Journal of Diabetes Science and Technology
Volume 7, Issue 6, November 2013

COMMENTARY

Diabetes Professionals Must Seize the Opportunity in Mobile Health

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Abstract

The number of diabetes management mobile applications (apps) available on the market has grown exponentially since 2009; however, most patients lack the skills necessary for finding relevant health care information. Thus, clinical best practices emphasize the need for ongoing patient education. Despite the importance of education in clinical guidelines, very few of these apps include education in their top functionalities. Most diabetes management mobile apps are not medical devices by definition, according to the U.S. Food and Drug Administration, and therefore do not require clearance or approval for market, and very few have been subject to clinical evaluation. There has been little research on the use of diabetes management mobile apps, marginalizing the role of diabetes professionals and educators in a burgeoning market, hungry for information and an improved quality of life. Still, mobile technology holds great promise as a platform for self-management. Health care providers must not only educate patients about these resources, but take steps to ensure that mobile apps follow accepted best practices and guidelines.

J Diabetes Sci Technol 2013;7(6):1616–1620

Ready or Not, the Age of Mobile Health Has Arrived, Claiming to Reshape Health Care Delivery as We Know It

While mobile health is a small fraction of the application (app) market, Global Information Inc. has reported that there are approximately 97,000 mobile health apps currently available for download from the major app stores.[1] The mobile health app market is one of the most rapidly expanding segments, growing at a rate of nearly 40% annually and expected to reach $26 billion by 2017.[1] Many of these apps are marketed broadly as "diabetes management" apps; however, very few provide a clinical benefit.

Diabetes management apps generally provide insulin and medication recording, data export and communication, diet recording, and weight management functionalities. And while self-monitoring of blood glucose has been shown to be a useful tool in improving glycemic control in type 2 diabetes,[2] helping patients make informed decisions in managing blood glucose, many of the "diabetes management" apps available on the market today tend to focus individually on other aspects of diabetes care, such as exercise, diet management, and medication adherence rather than taking a holistic approach to disease management.

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Abbreviation: (AACE) American Association of Clinical Endocrinologists, (AADE) American Association of Diabetes Educators, (app) application, (FDA) Food and Drug Administration

Keywords: diabetes self-management education, health and wellness, mobile health, smartphone

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Limitations of these mobile health apps generally include a lack of personalized feedback, data entry challenges, and integration with electronic health records, and many fail to include human factors in their design principles to improve usability, perceived usefulness, adoption of the technology, and, ultimately, patient expectations and providers' needs.[3]

In 2010, Ciemins and coauthors[4] surveyed diabetes management tools available on the market and found the WaveSense Diabetes Manager to be the easiest, fastest, and most trustworthy; however, while it provided educational videos about living with diabetes, including diet and exercise, it lacked the capability for logging nondiabetes medications and weight.

The iBGStar diabetes manager app, developed from the WaveSense Diabetes Manager by Agamatrix Inc. as an accessory to its blood glucose meter, stores and analyzes test results on the iPhone or iPod Touch and is one of the few mobile health apps on the market today that has been cleared by the U.S. Food and Drug Administration (FDA). The app can be used to store and manage a patient's diabetes information, review trends, or share with the patient's health care team. The iBGStar diabetes manager app holds the potential to benefit patients by helping to better inform clinical decisions, but it omits the video feature of the WaveSense Diabetes Manager app, leaving the burden with the health care provider to manage the patient's condition effectively.

Perhaps the most comprehensive device and app available today, the Telcare Wireless Blood Glucose Meter and Telcare Diabetes Pal mobile app is the first FDA-cleared wireless (cellular) blood glucose meter that automatically transmits each blood glucose reading to Telcare's secure clinical server while returning immediate guidance and clinical coaching back to the patient.

