and Variables

The keywords used for this IR were: *Type 2 diabetes, continuous glucose monitoring, hemoglobin A1c, T2DM, self-monitoring blood glucose, hypoglycemia, and adults.* For the purpose of this review, *continuous glucose monitoring* is conceptually defined as a glucose monitoring system that can track glucose levels at any time, day and night, and provides a way to see trends at a glance (NIDDK, June 30, 2021). Continuous glucose monitoring is operationally defined for this IR as the device used to manage glucose levels for the purpose of lowering Hemoglobin A1c levels. *Hemoglobin A1c* is conceptually defined as the amount of blood sugar (glucose) attached to hemoglobin for the past three months. Other names for hemoglobin A1c include HbA1c, A1c, glycol-hemoglobin, glycated hemoglobin, and glycosylated hemoglobin. Operational definition of *Hemoglobin A1c* in this IR is the laboratory result after T2DM patients use continuous glucose monitoring to manage their diabetes.

In identifying a topic for this IR, the reviewer chose a topic of interest that "stimulated curiosity and is meaningful to the reviewer and the profession" (Toronto & Remington, 2020, p. 14). The topic of CGMs is important to this reviewer because of the large number of people suffering with diabetes daily. Type 2 diabetics should be able to control their glucose levels by seeing their real-time glucose levels, giving them the opportunity to make decisions that will help lower their HbA1c levels. Carlson et al. (2017) explained that CGMs can be used as a "tool to help personalize a diabetes treatment plan" (p. S4). Knowledge of the trends of a patient's glucose levels also provides the health care provider with the information needed to present optimal treatment options for the diabetic patient.

Rationale for Conducting the Review

The purpose of this IR was to critique and review the literature to uncover what is known about T2DM patients who use CGMs and whether there is evidence of lower HbA1c levels as a result of the use of a CGM. This IR answers the "who, what, when, why and where" questions suggested by Toronto and Remington (2020, p. 16). CGMs use a small sensor inserted under the skin to track interstitial glucose levels automatically on a 24-hour basis (NIDDK, 2017). The monitor can be used alone or in combination with an insulin pump. Many CGMs have special features that allow the user to set alarms for high and low glucose levels and download data to a computer or a smartphone to view trends more easily. The monitors are used to see trends over a few hours or a few days. Although most CGMs are worn by patients with T1DM, evidence shows that T2DM patients can benefit from using them as well (Ajjan et al., 2019; Carlson et al., 2017). CGMs give real-time data to help those with T1DM and T2DM view their glucose trends at a glance. Having the ability to know their glucose level and see trends allows patients to make the needed exercise, dietary, or treatment changes and ultimately reduce their HbA1c levels

(Carlson et al., 2017). According to Sherwani et al. (2016) and Carlson et al. (2017), the HbA1c test is now the standard of care in diagnosing and monitoring T2DM patients. If this test is used in combination with CGMs, significant improvement can be seen in these patients (Azhar et al., 2020; Carlson et al., 2017). Given the high prevalence of T2DM and the comorbidities associated with it, CGMs can play a role in reducing many disease-related complications. This IR presents published evidence on the relationship between the use of CGMs and lower HbA1c levels. This IR lays the groundwork for changes in the care management of T2DM patients. Health care providers may use the nursing science and information associated with this IR to make more informed decisions and achieve better health outcomes for Type 2 diabetic patients. Type 2 diabetics may use this IR to play a larger role in self-management of their disease.

Purpose or Review Question

The purpose for this IR was to review the literature published from 2015 to 2021 to help determine if there is a relationship between the use of CGMs and lower HbA1c levels in adults with T2DM. Type 2 diabetics check their blood sugar levels at random throughout the day, normally around meals and at bedtime, which allows these patients to see what their blood sugar level is only at that point in time. With CGMs, these same patients can, at a glance, see what their glucose levels are every one to five minutes, as well as see the trend of their levels throughout the day (Reddy et al., 2020). The ability to see trends in glucose levels allows patients who are diagnosed with T2DM to make adjustments in their diet, exercise plans, and medication regimen (Carlson et al., 2017). Reddy et al. (2020) supported this adjustment in behavior by saying, “Use of CGM can help both the patient and their medical provider make fine tune adjustments to medication therapy and provide insight to the patient on behavioral changes to achieve glycemic control” (p. 3). Practitioners can use this data to better manage T2DM

patients by seeing these trends via computer and making more insightful decisions regarding medication dosages and diet plans (Carlson et al., 2017; Ida et al., 2019). In the end, integrating CGMs into T2DM patients' health management plan will help patients and providers alike to maintain better control over glucose levels and achieve better health outcomes of lower HbA1c levels, thereby decreasing other related health issues that are inevitable when glucose levels are constantly high.

This project purposed to analyze and synthesize information from articles describing the outcomes of the use of CGMs in T2DM patients. This research is significant because most CGMs are used by T1DM patients at this time but are also beneficial in the management of T2DM patients as well (Anders et al., 2017). Based on the evidence regarding the impact of the use of CGMs on HbA1c levels in Type 2 diabetics, the use of CGMs is proposed to play a vast role in health management of these patients.

The IR addresses the following clinical statement: In T2DM adult patients, the use of CGMs as compared to random blood sugar checks will help increase the TIR of glucose levels, thus leading to a reduction of HbA1c levels. The following questions helped support and focus the review process:

1) How are patient outcomes affected by using CGMs, particularly HbA1c levels?
2) What factors contribute to health care providers' use of CGMs in T2DM patients?
3) When using CGMs in T2DM patients, is TIR positively effected?

Inclusion and Exclusion Criteria

It is with a clear review question that the reviewer is able to develop inclusion and exclusion criteria for studies located through the literature search (Toronto & Remington, 2020). In order to maximize the number of resources for this literature review, a systematic search was

conducted by using these databases: CINAHL, PubMed, ProQuest, and Medline. The keywords used in the search were: *continuous glucose monitors, hemoglobin A1c, Type 2 diabetes, self-monitoring blood glucose levels, adults,* and *glucose management outcomes.* The search results were narrowed to include only articles written between the years of 2015 and 2021, peer-reviewed journal articles, full-text articles, and articles written in the English language. The disciplines that were used as search criteria were nursing, medicine, and public health. Newspaper articles, dissertations, and book reviews were excluded from the original search.

