

Diabetes Performance Improvement Program With Continuous Glucose Monitoring, Pharmacist Intervention, and Team Management

Andrew Behnke^{a, c}, Christopher G. Parkin^b

Abstract

The growing prevalence of diabetes in the USA continues to be a significant public health concern. A significant proportion of patients with type 2 diabetes (T2D) have elevated glucose levels, as evidenced by a glycated hemoglobin (HbA1c) level > 9.0%. Persistent hyperglycemia results in the development of chronic macrovascular and microvascular complications. Previous strategies to assist this high-risk population in achieving optimal glycemic control have not been as successful as desired. As the demand for healthcare providers and services continues to grow at an unprecedented pace, the USA is facing a national deficit in physicians, nurse practitioners, and physician assistants. Conversely, the number of pharmacists is projected to increase at a rate of 3% annually over the next three decades. Studies have demonstrated that pharmacist involvement in diabetes patient management has resulted in improvements in HbA1c, lowering of low-density lipoprotein (LDL)-cholesterol levels, and achievement of blood pressure targets. This suggests the potential for pharmacists to play a key role in narrowing the gap. We implemented a Diabetes Performance Improvement Program (DPIP) that facilitates a comprehensive lifestyle intervention designed to improve diabetes management and outcomes. The DPIP care team comprises endocrinologists, certified diabetes educators, pharmacists, and supporting staff. The intervention includes utilizing continuous glucose monitoring (CGM) supported by diabetes self-management training (DSMT) and medical nutrition therapy (MNT) delivered by a certified diabetes education specialist (CDES) and registered dietitian (RD). This article reviews the evidence supporting the use of an interdisciplinary team-based approach to diabetes care, describes the DPIP components, and provides guidance for implementing the program in clinic-community settings.

Keywords: Diabetes; HbA1c; Continuous glucose monitoring; Diabetes care team

Manuscript submitted July 12, 2024, accepted September 3, 2024 Published online October 31, 2024

^aEndocrine Section, Carilion Clinic, Roanoke, VA, USA

^eCorresponding Author: Andrew Behnke, Endocrine Section, Carilion Clinic, Roanoke, VA 24016, USA. Email: ajbehnke@carilionclinic.org

doi: https://doi.org/10.14740/jem1013

Introduction

The growing prevalence of diabetes in the USA continues to be a significant public health concern. An estimated 38.4 million Americans are living with diabetes [1]. Approximately 36.1 million have type 2 diabetes (T2D), and 2.3 million have type 1 diabetes (T1D) [1]. This number is projected to increase to more than 54 million by 2030 [2]. While most T2D is diagnosed in middle-aged and older adults, the number of young people < 20 years is rapidly increasing [3, 4]. As recently reported by Rodriquez et al, youth-onset T2D results in more precipitous and severe complications than observed in adults who are diagnosed later in life [5].

Concurrent with the growing diabetes population is the increasing cost of healthcare resource utilization (HCRU). The total cost of diabetes in the USA was recently reported to be \$412.9 billion, including \$306.6 billion in direct medical costs and an additional \$106.3 billion attributed to lost workforce productivity, mortality, and other factors [6]. More than one-third (\$129 billion) of the direct costs were attributed to increased inpatient hospitalizations, emergency department visits, and outpatient hospital visits, resulting from suboptimal glycemic control and other diabetes-related conditions.

Recent data from the Centers for Disease Control and Prevention (CDC) estimate that approximately 50% of all patients with T2D patients have elevated glycated hemoglobin (HbA1c) levels > 7.0%; more than 14% have HbA1c levels > 9.0% [7]. As demonstrated in the landmark UK Prospective Diabetes Study, persistent hyperglycemia results in the development of chronic macrovascular and microvascular complications in both T1D and T2D [8-11].

Although innovative technologies such as continuous glucose monitoring (CGM) can enable patients to achieve better glycemic control [12-27], addressing the growing diabetes population, improving the quality of care, and controlling healthcare costs requires unfettered access to an adequate number of qualified healthcare providers [28]. Unfortunately, as the demand for healthcare services continues to grow at an unprecedented pace, the USA is facing a national deficit in physicians [29-33]. As reported by Zhang et al, the projected deficit will rise to a shortage of almost 149,000 physicians by 2030 [33]. Similar shortages in nurse practitioners and physician assistants have also been projected [30].

