Optimizing mHealth Technologies in Real-World Clinical Practices

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IN BRIEF Therapeutic inertia and suboptimal treatment adherence remain the key drivers of chronic poor diabetes control. Advances in mHealth technologies have spurred the development of a new generation of blood glucose monitoring systems that enable individuals with diabetes to automatically transfer glucose data and other information from their smartphones to their health care providers for analysis and interpretation via diabetes data-management software. This report discusses key lessons learned from two investigations that assessed the effects of interventions using the Accu-Chek Connect diabetes-management system (Roche Diabetes Care, Indianapolis, Ind.) within diverse diabetes populations.

Diabetes in the United States is a significant and growing health emergency. It is estimated that ~30.3 million people of all ages in the United States have diabetes, accounting for 9.4% of the population (1). The most recent data indicate that the total cost of diabetes in the United States increased >26% since 2012, from $245 billion (2) to $327 in 2017, which includes $237 billion in direct medical costs and $90 billion in reduced productivity (3). The increasing prevalence of diabetes and its associated clinical, social, and financial costs is particularly concerning among the elderly. An estimated 25.2% of individuals ≥65 years of age have diabetes (1) and account for almost one-third of all Medicare costs (4). The increasing cost of diabetes is driven by poor glycemic control (3). Recent data show that a significant percentage of individuals with diabetes are not meeting their glycemic targets (5,6).

Treatment inertia is recognized as a key contributor to suboptimal diabetes control (7). Clinicians often do not initiate or intensify therapy as rapidly as recommended in guidelines (8–10), and many patients are resistant to making therapy adjustments due to negative perceptions about the efficacy of treatment, medication side effects/tolerability, complexity of treatment regimens, and cost (11). Patient resistance, in conjunction with increasing time constraints and insufficient patient data, further reinforces clinician reluctance to titrate therapy as needed.

Even when data are available, the information is not presented and organized in a meaningful way via decision-support tools, which further exacerbates inertia.

Use of telemedicine strategies to monitor and adjust therapy has been shown to improve glycemic control (12–16), patient self-efficacy (17), and quality of life (12) in individuals with type 1 or type 2 diabetes. Early studies also suggest cost benefits associated with the use of telemedicine interventions (18,19). A sub-segment of telemedicine is mobile health (mHealth), which uses mobile communications devices such as smartphones, tablets, and other tech-

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nologies to exchange health-related information.

Advances in mHealth technologies have spurred the development of a new generation of blood glucose monitoring systems that enable individuals with diabetes to automatically transfer glucose data and other information from their smartphones to their health care providers (HCPs) for collaborative analysis and interpretation via diabetes data-management software. Use of smartphone interventions with these systems has been shown to significantly improve glycemic control by promoting improvement in diabetes self-management activities (20–22).

One such system is the Accu-Chek Connect diabetes-management system (Roche Diabetes Care, Indianapolis, Ind.). The system consists of a blood glucose meter, smartphone application (app), and online data-management web portal. The meter connects wirelessly, via Bluetooth low-energy technology, to the user's smartphone app, which provides multiple functions to facilitate diabetes management. The meter automatically sends glucose results to the app each time a test is performed. The app sends the test result and other related information to a secure personal and/or clinician web portal for analysis; manual download of data is unnecessary. Users also have the option to share glucose data with others via text message. A key feature of the system is the clinician portal home page "dashboard," which automatically organizes patient data, identifying patients who are at risk for acute glycemic events and thereby providing clinicians the ability to triage patients according to greatest need.

Mora et al. (23) recently reported findings from the Personal Diabetes Management (PDM) Connect trial, a 6-month, prospective, multicenter, single-arm study that assessed the impact of using the system on changes in treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire [DTSQc]) (24) and glycemic control among 87 adults with type 1 diabetes or insulin-treated type 2 diabetes. The study also investigated the impact of using the system on clinicians' ability to make informed decisions about diabetes-management therapy changes and the number of unscheduled patient visits/consultations generated by the availability of near–real-time data. Significant improvements in DTSQc scores were observed at 6 months, with a total mean score of 14.3 (SD 5.1) (P <0.0001), and significant reductions in mean A1C from 8.8% at baseline (–0.9 ± 1.6%, P <0.001) were reported. Importantly, investigators found that 130 unscheduled medical visits occurred during the study among 36 patients (41.1%); 118 (90.8%) were initiated by clinicians, and 107 (90.7%) of these were conducted remotely. Among the clinician-initiated remote visits, 103 (96.3%) were for medication changes and 3 (2.8%) involved education/training only.