Literature Search Results

After applying inclusion criteria and searching using the term *continuous glucose monitoring*, results showed 12,906 articles. After adding the terms *hemoglobin A1c* and *Type 2 diabetes mellitus,* 2,470 articles were found. Next, the results were narrowed to only include articles containing such terms as *adults and outcomes, hypoglycemia,* and *self-monitoring of blood glucose,* and 286 articles remained. Studies included in the review focused on Type 2 diabetics using CGM devices and the effects of the use of the CGM on HbA1c levels. After adding the exclusion criteria of pregnancy, children, Type 1 diabetes, specific technology companies, retinopathy, and oral anti-glycemic, 57 articles resulted from the search. After articles that were duplicates or did not meet the criteria for this IR were removed, the remaining 19 studies spoke directly to Type 2 diabetes management and reduction of HbA1c through the use of CGMs.

An analysis of the articles retrieved revealed that some did not meet the criteria to answer the research question. Articles were also excluded that only addressed barriers to using CGMs and how to access them. Others were excluded because they only addressed gestational diabetes and CGMs, focused on children and adolescents, or only studied T1DM. Articles were chosen

for inclusion if they related entirely to CGMs and the lowering of HbA1c levels (Azhar et al., 2020; Chehregosha et al., 2019; Cowart et al., 2020; Haak, 2018; Hajime et al., 2018; Ida et al., 2019; Janapala et al., 2019; Mariani et al., 2017; Taylor et al., 2018; Toschi & Wolpert, 2016; Vigersky & Shrivastav, 2017; Yeoh et al., 2018). Other articles contain supporting information regarding other outcomes of using CGMs such as increased TIR and glycemic efficacy, and decreased hypoglycemic events and may be used to further increase the evidence level of this IR (Battelino et al., 2019; Carlson et al., 2017; Gomez-Peralta et al., 2020; Haak, 2018; Ida et al., 2019; Ishikawa et al., 2018; Mohan et al., 2016; Park & Le, 2018; Torimoto et al., 2017; Yeoh et al., 2018). Still other articles were chosen because they focused on Type 2 diabetics who are using insulin along with CGMs and may be useful in further research (Beck et al., 2017; Ishikawa et al., 2018).

Articles chosen included randomized controlled trials (RCT), descriptive/qualitative studies, systematic reviews, meta-analyses of RCTs, and quasi-experimental controlled trials. The articles selected included several Level 1 and 2 evidence articles, according to the Melnyk & Fineout-Overholt (2015) framework, and several studies used large number of participants, factors which strengthen this IR. However, a few of the studies did not show enough data to support of the IR or the length of the study was not long enough to provide accurate data. HbA1c levels take longer than 30 days to show results (normally 90 days), and any study conducted in less time would not prove strong enough to support this IR.

The articles chosen for this IR were ones that give strength to the clinical question of whether using CGMs in adults with T2DM has an effect on HbA1c levels. In the past, the use of CGMs was assessed only with T1DM patients but has more recently been shown useful in T2DM patients, especially those T2DM patients who take insulin (Reddy et al., 2020). The

usefulness of CGMs is seen in lower HbA1c, which in turn decreases the risk of secondary diabetes-related conditions such as kidney disease, retinopathy, hypoglycemia events, and peripheral nerve damage.

Conceptual Framework

The conceptual framework used for this IR served to connect all aspects of the review (Toronto & Remington, 2020). Whittemore and Knafl (2005)'s research on IRs was used as the framework for this IR. Using this framework allowed the inclusion of current information that addressed the issues specific to the review question. The stages included in this conceptual framework to conduct this IR were: identifying the problem, searching the literature, evaluating the data, analyzing the data, and presenting the results (Whittemore & Knafl, 2005).

Whittemore and Knafl (2005) suggested that the problem be clearly identified so the reader knows clearly what the IR addresses. The problem should also include the target population and the health care problem, T2DM adult patients in this IR. In the literature search stage, Whittemore and Knafl (2005) recommended that the writer include the search methods, such as databases used or hand searches. Data evaluation should include empirical and theoretical sources used in the search for literature. Data analysis includes data reduction, data display, data comparison, and conclusion drawing (Whittemore & Knafl, 2005). The last stage of the framework described by Whittemore and Knafl (2005) is presentation. Primary source details and evidence that gives the reader assurance that there is a logical chain of evidence within the review should be presented during this stage.

SECTION TWO: COMPREHENSIVE AND SYSTEMATIC SEARCH

Search Organization and Reporting Strategies

Maximum resources for this IR were obtained through a systematic search approach using these databases: CINAHL, PubMed, ProQuest, and Medline. These platforms included comprehensive databases for nursing research and information that contained peer-reviewed articles from science journals with full-text availability (Toronto & Remington, 2020). The keywords used in the search were: *continuous glucose monitors, hemoglobin A1c, Type 2 diabetes, self-monitoring blood glucose levels, glucose management,* and *outcomes*. The search was narrowed by setting parameters for articles published between 2015 and 2021, articles that were peer reviewed, and articles written in the English language. Discipline criteria were also set to include nursing, medicine, and public health. Excluded from the search were newspaper articles, dissertations, and book reviews.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), (Appendix C) was the reporting model used to show the flow of information through the different phases of the review (Toronto & Remington, 2020). The methodology used to search was comprehensive, and more than one database was searched in order to locate the most information possible about the use of CGMs and its relationship to HbA1c levels. This methodology also helped to minimize bias and increase the rigor of the study.

Terminology

The term *database*, as used in this IR, referred to the electronic, searchable collection of published materials which included professional journals that were peer-reviewed (Toronto & Remington, 2020). The term *search engine* referred to a library search of multiple databases using Liberty University's Jerry Falwell library. Databases used were Medline, PubMed,

CINAHL plus with full text, ProQuest's Health and Medical Collection, *Journal of the American Medical Association,* and ProQuest's Nursing and Allied Health Database (Toronto & Remington, 2020).

SECTION THREE: MANAGING THE COLLECTED DATA

The initial step during the review involved evaluating the titles and abstracts of the articles that resulted from the search for relevancy to the review topic. Articles were not discarded if they did not exactly match the eligibility criteria but were discarded if they were related to T1DM, children, or pregnancy. Abstracts of the articles were read and used to locate relevant information regarding CGMs and their relationship to HbA1c levels. Articles were also selected based on whether they included full text. These articles were stored and sorted into categories in a Word document provided by this author (see Appendix B). Studies that were described in more than one report were counted as one study, but both reports were used to collect data about this IR project (Toronto & Remington, 2020). A visual representation of the screening and selection process was created using the PRISMA flowchart (Moher et al., 2009). The PRISMA flowchart depicts the process of obtaining data and articles, including the numbers of articles included and excluded (see Appendix D).

