

The Current Status of mHealth for Diabetes: Will It Be the Next Big Thing?

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Abstract

mHealth is an emerging concept in health care and uses mobile communications devices for health services and information. Mobile phones, patient monitoring devices, tablets, personal digital assistants, and other wireless devices can be part of mHealth systems. With mHealth systems, glucose data can now be automatically collected, transmitted, aggregated with other physiologic data, analyzed, stored, and presented as actionable information. mHealth systems use mobile decision support software applications (or apps) to assist or direct health care professionals to make decisions, or they can assist or direct patients to make decisions without waiting for input from a clinician. With real-time decision support for patients, appropriate actions can be taken in real time without waiting to see a clinician. Decisions can be personalized if individual treatment goals and personal preferences for treatment are inputted into an app. Few mHealth apps for diabetes have been rigorously tested. Outcome studies of the use of mHealth for diabetes from the literature have shown the potential for benefits, but higher-quality studies are needed. Regulatory approval of mHealth products will require demonstration of safety and effectiveness, especially where information and trends are not just presented to patients, but used to make treatment recommendations. Three additional hurdles must be overcome to facilitate widespread adoption of this technology, including demonstration of the following: (1) privacy to satisfy regulators, (2) clinical benefit to satisfy clinicians, and (3) economic benefit to satisfy payers. mHealth for diabetes is making rapid strides and is expected to be a transforming technology that will be the next big thing.

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What Is mHealth?

mHealth (short for mobile health) is a term for using mobile communications devices for health services and information.¹ These devices can be mobile phones, patient monitoring devices, tablets, personal digital assistants, or other wireless devices. The purposes of mHealth are listed in **Table 1**. mHealth is a subset of telemedicine as well as

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Abbreviations: (AUS) average usability score, (CDSS) clinical decision support system, (CUS) composite usability score, (FDA) Food and Drug Administration, (HbA1c) hemoglobin A1c, (HCP) health care professional, (HIPAA) Health Insurance Portability and Accountability Act of 1996

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a subset of information technology. These two terms are defined in **Table 2**. mHealth removes geographic barriers by allowing remote communication and treatment and removes time barriers by allowing continuous monitoring of physiologic metrics.

Another term that encompasses much of mHealth is wireless health. This term is defined in **Table 3**. Not all mobile health is wireless, and not all wireless health is mobile, however. Some systems using wireless cellular technology do not require that the monitoring device actually be mobile. Other mobile sensors might link to a cell phone or other wireless device by way of a cable in order to achieve data transmission or input. In this article, all the mHealth applications that are described are wireless. For a classification of diabetes management systems according to whether or not they are wireless or mobile, see **Table 4**.

Interest in mHealth is rapidly increasing because of increasing use of smartphones and tablets that allow greater access to the Internet. A smartphone is a mobile phone that is also a mobile personal computer.

Table 1.
Purposes of mHealth

1. To provide enhanced access to health information to patients, HCPs, and researchers
2. To facilitate remote monitoring and diagnosing of patients
3. To deliver timely recommendations for health care.

Table 2.
Definitions of Telemedicine and Health Information Technology

Telemedicine is the use of any type of telecommunications system for transmission and remote interpretation of health care data.

Health Information Technology is the comprehensive management of health information across computerized systems and its secure storage, retrieval, and exchange between consumers, HCPs, quality entities, insurers, and researchers.

Table 3.
Definition of Wireless Medicine

Wireless medicine is the use of wireless technologies for personal health management and health care delivery.

Table 4.
Classification of Diabetes Management Systems According to Whether or Not They Are Wireless or Mobile

	Mobile	Not Mobile
Wireless	Mobile decision support applications (or apps). Currently, these apps are almost only found within phones or tablets. In the future, they could also be housed within glucose monitors or other standalone mobile devices or sensors containing nontelephone wireless capability.	Web-based software for data management accessed wirelessly by a laptop computer.
Not Wireless	Pattern recognition or bolus calculator software. Currently, these types of software are almost only found within glucose monitors, but in the future, they could be housed within other standalone mobile devices.	Software that is downloaded or installed onto the hard drive of a desktop or laptop computer for data management or Web-based software that is accessed by a desktop or laptop computer via a cable connection.

Commonly enabled features of smartphones with advanced operating systems are presented in **Table 5**. Furthermore, some mobile remote monitoring devices are now being developed with embedded cellular modems to transmit data directly without using a smartphone. Increasingly, mobile wireless technologies provide from anywhere in the world: (1) instant access to information, including stored personal health data; and (2) the capacity to send and receive communications instantly, including health-related communications.

