Improving patient self-care using diabetes technologies

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Abstract: Diabetes technologies are an unstoppable phenomenon. They offer opportunities to improve patient self-care through empowerment. However, they can be a challenge for both patients and clinicians. Thus, the use of technology may empower or burden. To understand and benefit from the use of diabetes technologies, one must understand the currently unmet needs in diabetes management. These unmet needs call for perspectives beyond glycated hemoglobin and an evaluation of technology solutions. Optimal use of these technologies is necessary to obtain benefits and achieve cost-effectiveness; this process depends on diabetes education and training. This review evaluates clinician and patient perspectives regarding diabetes technologies, followed by an evaluation of technology solutions. Diabetes technology solutions are evaluated according to available results about their effectiveness and their potential to empower people living with diabetes.

Keywords: biomedical technology, diabetes mellitus, therapy, patient participation, self-care

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Introduction

Optimization of glycemic control has shown to reduce diabetes complications. Glycated hemoglobin (HbA1c) has proven to be helpful in long-term glucose management; however, it is useless on a daily basis given that it does not provide any information regarding glucose variability. In general, a high burden of diabetes management is still present on a daily basis. For most people living with diabetes, glycemic control optimization involves important and constant decision-making; and for many a continuous struggle between hyperglycemia and hypoglycemia due to glycemic variability. In this context, feelings of powerlessness and futility are commonly reported sources of diabetes distress, as well as fear of chronic complications, hypoglycemia risk and stigma in the working and social environments.[1–3] These sources of distress are common barriers that limit treatment adherence, quality of life and glycemic control.[2]

Diabetes technologies have shown to improve health outcomes.[4,5] They are evolving to offer more precise treatments increase glucose information, safety and discretion. They may offer solutions to overcome frequently encountered barriers, and empower people living with diabetes. However, diabetes technologies and devices may also be sources of burden if approached inappropriately. This paper reviews the literature regarding patient and clinician perspectives on the use of diabetes technologies, suggestions to improve patient self-care and an overview of the pros and cons of some of the potential technology solutions. The main limitation of this review is the growing number of potential technology solutions becoming available; only the most relevant to self-care will be discussed.

Patient and clinician perspectives on the use of diabetes technologies

Studies have found that diabetes technologies in general do not seem to decrease diabetes distress scores, nor do they increase them.[6] However, as technology becomes friendlier and more effective for performing automatic tasks, users do report a reduced sense of burden of diabetes and an increase in quality of life.[6–8]

Most patients consider adaptability of diabetes devices a key desirable characteristic. In interview studies, users describe an effective diabetes device

as the one that will easily become a part of their own selves in their daily lives.[9] Also, a diabetes technology or device should provide enough advantages, for it to be worthwhile considering the learning curve required to incorporate its use on a daily basis and other potential costs. Potential advantages include discretion, safety, precision, and availability of more glucose and performance information. When these advantages can be provided by a device or technology and the individual feels the learning curve is affordable, then it is the right device for them and adherence is more likely to be achieved.[10]

Adherence to diabetes technologies and devices is directly related to improved glycemic control. However, studies show that adherence is still hard to achieve and sustain, tending to decrease in time, especially in adolescent populations.[6,11] A reason for this may be that the use of diabetes technologies requires multiple behaviors and tasks on a daily, weekly or monthly basis. These behaviors and tasks may include responding to continuous glucose monitoring (CGM) readings and alarms, administering insulin boluses, refilling or replacing insulin cartridges, keeping sensors in place, replacing them, charging batteries, among many others. Fortunately, some of these tasks have become simpler or nonexistent with the development of simpler and more automatic devices.[12]

Human factors are also involved in the differences between a patient's response, regarding adherence, treatment success and satisfaction.[6,13,14] Uptake of technology solutions depends on individual characteristics and also on specific treatment modalities. As an example of this, Naranjo and colleagues, in an interview study, found that multiple doses of insulin (MDI) and blood glucose meter (BGM) users had more negative opinions regarding diabetes technologies than pump and CGM users.[6]