SECTION FOUR: QUALITY APPRAISAL

Sources of Bias

This IR used the PRISMA framework (Moher et al., 2009). The flowchart developed for this study helped to reduce the possibility of ensuring the focus was not too narrow and reduced bias accordingly. This IR serves to educate clinicians in the area of their specialty, which in this case is T2DM, and reducing bias is necessary for this process. During the review of the article topics and themes for this IR, there was no evidence of bias. Reducing bias is necessary for

clinicians to use this IR as a place to start when clinical practice guidelines are developed (Moher et al., 2009).

Internal Validity & External Validity

It is important to reduce bias to keep from compromising the validity of the results of the IR (Toronto & Remington, 2020). In order to achieve internal validity, the study results should be as near to the truth as possible (Toronto & Remington, 2020). The methods used to obtain results for this IR also provide validity to this study. External validity will assist in the critical appraisal of this IR in that the results will be applied to those who have T2DM and who use CGMs, which is the population of interest. Some may suggest that internal validity, or "believability," is just as important in the critical appraisal of the IR as the external validity (Toronto & Remington, 2020, p. 48).

Appraisal Tools (Literature Matrix)

Health care workers use critical appraisal tools to look at and evaluate evidence. These tools may include checklists or structured questions, but there is no gold standard for which tool to use. Therefore, using a common, familiar tool such as a literature matrix is recommended (Buccheri & Sharifi, 2017). The tool used to appraise the quality of the included studies of this IR was a literature matrix using the Melynk model to evaluate the levels of evidence. The Melynk model was used to appraise and rank the power of each article. Melynk's (Melnyk & Fineout-Overholt, 2015) levels of evidence include Levels I through VII, with Level I being the strongest. Level I incudes systemic reviews and meta-analyses of RCTs. Level II includes articles that consist of one or more RCTs. Level III articles are controlled trials with no randomization. If an article includes case-controlled or cohort studies, it is considered Level IV. Articles containing systematic review of descriptive and qualitative studies are Level V, and

single descriptive or qualitative studies are considered Level VI. And finally, Level VII articles are expert opinions on the subject of continuous glucose monitoring (Melnyk & Fineout-Overholt, 2015).

Applicability of Results

The articles chosen were relevant to the question for this IR. In order to support the credibility of the data analysis and findings of the studies used, results were entered into the literature matrix (Toronto & Remington, 2020). The literature matrix was used to critically appraise the study purpose, sample (including characteristics of the sample), methods used in the study, study results, level of evidence using the Melnyk framework (Melnyk & Fineout-Overholt, 2015), limitations of the study, and the ability to use the article to make a change.

Reporting Guidelines

The approach used to review data about CGM is the IR method. Whittemore and Knafl (2005) stated that the "integrative review method is the only approach that allows for the combination of diverse methodologies" (p. 546). This IR includes methodologies of both experimental and nonexperimental research. Future evidence-based practice initiatives for nursing will depend on these different types of methodologies (Whittemore & Knafl, 2005).

SECTION FIVE: DATA ANALYSIS AND SYNTHESIS

Data Analysis Methods

It was important to note that comparing data across studies is pertinent to conducting an IR and increases the rigor of this review (Toronto & Remington, 2020). The approach used was development of literature matrix to separate the article information into categories (Appendix B). The method used in this IR was a constant comparison method, which Whittemore and Knafl

(2005) described as having four phases: data reduction, data display, data comparison, and conclusion drawing and verification.

Data Reduction

The data from the articles retrieved were reduced and simplified through a search for themes and categorization of those themes. The enormous amount of information within these articles needed to be reduced to an amount that could be managed more easily. The project leader could then sort through the data for relevance and significance to be confident in the consistency of the review (Whittemore & Knafl, 2005). Along with the review questions, recommendations from the Centers for Disease Control regarding people other than T1DM patients who may benefit from CGMs were used to support and focus this review. Some of these groups who may benefit from the use of CGMs are: (a) people with T2DM who are receiving intensive insulin therapy, (b) people who have T2DM who are not meeting their glycemic targets and are not on insulin therapy, and (c) people who have T2DM who have hypoglycemia unawareness or frequent hypoglycemia episodes (American Diabetes Association, 2020). These categories were used to focus the search for articles.

Data Display

For the purpose of this review, the articles were displayed in a literature matrix (evidence table) which shows the title of the articles, authors, study purpose, sample, methods, study results, level of evidence, limitations, and use of the study (Appendix E). Data were then compressed and displayed in a matrix showing the articles that fit into each of the categories (Appendix B). The visual display of a matrix allows the reader to see the relationships and patterns within the literature (Whittemore & Knafl, 2005).

Data Comparison

The literature categories table (Appendix B) depicts themes and patterns as well as relationships between articles (Whittemore & Knafl, 2005). The categories found more abundantly in the literature were those that pertained to the relationship between CGMs and HbA1c levels or between TIR and CGMs. Also seen was the association of CGMs with the identification of hypoglycemia events. Another category that was shown quite often was the use of CGMs by those who are on insulin therapy.

Conclusion Drawing and Clarification

The article matrix and category matrix (table) were used during this study to identify the results of the review. During this phase, the articles were reviewed again to confirm truthfulness and also to show where there were similarities in the studies (Whittemore & Knafl, 2005).

Themes of Articles

There were three main themes found in the articles chosen for this IR. They are: (a) clinical improvement in T2DM HbA1c levels, (b) CGM, insulin users, and T2DM, and (c) effects of CGM use on HbA1c and TIR.

Clinical Improvement in T2DM HbA1c Levels

Thirteen of the articles obtained for this IR showed that with the use of CGMs, there was improvement in HbA1c levels. Azhar et al. (2020) showed evidence that T1DM and T2DM patients had improvement in their HbA1c levels when using CGMs. Three articles showed a decrease in HbA1c levels when they the use of CGMs was compared to SMBG (Chehregosha et al., 2019; Janapala et al., 2019; Taylor et al., 2018). In a systematic review of nine RCTs, Cowart et al. (2020) showed that there was a decrease in HbA1c levels in T2DM patients who use CGMs. Haak (2018) conducted a 24-week RCT of T2DM patients using CGMs and concluded

that there was a reduction of HbA1c levels to 7.7% compared to the control of 8%. A correlational study by Hajime et al. (2018) showed a correlation between the use of a CGM and lower pre-breakfast glucose levels therefore lower HbA1c levels as well. A systematic review of literature (meta-analysis) conducted by Ida et al. (2019) determined that time in hypoglycemia is and HbA1c levels are decreased when patients use CGMs. Toschi and Wolpert (2016) also maintained that the use of CGMs improves glycemic control and decreases the risks of hypoglycemic events. Mariani et al. (2017) demonstrated that if T2DM patients using a CGM start with an HbA1c level greater than 9%, their levels are decreased by their use of the CGM. Vigersky and Shrivastav (2017) conducted a systematic review of RCTs and provided evidence of a decrease in HbA1c levels of greater than 0.61% when patients used professional CGMs. In a retrospective study conducted by Mohan et al. (2016) it was found that when patients who had average HbA1c levels of 8%–10% used a CGM, mean A1c levels dropped from 8.6% to 8%. Still another retrospective study of RCTs studying CGM use by chronic kidney disease patients with T2DM showed that HbA1c levels were decreased after three months, and hyperglycemic episodes were decreased only after six weeks of use (Yeoh et al., 2018).

