Leveraging Technology to Improve Diabetes Care in Pregnancy

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Pregnant women with diabetes are at higher risk of adverse outcomes. Prevention of such outcomes depends on strict glycemic control, which is difficult to achieve and maintain. A variety of technologies exist to aid in diabetes management for nonpregnant patients. However, adapting such tools to meet the demands of pregnancy presents multiple challenges. This article reviews the key attributes digital technologies must offer to best support diabetes management during pregnancy, as well as some digital tools developed specifically to meet this need. Despite the opportunities digital health tools present to improve the care of people with diabetes, in the absence of robust data and large research studies, the ability to apply such technologies to diabetes in pregnancy will remain imperfect.

Diabetes is a global health problem affecting ~60 million women of reproductive age (18–44 years of age) (1). Diabetes during pregnancy, whether preexisting or gestational diabetes mellitus (GDM), confers significant risk to women and their offspring. Pregnant women with diabetes have higher rates of iatrogenic preterm birth (2), preeclampsia, gestational hypertension (3,4), and cesarean delivery (5) compared with gravidae without diabetes. In addition, babies born to individuals with diabetes in pregnancy have greater susceptibility for growth abnormalities, neonatal hypoglycemia, hyperbilirubinemia, shoulder dystocia, and stillbirth (6).

Studies of human pregnancies and research conducted in animal models of diabetes in pregnancy have revealed that hyperglycemia is a causative factor for adverse maternal and neonatal outcomes (7). Maintaining good glucose control (euglycemia) has been shown to mitigate these effects. However, euglycemia is difficult to sustain because pregnancy is characterized by physiological insulin resistance, hyperglycemia, and carbohydrate intolerance as a result of diabetogenic placental hormones (8). In women with normal pancreatic function, insulin production is sufficient to meet this challenge; in women with diabetes, hyperglycemia occurs if treatment is not adjusted appropriately and frequently.

Successful pregnancy outcomes in the context of diabetes require reducing A1C, decreasing glycemic variability, and increasing the amount of time spent within a target glycemic range. To attain these clinical goals, women must monitor their blood glucose more frequently, improve their nutrition habits, and enhance their physical activity levels. In addition to comprehensive blood glucose monitoring (BGM), women with diabetes in pregnancy are expected to attend more frequent in-office health care visits than expectant mothers without diabetes. Patients describe significant burdens associated with the testing and reporting of blood glucose values in pregnancy, as well as increased demands of attending in-person health consultations (9,10).

For women whose access to high-quality care is limited, diabetes in pregnancy presents an even greater challenge. Minority women and those of lower socioeconomic status are often disproportionately affected by both preexisting diabetes and GDM and have higher rates of diabetes-associated morbidity and mortality (11). Given that women from these vulnerable populations already experience greater rates of preterm birth, stillbirth, and maternal mortality (12,13), observance of the often-stringent BGM, medication modification, and face-to-face mediation regimens essential to reducing diabetes-associated adverse pregnancy outcomes can be difficult

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to achieve or maintain and, in some cases, may be unattainable.

Technological innovations, including smartphone applications (apps) and cellular-enabled blood glucose monitors, present opportunities to improve the delivery of care for all women with diabetes in pregnancy. In addition, artificial intelligence and telemedicine can offer an alternative to in-office visits, extending the reach of diabetes education and support while maintaining standards of care (14). Specifically, apps that aid in managing diabetes in pregnancy have the potential to significantly increase patient engagement. Approximately 92% of reproductive-age women in the United States have smartphones, with usage consistently high (66–95%) across racial/ethnic groups and socioeconomic classes (15). Leveraging the availability and pervasiveness of smartphones has empowered patients to become more proactively engaged in their health care and dramatically changed medical practice and biomedical research (16). In the nonpregnant population, cellular-enabled blood glucose monitors that transmit results in real time to a health care provider (HCP) have improved both glycemic control and patient satisfaction in the self-management of diabetes (17,18). Translating these successes into novel solutions for pregnant women with diabetes could help to achieve the ultimate goals shared by patients and their care: positive maternal and neonatal outcomes.