Table 5.
Commonly Enabled Features of Smartphones with Advanced Operating Systems

- Internet access
- Email
- Text messaging
- Data storage
- Navigation/geospatial tracking
- Touchscreen technologies
- Capacity to run third-party applications (also known as apps)

As of April 2012, 88% of U.S. adults own a cell phone and more than half of these cell owners have a smartphone to go online.² As of September 2012, 51% of the 234 million Americans aged 13 and older using a mobile device owned

a smartphone (119.3 million).³ Worldwide adoption of mobile broadband communication devices is estimated to be over 1.5 billion subscriptions at this time, and the number is expected to rise more than four-fold to 6.5 billion by 2018.⁴ Use of wireless broadband technology by region of the world is presented in **Table 6**.⁵

How Can mHealth Be Used for Diabetes?

Currently, glucose information about patients comes from blood glucose monitors or continuous glucose monitors. If a health care professional (HCP) is to provide advice remotely based on these data, then the data must go through five steps. The data must be (1) collected, (2) transmitted, (3) analyzed, (4) stored, and (5) presented.

Alternatively, a mobile device system can provide advice to a patient automatically with embedded decision support software that analyzes the same type of data. If other physiologic data are also being transmitted simultaneously, such as medication event information, timing of food intake, amount of carbohydrate intake, amount of exercise, or hypoglycemic symptoms, then the data must go through a sixth step, aggregation, which must occur after transmission and prior to analysis.

No commercially available phone contains blood glucose measurement capability. Manufacturers face two formidable barriers if they are to develop a combined-use product. First, the radio frequency emissions and heat from the phone might damage the glucose measurement elements, and second, the regulatory process for the entire monitor system could slow down introduction of next-generation phone features. One Food and Drug Administration (FDA)-approved glucose monitor contains wireless data transmission capability that is not telephone based.⁶

Currently, few patients use software or online tools for analysis of blood glucose data from their glucose monitors. For the vast majority of monitors, it is necessary to upload the data from the monitor with a cable or a wireless connection to their computer, and most patients do not choose to take the time to upload their data so that it can be analyzed with software in their computer or on the cloud. Furthermore, it is virtually unheard of for a patient to enter glucose data manually into a computer for analysis and interpretation by software. Few of the patients who perform self-monitoring of blood glucose have access to any software systems for interpreting their glucose results. A higher percentage of patients who use continuous glucose monitors are using Web-based analytics systems, but the absolute number of these patients remains small at the present time, because continuous glucose monitoring is not a widespread practice.

A new generation of blood glucose monitors will transmit glucose data automatically to the cloud, where patients will be able to review their glucose data on a personalized, secure website. Transmission will be either by way of wireless or cable transmission to their smartphone followed by optional automatic transmission to the cloud or by way of automatic transmission to the cloud through a global system for mobile communication radio chip that will be built into the glucose monitor. Transmission to the cell phone allows glucose data to be analyzed by software applications (or apps) loaded into the phone. Transmission to the cloud allows glucose data to be stored and analyzed on a personal secure website by cloud-based software. The data can also be transmitted automatically to a mobile phone for analysis by an application.

Once data are on the cloud, then various types of alerts, reminders, educational information, or recommendations for therapeutic responses can be automatically sent to the patient, the HCP, or a responsible third party. These alerts can notify that a glucose level or a pattern of glucose levels is out of a prespecified target range or that a patient has failed to test within a prespecified time window. In addition to notification, the system could be programmed to automatically provide educational information or advice for the patient, which could include summarizing recent

Table 6.
Active Mobile-Broadband Subscriptions by Region³

Region	Number of active mobile-broadband subscriptions (millions)	
	2010	2011
Africa	14	27
Arab States	26	42
Asia and Pacific	281	422
Commonwealth of Independent States	63	87
Europe	174	226
The Americas	206	279

glucose levels, recommending that the HCP should be notified, requesting a repeat measurement of a finger stick blood glucose measurement for a blood glucose monitor reading (or a finger stick blood glucose reading for a continuous glucose monitor), or instructing that the patient take some type of corrective action.

