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Evidence-based Mobile Medical Applications in Diabetes

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BACKGROUND

Management of chronic diseases such as diabetes mellitus (DM) is difficult. People living with chronic diseases face challenges related to knowledge deficiencies, inability to sustain lifestyle modifications, and scarce access to specialists for timely advice. In addition, people with DM need to master reading and mathematics skills to effectively incorporate the principles of basal, bolus, and correction insulin doses to effectively manage their disease. Health care professionals who care for patients with diabetes face challenges related to having inadequate time and ability to view and effectively analyze patient glucose and insulin dosing data, which is usually provided in a format too cumbersome for a quick analysis. An Institute of Medicine report from 2001 identified 3 major factors contributing to the gap in care of patients with chronic illnesses: (1) increased demands on medical care from the rapid increases in chronic disease prevalence and the complexity of underlying science and technology; (2) the inability of the system to meet these demands because of poorly organized delivery systems; and (3) constraints in using modern information technology.[1] Fifteen years later, these 3 factors are no less important.

Mobile health (mHealth), a subset of telemedicine and health information technology, encompasses the use of mobile communication devices (such as mobile phones and other wireless devices) for health services and information.[2] mHealth facilitates remote monitoring and delivery of timely recommendations for health care. The promise of this

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approach is to improve care through enhanced access to health information.[2] Specifically, for individuals with DM, mHealth could increase the capacity for self-management; facilitate decision-making processes needed for optimal insulin dosing; help sustain necessary lifestyle modifications; and improve communication between patients, family members, and health care professionals. Therefore, this approach has the potential to improve outcomes such as hemoglobin A1C (A1C), hypoglycemia incidence, and quality of life (QOL). In addition, self-management aims to involve patients in their own long-term care, which empowers individuals, increases self-efficacy, and reduces health care costs.

Smartphone technology provides an obvious platform for the development of mobile medical applications (apps) intended to help people with DM improve self-management and facilitate communication with their health care teams. Reviews have been published elsewhere that have evaluated commercially available mobile medical apps with a focus on functionality, usability, and outcomes[3–6] (including those focusing on specific populations, such as the very young and those >50 years old).[4,6] However, most of the more than 1100 currently available apps[7] are similar, offer only 1 or 2 functions, and lack published outcome studies in peer-reviewed medical journals. Therefore, aside from US Food and Drug Administration (FDA) clearance, there is little evidence to guide health care professionals in helping their patients choose the best DM app. Furthermore, additional platforms, such as computer tablets and glucose monitoring devices, including continuous glucose sensors and meters, can be used to provide digital health solutions. All of these devices can be produced containing decision support software that organizes data, analyzes data, and has the capability to further transmit the data to end users, including patients, families, and the health care team.

This article reviews mobile medical apps for DM that are commercially available in the United States or European Union (EU) and either have had clinical outcomes data published in peer-reviewed literature in the past 5 years or have been cleared by the FDA in the United States or have received a CE (Conformité Européenne) Mark in the EU. Identification of mobile medical apps was based on a search of 2 commercially available platforms: Apple and Android app stores. The PubMed database was searched for studies based on randomized controlled trials (RCTs), observational studies, post hoc analyses, and survey studies. Our search encompassed articles published between January 2010 and December 2015. Our search was completed on 3/10/16. The authors included apps intended to support blood glucose (BG) monitoring and DM self-management in patients with type 1 DM (T1DM) and type 2 DM (T2DM). Mobile medical apps and products were analyzed according to the criteria outlined in Box 1.

Box 1

Criteria used to evaluate mobile apps

Platform

Smartphone

Meter

Insulin pump

Computer: Web-based software

Other

Function/description

Insulin dose calculator

Basal bolus: pattern adjustment

Activity diary

Education

End user

T1DM

T2DM

Data collection: data source and mode of collection

Glucose

Carbohydrate/nutrition

Activity

Manual versus automatic

Connectivity

Cloud

Web

Electronic medical record

Other: SMS (short message service)

Availability/regulatory

US Government or EU

FDA cleared or CE marked

Clinical evidence

Study design

Outcomes: safety, efficacy, and QOL

A total of 14 mobile medical apps (summarized in Table 1) were identified. They can be divided into 2 major categories: smartphone-based apps and glucose meter (smart meter)–based apps.

A. Smartphone-based apps (and their developers)

1 Blue Star (WellDoc)

2. Share (Dexcom)
3. Diabeo (Voluntis)
4. Diabetes Diary (Norwegian Centre for Integrated Care and Telemedicine)
5. Diabetes Interactive Diary (DID) (METEDA)
6. Glooko Mobile App (Glooko)

B. Glucose meter–based mobile apps (and their developers)

7. Accu-Chek Aviva Expert (Roche)
8. Accu-Chek Connect (Roche)
9. Dario (LabStyle Innovations)
10. Diabetes Interactive Guidance System (Hygeia)
11. FreeStyle InsuLinx (Abbott)
12. Gmate (Philosys)
13. Livongo (Livongo Health)
14. Telcare (Telcare)

Fourteen studies are included in this article. These studies were published between January 2010 and August 2015, and they evaluated a total of 8 mobile medical app products: Blue Star[8,9] Diabeo,[10–12] Diabetes Diary,[13] DID,[14,15] Accu-Chek Aviva Expert,[16,17] Diabetes Insulin Guidance Systems,[18] FreeStyle InsulLinx,[19,20] and Telcare.[21] Six apps (Dexcom Share, Glooko, Accu-Chek Connect, Dario, Livongo, and Telcare) have received FDA clearance for use but do not have studies on efficacy and safety in peer-reviewed literature. A summary of studies is presented in Table 2. Only 6 out of the 14 studies were RCTs.[9,10,13–15,17] Sample size in RCT or observational studies ranged from to 7 to 203 subjects; a single survey study had 1412 subjects.[16] The interventions lasted from 4 weeks to 1 year, but the duration of most studies was 3 to 6 months. Most studies involved subjects with mean age 40 to 50 years, with an age range of 13 to 83 years. One small study targeted older adults more than 65 years of age.[8] Eight out of 14 studies enrolled only subjects with T1DM. A summary of the 14 studies, including design, methodology, and results, is provided in Table 2.