Here, we focus on mobile health (mHealth) apps and their applicability to the management of diabetes in pregnancy. We describe some of the core considerations when evaluating an app for use in patient care, discuss a number of apps developed specifically for diabetes self-management during pregnancy, and summarize key findings from the literature.

Functionality and Acceptability of mHealth Apps

mHealth is a growing field, and apps have been developed to address a variety of diseases and chronic conditions. Of the >400,000 mHealth apps currently available, ~7% are related to women's health (19), and ~16% are designed for diabetes management (20). The most common categories of pregnancy apps include pregnancy trackers, weight management, pregnancy education data collection, communication, and electronic health records (21,22).

Despite the diversity and quantity of pregnancy-related mHealth offerings and the considerable potential these solutions have for improving pregnancy management, few meet criteria for clinical use during antenatal care (23). Differentiating between helpful and not-so-helpful mHealth apps can be challenging for patients and their HCPs. Patient and HCP priorities concerning apps also may differ. Whereas a patient might focus on cost or specific features, an HCP might prefer a particular app for its built-in decision-making algorithm, ease of data transfer, or integration into an electronic health record (EHR) (24). Ultimately, apps that meet the needs of both patients and HCPs (functionality) will have the best chance for adoption during care (acceptability).

Accessibility, ease of use, and versatility are key factors to improving patient adoption and satisfaction. Carter et al. (25) examined these factors by performing a scoping review of studies that reported results on apps used to support clinical decision-making in pregnancy. Their analysis included both patients' and HCPs' perspectives regarding these key factors.

From the patients' perspective, apps that included picture or video tutorials for those with low literacy and apps available in multiple languages improved self-monitoring, thereby increasing accessibility (26–28). Apps that featured simple forms for inputting data and on-phone user manuals, as well as the convenience of managing diabetes via a smartphone, also enhanced patients' views regarding ease of use (25). In terms of versatility, capability to set medication reminders or appointment alerts or to connect to other health monitoring devices such as digital scales, blood pressure cuffs, pulse oximeters, or blood glucose meters, were noted as important app attributes (25). Importantly, Carter et al. (25) found that the use of apps improved patients' sense of support, trust, and confidence in HCPs, in part because the apps allowed patients to communicate more frequently and directly with their care teams.

From the HCPs' perspective, a vital component to improving accessibility was the ability to increase communication—either between the patient and practitioner or between members of the care team—through in-app or text messaging or via phone calls (27,29). Using mHealth apps to facilitate client education and behavioral change has been well studied as a means to provide prenatal care (21). Apps that can deliver information about warning signs or birth preferences or that encourage patients to log activities help practitioners identify priorities for in-office visits and further increase patient engagement with and adherence to care (30).

Based on their analysis, Carter et al. (25) found that the main features of mHealth apps that increased ease of use for the health care team included automatic validation and transfer of data and the ability to involve less educated staff or community health workers in front-line care, with support from experts. All of these steps served to streamline and personalize patient care. In terms of versatility, apps designed to take patient input and data collected from connected health monitoring devices or the smartphone's camera and apply this information to statistical modeling or decision trees to make recommendations for treatment were all deemed of value by HCPs (26,31). In addition, automatic transfer of data to EHRs allows HCPs to review patients' records in advance of appointments or alerts clinicians of concerns that could then be communicated directly with patients or other local HCPs (25).

Importantly, delivering care through mHealth apps allowed patients to provide feedback to the health care team to improve the end-user experience and gave HCPs an opportunity to modify management plans to better address patients' needs (25).

mHealth Apps Related to Diabetes

The types of digital health apps intended to augment management of diabetes in nonpregnant individuals include closed-loop control systems (discussed later), glucose monitoring apps, insulin device apps, insulin titration apps, nutrition apps, and physical activity apps (Table 1).

Glucose monitoring apps log blood glucose data from an external device such as a glucose meter or a continuous glucose monitoring (CGM) system, and display information in a graph format to assist patients and clinicians in analyzing readings to improve blood glucose control. Insulin delivery apps connect to insulin pumps and smart pens to collect and display data for bolus calculations, which are then available for download by clinicians. The Medtronic and Tandem Diabetes apps use real-time CGM data to reduce the frequency and duration of hypoglycemia. Insulin titration apps, some of which are approved by the U.S. Food and Drug Administration (FDA), integrate bolus calculations with the use of glucose meters to allow patients to calculate basal, prandial, and correction insulin doses. Nutrition apps and physical activity apps track eating habits, encourage physical activity, and increase medical engagement. There are numerous nutrition and exercise apps available; the choice of app should be left to patients because preference will determine consistency of use. However, none of the nutrition or physical activity apps are FDA-approved or are specially designed for women with preexisting diabetes or GDM. Therefore, careful review by HCPs and patients should be performed before their use.