Although clinical trials provide crucial evidence and valuable guidance regarding the efficacy and use of diabetes-management technologies, they do not necessarily reflect the utility of these technologies in real-world clinical practices (25). Moreover, despite evolving payment structures intended to provide adequate reimbursement to clinicians for remote patient consultation, the current fee-for-service payment system still creates obstacles for optimal use of mHealth tools. However, within different payment structures, such as accountable care organizations (ACOs), use of mHealth tools and technologies may provide significant cost benefits to HCPs in addition to improving patient health outcomes.

In this report, we discuss key lessons learned from the PDM Connect study and from a pilot quality improvement program (QIP) that used the Accu-Chek Connect system with high-cost diabetes patients treated at a large endocrinology specialty practice in an ACO.

Background

The ACO model is a market-based approach to Medicare patient care that integrates local physician practices, hospitals, and other HCPs who are responsible for the quality and total cost of care for their patients (26). ACO providers have access to both clinical patient information and claims data and strive to use this information to facilitate care coordination, ensure continuity of patient care, and enhance population management. The goals are to improve health care quality, reduce hospitalization admissions and readmissions, avoid emergency room visits, improve patient adherence to treatment, and reduce costs.

As with other HCPs, ACO participants are reimbursed through fee-for-service payments. However, ACOs receive additional compensation by sharing in the savings they create through improved care. ACOs that can lower spending (based on an established financial benchmark) while maintaining quality, receive a portion of that savings. The financial benchmark is the level of spending an ACO is projected within a given year for its patient population. The financial benchmark is unique to each ACO and is determined by historical spending, the patient population, and regional factors.

Pilot QIP

Practice Overview

The pilot QIP was a proof-of-concept assessment of the impact of remote monitoring interventions delivered by care coordinators and endocrinologists on hospitalizations and other costs among high-cost/high-risk Medicare patients with diabetes. The pilot program was conducted at Amarillo Medical Specialists in Amarillo, Tex., where ~35% of patients are covered by Medicare. Among Medicare patients, 22% have diabetes. Amarillo Medical Specialists is one of multiple medical groups that founded the Amarillo Legacy Medical ACO, which includes 330 independent medical group participants and covers >17,000 Medicare lives across nine counties in the Texas panhandle. The practice participates in the Medicare Shared Savings Program

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(MSSP), a payment arrangement through which HCPs receive their established fee-for-service reimbursement and a portion of the overall savings they achieve each year based on their annual financial benchmark. The financial benchmark for the practice was $7,968 per capita when the QIP pilot was implemented in 2016. A Roche Diabetes Care representative provided initial training to clinic staff on setting up the Accu-Chek Connect systems; however, monetary support for the intervention was obtained through monthly billing for chronic care management (CCM) and remote physiologic monitoring codes. No additional funding was received.

Pilot Implementation

The first step in the implementation process was to identify the key personnel who would be handling patient enrollment and care management and thoroughly train them in the set-up and use of the Accu-Chek Connect diabetes-management system. A workflow schemata and care plan template were developed to provide step-by-step guidance for patient management.

Patients were identified using complete, nonanonymized claims data for the past year. Cost metrics for evaluation included hospitalization rates, emergency room rates, physician costs, home health care utilization, and medications. Based on these analyses, the nine highest-cost/highest-risk patients were identified and contacted for enrollment in the QIP.

During the QIP enrollment phase, beginning the third quarter 2016 and ending the first quarter 2017, staff first determined whether each patient or a caregiver had a smartphone that was compatible with the Accu-Chek Connect diabetes-management app. If so, the system app was installed, and the phone and meter were paired. Patients and their primary family member(s)/caregiver(s) received training from clinic staff in how to use the system and how they would be interacting with their care manager throughout the process. Clinical challenges for each patient were assessed, documented, and incorporated into an individualized care plan.