Continuous Glucose Monitors, Insulin Users, and T2DM

This category includes evidence that T2DM patients who use CGMs may lower their HbA1c levels. In a 24-week RCT of 158 T2DM patients who use insulin, the CGM group lowered their HbA1c levels from 8.5% to 7.7% (Beck et al., 2017). In another single descriptive study by Ishikawa et al. (2018), 170 T2DM insulin-dependent patients were able to see their trends and lower their risks for hypoglycemia.

Effects on HbA1c and Time in Range

Besides the outcome of lowering of HbA1c levels, TIR is also addressed within the articles reviewed. Battelino et al. (2019) conducted a systematic review of 18 RCTs to show that there is a relationship between TIR and decreased HbA1c levels. TIR was seen to consistently lower HbA1c levels in each RCT. In another systematic review of RCTs, Carlson et al. (2017) found that after 12 weeks of using CGMs in real time, participants' mean HbA1c levels decreased by 1% compared to those who did not use CGMs. At 52 weeks, there were similar results, even without the addition of any medication or any additional hypoglycemic effects. In a retrospective RCT of 30 chronic kidney disease patients using CGMs, TIR increased after six weeks, time in hyperglycemia decreased, and HbA1c levels decreased after three months (Yeoh et al., 2018). In one cohort study, 54 patients with T2DM were educated about the use of CGMs before they were discharged from the hospital. At 12 weeks after discharge, all the patients' HbA1c levels were lower (Torimoto et al., 2017). Park and Le (2018) conducted a correlational study of RCTs involving 1,384 T2DM patients using CGMs and found a relationship between use of the device and lower HbA1c. One study focused on the use of flash glucose monitoring, which does not show trends, but shows glucose levels whenever patients scan the device. In 20 RCTs with 22,949 patients, results showed that more frequent scans were correlated with increased TIR and lower HbA1c levels, averaging 6.9% (Gomez-Peralta et al., 2020).

Descriptive Results

All of the articles obtained for this literature review are were published between 2015 and 2021. The use of this date range helped to maintain the accuracy of this review through the use of the latest and most updated research information. Matrices were used to organize the data collected, and information was sorted to show categories and the relationship between lower

HbA1c levels and the use of CGMs. Using a matrix helps display the evidence in order to assist the reader see the results clearly (Toronto & Remington, 2020). The data collected show that CGMs can be used in T2DM patients to lower HbA1c levels and increase the TIR, therefore protecting them from the harmful effects of hyperglycemia. There is also information that shows that the use of CGMs lowers the incidence of hypoglycemic events.

Synthesis

Each of the articles for this IR was not individually described in detail in the IR but rather synthesized within themes that were developed during the data analysis stage. These themes were presented as a table, and columns were used to show the articles that fell within the different categories. One category comprised articles that showed a relationship between CGMs and lower HbA1c levels (Azhar et al., 2020; Chehregosha et al., 2019; Cowart et al., 2020; Haak, 2018; Hajime et al., 2018; Ida et al., 2019; Janapala et al., 2019; Mariani et al., 2017; Mohan et al., 2016; Taylor et al., 2018; Toschi & Wolpert, 2016; Vigersky & Shrivastav, 2017; Yeoh et al., 2018). Another theme seen within the literature involved TIR and hypoglycemia, as several studies showed that using a CGM helps keep glucose levels in range (Battelino et al., 2019; Carlson et al., 2017; Gomez-Peralta et al., 2020; Haak, 2018; Ida et al., 2019; Ishikawa et al., 2018; Mohan et al., 2016; Park & Le, 2018; Torimoto et al., 2017; Yeoh et al., 2018). Additionally, several articles addressed T2DM patients who used insulin therapy and CGMs (Beck et al., 2017; Ishikawa et al., 2018). These articles all showed a relationship between CGMs and lower HbA1c.

Ethical Considerations

This project was submitted to the Liberty University Institutional Review Board and an email was received stating that this project was exempt from any ethical issues. After the email

from the Institutional Review Board was received, it was archived in a file of the researcher's choosing and included as an appendix for the final project write-up (Appendix F). The researcher then continued to develop this project.

SECTION SIX: DISCUSSION

Implications for Research/Practice/Education

A priority for future research can be the identification of barriers to using CGMs. Additionally, there is meager evidence on the use of CGMs in the hospital setting. Toronto and Remington (2020) stated that gaps in the literature such as these need to be identified in order to set priorities for future studies.

The data reviewed in this study clearly show and support that CGMs need to be used for T2DM patients, especially those who use insulin, who are prone to hypoglycemic episodes, who are hypoglycemic unaware, or who are not meeting their glycemic targets (i.e., HbA1c levels and/or TIR) (ADA, 2020). The information reviewed in this IR shows that keeping TIR by using CGMs and identifying glucose levels at a glance have a direct correlation to lowering HbA1c. Educational implications are also warranted considering the results of this review. The use of CGM data in medical practice for those with T2DM will assist the patient to have increased activity levels, make better food choices, and better manage hypoglycemic and hyperglycemic events. Controlling glucose levels by using CGMs will result in lower HbA1c levels.

Dissemination

The information reviewed in this IR is helpful to shape policy and practice to improve care for patients with diabetes. The practice audience for this review are those health care workers who address the needs of T2DM patients as well as T2DM patients themselves. The intent for dissemination for this IR is to spread information from the review to the targeted

audience through the use and distribution of materials. Distribution of materials to clinicians will help spread the information, as will writing an article for a nursing magazine. Poster presentations can also be conducted in formal or informal conferences within health care settings, although these are older approaches. New approaches should be used as well, such as the use of news media or social media (Toronto & Remington, 2020).