Evidence-Based Apps for Managing Diabetes During Pregnancy

Unfortunately, although the field of digital health apps has grown exponentially in the past few years, there remain limited mHealth tools designed for women with preexisting diabetes who become pregnant or for those who develop GDM. There are complex reasons for this dearth.

For patients with diabetes during pregnancy and their HCPs, tightly managing blood glucose is crucial to achieving the best maternal and neonatal clinical outcomes. However, the physiologic adaptations of pregnancy include dramatic changes in glucose metabolism, which, even in women without diabetes, lead to fasting hypoglycemia, postprandial hyperglycemia and hyperinsulinemia, reduction in basal glucose metabolism, and decreased peripheral insulin sensitivity. Any app with an automated algorithm would need to take into account these metabolic alterations as a baseline and then make recommendations for therapy.

In addition, type 1 diabetes, type 2 diabetes, and GDM have different etiologies, associated comorbidities (although some overlap exists), and pharmacologic intervention options (32). Maternal characteristics will also influence pregnancy management. The approach used for a woman with a BMI $\geq$40 kg/m^2 who develops GDM would not be the same as the approach used for a woman with a BMI in the normal range and type 1 diabetes who becomes pregnant. There are limited large clinical trials enrolling pregnant participants and even fewer that include gravidae with diabetes, which makes analyzing data difficult. Furthermore, many—if not most—app developers are not medical experts, and many mHealth apps are not created with patients or HCPs in mind, but rather for general consumers (33).

Despite these obstacles, a number of available apps are purported to aid in managing diabetes in pregnancy, some of which have been tested in clinical trials (Table 2). Evaluations of apps for their utility in pregnancy have focused on how well they improve certain patient behaviors such as compliance with blood glucose reporting, which subsequently can have a significant impact on maternal and fetal outcomes such as incidence of preeclampsia, cesarean section, large-for-gestational-age status, and perinatal morbidity and mortality (34). However, the impact of app use on maternal and fetal outcomes has yet to be studied.

BGM is an essential part of glycemic management for all people with diabetes. One of the major barriers to successful management of diabetes in pregnancy is variability

TABLE 1 Selected mHealth Apps to Manage Diabetes

Category	mHealth App	Platform	Uses/Features
Closed-loop control systems	Control-IQ	Android and iOS	Connects to Tandem t:slim ×2
	Guardian Connect	Android and iOS	Connects to Medtronic MiniMed 670G
Glucose monitoring	Dexcom Diabetes Companion FreeStyle LibreLink Glooko Mobile mySugr Tidepool Loop	Android and iOS iOS Android and iOS Android and iOS Android and iOS iOS	Log blood glucose from external glucose meter or CGM system; display data graphically
Glucose tracking	Dario Diabetes Sugar Sense	Android and iOS Android and iOS	Track blood glucose and insulin doses; share data with HCP
Insulin delivery	Companion Medical InPen MiniMed Connect Tandem t:simulator*	Android and iOS Android and iOS Android and iOS	Collect and display data for insulin dosing and bolus calculations; data available for clinician download
Insulin titration	BlueStar Diabetes Glooko Mobile My Dose Coach Insulia	Android and iOS Android and iOS Android and iOS Android and iOS	Integrate bolus calculations with use of glucose meter; calculate basal, prandial, and correction insulin doses
Nutrition	BiteSnap Calorie King Calorie Mama Carbs + Cals Foodility Fooducate Go Meals Healthy Out	Android and iOS Android and iOS Android and iOS Android and iOS iOS Android and iOS Android and iOS Android and iOS	Look up calories, carbohydrates, protein, and fats to assist with meal planning and tracking
Physical activity	Aaptiv Baby2Baby Prenatal Workout StrongHer	Android and iOS Android and iOS Android and iOS Android and iOS	Track activity, motivate, and set goals

*App for smartphone is only a simulation of actual pump user interface and is not connected to a medical device.

in patient self-reporting of BGM results (35,36). Because CGM use in pregnant women is not a standard of care, use of mHealth apps to improve patients' BGM is appealing.