Software Applications for Diabetes Data Streams

mHealth systems are capable of transmitting and providing an analysis of large amounts of data from mobile devices for instant delivery to the HCP or patient. Most clinicians do not have time for additional interactions on behalf of a patient unless review of the data will lead to improved outcome for the patient, time savings for the clinician, or economic benefit to the clinician or the health care system. The question that many clinicians ask when they learn about a new telemetric system intended to provide additional patient data to them on the Internet is, "What am I going to do with all that data?" In addition to data overload, the potential problem of data dropout can also be a concern to clinicians whose patients are using mHealth apps.⁷

Effective use of rich data streams requires a system to analyze the information. Clinical decision support system (CDSS) technology serves that function by providing clinicians or patients with computer-generated clinical knowledge and patient-related information intelligently filtered or presented at appropriate times to enhance patient care.⁸ New mobile decision support software apps will be needed to assist with interpretation of the impending torrential real-time data streams that will be delivered by wireless mobile sensor systems for measuring and transmitting glucose and other physiologic data.⁹ These apps can be intended to assist or direct HCPs to make decisions or they can be intended to assist or direct patients to make decisions. Clinical decision support systems for diabetes are intended for clinicians to allow them to provide better advice to their patients. Mobile decision support apps for diabetes are intended for patients to allow them to make better decisions without waiting for input from a clinician.

Clinical Decision Support Systems for Diabetes Intended for Clinicians

The main purpose of modern CDSS technology intended for clinicians is to assist clinicians at the point of care. Clinical decision support systems can generate alerts and information with little real-time input from clinicians. For treatment decisions, however, clinician input is necessary. Whereas older CDSSs would make decisions for clinicians, newer CDSSs require clinicians to interact with the system to formulate a decision based on both the clinician's knowledge of that patient and the software's bank of standards and best practices. The use of these two types of input leads to better decisions than either the clinician or computer could make without collaboration. Typically, a CDSS will make suggestions and the clinician selects the best one. The CDSS can be programmed to deliver many alerts but few choices to the clinician, which has been likened to donning a straightjacket. Alternatively, the CDSS can allow more treatment options but make it inconvenient to prescribe the less desirable pathways, which has been likened to driving with guardrails.¹⁰

Most decision support software was initially developed for use by HCPs during an office visit or a hospital visit. Apps for mobile diabetes decision support can also be used by patients to respond to data from monitoring devices. Apps can automatically deliver graphical color-coded data summaries analyzed according to preprogrammed settings determined by HCPs. Mobile diabetes applications make decisions and treatment recommendations based on blood glucose levels, continuous glucose levels, or other physiologic measures. Decisions can be personalized if individual treatment goals and personal preferences for treatment are inputted into the mHealth system. ~~The data analysis can be performed either by a~~ chip located within the monitor and immediately displayed by the monitor or by a server in the cloud and immediately transmitted into the monitor. Therefore, the quality of the decision supported input does not have to be degraded by a time delay. Without access to immediate data analysis or actual treatment recommendations, a patient must wait to see their HCP. By then, the patient might be in a different metabolic state and might miss out on the opportunity to receive useful advice at the time of a perturbation in the glucose level or in other physiologic measures. A patient can receive input automatically and immediately with preprogrammed input from a HCP by way of transmission into a mobile device by using a mobile diabetes decision support system to enable the decision. Such input is potentially very helpful to guide the patient to better choices, leading to better outcomes.

Mobile Decision Support Apps for Diabetes Intended for Patients

Many mobile decision support software apps for smartphones are now available for diabetes and are intended to assist patients to make decisions for themselves in real time without having to contact their HCP. In 2010, Rao and coauthors¹¹ reported that they had visited the Apple iTunes store on October 9, 2009, and selected the 12 diabetes apps with the highest ratings. They found that these apps contained 22 types of data management features (see **Table 7**).

In 2013, El-Gayar and coauthors¹² identified and reviewed 71 commercial mobile diabetes applications available at the Apple applications store as well as 16 mobile diabetes applications from the medical literature. They found that these applications, as a group, (1) incorporated inputted data from up to six monitoring tasks and (2) provided up to seven support tasks. The percentages of applications incorporating data from monitoring tasks are presented in **Table 8** and the percentages of applications incorporating support tasks are presented in **Table 9**. Future mobile decision support applications are expected to also incorporate information guided by global positioning systems, such as where to find nearby healthy restaurant foods.

Patients with diabetes can use the information presented by apps to help guide their choices of medication doses, foods, or exercises. For many minute-to-minute decisions, the questions are not sufficiently significant to warrant contacting an HCP and there is insufficient time to wait for a reply. Mobile decision support apps can be helpful to assist patients to identify data patterns and make it easier for them to come to an immediate decision on their own. However, few treatment apps for any disease have been approved by the FDA to actually make decisions or treatment recommendations, even if the app’s automatic treatment decision was generated from a decision tree prepopulated by an HCP specifically for an individual patient. Mobile software apps that provide treatment decisions based on data in the presence of prepopulated input from a HCP are known as mobile decision support apps.