Conversely, the number of pharmacists is projected to in-

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^bResearch and Education, CGParkin Communications, Inc., Henderson, NV, USA

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crease at a rate of 3% annually over the next three decades [34]. This suggests that pharmacists can play a key role in narrowing the gap. Studies have demonstrated that pharmacist involvement in diabetes patient management has resulted in improvements in HbA1c, lowering of low-density lipoprotein (LDL)-cholesterol levels, and achievement of blood pressure targets [35]. Team-based pharmacist interventions in hospital and community settings have also been shown to improve clinical outcomes for patients with many acute and chronic diseases, including diabetes [36-38].

We recently reported findings from a prospective study that assessed the impact of an intensive lifestyle intervention conducted by an interdisciplinary diabetes care team in a cohort of 16 patients with poorly controlled T2D [39]. The care team comprised endocrinologists, certified diabetes educators, pharmacists, and supporting staff. The intervention included use of CGM supported by diabetes self-management training (DSMT) and medical nutrition therapy (MNT) delivered by a certified diabetes education specialist (CDES) and registered dietitian (RD). At 3 months, HbA1c levels had dropped from 11.79% to 7.88%, P < 0.001, with all subjects achieving HbA1c levels of < 10%. The percentage of patients with > 9.0% HbA1c at baseline dropped from 72% to 19% after completing the intervention, and the percentage of patients with < 7.0% at baseline rose from 3% to 28%.

Our approach to diabetes management has since been formalized into the Diabetes Performance Improvement Program (DPIP), which facilitates a comprehensive lifestyle intervention designed to improve diabetes management and outcomes. The program utilizes clinic and community-based healthcare providers to implement personalized, intensive diabetes education programs that provide individualized assessment, targeted treatment and education, CGM, and diabetes self-management skill building for improving glycemic control. This article describes the interdisciplinary team-based approach to diabetes care, summarizes the DPIP components, and provides guidance for implementing the program in clinic-community settings.

Key Concepts

Utility of CGM

The introduction of innovative diabetes technologies, such as CGM, has transformed the way patients and their clinicians manage diabetes [40]. Unlike traditional fingerstick blood glucose monitoring, which provides only a "point-in-time" glucose value, CGM transmits a continuous stream of real-time glucose data to patients' smartphones or handheld readers. The data are displayed in numerical and graphical formats, indicating the current glucose level, historical trends, and trend arrows that show the direction and velocity of changing glucose levels. As an added safety measure, current CGM devices feature programmable alerts that warn patients of immediate and impending hypoglycemia and hyperglycemia.

Numerous studies have demonstrated that daily use of CGM improves overall glycemic control [12-27] and reduces diabetes-related events and hospitalization rates and associated

costs [18, 41-44] in insulin-treated and noninsulin-treated patients. CGM use has also been shown to enhance patients' understanding of their diabetes and increase engagement in daily self-management [45-48].

Factors impacting poor glycemic control

Therapeutic inertia

A major driver of suboptimal glycemic control is the failure to intensify therapy when clinically indicated. This phenomenon is referred to as therapeutic inertia [49]. Clinicians are challenged by different barriers to intensifying therapy. These can include time constraints, inadequate staffing, lack of clinician/ staff training/education in diabetes, perceptions about patients' ability and/or willingness to follow prescribed regimens, hypoglycemia, and management of patient's comorbidities [50].

Equally important is the impact of patients' adherence to prescribed therapy on poor glycemic control. While disinterest and lack of motivation are often cited as the cause of poor adherence [51], other factors create barriers that are difficult for patients to overcome. Perceptions of medication efficacy, cost constraints, medication side effects, regimen complexity, weight gain, lack of appropriate education/training, diminished quality of life due to the burden of daily self-management regimens, and concerns about hypoglycemia create barriers to desired self-management behaviors [52, 53].

Reduced access

Individuals residing in higher-income communities are more likely to have access to primary care physicians (PCPs) and diabetes specialists than those living in rural areas and low-income urban communities in which racial/ethnic minorities are often overrepresented [54, 55]. The lack of diabetes specialists in these communities is particularly concerning, given the small percentage of these physicians who prescribe diabetes technologies. In a survey of 102 US PCPs and 100 endocrinologists, only 28.4% reported prescribing CGM for their patients compared with 87.0% of endocrinologists who regularly prescribe this technology [56].

Economic status and occupational issues

Lack of health insurance is a significant barrier to treatment adherence, achievement of glycemic goals, and improved outcomes [57, 58]. Data from the National Health and Nutrition Examination Survey (NHANES) 2017 - March 2020 showed that HbA1c levels and cholesterol management were worse for uninsured adults with diabetes compared to those who were uninsured compared with those covered by insurance [58]. An individual's employment situation can also impact adherence and access to diabetes care. While income and occupational status are recognized social determinants of health [59], lost wages can impact the patient's willingness and ability to attend clinic visits for patients with hourly employment that does not provide paid leave.

