Journal of Diabetes Science and Technology
2018, Vol. 12(1) 3–6

DOI: 10.1177/1932296817732459
journals.sagepub.com/home/dst
SAGE

# Overcoming Barriers to Adoption of Digital Health Tools for Diabetes

**David C. Klonoff, MD, FACP, FRCPE[1] and David Kerr, MD, FRCPE[2]**

**Keywords**
digital health, IT, apps, cybersecurity

Digital health represents the intersection of health care with the internet in which wearable devices, information technology (IT) and electronic communication tools converge to support the practice of medicine. There is already growing pressure on clinicians to embrace digital health tools fueled by the concept of the Internet of Things. Sensors are becoming smaller, requiring less power and are increasingly more aesthetically pleasing. These sensors can provide real-time information about an individual's physiology, transmit the data to smartphones and subsequently via cloud computing decision support, offer treatment recommendations, and in the near future automate closed-loop algorithms to control effector devices intended to achieve physiologic homeostasis. In addition to sensor-generated treatment recommendations from the sensor manufacturer per se, supplementary free-standing software embedded within the smartphone can also use the sensor information for the same purposes. We are heading for a time when hardware will become increasingly unobtrusive and software will become increasingly intelligent and able to learn how to achieve predetermined target outcomes via artificial intelligence.[1] The combination of sensors, software, and smartphones will come together to create a "digital health tsunami"—fine-tuning personal health outcomes and lowering the individual and family burdens for people with diabetes that are scarcely imaginable today.

## Digital Health for Diabetes

The management of diabetes is almost unique as a disease in that it demands frequent daily decision making based on real time data where any error could have catastrophic consequences. However, taking a more positive perspective, combining the need for data many times daily for treatment decision making and with the number of people already living with diabetes, this actually provides a major opportunity for digital health systems. To maximize immediate and longer-term benefits, diabetes treatment decisions are best made based on inputs about current and historical trends in the achieved and direction of blood glucose levels as well as information about food, exercise timing, type, and intensity, medications, and other factors affecting insulin sensitivity as well as personal stressors (some of which can be idiosyncratic) affecting achieved glycemia. These influencing factors will be best interpreted and the appropriate responses best determined by the sensors, analytical tools, and treatment-recommending software that are being developed as part of the digital diabetes revolution.

Development of digital health sensor hardware and decision support software are part of the Internet of Medical Things, which is defined as the collection of medical devices and applications that connect to health care IT systems through online computer networks which is most widely accessed by smartphones (see Figure 1).[2]

The recent explosion in development of wearable sensors has also led to accumulation of big data, which, by using artificial intelligence, have the potential to create digital health solutions personalized for each individual—this is the basis of precision medicine. Overall, data are the key currency in digital health. Data have value for developers of diabetes treatments and can be considered as the intellectual property of our times and an asset that can be used to support software for treating diabetes and other conditions.

## Barriers to be Overcome

Five key barriers must be overcome to satisfy the needs of five major stakeholders in diabetes care to facilitate widespread adoption of software tools for a diabetes digital future:

- usability to satisfy people with diabetes
- clinical benefit to satisfy clinicians
- economic benefit to satisfy payers

[1]Medical Director, Diabetes Research Institute, Mills-Peninsula Medical Center, San Mateo, CA, USA
[2]Director of Research and Innovation at William Sansum Diabetes Center, Santa Barbara, CA, USA

**Corresponding Author:**
David C. Klonoff, MD, FACP, FRCPE, Diabetes Research Institute, Mills-Peninsula Medical Center, San Mateo, CA 94404, USA.
Email: dklonoff@diabetestechnology.org

**Figure 1.** The Internet of Medical Things is characterized by wearable sensors transmitting data wirelessly to a monitor that can be a smartphone and from there the data are sent to the cloud. Data on the cloud can be analyzed, stored, and transmitted back to the patient's smartphone or computer as well as to a health care professional or a caregiver.