BRIEF OVERVIEW OF PRODUCTS

Smartphone-based Mobile Medical Applications

Blue Star (WellDoc)—This automated patient coaching system is an algorithm-driven app, based on patient-reported data. The mobile device is connected to the Web portal, and patients can use a mobile phone and/or a computer to access the app. Patients enter their medical history, medications, and clinical data. The Blue Star clinical/behavioral analytical engine automatically delivers real-time messages and contextually relevant content to the patient through proprietary algorithms when clinical data, such as BG values, are entered.

Options exist to use a Bluetooth-enabled OneTouch Ultra BG meter, which transmits the patient's glucose values directly to the patient's cell phone. If the BG value is more or less than a target value, then the patient is provided with real-time feedback, including suggestions on how to bring values into the target range. Blue Star also performs blood sugar pattern analysis and uses this information to provide general suggestions for lifestyle or medication interventions. This product is indicated only for T2DM. Patients can send a SMART Visit report by fax to their health care professionals by clicking on an icon within the product. It is FDA cleared and available by prescription as mobile prescription therapy (MPT). The definition of MPT is a treatment prescribed by a health care professional and generated by a mobile device that is (1) automated and personalized, (2) associated with published outcomes, (3) adherent to governing regulations or standards, and (4) reimbursed by a health plan.[22] Studies have shown A1C level reduction with Blue Star.[9]

Share (Dexcom)—Dexcom continuous glucose monitoring (CGM) system with Share is an FDA-approved CGM system with Bluetooth technology built into the receiver that allows uploading of real-time CGM data via an iOS device onto a Health Insurance Portability and Accountability Act (HIPAA)–compliant server that can be shared with family and the care team. Data can be shared with up to 5 designated recipients (followers) who can remotely monitor the patient's glucose information and receive alert notifications. CGM systems have been shown to achieve A1C level reduction; however, no studies of outcomes using the Share product as a standalone intervention have been published.

Diabeo (Voluntis)—Diabeo provides a bolus calculator with a validated algorithm for insulin dosage adjustments based on premeal BG, carbohydrate intake, and anticipated physical activity. It also has an algorithm for adjustment of insulin/carbohydrate ratio and basal insulin doses or insulin pump infusion rates based on postprandial or fasting glucose levels. If the patient desires, data can be uploaded to a Web site for a teleconsultation with a professional. It was initially reported for use by patients with T1DM (including pump users), but can also be used for T2DM. Diabeo does not offer electronic medical record connectivity. It is currently available only in Europe, but its developer has announced plans to introduce this product in the United States.[23] A1C reduction has been reported with this product.[10,11]

Diabetes Diary (Norwegian Centre for Integrated Care and Telemedicine)—Diabetes Diary is a mobile phone app designed for patients with T1DM. The app functions as a bolus calculator and allows wireless transfer of BG values, which is achieved by pairing the mobile phone with a Bluetooth adapter connected to a BG meter. The Diabetes Diary allows BG levels, insulin, food, and activity to be registered. It stores historical data so patients can analyze previous events by searching for similar situations in the database. The events are identified by several factors, including the amount of carbohydrate ingested, time of day, physical activity, and the most recently registered BG, which aids decisions regarding food and medicine. It is available in Europe only. A study has shown A1C level reduction.[13]

Diabetes Interactive Diary (DID) (Meteda)—DID is an iOS app that serves as a logbook for BG, insulin dosing, physical activity, and notes.[14,15] The app also provides a nutritional database for carbohydrate counting and food exchanges. The app contains a built-in insulin dose calculator. When DID is downloaded, it is immediately active as a food diary. In order to become a bolus calculator, it needs to be activated remotely by the health care team, using My Star Connect software. The health care professional sets the insulin/carbohydrate ratio, correction factor, and target BG level. The app allows patients to send text messages to their DM care professionals. All the data and graphs are received and managed through My Star Connect software. DID has obtained a CE mark in Europe and is available through the Apple App store in Italy only. Studies have not shown A1C level reduction[14,15] but have shown improvement in QOL and a reduction in hypoglycemia.[15]

Glooko (iOS and Android)—Glooko is a smartphone app and transmission device for BG meters, CGMs, and insulin pumps that syncs with an HIPAA-compliant server, whose data is shared with the patient's DM care team. Glooko also integrates with many commonly used lifestyle apps and automatically incorporates activity/exercise, blood pressure, and weight data. Patients can use the smartphone app to enter carbohydrate intake, insulin doses, and exercise. The app contains a nutrition database to aid carbohydrate counting. Data are displayed in an integrated fashion using graphs, charts, and trends to allow patients and health care professionals to gain insights needed for management decisions. Glooko is an FDA-cleared app, but no outcome studies have been published.