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Appendix A

Collaborative Institutional Training Initiative Certificate

Appendix B

Categories Matrix Table for Literature Related to CGMs

Clinical Improvement in T2DM HbA1c levels	CGM, Insulin Users, & Type 2 DM	Effect on HbA1c and TIR
Azhar, A., Gillani, S. W., Mohiuddin, G., & Majeed, R. A. (2020).	Beck, R. W., Riddlesworth, T. D., Ruedy, K., Ahmann, A., Haller, S., Kruger, D., McGill, J. B., Polonsky, W., Price, D., Aronoff, S., Aronson, R., Toschi, E., Kollman, C., & Bergenstal, R. (2017).	Carlson, L., Mullen, D., & Berrgenstal, R. (2017). Gomez-Peralta, F., Dunn, T., Landuyt, K., Xu, Y., & Merino-Torres, J. F. (2020).
Chehregosha, H., Khamseh, M. E., Malek, M., Hosseinpanah, F., & Ismail-Beigi, F. (2019).	Ishikawa, T., Koshizaka, M., Maezawa, Y., Takemoto, M., Tokuyama, Y., Saito, T., & Yokote, K. (2018).	Mohan, V., Jain, S., Kesavadev, J., Chawla, M., Mutha, A., Viswanathan, V., Saboo, B., Kovil, R., Mithal, A., Punatar, D., & Shin, J. (2016).
Cowart, K., Updike, W. & Bullers, K. (2020).		Park, C., & Le, Q. A. (2018).
Haak T. (2018).		
Hajime, M., Okada, Y., Mori, H., Otsuka, T., Kawaguchi, M., Miyazaki, M., Kuno, F., Sugai, K., Sonoda, S., Tanaka, K., Kurozumi, A., Narisawa, M., Torimoto, K., Arao, T., & Tanaka, Y. (2018).		Torimoto, K., Okada, Y., Sugino, S., & Tanaka, Y. (2017).
Ida, S., Kaneko, R., & Murata, K. (2019).		
Janapala, R. N., Jayaraj, J. S., Nida, F., Tooba, K., Norina, U., Amulya, D., Nusrat, J., & Issac, S. (2019).		Yeoh, E., Lim, B. K., Fun, S., Tong, J., Yeoh, L. Y., Sum, C. F., Subramaniam, T., & Lim, S. C. (2018).
Mohan, V., Jain, S., Kesavadev, J., Chawla, M., Mutha, A., Viswanathan, V., Saboo, B., Kovil, R., Mithal, A., Punatar, D., & Shin, J. (2016). Mariani, H. S., Layden, B. T., & Aleppo, G. (2017).		Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R., Biester, T., Bosi, E., Buckingham, B. A., Cefalu, W. T., Close, K. L., Cobelli, C., Dassau, E., DeVries, J. H., Donaghue, K. C., Dovc, K., Doyle, F. J.. III., Garg, S., Grunberger, G.,

		Heller, S., . . . Phillip, M. (2019).
Taylor PJ, Thompson CH, Brinkworth GD. (2018).		
Vigersky, R., & Shrivastav, M. (2017).		
Toschi. E., & Wolpert, H. (2016).		
Yeoh, E., Lim, B. K., Fun, S., Tong, J., Yeoh, L. Y., Sum, C. F., Subramaniam, T., & Lim, S. C. (2018).		