- security to preserve safety and satisfy product regulators (such as the US Food and Drug Administration)
- data privacy to satisfy legal regulators of personal information (eg, Department of Health and Human Service's Office for Civil Rights in the United States)

Currently there is a need to expand the evidence base necessary to show the safety, effectiveness, security, and data privacy of digital health products including smartphone applications. Clinical and economic benefits can be quantified by performing randomized clinical trials. Security can be determined by meeting standards such as DTSec, the first consensus cybersecurity standard for manufacturers of diabetes devices based on stakeholder inputs from FDA and other US government agencies as well as the Canadian government and professional organizations, industry, the IT community, health care professionals, people with diabetes, and hackers. The need for medical devices to maintain privacy is increasingly being discussed.[3,4]

## Usability

At present usability of digital health tools remains the biggest challenge to their widespread adoption. Simply put, usability means that digital health tools must be

- Safe
- Effective
- Interoperable with health data records and other existing electronic tools
- Compatible with clinical guidelines, that is, evidence-based

Specific features for improving usability to increase adoption include (1) simplified data displays; (2) easy log-in access; and (3) alerts, or notifications that explain results in layman's terms and tell the user whether additional care is needed.[5] Furthermore, adoption of these tools requires that they be usable by health care professionals so that their workload will not increase and their revenue will not decrease or else they will have little enthusiasm to adopt them.

Incorporating electronic devices that individuals are more inclined to utilize is a promising strategy to improve acceptability of digital health tools.[6] However, the usability of most diabetes smartphone applications (apps) leaves much to be desired. A 2011 review of 42 Android diabetes apps scored six functions for each app according to their (1) usability, 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. The investigators awarded from 1 to 5 points for each of these six functions and they awarded no points if the function did not exist. The mean score for this set of apps was 11.3 out of a possible 30. An "average usability score" (AUS) was also awarded based on the mean the existing nonzero scores of the six functions of each 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 studied had a score above 20.[7]

Arnhold and colleagues analyzed 66 diabetes apps from the Google Play and Apple App Stores for five usability criteria: (1) comprehensibility; (2) presentation of images and text; (3) usability; (4) fault tolerance and fault management; and (5) password protection, with each scored on a 1-5 scale. Scores for these five criteria were, respectively, 4.0. 3.5, 3.3, 2.8, and 1.8, with an average score across all criteria and all apps of 3.3. Among apps developed for both operating systems, only 8% were interoperable to the extent of being able to connect with an external sensor/device.[8] Elsewhere, Payne and colleagues reviewed 24 health-related apps (4 of which were for diabetes) and concluded that, in reality, users want apps that (1) are fast and easy to use; (2) allow for discrete interactions in public to avoid having to record personal data in public; (3) raise awareness of certain behaviors and provide potential cues to action; and (4) integrate rewards into the interventions to drive better behavioral outcomes.[9] Others have highlighted a lack of confidence with current technology, frustration with design features and navigation, but at the same time continuing interest in acquiring technology to support diabetes self-management.[10]

## Clinical and Economic Benefits

In health care, much of the decision-making processes as well as reimbursement for new therapies and devices need to be evidence-based. Unfortunately, there is currently a lack of effectiveness data from clinical trials to help prescribers and payers support the use of digital health tools as part of routine diabetes care. Hou and colleagues recently reported a review of 14 randomized controlled trials of mobile apps for diabetes published between January 1, 1996, and June 1, 2015, and showed that the use of this type of intervention resulted in a mean reduction in A1C of 0.49%. Most of the benefits occurred in 10 studies of apps for patients with type

2 diabetes (median duration: 6 months). The authors pointed out that the interventions they reviewed were not blinded and the benefits of app use might have been due to how the investigators managed the subjects using the apps. Also, publication bias might have led to results of poorly performing apps data not being reported. Among the 7 studies for type 2 subjects that were described by the authors as fair or good quality, there were only 181 intervention subjects and 180 controls.[11] This is a small number on which to base policy decisions, but the study findings were still encouraging. Larger studies of longer duration are needed.

Creators of digital diabetes tools have suggested that their technologies are being updated at such a pace that it would be almost impossible to undertake a traditional randomized controlled clinical trial. Although n = 1 studies can be implemented by do-it-yourself technology developments these approaches require certain skills and financial resources which make them challenging to use for the majority.[12] Therefore, there needs to be discussions around alternative approaches to defining metrics of success for these technologies which will satisfy the demands of people with diabetes, clinicians, payers and regulators and will also allow for meaningful comparisons between digital technologies.

Interoperability between sensors and electronic medical records (EMRs) is also vital for mobile apps and sensors to effectively deliver maximal benefit.[13] Many of the types of EMRs that are in widespread use in both outpatient and inpatient settings do not readily allow individual sensor data points to be uploaded, which limits the usefulness of sensor measurements. It is then necessary to scan a printout of a sensor report and upload the scanned report. This report will not be searchable and will often therefore be quickly lost within the record or forgotten. This aspect of digital health has the potential to add burden for clinicians especially and therefore would diminish the potential for widespread adoption.