Glucose Meter–based Mobile Medical Applications

Accu-Chek Aviva Expert (Roche)—Accu-Chek Aviva Expert is a bolus calculator embedded in the Accu-Chek meter. It helps with accuracy of preprandial and correction insulin dosing, reduces stacking, and provides real-time feedback. The meter is indicated for use by individuals with T1DM, and those with T2DM using insulin. There is Web access for health care professionals and patients through Accu-Chek 360 View software to help patients evaluate a 3-day glucose profile to view trends and to learn how activity, food, and treatment affect BG levels. It is FDA cleared in the United States and available with a prescription from a health care professional. Studies have shown improvement in glycemic control and treatment satisfaction.[16,17]

Accu-Chek Connect (Roche)—Accu-Chek Connect is a glucose meter that wirelessly transfers test results to the Accu-Chek Connect app on a smartphone or an online portal. The Bolus Insulin Advisor, which needs to be activated by the patient's health care professional, is an FDA-cleared insulin calculator embedded in the Accu-Chek Connect app. Meal photographs can be attached to any BG result to help check the accuracy for patients learning to count carbohydrates. Results can be shared with a designated other person, such as a parent or caregiver, by using autogenerated texts. The app includes the Accu-Chek 360 View tool software described earlier. Data are automatically uploaded to a health care professional portal for access during and between visits. The Accu-Chek Aviva Connect meter is available at retail stores. Accu-Chek Connect app can be downloaded from Apple App store and Google Play. The use of this bolus calculator has been shown to improve A1C levels.[17]

Dario (LabStyle innovations)—Dario is a coin-sized glucose meter that plugs directly into an Android or iOS phone jack and transmits glucose readings directly to these smartphones using a downloaded app. The Dario app automatically syncs with the Dario meter each time it is connected to the mobile device, and stores the information in the cloud. Through the app, activity or medication data can be entered and there is easy access to tools for insulin bolus calculating and carbohydrate counting. Dario's cloud-based software allows patients to record, save, track, analyze, manage, and share diabetes-related information with caregivers and family members. Dario has obtained FDA clearance in the United States as well as the CE mark in EU. No outcome studies have been published in peer-reviewed literature.

Diabetes Insulin Guidance System (Hygieia)—The Diabetes Insulin Guidance System (DIGS) is a service provided by Hygieia for people with T1DM and T2DM on insulin therapy. Following a visit with a diabetes health care professional, the insulin plan is entered into the d-Nav device, which functions as both a glucose meter and an insulin dose calculator. Patients use the d-Nav device to monitor their BG level before a dose of insulin. Based on the patient's historical BG patterns and insulin dosing, the device automatically adjusts the insulin plan and displays a recommended dose incorporating a correction factor, prandial dose, and insulin on board. As a safety feature, a company service nurse is able to periodically view the data and provide follow-up with patients. This product has a CE mark in Europe. One observational study has shown improvement in A1C.[18]

FreeStyle Insulinx (Abbott)—FreeStyle Insulinx is a bolus calculator embedded in the Insulinx BG meter. The focus is on insulin dosing and real-time feedback. There are 2 modes: the easy mode for a fixed dose of rapid-acting insulin with standard meals, and the advanced mode for carbohydrate counting. The meter is indicated for use by people with T1DM and those with T2DM on insulin therapy. There is Web access for health care professionals and patients through FreeStyle Auto-Assist DM management software. It is not available in the United States. Insulinx has a CE mark in Europe, and is prescribed by health care professionals. Studies have shown improvement in confidence and in the accuracy of prandial insulin dosing.[19,20]

Gmate (Philosys)—The Gmate meter (which is approximately the size of a US quarter dollar) plugs into the headphone jack of an iOS or Android device. The Gmate SMART app, which is downloaded from the iTunes or the Google Play app store, interfaces directly with the phone's operating system. BG results are displayed on the screen of the iOS or Android device. In addition, the data are uploaded to the cloud and can be accessed by a caregiver for real-time patient management. Alternatively, BG results can be emailed or sent via text to the health care team or a single caregiver. This FDA-cleared app is available for iOS, and soon it will be available for Android. No efficacy outcomes have been published in the peer-reviewed literature.

Livongo (Livongo Health)—Livongo is a disease management program that offers coaching support as a covered benefit by health insurance plans. It uses a cellular-enabled, connected BG meter (In Touch) that uploads BG readings and important contextual information (eg, the time of day, the type of meal, and physical activity) in real time to the company cloud system. An instant feedback message tells the patient whether the BG level is in range, and provides tailored educational messages from the American Association of Diabetes Educators (AADE) curriculum. In addition (and if desired), cloud connectivity allows for real-time coaching by certified diabetes educators (CDEs) located in Livongo's call center. It is FDA cleared and also accredited by the AADE Diabetes Education Accreditation Program, indicating that the diabetes self-management education program meets the national standards. No efficacy outcomes have yet been published in the peer-reviewed literature.

Telcare (Telcare)—Telcare is an FDA-cleared BG monitor that uses cellular technology to transmit data directly to an HIPAA-compliant data repository for sharing with the patient's family and health care team. Following each BG check, the meter receives automatic contextual messages to provide feedback. Telcare has its own 3G cellular antenna and automatically uploads BG values to the central cloud system. Users can access their data through a Web browser or use the partner app Diabetes Pal for Android or iOS. Because data are uploaded to the cloud, users do not need to own an Android device or an iOS device. Telcare has been evaluated for use in patients with T1DM, T2DM, and gestational DM (GDM). Users can grant read-only access to family members and full access to health care professionals who are then able to monitor the service and provide messaging. Telcare has shown a potential for cost savings when used with a diabetes management call center in an employer-sponsored disease management intervention.[21] According to a recent press release, when Telcare was used with a recently FDA-cleared software program for outpatient disease and pattern management, Glucommander (Glytec), in a small study a reduction in A1C was noted.[24]

DISCUSSION

The authors reviewed the current status of mobile medical apps with the goal of understanding the content, common design features, evidence for efficacy, and benefits as well as regulatory requirements governing mobile medical apps. This article addresses the following 7 questions.