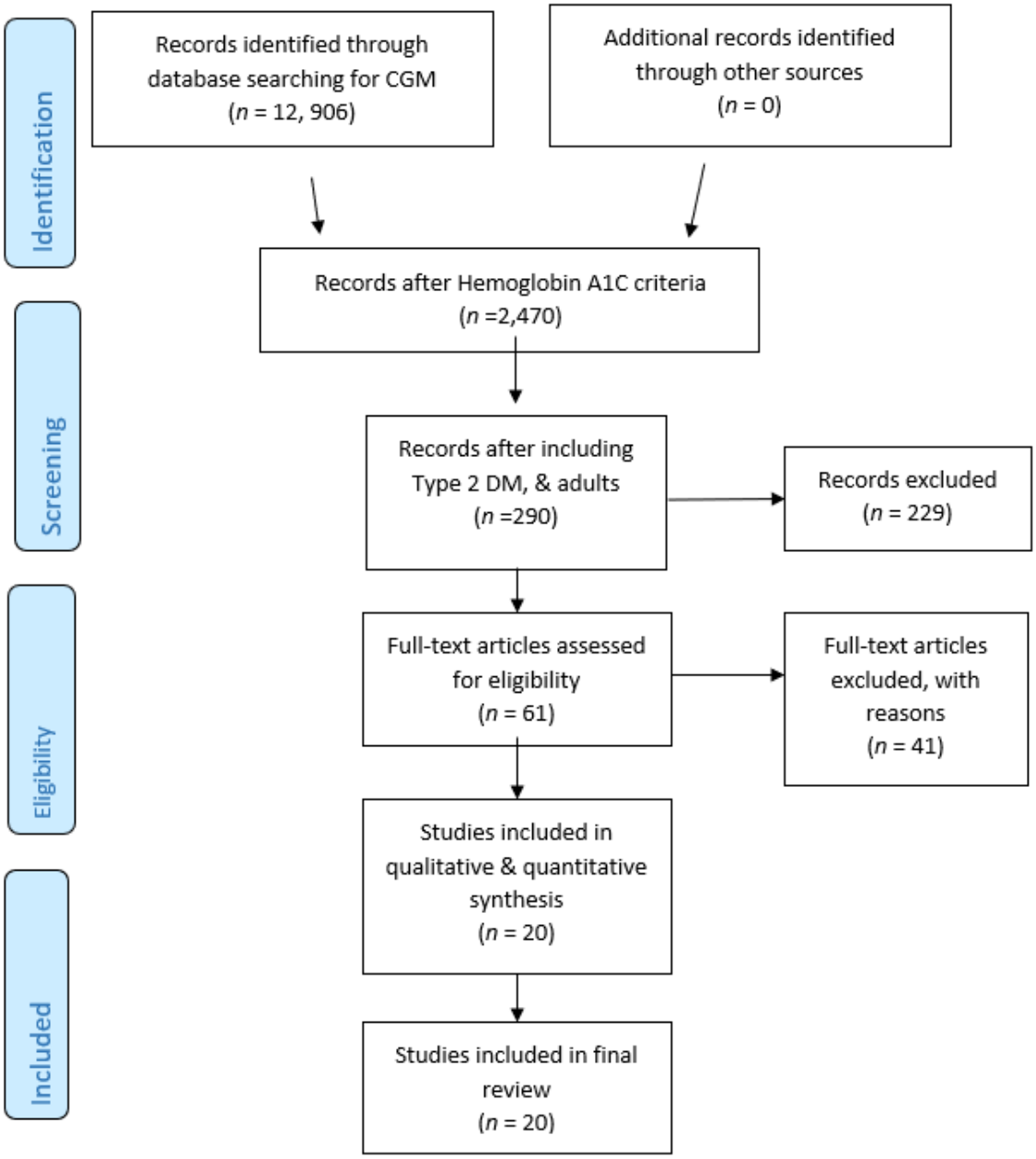
Appendix C

Timeline

Action Item	Action	Anticipated Date of Completion
Abstract page	Make sure to include a brief summation of the project results and relevance to practice	June 19, 2021 revised
Introduction	Check to make sure that the relevance to Advanced Nursing Practice is Included	June 19, 2021 revised
Background		June 19, 2021 revised
Problem statement	Address the importance for the need for change	May 23, 2021
Purpose of the project	Check that the Purpose includes what is the significance of the project	May 23, 2021
Clinical question		May 23, 2021
Inclusion/exclusion criteria	Add references: in text	June 19, 2021 revised
Review of literature	Make sure that this section is comprehensive vs. exhaustive	June 19, 2021 revised
Conceptual framework		Completed
Methodology		Completed
Evaluation, analysis, dissemination	Complete the results of analysis of data	June 7, 2021
Sources of bias		Completed
Internal validity		Completed
Appraisal tools		Completed
Applicability of results	Continue to develop	June 7, 2021
Significance/implications for practice	Include how the results of the project influence nursing practice Include how the results provide new and fresh insights into CGMs	June 7, 2021
Reporting guidelines	Continue to develop	June 7, 2021
Descriptive results	Continue to develop	June 7, 2021
Synthesis	Continue to develop	June 19, 2021 revised
Dissemination of results	Continue to develop	June 7, 2021
References	Make sure that all cited literature is on the reference page and in APA order	June 7, 2021
Appendices	PRISMA Add IRB approval documentation Put CITI information in Update Literature Matrix as indicated	June 19, 2021 revised

Appendix D

PRISMA 2009 Flow Diagram



Note. Adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement,: by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman, & The PRISMA Group, 2009, *PLoS Med, 6*(7): Article e1000097. (https://doi.org/10.1371/journal.pmed1000097)

Appendix E

Matrix/Evidence Table

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Azhar, A., Gillani, S. W., Mohiuddin, G., & Majeed, R. A. (2020). A systematic review on clinical implication of continuous glucose monitoring in diabetes management. *Journal of Pharmacy & Bioallied Sciences*, *12*(2), 102–111. https://doi.org/10.4103/jpbs.JPBS_7_20	To show the clinical implication of CGM on HbA1c levels.	Seventeen articles were analyzed according to the search criteria.	Using Medscape, Pubmed, Prospero, Wiley Library, Scopus, Clinical Trial registry and Trip were used to search the 17 articles for clinical outcomes of CGM and HbA1c levels.	Significant improvement was seen in HbA1c levels with Type 1 and Type 2 DM.	Level 5: Systematic review	This study is limited to Type 1 and Type 2 DM patients and does not include pregnant women.	Yes. Even though it is Level 5, it does give good information and add strength to the IR because it shows a relationship of CGM and Type 2 DM patients with outcomes of lowering HbA1c levels.
Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R., Biester, T.,	Includes the relationship of Time in	Review of literature of studies	Review of RTC trials	TIR was shown to	Level 1	Dual interest in authors	This article provides informatio

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Bosi, E., Buckingham, B. A., Cefalu, W. T., Close, K. L., Cobelli, C., Dassau, E., DeVries, J. H., Donaghue, K. C., Dovc, K., Doyle, F. J.. III., Garg, S., Grunberger, G., Heller, S., . . . Phillip, M. (2019). Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care, 42*(8), 1593–1603. https://doi.org/10.2337/dci19-0028	Range (TIR) to HbA1c levels when using CGMs	including 18 RCT's		complement HbA1c			n that will allow the reader to see a relationship between CGM and lower A1c levels
Beck, R. W., Riddlesworth, T. D., Ruedy, K., Ahmann, A., Haller, S., Kruger, D., McGill, J. B., Polonsky, W., Price, D., Aronoff, S., Aronson, R., Toschi, E., Kollman, C., & Bergenstal, R. (2017). Continuous glucose monitoring versus usual care in patients with	This was a RCT to determine effects of CGM on Adults with Type 2 DM who were receiving Insulin. This	158 participants who had DM Type 2 for at least 17 years. Average age was 60, with a mean	CGM group and Control group were randomly assigned. Control group used normal treatment	This study supports better management of HbA1c levels by using CGM. The CGM group lowered their	Level 2: Randomized control trial	The need for a 6 month follow-up.	Yes.. This study would benefit and strengthen the IR because of the results lowering HbA1c

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
type 2 diabetes receiving multiple daily insulin injections: A randomized trial. *Annals of Internal Medicine*, *167*(6), 365–374. https://doi.org/10.7326/M16-2855	study lasted 24 weeks.	HbA1c level of 8.5%.	and CGM used CGM monitoring an average of 6.7 days per week for 24 weeks.	HbA1c levels to a mean of 7.7% compared to 8..5% at the beginning of the study.			levels, leading to better ways to manage care but is mainly used with patients that use Insulin.
Carlson, A. L., Mullen, D. M., & Bergenstal, R. M. (2017). Clinical use of continuous glucose monitoring in adults with Type 2 diabetes. *Diabetes Technology & Therapeutics, 19*(Suppl. 2), S4–S11.	The article looks at the benefits of CGM's in T2DM patients in a 12 week study	Systematic review of severy RCT's: 104 patients	SR of RCT's	After 12 weeks ther was a derease of 1% in HbA1c levels compared to those who did not use CGM	Level 1: SR of RCT's	None	Yes. This study has much evidence to show a relationship between CGMs and lowering of HbA1c levels
Chehregosha, H., Khamseh, M. E., Malek, M., Hosseinpanah, F., & Ismail-Beigi, F. (2019). A view beyond HbA1c: Role of continuous glucose monitoring. *Diabetes*	This article looks at the advantages and limitations of using CGM as a standard in	This article describes statistics and data from previous studies.	Descriptive design	Results show data that is associated with using CGM and relays the effects of	Level 6: single descriptive study	Limitations is that it a very small descriptive study.	Yes. with limited information since the article is based on a

