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Exploring Self-Efficacy in the Current Era of Type 1 Diabetes Management in Youth

Lisa Ellen Rasbach
Medical University of South Carolina

Exploring Self-Efficacy in the Current Era of Type 1 Diabetes Management in Youth

by

Lisa Ellen Rasbach

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Approved by:

Carolyn H. Jenkins, DrPH, APRN, BC-ADM, RD, LD, FAAN
Chair, Dissertation Committee

Mathew Gregoski, PhD, MS

Martina Mueller, PhD

Lori M. B. Laffel, MD, MPH

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Dedication and Acknowledgements

This dissertation is dedicated to my husband, Kyle Alexander Rasbach, and to the rest of my family for their love and support.

I gratefully acknowledge the guidance, support and mentorship of Dr. Carolyn Jenkins, which enabled the completion of this project. In addition, I am thankful to the other members of my committee: Drs. Mathew Gregoski, Martina Mueller, and Lori Laffel for their scientific contributions and guidance. I would like to acknowledge Dr. John Dinolfo of the Writing Center at the Medical University of South Carolina for his review of this dissertation. I would also like to acknowledge the Joslin Diabetes Center in Boston, MA. Specifically, I would like to gratefully acknowledge Dr. Lori Laffel and Lisa Volkening for their time and scientific mentorship. It has been an incredible privilege to learn from and work with them throughout this project. Their guidance has been invaluable and I am truly grateful. I would also like to acknowledge the Laffel lab, the pediatric clinical staff at the Joslin Diabetes Center, and the families who participated in this investigation. Lastly, I would like to acknowledge several members of the Laffel lab for generously providing their time to assist in the completion of this project; they are (in alphabetical order): Debbie Butler, Carly Dougher, Dr. Michelle Katz, and Dr. Jessica Markowitz.

Abstract

Type 1 diabetes is a chronic incurable autoimmune disease characterized by dysregulated carbohydrate metabolism. Nearly 3 million individuals in the United States with type 1 diabetes are challenged to meticulous self-management to avoid diabetes-related complications. Self-efficacy is an important construct associated with health behavior change that may be relevant for adherence to diabetes self-management tasks involving diabetes technologies, such as continuous glucose monitoring (CGM). Yet, there is a fundamental gap in understanding how self-efficacy relates to CGM use in youth with type 1 diabetes. This dissertation focuses on the behavior of CGM use in youth with type 1 diabetes as well as the relationship of self-efficacy and self-management adherence in the contemporary era of diabetes technologies. Specifically, the following research questions are addressed: (a) how do masked CGM and treatment recommendations following sensor wear affect glycemic control in a contemporary cohort of youth with type 1 diabetes, (b) what instruments are available to measure self-efficacy related to contemporary diabetes management in youth with type 1 diabetes and their caregivers, (c) how does self-efficacy, measured by a novel CGM Self-Efficacy instrument (CGM-SE), relate to CGM use and glycemic control in a cohort of youth with type 1 diabetes initiating CGM therapy. The conclusions from this research are that: (a) masked CGM offers opportunities to guide advanced insulin management and requires orchestration of the multidisciplinary diabetes team, particularly nurse educators, (b) an integrative review identified 10 different instruments to measure self-efficacy related to diabetes management with varying levels of reliability and validity, yet there is a deficit in available instruments to measure self-efficacy related to diabetes technologies such as CGM, (c) a novel CGM-SE instrument used in a contemporary cohort of youth with type 1 diabetes appears to have strong psychometric properties and demonstrated

predictive validity as youth that reported higher baseline self-efficacy had significantly greater CGM wear and lower hemoglobin A1c (HbA1c) at 3 and 6 months compared to youth reporting lower self-efficacy. This body of work provides a greater understanding of the use of masked CGM technology, the concept of self-efficacy as it relates to youth with type 1 diabetes and their caregivers, and how to measure self-efficacy related to CGM use in a contemporary cohort of youth with type 1 diabetes. Importantly, this dissertation refines the relationship between self-efficacy and CGM use by establishing the utility of the CGM-SE instrument. Identifying elements, such as self-efficacy, that may promote and improve self-management behaviors is an important step towards improving diabetes outcomes and consistent use of CGM technology. This is especially relevant to diabetes nurse educators who play a critical role in supporting the self-management of youth with type 1 diabetes and their families.

Table of Contents

Chapter 1: Introduction

Knowledge in the Field of Study

To date, there is no cure for type 1 diabetes, a chronic disease affecting around 3 million people in the United States.[1] While ongoing research focuses on the etiology of type 1 diabetes, additional efforts must concentrate on improving diabetes self-care and glycemic control through the use of technology as well as attributes, such as self-efficacy, that may promote adherence. Technological advances, such as continuous glucose monitoring (CGM), continue to refine diabetes self-care management yet can increase patient burden by an increased awareness and attention to diabetes tasks. Masked CGM is a retrospective form of Real-Time CGM (RT-CGM) without the burden of sensor alarms. Although studies have demonstrated the clinical utility of the masked CGM device; information on device implementation in the pediatric setting as well as the treatment recommendations generated and impact on hemoglobin A1c (HbA1c) following masked CGM wear in today's youth with type 1 diabetes is limited. Investigating psychosocial factors, such as self-efficacy, and implications of this intensive disease management are essential for nurse educators to effectively educate and support patients with type 1 diabetes in successful disease outcomes in the era of diabetes technologies. The value of self-efficacy research in the efforts to improve youth glycemic control and type 1 diabetes self-management should not be undermined. Although there is extensive literature on self-efficacy and different factors of diabetes management in type 1 diabetes youth as well as the importance of self-efficacy in promoting general health behaviors of adolescents, there is a gap in how self-efficacy relates to or predicts CGM use in type 1 diabetes among youth. A focus of this dissertation is to adequately address the knowledge gaps of masked CGM use and self-efficacy related to CGM technology in

youth with type 1 diabetes; such research approaches must occur within a comprehensive understanding of type 1 diabetes epidemiology, pathophysiology, and disease management.

Type 1 Diabetes Overview

Epidemiology

The diagnosis of type 1 diabetes often penetrates a child and family's life without warning, adding layers of complexity to the normal stages of childhood growth and development. Classified as an autoimmune condition, type 1 diabetes in youth typically affects patients under 18 years of age.[2] Type 1 diabetes affects an estimated 3 million people in the United States with an estimated incidence of over 18,000 youth diagnosed.[1] Globally, 78,000 youth are diagnosed with type 1 diabetes each year; yet the worldwide prevalence data are not known.[1] Despite the growing understanding of type 1 diabetes as a national and global public health challenge, the etiology of this chronic condition remains unknown.[2] First-degree relatives have an estimated 5% risk of developing type 1 diabetes;[1] this relatively modest percentage leaves many families wondering how the disease could affect children without a prior family history. Type 1 diabetes can occur throughout the lifespan; however, there are certain time points that are associated with an increased chance of disease development. The likelihood of type 1 diabetes developing in youth peaks between the ages of 10-14 years[3] and is likely related to the insulin resistance associated with the hormonal surges during puberty. Recent reports from different countries suggest that the incidence of type 1 diabetes may be leveling off[3-5] yet continued research focused on identifying the cause of type 1 diabetes is warranted. As with many health related conditions, genetic and environmental factors are thought to influence development of this chronic disease.[6]

Pathophysiology

Type 1 diabetes is an autoimmune disorder characterized by the destruction of pancreatic β cells, which leads to dysregulated insulin/glucagon production and an inability to sustain normal glucose metabolism. The loss of the body's ability to regulate and maintain glucose levels results in a subsequent dependence on exogenous insulin for survival.[1,2,6] The usual clinical signs and symptoms indicative of a diagnosis of type 1 diabetes consist of hyperglycemia, polydipsia, polyuria, and weight loss as well as the presence of positive pancreatic autoantibodies.[1] The Diabetes Control and Complications Trial (DCCT) was a landmark randomized clinical trial (RCT) that set the precedence for intensive therapy (e.g. multiple daily injections or insulin pump therapy) in people with type 1 diabetes to maintain euglycemia to mitigate the risk of long-term micro- and macrovascular complications.[7]

The literature describes potential environmental triggers that may influence the development of type 1 diabetes, including cow's milk protein exposure, vitamin D deficiency and viral infections including coxsackie, Epstein-Barr, and the enterovirus.[6] Additional research on possible environmental causes suggests that microbial stimuli such as mycobacteria may be a protective factor related to the development of type 1 diabetes.[2] In addition to investigating environmental factors, extensive research has also explored immune pathways related to type 1 diabetes to identify possible immunotherapies.[2] Research on the progression of type 1 diabetes suggests that an imbalance between T regulatory cells and effector T cells affects the immune response and contributes to type 1 diabetes progression.[2] Additionally, research involving stem cells seeks to develop functional insulin-producing β cells for transplantation, which has been explored with diabetic mouse models.[8] Ongoing efforts are necessary to identify specific pharmacologic targets at the cellular level by isolating the cellular mechanisms that regulate the

immune response involved in the development of type 1 diabetes as well as further work with stems cells that focus on drug discovery and transplantation.[2,8] Although continued research is necessary to identify a cure for type 1 diabetes, improving self-care management for the millions affected by this disease is also paramount. To improve the lives of those with type 1 diabetes through research and clinical care, it is necessary to understand the intensive nature of type 1 diabetes management and the importance of approaching youth with type 1 diabetes from a developmental perspective.

Diabetes Management

In diabetes management, the metric that measures the normalization of glucose control and is a significant marker to target related to diabetes complications is the HbA1c,[1] which is a measure of the mean glucose over the past 2-3 months. The HbA1c goal for youth with T1D is <7.5% (reference range 4-6%).[1] Today, diabetes management includes frequent daily blood glucose monitoring and intensive insulin therapy to maintain glycemic control. Research has shown that the frequency of glucose monitoring is related to glycemic control; adding one glucose check a day can improve the HbA1c by almost 0.5% in patients checking 0-5 times daily.[1,6] Often, patients with type 1 diabetes conduct blood glucose self-monitoring 6-10 times daily to balance food, insulin and exercise as well as to prevent and treat hypo- and hyperglycemia.[1] In addition to frequent blood glucose checks, patients with type 1 diabetes need to administer either multiple daily insulin injections (3 or more) or multiple insulin boluses via subcutaneous insulin infusion (insulin pump) to maintain glycemic control. While the DCCT demonstrated the importance of intensive insulin therapy, advances in diabetes technologies also have proven effective. A more recent randomized controlled trial comparing sensor-augmented pump therapy (RT-CGM and insulin pump) with multiple daily injections demonstrated that

patients with type 1 diabetes who received sensor-augmented pump therapy had a significant improvement in HbA1c at 12 months when compared to the injection-based group.[9] Yet, new educational and behavioral strategies are needed to help youth with type 1 diabetes implement and benefit from advanced diabetes technologies.

Even with such developments in evidence-based practice and advancements in diabetes therapies, management of this disease is challenging. Despite a patient and family's best efforts with diabetes management, blood glucose values often fluctuate leading to intermittent hypo and hyperglycemia. Patients and families must be cognizant of the acute complications associated with hypo- and hyperglycemia in the short term, and they must be aware of the importance of glycemic control over time. Type 1 diabetes is unrelenting and the management required to maintain glycemic control and mitigate the risk of long-term complications is meticulous. However, children with type 1 diabetes have the full potential to live active healthy lives supported by knowledgeable caregivers.

The multidisciplinary diabetes team is another key component to diabetes management success.[10] Typically composed of endocrinologists, nurse educators, dieticians, psychologists, and child life staff, the team provides developmentally appropriate education to enhance diabetes self-management skills. As a child goes through certain developmental stages, the diabetes team must direct their education and communication with the child and family from the perspective of the child. Developmentally appropriate care is critical because the educational approach and care needs of the child and family differ based on a child's developmental stage.[1] This tailored patient care is particularly important during the transition to adolescence, which can be a time of unique challenges associated with increased adolescent independence with self-care tasks, diabetes-related family conflict, and risk taking behaviors.[1] Specifically, diabetes providers facilitate

identifying barriers to self-care and goals to overcome such challenges.[1] Adhering to type 1 diabetes management tasks during childhood and adolescence is demanding and provides challenges to both patients and families. Improvements in diabetes therapies can augment the demands of diabetes because most technology advances require time and effort on behalf of the child and family. For example, insulin pump therapy can provide greater flexibility with insulin dosing as well as more fine-tuned improved control.[1,6] Yet, pump therapy requires more frequent blood glucose monitoring and a heightened awareness of ketone monitoring to avoid diabetic ketoacidosis related to failure of an insulin pump/site.[6] Thus, the multidisciplinary team must be aware of the potential for increased burden given the demands of intensive insulin therapy. The team is a pivotal form of support, helping to navigate the complexities of diabetes management, particularly with the advent of new technologies.

Although the DCCT established the necessity of intensive insulin therapy to optimize long-term health outcomes, today's youth continue to struggle with effectively maintaining this intensive therapy. Following the DCCT, a cohort of adolescents from the original trial participated in a longitudinal observational study entitled The Epidemiology of Diabetes Interventions and Complications (EDIC).[11] During the first 4 years of the EDIC study, there was a small but significant increase in the HbA1c of the adolescents who had been in the intensively treated DCCT group. Researchers speculate this deterioration in control was likely due to the removal of intensive staff support that the DCCT previously provided.[11] The multidisciplinary clinical and research team must work to identify ways to effectively implement and sustain type 1 diabetes self-management during the dynamic process of childhood development. An important construct to consider within diabetes management and the changing landscape of diabetes therapies is self-efficacy. Self-efficacy research holds the potential to inform and assist

the diabetes team as well as patients with type 1 diabetes, particularly as diabetes treatments advance.

Continuous Glucose Monitoring

A majority of today's youth with type 1 diabetes do not meet HbA1c targets necessary to mitigate the risks associated with diabetes complications.[12] In 2014, the American Diabetes Association lowered the glycemic or HbA1c target across the pediatric age span, reinforcing the need to optimize glycemic control. RT-CGM, can improve glycemic control; however, adhering to rigorous type 1 diabetes management and consistent CGM use is a challenge because many youth find it difficult to wear CGM for daily self-management.[13] CGM entails inserting a sensor into the skin, wearing the device continuously, and responding to alarms and glucose data. Given these demands, youth may be resistant to this technology. However technological improvements, such as thinner sensors/receivers[14] and water resistant capabilities,[15] as well as use of CGM in Artificial Pancreas (AP) research[16] support continued efforts to foster use of this technology in youth with type 1 diabetes.

The JDRF landmark RCT evaluated CGM vs. standard of care blood glucose monitoring in both youth and adults with the primary outcome being change in HbA1c from baseline to 26 weeks.[17] For the between group analysis, this study demonstrated no significant change in HbA1c for youth ages 8-24 years on CGM, while the adult participants (≥25 years) in the CGM group showed a significant improvement in HbA1c from baseline to 26 weeks; however the youngest participants who were 8-14 years of age and those older than 24 years showed improvement in HbA1c when compared to the control group who did not wear CGM. Moreover, consistent use (6 days or more) was found in only 30% of participants 15-24 years and in 50% of participants 8-14 years compared to 83% of those 25 years or older. This study revealed the

benefit of CGM on glycemic control when used consistently as well as the challenge of wearing the device consistently. The results also highlight the unique challenges related to CGM use during the transition to adolescence. A follow-up study to this RCT investigated the 12-month outcomes in this same cohort of youth.[13] The results indicated that 21.3% (17/80) of youth were consistently using CGM at the 12-month time point, with consistent users having a significantly lower HbA1c. A subsequent study evaluated psychosocial correlates to CGM in a cohort of youth participating in the JDRF trial.[18] Although constant use proves advantageous, CGM may be associated with a negative affect regarding blood glucose monitoring as well as more long-term (trait) characteristics of anxiety.[18] CGM has the potential to increase burden given the increased time and patient effort required to effectively utilize the technology, as well as the potential for physical discomfort and body issues related to wearing the device.[19] In the pediatric population, adherence to the use of CGM and the integration of CGM data into daily diabetes self-management remain difficult despite the benefits to glycemic control.[13]

Other research has investigated the safety, accuracy, and effectiveness of a closed-loop system or artificial/bionic pancreas involving CGM and pump therapy. This automated system delivers insulin as well as glucagon based on algorithms that incorporate CGM data and has the potential for less patient burden.[20] A recent random-order crossover study was one of the first to evaluate the bionic pancreas system in an outpatient free-living environment over several days.[20] Specifically, this study compared the artificial pancreas system to the insulin pump for five days in 20 adults and 32 teens with type 1 diabetes, with the primary outcomes of mean blood glucose and mean percentage of time with hypoglycemia.[20] During the control period, patients wore a masked CGM and also had the option of using their own CGM. The results demonstrated significantly lower mean blood glucose for both adults and adolescents when using the bionic

pancreas vs. the control period with the routine insulin pump. Additionally, adults experienced significantly less time with hypoglycemia when using the bionic pancreas. This study demonstrated the effectiveness of the artificial pancreas system outside of the controlled hospital setting and the related benefits to glycemic control. Although ongoing research is required to fine-tune the artificial pancreas system including a more stable form of glucagon as well as a more rapid form of short-acting insulin,[20] the initial results are promising. With the future of diabetes management technologies on the horizon, evaluating the psychosocial implications is necessary to determine barriers and facilitators to the use of these technologies. Addressing such barriers at the development and initiation of such therapies will be imperative to the technology and patient success.[19]

Self-Efficacy

Self-efficacy is an important concept to consider with the use of CGM technology. This concept is especially relevant to explore in youth with type 1 diabetes because self-efficacy can augment one's level of drive and action to perform certain challenging tasks,[21] (e.g. CGM use). Self-efficacy relates to an individual's assessment of personal capabilities in a certain situation and the belief that carrying out self-directed behaviors will lead to a specified desired outcome.[22,23] Self-efficacy incorporates the element of personal control in goal setting and commitment towards goal completion,[24] making the level of perceived self-efficacy an important factor. The greater the perceived self-efficacy one has, the more likely the individual is to pursue and overcome a challenging task.[24] Many factors make up self-efficacy including one's experiences, persuasion by others, and knowledge.[25] Knowledge or information affecting self-efficacy comes from various forms such as observation, enactive attainment or the chance to proficiently complete a task, and physical elements such as emotions felt during the performance

of a task.[26] Thus, self-efficacy is a dynamic concept. Additionally, self-efficacy can be transferable. Attainment of self-efficacy in one area often translates to an increased perceived ability to accomplish other difficult yet similar tasks.[22] This attribute of self-efficacy may prove advantageous in the population of youth with type 1 diabetes, given the multitude of daily tasks necessary in diabetes management.

Self-efficacy has been widely studied and utilized as a foundational construct in health behavior change theories and interventions.[25] This construct is applicable across the spectrum of health behavior change because the elements that make up self-efficacy are adaptable and can be a target of influence.[25] Subsequently, health behavior change interventions can focus on any factors influencing self-efficacy to create or bolster change.[26]

Studies have explored the relationship of self-efficacy with various variables related to youth with type 1 diabetes. Research has demonstrated that higher levels of self-efficacy have been associated with higher diabetes self-management adherence,[27,28] improved glycemic control[27] and lower HbA1c,[29] and increased blood glucose monitoring (BGM) frequency.[30] Studies also have evaluated self-efficacy pertaining to youth and families using diabetes technologies. One cross-sectional study evaluated the relationship between pump therapy and self-efficacy in a cohort of female youth with type 1 diabetes and found that the female adolescents on insulin pump therapy reported higher self-efficacy than those on multiple daily injections.[31] Another study assessed self-efficacy related to perceived confidence in diabetes management in youth initiating insulin pump therapy[32] and found that youth reported higher self-efficacy 6-months after starting an insulin pump.[32] The authors suggest this increase in self-efficacy 6-months following initiation of pump therapy may be related to families feeling more independent in making treatment adjustments.[32] Since this was a cross-sectional study, the results

can only infer associations and not causality.[33]

Self-efficacy also has proven important when investigating health behaviors in adolescents without diabetes. One study in over 400 teens found that higher self-efficacy was associated with healthier dietary choices.[34] Another study used self-efficacy and Bandura's social cognitive theory (SCT) to develop an intervention related to increasing physical activity in female adolescents; the results showed that participants in the intervention group significantly increased their number of steps as measured by a pedometer.[35] Despite the many studies exploring self-efficacy and diabetes self-management tasks in youth with type 1 diabetes as well as the literature identifying the importance of self-efficacy in general health behavior change, there is little research on how self-efficacy relates to the advancements of CGM or whether self-efficacy is predictive of CGM use in youth with type 1 diabetes.

Identification of Gaps in Knowledge

Masked CGM in Youth with Type 1 Diabetes

As described above, studies have demonstrated the benefits as well as challenges of RT-CGM technology in youth with type 1 diabetes. Masked CGM technology uses similar sensor technology to RT-CGM but is worn for 3 days and can be used on a periodic basis to identify glucose patterns. The data are obtained retrospectively vs. real-time; therefore, the data are "masked" during the sensor wear and provide an alternative to RT-CGM. Additionally, masked CGM technology has the potential to be less burdensome for the patient because there are no alarms to trouble-shoot, and patients do not need to manage glucose data every five minutes. Masked CGM provides options for patients who are interested in trying intermittent sensor wear prior to obtaining a RT-CGM system or to visualize glucose trends over time not readily available from the routine self-blood glucose monitoring checks.

Research has confirmed the effectiveness of masked CGM in both pediatric and adult patients with diabetes. One prospective cohort study evaluated the use of masked CGM over three days related to the ability to detect hypoglycemia in 27 youth with type 1 diabetes.[36] The results of this six-week study demonstrated the benefit of this technology's ability to identify unrecognized hypoglycemia as well as decreasing future hypoglycemia by making insulin adjustments from the CGM data. Another study used the masked CGM device in 56 youth with fairly well controlled type 1 diabetes to evaluate glucose patterns.[37] The findings showed that the masked CGM was useful in identifying substantial post meal hyperglycemia even with pre meal glucose values near target and with a mean HbA1c of 7.7 ± 1.4% for the participating youth, demonstrating the benefit of masked CGM in conjunction with routine self-blood glucose monitoring. Lastly, two other studies conducted a retrospective analysis of adults with type 1 diabetes or type 2 diabetes who had undergone a three day wear of masked CGM to evaluate the impact on HbA1c.[38,39] Pepper and colleagues[38] did not find a significant difference in the HbA1c pre and 3.8 ± 1.6 months post masked CGM wear, while the article by Leinung et al.[39] found a small decrease in HbA1c (0.18%, $p = 0.04$) overall with the greatest improvement noted in patients starting with a higher HbA1c as well as those with type 2 diabetes.