What Are the Common Characteristics of High-quality Mobile Medical Applications?

The apps that were selected for review based on the outlined criteria (peer-reviewed literature data, FDA clearance, or CE marking) have the potential to benefit individuals with both T1DM and T2DM. Not only do many of the apps function as basal/bolus calculators, incorporating carbohydrate/insulin ratios, but some also provide feedback regarding the insulin regimen or behavior change.

What Are the Benefits of Using Digital Health Applications (What Are the Efficacy Outcomes)?

Despite design features instilling hope for achieving favorable disease management outcomes with digital health apps, limited supporting data are available in the peer-reviewed literature. Fourteen articles published in the past 5 years, summarized in Table 1, evaluated following outcomes.

Efficacy outcomes

- A1C (as a change in A1C level from baseline to end point or the proportion of patients reaching A1C target)[9–11,13–15,17,18,20]
- Self-efficacy (following a healthy eating plan, choosing healthy foods, exercise, confidence in ability to control DM as reported by patients), and self-management[8,12,19,20]
- Change in self-monitoring frequency[16]
- Change in QOL as assessed by diabetes QOL questionnaire[8,14,15]
- Cost of care[21]

Safety outcomes

- Major hypoglycemic episodes (requiring third-party assistance) and minor hypoglycemic episodes (defined as symptomatic hypoglycemia with BG level <70 mg/ dL, self-reported by the participant)[10,14,15,17]
- Fear of hypoglycemia[16]

Historically, the impact on A1C of many digital health systems has been disappointing because of multiple factors. Earlier interventions involved electronic transmission of data that did not incorporate a complete feedback loop with recommendations for actionable treatment or specific behavior changes for the patient to follow. Tele-health remote monitoring interventions that incorporate multiple elements of structured self-monitoring of BG have been shown to be the most effective in achieving A1C level reduction.[25]

Overall, the impact on A1C varies widely from study to study, depending not only on the intervention but on the design, population studied, and baseline A1C level. Some studies reported no improvement in A1C,[14,15] 1 reported a modest A1C reduction,[17] and some reported larger A1C decreases of up to 1.9%.[9,10] However, even modest A1C reductions, of as little as 0.4 percentage points, are all that are required for a new medication to receive FDA approval.[26] In some of the studies it was difficult to distinguish the health care professional effect from the technology effect on the A1C level. Patients receiving Diabeo support via teleconsultation had a greater improvement in A1C than those who did not (−0.93% vs −0.46% respectively).[11] Similarly the Blue Star system showed a greater decrease in A1C level when health care professional support was added to the treatment.[9] The clinical significance of these differences is unclear and there is a need for further studies incorporating analyses of the clinical benefits and economic impact of providing professional support along with mobile diabetes apps. Technology enables productive interactions between patients and the health care teams, so it is useful to design studies that can evaluate digital health interventions as a whole. Furthermore, in studies in which there was a beneficial effect on A1C level, it is unclear whether this effect continued after the study period ended. Similar to A1C data, hypoglycemia outcomes varied widely from study to study, with some showing no improvement[21] and others reporting substantial decrease in hypoglycemia.[15]

Overall, RCTs of mobile apps for diabetes have tended to be underpowered to show a large clinical benefit and have tended to be too short to exclude a novelty effect. Large adequately powered studies of at least a 1-year duration are needed to establish the clinical and economic impacts of this type of intervention.

What Are the Barriers to Mobile Medical Application Adoption?

Limited data are available to answer this question, because none of the studies included in this article were specifically designed to evaluate barriers. However, some indirect observations can be made from the data presented. Ability to afford, use, understand, and adjust to technology are important barriers to consider. Smart-phone apps are easily adopted because today 68% of US adults have a smartphone[27] and the price of most DM apps is modest. The capability to adopt apps associated with BG meters and insulin pumps is likely to depend on insurance coverage for those products. Education level may influence the adoption of apps, as suggested by 56% of Diabeo participants in one study having a university degree.[10] In addition, because smartphone ownership significantly declines after the age of 50 years,[28] age greater than 50 years may be another potential barrier to consider. In a survey of more than 1400 patients evaluating the use of an automated bolus calculator (Accu-Chek Aviva Expert), almost 90% of participants were younger than 50 years.[16] In addition, language is a barrier to consider because most smartphone apps are written in English, which limits access for non–English speakers.

What Are the Regulatory Requirements Governing Mobile Medical Application Use?

All of the 14 mobile apps reviewed have FDA clearance and/or a CE mark, highlighting the issue of regulatory requirements governing certification of apps. FDA guidance on mobile medical apps, released in February 2015, states: “When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.”[29] In a similar way, the European Commission Medical Devices Directive covers the regulatory requirements of the EU for medical devices. Therefore, although FDA/CE clearance is not mandatory for all mobile medical apps, it is the opinion of many prescribing health care professionals that cleared apps may be better than noncleared apps.

What Is the Spectrum of New Innovations Offered via mHealth?