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Therapy: Research, Treatment and Education of Diabetes and Related Disorders, *10*(3), 853–863. https://doi.org/10.1007/s13300-019-0619-1	assessment of Diabetes related outcomes.			lower HbA1c levels compared to SMBG.			very small study.
Cowart, K., Updike, W. & Bullers, K. (2020). Systematic review of randomized control trials evaluating glycemic efficacy and patient satisfaction of intermittent-scanned continuous glucose monitoring in patients with diabetes. *Diabetes Technology & Therapeutics, 22*(5), 337–345. http://doi.org/10.1089/dia.2019.0345	To provide an updated analysis of the efficacy and patient satisfaction of isCGM in patients with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM).	Nine randomized control trials were included in this systematic review.	Studies were identified for assessing efficacy and use of isCGMs in patients with T1DM and T2DM by using Pubmed, Cochrane library, and EMBASE.	Evidence shows that using Intermittent CGM may lower Hemoglobin A1C levels in certain subgroups.	Level 1: Systematic Review of RTC's	Does not provide information for patients who are on insulin or oral antidiabetics.	Yes. This study will be useful in distinguishing the usage of CGM in Type 2 patients.
Gomez-Peralta, F., Dunn, T., Landuyt, K., Xu, Y., & Merino-Torres, J. F. (2020). Flash glucose monitoring reduces glycemic variability	Purpose is to show that flash glucose monitoring improves	20 equal groups of N= 22, 949	Randomized Control Trials	HbA1c levels were lowest in the highest scan group at 6.9%.	Level 2: 20 RTC's	Only diabetic patients receiving insulin were	Yes. Given the evidence of lowering

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
and hypoglycemia: Real-world data from Spain. *BMJ Open Diabetes Research & Care*, *8*(1), Article e001052. https://doi.org/10.1136/bmjdrc-2019-001052	glycemic control.			Frequent scan of flash glucose monitoring increases the rate of glucose TIR, and decreases time in hypo and hyperglycemia.		included in the study.	HbA1c levels.
Haak, T. (2018). Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections. *Annals of Internal Medicine*, *168*(7), 525–526. https://doi.org/10.7326/L17-0705	This study aimed to show the effectiveness of CGM and the amount of decrease in HgbA1c levels at 24 weeks.	158 patients in 25 different enocrinology practice across North America. Each patient had a mean HgbA1c level of 8.5%.	Experimental design using random assignment with 79 patients receiving CGM and 79 patients in the control group.	The patients receiving CGM lowered their HgbA1c levels to a mean of 7.7% while the control group lowered theirs to 8%.	Level 3: Randomized control trial	The study was limited because it require a 6 month follow-up for HgbA1c levels.	This is a strong article that will give evidence to the study by showing a correlation of CGM and a decreased A1c level.

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Hajime, M., Okada, Y., Mori, H., Otsuka, T., Kawaguchi, M., Miyazaki, M., Kuno, F., Sugai, K., Sonoda, S., Tanaka, K., Kurozumi, A., Narisawa, M., Torimoto, K., Arao, T., & Tanaka, Y. (2018). Twenty-four-hour variations in blood glucose level in Japanese type 2 diabetes patients based on continuous glucose monitoring. *Journal of Diabetes Investigation, 9*(1), 75–82. https://doi.org/10.1111/jdi.12680	To evaluate the relationship between CGMs and HbA1c levels in Type 2 diabetics	294 patients with Type 2 diabetes	Correlational design controlled trial	Mean glucose level and pre-breakfast blood glucose level were significant and independent determinants of HbA1c.	Level 4	Short study: 2-3 days	Yes, but very limited because of the length of study.
Ida, S., Kaneko, R., & Murata, K. (2019). Utility of real-time and retrospective continuous glucose monitoring in patients with type 2 diabetes mellitus: A meta-analysis of randomized controlled trials. *Journal of diabetes research*, *2019*, 4684815.	Investigation of effects of CGM on weight, glucose levels, BP, and hypoglycemia in T2DM patients.	7 RCT's with 669 patients with T2DM.	Literature search of 7 RCT's searching the effectiveness of using CGM's	CGM in patients with T2DM could help reduce HbA1c levels and decrease the amount of time in hypoglycemic episodes.	Level 1: Meta-analysis of RTC's	Less than 10 RCT's need a funnel plot. There was an increased risk of bias.	Yes. This study would be useful in that it addresses the hypoglycemic episode

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
https://doi.org/10.1155/2019/4684815							reduction as well as decreasing HbA1c levels.
Ishikawa, T., Koshizaka, M., Maezawa, Y., Takemoto, M., Tokuyama, Y., Saito, T., & Yokote, K. (2018). Continuous glucose monitoring reveals hypoglycemia risk in elderly patients with type 2 diabetes mellitus. *Journal of Diabetes Investigation*, *9*(1), 69–74. https://doi.org/10.1111/jdi.12676	Identifying CGM and relationship of hypoglycemic episodes.	170 patients older than 65 who have T2DM receiving medications were grouped to show the relationship in using CGM and hypoglycemic risks	Descriptive study to show relationship between CGM and hypoglycemic risks	CGM shows that hypoglycemic risk are greater in those who are taking insulin injections	Level 6: Single descriptive study.	Small single study, risk of problems with calibration of CGM.	Yes. Although this is a lower level of study, it could still be used to provide strength to the IR showing a relationship in how CGM can assist in seeing trends in hypoglycemia
Janapala, R. N., Jayaraj, J. S., Nida, F., Tooba, K., Norina, U., Amulya, D., Nusrat, J., & Issac, S.	Systematic literature search of Metanalysis	CGM can reduce glycated hemoglobin	Systematic review & meta analysis	CGM's in T2DM prove to be beneficial in	Level 1	The literature search was conducted	Yes. The level of evidence, length and

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
(2019). Continuous glucose monitoring versus self-monitoring of blood glucose in type 2 diabetes mellitus: A systematic review with meta-analysis. *Cureus, 11*(9), Article e5634. https://doi.org/10.7759/cureus.5634	of RCT's for Type 2 diabetic patients who use CGM's	(HbA1c), hypoglycemic events, and increase patient satisfaction		lowering hbA1c levels when compared to SMBG		only in one electronic database, Medline (PubMed) database.	size of the study give strength to this study.
Mariani, H. S., Layden, B. T., & Aleppo, G. (2017). Continuous glucose monitoring: A perspective on its past, present, and future applications for diabetes management. *Clinical diabetes: A publication of the American Diabetes Association*, *35*(1), 60–65. https://doi.org/10.2337/cd16-0008	This article looks at the clinical benefits of using CGM, including lowering HbA1c levels. It provided data about the accuracy in CG monitoring systems.	Looks at data from other studies to provide information on outcomes for CGM.	This article is more of opinions of experts who are using other studies for data.	There is evidence of using CGM to lower HbA1c especially if their levels begin at >9	Level 6-7: More of expert opinions	Possible conflict of interest with one of the authors receiving research money from Dexcom.	Yes, but very limited due to expert opinion and much data is about the accuracy of the CGM systems.

