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COMMENTARY

Can Wireless Technology Enable New Diabetes Management Tools?

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Abstract

Mobile computing and communications technology embodied in the modern cell phone device can be employed to improve the lives of diabetes patients by giving them better tools for self-management. Several companies are working on the development of diabetes management tools that leverage the ubiquitous cell phone to bring self-management tools to the hand of the diabetes patient. Integration of blood glucose monitoring (BGM) technology with the cell phone platform adds a level of convenience for the person with diabetes, but, more importantly, allows BGM data to be automatically captured, logged, and processed in near real time in order to provide the diabetes patient with assistance in managing their blood glucose levels. Other automatic measurements can estimate physical activity, and information regarding medication events and food intake can be captured and analyzed in order to provide the diabetes patient with continual assistance in managing their therapy and behaviors in order to improve glycemic control. The path to realization of such solutions is not, however, without obstacles.

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The Evolution of the Cell Phone into a Connected Handheld Computer

With the introduction of high-speed packet data services earlier this decade, the ubiquitous cell phone has evolved rapidly from simply a voice telephony device to a multifunction consumer electronics device incorporating personal information management functions (email, contacts, calendar), Web browsing, entertainment (music players, digital cameras, video players), and other forms of personal computing. High-end cell phones contain processing units capable of hundreds of million instructions per second and hundreds of million floating-point operations per second, hundreds of megabytes of memory, mass memory devices, high-resolution quarter video graphics array color screens, and wireless networking transceivers. These capabilities enable the cell phone to serve as a platform for highly personalized applications and services that an individual interacts with on a very frequent basis. It is the computer that is always with you.

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Abbreviations: (BGM) blood glucose monitoring, (FDA) Food and Drug Administration, (MVNO) mobile virtual network operator

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A Platform for Health Management Services

The modern cell phone has become an ideal platform for hosting highly personalized applications and delivering very "personal" services such as those associated with health and wellness. Working in concert with appropriately integrated bio-measurement devices, a cell phone-based health management platform could automatically capture biological and physiological information and deliver health-related applications and services directly to the individual as he/she navigates through his/her typical day. In addition, the cell phone can be used to query the individual for relevant information input anywhere, anytime. This timely "personal health information" can be processed locally on the device, transferred immediately to a network-connected server for further processing and/or display for human analysis, and stored for later retrieval and analysis by a number of stakeholders, including the individual himself, his/her caregiver(s), or health providers. Conversely, the results of computer or human analysis of the personal health information can be conveyed immediately back to the user in the form of suggested actions, educational information, assessment of current health state, therapy reminders, and so on.

Cell Phone-Based Diabetes Management Tools

Such capabilities could be employed to create tools for assisting the diabetes patient in managing his/her disease. Several organizations are working on the development and deployment of cell phone-based tools for diabetes patients. The typical approach is to integrate a blood glucose monitoring (BGM) device, a cell phone, and a suite of software applications that provide the user with features such as reminders to test, reminders to medicate, food intake advice, automatic logging of test results, blood glucose trend charts, alerts to caregivers, and delivery of test data to health care professionals. Technical approaches vary, as do the business models employed by the different organizations currently pursuing these solutions. This article examines some of the technical alternatives to implementation of solutions, business model approaches, and the potential for such solutions to make a significant impact on the lives of the growing population of diabetic individuals.

Alternative Technical Approaches

BGM devices (meters) can be integrated into the solution several different ways. The simplest approach for the implementer is to require the user to do the integration by reading the results from a meter and entering them manually on the phone device where they can be processed and/or transmitted to a server for further processing and dissemination. This phone–meter integration approach permits the greatest flexibility in the choice of meters and phones but is the least elegant and requires the most amount of participation by the user, possibly limiting the effectiveness of the solution. Another approach is to use a cable to connect an off-the-shelf meter to an off-the-shelf phone device and add appropriate software to allow the phone device to communicate with the meter device. This approach also permits flexibility in the choice of meters and phones. Many meters support such connections and some phones do; however, each pairing of a meter and a phone typically requires a specific engineering effort, as the connectors are not standard and the communications protocols vary. Given the short life cycle of cell phones and to some degree the meters, this can quickly become an expensive and unwieldy proposition given that the devices are constantly changing. Each device pair may also require a separate 510K before it can be marketed. Thus, this approach is generally not tenable.

Another approach is to integrate the devices using a wireless data link. Most cell phones today support Bluetooth® data links that can be used to accomplish this. Most meters, however, do not support Bluetooth and therefore the implementer is generally required to introduce an additional device in order to complete the interface. This approach should reduce the issues associated with the constantly changing cell phone component but adds a level of complexity and more "equipment" for the user to carry. Unfortunately, Bluetooth implementations vary somewhat from cell phone to cell phone so once again each pairing of a meter and a phone requires some amount of engineering and integration testing, not to mention the potential that the Food and Drug Administration (FDA) may require a separate 510K for each pair. Another issue with the use of Bluetooth is the drain it puts on the batteries of the respective devices.