While research has demonstrated the clinical utility of masked CGM, few studies have described the process of implementing masked CGM in clinic, specific treatment recommendations following masked CGM wear, and the effect of masked CGM and treatment recommendations on HbA1c in a contemporary cohort of youth with type 1 diabetes. A greater understanding of masked CGM implementation and effectiveness in this specific population will add to the state of the science regarding diabetes management technologies in this current era. The purpose of manuscript 1 of this dissertation was to address this gap related to masked CGM

technology in the pediatric population with type 1 diabetes by conducting a study to evaluate the masked CGM process, treatment recommendations, and effect on glycemic outcomes in a sample of youth with type 1 diabetes. The investigator led this study's efforts in terms of data collection, analysis, interpretation, and the preparation and submission of the findings as a manuscript. Additionally, the investigator was a part of the pediatric nursing team that provided sensor insertion, education, interpretation, and data review with the family.

Instruments to Measure Self-Efficacy in Youth with Type 1 Diabetes

The literature has established the importance of self-efficacy related to health behavior changes, including how self-efficacy may correspond with diabetes management in youth with type 1 diabetes. While research has established the relevance of this concept, it is necessary for the multidisciplinary diabetes team to understand how self-efficacy may affect diabetes self-care. To understand this construct to a greater extent, quantifying self-efficacy through questionnaires or survey instruments is pertinent. Although various instruments are available to measure self-efficacy, to the investigator's knowledge, no integrative review has evaluated current instruments that measure self-efficacy related to type 1 diabetes management in youth and their caregivers.

The purpose of manuscript 2 in this dissertation was to complete an integrative review spanning the past decade (2003-2013) to assess and evaluate critically the extant literature on instruments to measure self-efficacy in youth with type 1 diabetes and their caregivers. Exploring self-efficacy related to caregivers is significant, given the pivotal role parents and families play in a child's diabetes management. By critically evaluating the available instruments, the health-care team will be able to identify which instruments are reliable and valid and may be appropriate to use in the clinical and research settings and with certain populations. Additionally, given the advances in diabetes technologies and management over the past several decades, a

contemporary assessment of self-efficacy instruments will help distinguish how to measure self-efficacy in the current era, as well as identify gaps that warrant future research.

Instrument to Measure Self-Efficacy Related to CGM in Youth with Type 1 Diabetes

As discussed, technology that enhances diabetes management and subsequent glycemic control can provide substantial benefit to an individual living with type 1 diabetes. However, such advancements can increase patient burden, given the time and effort the technology can add to self-care tasks. Therefore, evaluating psychosocial attributes associated with diabetes advances, such as CGM, is important to determine the impact on, and ways to improve, CGM wear and to identify youth who may have difficulty with successful CGM use. A systematic review and meta-analysis identified two studies that assessed quality of life (QOL) as a secondary outcome in relation to CGM use.[40] Both studies found that QOL scores were higher after using CGM.[40] Another study that investigated QOL related to CGM consisted of a sample from the landmark JDRF CGM trial.[18] The study found no differences in the QOL scores between youth, parent, or adult participants in the CGM group as compared to those in the standard BGM group. Additionally, a recent consensus statement from the International Society of Pediatric and Adolescent Diabetes examined the available evidence related to CGM efficacy, as well as the advantages and disadvantages of this technology, and provided recommendations related to CGM use.[41] The authors concluded that CGM did not seem to affect QOL in youth negatively.[41]

Yet despite the recent research focus on QOL and CGM, few studies have evaluated self-efficacy as a construct related to CGM adherence. Thus, ongoing research is necessary to determine facilitators of CGM use and to promote adherence to this technology. CGM can significantly improve glycemic control if used consistently, but has proven challenging in the

pediatric type 1 diabetes population. In particular, research is needed to assess how self-efficacy relates to CGM use and adherence in youth with type 1 diabetes in the current era of intensive insulin therapy and advanced diabetes technologies. Such research may provide insight on whether self-efficacy may be a mediator in a youth's ability to successfully use and integrate CGM into daily diabetes self-management. Additionally, evaluating how self-efficacy relates to the use of CGM technology may provide insight on areas of focus in diabetes management education and future research efforts.

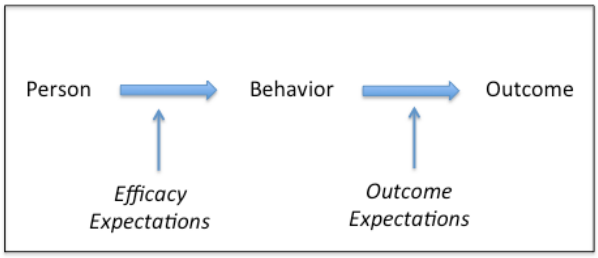
While it is important to determine the relationship of self-efficacy related to CGM use, there are limited instruments that measure self-efficacy related to recent advances in diabetes technologies. To the investigator's knowledge, there are no available instruments that assess the concept of self-efficacy in youth with type 1 diabetes and their parents related to CGM use. Therefore, the purpose of manuscript 3 of this dissertation was to determine how self-efficacy relates to CGM use by measuring self-efficacy in a cohort of youth with type 1 diabetes who are initiating CGM therapy using a novel CGM Self-Efficacy (CGM-SE) instrument and to establish its psychometric properties. This research was designed to provide a greater understanding of the relationship of self-efficacy to CGM use and thus elucidate important characteristics to foster in youth who wear CGM. Such findings pertaining to the relationship of self-efficacy and CGM use have potential to increase clinician awareness of an important factor related to youth success with the technology and, thus, provide an ability to measure this attribute during a clinic or research visit.

Theoretical Framework

The Social Cognitive Theory (SCT)

The guiding theoretical framework for this dissertation is Bandura's SCT and, specifically, Bandura's model of self-efficacy. The SCT utilizes a model of adaption and change instead of a reactive approach to situations.[42] This model highlights how individuals proactively cope and adapt to environmental stressors by relying on personal cognitive and emotional resources.[42] The SCT also posits that the environment interacts with personal and behavioral factors to affect an individual's behavior and that the individual can influence this relationship by affecting the environment.[25] To incorporate all of these various interactions that influence behavior, the SCT consists of the following five categories: a) psychological determinants, b) observational learning, c) environmental determinants of behavior, d) self-regulation, and e) moral disengagement.[25] Self-efficacy, a focus of this dissertation, is an integral concept to the SCT and incorporates psychological determinants of behavior.[25] Bandura highlighted the role of self-efficacy in health behavior change and outcomes with a pictorial representation that is adapted below in Figure 1.[22]

Figure 1. Adapted figure of Bandura's model of self-efficacy and the influence on behavior change.[22]



The value in utilizing the SCT for behavior change lies in its holistic approach. The SCT identifies the importance of an individual's knowledge and confidence (or self-efficacy) in

controlling or changing a behavior, as well as the social and environment facilitators/barriers of change.[24] While behavior change interventions can target various constructs within the SCT, bolstering self-efficacy may enhance one's coping mechanisms and efforts towards successful behavior change.[22]

Together, the three manuscripts of this dissertation build upon one another to explore the opportunity to improve glycemic control with CGM data, evaluate the measurement of self-efficacy in youth with type 1 diabetes, and identify a key gap in knowledge that warrants further research i.e., how self-efficacy relates to CGM use in youth with type 1 diabetes and their families in the current era of intensive diabetes management. The first dissertation manuscript focuses on the behavior (CGM use) component of the above model (Figure 1). The second manuscript explores efficacy expectations or self-efficacy related to self-management in youth with type 1 diabetes. Lastly, the final manuscript targets both the behavior and efficacy expectations by evaluating a novel instrument to measure self-efficacy related to CGM technology. Guided by the SCT and Bandura's model of self-efficacy, this body of work seeks to answer the following research question: How does self-efficacy relate to CGM use and subsequent glycemic control in a cohort of youth with T1D and their parents after the initiation of CGM therapy?

Chapter 2: Treatment Recommendations Following 3-Day Masked Continuous Glucose Monitoring (CGM) in Youth With Type 1 Diabetes

Rasbach, L., Atkins, A., Milaszewski, K., Keady, J., Schmidt, L., Volkening, L., Laffel, L.

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Background: Glycemic control remains suboptimal in youth with type 1 diabetes. Retrospective continuous glucose monitoring (CGM) has demonstrated utility in fine-tuning diabetes management by detecting post-prandial hyperglycemia and hypoglycemia. In this study, we explored the process of 3-day masked CGM use, subsequent treatment recommendations, and impact on hemoglobin A1c (HbA1c) in a clinic-based sample of youth with type 1 diabetes.

Methods: Over 2 years, 122 youth were referred for masked CGM. Patients/families completed a diary of blood glucose levels, insulin doses, food intake, and exercise during CGM use. HbA1c was assessed pre- and 2-3 months post-CGM. Treatment recommendations were formulated using data from CGM reports and diaries.

Results: Mean age was 14.3±3.9 years, diabetes duration was 7.5±4.7 years, and HbA1c was 8.5±1.1% (69±12 mmol/mol); 61% were pump-treated. Patients received an average of 3.1±1.1 treatment recommendations following review of the CGM report. Most (80%) received reinforcement of the importance of pre-prandial bolusing; 37% received a recommendation regarding advanced insulin management (use of combination boluses/attend to active insulin). Receipt of the latter recommendation was related to HbA1c improvement ≥0.5% (OR: 4.0, $P<0.001$).

Conclusions: Masked CGM offers opportunities to guide advanced insulin management (by injection or pump), which may yield HbA1c improvements in youth with type 1 diabetes

Introduction

Glycemic control remains suboptimal in youth with type 1 diabetes.[12,43] Modern treatment tools, such as continuous glucose monitoring (CGM), can reduce hypoglycemia and hemoglobin A1c (HbA1c);[17,44] however, youth are often reluctant to use CGM continuously.[13] HbA1c improvement has been associated with real-time CGM (RT-CGM) use ≥6 days/week, a challenge for pediatric patients.[13]

Masked or retrospective CGM provides an alternative to RT-CGM for patients.[38] Studies have demonstrated the utility of masked CGM to identify post-prandial hyperglycemia[37] and hypoglycemia[36] in pediatric patients. In this study, we explored the process of masked CGM use, subsequent treatment recommendations, and impact on HbA1c in youth with type 1 diabetes.

Methods

Over 2 years, we identified young patients with type 1 diabetes referred for masked CGM within a pediatric, adolescent, and young adult diabetes clinic. The Institutional Review Board granted waivers of informed consent and authorization for use/disclosure of protected health information from the electronic medical record. Following clinician referral, pediatric nurses implemented masked CGM (Medtronic iPro™) according to manufacturer's recommendations. Numbing cream/spray and/or child life support facilitated device insertion as needed.

Patients/families received a diabetes diary to record details of daily blood glucose levels, insulin doses, food intake, and physical activity during CGM use. (Copies of the diary are available from the authors upon request.) The research team determined completeness of diaries based on the 3 aspects of management; diet, insulin, and exercise; used to inform clinical decision-making. A lack of recorded data was deemed as incomplete and given the score of 1; some data but lacking significant detail was described as partial and given the score of 2;

comprehensive data recorded for diet, insulin, and exercise was considered complete and given the score of 3. Three research team members established inter-rater reliability of this scoring method, which was subsequently used to describe the completeness of the diaries. Patients/families received training related to completing the diabetes diary, calibrating the CGM 1 and 2 hours after insertion, synchronizing CGM and meter times, checking blood glucose values pre-prandially 4+ times/day, removing sensor after 3 days, and returning CGM and diary to the clinic.

Following device return, staff downloaded CGM data according to manufacturer's guidelines. Download included the number of interstitial glucose values, mean sensor glucose, and standard deviation (SD) of sensor glucose values. A nurse practitioner reviewed CGM reports for safety to assess unrecognized hypoglycemia or sustained hyperglycemia with immediate contact to family when needed. At a subsequent phone or in-person visit, a nurse practitioner reviewed reports with the patient/family and made appropriate treatment recommendations (Figure 1). Patients/families were sent copies of the CGM reports prior to visits that occurred by phone. Treatment data, demographics, and HbA1c (obtained pre- and ~2-3 months post-CGM use) were extracted from medical records.

Data Analysis

Data are reported as mean ± SD (range), median (interquartile range, IQR), and proportions. We defined improvement as a decrement in HbA1c ≥0.5%. Analyses, performed using SAS (v9.2; SAS Institute Inc., Cary, NC), included paired and unpaired *t* tests and Chi-square tests; $P \leq .05$ defined significance.

Results

Sample

Patients referred for masked CGM (N = 122, 53% female) were 14.3 ± 3.9 years old (range 7-28) with type 1 diabetes for 7.5±4.7 years (range 1-23). All received intensive therapy: 61% pump, 39% multiple injections (34% basal-bolus, 5% basal analog with AM NPH). Mean baseline HbA1c was 8.5 ± 1.1% (range 5.8-12.6%) (69 ± 12 mmol/mol [range 40-114]).

Reasons for Masked CGM

Patients were often referred for multiple reasons. The most common reasons were assessment of hyperglycemia (39%) or hypoglycemia (37%), patient/family interest in RT-CGM (37%), and insulin dosing adjustments (27%). Other reasons included evaluation of impact of food and exercise and follow-up after diabetic ketoacidosis.

CGM Data

Most patients successfully wore CGM following a single insertion; 3 required reinsertions. Mean number of sensor glucose readings/patient was 894 ± 136 (range 435-1151), capturing 1.5–4 days of CGM. Mean sensor glucose was 181 ± 34 mg/dL (range 103-265 mg/dL), and mean SD of sensor glucose was 75 ± 16 mg/dL (range 34-114 mg/dL).

Treatment Recommendations

Almost all patients (n = 116, 95%) received multiple recommendations following CGM, 5 (4%) received a single recommendation, and one received none. The mean number of recommendations/patient was 3.1 ± 1.1 (range 0-6). Most (80%) received the reminder to give insulin pre-prandially as reinforcement of standard care. Other common recommendations included specific dose adjustments (bolus and/or basal) and review of insulin action (advanced boluses/attention to active insulin) (Figure 1).

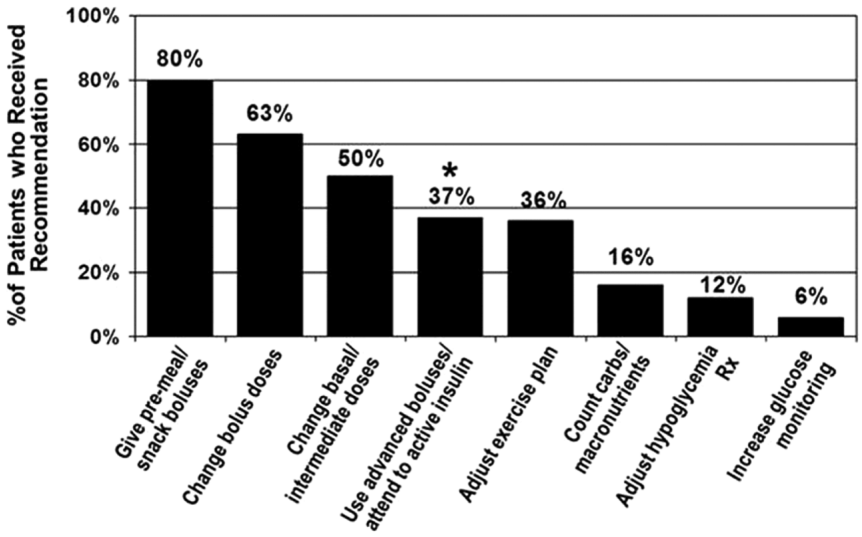

Figure 1. Percentage of patients who received each treatment recommendation following CGM. *Those who received the recommendation to use advanced boluses/attend to active insulin were 4.0 times more likely to improve HbA1c ≥0.5% than those who did not receive this recommendation ($P < .001$).

Treatment Outcomes

To assess impact of recommendations following CGM, we compared patients' HbA1c levels a median of 2.6 months (IQR 1.8-4.3) post-CGM. Mean follow-up HbA1c was 8.4 ± 1.1% (range 5.9-12.3%) (68 ± 12 mmol/mol, range 41-111); mean HbA1c change was -0.1 ± 0.7% (range -1.9-2.1%) (1 ± 8 mmol/mol, range -21-23).

About a third of patients (n = 39, 32%) improved HbA1c by ≥0.5%. These patients, compared to those without improvement, were older (15.5 ± 4.4 vs. 14.0 ± 3.6 years, $P = .04$), had longer diabetes duration (8.7 ± 4.9 vs. 6.9 ± 4.5 years, $P = .05$), had higher initial HbA1c (8.9 ± 1.0 vs. 8.2 ± 1.1%, $P < .001$), and received more treatment recommendations (3.5 ± 1.1 vs. 3.0 ± 1.1, $P = .01$). HbA1c improvement ≥0.5% was associated with the recommendation to use advanced boluses/attend to active insulin); receiving this recommendation increased the odds of improving HbA1c ≥0.5% by 4-fold ($P < .001$). Of those who improved, 60% received this

recommendation. Over 95% of participants provided complete or partially complete records with respect to diet intake, insulin administration, and exercise over the period of masked CGM use that offered adequate information to inform interpretation of the CGM data and direct treatment recommendations.

Discussion

Among intensively treated young patients with type 1 diabetes, 32% improved their HbA1c by ≥0.5% following masked CGM use. Specifically, those who improved were significantly older, had longer diabetes duration, had higher baseline HbA1c, and received more treatment recommendations following CGM than those without improvement (all $P \leq .05$). As those with higher baseline HbA1cs were more likely to improve, this could represent regression to the mean. Additionally, it is important to note that although the majority did not experience an improvement in HbA1c, this improvement was significant for older youth in worse glycemic control who need lower HbA1c levels. It is possible that more patients could experience HbA1c improvement if CGM use were repeated to confirm patterns to inform management decisions. Future research is needed to determine the optimal frequency of diagnostic CGM use to improve glycemic outcomes. Nonetheless, patients/families who received guidance about insulin action, i.e., advanced boluses/attention to active insulin, were 4.0 times ($P < .001$) more likely to improve HbA1c by ≥0.5%. Notably, this recommendation applied to those treated by injections or pumps, and insulin treatment modality was not related to HbA1c improvement.

The study's aim was to explore use of masked CGM and identify treatment recommendations associated with fine-tuning diabetes management and improving glycemic control. Our findings suggest that 3-day masked CGM may offer opportunities to improve HbA1c in pediatric patients with type 1 diabetes. Additionally, while a need for reinforcement of

fundamentals, like pre-meal bolusing, remains, focusing on advanced skills, like complex boluses/attention to active insulin, may yield improved glycemic control. This improvement may be attributable to an increased awareness of and adherence to the intricacies of the balance between insulin delivery and food intake that is essential to diabetes self-management. Review of CGM reports with patients/families helps to reinforce insulin kinetics/pharmacodynamics in efforts to explain the delayed peak in insulin action for rapid-acting analogs[45] and the impact of different foods on post-prandial glycemic excursions.[46,47] CGM provided opportunities for patient self-management and family education around complex areas pertaining to diabetes management, particularly insulin action and use of advanced boluses.

This study also assessed the role of the pediatric team in clinical use of masked CGM, similar to its use in adult patients.[48] Successful masked CGM requires qualified and trained nurses for multiple tasks including: CGM insertion and instruction/training regarding proper calibration and completion of the diabetes diary, CGM data downloads, safety assessment of CGM reports, and careful reviews of CGM reports alongside the detailed family-completed glucose, insulin, diet, and physical activity diary.

There are caveats to this analysis. We were unable to assess use of complex bolus doses (given by pump or prandial insulin separated into 2 doses for those treated by injections) or avoidance of insulin stacking. Additionally, this study only included one-time masked CGM use. While all patients received a review of the masked CGM data by phone or in-person, we are unable to evaluate whether the method of review or diary completeness directly impacted HbA1c change, future research can assess such details. Another limitation in our report is that we are unable to compare rates of hypoglycemia pre- and post-CGM use. Finally, as this was an observational, descriptive study, we were not able to assess if patients implemented the treatment

recommendations and the relationship between adherence to treatment recommendations and HbA1c. Nonetheless, it is encouraging to see opportunities with CGM to improve HbA1c in young patients. Additional research could also explore the mode of masked CGM review to determine the optimal approach for relaying the data to the family, especially in the current era of telehealth and m-health. The need and timing of repeat masked CGM use and its potential long-term benefits related to implementation of treatment recommendations require additional study. Future studies can also evaluate whether patients are more likely to transition to RT-CGM after masked CGM use and whether such patients are more likely to sustain use of RT-CGM.

Conclusions

In summary, this study demonstrated that masked CGM offers opportunities to guide advanced insulin management (by pump or injection) and may yield HbA1c improvements in young people with type 1 diabetes.

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DISCLOSURES

Portions of this manuscript were presented at the 2012 Scientific Sessions of the American Diabetes Association and the 2012 Annual Meeting & Exhibition of the American Association of Diabetes Educators. The authors have the following potential relevant conflicts of interest to disclose: K.M.M and J.K. – were consultants for Medtronic at the time of the study.

AUTHOR CONTRIBUTIONS

L.E.R. researched the data, conducted analyses, and wrote the initial draft of the manuscript. K.M.M., J.K., and L.M.S. researched the data and reviewed the final manuscript. A.E.A., L.K.V., and L.M.L. researched the data, conducted analyses, and reviewed/edited the manuscript. L.M.L. is the guarantor of this work and takes responsibility for the integrity of this work.

Chapter 3: An Integrative Review of Self-Efficacy Measurement Instruments in Youth with Type 1 Diabetes (T1DM)

Rasbach, L., Jenkins, C., Laffel, L.

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Purpose: The purpose of this study is to assess the extant literature on instruments used to measure self-efficacy in youth with type 1 diabetes and their caregivers and to critically evaluate these measurements.

Methods: An integrative review (2003-2013) was conducted searching PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and U.S. National Library of Medicine PubMed service (PubMed) databases using key words diabetes, type 1 diabetes, and self-efficacy. The authors reviewed the resulting 294 references for inclusion criteria of (a) sample of youth with type 1 diabetes or sample of caregivers of youth with type 1 diabetes, (b) description of the self-efficacy instrument as primary research, and (c) the instrument measured self-efficacy specifically related to diabetes management. Forty-five articles out of the initial 294 met criteria.

Results: Of the 45 articles, 10 different self-efficacy instruments were identified. The primary theoretical framework used was Bandura's social cognitive theory and model of self-efficacy. Most participants were white middle class type 1 diabetes youth. Evaluations to assess validity often were not reported; however, a majority of studies reported high internal consistency of the instruments.

Conclusions: Sample homogeneity could limit the applicability of results to certain patient populations. Further psychometric analysis, including validity assessments, should be conducted in more diverse samples. Development of valid and reliable instruments for measuring self-efficacy that are sensitive to change across a wider caregiver base over time is necessary. While

this review examined reliable and valid instruments used in research, future opportunities include evaluation of measuring self-efficacy in type 1 diabetes youth exposed to recent advances in diabetes management technologies.

