Journal of Diabetes Science and Technology
2015, Vol. 9(3) 701–705

DOI: 10.1177/1932296814568806
dst.sagepub.com
SAGE

Device Connectivity: The Next Big Wave in Diabetes

John Walsh, PA, CDTC[1], Ruth Roberts, MA[2], Richard Morris, BS[2], and Lutz Heinemann, PhD[3]

Abstract

Patients with diabetes have to take numerous factors/data into their therapeutic decisions in daily life. Connecting the devices they are using by feeding the data generated into a database/app is supposed to help patients to optimize their glycemic control. As this is not established in practice, the different roadblocks have to be discussed to open the road. That large telecommunication companies are now entering this market might be a big help in pushing this forward. Smartphones offer an ideal platform for connectivity solutions.

Keywords

diabetes therapy, telehealth, data connectivity, insulin pumps, glucose meters, continuous glucose monitoring systems

Tracking the wealth of data that patients with diabetes generate each day, such as glucose readings, glucose trend lines, insulin doses, calorie and carb intake, activity levels, weight, and blood pressure, is a challenge both for the people with diabetes and health care professionals. The data enable multiple health-related decisions each day by the person with diabetes that cannot wait until their next clinic visit. Decisions about how much insulin a meal requires, the onset of frequent hypoglycemia or hyperglycemia, erratic glucose readings, unexplained hyperglycemia, starting or stopping a diet, or beginning to train for a marathon occur when expert health care advice is not available.

A number of factors are currently in play that promises to transform management of the multiple sources required for proper diabetes care. The internet, cell phones, cell phone standards, activity monitors, Bluetooth ultra-low energy (BULE) communication for medical devices, and the development of the Continua Health Alliance (CHA) are rapidly changing medical care. CHA is a consortium of 220 companies that are working to develop systems of interoperable telehealth devices and services. People with diabetes have been pioneers in quantification of data. Such data help to gain a comprehensive overview required to make significant clinical interventions.[1]

Ideally, data would be automatically loaded from devices to a smartphone, computer, or the cloud without any input needed from the user. After collecting, downloading, and integrating data, an expert computer system would provide analysis and timely advice. Expert systems have the potential to solve the ongoing problems encountered by many regarding insufficient glycemic control, glycemic variability, and acute metabolic deterioration. The hope is that more effective diabetes care can be delivered at a lower cost once the data are directed to smartphones or servers with apps or programs that provide guidance. The speed of these innovations will soon be clarified as the FDA considers its role in the approval and regulation of consumer health apps.

Connectivity combines the interoperability of diabetes devices with expert advice systems that recommend actions. The easier it becomes to move data between medical devices and the faster expert systems are developed, the quicker people with diabetes will see benefits and health care professionals will see reduced workloads. Connectivity could make glucose control more accessible, more affordable, and bring greater clarity to day-to-day interventions.

Where We Are

All the data from glucose meters, continuous glucose monitoring systems (CGMs), insulin pumps, fitness monitors, bathroom scales, and blood pressure monitors are in principle already available. The problem is that most devices do not speak the same ‘language’ and cannot talk with each other. Only technically savvy individuals or dedicated clinicians have the know-how to collect and analyze the data on their own (www.nightscout.info).

[1]Advanced Metabolic Care and Research, Escondido, CA, USA
[2]Diabetes Services, Inc, San Diego, CA, USA
[3]Science & Co, Düsseldorf, Germany

Corresponding Author:
Lutz Heinemann, PhD, Science & Co, Kehler Str 24, Düsseldorf, 40468, Germany.
Email l.heinemann@science-co.com

Traditionally, the diabetes industry has viewed data as proprietary, partly due to the lack of interoperability standards and communication methods but also for competitive reason. CHA has developed Bluetooth and wireless local area network standards for CGMs. Additional standards are expected soon for blood glucose monitors (BGMs) and insulin pumps. The CHA standards are expected to greatly simplify data sharing between medical devices, smart phones, and the cloud.

If you own a multimillion-dollar business and arrive at your accountant's office with only your payroll stubs, your accountant will send you right back out the door. Unfortunately, most clinicians have to treat a patient when he or she arrives with minimal or inaccessible glucose and insulin dosing data because the patient doesn't have the time or skill to create or collect it. Many physician offices and clinics do not have the resources and personnel to aggregate and analyze the data that the patient may bring in. This opens up conflicting points of view between patients and clinicians. Even if the communication hurdle can be overcome, the models and algorithms that tie all these data together, that is, Carelink, Diasend, Tidepool, are complex and exist in part at best. Expert systems or the medical-provider-on-a-chip are only starting to be developed to provide clear and simple guidance to patients along with useful summary data at a glance to providers. Expert systems are also likely to be the core of what the FDA will need to regulate, creating some additional costs and delays.