Poorly designed apps, unevaluated recommendations, overuse of disclaimers, and those that don't function as intended pose a significant risk to users and damage confidence. While education and tracking apps often do not adhere to defined standards of care from learned organizations and may lead to incorrect beliefs and ineffective behaviors these are unlikely to be directly harmful. Failure to perform if a person with diabetes is depending on a robust recommendation can be problematic. A 2015 assessment of the performance of 65 free diabetes management apps from the three most popular mobile app stores: 21 from Google Play (Android), 31 from the App Store (iOS), and 13 from the Windows Phone Store. The apps were assessed for tracking four metrics: blood glucose levels, insulin therapy, nutrition, and physical exercise. They found that 56 of these apps either did not meet all of these four basic requirements or else did not work properly.[14] A more worrisome assessment was reported by Huckvale and colleagues in 2015; of 46 insulin dose calculator apps that performed simple mathematical operations using planned carbohydrate intake and measured blood glucose. the majority were found to produce one of three types of errors in their calculations. These errors included (1) input errors where incorrect values could be used for calculation; (2) output errors where errors could arise from the output of the calculator despite no error on the part of the user; and (3) unavailability of the calculator. The authors concluded that these insulin dosing errors put users at risk of "catastrophic overdose."[15]

Digital health (especially app) developers are often not transparent in terms of defining their target populations(s) and metrics of success. The perception of many technology companies is to view people with diabetes as a homogenous group rather than as individuals—a view often perpetuated by investors in start-up companies who traditionally look for short-term financial returns based on the enormous number of people currently living with a diagnosis of or at risk of developing diabetes. Going forward the ability of an app to personalize diabetes care and support self-management may turn out to be the unique selling point. Furthermore, currently the burden of diabetes and its complications falls unfairly on minorities in the United States, yet their participation in diabetes-related technology innovation including the development of artificial pancreas systems is limited.[16]

## Safety

Unfortunately, there is a paucity of data about the safety and the effectiveness of most existing digital health tools, especially apps, currently proposed for use in diabetes care. As of September 2015, IMS had identified more than 165 000 health-related apps[17] but few diabetes focused apps have been either approved by FDA or have supporting data described in the medical literature. A recent review of articles published between 2010 and 2015 identified only 14 such mobile medical apps.[18] Other diabetes apps did not have either such imprimatur to provide confidence in their safety. In practical terms, it is impossible for people with diabetes and health care providers to keep up with the safety (if such a metric is even presented by the app developer at any time) for such a large set of apps, many of which are frequently altered or updated by their developers on a regular basis. Likewise, for apps and other digital health tools embedded within smartphones—the latter are also subject to updates/upgrades. Thus a case can be made for an independent rating service focusing on safety diabetes apps and the impact of updates/upgrades on performance.[19,20] Wicks and Chiauzzi have proposed five potential approaches to improving the quality of medical apps (Table 1).[21] Many apps are free, and many are produced by small companies that are struggling economically. It is not clear how an app rating service would be funded. Whether the cost of the rating service would be borne by the app developer, the user, the user's health care provider, payers, or another organization is currently unknown. Regarding effectiveness, IMS found that only 10% of the mobile apps they reviewed could connect to a device or sensor to provide feedback. They concluded that better functionality would greatly improve both accuracy and convenience of data collection.[17]

**Table 1.** Five Potential Approaches to Improving the Quality of Medical Apps.[21]

| | |
|---|---|
| A. | Campaign to boost app literacy of consumers |
| B. | App Safety Consortium of app developers to assess safety as needed |
| C. | Enforced transparency of formulas to app stores and researchers |
| D. | Active medical review by app stores, which would be responsible for safety |
| E. | Government regulation by regulators prior to app release |

## Conclusions

Digital tools are an emerging force in health care. The "newness" is viewed as exciting for some but burdensome for others. Widespread adoption of digital health tools will require meeting the needs of people with diabetes, clinicians, payers, product manufacturers, and legal regulators. Mobile applications and wearable sensors are most likely to be adopted if developers and clinician champions of these new types of technologies can demonstrate appropriate usability, safety, effectiveness, robust design, and attention to the needs of target populations. The Internet of Things is becoming widely established in many areas of our lives. We expect that soon that technical barriers to digital health adoption will be overcome and irrespective of the views of clinicians, people will seek aggregated medical sensor information analyzed and presented on demand by software and be enthusiastic users of digital health tools as a consequence of the Internet of Medical Things.