Implementing the DPIP

Intensive intervention programs that utilize a pharmacist-physician collaborative care model address many of these issues and have been used in several healthcare systems with proven benefits [60-62]. These programs are sometimes referred to as diabetes boot camps and are included in the American Diabetes Association (ADA) Standards of Care [63]. It is important to note that these programs are intended to "jump start" more effective self-management behaviors and lay the foundation for long-term, individualized care and follow-up.

Building the care team

Whereas person-centered diabetes care is essential to helping individuals effectively manage their diabetes, the care team provides expert clinical guidance and long-term support. The team can have as few as three members, but more may be necessary in larger programs. The essential members are a team leader, a CDES, a pharmacist, and a program administrator.

Team leader

The team leader oversees all aspects of the program. Specifically, the team leader directs and manages medical issues that are essential in the management of patients with T2D. This includes managing medication changes and adjustments either individually or by creating algorithms for others to follow. The team leader is also responsible for ordering appropriate laboratory tests, making referrals to other providers, and ensuring that patients receive the care they need in a timely fashion. Generally, this person is a physician - either an endocrinologist or an internal medicine/family practitioner - with a special certification or expertise in diabetes.

CDES

The CDES is responsible for providing longitudinal diabetes education and self-management training to the participants. The training content is consistent with a curriculum set up by the ADA [64]. If the CDES is also an RD, they can instruct and bill for MNT.

Clinical pharmacist

The clinical pharmacist meets with each individual initially to assess medication interactions, appropriate dosages, and administration. The clinical pharmacist can also provide periodic check-ins with patients and adjust dosages following the algorithm provided by the team leader.

Program administrator

The program administrator is generally skilled in healthcare administration and knowledgeable about diabetes. Their role is to verify insurance, submit appropriate claims, remind patients about visits and appointments, and provide any administrative oversight necessary for the program. Current Procedural Terminology (CPT) codes for the services associated with the DPIP are presented in Supplementary Material 1 (www.jofem. org).

Selecting appropriate patients

The purpose of the health team is to surround patients with individuals who can provide expert clinical advice, initial and ongoing education/training, and close monitoring of patients' health and progress. The ability and willingness of each patient to actively participate in and engage with the program is essential to success. Not all patients meet these criteria. Generally, we are looking for patients with T2D, > 10% HbA1c, willing to wear a CGM device, and willing to attend at least two 2-h education and treatment sessions (in-person or virtually) during the 3-month program.

DPIP Protocol and Procedures

The DPIP protocol is provided to team members as a 16-page manual. A summary of the DPIP protocol is presented in Table 1. The full manual can be obtained by contacting the corresponding author of this report.

Once enrolled in the program, patients first meet with the CDES who assesses the patient's understanding of diabetes and provides DSMT to support decision-making and skill building. The CGM sensor is placed during this session and laboratory testing of HbA1c other standard measurements are taken. Patients will participate or in groups via face-to-face visits, telephone, or telehealth visits for additional education sessions over the three-month period as needed. Patients who miss scheduled visits are rescheduled.

These sessions include topics about medication management and psychological well-being. A final wrap-up session occurs at the end of the 3-month period. These sessions are conducted in-person or virtual. Although led by the CDES, they may also involve input from clinical pharmacists, social workers and psychologists. Progress on behavioral goals is measured during these meetings.

Participants receive one Specific, Measurable, Achievable, Relevant, and Time-Bound (SMART) goal in their initial session with the CDCES. This approach incorporates four key criteria: 1) the goal is specific and defines exactly what is to be achieved; 2) the goal is measurable and provides tangible evidence when it has been achieved; 3) the goal is achievable but challenges the patient slightly so that he/she feels a sense of accomplishment; and 4) the goal should be attainable over a short period of time [65]. For example, a SMART goal may be as simple as: "increase my time spent in glucose range (%TIR)