In the short term, a health care professional will be able to download and analyze patient data from multiple devices before an office visit or have them emailed or faxed to them ahead of a visit. Standardization of data presentations is now underway from work at the International Diabetes Center where the Ambulatory Glucose Profile is under development for CGM data and eventually BGM data. This type of standard data format that can be modified for a particular clinician's needs provides a path toward data simplification.

There is a great need for software that can effectively identify acute medical risks and then alert the provider. However, a critical concern is that the provider might become responsible for an adequate action once he or she has received the masses of data while the software is under development. Without a system that provides clinicians with clear actionable information, minimizes liability, and pays for clinical expertise, they may prefer to avoid receipt of data.

In addition, diabetes data transfer and analysis lacks standardization. Data from other medical devices like X-rays and MRI machines are easy to exchange and share because they exist in standardized formats that have taken years to develop. The DICOM standards that are unique to the radiology community were initially developed over an 8-year period (1985-1993) to address technical interoperability issues in medical imaging. Once standardized, DICOM began to be widely utilized by military and VA medical facilities and spread to become the standard now in use. To provide a useful clinical workflow, an Integrating the Healthcare Enterprise (IHE) initiative has been developed on top of DICOM in the last 15 years.

As with the medical imaging field, transfer of diabetes data could also have a profound impact on health. Diabetes data standards are in development while data from blood glucose meters, CGM systems, and insulin pumps are still presented in differing formats and largely remain locked behind the bars of proprietary software. Even when someone collects data from 2 glucose meters of the same brand, it is usually impossible to combine the data into a single database. Integration of insulin doses from a pump with glucose readings from most meters and CGMs into 1 database often cannot be done. Data transfer from devices typically involves multiple steps to initiate and complete a sharing process. The need to simplify and harmonize diabetes data formats became clear as researchers attempted to integrate pumps, meters, and CGMs from different manufacturers into an artificial pancreas.

As with the arrival of telecommunication and DICOM standards, proprietary software and proprietary communication modes will be superseded by the benefits that data liberation brings for wider and often unrecognized partnerships as well as innovations brought in by a larger group of app and software developers. Simply connecting to a smartphone with its potential to enhance utility and benefits will do far more to drive sales for diabetes devices than remaining proprietary.

What Can Be Learned From the Fitness Industry?

Fitness device companies will ship some 17 million "smart bands" like FitBit, Nike FuelBand, and Jawbone in 2014 and this is expected to increase to 45 million by 2017. Such wearable fitness devices track data automatically and are easily synced to a smartphone and the cloud via Bluetooth. Fitness data can then be immediately viewed or shared with a clinician, friend, or family member. Apps are available that can quickly integrate data from different fitness devices to display speed, calorie output, elevation change, competitive rank, and more.

Although the accuracy of fitness devices sometimes comes into question because the algorithms used by the fitness gadgets are all proprietary, fitness devices have become popular because they provide wearers with feedback that is simple and easy to use. Diabetes devices will also see increased patient acceptance once they provide not only accurate but useful information. It is clear that medical data differ from fitness data in terms of data privacy, medical safety, the depth of analysis required, ease of use, and regulatory restrictions. Yet unless great strides are taken to improve access to health data, this critical information will remain largely unavailable to people with diabetes and clinicians.

The BULE Future

Depending on regulatory activity, the interoperability of diabetes devices could quickly parallel fitness devices using data transfers with BULE (or Bluetooth Smart) technology that offers secure 128 bit encrypted data transfer capabilities (military encryption)[2] with a broadcast range of 15 to 30 meters. Currently, BULE is the only wireless technology that addresses all 6 of the requirements for wearable medical devices.[3] Blood glucose readings would be sent to a smartphone from a glucose meter or CGM system. Automatic estimation of the carbohydrate content of meals is still in its infancy (www.gocarb.eu), but data from devices like General Electric's Easy Cal calorie and fat counter or any number of bite counter apps may provide an intermediate step in this undernourished area. Insulin doses could be transferred automatically from a BULE enabled insulin pump or insulin pen. Physical activity could be monitored by a variety of fitness devices or even by an accelerometer integrated within a CGM or insulin pump. Blood pressure readings from a BULE enabled blood pressure monitor and weight data from a scale could be gathered as well.

As these local data are collected, graphs and charts can be displayed in data-enriched reports on a smartphone to users, family members, friends, or health care professionals in real time. Expert phone apps or specialized computer software at the terminus could then search these integrated data for patterns and relationships, and offer advice to help the wearer optimize glycemic control.