Monitoring Process

The monitoring process began with each patient or caregiver obtaining a blood glucose test result, which was automatically transferred to the Accu-Chek Connect online diabetes-management system dashboard. The care manager reviewed these data daily, Monday through Friday. The care plan provided an algorithm for decision-making, indicating when the care manager should notify the physician, the patient/caregiver, or both based on the glucose data received. When therapy or behavior changes were indicated, the care manager collaborated with the patient to identify any obstacles to adherence and determine how these changes could be implemented within the context of the patient's circumstances.

Results

Comparisons of 6-month pre-QIP to 6-month post-QIP health care utilization and costs for each patient showed a total net savings of ~$100,000 (Table 1). The largest savings were observed in total hospital expense and emergency room (ER) visits with hospital admissions. Notable decreases in other Medicare Part B expenses, hospital outpatient costs, and home health agency utilization were observed.

As expected, results showed an increase in Medicare Part D expenses. Although ACOs that participate in the MSSP are held responsible for Part A and Part B Medicare spending, medications are Part D expenses and are not included. The increase in medication costs was likely due to the effect of the care managers in improving treatment adherence, resulting in a higher rate of medication use. It is known that patients treated for chronic conditions adhere to their prescribed medications only 50–60% of the time (27–29).

Lessons Learned from PDM Connect Study and Pilot QIP

General Lesson: Need for Technology Infrastructure Within Clinical Practices

Use of smartphone technology continues to accelerate and has potential to integrate all connected technologies with a positive impact on health-relat-

TABLE 1. Changes in Total Costs, Hospital Expenses, and Home Health Agency Costs from 6 Months Before to 6 Months After the QIP Intervention (*n* = 9)

	6 Months Before QIP	6 Months After QIP	Change
Total	$215,325	$115,099	–$100,226
Total hospital costs	$86,121	$15,111	–$71,010
Non-ER hospital admissions	$36,738	$0	–$36,738
ER visits with hospital admissions	$49,383	$15,111	–$34,272
ER visits with no hospital admissions	$4,880	$4,638	–$242
Hospital outpatient services	$41,045	$31,933	–$9,112
Skilled nursing facilities	$1,047	$0	–$1,047
Home health agencies	$25,103	$17,754	–$7,349
Other Medicare Part B costs	$38,986	$28,080	–$10,906
Medicare Part D costs	$9,136	$14,294	$5,158
Durable medical equipment	$6,738	$3,292	–$3,446

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ed applications. In the United States, 77% of Americans report owning a smartphone, with adoption rates rising most notably among older and lower-income Americans; 42% of individuals ≥65 years of age, and 64% of individuals in lower-income households (<$30,000/year) own a smartphone (30). With the increasing number of smartphone users in all population segments, this technology offers a usable platform for diabetes data optimization. The challenge for clinical teams is to create an infrastructure that supports the use of digital technologies to obtain data for analysis and integration into the electronic medical record (EMR) system to support medical recommendations and provide guidance to other clinicians. Importantly, implementation of mHealth technologies should include defining the crucial factors that support the daily operation of a busy clinic, such as identifying the individuals who are responsible for specific tasks, and how to incorporate these technologies into the routine office workflow.

PDM Connect Study

Barriers to Technology Adoption Must Be Addressed

Cost and liability issues, lack of time and workload, proof of utility, and inadequate training and support have been cited as key barriers to mHealth technology adoption (31). Although utilization of the remote data-management capability between scheduled visits was relatively high among primary care physicians in the PDM clinical study, it is assumed that one or more of these barriers inhibited use by the diabetes specialist; only one specialist made extensive use of remotely conducted unscheduled visits. Clinicians' unwillingness to utilize mHealth technologies highlights a critical need to further investigate and elucidate each of these barriers and develop solutions that can be individualized to specific clinical scenarios. Although many of these barriers (e.g., time constraints/workload) can be addressed through training and support, others, such as threatened clinical autonomy and proof of efficacy, will prove more difficult. More studies that demonstrate overall efficacy of mHealth interventions are needed.