Adhering to rigorous type 1 diabetes management during the complex stages of normal growth and development in childhood and adolescence is a significant challenge that impacts both youth with diabetes and their parents/guardians. Improved intensive therapy options can add to these challenges, as currently available therapeutic advances require self-management. Despite these improvements and a well-established correlation between adequate glucose control and reduced risk of complications, youth with type 1 diabetes often fail to meet the suggested hemoglobin A1c (HbA1c) targets necessary to mitigate associated risks.[49-52] Enhanced diabetes self-efficacy has been linked to improved diabetes self-care and glycemic control and is an important indicator of health behavior changes in youth.[27,53] Self-efficacy, or one's perceived ability to follow a diabetes treatment program, is important to foster in type 1 diabetes youth and their caregivers given the demands of diabetes self-management.[54] Therefore, it is important for diabetes educators to understand the concept of self-efficacy and what measures are available to assess self-efficacy in youth with type 1 diabetes. The purpose of this integrative review was to identify measurement instruments to assess self-efficacy in youth with type 1 diabetes and to evaluate the reported psychometric properties of those instruments.

Theoretical and operational definitions allow for greater understanding and means to measure self-efficacy.[55] A theoretical definition of self-efficacy includes the belief that an individual has the ability to create change by personal actions.[24] In type 1 diabetes, operational definitions are informed by data from self-report surveys that assess one's level of confidence or self-efficacy to accomplish diabetes management tasks, such as blood glucose monitoring,

insulin administration, and attention to diet and exercise, in everyday living and in difficult situations that may occur. Self-efficacy is important to capture in youth with type 1 diabetes because higher levels of diabetes specific self-efficacy may result in increased resilience when youth face barriers or challenges associated with diabetes self-management.[27] Therefore, ongoing work to measure and optimize self-efficacy in youth with type 1 diabetes is necessary to equip youth to manage this disease long-term. This can be particularly important during transition periods across the lifespan of childhood as diabetes management gradually transitions from parents to older children and adolescents and then becomes the sole responsibility of college aged youth or young adults living on their own.

Methods

The literature search focused on (a) identifying instruments used to measure the construct of self-efficacy in youth with type 1 diabetes and their parents and (b) evaluating the reported psychometric properties of those instruments. For an appropriate literature search, at least two different search strategies are necessary according to Whittemore and Knafl's integrative review methodology.[56] This literature search used PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and U.S. National Library of Medicine PubMed service (PubMed) to obtain applicable articles. Search engines from nursing, psychology, allied health, and medical literature provided the opportunity to assess the measurement of self-efficacy across disciplines. Because of the unique attributes of type 1 diabetes disease management in this particular population, the search focused on studies of youth with type 1 diabetes. Additionally, the search included articles across all pediatric age groups and their caregivers involved in the care and management of type 1 diabetes. International literature that was translated into English was retained because evaluating the concept across geographies could add a valuable cultural

perspective. This search included articles measuring specific areas of self-efficacy within diabetes management (healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, and healthy coping, which are the seven self-care behaviors guiding diabetes education).[57] To obtain a contemporary perspective on available instruments, only primary research published between 2003 and 2013 was included.

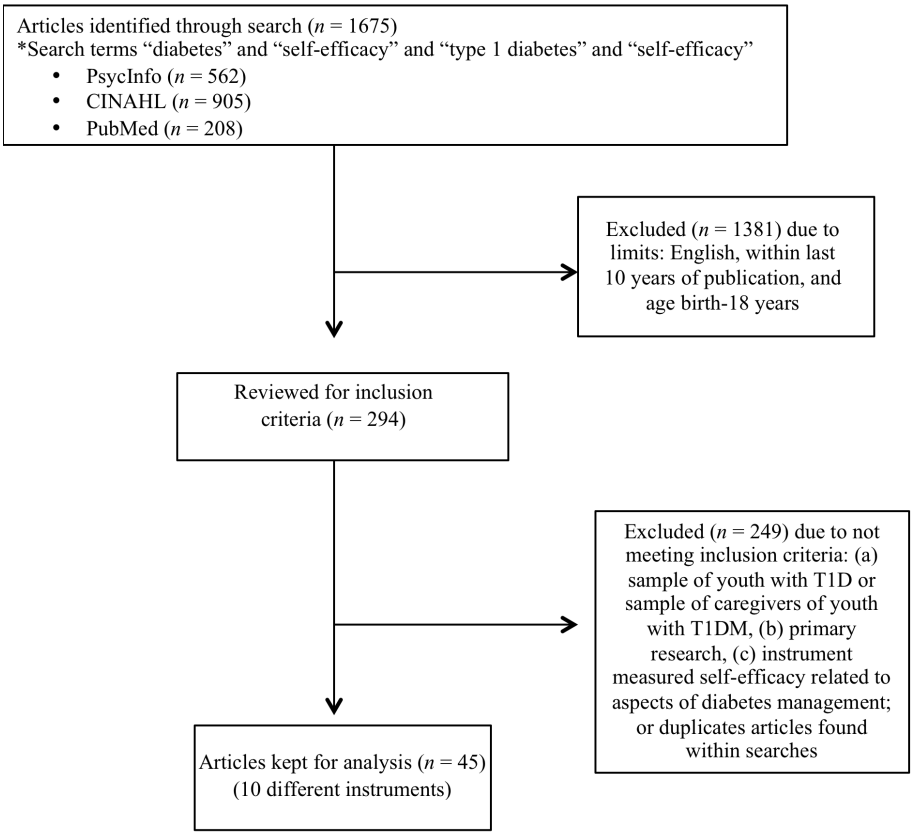

Figure 1: Flow diagram of the search process

Figure 1 presents an overview of the literature search and is a CONSORT flow diagram of the search methodology.[58] The first database search occurred with PsycINFO. An initial search included the terms "diabetes" and "self-efficacy", and an additional search included the terms "type 1 diabetes" and "self-efficacy". The investigators conducted searches with both diabetes and type 1 diabetes to ensure comprehensiveness. Limits of "English, last 10 years of

publication, and childhood age (birth-17 years)" were applied. The age limit for the PsycINFO search ended at 17 instead of 18 years because 18 years and older is classified as adulthood in this search engine. The results were evaluated for applicability, availability, and relevance; a total of 28 articles met inclusion criteria. The second database search occurred with CINAHL and included combined searches with "diabetes" and "self-efficacy" as well as "type 1 diabetes" and "self-efficacy". After applying the limits of "English, last 10 years of publication, and ages birth-18 years", this search identified 16 articles that met inclusion criteria and were not duplicates from the prior search. A third search occurred in PubMed and included the MeSH terms "diabetes mellitus" and "self-efficacy" and then "type 1 diabetes" and "self-efficacy". To add precision to the search, the authors specified the MeSH term "self-efficacy" as a major term. Adding the limits of "English, last 10 years of publication, and ages birth-18 years" yielded one additional article that was not a duplicate from prior searches. The search provided a total of 45 articles that discussed the use of 10 instruments for measuring self-efficacy in youth with T1DM and/or their caregivers.

Tables 1 to 3 contain matrices of relevant articles categorized by type of self-efficacy instrument with particular attention to study sample, instrument characteristics, and instrument psychometrics. The Oxford Centre for Evidence-based Medicine-Levels of Evidence was used to evaluate each study based on study design and analysis.[59] Two of the investigators (LR and CJ) evaluated each study to determine the level of evidence and to establish inter-rater reliability. The level of agreement was 100 percent.

Results

Research Process

The authors summarized the results based on theoretical frameworks for the respective articles, sample characteristics, instrument descriptions, scoring, and psychometrics (Tables 1 to 3). Table 1 identifies and describes the various instruments and the identified studies, while Table 2 includes information about the theoretical framework and sample in each article, and Table 3 describes the psychometric details of the measurements and outcomes related to self-efficacy.

Table 1. Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

Instrument/ Reference	Instrument Description/Scoring	Comments
Self-Efficacy for Diabetes Scale (SED)[31,32,54,60-75]	Instrument: 3 subscales: diabetes-specific self-efficacy (24 items), medical situations self-efficacy (5 items), general situations (6 items) questionnaire assessing perceived self-efficacy to manage T1DM[60]; Likert-like response categories 1-5 with "1 = very sure I cannot" to "5 = very sure I can"[61,63,67,70,73-75] or "1 = very sure I can" to "5 = very sure I can't"[65] or a 6-point Likert-like scale[31,62,64,72] or a 5-point Likert scale with 0-4 "0 = very sure I can" to "4 = very sure I cannot".[69] Some studies report 12-item[70] or 33-item[72] instrument. Scoring: Scoring differed by study(ies). Total scores represented by mean item score.[61] Higher scores reflect greater self-efficacy[31,67,72-75] or more confidence.[70]	Modified to include current aspects of T1DM (pump therapy).[71] SED adapted for parent use with 22-items and youth parent dyads completed the survey.[67,73] SED adapted for parent use only with 19-items.[54,74,75] SED adapted for camp counselor use.[70]
Self-Efficacy for Diabetes Self-Management (SEDM)[£ 27-]	Instrument: 10 item questionnaire assessing perceived self-efficacy to perform diabetes care behaviors with Likert-like response categories 1-10 with "1 = not at all sure" to "10 = completely sure". One study used a scale ranging 1-5.[30] Scoring:	Instrument adapted for use in youth-parent dyads (either mother, father, or both).[53,78,80,81]

Table 1. Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

[30,53,76-82]	Scoring differed by study(ies) Higher scores indicating higher levels of self-efficacy.[28,30,53,81,82] Youth and parent scores combined to measure family self-efficacy.[53]	
Diabetes Empowerment Scale (DES)[54,83]	Instrument: 28 items composed of 3-subscales rating diabetes specific self-efficacy in managing psychosocial aspects of diabetes, assessing dissatisfaction, and readiness to change and setting and achieving diabetes goals, using 5-point Likert-like scale ranging from 1 = strongly agree to 5 = strongly disagree.[83] Scoring: Mean scores provided in each study.[54,83]	One study used the DES in parents of youth with T1DM.[54]
Diabetes-Specific Self-Efficacy Scale[84-87]	Instrument: 7 items indicating confidence about ability; for each item, numbers converted to A+ = 100 "could not do better" to F = 20 "you are a disaster" using scale 20-100.[87] 8 item questionnaire assessing perceived related to diet, glucose monitoring, insulin administration, exercise, and hypoglycemia behaviors with grading A+ = 9 could not do better" to F = 1 "you are a disaster"[85]; Participant graded themselves on tasks with grade ranging from A+ to F with total score ranging 8-72.[84,86]	Two studies used modified instrument adding item related to hypoglycemia to make total of 8-items.[84-86]

Table 1. Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

	Scoring: Scoring differed by study. A+ was equal to a score of 9 and F equal to a score of 1 for each item with the total score being the sum.[85] Higher scores indicate higher self-efficacy.[86,87]	
Dietary Self-Efficacy Scale[88-90]	Instrument: 9 items rating confidence about following dietary plan related to barriers of temptations, negative mood, and uncontrollable situations; 10-point scale ranging from 0 = not confident in following dietary plan to 10 = confident in following dietary plan[88]; adapted scale to measure confidence in dietary self-care activities with 26 items/common barriers, using 11-point Likert scale of 0 = not at all confident to 10 = totally confident.[89,90] Scoring: Higher scores indicate more self-efficacy	Adapted to use with adolescents and parents.[89]
Perceived self-efficacy scale related to exercise[91]	Instrument: 8 item questionnaire assessing beliefs about personal exercise capability, Likert-like response categories with "1 = not at all true" to "5 = very true".[91] Scoring:	Survey assisted in development of exercise program and examined changes post intervention.[91]

Table 1. Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

	Mean of items calculated[91]	
Diabetes self-efficacy scale[92]	Instrument: 8 item questionnaire measuring level of self-confidence performing diabetes care-related tasks, 10-point semantic differential scale with "1 = not at all confident" to "10 = totally confident".[92] Scoring: Ratings summed and higher scores indicate greater self-efficacy[92]	
Perceived Diabetes Self-Management Scale[93]	Instrument: 8 item questionnaire measuring confidence in managing glycemic control well, 5-point Likert-like scale with "1 = strongly disagree" to "5 = strongly agree".[93] Scoring: Four items reverse-scored, scores ranged 8-40 with higher scores indicating greater confidence.[93]	Survey was translated for current study.[93]
Maternal Self-Efficacy for Diabetes Scale[94]	Instrument: 17 item questionnaire to assess maternal self-efficacy in areas of illness, exercise, response to high or lower blood glucose, adjusting insulin doses, and acting as child's advocate, 5-point Likert scale with "1 = not at all confident" to "5 = very confident without help".[94]	

Table 1. Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

	Scoring: Not reported[94]
Self-Efficacy in Diabetes Education[23]	Instrument: 11 item questionnaire measuring self-efficacy about specific factors related to performing diabetes care and education in school setting, 5-point Likert scale with "1 = not at all confident" to "5 = completely confident", stem " I feel confidence with diabetes education when…"[23] Scoring: Determined by adding responses of all questions, highest score 55 indicates complete confidence, score 44 high confidence, score 33 moderate confidence, 22 low confidence, lowest score 11 no confidence[23]

NOTE: A table summarizing each study is available from the author.
[£]One study[82] used the Diabetes Management Self-Efficacy Scale (DMSES) by Iannotti et al. (2004) from paper presented at the Society of Pediatric Psychology National Conference on Child Health Psychology.
Legend for abbreviations: Type 1 Diabetes (T1DM), Self-Efficacy for Diabetes Scale (SED), Self-Efficacy for Diabetes Self-Management (SEDM), Diabetes Empowerment Scale (DES)

Table 2: Theoretical Framework and Sample Used in Articles Measuring Self-Efficacy

Instrument/ Reference	Theoretical Framework	Sample/Subjects
Self-Efficacy for Diabetes Scale (SED)[31,32,54,60-75]	Self-efficacy theory[54]; Self-efficacy: Not stated but implied[31,72]; Stress adaptation model[60,65,71]; Social ecological model[61]; Bruhn and Parcel model of health promotion[63]; Social cognitive theory[65]; Biopsychosocial model[66]; Johnson's biobehavioral model[75]; Transtheoretical model[67]; Self-regulation theory[70]; Not identified[32,62,64,68,69,73,74]	Sample size: n = 14[54] to 515[69] Subjects largely white or white and upper/middle income[31,60-63,65-67,69-75] Age range across studies: 3.9-21 years old*[31,32,60-73] Parents of youth with T1DM[54,60,62,65-68,73-75] Adolescent camp counselors[70]
Self-Efficacy for Diabetes Self-Management (SEDM) [27-30,53,76-82]	Self efficacy: Not stated but implied[77,80,81]; Bandura's Social Cognitive Theory[27]; Dyadic models of coping[79]; Risk and Resistance model of chronic illness adaptation[82]; Family organization[53]; Not identified[28-30,76,78]	Sample size: n = 137[29] to 766[28] Subjects largely white and/or upper/middle income[27,29,30,53,76-82] Age range across studies: 2-18 years old* Parents of youth with T1DM[27-30,53,76-82]
Diabetes Empowerment Scale (DES)[54,83]	Extended health belief model[83]; Self-efficacy theory[54]	Sample size: n = 14[54] to 118[83] Age range: 16-25 years old[83] Parents of youth with T1DM[54]
Diabetes-	Social cognitive perspective-self-efficacy[86]; Self-	Sample size: n = 56[87] to 204[86]

Table 2: Theoretical Framework and Sample Used in Articles Measuring Self-Efficacy

Specific Self-Efficacy Scale[84-87]	efficacy[87]; Not identified[84,85]	Subjects were largely white or white and upper/middle income[84-86] Age range across studies: 10-23 years old[84-87]
Dietary Self-Efficacy Scale[88-90]	Self-Determination Theory[88]; Leventhal, Meyer, and Nerenz's self-regulatory model of illness representations[89,90]; Social-cognitive theory/self-efficacy[90]	Sample size: n = 151[90]-289[88] Age range across studies: 11-18 years old[88-90] Parents of youth with T1DM[89]
Perceived self-efficacy scale related to exercise[91]	Personalized exercise prescription intervention model[91]	Sample size: n = 12[91] 9 subjects non-Hispanic white, 3 subjects Hispanic; no SES data[91] Age range: 12-19 years old[91] Parents of youth with T1DM[91]
Diabetes self-efficacy scale[92]	Not identified[92]	Sample size: n = 123[92] Age range: 13-25[92]
Perceived Diabetes Self-Management	Not identified[93]	Sample size: n = 52[93] Age range: 12-20 years old[93]

Table 2: Theoretical Framework and Sample Used in Articles Measuring Self-Efficacy

Scale[93]		
Maternal Self-Efficacy for Diabetes Scale[94]	Self-efficacy[94]	Sample size: n = 41[94] Mothers of youth with T1DM[94]
Self-Efficacy in Diabetes Education[23]	Bandura's Theory of Self-Efficacy[23]	Sample size: n = 115[23] School nurses at elementary and middle schools in suburban New England[23]

*Youth as young as 8 years old completing surveys may alter results for adolescents[60,65]; youth as young as 8 years old interviewed for scale development[27]; study recruited families of youth with T1DM between ages of 2 and 17 years old; however, only adolescents ages 12 to 17 years old completed SEDM[28]

Legend for abbreviations: Type 1 Diabetes (T1DM), Self-Efficacy for Diabetes Scale (SED), Self-Efficacy for Diabetes Self-Management (SEDM), Diabetes Empowerment Scale (DES)

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

Instrument/ Reference	Validity of Instrument	Reliability of Instrument	Outcomes related to Self-Efficacy/Level of Evidence
Self-Efficacy for Diabetes Scale (SED)[31,32,54,60-75]	Confirmatory factor analysis[66]; Used to establish construct validity for a novel instrument measuring diabetes self-management in adolescents[69]; No other evaluation for validity reported[31,32,54,60-64,67,68,70-75]	Internal consistency: Cronbach's α = .88 to .94[63,64,70]; diabetes subscale .84 to .90[60,64,71]; medical subscale .60[64] and .71[60]; general subscale .58[64] and .70[60]; α = .84[65] and .87[69] for diabetes subscale only, .87 to .88 for parents only,[74,75] .88 to .90,[61,62,64]; .90 for youth and parents[67,73]; reliability coefficient =.90 to .92 (unclear if established in this study or previous studies)[68]; not reported[31,32,54,66,72]	Outcomes: Higher self-efficacy for female teens on pump therapy compared to multiple daily injections[31]; more parental emotional support and maternal acceptance associated with higher self-efficacy[62,63]; better diabetes problem solving related to higher self-efficacy and youth self-efficacy predicted youth responsibility for more diabetes management[66]; higher self-efficacy reported six months after starting pump therapy[32]; higher maternal self-efficacy associated with lower rates of health-care utilization by youth[73]; positive relationship between social support and self-efficacy in parents of T1DM youth, greater self-efficacy found following web-based intervention to improve social support in parents of T1DM youth.[54]

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

			Critical parenting associated in lower self-efficacy in preteens, mediated by depressive symptoms[61]; lower self-efficacy mediated relationship between depressive symptoms and fewer self-care behaviors[61]; adolescents describing mothers as having firm control had worse self-efficacy[62]; parents reporting lower self-efficacy also reported more frequent pediatric parenting stress.[75] Level of Evidence: 1b[32,60,64,65,68,70]; 2b[31,54,61-63,66,67,69,71,73-75]; 3b[72]
(Self-Efficacy for Diabetes Self-Management SEDM)[27-30,53,76-82]	Face validity assessed by developmental psychologists and pediatric endocrinologists[27];	Test-retest reliability:.89[27] Internal consistency: Cronbach's α = .90[27]; α = .81 to .90,[29,76,77,79-82] .87	Outcomes: Higher self-efficacy associated with diabetes self-management adherence,[27,28] good glycemic control,[27] more collaboration between youth and primary caregivers,[82] patient

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

	Principal Component Factor Analysis reported[27]; Predictive validity determined through hierarchical regression analysis[27]; SEDM used as convergent validation of the Perceived Coping Effectiveness (PCE) measure[79]; SEDM used to establish concurrent validity with novel Adherence in Diabetes Questionnaire[28]; No other evaluation for validity reported[29,30,53,76-78,80-82]	to .88 for mothers and .90 to .91 for fathers,[80,81] .85 for youth and parents,[53] .88 at baseline and .90 at 6 month for youth and .90 at baseline and .93 at 6 month for parents[78]; not reported[28,30]	centered communication with their provider,[78] blood glucose monitoring frequency,[30] lower HbA1c and higher self-control.[29] Higher perceived coping effectiveness associated with self-efficacy across age[79] Self-efficacy is mediator for association between parental-teen relationship and diabetes management.[77] Higher levels of family conflict associated with lower diabetes self efficacy.[30] Level of Evidence: 2b[27-30,53,76-82]
Diabetes Empowerment	None reported [54,83]	Test-retest reliability: .79[83]	Outcomes: High levels of self-efficacy predicted the benefits of

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

Scale (DES)[54,83]		Internal consistency: Cronbach's α = .87, .68, .91 for respective subscales (psychosocial aspects of diabetes, dissatisfaction, and readiness to change/achieving diabetes goals)[83]; None reported[54]	adhering to self-care regimen[83]; no significant difference in parent DES scores after receiving a web-based intervention to improve social support.[54] Level of Evidence: 2b[54,83]
Diabetes-Specific Self-Efficacy Scale[84-87]	None reported[84-87]	Internal consistency: Cronbach's α = .85,[84-86] .86[87]	Outcomes: For youth living independently higher self-efficacy associated with greater responsibility[84]; diabetes management better for youth with higher self-efficacy.[85] Lower self-efficacy associated with greater responsibility for adolescents living at home after high school.[84] Level of Evidence: 2b[84-87]
Dietary Self-	None reported[88-90]	Internal consistency:	Outcomes: Dietary self-care

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

Efficacy Scale[88-90]		Cronbach's α =.86,[88] .95,[89,90] .98 for parents[89]	positively and significantly related to self-efficacy[88]; higher levels of dietary self-efficacy associated with less perceived consequences of diabetes and diabetes distress but stronger beliefs about the effects of dietary self-care to control symptoms and greater dietary self-care.[90] Adolescent diabetes distress related to lower self-efficacy and dietary self-efficacy predicted adolescent diabetes distress.[89] Level of Evidence: 2b[88-90]
Perceived self-efficacy scale related to exercise[91]	None reported[91]	None reported[91]	Outcomes: Perceptual factors influencing adherence to exercise was not strongly associated with exercise self-efficacy.[91] Level of Evidence: 1b[91]
Diabetes self-efficacy scale[92]	None reported[92]	Internal consistency: α = .77[92]	Outcomes: No difference in self-efficacy between rural/urban youth;

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

			higher diabetes self-efficacy, lower risk behavior, predicted better diabetes self-care, which subsequently predicted better glycemic control and mental health.[92] Level of Evidence: 2b[92]
Perceived Diabetes Self-Management Scale[93]	None reported[93]	Internal consistency: α = .80[93]	Outcomes: Higher self-efficacy related to good metabolic control and patients more likely to reach target diabetes control.[93] Lower self-efficacy found in youth who had longer diabetes duration.[93] Level of Evidence: 2b[93]
Maternal Self-Efficacy for Diabetes Scale[94]	Content validity established from 2 parents of youth with diabetes and 3 nurse practitioners[94]	Test-retest reliability: coefficient of stability = .75[94]	Outcomes: Maternal coping resources significantly related to maternal diabetes self-efficacy.[94] No significant relationship between maternal self-efficacy and maternal diabetes management behaviors.[94]

Table 3. Assessment of Instruments Used to Measure Self-Efficacy in T1DM Youth and Caregivers

			Level of Evidence: 2b[94]
Self-Efficacy in Diabetes Education[23]	Sent to 5 school nurse experts for content[23]	Internal consistency: α = .94[23]	Outcomes: Significant relationship between greater self-efficacy and having a diabetes curriculum; significant positive relationships between self-efficacy and participating in care of children with diabetes, having T1DM youth in the school system, and supervising blood glucose monitoring.[23] Level of Evidence: 2b[23]

Legend for abbreviations: Type 1 Diabetes (T1DM), Self-Efficacy for Diabetes Scale (SED), Cognitive Behavioral Therapy (CBT), Self-Efficacy for Diabetes Self-Management (SEDM), Diabetes Empowerment Scale (DES)
Legend for Levels of Evidence: 1a systematic review (SR) of randomized controlled trials (RCT)/inception cohort studies/diagnostic studies/prospective cohort studies/economic studies; 1b individual RCT, individual inception cohort study with >80% follow-up, validating cohort study, prospective cohort study with good follow-up; 1c all or none case series; 2a SR of cohort studies/retrospective cohort studies or untreated control groups in RCTs; 2b individual cohort study (including low quality RCT), retrospective cohort study, exploratory cohort study; 2c outcomes research/ecological studies; 3a SR of case-controlled studies; 3b individual case-control study, non-consecutive cohort study; 4 case-series; 5 expert opinion without critical appraisal.[59]

Theoretical frameworks

Theory driven measurement assigns meaning to a research question, clarifies associations between concepts, and gives researchers a guide to explore a specific concept.[55,95] A lack of a theoretical framework in instrument development jeopardizes the ability to adequately measure a

concept. Despite the importance of a theoretical framework, many of the articles analyzed in this integrative review did not identify a theoretical framework, as indicated in Table 2, column 2.