Clinicians' main concerns are: costs, achieving adherence and the learning curves involved in the use of diabetes technologies both for patients and health professionals. A study comparing clinician *versus* patient perspectives, found discrepancies regarding the reported barriers.[10] In this study younger health professionals tended to prescribe and use more diabetes technologies with their patients and had more positive opinions regarding diabetes technologies compared with older clinicians. The barriers that both patients and clinicians agreed on as the most frequently encountered were technology costs and lack of healthcare system coverage. However, large discrepancies were found in reported modifiable barriers such as: patients not wanting to wear a device on them or patients not knowing how to handle the device or the information provided by it. In general, clinicians reported a larger number of modifiable barriers to the use of diabetes technologies than adult patients with type 1 diabetes. In a previous study by James and colleagues, similar discrepancies were shown when evaluating diabetes educators' intended use *versus* their actual use of diabetes technologies.[15] These results suggest a need for specific training to improve the prescription and use of diabetes technologies among healthcare providers.

The use of diabetes technologies has tended to increase in North America and European countries in the past 10 years. However, very different approaches and rates of coverage have been achieved depending on the country's healthcare system structure and resources.[16,17] Large transatlantic registry comparisons have shown differences in metabolic outcomes, in spite of similar population characteristics, partly in relation to the different frequencies of use of diabetes technologies.[18] Cost-effectiveness of diabetes technologies has also shown differences depending on the type of technology, setting, healthcare system structure and the endpoints considered.[16,19–23] On the other hand, there is a potential high economic burden from healthcare resource waste associated with nonadherence or early discontinuation. Shengsheng and colleagues, reported an estimated resource waste of US$72,648 to $220,289, and $5,675 to $21,775 for every 100 patients initiating CGM, for nonadherence and early discontinuation respectively.[16] These results suggest the need for tailored approaches to individualize diabetes therapy to achieve an optimal use of diabetes technologies and devices.

Diabetes education is key to approaching an optimal use of diabetes technologies.[4,10,13] A team composed of certified diabetes educators, physicians and other healthcare professionals in a patient-centered approach best performs this process.[24] Psychosocial techniques involving direct questioning and motivational interviewing are the recommended strategies to approach tailored treatments and overcome most of the barriers encountered in the use of diabetes technologies.[11,13,24,25] Direct questioning must be directed

to explore patients' expectations and needs, contrasting with reality and what a specific technology or device can actually do for them. Questioning must also be directed to explore real-life scenarios and how a device or technology may be used in those specific situations; this will promote and develop the problem-solving skills required to deal with diabetes on a daily basis.[25]

Solutions offered by diabetes technologies

Technology solutions offer opportunities to improve self-management through empowerment. These opportunities include increased safety, support, self-efficacy through the use of information, and comfort. Safety includes hypoglycemia prevention and achieving glycemic control beyond HbA1c. Support sources include communities and communication with healthcare providers. Self-efficacy sources include increased information on performance and accomplishments; having one's own experience as a reinforcement is empowering.[26] Comfort may come from devices that reduce the diabetes burden by offering decision aids, or that favor normalization and discretion.[9]

Automated bolus calculators

Automated bolus calculators (ABCs) are incorporated into insulin infusion systems, BGMs and diabetes mobile applications. The use of ABCs coupled with advanced carbohydrate counting has shown HbA1c improvements, increases in treatment satisfaction, and reductions of hypoglycemia and the fear of hypoglycemia.[27–33] Useful features include accounting for insulin on board, and adjustments for special situations such as exercise, the menstrual cycle, stress or ailments.