Use of mHealth Technologies Is Both Feasible and Desirable in Primary Care Clinical Settings

The ability to more effectively monitor patient status through the web portal triage function likely encouraged and facilitated remote diabetes management. This circumstance not only suggests that clinicians were utilizing the triage function to monitor patients, but also indicates their perception of the high value and utility of remote consultations. This result was associated with improved glycemic control as well as reduced burden of diabetes on patients as their clinic needs were met without the added time and inconvenience of coming to the clinic. Additionally, the immediate availability of accurate patient data, presented in formats that can be easily interpreted and used to assess the patients' glycemic control and guide treatment adjustments, provides greater efficiency and more informed therapy decision-making. Seamless integration of patient data into the EMR was requested to reduce clinician burden relevant to documentation requirements and facilitate data visibility with others (clinicians and health systems) to guide health care protocols and enhance population health management initiatives.

QIP Pilot

Coding for Reimbursement Drives Financial Viability in CCM

An important aspect of using mHealth technologies within the context of CCM is establishing a strategy for obtaining reimbursement. The original Current Procedural Terminology (CPT) code for CCM (CPT 99490) reimburses practices ~$43 per month, which allows practices to bill for at least 20 minutes of non–face-to-face clinical staff time each month to coordinate care for patients who have two or more chronic conditions. The Centers for Medicare & Medicaid Services (CMS) recently added three new codes to the program: CPT 99487, CPT 99489, and HCPCS (Healthcare Common Procedure Coding System) G0506. CPT 99487 covers complex CCM services, reimbursing $94 for 60 minutes of clinic staff time per month. CPT 99489 is an add-on code that reimburses practices $47 for each additional 30 minutes of clinic staff time. HCPCS G0506 is an add-on code to the CCM initiating visit, providing an average, one-time reimbursement of $64. Along with these new codes, CMS has streamlined its service and reporting requirements, allowing for verbal patient consent, relaxed technology requirements (a certified electronic health record is no longer needed), simplified care plan requirements, and more flexible documentation.

Clinical Staff Must Be Knowledgeable and Well-Trained

Clinical staff who use mHealth technologies must have a clear understanding of patients' treatment goals and written parameters on the specific actions to take in various situations. It is important that at least one individual within the practice receive comprehensive training in the set-up and use of the selected technology so that he or she can provide comprehensive training and support to patients and assist in troubleshooting any technical problems that may arise. It is also important that care managers have or acquire expertise in the chronic diseases they will be treating. In addition to their medical knowledge, care managers must have a deep understanding of the emotional burdens of the diseases their patients must deal with every day. Equally important are the care managers' communication skills and ability to use patient data to support patient goals and counsel patients remotely.

A "Decision Tree" Is Needed for Care Managers and Other Staff

A central component of using remote monitoring in CCM is creating the al-

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TABLE 2. Roles and Responsibilities

Point of contact	Medical assistant or physician extender
Point of decision	Physician extender, case manager, or certified diabetes educator
Supervision of process	Physician, pharmacist, certified diabetes educator, or other qualified staff member
Coordination of care	Case manager, medical assistant, or other qualified staff member
Quality control	Case manager, physician, or other qualified staff member

gorithm or "decision tree" within the care plan for each patient that clearly defines the specific actions the care manager must take based on the data remotely received from the patient. Care managers must have clear direction regarding who to call, the specific circumstances when the physician must be notified, and how to follow up with the physician and the patient. Because CCM is delivered within the context of the overall clinical practice, workflow and documentation processes must be carefully organized to optimize efficiency and eliminate duplication of tasks. The roles, responsibilities, and accountabilities of each staff member must be clearly defined. Who is empowered to do what? Who owns what in the care process? How is the patient experience handled from team member to team member? Table 2 presents suggested roles and responsibilities for CCM.

Implementation of CCM Requires a Shift in the Health Care Delivery Paradigm

Importantly, clinicians need to have confidence in their staff, trusting them to provide the necessary care and follow-up within the established guidelines. This delegation of responsibility to care managers requires a significant change in paradigm for many primary care and endocrinology practices. Many practices feel that they are already providing this type of service, when in fact they are either not providing the service at all or providing it in a haphazard and nonstandardized way.