Obstacles for Connectivity

Data ownership and privacy remain as issues. Data often seem to be owned by device manufacturers, insurance companies, electronic medical record (EMR) companies, and labs, yet the person with diabetes pays directly or indirectly for all of this. Health data should always be freely and openly accessible to the person with diabetes, and he or she should be able to share them with those he or she chooses.

Three simple rules should dominate diabetes data:

- People own and should have easy access to all their health data.
- Data cannot be shared with anyone else until the owner approves.
- All health-related data must be easy to export in a standard database format.

The privacy of sensitive health data is clearly a larger challenge than with fitness data. However, technology and telecommunication companies have expertise in secure data transfer and can handle privacy concerns as well as anyone.

Does Connectivity Help Those with Diabetes and Health Care Providers?

Wearing a CGM has been shown to improve the communication of glucose data from patients to physicians, and assist people with diabetes to manage their own glucose levels.[4] Connectivity allows health care professionals to have ongoing access to patient data from the devices each patient regularly uses. This allows the clinician to make rapid and appropriate changes to treatment during and between clinic visits. If someone does not have an appointment, the physician or even the analysis software can make a suggestion after analyzing current health data via an email or text message. A suggestion might be "Here are three things people typically do to address the high breakfast readings you are experiencing." Three interventions would be selected from an expert panel's recommendations by the physician or by a software program. Expected outcomes would be improved clinical care, reduced healthcare costs, and enhanced patient satisfaction.

The aim is to allow connectivity to speed up the collection and analysis of data, utilizing algorithms that reduce the time and workload of the diabetes team and the person with diabetes. Consider a fitness device that finds its user has taken 20,000 steps today (about 9 miles), well above their usual 4,000 steps. A "smart" insulin-dosing algorithm would simultaneously analyze the CGM data and pump dosing histories and help the user avoid a night low by suggesting a basal rate reduction of 15% (85% of normal) from dinner until breakfast and consumption of 40 grams of free carbs during the evening hours. The user is clearly free to override or alter these suggestions as is currently done with bolus calculator recommendations, while gaining better guidance derived from more comprehensive data. Feedback can be provided the next morning on the success of the treatment or on ways to improve treatment the next time this situation arises.

CGM usage will increase once patients get better feedback with detailed information that allows them to more effectively manage their diabetes. If this information is forwarded simultaneously to health providers or preferably expert health systems, the higher information level empowers both to manage diabetes at a higher level. Payment to providers for telehealth care or utilization of expert advice systems could easily be paid for if these systems widely enhance normoglycemia. One model of integrated mobile therapy with EMR that provides insight into logistics and management for Type 2 diabetes is WellDoc.[5]

Regulatory Hurdles

Strict regulatory hurdles by the FDA are clearly needed for a closed-loop system that provides automated insulin dosing, but the question is how high must regulatory requirements be for apps like bolus calculators and those that provide insulin

dose guidance? The FDA is working to clarify whether they will regulate phone apps that display BGM and CGM data. For devices, the FDA may opt to continue to regulate the safety and efficacy of those that generate health data, such as BGMs and CGMs, but not regulate those that store, transfer, and display data. We would like to suggest a different definition or classification of patient "guidance" in the form of "estimator tools." Helpful health apps can provide a service similar to and presumably better than what patients do on their own with CGM data (eg, estimating their insulin needs with various meals, exercise, stress, etc). Lowering the regulatory hurdles would speed access to these apps.

Monitoring of diabetes apps and software with respect to their quality and performance might be simplified by having them rated anonymously by their users in a centralized database. Analysis of outcome data from patients, who use these apps, could provide the real proof of their value. Once diabetes device data standards are formalized, a central server could determine whether app or software A, B, or C lowers HbA1c levels, reduces hypoglycemia, and increases the time spent in the target range. Thus, the patient community could develop and select their own crowd sourced experience-based apps for diabetes management that fall outside of FDA regulation. If apps were tested in this way in the open market, the user would ultimately make all the decisions. If they do not perform well, the FDA might then reclassify them to a more restrictive category until they demonstrate that they can give reasonable advice.

For supervision of diabetes software, the FDA might rethink its role and consider deregulation to speed advances in this critical health care area. Although mistakes will be made whether FDA regulation is strict or relaxed, access to diabetes information is like turning on a light in a dark room and will benefit people with diabetes and health care providers alike.

How Soon Will Connectivity Occur?