The main cons of this technology are: there are still scarce data about real-life and long-term use, lack of standardization (not all ABCs perform insulin-dosing calculations the same way) and that they still rely on advanced carbohydrate counting.[34]

New advances include ABCs that are coupled with insulin-dosing pens. These so-called 'smart pens' allow users to track and account for previous insulin doses, preventing insulin dose stacking. Other interesting features are: tracking the insulin temperature and expiration date. Both patients and clinicians have a better control of the treatment that is being administered. This degree of control on insulin dosing was previously only available for insulin pump users; with this technology, now it may also be available for MDI users.[35]

Continuous glucose monitoring

CGM offers large amounts of glucose information at almost zero effort from its users. Intermittently viewed CGM (iCGM) offers this same amount of information on demand in a retrospective manner. Devices that perform real-time CGM (rtCGM) provide data and the possibility of incorporating alarms to alert the user of rapid glucose drops or glucose excursions. These features of rtCGM also allow for insulin infusion suspension for pump users. The use of these devices both for pump and MDI users, has shown improvements in HbA1c of −0.3–0.6% without increasing hypoglycemia, and hypoglycemia reductions of up to 72% in people with type 1 diabetes with hypoglycemia unawareness.[36,37]

The large amount of glucose information provided by CGM might be overwhelming for both patients and clinicians; especially considering the time restrictions frequently encountered in diabetes care appointments. The ambulatory glucose profile (AGP) is a tool for standard report and visualization of CGM data. An AGP should provide the key 15 CGM metrics that enable optimal analysis and allow for treatment-related decision-making. For optimal AGP interpretation, a minimum of 14 consecutive days of data with approximately 70% CGM readings is required.[36]

CGM coupled with AGP, has enabled another type of glucose management; one that is more dynamic and goes beyond the HbA1c metric. As mentioned before, HbA1c does not provide any information regarding daily glucose variability. In contrast, CGM provides metrics that have a practical impact on a daily basis. An example of this is the so-called 'time in range' (TIR) or time in target range. TIR can be expressed as the percentage of CGM readings that are in the target glucose range or as hours per day spent in the target glucose range. Target glucose range should be individualized according to patient needs; a generally suggested range is 70–180 mg/dl. Although it is not the only metric to evaluate in an AGP, TIR directly expresses whether glucose control is on the right track with an acceptable amount of variability. Other AGP metrics that are important for safety reasons are: time spent in hypoglycemia by

thresholds and number of events. The hypoglycemia alert threshold (level 1) refers to glucose readings <70–54 mg/dl. Having <3–5% of time spent in this range is a desired result. Clinically significant hypoglycemia (level 2) threshold is defined as a glucose <54 mg/dl. Severe hypoglycemia (level 3) threshold is not defined numerically but as a state of need for external help.[36] These metrics, together with graphic visualizations are easy for both patients and clinicians to understand and act on. They directly inform people living with diabetes about their daily safety and achievements.

To have enough information to act upon and then evaluate achievements on a daily basis is a source for empowerment in itself. In this sense, an observational study about CGM has shown that most users feel safer and more in control when using CGM devices. Users reportedly felt CGM was an empowering tool because they could see glucose readings in real-time almost effortlessly. Data were very easy to act upon by interpreting trend arrows as a visual guide for the rate of change. These data had a practical impact in short-term daily life planning. In this study, users also seemed empowered for long-term lifestyle changes. Users could see the impact of certain foods and activities on their glucose curves in a dynamic fashion. They felt the need to introduce lifestyle changes to further improve their glucose readings and to see the improvements achieved when those changes were applied.

The use of alarms has proven to be effective, especially for reducing hypoglycemia; however, users regard alarms with ambivalence. Some users have discretion complaints, since they feel uncomfortable with alarms going off in their work or school environments. Though seemingly innocuous, excessive alarms can be stressful and can have side effects. An extreme example of this is an event with excessive repeated night-time alarms that could favor the onset of seizures due to stress and sleep deprivation in a predisposed individual.[38] This is an extreme and rare situation in clinical practice but should be taken as a reminder for the need of individualized approaches to alarms. Alarms are highly important for patients with hypoglycemia unawareness, while regarded as unnecessary or even intrusive by other users who are not afflicted by this condition.[13] The main strategy to cope with this issue is to program and use alarms judiciously. They should be programmed and agreed upon by both clinicians and patients, and most importantly patients should be instructed on how to act in response to these alarms. More recent systems have incorporated discrete vibratory alarms that are highly accepted by patients.[39]