Five apps have been evaluated to date: Dnurse (37), GDm-health (38), Glucose Buddy (39), MobiGuide (40), and Pregnant+ (41) (Table 2). In these trials, app use was compared against routine, in-office prenatal counseling for women with GDM. Outcomes included patient compliance with blood glucose reporting, change in mean blood glucose, and evidence of persistent diabetes after a pregnancy complicated by GD. However, the impacts of these apps on cost-effectiveness and on rates of cesarean delivery, preeclampsia, macrosomia, or neonatal morbidity were not evaluated.

Guo et al. (37) evaluated the Dnurse app and demonstrated a significant difference in compliance with blood glucose reporting. Rigla et al. (40) reported that women who used MobiGuide had a higher number of daily blood glucose values reported (1.01 ± 0.1 vs. 0.87 ± 0.3, $P < 0.05$) compared with that observed in a historical cohort, although this increase in compliance did not translate into a reduction in mean blood glucose levels to <140 mg/dL. Women with GDM who used the GDm-health app had more BGM readings than those receiving standard care (3.80 ± 1.80 vs. 2.56 ± 1.71 readings per day, respectively; $P < 0.001$) (38). Miremberg et al. (39) compared routine in-office prenatal care visits with use of the Glucose Buddy app, which provided daily communication between patients and HCPs. They demonstrated an 18% improvement in BGM compliance between the control and intervention groups in the study period ($66 \pm 0.28\%$ vs. $84 \pm 0.16\%$, respectively; $P < 0.001$). Although women who participated in the trial evaluating the Pregnant+ app began using the app during pregnancy (at <33 weeks' gestation), the trial was designed to measure delivery and postpartum characteristics and did not collect data on behaviors during pregnancy (41). The discrepancy in the impact of these mHealth apps on blood

TABLE 2 Trials of mHealth apps for GDM Management and Selected Outcomes

App	Study Design	Participants, *n*	Groups	Primary Outcomes
Dnurse (37)	Nonblinded RCT	124 total: 60 control, 64 intervention	Usual care (control); Dnurse app and usual care (intervention)	*Compliance with blood glucose reporting
GDm-health (38)	Nonblinded RCT	203 total: 85 control, 98 intervention	Usual care (control); GDm-health app (intervention)	Change in mean blood glucose (study recruitment through delivery)
Glucose Buddy (39)	Nonblinded RCT	120 total: 60 control, 60 intervention	Usual care (control); Glucose Buddy app and usual care (intervention)	Compliance with blood glucose reporting
MobiGuide (40)	Pilot study	20 intervention†	Historical cohort with usual care (comparison); technology-enabled care (intervention)	Feasibility and acceptability of mobile decision-support system
Pregnant+ (41)	Nonblinded RCT	238 total: 123 control, 115 intervention	Usual care (control); Pregnant+ app and usual care (intervention)	2-hour blood glucose level on postpartum oral glucose tolerance test

*No primary outcomes indicated for study; however, patient compliance emphasized as key finding. †No control group included in study. Historical cohort used as comparison with intervention group. Size of cohort not reported. RCT, randomized controlled trial.

glucose reporting compliance (Dnurse and MobiGuide vs. GDm-health and Glucose Buddy) lies in the different app characteristics, study populations, and standard-of-care treatment in the historical control groups. In practice, any tool that improves patient-provider communication and self-reporting of blood glucose will result in improved glycemic management and, in turn, improved outcomes.