Of the 28 articles evaluating youth or caregiver self-efficacy that identified or implied a theory, the most common framework was Bandura's social cognitive theory (SCT) or model of self-efficacy.[23,27,54,65,86,87,90,94] Although not explicitly stated, an additional five studies implied Bandura's model of self-efficacy.[31,72,77,80,81]

Less common, yet applicable, frameworks included the extended Health Belief Model (HBM),[83] the risk and resistance model of chronic illness adaptation,[82] and the stress-adaptation model.[60,65,71] Each of these guiding models related to the construct of self-efficacy or patient/family adaptation to chronic disease management.

Sample and subjects

Since the purpose of this integrative review was to identify self-efficacy measures in youth with T1DM and their caregivers, all identified studies included a sample of children or adolescents or parents/caregivers. Many studies had youth ≥10 years old complete the various instruments; yet, a few had participants as young as 8 years old.[60,65] Of the 45 articles in the review, 39 encompassed an adolescent age range of participants[27-32,53,60-73,76-93] (10-18 years old as defined by the American Psychological Association),[96] 25 studies included parents as participants,[27-30,53,54,60,62,65-68,73-82,89,91,94] and 11 studies measured parental self-efficacy in diabetes management[53,54,67,73-75,94] or parental confidence in their child.[78,80,81,89] One study measuring self-efficacy in diabetes care and education focused on the role of school nurses in diabetes management (including both type 1 diabetes and type 2 diabetes),[23] and one focused on the role of camp counselors.[70]

An analysis of participant demographics revealed that 31 studies had a homogenous sample that included white and/or middle-class participants.[27,29-31,53,60-63,65-67,69-82,84-86,91,94] Additionally, 10 studies took place internationally, outside of the United States.[28,32,64,83,87-90,92,93]

Evaluation of Instruments

This integrative review identified 10 instruments to measure self-efficacy in youth with T1DM and their caregivers. Given the inclusion criteria of articles from the last decade (2003-2013), the initial literature search did not reveal the original articles that described all of the instruments. The following instruments were identified: a) Self-Efficacy for Diabetes scale (SED); b) Self-Efficacy for Diabetes Self-Management scale (SEDM); c) Diabetes Empowerment Scale (DES); d) Diabetes-Specific Self-Efficacy Scale; e) Dietary Self-Efficacy Scale; f) Perceived Self-Efficacy Scale related to exercise; g) Diabetes Self-Efficacy Scale; h) Perceived Diabetes Self-Management Scale (PDSMS); i) Maternal Self-Efficacy for Diabetes Management Scale; j) Self-Efficacy in Diabetes Education (SEDE). Of the 10 instruments, four were used in youth,[84-87,91-93] three were used in youth/parents,[27-30,53,54,76-83,88-90] one was used in youth/parents/camp counselors,[31,32,54,60-75] one was used in mothers,[94] and one was used in school nurses.[23] The most commonly used instruments were the original and adapted SED[31,32,54,60-75] and the original and adapted SEDM.[27-30,53,76-82] One study used two instruments, the SED and the DES, to measure parental self-efficacy.[54]

Instrument description

All instruments used either a Likert-like scale or a semantic differential scale,[97] except the Diabetes-Specific Self-Efficacy Scale, which used scoring from 20 (F) to 100 (A+) to evaluate perceived self-efficacy. The instruments ranged from 7 to 35 items with two of the surveys (SED and DES) consisting of three different subscales within the self-efficacy

measurement. The SED included subscales for diabetes, medical, and general situations. The three DES subscales included managing psychosocial aspects of diabetes, assessing dissatisfaction, and readiness to change/goal setting. While all questionnaires assessed perceived self-efficacy related to confidence in diabetes management, one instrument explicitly measured dietary self-efficacy,[88-90] another measured exercise self-efficacy,[91] and one assessed confidence in diabetes education,[23] Surprisingly, only one study described modifying an instrument (SED) to incorporate pump therapy.[71] The literature search did not identify other measures that assessed youth self-efficacy related to current technologies, e.g. pump therapy or continuous glucose monitoring.

Measurement of perceptions and scoring

The instruments' response categories ranged from five- to eleven-point Likert-like scales and varied as to whether low or high scores indicated less or greater self-efficacy. All articles discussed how scoring related to the level of self-efficacy and/or provided the mean participant scores with the respective instruments. One study using the SEDM survey combined youth and parent scores to evaluate family self-efficacy,[53] although this combination in scoring differed from the original description of the instrument.[27]

Method of administration

The method and site for instrument completion varied, ranging from the clinical or camp setting to completion by mail, the web, or telephone; some studies utilized more than one approach. The majority of studies had participants complete the instruments at the time of a medical or study visit.[30,31,53,60,64-69,73,75-79,81,82,87,88,92,93] The second most frequent method of administration was via the mail[23,27,29,54,62,74,80,83,90] followed by the web.[28,71,84-86]

Reliability

Most articles reported reliability statistics for the self-efficacy instrument under study. Although certain studies may not have explicitly stated reliability or validity data, the psychometrics from the original studies prior to 2003 were identified; however, caution is warranted when applying these psychometrics to different samples. Most studies using the SED or an adapted version of the scale reported internal consistency for the diabetes specific subscale[65,69,71] or total scale[61-64,67,68,70,73-75] with α values ranging from .84-.94, indicating a high internal consistency. Cronbach's α values of .70 and greater are considered acceptable.[98] Other studies using all 3 subscales of the SED reported α values of .84 and .90 for the diabetes subscale, .60 and .71 for the medical subscale, and .58 and .70 for the general subscale.[60,64] The original article by Grossman and colleagues cited a Kuder-Richardson coefficient α of .90 for the total scale, .92 for the diabetes subscale, as well as significant intercorrelations among the scales in a study sample of 68 adolescents with type 1 diabetes.[99]

Studies using the SEDM scale revealed high alpha coefficients ranging from .81-.93.[27,29,53,76-82] Adapted versions of the SEDM used in parents as well as youth performed well, with high levels of internal consistency for parents (α = .85 - .93)[53,78,80,81] and slightly lower levels for youth (α = .81 -.90).[53,78,80,81] The DES demonstrated internal consistency across the three subscales of psychosocial aspects (α = .87), dissatisfaction (α = .68), and readiness to change/goal setting (α = .91),[83] which were slightly lower than the original assessments of the total scale (α = .96) and subscales of psychosocial aspects (α = .93), dissatisfaction (α = .81), and achieving goals (α = .91).[100] The Diabetes Specific Self-Efficacy Scale reported Cronbach's α of .85[84-86] and .86,[87] which was higher than the originally reported .78.[101] The Dietary Self-Efficacy Scale also reported high internal consistency with Cronbach's α of .86[88] and 0.95[89,90]

for youth and .98 for parents,[89] while the original Dietary Self-Efficacy Scale reported a Cronbach's α of .94.[102] All but one of the studies representing the remaining five self-efficacy scales reported reliability information for the current study participants. The study using the Perceived Self-Efficacy Scale related to exercise reported reliability coefficients from past studies only.[91] The internal consistencies for the Diabetes Self-Efficacy Scale, the PDSMS, and the SEDE survey ranged from α = .77-.94.[23,92,93] The original PDSMS reported a relatively high internal consistency with a Cronbach's α of .83 in a sample of adults with type 1 diabetes or type 2 diabetes.[103] Similarly, the original report of Diabetes Self-Efficacy Scale had an α of .85 in a sample of adults with type 2 diabetes.[104]

Test-retest reliability was reported for the Maternal Self-Efficacy for Diabetes Management Scale, with a 37% response rate in repeating the measure after two weeks and a modest correlation of .75,[94] and was reported for the DES with test-retest reliability of .79[83]. In the original study, researchers expanded the SEDM psychometrics by establishing test-retest reliability[27]; they administered the survey twice in 1 week to 38 youth, revealing a test-retest intra-class correlation coefficient of .89, reflecting the stability of the scale over time.[105] The original Perceived Self-Efficacy related to exercise scale also reported reliability using the test-retest method with a result of 0.989[106] and the original Diabetes Self-Efficacy Scale reported a test-retest of .80.[104]

Validity

A few of the articles reported content and face validity of the self-efficacy instruments. Content validity was established by consulting school nurses as experts for the SEDE instrument[23] and parents of youth with diabetes plus nurse practitioners for the Maternal Self-Efficacy for Diabetes Management Scale.[94,107] Similarly, nine family interviews and consultation

with experts in developmental psychology and pediatric endocrinology established face validity for the original SEDM scale.[27]

Factor analysis was another approach to establish validity. In one article using the SED, the researchers performed a confirmatory factor analysis among variables that included self-efficacy to determine the strength of relationships among the variables.[66] In the original publication of SEDM scale, the authors reported extensive validity metrics, including factor analysis and predictive validity.[27] They identified significant although modest correlations between the SEDM scale and glycemic control (r = .21) and the youth (r = .37) and parent (r = .29) report on the Diabetes Self Management survey.[27] The original article describing the DES reported a single factor for the measure.[101]

Other articles described construct, convergent, and concurrent validity. One study used the SED to establish construct validity for the survey measuring diabetes self-management, the Self-Management of T1DM in Adolescents.[69] Although not directly related to the validity of the SEDM scale, one study used this instrument to establish convergent validity for another measure, Perceived Coping Effectiveness (PCE),[79] and another study used the SEDM survey to establish concurrent validity with an Adherence in Diabetes Questionnaire.[28]

To identify other validity assessments, one must evaluate the original articles describing the self-efficacy instruments. The initial article using the SED reported evidence for criterion and construct validity for this measure[99] while the original DES article reported evidence for concurrent validity.[100] The original article describing the PDSMS also reported sufficient establishment of construct validity.[103] Pender and colleagues reported predictive validity, which was established with significant correlations with other variables for the Perceived Self-Efficacy

Scale related to exercise.[106] The original Dietary Self-Efficacy article did not describe a validity assessment.[102]

Feasibility of instrument use

The identified studies did not readily discuss the feasibility of implementation of the instruments.[55] In some cases, authors identified compensation amounts for study participation or the time required for completion; however, the time reported often involved completion of multiple questionnaires, not just the self-efficacy instrument. Therefore, it is difficult to ascertain how long each measure takes to complete. However, Table 1 lists the number of items per survey. Access to the instrument is another feasibility consideration. On an initial search, the majority of surveys does not seem readily available within the public domain and often require identifying the original article describing the instrument. The following instruments are publicly accessible: the DES is accessible on the Michigan Diabetes Research and Training Center website,[108] the Perceived Self-Efficacy Scale related to exercise[91] and the Diabetes Self-Efficacy Scale[92] are available through websites noted in the studies' reference lists. The SEDM and PDSMS items are listed as tables in the original studies.[27,103] Additionally, the original studies describing the Maternal Self-Efficacy for Diabetes Management Scale and the SED included the scales as appendices in the articles.[99,107]

Conclusions

Research Process

Theoretical Issues

Despite the importance of theory driven research, not all articles in this integrative review on self-efficacy identified a theoretical framework. Instruments based upon a theoretical framework and theoretical definition of the concept of interest will ultimately provide a better

means to operationalize the concept.[55] Not surprisingly, most studies that did recognize a guiding framework used Bandura's SCT or the model of self-efficacy. The six constructs of the SCT provide a framework for health promotion and chronic disease management to translate health knowledge into positive health outcomes.[24] These health behavior constructs include the following: knowledge, perceived self-efficacy, outcome expectations, goals, perceived facilitators, and impediments.[24] Knowledge and personal motivation will help individuals face challenging situations, which is particularly important in the self-management of chronic disease.[24] Moreover, the SCT highlights how individuals proactively cope and adapt to environmental stressors by relying on personal cognitive and emotional resources.[42] The SCT is a natural framework to explore the concept and measurement of self-efficacy as well as one's perceived ability to face challenging situations,[22] especially in youth managing the rigors of type 1 diabetes while navigating the developmental stages of pediatric growth and development. Additionally, self-efficacy, a central component to the SCT, relates to an individual's assessment of personal capabilities in a certain situation and the belief that carrying out behaviors will lead to a specific outcome.[22,23] Utilizing the SCT or the model of self-efficacy as the underlying framework for development of self-efficacy instruments provides a theoretical overview of how youth with type 1 diabetes or their caregivers may carry out specific behaviors related to diabetes management in various scenarios.

Researchers should also consider the Social Ecological Model (SEM) when measuring self-efficacy in youth with type 1 diabetes, as one study identified through this review did.[61] Similar to SCT, the SEM has been used to guide health promotion and may provide a unique perspective to assess the multifactorial relationships involved in the concept of self-efficacy for youth with type 1 diabetes.[109] This widely used framework highlights the potential for dynamic

interactions between the individual's environment and layers of social support. Furthermore, this model would have direct application to evaluating various levels of caregiver self-efficacy particularly as it relates to the youth with type 1 diabetes.

Methodological Issues

The prevalence of type 1 diabetes in older children is highest in non-Hispanic white youth,[110] as reflected in the homogenous participant pool of predominately white youth in the studies reviewed above. Thus, the results of this integrative review may not be generalizable to non-white youth with type 1 diabetes. Future research should include purposeful sampling of minority youth with type 1 diabetes. Additionally, the majority of participants across the reviewed studies were from higher socioeconomic status (SES) backgrounds. This further limits the generalizability of the current assessments of self-efficacy instruments, because youth and families from lower SES backgrounds may inherently face more challenges related to financial stressors, additionally impacting self-efficacy. Identifying and testing appropriate measurement instruments to evaluate self-efficacy in these vulnerable populations may be increasingly important to provide greater understanding of the relevance of this concept in all youth with type 1 diabetes.

This integrative review identified self-efficacy instruments at the individual, parent, camp counselor, and school nurse level. The SED, SEDM, DES, Dietary Self-Efficacy scale, the Maternal Self-Efficacy for Diabetes scale, and the SEDE, all measure an aspect of caregiver self-efficacy. Instrument selection depends on the specific participant sample and focus. Capturing caregiver self-efficacy is valuable as both family and caregivers outside of the family are an integral part of a youth's success with diabetes management. Additionally, researchers and clinicians will be able to fine-tune education efforts by identifying gaps in confidence related to

aspects of diabetes management for those involved in the care of the child. However, no articles evaluated peer self-efficacy or the perceived confidence of helping a friend manage diabetes in challenging situations. Because support typically shifts from the family system to friends and peers in adolescence,[111] it would be useful to evaluate peer self-efficacy in diabetes management to further guide adolescents through this developmental transition. Furthermore, youth with type 1 diabetes often have multiple caregivers beyond the parents or school nurse. Use of self-efficacy instruments to assess confidence levels in type 1 diabetes management for grandparents, babysitters, and athletic coaches, among others, may expand the self-efficacy knowledge base and identify essential educational needs of these important caregivers and other key support groups in the community.

Instruments

Methods of administration, feasibility, and psychometrics

There were no major issues identified in administering the 10 instruments to youth or their caregivers, since the majority of surveys were administered during an office visit or by mail. One might not expect different psychometric properties according to response mode but future research could clarify this issue. Although none of the studies noted the exact time required to complete the respective self-efficacy assessments, time-to-completion did not appear to be a burden for survey administration. One must also consider that all instruments, except for three, were administered in English,[28,87,93] an important consideration when establishing eligibility criteria. Survey translation would help broaden international access and generalizability. The main feasibility issue in fielding the various surveys is access to the instruments. The research team should consider the need to search for and possibly purchase surveys when developing a study budget.

Most instruments measuring self-efficacy demonstrated internal consistency, a form of equivalence reliability, indicating the items within the instrument conceptually fit with one another.[105] However, it is important to consider that the internal consistency may vary based on the number of response options used in the Likert scale with a higher number of responses resulting in greater internal consistency[112] and that the alpha value may also vary based on the number of survey items.[98] Both the number of Likert options and survey length varied based on the different instruments. Apart from the SED and SEDM, extensive validity assessments for the different instruments were not frequently described. Often, the authors had to revert back to the original article describing the psychometrics of the self-efficacy instrument to obtain validity evidence. Even in these cases, the original sample may have included adults with type 1 diabetes or type 2 diabetes vs. youth with type 1 diabetes. The lack of validity data reported in the identified articles is a limitation of the contemporary literature. Validity assessments are paramount to evaluating an instrument's capacity to measure self-efficacy or the concept of interest within a certain population.[105] During instrument development and refinement, when translating available instruments into different languages, or when using instruments in different patient samples, validity tests reinforce the adequate measurement of self-efficacy. Additional research efforts should establish further psychometric analysis of these instruments in diverse populations of youth with type 1 diabetes because the sample homogeneity from the identified articles could limit the applicability of the results.

When evaluating the various self-efficacy instruments identified, it is important to acknowledge that many of the self-efficacy instruments were used in multiple articles highlighting the affinity for use. The SED and SEDM were the self-efficacy instruments most often used in the identified articles. Additionally, several studies from this integrative review

revised or adapted the self-efficacy instrument to include a certain population, such as youth parent dyads for example, which clinicians and researchers should consider when selecting an instrument based on a specific population.

Another element to consider when evaluating self-efficacy instruments for future research and clinical care pertains to the ability to measure self-efficacy in the contemporary era of diabetes technologies. One article described modifying the SED instrument to include current aspects of type 1 diabetes (pump therapy),[71] yet a lack of instruments to measure self-efficacy pertaining to current diabetes technology is a pertinent limitation of the available instruments. A caveat to this is that not all articles identified through the integrative review or the original articles describing the instruments included a description of survey items. While advances in diabetes technology aim to improve self-management and glycemic control, it is important to assess an individual's confidence in the ability to use such devices. Currently available self-efficacy instruments would provide added benefit with the inclusion of assessments of self-efficacy related to technology advancements in the contemporary diabetes era. Alternatively, clinicians and researchers could design instruments to specifically evaluate youth and parent confidence related to using diabetes technologies, such as continuous glucose monitors, which are increasingly relevant with the advent of the Artificial Pancreas Project.[113]

Implications

Reliable and valid instruments to measure a concept of interest, such as self-efficacy, are essential for quality research and use in clinical care. The use of well-constructed measurements will confirm potential results and enhance opportunities to generalize findings to populations at large. This review is relevant to research, clinical care, and diabetes education of youth with type 1 diabetes because it identified several reliable and valid instruments to evaluate self-

efficacy, an important component of diabetes self-management. The available instruments vary in length, with respect to the targeted participant age group, and whether caregivers are the focus of the assessment. Although certain studies may not have explicitly stated reliability or validity data, the psychometrics were identified in articles published prior to the 2003-2013 timeframe; however, caution is warranted if applying these psychometric properties across time and in different groups.[98]

This integrative review identified various gaps that could guide future research and instrument development. This search was restricted to the past decade and, thus, was not exhaustive. Of particular note is the absence of self-efficacy instruments or proxy reports that focus on peers of youth with type 1 diabetes. During the teenage years, adolescents often seek support of friends and peers, with less emphasis on support from the family unit.[111] Therefore, it would be important to assess peer self-efficacy in assisting friends with type 1 diabetes in various diverse settings. Additionally, in all youth, and specifically younger children, it would be beneficial to identify valid and reliable instruments to measure self-efficacy in other caregivers, e.g. grandparents. Such research across other care providers and possibly peers could help to identify knowledge deficits and avenues for education of important groups for social support of youth with type 1 diabetes. Future studies are needed to implement self-efficacy measurements in minority populations, as well as international samples, to further assess the psychometric properties of these instruments and to broaden their application to youth with type 1 diabetes globally. Additionally, instruments to measure the construct of self-efficacy in the current era of advanced diabetes technologies, including use of insulin pumps and continuous glucose monitoring technologies, appear to be needed. A lack of instruments to measure self-

efficacy related to diabetes technologies implies that the available self-efficacy instruments need to be adapted or new instruments need to be developed to be relevant in the contemporary era.