Table 1. Summary of DPIP Protocol

Personnel	Time needed	Description of duties
Team leader	0.1 FTE	Defining criteria for enrollment. Managing medication by creating algorithms for others to follow. Ordering appropriate laboratory tests and referrals to a physician (MD or DO) or advanced care practitioner (ACP).
Clinical pharmacist	0.2 FTE	Meets with the individual initially to assess medication interactions, appropriate dose, and administration. Provides weekly check ins with the patient and follow dose adjusting by the algorithm provided by the team leader.
CDES	0.1 FTE	Provide diabetes education consistent with a curriculum as set up by the American Diabetes Association.
Visit schedule	Personnel	Tasks
Week 1	Team leader, CDES, clinical pharmacist	Introduce yourself and the role you play. Provide CDES education based on your program's curriculum. Set up CGM and ensure the CGM is connected with the web based monitoring program. Ensure access to reliable electronic communication.
Week 2-12	Clinical pharmacist	Establish either video or telephone contact with the patient. Review the data from the CGM. Review the medication regimen prescribed and assess compliance. Adjust insulin or medications as per the algorithm provided. Arrange for a follow-up visit next week.
Week 13	Team leader, CDES, clinical pharmacist	Review progress of glucose monitoring and adjustments made at previous weekly visits. Assess levels of compliance and troubleshoot areas of concern. Order HbA1c and labs as indicated by the assessment. Encourage progress and review plans for long term success. Write a note to the referring provider summarizing the results and value of the program.

CDES: certified diabetes education specialist; CGM: continuous glucose monitoring; DPIP: Diabetes Performance Improvement Program; FTE: total amount of full-time employees; HbA1c: glycated hemoglobin.

by 5% next week's visit". The SMART goal is related to the Association of Diabetes Care & Education Specialists 7 Health Behaviors (ADCES7) Self-Care BehaviorsTM (Healthy Eating, Being Active, Monitoring, Taking Medication, Problem Solving, Reducing Risks, and Healthy Coping) [66]. The CDCES follows up on the patient's progress in his or her behavioral goal in the final session at the end of the 3-month program.

Data from the CGM are shared with the patient's team. Throughout the program, the patient has weekly interactions with the physician, pharmacist, or member of the team designated to make changes. Medical decisions are based on the specialist's advice as per the ADA-published standard of care. A second HbA1c is obtained at the end of the 3-month program.

Summary

Therapeutic inertia is widely recognized as the primary contributor to suboptimal diabetes management [49]. The DPIP squarely addresses this problem, utilizing a structured approach that leverages the informational and psychological benefits of CGM use in combination with nutritional consultation, clinical pharmacist intervention, and frequent follow-up by an interdisciplinary diabetes management team. As previously reported, this approach facilitates significant improvements in glycemic control in a relatively brief period [39]. These improvements were achieved without significantly increasing weight, insulin dose, or the number of non-insulin antihyperglycemic medications. We believe that the various components of the DPIP may be synergistic and are eager to identify the one(s) that are most influential.

With the growing prevalence of diabetes in the USA, health systems will be increasingly challenged to meet the healthcare needs of the expanding diabetes population. The situation is further exacerbated by a growing shortage of healthcare providers with the expertise to manage these patients. Our success with the DPIP demonstrates that pharmacists can play a crucial role in filling this deficit. Moreover, our approach to patient care and diabetes management has not only been proven effective in improving the quality of diabetes care but has the potential to shift our current paradigm of healthcare delivery away from the traditional acute-care model to an approach that addresses the holistic needs of each patient with diabetes.

Supplementary Material

Suppl 1. Summary of Medicare Requirements for Coverage for CGM, DSMT, and MNT.

Acknowledgments

None to declare.

Financial Disclosure

Funding for editorial assistance was provided by Abbott Diabetes Care. Funding for publication of this manuscript as an Open Access article was provided by Virginia Tech.

Conflict of Interest

AJB receives research support from Abbott. CGP has received consulting fees from Abbott Diabetes Care, Biomea Fusion, CeQur, Dexcom, Embecta, Hagar, Insulet, Roche Diabetes Care, and Tandem Diabetes Care.

Informed Consent

The study was deemed not human research by the institutional IRB. In light of that, no informed consent was obtained.

Author Contributions

AJB initiated the concept of the manuscript. AJB and CGP wrote the manuscript, conducted critical review of the content, and approved the final draft for submission.

Data Availability

The authors declare that data supporting the findings of this study are available within the article. Any inquiries regarding supporting data availability of this study should be directed to the corresponding author.

Abbreviations

ADA: American Diabetes Association; ADCES7: Association of Diabetes Care & Education Specialists 7 Health Behaviors; CDC: Centers for Disease Control and Prevention; CDES: certified diabetes education specialist; CGM: continuous glucose monitoring; CPT: Current Procedural Terminology; DPIP: Diabetes Performance Improvement Program; DSMT: diabetes self-management training; HbA1c: glycated hemoglobin; HCRU: healthcare resource utilization; LDL: low-density lipoprotein; MNT: medical nutrition therapy; NHANES: National Health and Nutrition Examination Survey; PCPs: primary care physicians; RD: registered dietitian; SMART: Specific, Measurable, Achievable, Relevant, and Time-Bound; T2D: type 2 diabetes

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