Discussion

The growing population of individuals with poorly controlled diabetes is creating an unsustainable burden on health care systems. Approximately $142.2 billion of the $237 billion in direct diabetes costs are attributable to hospital inpatient care (30%) and prescriptions to treat complications (30%) (3). The indirect costs of diabetes—$90 billion—are due to increased absenteeism, lost productive capacity due to early mortality, inability to work as a result of disease-related disability, and reduced productivity while at work (3).

Although suboptimal treatment adherence is well recognized as the primary driver of poor diabetes control and its associated costs, we also know that treatment adherence is improved when HCPs possess an accurate assessment of their patients' knowledge and understanding of their regimens, can clearly and effectively communicate with their patients, and, importantly, have established a relationship that is based on trust and collaboration (32). Use of mHealth technologies facilitates seamless transfer of diabetes data and, at the same time, supports collaborative clinician-patient relationships.

As demonstrated in the PDM Connect study, use of the Accu-Chek Connect system is associated with frequent clinician-patient collaborations and interactions, more timely therapy adjustments, and significant improvements in treatment satisfaction and glycemic control. Moreover, the ability to more effectively monitor patient status through the web portal triage function improved efficiencies by allowing clinicians to prioritize patients according to their level of glycemic risk.

Findings from the pilot QIP suggest that a care process that uses automated transmission of patient glucose measurements to skilled care coordination nurses is associated with significant cost savings in the treatment of high-risk, high-cost patients, a population seldom studied. Although medication costs (Medicare Part D) increased during the pilot, we do not feel that improved adherence to prescribed therapy should be viewed as an added expense. Although it is estimated that ~50% of suboptimal adherence is intentional, many patients are nonadherent to their prescribed therapies because they do not know how to take their medications or their regimens are too complex, involving different medication combinations and multiple daily dosing (33). Thus, strong patient-clinician relationships that foster clear communications and an understanding of patients' potential obstacles to effective disease management can positively influence treatment adherence (32). Although findings from the pilot QIP are inconclusive due to the small number of program participants and short duration of follow-up, we believe they demonstrate proof of concept for the intervention.

Because ACOs have access to more complete patient information, including medical history and insurance claims data, they are in a unique position to analyze cost and implement cost-saving measures while improving patient care. The use of mHealth technologies that provide visibility to patient-generated health data offers the potential to enhance patient quality of care and yield financial benefits. The examples discussed here clearly demonstrate the vast potential of mHealth technologies in real-world clinical practices.

With the emergence of mHealth technologies, we have seen the development of "connected" glucose monitoring systems, as well as numerous apps and other digital tools to help

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patients stay engaged with their diabetes self-management. Connectivity through a mobile platform allows the integration of available data with decision-making encounters. However, implementation of mHealth strategies requires planning. Data analysis through artificial intelligence protocols have the potential to enhance management of chronic conditions efficiently and ideally prevent provider burnout. As federal regulators approve more mHealth devices for diabetes care management and coordination, adoption of these technologies in clinical practices and throughout health care systems is likely to increase.

In the very near future, we expect to see an expanding diabetes-management ecosystem that uses "open platform" devices and apps that will operate alone or in a coordinated manner to facilitate seamless sharing of information between patients, caregivers, clinicians, and payers. Analysis of this information, coupled with innovations in automated decision-support technologies, has the potential to provide meaningful clinical insights to patients, HCPs, and health care systems. This level of integration will confer benefits to all stakeholders through improved treatment adherence, better clinical and quality-of-life outcomes, and greater cost-efficiencies. However, creating and implementing these types of digital solutions will require fundamental changes in how health care is provided.

Duality of Interest

P.M. has received consulting fees/speakers bureau honoraria from AstraZeneca, Dexcom, Insulet, Medtronic, Merck, Novo Nordisk, and Valeritas and research support from Roche Diabetes Care. W.C.B. has received research funding from AstraZeneca, Dexcom, Novo Nordisk, Roche Diabetes Care, and Sanofi. C.G.P. has received consulting fees from Dexcom, Insulet, Johnson & Johnson, Mannkind, Roche Diabetes Care, and Senseonics.

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Author Contributions

P.M., W.C.B., and C.G.P. researched the data, wrote the manuscript, and reviewed and approved the final manuscript. P.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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