In selecting an instrument to measure self-efficacy in the pediatric population with type 1 diabetes and their caregivers, the clinical or research team must contemplate various factors. One must consider the population (i.e. youth, parents, school nurses, camp counselors), length of the scale, available psychometric data, availability of the measure, and the particular aspect related to diabetes management that the self-efficacy scale measures (i.e. diet, physical activity, general diabetes self-efficacy). Having specific criteria will guide the instrument selection. Additionally, when identifying instruments for use in the pediatric population and in the context of diabetes education, it is important to consider how the concept of self-efficacy can span throughout childhood and at what age youth are able to understand and answer questions related to self-efficacy. Many studies identified in this integrative review had youth ≥10 years old complete the various instruments, including the self-efficacy assessments; however, some studies had participants as young as 8 years old. A final consideration when evaluating instruments for use with caregivers is to determine whether the purpose of the instrument is to assess the caregiver's own perception of confidence related to diabetes management or whether the instrument assesses the caregiver's confidence in the child's self-care, an important component to keep in mind when measuring the construct of self-efficacy.

In conclusion, when selecting an instrument to measure self-efficacy in youth with type 1 diabetes and their caregivers, it is important to remember that one's perceived ability for diabetes self-management reflects a constellation of behaviors. Furthermore, improvements in intensive therapy options can add to self-management challenges as diabetes technologies continue to evolve, reinforcing the need to capture self-efficacy. The evolvement of type 1 diabetes

technologies will require either making modifications to existing self-efficacy instruments or developing new instruments altogether; evaluation of the psychometric properties of these instruments will be necessary. It is essential to select an instrument that is appropriate, acceptable, feasible, and responsive to both the needs of the patient and the clinician or researcher as well as an instrument that it is valid, reliable, and precise in measurement to ensure clinical and research integrity are maintained.

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Chapter 4: Youth and Parent Measures of Self-Efficacy for Continuous Glucose Monitoring (CGM): Survey Psychometric Properties

Objective: The purpose of this study was to investigate the psychometric properties of a novel instrument to measure self-efficacy related to continuous glucose monitoring in youth with type 1 diabetes and their parents. This evaluation also assessed the predictive validity of the CGM-Self-Efficacy (CGM-SE) instrument scores upon CGM use and hemoglobin A1c (HbA1c).

Research Design and Methods: Study participants included 120 youth with type 1 diabetes for ≥ 1 year who were enrolled in a 2-year randomized clinical trial (RCT) comparing CGM use with and without the addition of a family-focused CGM behavioral intervention. Youth and parents completed the CGM-SE instrument at randomization after a 1-week run-in period to assess CGM tolerability and again at 6 months. Analysis of predictive validity excluded the intervention group and included 61 youth in the control group to assess CGM use and HbA1c outcomes 3 and 6 months after randomization.

Results: At study entry, youth were on average 12.7 ± 2.7 years old with a mean diabetes duration of 6.1 ± 3.6 years and mean HbA1c of 8.0 ± 0.8%; mean blood glucose (BG) monitoring frequency was 6.8 ± 2.4 times/day and 84% pump received therapy. The CGM-SE had acceptable internal consistency (Cronbach's $\alpha = 0.80$ for youth; 0.82 for parents). Exploratory factor analysis yielded two factors for both the youth and parent surveys; "home" and "away" were the two factors for the youth survey and "relational" and "technical" for the parent survey. Youth reporting higher baseline CGM self-efficacy (score > 80) had statistically significantly greater CGM use and lower HbA1c after 3 and 6 months compared to youth reporting lower baseline CGM self-efficacy (score ≤ 80).

Conclusions: The novel CGM-SE instruments appear to have strong psychometric properties. CGM self-efficacy may offer an opportunity to assess the likelihood of CGM adherence and glycemic improvement in youth with type 1 diabetes in clinical and research settings.

The current era of intensive insulin therapy places substantial demands upon children and adolescents with type 1 diabetes along with their parents. Intensive insulin therapy requires numerous self-care behaviors, which are particularly evident in the use of continuous glucose monitoring (CGM) technologies, in order to maintain glycemic control. The JDRF CGM RCT yielded significantly improved glycemic outcomes without severe hypoglycemia in adults; however, children and adolescents only demonstrated improved glycemic control with consistent CGM use.[13,17] Thus, there has been substantial interest in uncovering approaches to encourage consistent CGM use in the pediatric population. Specifically, we were interested in understanding how self-efficacy may relate to CGM use in children and teens with type 1 diabetes and their parents.

Self-efficacy, a central part of Bandura's Social Cognitive Theory, is an individual's perceived ability to carry out a certain behavior.[22,114] Self-efficacy can augment one's motivation to perform certain tasks[21] and can be an important indicator of health behavior change.[27] Measuring self-efficacy is an integral part of the predictive evaluation of whether an individual will carry out a specific task and the level of perseverance they will exert when faced with challenges or barriers. Self-efficacy also influences outcome expectations or the result an individual anticipates that his/her actions will generate.[24] Higher levels of self-efficacy often parallel more positive outcomes expectations.[24]

Given the exceeding demands that type 1 diabetes self-management imposes on patients and families, particularly with the advancements in diabetes technologies, self-efficacy is an

important construct to evaluate in youth with type 1 diabetes and their caregivers. Type 1 diabetes management necessitates a complex orchestration of family and self-care tasks. Specifically, optimal diabetes management requires adherence to frequent blood glucose monitoring as well as balancing food and exercise with timely insulin administration. Additionally, youth and their caregivers may use advanced diabetes technologies, such as CGM, to maintain glycemic control. Use of CGM can help improve glycemic control in youth; yet consistent CGM use is challenging due to the potentially increased burden of wearing the device regularly.[13] High self-efficacy, or strong perceived ability to make positive health behavior changes despite challenges,[24] may facilitate complex behaviors like CGM use in youth with type 1 diabetes. Given the challenges of consistent CGM use in youth with type 1 diabetes, it is important to determine whether self-efficacy is a factor in consistent CGM use, and whether the level of self-efficacy predicts CGM use, and, in turn, glycemic outcomes. Evaluating CGM self-efficacy in both youth and parents is particularly important considering the level of support and family involvement that are necessary for diabetes self-care tasks with intensive insulin therapy and advanced diabetes technologies. The ability to measure self-efficacy related to CGM use may help the pediatric multidisciplinary team to identify those youth and parents who may benefit from additional education and support. However, there is a paucity of published research in the area of assessing self-efficacy related to CGM in youth with type 1 diabetes.

This first aim of this study was to evaluate the psychometric properties of a novel instrument designed to assess self-efficacy related to CGM in children and adolescents with type 1 diabetes and their parents. The second aim of the study was to assess the predictive validity of the CGM-SE in a subset of participants to determine whether CGM self-efficacy predicts CGM use and subsequent glycemic control.

Research Design and Methods

Study Population

This study is part of a larger 2-year randomized clinical trial (RCT) comparing CGM use with and without the addition of a family-focused CGM behavioral intervention. Initially, the Dexcom SEVEN PLUS CGM was used in the study. Patients transitioned to the Dexcom G4 when it became available on the market. Study participants were 120 youth with type 1 diabetes and their parents; they were randomized in a 2-year RCT and followed at a tertiary care center in the northeastern United States. Eligibility criteria included youth ages 8-17 years with type 1 diabetes ≥ 1 year; established use of intensive insulin therapy (pump or multiple daily injections); insulin dose of ≥ 0.5 units/kg/day; blood glucose (BG) monitoring frequency of ≥ 4 times/day; hemoglobin A1c (HbA1c) 6.5%-10%; no consistent CGM use (defined as 6+ days/week) in the previous 6 months; and anticipation for ongoing care at the diabetes center. Parents provided written informed consent and youth provided written informed assent prior to initiating any study procedures. The Institutional Review Board at the tertiary care center approved the study protocol and the investigator's university granted reciprocity.

The current report utilizes the entire sample of 120 youth at baseline to evaluate the CGM-SE surveys (Aim 1) and the 61 participants randomized to the control group to assess the predictive validity of the CGM-SE survey on CGM wear and subsequent glycemic control (Aim 2).

Data Collection

The electronic medical record, parent-youth interviews, and blood glucose meter downloads provided clinical and diabetes management data at each of the baseline, 3, and 6 month study visits as part of the larger study. The CGM data were obtained at the 3 and 6 month

visits by downloading the data stored on the CGM device. Youth and parents completed the following questionnaires at the baseline and 6 month study visits: the Pediatric Quality of Life Inventory (PedsQL) Generic Core Scales and the Type 1 Diabetes Module,[115,116] the Diabetes Management Questionnaire (DMQ),[117] the Problem Areas in Diabetes Survey-Parent Revised and Pediatric Version (PAID-PR/PAID-Peds),[118,119] the State-Trait Anxiety Inventory (STAI) and the STAI for Children (STAIC),[120,121] and the Center for Epidemiologic Studies Depression Scale (CES-D) for parents and the CES-D for Children (CES-DC).[122,123] All measures have been demonstrated to be reliable and valid for use in populations with diabetes (see below). Immediately following the baseline study visit, youth wore the CGM for a 1-week run-in period to assess CGM tolerability. At the end of the 1-week run-in period, participants were randomized and youth and parents completed the CGM-SE instrument developed for the 2-year RCT.

Measures

Development of the CGM Self-Efficacy Instrument (CGM-SE)

A pediatric multidisciplinary diabetes team, experienced in clinical research and CGM use, developed the self-efficacy instrument items following a literature review. Item refinement occurred through pre-testing and cognitive interviewing in youth and parents prior to the 2-year RCT. Items assessed the confidence of youth and parents to manage the technical and behavioral aspects of CGM use. The stem of the items stated, "I am sure that I can…". There are two versions of youth instruments based on age (ages 8-12: 11 items; ages 13+: 15 items) and one version for parent instrument (14 items). The 4 additional items on the version for ages 13+ address performance of more complex tasks, such as downloading CGM data and making insulin adjustments based on CGM data. All item responses are scored on a 7-point Likert scale (0 = strongly disagree, 6 = strongly agree). The total score is obtained by computing the mean of all

items, multiplying the mean by 100, and then dividing by 6. Scores can range from 0-100, with higher scores reflecting higher self-efficacy. Each version requires < 5 minutes for completion.

Pediatric Quality of Life Inventory (PedsQL) Generic Core Scales and Type 1 Diabetes Module[115,116]

The PedsQL Generic Core Scales (23 items) and PedsQL Type 1 Diabetes Module (28 items) assess generic and diabetes-specific youth quality of life over the past month. Items are scored on a 0-4 Likert scale (0=never, 1=almost never, 2=sometimes, 3=often, 4=almost always) with higher scores indicating greater quality of life. The youth instrument is a self-report of youth quality of life; the parent instrument is a proxy report of youth quality of life. The Cronbach's α for the current sample was the following: PedsQL Generic Core Scales (youth α = 0.94; parents α = 0.90) and PedsQL Type 1 Diabetes Module (youth α = 0.91; parents α = 0.86). In a sample of youth with T1D and T2D, the published literature has reported a Cronbach's α for the PedsQL Generic Core Scales of 0.88 for youth and 0.89 for parents.[116] For the PedsQL Type 1 Diabetes Module, the Cronbach's α has ranged from 0.63-0.77 for the subscales for youth and 0.81-0.84 for parents.[116]

Diabetes Management Questionnaire (DMQ)[117]

The DMQ assesses adherence to daily diabetes self-management tasks. Items are applicable to both injection-based therapy and insulin pump therapy. Both youth and parent measures consist of 20-items based on a 5-point Likert scale ranging from "almost never" to "almost always", with higher scores indicating higher levels of adherence to diabetes management. The youth survey is a self-report adherence; the parent survey is a proxy report of adherence. The Cronbach's α for the current sample was α = 0.67 for youth and α = 0.73 for

parents. In a sample of youth with T1D and their parents, the published literature has reported Cronbach's α of 0.77 for youth and 0.81 for parents.[124]

Problem Areas in Diabetes Survey-Parent Revised (PAID-PR)[118] and Pediatric (PAID-Peds)[119] versions

The PAID-PR (18 items) and PAID-Peds (20 items) assess diabetes burden over the past month. Item responses are on a 5-point Likert scale (0 = agree, 4 = disagree). Higher scores indicate more burden related to diabetes management.[125,126] The PAID-PR is a self-report of parent burden; the PAID-Peds is a self-report of youth burden. The Cronbach's α for the current sample was α = 0.94 for youth and α = 0.90 for parents. The published literature has reported a Cronbach's α of 0.87 for the PAID-PR[118] and 0.93 for the PAID-Peds in a sample of youth with T1D.[119]

State-Trait Anxiety Inventory (STAI)[121] and STAI for Children (STAIC)[120]

The STAI (40 items) and STAIC (40 items) assess feelings of anxiety "right now" (state anxiety) and in general (trait anxiety). Youth responses are on a 3-point Likert scale (1 = hardly ever, 3 = often) and parent responses are on a 4-point Likert scale (1 = not at all, 4 = very much so). Higher scores indicate more symptoms of anxiety. The STAI is a self-report of parent anxiety; the STAIC is a self-report of youth anxiety. The Cronbach's α for the current sample was α = 0.93 for youth and α = 0.96 for parents. In a sample of parents of youth with T1D, the published literature has reported Cronbach's α of 0.92-0.93 for the STAI.[127] In a sample of youth with chronic disease, including diabetes, the published literature has reported Cronbach's α ranging from 0.89 to 0.93 for the STAIC.[128]

Center for Epidemiologic Studies Depression Scale (CES-D)[123] and CES-D for Children (CES-DC)[122]

This depression scale has 20-items. The youth response options are on a 4 point Likert scale ranging from 0 = not at all to 3 = a lot. The parent response options range from 0 or "rarely or none of the time (< 1 day/week)" to 3 or "most or all of the time (5-7 days/week)". Higher scores reflect higher depressive symptoms over the past week. The CES-D is a self-report of parent depressive symptoms; the CES-DC is a self-report of youth depressive symptoms. A mental health professional followed-up with the family according to the RCT study protocol if youth scored ≥ 15 or if parents scored ≥ 16. These validated measures have been used in other ongoing studies involving youth with type 1 diabetes and their parents.[127,129,130] The Cronbach's α for the current sample was α = 0.90 for youth and α = 0.91 for parents. In a sample of parents of youth with T1D, the published literature has reported Cronbach's α of 0.91 for the CES-D.[127] The study that validated the CES-DC in youth reported a Cronbach's α of 0.89.[122]

Glycemic Control

HbA1c was measured uniformly at baseline and 3 and 6 months after randomization using an assay standardized to the Diabetes Control and Complications Trial (reference range 4.0-6.0%; Roche Diagnostics, Indianapolis, IN).

CGM Use

CGM data were downloaded at study visits using Dexcom™ proprietary software. We calculated the amount of weekly CGM use by averaging the total hours of wear during the 4 weeks preceding the 3 and 6 month visits. The baseline CGM wear consisted of the total hours of CGM wear during the 1-week run-in period. CGM use could range from 0 to 168 hours/week. We also created a categorical variable of CGM use with three categories 0-2 days (≤ 48 hours), 3-5 days

(> 48-120 hours), and 6-7 days (> 120-168 hours) based upon previously identified amounts of CGM use associated with glycemic outcomes.[17,131] Rules for missing data, determined by the study team, consisted of using the average hours of CGM wear for the preceding study visit, if there were missing data for the 3 and 6 month visits. A total of three participants did not have data for the preceding visit so their data from the subsequent visit were used. A similar approach was used for HbA1c data.

Statistical Analysis

Data were analyzed using SAS version 9.2 for Windows (SAS Institute, Cary, North Carolina). Demographic and clinical characteristics are presented as mean ± SD, median, or percentage.

Psychometric analyses: Cronbach's α was used to assess internal consistency or the level to which the items are conceptually similar.[105] Item-to-total correlations for each of the items in the youth and parent instruments were calculated and analyzed to determine the interrelatedness of the items.[112] To evaluate the psychometric properties of the CGM-SE across the sample age range, and given the two different youth instrument versions based upon age, we performed separate analyses by age. We did not assess test-retest reliability because we did not anticipate that self-efficacy would be a stable construct in youth starting CGM. We assessed criterion validity of the CGM-SE for all youth and parent participants at baseline. Pearson correlations of the CGM-SE with the PedsQL (general and diabetes specific) and the DMQ instruments assessed convergent validity and correlations with the PAID-PR/PAID-Peds, STAI/STAIC, and CES-D/CES-DC assessed discriminant validity.

Construct validity was assessed by exploratory factor analysis for the youth instrument (all youth completing items 1-11) and the parent survey (items 1-14) completed at baseline. The

Kaiser-Meyer-Olkin measure of sampling adequacy test was used to evaluate whether the sample was appropriate for factor analysis. The factor analysis for the youth version combined the uniform youth items 1-11 but did not include the additional items on the 13+ version because of the small sample size. The Principal Components Analysis (PCA) method was used to extract the factors. Criteria used to determine the number of factor extracted included the Scree Test and Kaiser's criteria that recommends retaining factors with Eigenvalues > 1.[132] To facilitate factor interpretation, factors were rotated using the Promax oblique rotation method, which assumes the factors are related.[132] The rotated factor pattern matrix was assessed to identify the items that loaded the highest on each of the factors. The research team analyzed the items and factor loadings to label and assign meaning to the factors.

Predictive validity analyses: To assess predictive validity, we included the 61 participants from the control group of the RCT as CGM self-efficacy was expected to change among intervention subjects. We used *t*-tests and chi-square tests to compare baseline participant characteristics between those in the control group (n = 61) and those in the experimental group (n = 59). In analyses (correlations/regressions) of the predictive validity of the CGM-SE, we examined CGM use and HbA1c outcomes 3 and 6 months after randomization.

Paired *t*-tests were used to assess differences between baseline and 3- and 6-month variables such as CGM use and HBA1c outcomes in the control group.

As there is no a priori level of adequate CGM self-efficacy to affect CGM use, we explored the distributions of youth and parent CGM-SE scores according to the 3 recognized categories of CGM use. Specifically, we used ANOVA to assess differences in baseline CGM-SE scores according to 3- and 6-month CGM use considered as a categorical variable (≤ 2 days, 3-5 days, 6+ days). When looking at the self-reported CGM self-efficacy levels at each of the

CGM use categories, there appeared to be a separation by youth reporting a CGM-SE score over 80. Based upon these observations, baseline CGM-SE scores were grouped into 2 categories. We identified a self-efficacy score of 80 as a threshold, and then categorized youth and parent baseline self-efficacy scores in groups of ≤ 80 and > 80. Independent groups (pooled) *t*-tests were used to compare 3- and 6-month CGM use and HbA1c outcomes by CGM-SE category.

Spearman's correlations determined predictive validity of the youth and parent baseline self-efficacy score with HbA1c and CGM use at 3 and 6 months for the 61 control participants. Further correlations assessed the relationship of youth and parent self-efficacy scores with other baseline characteristics and change in self-efficacy from baseline to 6 month to determine whether self-efficacy changes were based on CGM use, which would support enactive attainment or performance accomplishments as a source of self-efficacy.[22]

To confirm the predictive value of youth baseline CGM self-efficacy on both CGM use and HbA1c outcomes at 3 and 6 months, multiple regression was used, controlling for youth age and duration of type 1 diabetes. Additional multiple regression was performed to determine potential predictors of HbA1c at 3 and 6 months based on age, diabetes duration, CGM wear at 3 and 6 months, and youth baseline CGM self-efficacy. A p value of ≤ 0.05 defined significance.

Results

Participant Characteristics

Overall, youth (N = 120) were on average 12.7 ± 2.7 years old, 49% were female, and 89% lived within 2- parent households. Youth had mean diabetes duration of 6.1 ± 3.6 years, checked BG levels on average 6.8 ± 2.4 times daily, and the majority (84%) received insulin pump therapy. Eighty-three percent of participating parents were mothers. The younger group was composed of 68 youth < 13 years old and the older group was composed of 52 youth;

HbA1c was similar in both age groups with mean value of 7.9% ± 0.8% for youth < 13 and 8.0 ± 0.8% for youth ≥ 13. Participant characteristics are presented in Table 1.

Table 1. Baseline participant characteristics

	All Youth (N = 120)	Youth <13 (n = 68)	Youth ≥13 (n = 52)
Age (years)	12.7 ± 2.7 (8.0-17.9)	10.8 ± 1.4 (8.0-12.9)	15.3 ± 1.5 (13.0-17.9)
Gender (% male)	51	49	54
Race/ethnicity (% white)	95	94	96
Gender of participating parent (% female)	83	87	79
Family structure (% 2-parent home)	89	87	92
Highest level of parent education (%)			
High school/GED	11	13	8
Junior/technical college or associate's degree	26	24	29
College degree			
Graduate degree	34 29	34 29	35 29
Average annual household income (%)			
<$30,000	7	11	2
$30,000-$49,000	11	9	14
$50,000-$99,000	30	26	36
$100,000-$149,000	24	29	18
$150,000+	28	26	30
Health insurance (%)			
Private or military	88	88	87
Public	13	12	13
Age at type 1 diabetes diagnosis (years)	6.6 ± 3.6 (0.7-15.8)	5.9 ± 2.8* (0.7-11.5)	7.5 ± 4.3* (0.8-15.8)
Type 1 diabetes duration (years)	6.1 ± 3.6 (1.0-15.9)	4.9 ± 2.6† (1.1-10.1)	7.7 ± 4.0† (1.0-15.9)
Insulin dose (U/kg/day)	0.9 ± 0.3 (0.4-1.9)	0.9 ± 0.3 (0.5-1.9)	0.9 ± 0.2 (0.4-1.6)
Blood glucose monitoring (times/day)	6.8 ± 2.4 (1-12)	7.5 ± 2.1‡ (3-12)	5.9± 2.5‡ (1-12)
Insulin regimen (%)			
Pump	84	85	83
Basal/bolus injections	16	15	17
HbA1c (%)	8.0 ± 0.8 (6.2-11.1)	7.9 ± 0.8 (6.2-11.1)	8.0 ± 0.8 (6.4-10.3)

Data are means ± SD (range) or %; * $p = 0.02$; † $p < 0.0001$; ‡ $p = 0.0002$

CGM-SE Scores

Youth and parents reported relatively high self-efficacy at the baseline assessment following 1 week of CGM wear (Table 2 and Figure 1). Mean baseline CGM-SE scores were 87 ± 10 for youth (ages 8-12: 87 ± 11, ages ≥ 13: 88 ± 9) and 84 ± 10 for parents. In additional analyses, youth scores were combined due to their similar distributions. As parental responses on the CGM-SE were essentially identical when comparing responses of parents of youth < 13 and responses of parents for youth ≥ 13 by distribution, mean, and median, all parent scores are presented together. While there was no statistically significant correlation between youth and parent scores ($r = 0.13$, $p = 0.15$) or between youth and parent scores when youth were stratified by age (ages 8-12: $r = 0.19$, $p = 0.13$; ages ≥ 13: $r = 0.05$, $p = 0.72$), youth and parent scores were each significantly correlated with a number of demographic variables and diabetes management variables. Youth with lower mean glucose levels from meter download reported more confidence in CGM use (all youth: $r = -0.30$, $P = 0.0009$; ages 8-12: $r = -0.27$, $p = 0.03$; ages ≥13 $r = -0.35$, $p = 0.01$) (Table 3). Parents of youth diagnosed at a younger age reported higher CGM self-efficacy ($r = -0.22$, $p = 0.01$) and parents of youth with higher HbA1c levels reported higher CGM self-efficacy ($r = 0.27$, $p = 0.003$) (Table 3). Neither youth or parent self-efficacy scores differed according to family structure or insulin regimen; scores were not related to youth age, duration of diabetes, or frequency of BG monitoring.