Although technologically the apps appear to be similar, they all offer unique characteristics that may fit individual needs in specific ways. For instance, the bolus calculator feature, which is available in Diabeo, Diabetes Diary, DID, Accu-Chek Aviva Expert, Accu-Chek Connect (Roche), Dario, DIGS, and FreeStyle InsuLinx, may be a particularly desirable feature for patients with T1DM or insulin-treated patients with T2DM, but may not provide value to other patients. In addition, some patients may prefer bolus calculators embedded in meters (FreeStyle InsuLinx, Accu-Chek Aviva, DIGS) versus those available through an app (Diabeo, Diabetes Diary, DID Accu-Chek Connect [Roche]). The data sharing feature, especially one intended for sharing with family members (eg, Blue Star, Dexcom Share, Telcare, Gmate, Dario, Livongo), may offer additional advantages for treatment of children, young adults, patients with intellectual impairment, and those with hypoglycemia unawareness. The ability to share data with the health care team (Blue Star, Diabeo, Glooko, Dexcom Share, Livongo, as shown in Table 2) and the option for real-time feedback by a professional (Diabeo, DID, Livongo, Telcare) provide an additional layer of safety.

Apps that do not necessarily require ownership of smartphones (eg, apps embedded in the Accu-Chek Aviva, Telcare, DIGS d-Nav device, FreeStyle InsuLinx, Livongo) provide a particular advantage to patients who do not own an Android or iOS device. In contrast, the design of some new meters (Gmate, Dario) challenges the traditional concept of a meter as a device that displays a BG value. With their exceptionally small size and close integration with smartphones, they turn the smartphone into a meter.

Education features are innovative, from standardized feedback messages available on many apps to the ability to attach mealtime photographs to BG (Accu-Chek Connect [Roche]), which can further help estimate adequacy of carbohydrate counting.

Perhaps the most intriguing (and least intuitive) innovation that the new technology offers is the creation of new medical management paradigms and business models that emerge with the development of technology. The Telcare glucose meter has been combined with a disease management call center and offered as an employer-sponsored benefit. Livongo has created a new disease management and business model by offering a comprehensive program that encompasses access company–employed CDEs for a BG review and feedback as needed, through services that are covered by the participating insurance company. Glytec offers integrated outpatient technology with computerized glucose management decision support software (Glucommander) based on glucose data from the Telcare cellular-enabled meter. This system can effectively adjust insulin therapy.

What Is Desired for the Future of Mobile Medical Apps?

Technology is continuing to develop and adoption of medical mobile apps is becoming widespread, which provides an opportunity to consider the requirements for future app designs and research. A useful app cannot be merely a static repository of information; it must provide real-time feedback to the patient independent of the health care professional and foster a complete feedback loop.[30] In addition, the ability to integrate and analyze multiple sets of data is needed (in addition to that obtained from glucose meters), such as from sensors measuring exercise, sweat, and cardiovascular physiology. Interoperability is needed to allow all devices to communicate and be compatible with each other and with electronic medical records. For health care professionals, work flows and time constraints as well as reimbursement for time spent reviewing the data need to be considered. The capability of apps to provide real-time feedback without health care professionals' input in real time provides a potential solution to this dilemma, but raises the issue of safety and accuracy as well as liability in the event of a risky recommendation by the software program.

What Are the Directions for Future Research?

Most studies evaluated short-term outcomes, thus a longer-term impact on glycemic control and A1C levels needs to be evaluated. Clinicians need to know whether the A1C outcomes seen in initial studies are sustainable over time, after the excitement over novel technology subsides. In addition, it is important to find whether (and to what degree) some interaction with a health care professional is needed for the A1C benefit to be achieved.

Other outcomes, including incidence of hypoglycemia, time in range, QOL, and self-management behaviors, are equally important to evaluate. Additional studies need to be conducted to determine the features that improve adoption and the needs of special populations, including children and older adults.

In conclusion, several mobile medical apps are available to patients with DM on various platforms. In general, the 3 main features of these apps are (1) guidance for insulin management via a dose calculator, (2) feedback based on BG pattern analysis independent of the health care team, and (3) data sharing with family and health care professionals. Mobile medical apps have been shown to positively affect outcomes, including A1C level. More long-term studies are needed to identify best practices and evaluate the sustainability of the effects of technology on A1C level and hypoglycemia. Consumers need practical evidence-based guidance when selecting the best mobile medical app for their specific needs. Until more data are available, consumers and health care professionals can consider guidance based on FDA/CE status. Digital technology and mobile medical apps, when incorporated within an expanded mHealth enhanced chronic care model, can revolutionize diabetes management.[31] Patients with diabetes need to self-manage. Mobile medical apps that can increase the frequency and value of feedback to initiate behavior change or treatment adjustment may affect the clinical outcomes, and more importantly QOL, of patients living with diabetes. Diabetes is a dynamic condition needing more than glycemic management alone to improve health quality. In future, the glucose-oriented apps that are reviewed here will need to be integrated with other health-related apps to be even more effective.

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KEY POINTS

- Many mobile medical applications (apps) are available to consumers with diabetes, but only 14 currently have clinical outcomes data published in the peer-reviewed literature or have been cleared by the US Food and Drug Administration or have received a Conformité Européenne (CE) mark in Europe.
- Apps provide guidance for insulin management and feedback based on blood glucose pattern analysis, and can permit data sharing with family members and health care professionals.
- Apps can positively affect such outcomes, such as hemoglobin A1C, hypoglycemia incidence, and diabetes self-care measures.