In addition to significantly improving patients' BGM usage, mHealth apps resulted in other benefits for patients in the intervention arms of these trials (Table 3). Women who used Dnurse, which also provides education on weight management and exercise, demonstrated significantly less weight gain compared with those receiving usual prenatal care (37). In addition, the Dnurse group had a lower frequency of outpatient care, lower A1C before delivery, and lower rates of off-target fasting and 2-h postprandial glucose measurements (37). MobiGuide includes a feature that integrates a glucose meter and blood pressure cuff, via Bluetooth, with the app. Accordingly, women who used MobiGuide had significantly lower systolic and diastolic blood pressure levels (P <0.001 for both) compared with the control cohort (40). The investigators who evaluated the use of GDm-health reported that patients in the app group had fewer cesarean deliveries (26.7 vs. 46.1%, P = 0.005) and lower rates of preterm birth (5.0 vs. 12.7%, odds ratio 0.36, 95% CI 0.12–1.01) than women in the control group (38). Use of Glucose Buddy resulted in a reduced need for insulin (13.3 vs. 30.0%, P = 0.044), which also coincided with lower rates of off-target fasting and 1-h postprandial glucose measurements (P <0.001 for both) (39).

One of the major concerns for women who develop GDM is their higher risk for developing type 2 diabetes after delivery (42). Although using an app to manage GDM cannot affect genetics, modifiable risk factors may affect long-term outcomes. Two studies have examined the potential impact of mHealth technologies in the postpartum period. Nicholson et al. (43) used a Web-based behavioral intervention called GooDMomS to determine whether online education, self-tracking of weight and glucose, automated feedback, and peer support via message boards would affect postpartum weight gain. They found that the intervention helped participants return to prepregnancy weight by 30 weeks postpartum. Borgen et al. (41) conducted a randomized controlled trial in Norway examining whether using the Pregnant+ app in additional to usual care improved results of the postpartum oral glucose tolerance test for women with GDM compared with usual care alone. Although the app was used throughout pregnancy and designed to encourage healthy lifestyle habits (i.e., improved diet and physical activity) and track blood glucose, the investigators found that it had no impact on the postpartum blood glucose measures (the trial's primary outcome) or on any other outcome measures (e.g., cesarean delivery, neonatal intensive care unit admission, and birth weight).

Although the findings from these studies indicate a beneficial use of apps to manage pregnancy, there are notable limitations. As with many clinical studies enrolling pregnant women or pregnant women with

TABLE 3 Reported Benefits of mHealth Apps Versus Usual Care to Manage GDM

Outcome	App	Control Group	Intervention Group	*P*	Summary of Results
Cesarean delivery, %	Dnurse (37)	33.3	25	NS	One out of five studies showed reduction in cesarean delivery.
	GDm-health (38)	46.1	26.7	0.005	
	Glucose Buddy (39)	33.3	20	NS	
	MobiGuide (40)	25.1	10.5	NS*	
	Pregnant+ (41)	22.1	8.8	NS†	
Compliance‡	Dnurse (37)	70.4 ± 10.1	83.3 ± 12.5	<0.001	All studies demonstrated an improvement in compliance.
	GDm-health (38)	61.2	79.5	*P* not reported (odds ratio 2.44, 95% CI 1.29–4.61)	
	Glucose Buddy (39)	66 ± 0.28	84 ± 0.16	<0.001	
	MobiGuide (41)	0.87 ± 0.3	1.01 ± 0.1	<0.05	
Mean blood glucose§	GDm-health (38)	93.3	94.8	NS	One-third of studies demonstrated a reduction in mean blood glucose.
	Glucose Buddy (39)	112.6 ± 7.4	105.1 ± 8.6	<0.001	
	MobiGuide (40)	111.6 ± 8.7	114.3 ± 7.6	NS	
Patient satisfaction	GDm-health (38)	Highly satisfied based on responses to questionnaire; 85% would consider using app	Highly satisfied based on responses to questionnaire; 95% would use app again; 98.3% would recommend app to others	NS	Patient satisfaction was high across all five studies.
	Glucose Buddy (39)	–	Highly satisfied based on responses to questionnaire; 80% reported ease of use	–	
	MobiGuide (40)	–	Highly satisfied based on responses to questionnaire	–	
	Pregnant+ (41)	63.5% agreed that apps encourage engagement in health	84.4% agreed that apps encourage engagement in health	NS‖	