Table 2. Baseline CGM-SE total scores for all participants

CGM-SE Score	All Youth (N = 120)	Youth <13 (n = 68)	Youth ≥13 (n = 52)	Parent (N = 119)
Mean ± SD	87 ± 10	87 ± 11	88 ± 9	84 ± 10
Median	90	89	90	85
Range	53-100	53-100	63-100	61-100

Figure 1. Baseline CGM-SE score distribution for all youth and parents

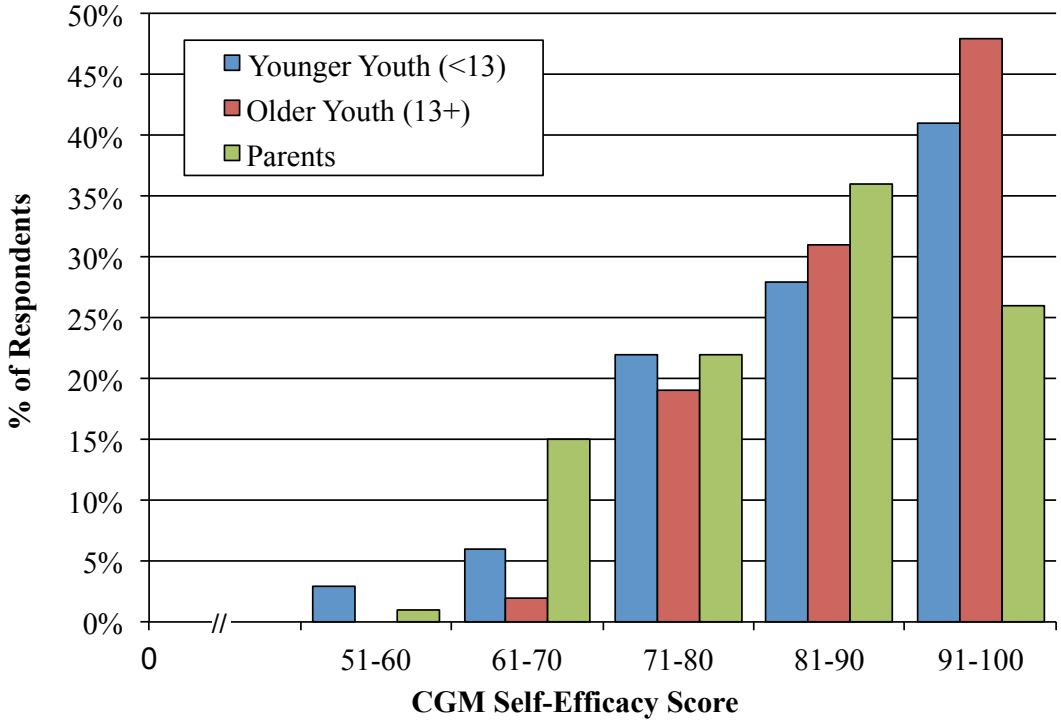


Table 3. Correlations of baseline age, clinical characteristics, quality of life, adherence, problem areas in diabetes, anxiety, and depression with baseline CGM-SE score for all youth

	All Youth	Youth <13	Youth ≥13	Parent
Age	0.14	0.16	0.14	-0.10
Diabetes duration	0.01	0.18	-0.24	0.15
Age at diagnosis	0.09	-0.09	0.27	**-0.22***
HbA1c	-0.07	-0.01	-0.18	**0.27***
Blood glucose monitoring	-0.11	-0.09	-0.11	0.06
Mean blood glucose	**-0.30***	**-0.27***	**-0.35***	0.18
DMQ	0.14	0.20	0.10	**0.19***
PedsQL				
General	0.12	-0.01	**0.32***	0.10
Diabetes	0.10	0.03	0.25	**0.25***
PAID-PR/PAID-Peds	-0.05	-0.02	-0.12	-0.08
STAI/STAIC				
State	-0.09	-0.11	-0.09	-0.12
Trait	-0.08	0.00	-0.22	-0.08
CES-D/CES-DC	-0.12	-0.07	-0.21	0.02

*$p \leq 0.05$

Legend for abbreviations: Diabetes Management Questionnaire (DMQ), Pediatric Quality of Life Inventory (PedsQL) Generic Core Scales and Type 1 Diabetes Module, Problem Areas in Diabetes-Parent Revised (PAID-PR) and Pediatric (PAID-Peds), State-Trait Anxiety Inventory (STAI) and STAI for Children (STAI-C), Center for Epidemiologic Studies Depression Scale (CES-D) and CES-D for Children (CES-DC)

Psychometric Properties of the CGM-SE Survey (Aim 1)

The 11-item version for youth < 13, the 15-item version for youth ≥ 13, and the 14-item parent version demonstrated high internal consistency (Cronbach's α = 0.80, 0.80, and 0.82, respectively). The instruments demonstrated good item-to-total correlations with almost all items falling within the recommended range of 0.20-0.80 for scale development[112] (Table 4). The majority of items were > 0.40 for youth (range 0.28 - 0.61 for youth aged 8-12; range 0.26 - 0.63 for youth ≥ 13; range 0.34 - 0.58 for parents). Items < 0.40 (2 items for youth aged 8-12; 4 items for youth aged ≥ 13; 1 item for parents) were retained due to clinical relevance.

Convergent validity was established for the older youth CGM-SE, as evidenced by statistically significant positive correlations with the PedsQL Generic Core score (r = 0.32, p = 0.02) (Table 3). Similarly, convergent validity was established for the parent CGM-SE given the positive correlations with the PedsQL diabetes specific module (r = 0.25, p = 0.0073) and the adherence measure, the DMQ (r = 0.19, p = 0.037) (Table 3). As these correlations were weak, their clinical relevance requires further evaluation. There were no statistically significant correlations between the youth and parent CGM-SE with the PAID-PR/PAID, STAI/STAIC, or CES-D/CES-DC supporting discriminant validity.

Table 4. Internal consistency for CGM-SE: Item-to-total correlations and Cronbach's α

Items "I am sure I can…"	Youth <13	Youth ≥13	Parents
Insert sensor	0.28	0.28	0.34
Calibrate sensor	0.58	0.62	0.51
Keep the receiver	0.32	0.41	0.58
Look at the receiver	0.48	0.59	0.53
Respond to CGM alarms	0.42	0.48	0.50
Charge the CGM receiver	0.61	0.54	0.51
Ask for help with CGM	0.49	0.55	-
Wear/work with child to wear CGM at least 6 days a week	0.61	0.26	0.45
Talk to my parents if having a hard time using CGM	0.43	0.38	-
Respond to CGM alarms at school	0.55	0.55	-
Respond to CGM alarms when with friends	0.51	0.63	-
Download CGM data	-	0.17	0.53
Problem-solve technical difficulties with device	-	0.60	0.53
Adjust insulin dose based on real-time data	-	0.55	0.52
Adjust insulin dose based on downloaded CGM data	-	0.46	0.52
Speak with medical team if needing help with CGM	-	-	0.50
Share CGM responsibilities with child	-	-	0.42
Be encouraging and supportive working with child on CGM	-	-	0.41
Cronbach's α	0.80	0.80	0.82

Items are shortened for ease of presentation

CGM-SE Factor Analysis

The Kaiser-Meyer-Olkin test (KMO), an overall measure of sampling adequacy, had a value of 0.77 for youth and 0.82 for parents, which indicated the sample sizes were sufficient and the data acceptable for factor analysis on the baseline 11-item youth and 14-item parent CGM-SE instruments.[132] Factors were extracted using the PCA method. Promax (oblique) rotation was used because the items forming the factors were theoretically related and measured elements of CGM self-efficacy.[132] Additionally, oblique rotations are commonly used in research that

evaluates human behaviors.[132] Factor analysis resulted in two factors for the youth version and two factors for the parent version with factor loadings > 0.40, except for item five on the youth version (see below) (Table 5 and 6). The items that loaded highest on factor 1 and factor 2 for each version embodied common themes, thus providing the basis for meaningful factor interpretation.[132]

Table 5. Rotated factor loadings of the youth CGM-SE

Items	Factor 1	Factor 2
Insert sensor	0.06	**0.42**
Calibrate sensor	**0.51**	0.33
Keep the receiver	**0.80**	-0.29
Look at the receiver	**0.71**	0.03
Respond to CGM alarms	**0.35**	0.35
Charge the receiver	0.22	**0.67**
Ask for help with CGM	-0.14	**0.90**
Wear CGM at least 6 days a week	**0.62**	0.21
Talk to my parents if having a hard time using CGM	-0.05	**0.73**
Respond to CGM alarms at school	**0.63**	0.17
Respond to CGM alarms when with friends	**0.74**	0.04

Conducted exploratory factor analysis using PCA as extraction method (SAS default). Rotation method: Promax. Items are shortened for ease of presentation; related factor loadings are in bold.

Table 6. Rotated factor loadings of the parent CGM-SE

Items	Factor 1	Factor 2
Insert sensor	0.02	**0.52**
Work with child to calibrate sensor	**0.47**	0.30
Work with child to keep the receiver	**0.76**	0.11
Work with child to look at the receiver	**0.78**	0.03
Work with child to respond to CGM alarms	**0.83**	-0.04
Ensure CGM receiver stays charged	**0.49**	0.28
Speak with medical team if needing help with CGM	**0.76**	-0.00
Download CGM data	0.04	**0.74**
Problem-solve technical difficulties with device	0.27	**0.53**
Adjust insulin dose based on real-time data	-0.00	**0.77**
Adjust insulin dose based on downloaded CGM data	-0.12	**0.87**
Share CGM responsibilities with child	**0.46**	0.19
Work with child to wear CGM every day	**0.87**	-0.15
Be encouraging and supportive working with child on CGM	**0.77**	-0.12

Conducted exploratory factor analysis using PCA as extraction method (SAS default). Rotation method: Promax. Items are shortened for ease of presentation; related factor loadings are in bold.

We labeled factor 1 (seven items) for the youth version "away" because the items that loaded highest on this factor represented CGM tasks the youth would likely perform away from the home environment. We labeled factor 2 (four items) for the youth version "home" because these items describe tasks or behavioral aspects related to CGM wear that the youth would likely do within the home environment. Item five ("Respond to the CGM receiver alarms") on the youth instrument had a factor loading of 0.35 on both factor 1 and factor 2. We retained item five on the youth factor 1 because of its consistency with other items on factor 1. There was good internal consistency for the youth factor 1 (Cronbach's $\alpha = 0.81$). The internal consistency was not as high for youth factor 2 (Cronbach's $\alpha = 0.62$) in relation to the low item to total correlation of item one ("Insert the CGM sensor"); however, we retained this item for its clinical relevance. The two youth factors ($r = 0.51$, $p < 0.0001$) were correlated.

We labeled factor 1 (nine items) for the parent version "relational" because these items represent working with the youth for CGM wear and factor 2 (five items) "technical" because these items represent technical aspects related to performing CGM tasks. There was good internal consistency within the two factors for the parent version (factor 1 Cronbach's $\alpha = 0.86$; factor 2 Cronbach's $\alpha = 0.76$). The two parent factors ($r = 0.37$, $p < 0.0001$) were correlated.

Predictive Validity of the CGM-SE (Aim 2)

Participant Characteristics

Control group participants (48% female) included in the predictive validity analyses consisted of 61 youth with type 1 diabetes. Their mean age was 12.7 ± 2.9 years old; they had a mean diabetes duration of 6.3 ± 3.8 years, mean daily insulin dose was 0.88 ± 0.3 units/kg/day, and mean BG monitoring frequency of 7.0 ± 2.6 times daily. The majority (80%) received pump therapy (Table 7). Characteristics of these control group participants were similar to the intervention participants.

Table 7. Participant characteristics for youth in the control group

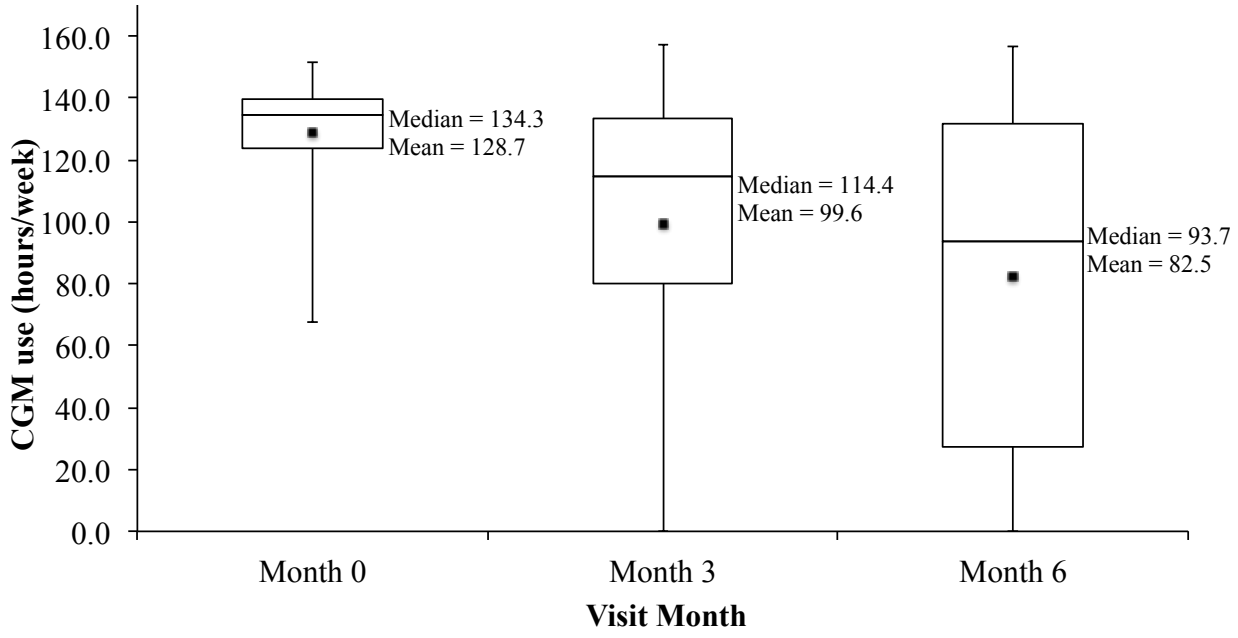
	Control Group Youth (n = 61)
Age (years)	12.7 ± 2.9 (8.0-17.9)
Gender (% male)	52
Race/ethnicity (% white)	93
Gender of participating parent (% female)	87
Family structure (% 2-parent home)	87
Highest level of parent education (%)	
High school/GED	10
Junior/technical college or associate's degree	21
College degree	38
Graduate degree	31
Average annual household income (%)	
<$30,000	5
$30,000-$49,000	13
$50,000-$99,000	28
$100,000-$149,000	25
$150,000+	28
Health insurance (%)	
Private or military	84
Public	16
Age at type 1 diabetes diagnosis (years)	6.3 ± 3.5 (0.7-15.8)
Type 1 diabetes duration (years)	6.3 ± 3.8 (1.2-15.9)
Insulin dose (U/kg/day)	0.9 ± 0.3 (0.5-1.9)
Blood glucose monitoring (times/day)	7.0 ± 2.6 (1-12)
Insulin regimen (%)	
Pump	80
Basal/bolus	20
HbA1c (%)	
Baseline	7.9 ± 0.9 (6.2-11.1)
3 month	7.7 ± 0.8 (6.1-10.1)
6 month	7.8 ± 0.8 (6.0-10.6)

Data reported as means ± SD (range) or %

CGM Use

Randomization required demonstration of CGM wear during the 1-week run-in period. During the run-in week, the mean CGM use for the 61 controls was 128.7 ± 18.9 hours/week (range 67.6-151.6); after 3 months mean CGM use was 99.6 ± 49.0 hours/week (range 0-157.3); and after 6 months mean CGM use 82.5 ± 55.6 hours/week (range 0-156.8) (Figure 2). CGM use data were unavailable for only one participant due to multiple missed visits. Not unexpectedly, the mean hours of CGM use decreased over time with a statistically significant difference in baseline to 3 month CGM wear ($p < 0.0001$), 3 month to 6 month CGM wear ($p = 0.0013$), and baseline to 6 month ($p < 0.0001$).

Figure 2. CGM use (hours/week) for baseline, 3 month, and 6 month visits for control group participants. The top and bottom of the boxes denotes the 25th and 75th percentiles, the line represents the median, and the dot represents the mean.



Glycemic control

At baseline, mean HbA1c for the 61 controls was 7.9 ± 0.9% (range 6.2-11.1), after 3 months the mean HbA1c was 7.7 ± 0.8% (range 6.1-10.1), and after 6 months the mean HbA1c

was 7.8 ± 0.8% (range 6.0-10.6) (Table 7). There was only one missing HbA1c value at 3 months due to missed visits. There was a statistically significant difference between baseline versus 3 and 6 month HbA1c ($p = 0.03$ and $p = 0.01$, respectively); no statistically significant difference was observed between the 3 month and 6 month HbA1c values.

CGM Self-Efficacy

At baseline, the mean CGM-SE score for the 61 youth in the control group was 87 ± 11 compared to 86 ± 12 for the 6-month visit (Table 8 and Figure 3). There was no statistically significant difference observed between the youth baseline and 6 month CGM-SE scores ($p = 0.49$). Sixty-one youth in the control group completed the CGM-SE at baseline, and 58 youth completed the instrument at the 6-month visit. Youth without 6-month CGM-SE data either missed the 6-month visit or were not wearing the CGM and therefore did not complete the CGM-SE.

Table 8. CGM-SE score for control group at baseline and 6 months

CGM-SE	Control Youth	Control Parents
Baseline n	61	60
Mean ± SD	87 ± 11	84 ± 10
Median (Range)	91 (53-100)	85 (62-100)
Score ≤ 80 (% participants)	26	36
Score > 80 (% participants)	74	64
6 month n	58	49
Mean ± SD	86 ± 12	83 ± 15
Median (Range)	88 (50-100)	83 (20-100)

Data reported as means ± SD, median (range), or %

For parents, the baseline mean CGM-SE score was 84 ± 10 (62-100) compared to 83 ± 15 for the 6 months score (Table 8 and Figure 4). There was no statistically significant difference observed between the parent baseline and 6 month CGM-SE scores ($p = 0.96$). At baseline, 60 parents of the control youth completed the CGM-SE and at the 6-month visit, 49 parents completed the instrument. Parents with missing 6-month CGM self-efficacy data either had

youth who stopped wearing CGM and did not complete the instrument, or a patient visit was missed, or the parent who completed the CGM-SE at baseline was not the same parent who completed the instrument at 6 months. There was a statistically significant difference in youth CGM-SE scores according to CGM use at 3 and 6 months divided into 3 categories. Youth who wore CGM 0-≤48 hours/week at the 3 month visit had statistically significantly lower baseline CGM self-efficacy compared to youth who wore CGM >48-120 hours/week or >120 hours/week (80 ± 3 versus 88 ± 2 for both comparisons; $p = 0.04$ and $p < 0.05$, respectively) (Figure 5). Similarly, youth who wore CGM 0-≤48 hours/week at the 6 month visit had significantly lower baseline CGM self-efficacy (82 ± 2) compared to youth who wore CGM >48-120 hours/week (90 ± 2) ($p = 0.03$) or >120 hours/week 88 ± 2 ($p = 0.08$), which indicated a trend towards significance (Figure 6). Interestingly, parent baseline CGM-SE scores did not differ according to youth CGM use at either 3 or 6 months.