Table 7.
Data Management Features of the 12 Diabetes Mobile Applications with the Highest Ratings at the Apple iTunes Store as of October 9, 2009¹¹

1. Glucose tracking
2. Carbohydrate tracking
3. Insulin/medicine tracking
4. Activity tracking
5. Weight tracking
6. Blood pressure tracking
7. Meal-time tagging
8. Preset notes
9. Custom notes
10. Food database
11. Color coded for hypoglycemia/hyperglycemia
12. Trend chart length
13. Widescreen mode
14. Logbook view
15. Direct entry from logbook
16. Averages
17. Standard deviation
18. Email composer
19. Target range settings
20. Background themes
21. Email (comma-separated values)
22. AutoSync to Website

Table 8.
Percentage of Applications Incorporating Data from Monitoring Tasks¹²

Function	Apple App Store	Literature
Blood glucose	100	88
Medication	76	38
Diet	68	75
Physical exercise	41	50
Weight	25	6
Blood pressure	23	16

Table 9.
Percentage of Applications Incorporating Support Tasks¹²

Function	Apple App Store	Literature
Education	18	31
Communication	83	69
Patient health record	21	63
Decision support	17	19
Data entry automation	4	57
Social networking	7	0

Insulin bolus doses are frequently determined with algorithms, and software is well suited for generating algorithm-driven outputs, so there has been interest in the engineering and medical communities in seeing development of software apps for insulin bolus dosing.¹³ Such apps regulate dosing of a potentially dangerous drug (insulin). Such a high-risk

purpose puts these apps under the purview of the FDA, and none have been approved by this agency (other than bolus software programs contained in many insulin pumps). Many apps are currently available to make insulin dosing recommendations. These dosing apps lack three types of important reassuring information. First, they generally provide no explanation of the factors or formulas that generate the calculated bolus dose, and the patient does not know whether they might be using a dose of insulin that does not fit their personal requirements. Incorporation of context recognition features into these systems would allow modification of the algorithm output and improve safety.¹⁴ Second, they generally do not explain whether they have any safety mechanisms to avoid accidental insulin overdoses and hypoglycemia. Third, they are written by programmers whose qualifications are generally unknown, and they might even be written by nonmedical people with only technical training (such as computer software engineers) and without a medical background.¹³

Demidowich and coauthors¹⁵ identified and described 42 Android apps that, as of April 2011, could: (1) track self-monitored blood glucose levels; (2) track doses of insulin or other diabetes medications; and/or (3) calculate prandial bolus insulin dosages. The investigators scored six functions for each app according to its: (1) usability, which was defined as ease of use; (2) user interface design; (3) customizability; (4) data entry and retrieval; (5) integration of data into charts or graphs; and (6) data sharing. They awarded 1–5 points for each of the six existing functions and 0 points if the function did not exist. A composite usability score (CUS) was defined as the sum of the usability scores of the six different app functions: (1) self-monitoring of blood glucose recording, (2) diabetes medication tracking, (3) prandial insulin calculation, (4) data graphing, (5) data sharing, and (6) other data tracking (e.g., body weight, calorie intake). The mean CUS was 11.3 out of a possible 30. An average usability score (AUS) was also created and was defined as the mean score of the existing (i.e., nonzero scoring) functions of an app on a scale of 1–5. The mean AUS was 3.0 out of a possible 5.0. Only 4 of the 42 apps had a CUS above 20. Self-monitoring of blood glucose recording was present in 36 (86%) apps, a tool to track insulin or oral diabetes medications was found in 19 (45%) apps, and a prandial insulin dose calculator was found in 11 (26%) apps. Eighteen apps were free of charge. The other 24 apps had a mean purchase price of \$2.86 (range \$0.99–6.99).¹⁵ It is clear that there is room for improvement in this new class of software products to enhance the user experience.