The most elegant approach is to physically integrate the meter *onto* or *into* the phone device. These approaches reduce the user's choice of meters and phones but tend to produce the most robust solution from a usability perspective. Integration of the meter *onto* or *into* a phone device requires the collaboration of the meter device company, as the meter form factor and functionality must be altered in order to mate to a given phone model. Integration of the meter *into* a phone device requires collaboration of both the meter device company and the phone device company. This last approach

incurs the greatest development cost, as it results in a truly customized device from both the meter and the phone perspectives. It also introduces unique technical issues, such as potential radio frequency and thermal contamination of the meter electronics by the phone electronics. Conversely, the fully integrated custom device approach allows the implementer to add other features to the resultant mobile device, which may lead to a significantly more compelling solution for the diabetes patient and therefore offset the issue associated with a reduced choice of devices. This is analogous to the case of the iPhone™. Additional biosensors can be added readily to a full custom device to permit the automatic collection of additional biodata, which can then be used to create a more robust and highly personalized set of service features that go well beyond simply the capture and display of logged blood glucose measurements. Such services might include robust insulin-dosing advisories, virtual (computerized) and/or live monitoring of the individual's health state, and delivery of personalized health improvement tips and advice, behavioral change coaching, and so on.

Market research on the various alternatives by the author's organization and others indicates that most potential users of a cell phone-based diabetes management tool would prefer a fully integrated, custom device hosting a portfolio of personalized services that adapt to the user's condition on the basis of monitored biodata. Until a collaboration of significant players from the wireless, medical device, and health services industries is assembled and adequate investment is made in the implementation of such robust solutions, it is unlikely that diabetic individuals will find the solutions sufficiently compelling to result in widespread adoption.

Alternative Business Models

In addition to the various technical implementation approaches, a number of business models could be employed to bring the envisioned tools to the population of diabetes patients. First, it is important to understand that cell phones are typically not open computing platforms that any third party can simply add hardware and software to in order to create a new product offering. The devices and the networks they operate on are typically "walled gardens" controlled by the wireless service provider and their phone device partners. This is especially true in the United States but is also true to varying degrees throughout most of the world. Developing and, more importantly, deploying a cell phone-based diabetes management tool therefore typically will require collaboration with one of the cellular service providers if there is to be any chance of a successful, broad-based deployment. "Velcro engineered" solutions that seek to piggyback on the wireless service provider's products and services without their involvement during development and active participation in deployment will unlikely find broad access to the market and will likely be a disappointing experience for the diabetic user who does purchase such tools. Unfortunately, most of the major wireless service providers in the United States are not in any hurry to become involved in the development and deployment of FDA-regulated solutions delivering health centric services along with their voice and information services. There are significant concerns within the industry about product/service liability, technical complexity of the solutions, and ramifications with respect to customer service, unfamiliar market dynamics, and uncertainty about the public's willingness to purchase and use such tools.

Assuming these obstacles can be overcome, the cell phone-based diabetes management tool implementer could choose from among a number of business models ranging from being just the diabetes application provider (analogous examples in the wireless industry include Research In Motion's BlackBerry™ wireless email solution and Apple with the iPhone solution) to becoming a full-fledged wireless service provider itself by employing the mobile virtual network operator (MVNO) business model. The former approach will require major participation by a generally reluctant (for the reasons outlined earlier) wireless network operator and its community of wireless device suppliers and therefore is not likely to come to fruition any time soon. The latter approach requires minimal participation by one of the existing wireless network operators but a very large amount of capital investment by the aspiring diabetes management tool implementer. The choice of the MVNO model is consistent with the choice of the full custom technical approach described earlier given that an MVNO is for all intents and purposes just like a full-fledged wireless service provider/network operator except that it does not own and operate an actual wireless network, i.e., it is a wireless service provider but not also a network operator as it simply purchases use of another service provider's physical wireless network. An MVNO has the freedom to define and develop its own devices exhibiting whatever features it so desires and to offer whatever services it so desires. Conversely, it is solely responsible for customer acquisition, device distribution, service delivery, and customer service, i.e., it owns the customer relationship. It is this combination of solution development freedom and willingness to take total responsibility for development,

deployment, distribution, and service delivery that will likely need to be employed before truly compelling wireless phone-based solutions become widely available to the diabetic population. Fortunately, there are such ambitious plans being pursued and therefore it is possible that such solutions may become available in the near future.

Disclosure:

Mr. Hedtke is employed by QUALCOMM Incorporated, a wireless technology, products, and services concern. The opinions expressed herein are the sole personal opinions of Mr. Hedtke and do not necessarily reflect the position of QUALCOMM Incorporated. The opinions expressed were not developed through any effort funded by any party other than the author's employer and no further acknowledgments are thus necessary.