But Most Mobile Health Applications Lack Any Robust Evidential Basis

A small fraction of mobile health apps are regulated by the FDA as medical devices and must undergo the FDA's 510(K) or premarket approval processes to be legally marketed. Most mobile health apps are not, by definition, medical devices and are therefore not regulated. A significant number of mobile health apps are consumer-directed "health and wellness" apps that, emboldened by the absence of regulatory oversight, make efficacy claims without the requisite clinical trial evidence. In a recent examination of 1500 mobile health apps, the New England Center for Investigative Reporting found that many do not follow established medical guidelines and few have undergone any rigorous clinical research.[5]

A survey of published clinical results of the effectiveness of mobile health technology interventions found that only 334 mobile health apps underwent clinical trials between 1990 and 2010. Surprisingly, only 75 included a control group.[6] Only two interventions were shown to achieve clinically significant results (text messaging to increase adherence to antiretroviral medication in a low-income setting and increase smoking cessation in a high-income setting). The authors concluded that other mobile technology health interventions required randomized controlled trials to establish the effects on clinically important outcomes.

The Hundreds, if Not Thousands, of Diabetes Self-Management Applications Are No Exception

Many of the mobile health apps on the market are relevant and useful to the 355 million worldwide diabetes patients, as well as prediabetes patients, and the clinical professionals dedicated to helping them learn to self-manage and treat their condition. However, these apps primarily address lifestyle self-management challenges, including blood glucose monitoring, diet, exercise, and medication tracking. As with mobile health apps in general, they too often ignore evidence-based best practices. In a survey of over 973 diabetes self-management apps, Chomutare and coauthors[7] concluded that "there are obvious gaps between the evidence-based recommendations and the functionality used in study interventions or found in online markets. Current results confirm personalized education as an underrepresented feature in diabetes mobile applications."

Only very few diabetes mobile health apps incorporate any clinical best practices established by diabetes professionals, including the American Diabetes Association, the International Diabetes Federation, the American Association of

Diabetes Educators (AADE), and the American Association of Clinical Endocrinologists (AACE). Mostly, they are data loggers, providing little assessment or analysis, personalized planning, or education.

With Unfortunate Consequences

Of all Americans with diabetes, nearly 85% report that they consult with their primary care providers for diabetes care, according to the AADE,[8] because they have limited access to education professionals and resources. These patients already face a steep learning curve on their way to successfully dealing with the disease, and the broad range of diabetes management mobile apps lengthen the learning curve, possibly shifting patients away from empowerment toward disillusionment.

Without the knowledge to make a distinction between clinically sound approaches and the poor execution of many mobile diabetes management apps with no clinical evidence, patients are less likely to embrace the technology, decreasing app usage and attitudes toward diabetes self-management.[3]

So How Did We Get Here?

Diverse forces, both within and outside health care, have forged the rather unsatisfactory mobile health situation we are in today. Central to the problem has been the emergence of what Morozov[9] has termed "technological solutionism," the ready belief that the brilliance and creativity of the minds behind the emergence of Web 2.0 and mobile technology can be brought to bear on large scale problems, such as health care and, specifically, diabetes management. In other words, it is the general belief that "there's an app for that," which perpetuates a perceived need to quantify human behavior. Morozov[9] believes that technology can be a strong force for improvement, provided we keep solutionism in check.

Unfortunately, Morozov[9] points out that too often, the leaders of Silicon Valley do not fully understand the problem and therefore are not necessarily providing true solutions. In the case of mobile health applied to diabetes management, Silicon Valley has grasped the concept that logging data is beneficial to diabetes patients and thus recast the diabetes management problem as one of "not enough information" that "big data" can solve.

Attaching sensors to the body that transmit data to a smartphone that subsequently packages and ships that data to the cloud to be shared with health care professionals and educators is not the solution; it is only the beginning. The real utility of the data is how it informs the decisions and action planning within the construct of a comprehensive management program, such as that advocated by the AADE.