Outcomes of Using Smartphone Apps for Diabetes

Two review articles have examined the specific outcomes of interventions using mobile phone apps for diabetes. Baron and coauthors¹⁶ reviewed studies of the clinical effectiveness of mobile-based applications that allowed adult patients with diabetes to record and send their blood glucose readings to a central server and where glycosylated hemoglobin (HbA1c) was a clinical outcome.¹⁶ They identified 20 studies. Ten of the 13 studies in type 2 diabetes and 4 of the 7 studies on type 1 diabetes found mHealth to lead to benefits. Studies without HCP feedback led to improved HbA1c, suggesting HCP feedback might not be necessary for intervention success. In general, the quality of many of the studies was poor, and the reported outcomes were often efficacy rather than effectiveness. The authors concluded that their results show the potential for beneficial change, but higher-quality studies with better standard of reporting are needed.

Holtz and Lauckner¹⁷ reviewed 21 studies identified through a literature search of the terms “diabetes,” “diabetes mellitus,” “mobile phone,” “cell phone,” “cellular phone,” “text messaging,” “text message,” “SMS,” and “short message service,” where a mobile phone was the primary device of the intervention. Fewer than half of the studies measured HbA1c, and in most of those studies, there was a statistically insignificant decrease. Fewer than half were randomized controlled trials, and many were efficacy studies. The authors concluded that there is promise in mobile phone interventions in that many of the outcomes in their series had positive trends, such as for HbA1c levels, self-efficacy, and diabetes knowledge. There was some overlap between the two methods for reviewing the literature in that 7 studies were included in both reviews and the remaining studies (13 for Baron and coauthors¹⁶ and 14 for Holtz and Lauckner¹⁷) were unique to only a single review. El-Gayar and coauthors¹² assessed six articles about mobile applications for diabetes from the literature, and only two of them reported a change in HbA1c in mobile application users compared with control subjects as an outcome. These two studies demonstrated a difference of 1.2–1.4%, favoring the use of mobile applications in both cases.

The need for effective decisions for diabetes embedded into mobile apps was underscored by a review of CDSSs for diabetes in ambulatory care settings presented by Jeffery and coauthors¹⁸ in 2012. Only 1 of 15 articles selected for analysis used a cell-phone-based system for delivering treatment recommendations. The outcomes of the studies were pooled and demonstrated a small improvement in HbA1c, hospitalizations, and quality of life with a CDSS compared with control treatments; however, these three differences were not statistically significant. Interventions using mobile apps (compared with once-monthly or once-quarterly data presentations) can promote much greater patient engagement by displaying in real time the latest glucose levels, meal calories, and exercise caloric expenditures (as well as possibly other measures). In this review, all the non-mobile-phone CDSS interventions occurred every 1–3 months. The potential benefit of ongoing real-time contact with mobile software makes it worthwhile to pursue development of even better mobile apps for patient-self-directed diabetes management or even HCP-directed decision support, even though outcomes for ambulatory non-mobile-phone CDSSs have been somewhat disappointing to date.

Sixteen randomized controlled trials of 3578 computer-based self-management interventions for adults with type 2 diabetes were reviewed. They appeared to have small benefits on glycemic control (pooled effect on HbA1c, -0.2%; 95% confidence interval -0.4 to -0.1; $p = .009$). The effect size on HbA1c was larger in a mobile phone subgroup (subgroup analysis, mean difference in HbA1c, -0.5%; 95% confidence interval -0.7 to -0.3); $p < .00001$).¹⁹ Like many meta analysis analyses, the small benefit of mobile technologies has been attributed by some mHealth experts as being due to a heterogeneous mix of old and new treatment methods, which could obscure benefit from a particular method. This type of interpretation of meta analysis results is viable when a truly effective method is only reported in a small number of studies.

Economic and Regulatory Barriers

A potential barrier to any new medical technology is the incremental additional cost of the technology. If the ratio of additional benefits to additional costs is comparable to that of benefits that are generally accepted for other interventions, then an intervention is defined as cost-effective. If the intervention results in a savings exceeding the additional costs, then the intervention is defined as cost saving.²⁰ Few high-quality long-term studies have been conducted on mHealth interventions for diabetes to date for the benefits to be clearly understood, and even fewer have been done with an economic arm to determine the ratio of benefits to costs. There are many reasons to assume that mHealth can generate significant benefits, but there is insufficient clinical and economic supporting evidence at this time to realistically tout this approach as being economically attractive. Many potential sources for payment of mHealth initiatives can be envisioned, and it is likely that no single source of payment for diabetes mHealth applications will emerge. See **Table 10** for a list of potential mHealth payers.