People with diabetes are themselves driving connectivity in a makeshift fashion to solve problems. At a social networking event at the 2014 American Diabetes Association conference in San Francisco, a gentleman was wearing a Pebble Smartwatch that read 154 mg/dl on its screen. Someone next to him asked if he had diabetes. He said no, that the reading was from his sleeping son's CGM system back home that he had hacked to read out on his Smartwatch. Such homemade solutions show the possibility for connectivity (www.nightscout.info).

Apps for diabetes self-management have undergone an unprecedented growth in recent years with hundreds of apps now available. However for users and clinicians, the wide variety of features, usability, and reliability can quickly become confusing.[6]

Telecommunications companies are contributing to the disruptive innovation in health care as they drive connectivity even further: Qualcomm is offering a $10 million Tricorder XPRIZE for the team that can provide the first device weighing less than 5 pounds that can best diagnose and monitor 16 different diseases and 5 vital signs. The prize is named after a similar device first seen in the 1960s TV series *Star Trek*. Major telecommunication players like Apple and Samsung are looking to open systems up and make the accumulation and sharing of health data easier. These new platforms offer numerous ways to improve connectivity for better diabetes (and health) care and treatment. Apple partnered with the Mayo Clinic and Epic Systems (which accounts for over half of all medical records in the United States) to share records and data with health care providers. This enables a person with diabetes to check a blood pressure at home and automatically pass this information to the Mayo Clinic's new app. Their app checks whether the reading is within the person's health care parameters and, if it is not, contacts the user's doctor for an intervention.

Electronic Medical Records

EMR companies coming together and unlocking patient data has been a long-standing dream as well as a headache since the American Recovery and Reinvestment Act of 2009 first introduced this mandate. Unless all physicians and specialists caring for a given patient use the same EMR, they cannot see what drugs, lab tests, or procedures other physicians have ordered. This lack of information is not only costly but also dangerous. Companies like Google and Microsoft tried in the recent past to improve this process with their own software developments, but neither system was adopted the way it was hoped.

Global standards for health data would greatly simplify this process. The goal of dominant EMR vendors, such as Epic, Cerner, Allscripts, and Meditech, is to create a single, integrated database that other apps can hook into. A more realistic goal may be the creation of national health record sharing by developing standards and protocols for efficient data exchange. Diabetes device and related data capture systems (which might include, eg, iPhone triaxial accelerometer data downloads of specific patient activities data, etc) need to move toward the same kind of "semantic web." Such common translation standards would enable the combination of data from multiple systems and make "connectivity" of diabetes management data a reality.

The Future

The devices and systems developed by large telecommunication companies won't fix problems with data aggregation and health records on their own. Yet the advances in health communication that are now underway provide a big push for improvements in diabetes therapy. Encouraging and even funding of novel activities will speed the development of wearable devices that generate diabetes relevant data.

Because diet, activity, emotions, and insulin dos have such a direct impact on glucose levels, diabetes offers the ideal arena for connectivity solutions. Meters, CGM systems, insulin pumps, and food/exercise/sleep tracking software connected together promise to be the next big step in diabetes care.

Abbreviations

BGM, blood glucose monitor; BULE, Bluetooth ultra-low energy; CGM, continuous glucose monitor; CHA, Continua Health Alliance; EMR, electronic medical record; IHE, Integrating the Healthcare Enterprise.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: JW is a consultant for a number of companies developing insulin pumps and infusion sets (including Roche Diagnostics) and is employed by Advanced Metabolic Care and Research, which conducts numerous studies in diabetes devices, medications, infusion sets, and insulins. LH hold shares in the Profil Institute for Metabolic Research, Neuss, Germany, and the Profil Institute for Clinical Research, San Diego, USA. LH and JW are also consultants for a range of companies that develop new diagnostic and therapeutic options for the treatment of diabetes.

Funding

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

References

1. Continua Health Alliance. H.810 Interoperability design guidelines for personal health systems. Version endorphin plus errata (CDG 2014).
2. Wikipedia. Advanced encryption standard. Available at: http://en.wikipedia.org/wiki/Advanced_Encryption_Standard. Accessed December 22, 2014.
3. Omre AH. Bluetooth low energy: wireless connectivity for medical monitoring. *J Diabetes Sci Technol*. 2010;4(2):457-463.
4. Klonoff D. Continuous glucose monitoring: roadmap for 21st century diabetes. *Diabetes Care*. 2005;28:1231-1239.
5. Peeples MM, Iyer AK, Cohen JL. Integration of a mobile-integrated therapy with electronic health records: lessons learned. *J Diabetes Sci Technol*. 2013;7(3):602-611.
6. El-Gayar O, Timsina P, Newar N, Eid W. Mobile applications for diabetes self-management: status and potential. *J Diabetes Sci Technol*. 2013;7(1):247-262.