Figure 3. CGM-SE score distribution for control group youth at baseline and 6 months

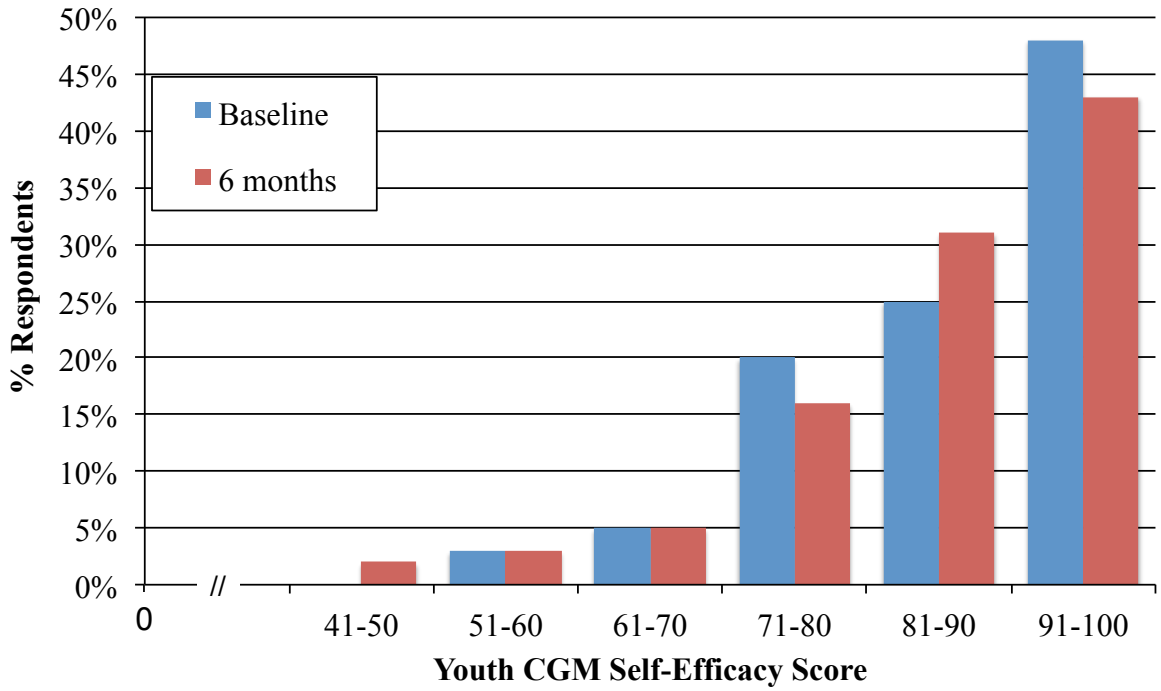


Figure 4. CGM-SE score distribution for control group parents at baseline and 6 months

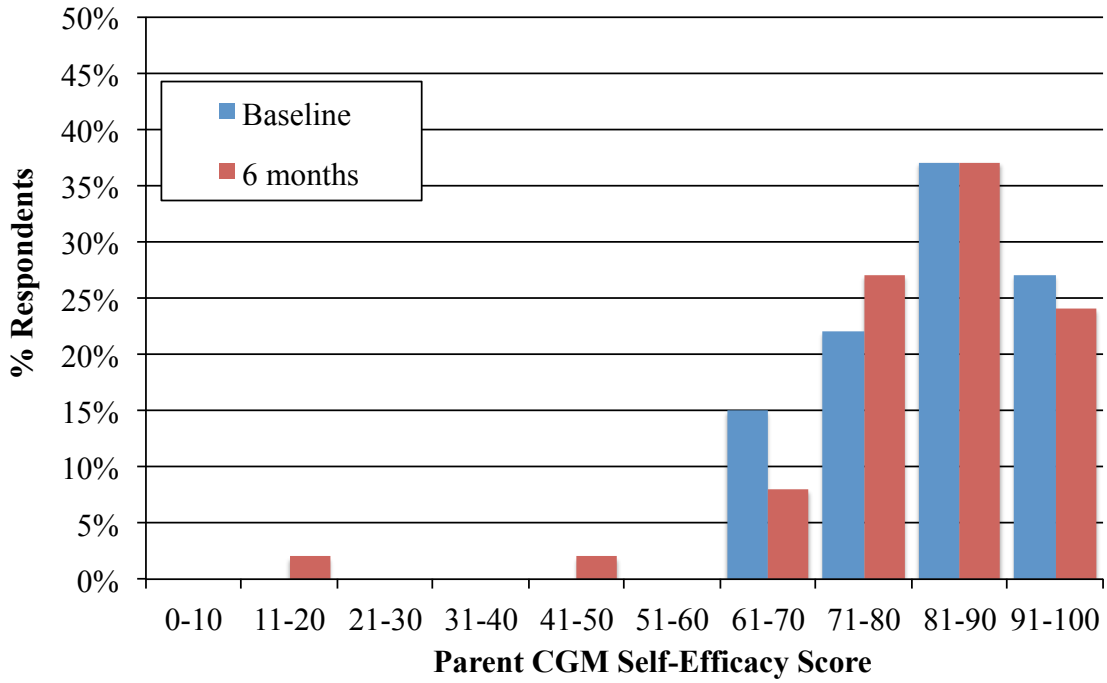


Figure 5. Baseline CGM-SE score (mean ± standard error) for youth and parents according to 3-month CGM use categories for control group participants. *$p \leq 0.05$

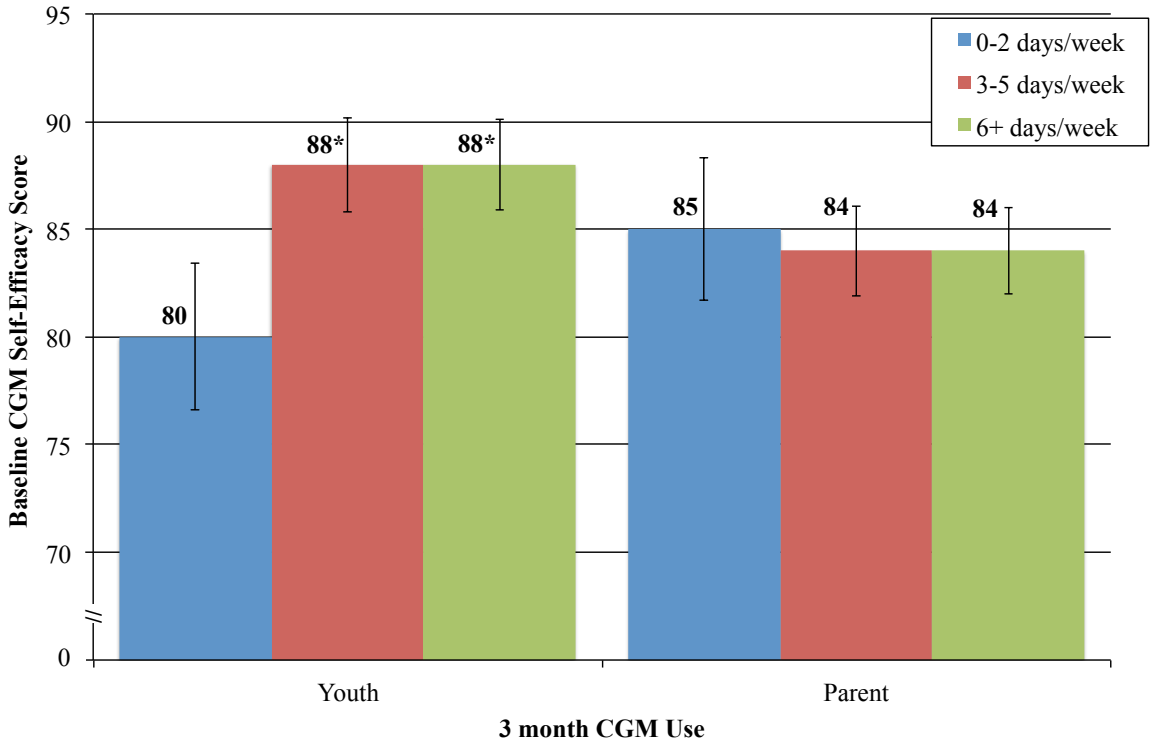
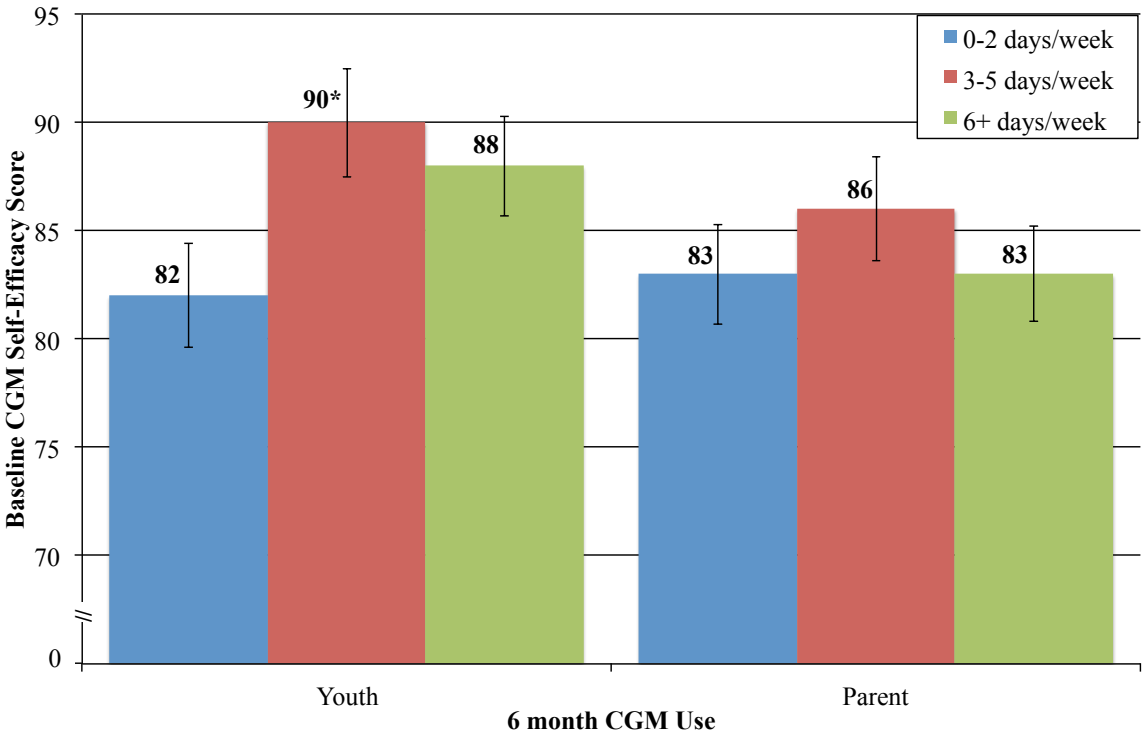


Figure 6. Baseline CGM-SE score (mean ± standard error) for youth and parents according to 6 month CGM use categories for control group participants. *$p \leq 0.05$



Spearman correlations showed a significant positive relationship between youth baseline and youth 6-month CGM-SE scores ($r = 0.52$, $p < 0.0001$), but this correlation was not statistically significant for parents (Table 9). Although youth and parent CGM-SE scores did not correlate for the control participants at baseline ($r = 0.20$, $p = 0.13$), a correlation was observed for the 6-month youth and parent scores ($r = 0.36$, $p = 0.01$). The higher parent baseline CGM-SE score was correlated to higher baseline HbA1c ($r = 0.32$, $p = 0.014$), likely reflecting parental hopefulness for improvement. Additionally, the 6-month parent CGM-SE score correlated positively with CGM use at 3 months ($r = 0.40$, $p = 0.005$) and 6 months ($r = 0.38$, $p = 0.008$), which implies that parents are more confident if they know their child is wearing the device. There was also a significant positive correlation between the change in CGM-SE score for parents and CGM use at 3 months ($r = 0.42$, $p = 0.003$) and 6 months ($r = 0.39$, $p = 0.007$),

which may support performance accomplishments or perceived mastery of a task as an instrumental source of self-efficacy.[22] Surprisingly, these correlations were not significant for the change in youth CGM-SE score. *T*-tests did not reveal a statistically significant difference in baseline youth or parent self-efficacy scores for control participants from a 2-parent versus single parent home or those on insulin pump therapy versus multiple daily injections.

Table 9. Correlations with control group youth and parent CGM-SE scores at baseline, 3 months, and 6 months.

	CGM-SE Score for Control Group Participants			
	Youth Baseline	Youth 6 months	Parent Baseline	Parent 6 months
Age	0.20	0.12	-0.12	-0.13
Diabetes duration	0.10	-0.23	0.03	-0.11
HbA1c				
Baseline	0.02	0.05	0.32*	0.08
3 months	-0.22	0.01	0.10	-0.06
6 months	-0.10	0.11	0.07	0.06
CGM Use				
Baseline	0.07	0.16	0.09	0.03
3 months	0.01	0.08	-0.06	0.40*
6 months	0.10	0.08	-0.03	0.38*
CGM-SE Score Control Youth				
Baseline	-	0.52†	0.20	0.03
6 months	0.52†	-	0.13	0.36*
CGM-SE Score Control Parents				
Baseline	0.20	0.13	-	0.20
6 months	0.03	0.36*	0.20	-

*$p \leq 0.05$; †$p < 0.0001$

To assess the predictive validity of the CGM-SE instruments, we examined CGM use and HbA1c after 3 and 6 months according to baseline CGM-SE scores. Youth who reported CGM-SE scores > 80 used CGM statistically significantly more often at 3 and 6 months compared to youth with scores ≤ 80; 3 month CGM use: 110.1 ± 41.1 versus 70.8 ± 58.2 hours/week, respectively, ($p = 0.005$) and 6-month CGM use: 94.4 ± 50.7 hours/week versus 48.8 ± 56.7 hours/week, respectively, ($p = 0.004$). Additionally, youth reporting higher baseline CGM self-

efficacy had significantly lower HbA1c after 3 and 6 months compared with youth reporting lower CGM self-efficacy (3 month HbA1c: 7.5 ± 0.7% versus 8.3 ± 0.9%, $p = 0.0004$; 6 month HbA1c: 7.6 ± 0.7% versus 8.2 ± 0.9%, $p = 0.02$, respectively). These results indicate that youth who reported higher baseline CGM self-efficacy had greater CGM use at 3 and 6 months, as well as lower HbA1c at 3 and 6 months compared to youth with lower baseline CGM self-efficacy. Parent reported CGM self-efficacy did not predict youth CGM use or youth HbA1c at 3 or 6 months.

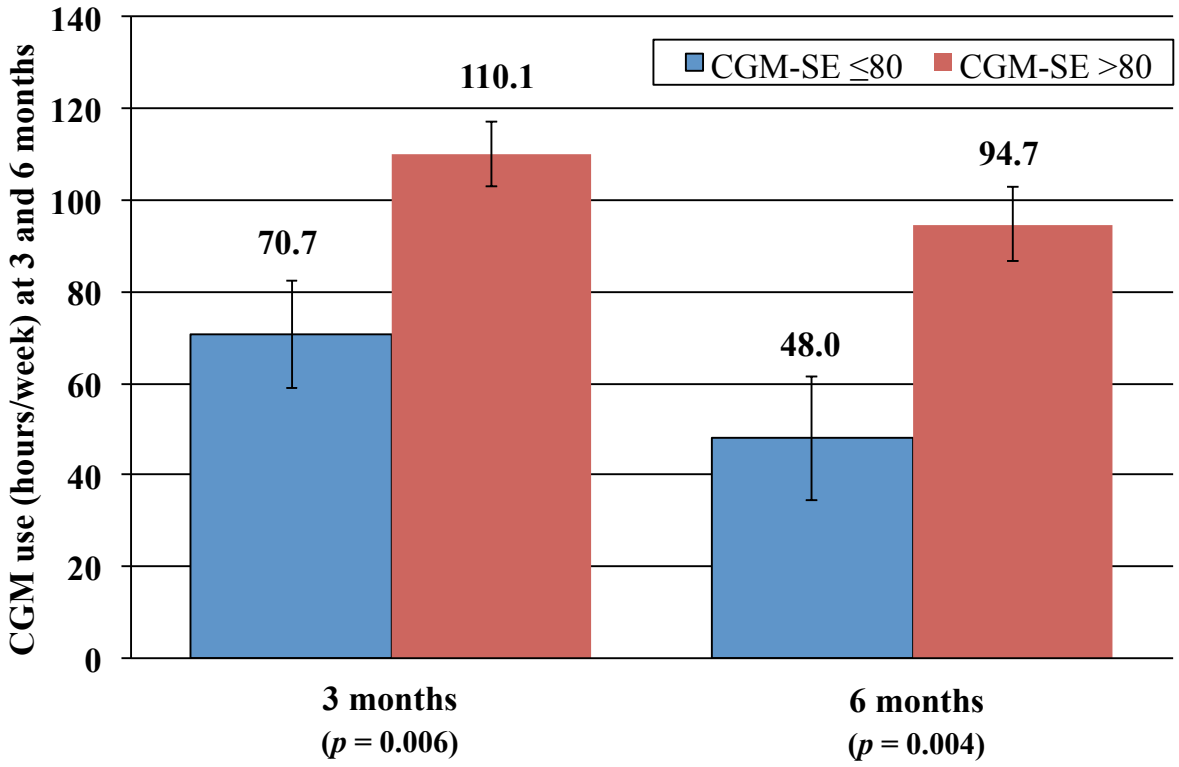
In a multivariate regression model ($R^2 = 0.13$, $p < 0.05$) controlling for youth age and diabetes duration, youth CGM-SE score ($p = 0.006$) significantly predicted 3-month CGM use (Figure 7 and Table 10). Youth reporting CGM-SE scores > 80 used CGM 110.1 hours/week compared with 70.7 hours/week after 3 months for youth reporting CGM-SE scores ≤ 80 at baseline. The second multivariate model ($R^2 = 0.14$, $p < 0.05$) also demonstrated that youth baseline CGM-SE score ($p = 0.004$) significantly predicted 6-month CGM use (Figure 7 and Table 10). Youth reporting CGM-SE scores > 80 used CGM 94.7 hours/week compared with 48.0 hours/week after 6 months for youth reporting CGM-SE scores ≤ 80 at baseline.

Table 10. Multivariate regression models

DV	R^2	Model *p*	Predictor	β	SE	t	*p*
CGM use	0.13	<0.05					
3 months			Age[£]	0.01	2.42	0.00	0.997
			Diabetes Duration[£]	-0.90	1.83	-0.49	0.62
			Baseline Youth CGM-SE[¥]	39.39	13.92	-2.83	0.006
CGM use	0.14	<0.05					
6 months			Age[£]	-1.04	2.73	-0.38	0.70
			Diabetes Duration[£]	0.80	2.07	0.39	0.70
			Baseline Youth CGM-SE[¥]	46.72	15.75	-2.97	0.004
HbA1c	0.22	0.003					
3 months			Age[£]	-0.05	0.04	-1.39	0.17
			Diabetes Duration[£]	0.02	0.03	0.69	0.49
			Baseline Youth CGM-SE[¥]	-0.78	0.23	3.42	0.001
HbA1c	0.11	0.08					
6 months			Age[£]	-0.05	0.04	-1.16	0.25
			Diabetes Duration[£]	0.03	0.03	1.08	0.28
			Baseline Youth CGM-SE[¥]	-0.48	0.24	2.06	0.04

[£]Continuous variables
[¥]Categorical variable due to findings in the bivariate analysis: CGM-SE >80 vs. ≤80

Figure 7. 3- and 6-month CGM use (hours/week) (mean ± standard error) according to level of baseline youth CGM self-efficacy for control group participants. Blue bars = youth CGM-SE score ≤ 80. Red bars = youth CGM-SE score > 80. In multivariate models, baseline youth CGM-SE score significantly predicted CGM use (hours/week) at 3 months (model: $R^2 = 0.13$, $p < 0.05$) and at 6 months (model: $R^2 = 0.14$, $p < 0.05$).

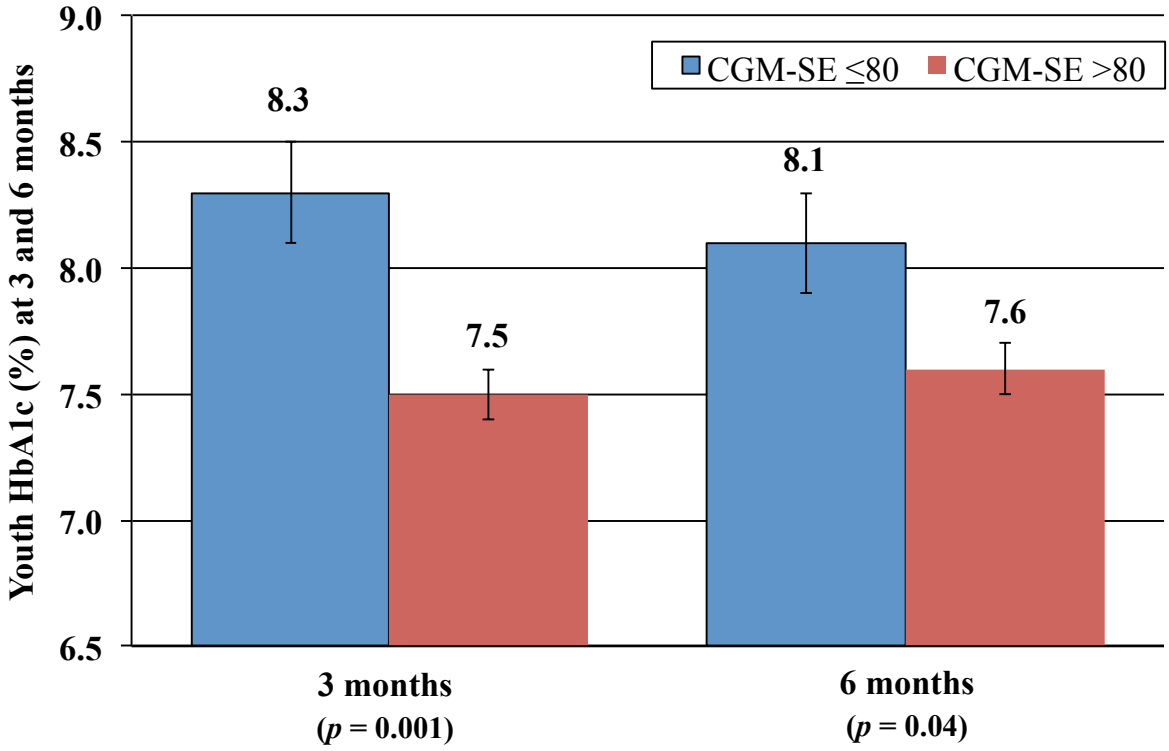


Similarly, in a third multivariate model ($R^2 = 0.22$, $p = 0.003$) controlling for youth age and diabetes duration, youth baseline CGM-SE score ($p = 0.001$) also significantly predicted 3 month HbA1c (Figure 8 and Table 10). Youth reporting CGM-SE scores > 80 had 3 month HbA1c values of 7.5% compared with 8.3% for those reporting lower CGM-SE at baseline. A fourth multivariate model controlling for youth age and diabetes duration ($R^2 = 0.11$, $p = 0.08$) demonstrated a trend towards significance with youth baseline CGM-SE score ($p = 0.04$) predicting 6 month HbA1c. Youth reporting CGM-SE scores > 80 had 6 month HbA1c value of 7.6% compared with 8.1% for those reporting lower CGM-SE at baseline (Figure 8 and Table 10). Lastly, in a multivariate model controlling for age, diabetes duration, baseline CGM-SE

score, and CGM use, youth baseline CGM-SE score ($p = 0.003$) significantly predicted 3 month HbA1c ($R^2 = 0.23$, $p = 0.0125$), but youth baseline CGM-SE score ($p = 0.16$) did not significantly predict 6 month HbA1c ($R^2 = 0.16$, $p = 0.08$) with CGM use in the model.

These results indicate that youth who reported higher baseline CGM self-efficacy (score > 80) had greater CGM use and lower HbA1c at 3 and 6 months compared to youth with lower baseline CGM self-efficacy (score ≤ 80) supporting predictive validity.

Figure 8. 3- and 6-month HbA1c (mean ± standard error) according to level of baseline youth CGM self-efficacy for control group participants. Blue bars = youth CGM-SE score ≤ 80. Red bars = youth CGM-SE score > 80. In multivariate models, baseline youth CGM-SE score significantly predicted HbA1c at 3 months (model: $R^2 = 0.22$, $p = 0.003$) and with a trend towards significance at 6 months (model: $R^2 = 0.11$, $p = 0.08$).



Conclusions

CGM technologies remain an underutilized approach to improving glycemic control in children and adolescents with type 1 diabetes.[133,134] Although youth may initiate CGM, many children and adolescents discontinue use due to the additional burdens associated with current

CGM devices,[135-138] where ongoing BG monitoring is required for CGM calibration and as well as for confirmation of glucose levels prior to initiating treatments for either high or low glucose readings. Nonetheless, CGM technologies offer opportunities to improve glycemic control while avoiding severe hypoglycemia.[17,139,140] Therefore, there remains a need to identify approaches to increase uptake and durability of CGM use, especially in the pediatric population. The current study identified the opportunity to utilize perceived self-efficacy related to CGM use in both children and adolescents with type 1 diabetes. The CGM-SE surveys demonstrated adequate psychometric properties for both the youth and parents versions while only the youth versions, for those ages 8-12 as well as for those 13 and older, had significant predictive value for CGM use 3 and 6 months after initiation.