Mobile medical apps for patients are receiving approval from the FDA. A review of the FDA's database of summary decisions for 510(k)-approved products reported in December 2012 found more than 75 510(k) clearances that included a mention or description of a mobile soft-ware component.²¹

The FDA issued draft guidance in July 2011 to announce its intention to exercise enforcement discretion for most mobile apps. The guidance also clarifies that the focus of the FDA's oversight will be the small subset of mobile apps, referred to as mobile medical apps, that meet the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act and that are either intended to (1) be used as an accessory to a regulated medical device or (2) transform a mobile platform into a regulated medical device. The FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile medical apps that present a potential risk to patients if they do not work as intended.²² In testimony to Congress on March 21, 2013, the FDA announced that (1) mobile medical apps make up merely 0.5% of the total medical devices it reviews each year and (2) the agency intends to finalize the guidance document by September 30, 2013.²³

Table 10.
Potential Payers for Diabetes mHealth Initiatives

1. Private insurance companies
2. Government (e.g., Medicare or Medicaid)
3. Accountable care/health maintenance organizations
4. Employers
5. Wireless service providers
6. Patients

A high-risk purpose of therapeutic decisions provided to patients on demand would put apps under the purview of the FDA. None have been approved by this agency (other than bolus software programs contained in many insulin pumps). One FDA-approved mobile application provides advice built on data-driven behavioral algorithms, but the user needs an invitation from their provider to use this product.

The Future of mHealth for Diabetes

Future development of mobile apps for diabetes will require clear practice guidelines for incorporation into recommendations. Some apps will be intended for HCPs to use to advise or warn their patients. Other apps will be intended to deliver automatic recommendations directly to patients without being filtered by an HCP. Whereas the first type of apps will face some regulatory hurdles depending on how specific the recommendations will be, the second set will face larger hurdles to demonstrate safety, because there will be no filtering mechanism by the HCP in case a particular patient should not use the app or in case a particular patient is in an atypical state where the app's usual recommendations are not appropriate.

mHealth systems will need to be made secure to maintain privacy. Security systems for wireless mHealth devices must support interoperability and must encrypt all data to allow for efficient file sharing and storage. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) covers mHealth applications where personal data are uploaded into a device or the Internet. The HIPAA requires that individually identifiable health information should be protected with reasonable administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure.²⁴ User authentication might depend on something known by the user, carried by the user, or inherent to the user's anatomy.²⁵

Greater focus on mHealth by the U.S. government might lead to additional guidelines and policies for standards. In December 2012, U.S. Congressman Michael Honda from California introduced the Healthcare Innovation and Marketplace Technologies Act to remove barriers in wireless health. This bill is intended to (1) establish an Office of Wireless Health at the FDA that will coordinate with other governmental agencies and private industry to provide recommendations to the FDA commissioner on how to develop and maintain a consistent, reasonable, and predictable regulatory framework on wireless health issues, and (2) establish an mHealth developer support program at the Department of Health and Human Services to help mobile application developers build their devices in line with current privacy regulations.²⁶

In September 2012, the Federal Communications Commission announced five mHealth initiatives including intentions to: (1) play a leadership role in advancing mobile health adoption to include hiring a health care director; (2) increase collaboration between support federal agencies to promote innovation, protect patient safety, and avoid regulatory duplication; (3) build on existing programs and link programs when possible in order to expand broadband access for health care; (4) continue efforts to increase capacity, reliability, interoperability, and radio frequency safety of mHealth technologies; and (5) support of continued investment, innovation, and job creation by industry in the mobile health sector.²⁷ It was reported in April 2013 that the Federal Communications Commission has now hired a director of health care initiatives.²⁸

Well-designed studies demonstrating both statistically and clinically significant improved outcomes for patients with mobile medical applications will be needed to increase interest in this type of product. Forty studies of mHealth were added to the clinicaltrials.gov database between April and November 2012.²⁹ Ultimately, widespread adoption of mHealth tools for diabetes will require studies demonstrating economic benefits from using such mobile medical applications.³⁰

Standard-of-care management of diabetes will very soon require analysis of an avalanche of physiologic data from new continuous sensors for measuring glucose, cardiovascular function, exercise, geographic location, and many other factors that can impact control. These types of information will increasingly be delivered directly to patients who are on the go and carrying smartphones. mHealth is one of the emerging technologies that is now transforming health care.

This approach to health information represents a new paradigm for analyzing and acting upon this avalanche of data to potentially deliver better health care recommendations in real time. mHealth is likely the next big thing in health care for diabetes.

Disclosure:

Dr. Klonoff consults for the following companies: Google, InsuLine, Roche and Sanofi.

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