CGM devices have become more accurate. Mean absolute relative difference (MARD) is the statistic frequently used to evaluate accuracy. MARD is the mean of the sum of the differences between reference and sensor readings divided by the number of observations. This statistic has its caveats; however, it may serve as a reference of how newer CGM systems tend to be more accurate. While older systems had MARDs of up to 15 or 20%, newer systems have MARDs of 9–11%. Expert consensus statements suggest the appropriate MARD to enable insulin dosing should be <10%.[40]

Even though accuracy has improved in current CGM systems and different technologies are being studied, most of glucose sensing is still performed in the interstitial fluid.[41] There will always be differences between interstitial fluid glucose when compared with blood glucose readings. Some devices require frequent manual calibrations with BGM readings. The difference between interstitial and capillary readings may decrease users' confidence in some of these devices. Situations in which glucose is changing rapidly such as postprandial states or during exercise are especially prone to these discrepancies. In fact, expert patients as well as recent studies have found discrepancies in trending arrows and the expected glucose values in these situations.[42] To overcome this issue, health professionals should always explain the expected lag, differences between these two types of readings and instruct their patients to perform BGM accordingly. BGM readings are still recommended for these specific scenarios: during the first 24 h after a new sensor application, when a trending arrow shows low, even if there are no symptoms or when symptoms suggest a low even if the reading and trend do not, before driving according to some European Union and United Kingdom legislations although this will soon change,[43] when taking new medications that could interfere with the sensor.[44] Another issue regarding interstitial fluid sensing is the tissue's response to the device. A recent study showed that macrophage activity at the insertion site is related to the sensor's decreased accuracy.[45] Understanding this process is an important step in the research towards safer and longer-lasting sensors.

The main cons for CGM are still cost and coverage by healthcare systems.

There are mixed results from studies regarding cost-effectiveness depending on the setting, the healthcare structure, the endpoints and methodology used.[19,46–49] However, several studies have shown reduced incremental cost-effectiveness per quality-adjusted life year (QALY) gained at different HbA1c thresholds. Results for all HbA1c thresholds were below the willingness-to-pay threshold of US$100 per QALY for people living with diabetes. For higher HbA1c thresholds the benefit is larger.[49–51] On the other hand, economic waste from nonadherence or early discontinuation, have been estimated and reported in different settings.[47] Optimal use of these technologies is required to avoid this loss.

Another issue with cost-effectiveness is that until recently, glucose readings from CGM systems alone were not recommended for supporting insulin-dosing decisions. Recent studies however, have shown CGM is as well tolerated and effective for insulin dosing as standard BGM readings.[52] There are proposed algorithms to interpret trend arrows into treatment decisions.[53] In response, systems of CGM have been approved as a tool for insulin-dosing decisions without BGM readings, except for the specific scenarios mentioned before. As sensors become more precise and more expert societies approve the use of CGM to enable treatment decisions and insulin dosing, CGM might be able to reduce BGM use in a larger number of patients. This would imply reducing costs in BGM strip use and still improve glucose control by incorporating a better control of glycemic variability.

Intermittently viewed continuous glucose monitoring

The so-called 'flash' glucose monitoring system is a type of iCGM in which glucose readings can be visualized on demand by scanning the sensor with a meter or a smartphone. Studies have found the iCGM system has a similar accuracy and efficacy as other CGM devices.[54,55] iCGM use has shown improvements in quality of life and sense of well-being and benefits for special populations, such as pediatric and pregnant women.[56,57]

These devices share most of the empowering characteristics already mentioned for CGM.[55] Given the sensor's duration and accessible cost, they have brought most of the benefits of CGM to a wider proportion of people living with diabetes. Another positively valued characteristic is that these devices do not require manual calibrations, since they are factory calibrated.