Specifically, the psychometric evaluation provided support for the reliability and validity of the CGM-SE. The instruments had good item-to-total correlations, which supported interrelatedness of the items.[112] The CGM-SE also demonstrated high internal consistency for youth and parents, which established equivalence reliability or that all items in the instrument reliably measured the concept of interest.[105] Factor analysis performed for the 11-item youth and 14-item parent versions yielded two unique factors for each of the instruments respectively. The CGM-SE was developed to measure self-efficacy related to behavioral and technical aspects of CGM wear. The two factors identified for the parent version, which consisted of factor 1 “relational” and factor 2 “technical”, reflect the intent of the instrument from a theoretical and conceptual perspective.[132] While the items of the youth version also assessed behavioral and technical aspects of self-efficacy related to CGM wear, the factor analysis and inductive process of labeling the factors resulted in a factor identified as “away” and a factor identified as “home”,

providing a context for the environment of the behavioral and technical aspects of CGM wear for the youth.

While baseline youth CGM-SE scores were not related to age, diabetes duration, HbA1c, or BG monitoring frequency, there was a statistically significant inverse relationship between self-efficacy scores and mean blood glucose levels, suggesting that youth with lower blood glucose levels seem to have greater confidence in their use of CGM. Although the literature has reported that greater general diabetes self-efficacy is associated with diabetes management adherence and BG monitoring, [27,28,30,83] we found no relationships between youth-reported self-efficacy and the diabetes adherence questionnaire, depression, or anxiety instruments. However, there was a statistically significant positive association between self-efficacy reported by teens and general quality of life, inferring a possible relationship between self-confidence in diabetes management and quality of life for teens with type 1 diabetes.

Parent CGM-SE scores had a significant positive relationship to youth HbA1c and an inverse relationship to youth age at diagnosis. These findings suggest that parents of youth with higher HbA1c levels report greater confidence in their child's use of CGM, possibly reflecting parental hopefulness for improvements in their child's glycemic control with new advances such as CGM. Not surprisingly, parent CGM-SE scores were also significantly related to parent reported diabetes management adherence and the parent proxy report of their child's diabetes specific quality of life.

In assessment of the predictive validity of the CGM-SE, only the youth-reported CGM-SE scores were significantly related to future CGM use and glycemic control. Youth who reported higher baseline CGM-SE score (> 80) had statistically significantly greater CGM use at 3 and 6 months compared to those youth with lower scores. Similarly, youth with higher baseline

CGM-SE scores (> 80) had lower HbA1c at 3 and 6 months compared to those youth with lower scores. Multiple regression analyses also revealed that youth baseline CGM-SE score was a statistically significant predictor of 3 and 6 month CGM use with a higher self-efficacy score predicting greater CGM use. Similarly, higher youth baseline CGM self-efficacy significantly predicted 3 month HbA1c with a trend towards significance at 6 months with a higher score predicting a lower HbA1c. The parent CGM-SE survey did not demonstrate the same predictive validity for pediatric CGM use, likely because the parent version assesses the parent's confidence in helping their child use CGM as well as their confidence in their child's ability to use CGM.

Overall, youth and parents reported high levels of self-efficacy related to CGM with youth and parent scores correlating for the control group analysis at 6 months. Surprisingly, youth with a lower HbA1c, from a 2-parent home, and using insulin pump therapy did not report higher self-efficacy related to CGM use despite the potential for a higher level of support at home, as well as increased attention for living with and managing the disease.

Importantly, this study revealed that youth CGM self-efficacy does predict CGM wear and improvement in glycemic control over a 6 month time period. This finding coincides with Bandura's theoretical model that self-efficacy is an important determinant of behavior, and greater self-efficacy translates to effort expended by an individual over a duration of time in the face of challenging circumstances.[22] This finding is pertinent given the known challenges that youth with type 1 diabetes face in wearing CGM technologies and achieving target glycemic control. Assessing self-efficacy at the onset of CGM use may be important for the multidisciplinary diabetes team to consider. In particular, youth who report low-self-efficacy at the start of CGM, with CGM-SE scores ≤ 80, likely warrant greater education and support for

CGM implementation for these youth to succeed with durable CGM use over time. Identifying ways to decrease the burden of new technologies like CGM and the artificial pancreas may enhance patients' self-confidence in their use. As the current artificial pancreas systems require substantial patient input,[141] their use will likely also benefit from an understanding of self-efficacy.

There are caveats to these analyses. Only the control group from the larger 2-year RCT was evaluated in this study to determine predictive validity of CGM-SE at baseline. It is not known how a behavioral intervention to support CGM use may influence the construct of CGM self-efficacy over time, the aim of the larger ongoing RCT. The factor analysis performed for the youth instrument combined the uniform youth items 1-11 and did not include the additional items on the 13+ version because of the small sample size. Future psychometric analysis should evaluate the instruments in larger samples. Furthermore, the study included a relatively small sample size of homogeneous young patients with type 1 diabetes. Additionally, all patients received intensive insulin therapy, and the overwhelming majority received pump therapy. Future assessments of the CGM-SE instruments can include more diverse populations. As the larger study of this evaluation was aimed at implementing CGM in a pediatric sample, it is not surprising that the patients had to demonstrate acceptance and use of intensive insulin therapy prior to starting CGM. Nonetheless, although the patients were all intensively treated and desired to start CGM by virtue of their agreement to enter the 2-year RCT, a number of patients in the control group had already reduced their use of CGM after only 6 months of implementing the device. Additionally, only data through the 6-month time point were available for this study. Additional follow-up will be needed to determine how CGM self-efficacy affects longer-term CGM use. Future research will be needed to assess changes in self-efficacy over time, in addition

to determining if and how behavioral interventions to overcome barriers to CGM use affect CGM self-efficacy. Evaluation of the performance of the parent CGM-SE survey only included youth aged 8-17; assessment in parents of patients under 8 years old is also needed, especially given the challenge associated with CGM use in this pediatric population.[142,143] Further work could also evaluate whether a change in device (e.g. a transition from the Dexcom SEVEN Plus to the Dexcom G4) affects self-efficacy and CGM outcomes.

Finally, future work should include dyadic analyses to take into account the different viewpoints from the youth and the parent related to the various study measures (i.e. QOL, DMQ) that assess different aspects of diabetes management and psychosocial constructs, including self-efficacy. Further research also could evaluate how self-efficacy may relate to outcome expectations pertaining to CGM use in youth with type 1 diabetes. Since both self-efficacy and outcome expectations are integral components of the behavior change process, identifying whether a relationship exists between these two constructs and CGM use would be pertinent.

In summary, the CGM-SE instruments for youth and parents demonstrate adequate psychometric properties for assessing confidence in using CGM. In addition, the youth CGM-SE instruments demonstrated significant predictive validity for future CGM use and glycemic control but the parent CGM-SE did not. Indeed, durable pediatric CGM use remains dependent on the child rather than on the parent. Thus, the youth CGM-SE instruments provide a method of assessing youth CGM self-efficacy in both research and clinical settings as efforts continue to address ways to increase uptake and to sustain use of CGM in pediatric populations with type 1 diabetes. Additional assessment of the parent CGM-SE instrument appears warranted.

Portions of Chapter 4 have been submitted as a manuscript by Lisa E. Rasbach, MSN, Lisa K. Volkening, MA, Jessica T. Markowitz, PhD, Deborah A. Butler, MSW, Michelle L. Katz, MD, MPH, and Lori M.B. Laffel, MD, MPH. The manuscript is under review by the journal *Diabetes Technology and Therapeutics*.

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Chapter 5: Summary and Conclusions

Synthesis

The three manuscripts of this dissertation evaluate CGM use and the role of self-efficacy in the pediatric population with type 1 diabetes. The literature has demonstrated the challenges of RT-CGM use in youth with type 1 diabetes, as well as the potential benefits of glycemic control. Given the documented difficulties of consistent CGM use in youth, it is important to explore barriers and facilitators of this technology. The work of this dissertation focuses on attributes of the youth experience with type 1 diabetes in the current era of diabetes technologies.

Masked CGM provides an alternative to RT-CGM, with the potential for improvement in glycemic control. While patients and providers eagerly await the reality of the AP as the future of advanced diabetes therapies, it is important to provide patients with therapy options that can help them transition to sensor technology. Masked CGM may provide such a transition with potential benefits, as described in manuscript one (Chapter 2) of this dissertation. Moreover, this research highlights the importance of the multidisciplinary diabetes team, in particular, the role of the nurse educator in equipping youth with knowledge to wear the device and recommendations to improve self-management following sensor wear.

Self-efficacy is also fundamental to health behavior change and an important component of self-management in patients with chronic diseases.[24] A youth's confidence or perceived ability to carry out diabetes tasks, especially in difficult situations, is significant for the diabetes team to recognize and foster. The second manuscript (Chapter 3) of this dissertation is an integrative review of instruments to measure self-efficacy in youth with T1D and their caregivers. Chapter 3 identified that self-efficacy is a meaningful construct to measure in relation to key behaviors in general diabetes self-management. Self-efficacy, as it relates to the use of CGM, is particularly

relevant in the current era of diabetes technologies, given the challenges youth have with consistent CGM wear. Despite the importance of self-efficacy, few instruments are available to measure this construct within the domain of CGM therapy. The third manuscript (Chapter 4) of this dissertation addresses this gap by exploring the psychometric properties of a novel CGM self-efficacy instrument. This study reports the results of a psychometric evaluation of a CGM self-efficacy instrument, which may prove useful for both clinicians and research teams focused on measuring self-efficacy in the contemporary era of diabetes technologies. This study revealed that self-efficacy related to CGM use in youth and parents may provide an important indicator of CGM success. The results demonstrated that self-efficacy related to CGM at baseline predicted CGM use and glycemic control at 3 and 6 months in a cohort of youth with type 1 diabetes who were initiating CGM therapy. Similar to the results in manuscript two (Chapter 3), this final manuscript identified that, in youth and families, self-efficacy may bolster self-management related to diabetes technologies and subsequent successful CGM adherence.

Limitations

There are caveats to each of the studies reported in this dissertation. For the first manuscript, youth wore the masked CGM at only one time point with an evaluation of the proximal HbA1c pre masked CGM wear and 2-3 months post masked CGM to determine the effect of masked CGM on glycemic control. Also, although treatment recommendations involving advanced blousing and attending to active insulin resulted in significantly higher odds of improvement in HbA1c, the study did not investigate the longitudinal effect of masked CGM use on glycemic outcomes over time. Further research also could explore whether adherence to those treatment recommendations relates to HbA1c improvement, since adherence was not assessed in this observational descriptive study. Additionally, in this study, participants received

the review of the sensor data and treatment recommendations either over the phone or in clinic. This difference in mode of data review is another limitation because the study did not control for this difference.

The second manuscript, an integrative review of self-efficacy instruments in youth with type 1 diabetes, also had limitations. While this study consisted of a thorough review of the extant literature from the past decade (2003-2013), the study may not have identified relevant self-efficacy instruments discussed in publications before 2003. Furthermore, not all identified self-efficacy instruments were publically available; thus, not all survey items could be assessed. This caveat is relevant because the study concluded that more instruments are necessary to measure self-efficacy related to advancements in diabetes technologies.

Lastly, the final study, which evaluated a novel instrument to measure CGM self-efficacy in a contemporary cohort of youth, only included participant data from baseline through the 6-month time point in a relatively small sample of homogeneous youth with T1D. The larger 2-year RCT will provide further results pertaining to outcomes over a longer duration of time.

Next Steps

This dissertation provides preliminary data towards the overall long-term research goal of optimizing self-efficacy in youth with type 1 diabetes in the current era of diabetes-related technological advances. Adherence to diabetes self-care tasks, particularly as they pertain to CGM technology, is challenging for the pediatric population with type 1 diabetes. Identifying elements such as self-efficacy that may promote and improve self-management behaviors is an important step toward improving diabetes outcomes and the consistent use of CGM technology.

The findings from the initial observational study in this dissertation, which used data obtained retrospectively from the electronic medical record, support the benefit of masked CGM

use in youth with type 1 diabetes. Because it has the potential to fine-tune glycemic control, masked CGM is an option the multidisciplinary diabetes team can provide to the youth and family to target glycemic control. While intermittent use of this technology may be less burdensome than continuous use of CGM, it is important to explore whether repeated masked CGM use and execution of the recommended therapy change one's self-management and affect HbA1c long-term. Additionally, masked CGM may provide a bridge in youth and families contemplating the transition to RT-CGM. Future work could investigate if patients who do a preliminary trial of masked CGM have more consistent and sustained use of RT-CGM as compared to patients who transition to RT-CGM therapy without prior CGM exposure. This would help identify whether routine masked CGM is an important first step in successful CGM initiation.

The second manuscript identified the apparent need for new instruments to measure self-efficacy in friends or peers of youth with type 1 diabetes in addition to instruments related to diabetes technologies. Since social support and the peer network are pivotal components of a child's development and may be integral to diabetes management, future studies could evaluate how diabetes self-efficacy from a friend/peer perspective may influence a youth's type 1 diabetes self-management.

In the last manuscript of this dissertation, establishing the psychometrics of the novel CGM-SE instrument and its correlation to CGM utility provides a basis for (a) the use of this instrument in future evidence based research with type 1 diabetes youth from various populations and (b) future hypothesis generation and testing in intervention-based studies that focus on the concept of self-efficacy in youth with type 1 diabetes who use CGM technology. Identifying if self-efficacy can predict CGM use will help guide future research efforts and hypothesis testing

related to CGM use, self-efficacy, and optimal health outcomes in youth with type 1 diabetes. Additionally, diabetes technologies continue to advance. The closed-loop AP project is at the forefront of such advances. While the AP project brings promise of significant lifestyle and glycemic improvements, evaluating how the AP may affect psychosocial correlates is just as important as the continued work to refine this technology. Future research and clinical efforts could utilize the self-efficacy instrument described in the third manuscript of this dissertation to evaluate patient confidence related to use of AP technology.

Bandura's SCT, and particularly his model of self-efficacy, should guide further studies exploring this construct related to diabetes technologies and behavior change. According to Bandura, four sources influence an individual's efficacy expectations including performance accomplishments, vicarious experiences, verbal persuasion, and emotional arousal.[22] Intervention research could target these unique areas to determine the effect on self-efficacy related to CGM wear. Specifically, as mentioned above, studies could investigate whether a trial of masked CGM wear prior to RT-CGM (performance accomplishments) strengthens CGM self-efficacy and subsequent adherence to RT-CGM technology. Research also could focus on preliminary CGM education to determine whether modeling of CGM use by youth already wearing CGM (vicarious experience) or nurse educator support/suggestion (verbal persuasion) may influence CGM self-efficacy in youth initiating this technology. Finally, multidisciplinary team research could incorporate psychologists in initial CGM education to discuss stressors or fears pertaining to CGM (emotional arousal) in an effort to desensitize anxiety that individuals may feel with trying a new device. Since there are multiple components that affect self-efficacy, research may benefit from concentrating on these various influences.

Contribution to Science and Nursing

This body of work provides a greater understanding of the use of masked CGM technology, the concept of self-efficacy as it relates to youth with type 1 diabetes and their caregivers, and how to measure the concept of self-efficacy related to CGM use in a contemporary cohort of youth with type 1 diabetes. Importantly, this dissertation contributes to the knowledge of the relationship of self-efficacy and CGM use. The research benefits youth with type 1 diabetes by establishing the utility of the CGM-SE survey, a novel self-efficacy instrument. The development and testing of this instrument address a pertinent gap in the literature related to measuring CGM self-efficacy and whether self-efficacy predicts CGM use in youth with type 1 diabetes.

The results of this dissertation (a) add to the state of the science pertaining to CGM and factors that may affect its use and (b) facilitate the learning process for diabetes healthcare providers regarding the measurement of self-efficacy for youth with type 1 diabetes in the current era of diabetes technologies. Nurses and nurse researchers are fundamental to diabetes self-care and technology education. Their close proximity to the patients and families provides an exceptional opportunity to understand the barriers and facilitators of adherence and self-efficacy as well as opportunities for improved outcomes, in particular, use of new diabetes technologies such as CGM. The nurse educator is central to the multidisciplinary diabetes team and serves as the hub of the medical home. To educate, support, and maintain an appropriate level of family-based diabetes management for youth with type 1 diabetes, it is essential for the nurse educator to understand how technologically advanced therapies affect glycemic control, self-management, and psychosocial attributes.

Use of the CGM-SE measure may enhance the ability of diabetes health care providers to identify youth at risk for suboptimal CGM adherence based on lower self-reported self-efficacy. Healthcare providers, particularly nurses, could then bolster resources to support at-risk youth. This research provides preliminary knowledge for further testing in studies related to self-efficacy. Ongoing efforts to establish a research knowledge base related to barriers and facilitators of CGM technology will allow the interdisciplinary team to refine evidence-based practices for youth with type 1 diabetes and, thus, target glycemic control more effectively in the current era of advanced diabetes technologies.

Appendix A: CGM-SE instrument youth 8-12 year old version

The following statements are about how confident you are with using a continuous glucose monitor (CGM). Having confidence means you think you can do something, whether or not you are doing it now. You may feel more confident in your ability to do some CGM tasks than others.

Please answer the questions below by filling in the circle that is closest to how confident you feel right now.

Example:

I am sure that I can…	**Strongly Disagree**	**Disagree a Lot**	**Disagree a Little**	**Neither Agree nor Disagree**	**Agree a Little**	**Agree a Lot**	**Strongly Agree**
Wear a raincoat or carry an umbrella when it is raining outside	⓪	①	②	③	④	⑤	⑥

I am sure that I can…	**Strongly Disagree**	**Disagree a Lot**	**Disagree a Little**	**Neither Agree nor Disagree**	**Agree a Little**	**Agree a Lot**	**Strongly Agree**
1. Insert the CGM sensor (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
2. Calibrate the CGM sensor (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
3. Keep my CGM receiver with me	⓪	①	②	③	④	⑤	⑥
4. Look at my CGM receiver screen during the day	⓪	①	②	③	④	⑤	⑥
5. Respond to the CGM receiver alarms (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
6. Charge the CGM receiver (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
7. Ask for help with using the CGM	⓪	①	②	③	④	⑤	⑥
8. Wear the CGM sensor at least 6 days a week	⓪	①	②	③	④	⑤	⑥
9. Talk to my parents if I am having a hard time using the CGM	⓪	①	②	③	④	⑤	⑥
10. Respond to CGM alarms when I am at school	⓪	①	②	③	④	⑤	⑥
11. Respond to CGM alarms when I am with my friends	⓪	①	②	③	④	⑤	⑥

Appendix B: CGM-SE instrument youth 13+ version

The following statements are about how confident you are with using a continuous glucose monitor (CGM). Having confidence means you think you can do something, whether or not you are doing it now. You may feel more confident in your ability to do some CGM tasks than others.

Please answer the questions below by filling in the circle that is closest to how confident you feel right now.

Example:

I am sure that I can…	**Strongly Disagree**	**Disagree a Lot**	**Disagree a Little**	**Neither Agree nor Disagree**	**Agree a Little**	**Agree a Lot**	**Strongly Agree**
Wear a raincoat or carry an umbrella when it is raining outside	⓪	①	②	③	④	⑤	⑥

I am sure that I can…	**Strongly Disagree**	**Disagree a Lot**	**Disagree a Little**	**Neither Agree nor Disagree**	**Agree a Little**	**Agree a Lot**	**Strongly Agree**
1. Insert the CGM sensor (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
2. Calibrate the CGM sensor (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
3. Keep my CGM receiver with me	⓪	①	②	③	④	⑤	⑥
4. Look at my CGM receiver screen during the day	⓪	①	②	③	④	⑤	⑥
5. Respond to the CGM receiver alarms (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
6. Charge the CGM receiver (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
7. Ask for help with using the CGM	⓪	①	②	③	④	⑤	⑥
8. Wear the CGM sensor at least 6 days a week	⓪	①	②	③	④	⑤	⑥
9. Talk to my parents if I am having a hard time using the CGM	⓪	①	②	③	④	⑤	⑥
10. Respond to CGM alarms when I am at school	⓪	①	②	③	④	⑤	⑥
11. Respond to CGM alarms when I am with my friends	⓪	①	②	③	④	⑤	⑥
12. Download the CGM data (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
13. Problem-solve when having technical difficulties with the sensor, transmitter, or receiver (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
14. Adjust my insulin dose based on the real-time CGM data (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥
15. Adjust my insulin dose based on the downloaded CGM data (on my own or with my parents' help)	⓪	①	②	③	④	⑤	⑥

Appendix C: CGM-SE parent version

The following statements are about how confident you are with using a continuous glucose monitor (CGM). Having confidence means you think you can do something, whether or not you are doing it now. You may feel more confident in your ability to do some CGM tasks than others.

Please answer the questions below by filling in the circle that is closest to how confident you feel right now.

I am sure that I can…	**Strongly Disagree**	**Disagree a Lot**	**Disagree a Little**	**Neither Agree nor Disagree**	**Agree a Little**	**Agree a Lot**	**Strongly Agree**
1. Insert the CGM sensor	⓪	①	②	③	④	⑤	⑥
2. Work with my child to calibrate the CGM sensor, even if he/she does not want to	⓪	①	②	③	④	⑤	⑥
3. Work with my child to keep the CGM receiver with him/her	⓪	①	②	③	④	⑤	⑥
4. Work with my child to look at his/her CGM receiver screen during the day	⓪	①	②	③	④	⑤	⑥
5. Work with my child to respond to the CGM receiver alarms	⓪	①	②	③	④	⑤	⑥
6. Ensure the CGM receiver stays charged	⓪	①	②	③	④	⑤	⑥
7. Speak with my child's medical team if I need help with the CGM	⓪	①	②	③	④	⑤	⑥
8. Download the CGM data	⓪	①	②	③	④	⑤	⑥
9. Problem-solve when having technical difficulties with the sensor, transmitter, or receiver	⓪	①	②	③	④	⑤	⑥
10. Adjust my child's insulin dose based on the real-time CGM data	⓪	①	②	③	④	⑤	⑥
11. Adjust my child's insulin dose based on the downloaded CGM data	⓪	①	②	③	④	⑤	⑥
12. Share the CGM responsibilities with my child	⓪	①	②	③	④	⑤	⑥
13. Work with my child to wear the CGM sensor every day	⓪	①	②	③	④	⑤	⑥
14. Be encouraging and supportive when working with my child to complete CGM tasks	⓪	①	②	③	④	⑤	⑥

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