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Mohan, V., Jain, S., Kesavadev, J., Chawla, M., Mutha, A., Viswanathan, V., Saboo, B., Kovil, R., Mithal, A., Punatar, D., & Shin, J. (2016). Use of retrospective continuous glucose monitoring for optimizing management of type 2 diabetes in India. *The Journal of the Association of Physicians of India*, *64*(4), 16–21.	To provide information about CGM and pattern which can help practitioners with determining interventions and care for Type 2 diabetics.	A 3 month study of Type 2 diabetics with an A1C between 8 and 10%. 148 participants completed the study.	Questionaires were used at each follow up visit of 5 different visits.	CGM shows that there was a change in one therapy after month 1 of the study and after 3 months, mean A1c levels were from 8.6% to 8%.	Level 3: Controlled trial, Quasiexperimental design	This study is limited in time, since A1c levels may need to be repeater and this study was only 3 months in length.	Although Level 3, this study may give significant amount of evidence that CGM may lead to better control because of the changes that may be made to treatment regimens.
Park, C., & Le, Q. A. (2018). The effectiveness of continuous glucose monitoring in patients with type 2 diabetes: A systematic review of literature and meta-analysis. *Diabetes Technology & Therapeutics*, *20*(9), 613–621.	The effectiveness of CGM on HgbA1c in T2D patients	1384 patients with T2DM using CGM & 4902 patients with T2DM using Flash glucose monitoring	Correlational design comparing patients using CGM & flash glucose monitoring.	Results show that CGM are effective in lowering HbA1c. No conclusive results for flash glucose monitoring.	Level 1: Systematic review & meta-analysis of RCT's.	This study did not address safety issues or cost-effectiveness of using CGM's.	Yes. This study would provide great information of 7 RCT studies to address CGM's

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https://doi.org/10.1089/dia.2018.0177							and effects on HbA1c levels.
Taylor, P. J., Thompson, C. H., & Brinkworth, G. D. (2018). Effectiveness and acceptability of continuous glucose monitoring for type 2 diabetes management: a narrative review. *Journal of Diabetes Investigation, 9*(4), 713–725. https://doi.org/10.1111/jdi.12807	Discusses the role of CGM in glycemic control	5,542 participants were included in 11 studies, the mean age was 51.7-60.	11 studies included 8 RCT's, and 3 observational trials	CGM promoted greater reductions in glycemic control (HbA1c)	Level 1: Systematic review of RTC's	High compliance is needed to have better outcomes.	Yes. The level of evidence is high with a very large participant number.
Torimoto, K., Okada, Y., Sugino, S., & Tanaka, Y. (2017). Determinants of hemoglobin A1c level in patients with type 2 diabetes after in-hospital diabetes education: A study based on continuous glucose monitoring. *Journal of Diabetes Investigation, 8*(3), 314–320. https://doi.org/10.1111/jdi.12589	Studied patients who were educated about CGMs before discharge and 12 weeks later to see the difference in A1c levels	54 patients with T2DM.	Single cohort study	CGMs helped to identify a relationship between of MBG levels at discharge and 12 weeks after discharge with a lower result in HbA1c.	Level 4 Cohort Study	Single study with small cohort.	Yes. Shows a relationship between HbA1c levels and CGMs after 3 months.

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
Vigersky, R., & Shrivastav, M. (2017). Role of continuous glucose monitoring for type 2 in diabetes management and research. *Journal of Diabetes and its Complications, 31*(1), 280–287. https://doi.org/10.1016/j.jdiacomp.2016.10.007	Addressed evidence for use of CGMs in patients with T2DM, hypoglycemic events discovered, and improvement of glycemic control	Summary of previous studies, RTCs	Summary of previous RTC's	Five randomized controlled trials showed that 3–7 days of professional CGM results in improvement in HbA1C (0.6%–2.3%)	Level 1: Systematic Review of RCT's	Very good evidence from previous studies	
Toschi, E., & Wolpert, H. (2016). Utility of continuous glucose monitoring in type 1 and type 2 diabetes. *Endocrinology and Metabolism Clinics*, *45*(4), 895–904. https://doi.org/10.1016/j.ecl.2016.06.003	To discuss the role CGM has on glycemic control in Type 1 & 2 diabetics	Endocrinology and metabolism clinics of North America		CGM improved glycemic control and decreased hypoglycemia risks	Level 6: Expert Opinion	Level 6	
Yeoh, E., Lim, B. K., Fun, S., Tong, J., Yeoh, L. Y., Sum, C. F., Subramaniam, T., & Lim, S. C. (2018). Efficacy of self-monitoring of blood glucose versus	To look at outcomes of using CGM on Type 2 diabetic kidney	Thirty patients with HbA1c >8% : 14 patients were in the CGM group	Randomized control trial, retrospective study	Percentage of HbA1c levels in the CGM groups decreased more after 3	Level 2: RTC Retrospective	Small study groups.	Yes. This is a high level of evidence and will show a

Article	Study Purpose	Sample	Methods	Study Results	Level of Evidence	Study Limitations	Would Use as Evidence to Support a Change?
retrospective continuous glucose monitoring in improving glycaemic control in diabetic kidney disease patients. *Nephrology*, *23*(3), 264–268. https://doi.org/10.1111/nep.12978	disease patients.	and 16 patients were placed in the SMBG group.		months, as well as time in hyperglycemia decreased after 6 weeks.			relationship between HbA1c levels and CGM's.

Appendix F

LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

April 26, 2021

Kimberly Fairchild
Sharon Kopis

Re: IRB Application - IRB-FY20-21-786 CONTINUOUS GLUCOSE MONITORING, TYPE 2 DIABETES AND HEMOBLOBIN A1C: AN INTEGRATIVE REVIEW

Dear Kimberly Fairchild and Sharon Kopis,

The Liberty University Institutional Review Board (IRB) has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study does not classify as human subjects research. This means you may begin your research with the data safeguarding methods mentioned in your IRB application.

Decision: No Human Subjects Research

Explanation: Your study is not considered human subjects research for the following reason:

-It will not involve the collection of identifiable, private information.
-Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected," are not considered research according to 45 CFR 46.102(l)(1).

Please note that this decision only applies to your current research application, and any modifications to your protocol must be reported to the Liberty University IRB for verification of continued non-human subjects research status. You may report these changes by completing a modification submission through your Cayuse IRB account.

Also, although you are welcome to use our recruitment and consent templates, you are not required to do so. If you choose to use our documents, please replace the word *research* with the word *project* throughout both documents.

If you have any questions about this determination or need assistance in determining whether possible modifications to your protocol would change your application's status, please email us at irb@liberty.edu.

Sincerely,

G. Michele Baker, MA, CIP
Administrative Chair of Institutional Research
Research Ethics Office