Table 1

Summary of commercially available mobile medical apps for DM management (N = 14)

Name	Platform	Function/Description	End User	Data Collection	Connectivity: Cloud Web EMR Communication	Availability/Regulatory	Clinical Evidence/Reference
Blue Star by WellDoc	App (Android and iOS) or Web based	• Real-time feedback • Touch point messages • Video education • Education library • Longitudinal reporting • The Easy Carb Education library • The Easy Carb Estimator and Restaurant Helper to support healthy eating	T2DM	Manual data entry into app Automatic BG entry with Bluetooth adapter	Cloud: yes Web: yes EMR: no Can send reports to provider	FDA cleared in United States Needs MD Rx	A1C reduction[9] Improvement in self-efficacy[8]
Dexcom Share	App (iOS) for Share (upload to cloud)	Share real-time CGM data with followers	T1DM; T2DM	Dexcom G4 Platinum CGM uploads data to cloud via Bluetooth-enabled receiver	Cloud: yes Web: yes EMR: no	FDA cleared in United States	None
Diabeo	App (Android and iOS)	• Bolus calculator • Adjusts for exercise • Basal bolus pattern recognition • Real-time feedback	T1DM; T2DM on insulin	Manual data entry into app	Cloud: no Web: yes for MD EMR: no Patient can communicate with provider for real-time assistance	Developed in France CE marked in EU	A1C reduction[10–12]
Diabetes Diary	App (Android and iOS)	• Bolus calculator • Tracks BG level, insulin, food, and activity • Provides historical data to facilitate decision making	T1DM	Manual data entry Automatic BG entry with Bluetooth adapter	Cloud: no Web: no EMR: no	Developed in Norway CE marked in EU	A1C reduction[13]
Diabetes Interactive Diary (DID) (Il Diario Interattivo per il Diabete)	App (iOS)	• Logbook for blood sugar, insulin dosing, and events • Nutritional database for counting carbohydrates • Food exchange data • Insulin dose calculator • Physical activity diary	T1DM	Manual data entry • BG • CHO selection • Physical activity	Cloud: no Web: no EMR: no Other: SMS sent to diabetes provider	Developed in Italy CE marked in EU	No A1C reduction[14,15] Improved QOL[14] Reduction in hypoglycemia[15]

Name	Platform	Function/Description	End User	Data Collection	Connectivity: Cloud Web EMR Communication	Availability/Regulatory	Clinical Evidence/Reference
		• Annual screening reminder • SMS to diabetes provider					
Glooko	App (Android and iOS)	• Downloads diabetes data from 401 meters, insulin pumps and CGMs • Integrates health and fitness apps • Nutrition database for CHO counting • Data sharing with providers • Analytics data on clinic population for providers • Hypoglycemia prediction algorithms • Reminders	T1DM/T2DM	BG upload data via cellular network and MeterSync Blue cable Dexcom CGM data obtained via Apple HealthKit Obtains data from fitness tracking devices	Cloud: yes Web: yes EMR: yes Can email, print, or fax standardized reports to provider	FDA cleared in United States	None
Accu-Chek Aviva Expert	Glucose meter	• Bolus calculator embedded in the meter • Accounts for CHO and insulin on board • Minimizes insulin stacking	T1DM; T2DM on insulin	Glucose data automatic Hand enter CHO and insulin dose	Cloud: no Web: yes Accu-Chek 360 diabetes management software for MD and patient EMR: no	FDA cleared in United States Needs MD Rx	ABACUS 1 RCT clinical trial with A1C reduction[17] Survey results[16]
Accu-Chek Connect (Roche)	Glucose meter and app (Android and iOS or Web based)	• Integrated meter, app, and online portal • Meter automatically transmits data to app • App incorporates bolus calculator • Data shared with health care provider	T1DM; T2DM	Glucose data automatic Hand enter CHO and insulin dose Meal photographs can be attached to BG	Cloud: no Web: yes Uses Accu-Chek 360 View tool for 3-d profile EMR: no	FDA cleared in United States Needs MD Rx	Bolus calculator studied in ABACUS 1 trial[17]
Dario	Glucose meter app (Android and iOS)	• Downloads BG when connected to a smartphone • App contains insulin calculator • Can chart CHO intake, insulin doses, notes • Share results with family, provider	T1DM; T2DM	Glucose data automatic Nutrition, activity, insulin doses manual	Cloud: yes Web: yes	FDA cleared in United States CE marked in EU	None

Name	Platform	Function/Description	End User	Data Collection	Connectivity: Cloud Web EMR Communication	Availability/Regulatory	Clinical Evidence/Reference
Diabetes Insulin Guidance System	Glucose meter	• Bolus calculator • Adjusts insulin dosing plan based on historical data • Uses time of day to suggest CHO bolus	T1DM; T2DM on insulin	Glucose data automatic Initial insulin dosing entered manually	Cloud: no Web: no EMR: no Other: connect device to computer to download data	CE marked in EU	A1C reduction, decreased hypoglycemia[18]
FreeStyle InsuLinx	Glucose meter	• Bolus calculator embedded in the meter • Easy mode for fixed CHO meals • Advanced mode for CHO counting • Real-time feedback • Trending reports	T1DM; T2DM on insulin	Glucose data automatic Hand enter CHO	Cloud: no Web: yes FreeStyle Auto-Assist diabetes management software for MD and patient EMR: no	CE marked in EU Needs MD Rx	More accurate meal bolus[19] Confidence in bolus calculation[20]
Gmate	Glucose meter App (Android and iOS)	Downloads BG when connected to a smartphone BG	T1DM; T2DM	Glucose automatic nutrition, activity manual	Cloud: yes Web: yes EMR: yes Data sharing with family, provider via texts, email	FDA cleared in United States	None
Livongo	Glucose meter (In Touch) App (Android and iOS)	• Cellular-enabled glucose meter with touch screen • Tags meals, exercise, medications • Real-time scripted feedback about BG • Displays logbook and patterns • Share results with family, provider, and coach via touch screen	T1DM; T2DM	Glucose and activity data automatically uploaded via cellular network	Cloud: yes Web: yes EMR: yes Patient can communicate with CDE for real-time assistance	FDA cleared in United States	None
Telcare	Glucose meter App (Android and iOS) Web portal	• Cellular-enabled glucose meter • Uploads BG automatically to cloud and from there to Web or smartphone • Real-time contextual feedback via text messages • Share data with diabetes care provider	T1DM; T2DM; GDM	Glucose data automatic	Cloud: yes Web: yes EMR: yes	FDA cleared in United States	Potential for cost savings when used with disease management program[21] A1c reduction when used with FDA-cleared glucose management software Glucommander[24]