Digital consumerists have rushed to fill a market void created by a perceived need for technological solutionism and a lack of regulatory oversight and the consistent application of clinical best practices in the design of said solutions. Nearly all currently available diabetes management apps have been developed by individuals or companies with experience in the digital consumer market but not in medical device development. As such, they exhibit the "fast and loud" common digital consumer market behaviors in both product development and marketing. The aim is to gain as many customers as quickly as possible with a "99-cent solution." Value for the company comes not from product revenues, but from the attractiveness of the customer base for e-commerce activities. First mover advantage is well recognized. Digital consumerists use terms like "agile development," "failing forward," and "pivoting" to justify quick release of a product even though it may not be completely debugged or fully functional. In digital marketing, hype is often a preferred tool. It is typically focused on the past successes of the development team and rather generalized promises about the app's utility. There are any number of online outlets and blogs through which they push media content with the aim of search engine optimization.

What Is the Diabetes Professional Community to Do?

Measurable behavior change is the desired outcome of diabetes education. The diabetes professional community must step into the market void and embrace mobile technology as part of the solution. It is difficult to argue that the power of the smartphone cannot be harnessed in some way to help empower users to manage their diabetes effectively.

All diabetes management apps should conform to clinical best practices. This means we must move beyond mere data logging and begin building upon the tenets of today's diabetes self-management education, embodying the principles of self-empowerment and incorporating established frameworks such as the AADE7™. This requires sophisticated software that leverages the smartphone's contextual awareness and utilizes expert systems.

Diabetes professionals must recognize their own limitations. If the nation's nearly 20,000 qualified diabetes educators each worked 40 h/week, they could only allocate approximately 8 min per month to each of the nearly 25 million diabetes patients alone, not to mention the 80 million prediabetes patients in the country who struggle to access diabetes education. A mobile app with the primary purpose of feeding data to a professional for analysis and feedback to the patient is never going to meet the needs of the entire diabetes population. Comprehensive diabetes self-management education as practiced today simply does not scale; however, software is scalable. If helping diabetes patients through some of the more routine challenges could be offloaded to a high-quality mobile app without the need of an intervention from a diabetes educator, then educators could be better utilized by handling the more difficult and unique challenges each diabetes patient faces. Diabetes professionals must acknowledge and accept that a quality diabetes management app may obviate the need for routine interaction with them.

The diabetes professional advocacy groups, such as the AADE and AACE and other international organizations must take ownership over the application of mobile technology in diabetes management. These organizations should become the definitive source for objective reviews and evaluations or perhaps form a representative committee to establish a standard in the development of diabetes management mobile health apps in the absence of regulatory oversight, similar to what the Association for the Advancement of Medical Instrumentation accomplished in establishing AAMI SW68 (Medical device software - Software life cycle processes), which later became IEC 62304, today's *de facto* standard in medical device software development.

The processes for such evaluation already exist within these organizations and could be readily deployed for use in the diabetes, prediabetes, and obese populations. For example, in evaluating commercial apps, the AADE can draw upon its existing criteria for certifying diabetes self-management education programs, and existing frameworks, such as the AADE7™, can be utilized to determine the overall compliance of a mobile app and drive market requirements for future development of mobile health apps while educating consumer app developers.

And How about the Application Developers?

If driven by the efforts of the diabetes professional community to instill a higher-quality, evidenced-based approach in product development, developers will adapt accordingly. Some will make the decision to cross the line and become a "medical-grade" diabetes management app complete with FDA regulatory clearances or approvals. Others will stay with "health and wellness" apps but take measures to establish their clinical validity. Still, others desiring to remain commercial but unwilling to establish their validity in studies will be forced to abandon claims as a diabetes management system and recast themselves as a diet or weight loss aid. In any event, the quality of apps will be positively impacted.

Disclosures:

Dr. Brandell is affiliated with bioMetric Holdings Inc., a development stage company developing implantable glucose sensing technology. This commentary expresses the personal opinions of Dr. Brandell only and does not necessarily reflect that of bioMetric Holdings Inc. or any of its associates or affiliates. No funding was provided by bioMetric Holdings Inc. or its affiliates in the development of this commentary.

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