### Abbreviations

AUS, average usability score; EMR, electronic medical record; IT, information technology.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

### References

1. Lyle AC, Naish MD. A software architecture for adaptive modular sensing systems. *Sensors (Basel)*. 2010;10(8):7514-7560.
2. Haghi M, Thurow K, Stoll R. Wearable devices in medical Internet of things: scientific research and commercially available devices. *Healthc Inform Res*. 2017;23(1):4-15.
3. Frenz C. Healthcare privacy plans need to account for medical device security. 2017. Available at: https://iapp.org/news/a/healthcare-privacy-plans-need-to-account-for-medical-device-security/. Accessed July 17, 2017.
4. Klonoff DC, Price WN II. The need for a privacy standard for medical devices that transmit protected health information used in the Precision Medicine Initiative for Diabetes and Other Diseases. *J Diabetes Sci Technol*. 2017;11(2):220-223.
5. Baldwin JL, Singh H, Sittig DF, Giardina TD. Patient portals and health apps: pitfalls, promises, and what one might learn from the other. *Healthc (Amst)*. 2016;5(3):81-85.
6. Vuong AM, Huber JC Jr, Bolin JN, et al. Factors affecting acceptability and usability of technological approaches to diabetes self-management: a case study. *Diabetes Technol Ther*. 2012;14(12):1178-1182.
7. Demidowich AP, Lu K, Tamler R, Bloomgardern Z. An evaluation of diabetes self-management applications for Android smartphones. *J Telemed Telecare*. 2012;18(4):235-238.
8. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res*. 2014;16(4):e104.
9. Payne HE, Lister C, West JH, Bernhardt JM. Behavioral functionality of mobile apps in health interventions: a systematic review of the literature. *JMIR Mhealth Uhealth*. 2015;3(1):e20.
10. Sarkar U, Gourley GI, Lules CR, et al. Usability of commercially available mobile applications for diverse patients. *J Gen Intern Med*. 2016;31(12):1417-1426.
11. Hou C, Carter B, Hewitt J, Francisa T, Mayor S. Do mobile phone applications improve glycemic control (HbA1c) in the self-management of diabetes? A systematic review, meta-analysis, and GRADE of 14 randomized trials. *Diabetes Care*. 2016;39(11):2089-2095.
12. Kerr D, Axelrod C, Hoppe C. Patient inputs for mobile health systems for type 1 diabetes care. *Diabetes Technol Ther*. 2017;19(4):201-202.
13. Mamlin BW, Tierney WM. The promise of information and communication technology in healthcare: extracting value from the chaos. *Am J Med Sci*. 2016;351(1):59-68.
14. Brzan PP, Rotman E, Pajnkihar M, Klanjsek P. Mobile applications for control and self management of diabetes: a systematic review. *J Med Syst*. 2016;40(9):210.
15. Huckvale K, Adomaviciute S, Prieto JT, Leow MK, Car J. Smartphone apps for calculating insulin dose: a systematic assessment. *BMC Med* 2015;13:106.
16. Huyett L, Dassau E, Pinsker JE, Doyle FJ III, Kerr D. Minority groups and the artificial pancreas: who is (not) in line? *Lancet Diabetes Endocrinol*. 2016;4(11):880-881.
17. Constantino T. IMS health study: patient options expand as mobile healthcare apps address wellness and chronic disease treatment needs. 2015. Available at: http://www.imshealth.com/en/about-us/news/ims-health-study:-patient-options-expand-as-mobile-healthcare-apps-address-wellness-and-chronic-disease-treatment-needs. Accessed July 18, 2017.
18. Drincic A, Prahalad P, Greenwood D, Klonoff DC. Evidence-based mobile medical applications in diabetes. *Endocrinol Metab Clin North Am*. 2016;45(4):943-965.
19. Comstock J. Apple picks 13 apps for people with diabetes. 2014. Available at: http://www.mobihealthnews.com/34568/apple-picks-13-apps-for-people-with-diabetes. Accessed July 18, 2017.
20. Smith J. Best of the diabetes apps of 2016—how to pick what is right for you. 2016. Available at: http://integrateddiabetes.com/best-of-the-diabetes-apps-how-to-pick-what-is-right-for-you/. Accessed July 18, 2017.
21. Wicks P, Chiauzzi E. "Trust but verify"—five approaches to ensure safe medical apps. *BMC Med*. 2015;13:205.