Name	Platform	Function/Description	End User	Data Collection	Connectivity: Cloud Web EMR Communication	Availability/Regulatory	Clinical Evidence/Reference
		• Two-way text messaging between patient and health care professional					

Abbreviations: ABACUS, Automated Bolus Advisor Control and Usability Study; CDE, certified diabetes educators; CGM, continuous glucose monitoring; CHO, carbohydrate; EMR, electronic medical record; GDM, gestational DM; iOS, iPhone operating system; MD, Doctor of Medicine; Rx, therapy; SMS, short message service.

Table 2

Summary of 14 published studies evaluating mobile medical apps in the period January 2010 to December 2015

Author, (Reference), Year	Design Country Time Frame	Sample Type of Diabetes Mean Age	*Platform/Name* I and C Groups	Outcome Measures	Main Results
Barnard,[16] 2012	Survey United Kingdom 4–12 wk	n = 1412 T1DM <18–70 y	• Glucose meter app: Accu-Chek Aviva Expert • Survey 270 hospitals • Patients using Accu-Chek Aviva Expert BG meter for at least 4 wk • Bolus advisor with integrated BG meter • Electronic log book		• 588 (41.6%) responded • 80% (n = 456) ↑ ability to act on SMBG data • ↑ of 28% in frequency of checking BG 4–5 times/d (n = 257–331) • ↑ of 42% in frequency of checking BG >6 times/d (n = 133–189) • ↓ fear of hypoglycemia
Bergenstal et al,[18] 2012	Observational United States 3 mo	n = 46 T1DM and T2DM (T1DM 43%)	• Glucose meter app: DIGS by Hygeia • DIGS provides weekly insulin dose adjustment based on sugar patterns 3 groups: • I: T1DM on basal bolus • II: T2DM on basal bolus • III: T2DM on twice-daily premixed insulin	Primary: % dose adjustments approved by study team Secondary: ↓ in mean BG A1C	• 99.9% DIGS adjustments approved • ↓ A1C 0.5% (P<.05)
Charpentier,[10] 2011	RCT TeleDiab 1 France 6 mo	n = 180 T1DM 33 y	• Smartphone app: Diabeo • Diabeo software with basal and prandial insulin dose advisor • 3 groups (G1, G2, G3) C: G1 paper log book with in-person visit at 3 and 6 mo I: 2 groups • G2 Smartphone with electronic logbook with in-person visit at 3 and 6 mo • G3 Smartphone with electronic logbook 1 teleconsultation every 2 wk and visit at 6 mo	Primary: A1C	• A1C ↓ 0.91 G3–G1 (P≤.001) • A1C ↓ 0.67 G2–G1 (P≤.001) • No difference in hypoglycemia • G1 and G2 had 5-h ↑ hospital appointments

Author, (Reference), Year	Design Country Time Frame	Sample Type of Diabetes Mean Age	*Platform/Name* I and C Groups	Outcome Measures	Main Results
Franc,[12] 2012	Observational France 4 mo	n = 35 T1DM 39 y	• Smartphone app: Diabeo • 1 group • Diabeo Software on smartphone with electronic logbook • Insulin bolus calculator using BG, CHO, and physical activity to suggest mealtime insulin dose • Algorithm calculated a 30% to 50% reduction in prandial insulin for the meal closest to the physical activity based on intensity of activity reported.	Primary: mean BG	• Significant ↑ in 2-h PPBG after physical activity ($P<.042$) • Returned to FBS/premeal levels by next meal ($P=.29$) • No difference in hypoglycemia with or without physical activity
Franc,[11] 2014	Post hoc analysis of TeleDiab 1 France 6 mo	n = 180 T1DM 33 y	• Smartphone app: Diabeo • See description of TeleDiab 1 Charpentier, 2011 • G1 high system users (greater than the median) • G2 low system users (less than the median)	Primary: high users vs low users on A1C and impact of teleconsultation	• High users had lower A1C at baseline ($P=.008$) and more familiar with CHO counting ($P\leq.001$) • High users ↓ A1C 0.05% with no difference between G2 and G3 ($P=.89$) • Low users ↓ A1C 0.93% in G3 vs 0.46% in G2 ($P=.084$)
Javitt,[21] 2013	Retrospective	n = 141 T1DM and T2 DM GDM	• Glucose meter app: Telcare • I: used Telcare for bolus calculations and call center monitoring for those with high or low BG • C: did not use product	Primary: change in allowed claims	↓ for $1600/y per person who used the product
Quinn,[9] 2011	Cluster RCT United States 12 mo	n = 163 T2DM 53 y	• Smartphone app: Blue Star WellDoc C: UCI: 3 groupsG1 • Mobile phone hand enter BG, CHO, medications • Automated real-time feedback with virtual coaching G2: • No analysis of log book data • No PCP Web access to log book	Primary: A1C	A1C ↓ 1.2% G4–UC ($P<.001$)