*Percentages for method of delivery (cesarean, operative, spontaneous) were pooled, resulting in no statistically significant differences. Individual percentages are provided in this table. †When data were stratified by parity, rates were not statistically significant ($P = 0.21$ for primiparous, $P = 0.55$ for multiparous). ‡Compliance is defined as the number of measurements downloaded/number of measurements expected; reported as mean % ± SD (Dnurse and Glucose Buddy), % (GDm-health), or number of measurements downloaded/number of measurements expected ± SD (MobiGuide). §Reported as mean fasting blood glucose (GDm-health) or mean ± SD (Glucose Buddy and MobiGuide). ‖Percentages were based on single, unvalidated question.

diabetes, the sample sizes were small. The patients included were diagnosed with GDM; to our knowledge, no studies have examined the use of mHealth apps in women with preexisting type 1 or type 2 diabetes in pregnancy. In addition, no studies to our knowledge have specifically examined the use of mHealth apps to manage diabetes in pregnancy in minority women or those of lower socioeconomic status, although pilot work using other technologies has shown great interest and opportunity for these populations (44). Given the potential commercial impact of these mHealth apps, it is worth mentioning that, although all of the authors claimed no conflict of interest, the group who investigated the GDm-health app received consulting fees from Drayson Technologies, which subsequently became the sole licenser of the GDm-health management system.

Perhaps most importantly, however, was that all studies demonstrated improvement in patient engagement with the medical team, as measured by level of communication with a provider, as well as with self-care (37–41,43).

Conclusion

Pregnancy provides an opportunity to educate, engage, and, hopefully, improve long-term health in women with diabetes. Successful management of a pregnancy complicated by diabetes begins with stringent control of blood glucose, which significantly influences pregnancy outcomes and future morbidity of both mother and child (7). Improved glycemic control in pregnancy can *1*) limit health care expenditures for visits, monitoring, and hospital expenses; *2*) decrease the risk of developing type 2 diabetes in women diagnosed with GDM; and *3*) reduce fetal exposure to diabetes in utero, which is linked to later development of heart disease, metabolic syndrome, and type 2 diabetes in offspring (6,8). Thus, the use of technology to improve diabetes management in pregnancy has the potential to affect the course of two lives.

Despite the incredible promise of mHealth apps and automated meters and insulin pumps to increase patient compliance and engagement with the health care team, only four devices—the Dexcom G6, FreeStyle Libre, FreeStyle Libre 2, and FreeStyle Libre 3 systems—have been approved for use in pregnancy outside of the United States (e.g., in Europe). (45). In addition, although a number of mHealth apps have been tested in clinical trials and shown to be of benefit (25), these products still lack robust studies demonstrating that their use is linked to improved pregnancy outcomes.

In addition, apps and wearable devices have yet to supersede traditional approaches to care. Using technology can reduce blood glucose in nonpregnant individuals with type 1 or type 2 diabetes (20,46,47); however, consistent use of these tools by patients and providers and the impact their use has on long-term outcomes and comorbidities such as high blood pressure, which can also negatively affect pregnancy outcomes, varies. App quality and availability (i.e., free versus paid) also varies, and there is no standard method to review or validate mHealth apps for safety and clinical utility (48).

Importantly, there remains a paucity of data regarding the success of digital technologies in the delivery of diabetes care for at-risk populations (44). Initial results of a large clinical trial indicated that, although mobile phone-based diabetes support improved patients' self-care, personalization of technology-driven care was crucial (49). Ultimately, patients—especially those from vulnerable populations—want to know that a person, rather than a computer algorithm, is providing their care.

Given the shift toward more individualized care in general medical practice and the unique challenges presented by pregnancy even without diabetes, a one-size-fits-all approach cannot be used to manage the care of gravidae with diabetes. Ergo, a single app, device, or cellular phone–based methodology to augment diabetes in pregnancy care also does not—and should not—exist. Increasing research and data will facilitate FDA approval and more widespread acceptance and use of technologies to improve the care we deliver to our pregnant patients with diabetes.

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AUTHOR CONTRIBUTIONS

S.D.C. developed the manuscript outline and wrote the review of clinical experience with this technology. A.G.-M. researched the data and wrote the description of the specific technologies. R.H.J. wrote and revised the manuscript. J.A.R. wrote the abstract, revised Tables 1 and 2, created Table 3, and revised, reviewed, and edited the manuscript. S.D.C. is the guarantor of this work and, as such, had full access to all the resources and takes responsibility for the integrity of the content.

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