Author, (Reference), Year	Design Country Time Frame	Sample Type of Diabetes Mean Age	*Platform/Name* I and C Groups	Outcome Measures	Main Results
			G3: • PCP access to log book data via Web portal G4: • SMBG real-time analysis with feedback using computerized decision support • PCP receives summary via fax or email • Fax or email to review an analyzed report of all patients		
Quinn,[8] 2015	Observational United States 1 mo	n = 7 T2DM 70 y	• Smartphone app: Blue Star WellDoc • 1 group • Entered glucose and self-care data and received automated feedback	Primary: self-efficacy SF-36 Depression	Trends in improvement in self-efficacy (P = .2), SF-36, and depression (P = .043)
Rossi,[14] 2010	RCT Italy United Kingdom Spain 6 mo	n = 130 T1DM 36 y	• Smartphone app: DID I: DID software installed in patient's smartphone that works as a CHO/insulin bolus calculator • Data sent to MD every 1–3 wk, reviewed, and new regimen texted to the patient C: received traditional education on CHO counting and bolusing (were not previously educated)	Primary: A1C Secondary: QOL Satisfaction with Rx Hypoglycemia	• No difference in A1C • No severe hypoglycemia in either group • Improved in some mental health components • Improved treatment satisfaction (P = .04)
Rossi,[15] 2013	RCT Italy 6 mo	n = 127 T1DM 37 y	• Smartphone app: DID I: DID software installed in patient's smartphone that works as a CHO/insulin bolus calculator • Data sent to MD every 1–3 wk, reviewed, and new regimen texted to the patient C: received traditional education on CHO counting and bolusing (were not previously educated)	Primary: A1C Secondary: glucose variability Mean daily insulin dose Hypoglycemia	• No difference in A1C (A1C ↓ 0.5% both groups, P = .73) • I: lower mean insulin dose (P = .04) • No reduction in glycemic variability • 86% decrease in severe hypoglycemia (requiring third-party assistance)
Skrovseth,[13] 2015	RCT Norway 6 mo	n = 30 T1DM 40 y	• Smartphone app: DD • DD is a bolus calculator in its basic version. Dia-stat module can be added to allow a wireless transfer of BG values	Primary: number of hypoglycemia and hyperglycemia events Secondary: A1C	• No difference in A1C or out-of-range BG

Author, (Reference), Year	Design Country Time Frame	Sample Type of Diabetes Mean Age	*Platform/Name* I and C Groups	Outcome Measures	Main Results
			via Bluetooth and feedback module with BG graphs, trends I: DD 1 Diastat C: DD		• All patients had ↓ A1C 0.6% (*P* = .001)
Sussman,[19] 2012	Observational United States 1 d	n = 205 T1DM and T2DM (T1DM: 48%) 51 y	• Glucose meter app: FreeStyle InsuLinx • 1 group • 2 modes of operation: easy mode with fixed doses of rapid-acting insulin; advanced mode for patients who count CHO and calculate insulin doses • Subjects had to calculate 2 prandial insulin doses: manually and via FreeStyle InsuLinx • Compared accuracy of bolus calculation	Primary: frequency of insulin errors	• 63% (n = 256) manually calculated doses were incorrect • 10 times fewer errors using meter (*P*<.0001)
Ziegler,[17] 2013	RCT United Kingdom Germany 6.5 mo	n = 193 T1DM (93%) 42 y	• Glucose meter app: Accu-Chek Aviva Expert C: Enhanced UC • Standard glucose meter, manual bolus calculation per individualized parameters • 7-point BG profiles over 3 d • Clinic visits focusing on diabetes care • BG data downloaded for therapy adjustments I: • Accu-Chek Aviva Expert meter with integrated bolus advisor to calculate insulin dosages • 7-point BG profiles over 3 d • BG data downloaded for therapy adjustments • Prandial and correction bolus recommendations based on BG, CHO intake, and individualized therapy	Primary: A1C Secondary: hypoglycemia	• ↓ A1C 0.2% (I – UC) (*P*<.05 1 sided) • 56% (C) vs 34.4% (I) had >0.5% A1C reduction (*P*<.01) • Improved treatment satisfaction (11.4% vs 9%; *P*<.01) • ↑ hypoglycemia in I compare to UC (*P*<.05)

Author, (Reference), Year	Design Country Time Frame	Sample Type of Diabetes Mean Age	*Platform/Name* I and C Groups	Outcome Measures	Main Results
Neil,[20] 2014	Observational United States 6 mo	n = 203 T1DM and T2DM (T1DM: 64%) Age not reported	• Glucose meter app: FreeStyle InsuLinx • One group • 2 modes of operation: easy mode with fixed doses of rapid-acting insulin; Advanced mode for patients who count CHO and calculate insulin doses	Primary: A1C Secondary: Confidence	• ↓ A1C 0.17% (P = .033) • ↑ confidence in insulin calculation(P<.01)

Abbreviations: C, control; DD, Diabetes Diary; DID, Diabetes Interactive Diary; DIGS, Diabetes Insulin Guidance System; FBS, fasting blood sugar; I, intervention; PCP, primary care physician; PPBG, postprandial blood glucose; SF-36, Short Form 36; SMBG, self-monitoring BG; UC, usual care.