The main concern regarding iCGM is that given its intermittent nature, these devices are not equipped with alarms. For this reason, iCGM is not currently recommended for people with hypoglycemia unawareness.[58] Other frequently reported issues are dermal reactions at the insertion site or to the sensor's adhesive, with a reported frequency of up to 11.5% in a controlled study.[59] This is a very important limitation considering that the sensor must remain in place for 14 days to provide glucose readings.

Preliminary results suggest iCGM will probably be found to be cost-effective in most settings of developed countries. A study from the United Kingdom suggests iCGM is cost-effective for people who require more frequent testing.[60]

Implantable long-term CGM sensors

An implantable subcutaneous fluorescence-based glucose sensor has demonstrated accuracy and benefits in long-term use.[39,61] The first devices worked for periods of 90 days, now they are available for up to 180 days and the pipeline's direction is to further extend this duration.

The main benefit of this system is the sensor's duration, which can potentially increase adherence to CGM use with all the previously mentioned advantages.[49] Other potential benefits for users are: avoiding frequent sensor insertions, no interferences with common use substances like acetaminophen or ascorbic acid,[62] silent vibration alarms offer safety while not sacrificing discretion, and compatibility with all types of physical activities given that the transmitter unit may be detached as needed.

Although this system's cost is still an issue in most settings, the possibility of long-term use facilitates adherence and optimal use.[49] If these goals are achieved the system's cost-effectiveness may be better when compared to other CGM systems with short-term sensors.[49]

Integrated systems

Diabetes technologies are approaching the artificial pancreas with developments that go from the

sensor-augmented pump (SAP), to hybrid closed loop systems.

SAP technologies have achieved significant reductions of nocturnal hypoglycemia and a TIR of up to 62% when using the function of low-threshold glucose suspension of insulin infusion.[63] This hypoglycemia reduction was achieved without increasing HbA1c or ketosis. Furthermore, the function of predictive low glucose suspension, available in several SAP systems, allows for insulin infusion to be stopped when an algorithm predicts a low. Predictive low glucose suspension effectively reduces hypoglycemia events in patients with type 1 diabetes of all age groups without increasing adverse events.[64,65]

Control algorithms and machine learning allow for a feedback loop between sensor and insulin delivery. Proportional-integral-derivative control algorithms assess glucose excursions by using the difference from target glucose level, glucose area under the curve, and glucose rate of change. Model predictive controllers are more complex, consisting of mathematical models that relate insulin delivery and meal ingestion to glucose excursions. Some of these models have the capability to improve as more data get introduced and therefore 'become smarter'. This is a trending area of research, given the benefit for diabetes technologies among many other fields. These benefits go from supporting insulin-dosing decisions, to controlling the rates of insulin infusion approaching the artificial pancreas.

The artificial pancreas is approached through closed loop insulin delivery. Fully automatic insulin delivery is still not possible. Partially automatic delivery is possible with a hybrid closed loop system. The hybrid closed loop has achieved a TIR as high as 73%.[66] This modality has shown to be fit to control basal insulin rate. A recent study proved personalized model predictive control in a hybrid closed loop also performed well in situations of overestimated, missed or extended meal boluses in adults with type 1 diabetes.[67]

Even though technological advances have been great, barriers to the fully artificial pancreas still remain. There are good clinical and *in silico* results of basal insulin control in closed loop systems, but the prandial and exercise scenarios are still challenging. Current hybrid loop systems require user input for these specific scenarios. Another barrier is that the peak insulin action is variable between patients and rapid-acting insulin analogues. New ultra-rapid-acting insulin may have more appropriate pharmacokinetics and improve this situation. Another barrier is subcutaneous insulin infusion; it is not ideal for postprandial glucose control. However, peritoneal insulin delivery has not been fully accepted due to its elevated costs, potential complications and limited experience.

The main cons for the use of integrated systems are cost and coverage. Most studies show increases in treatment satisfaction and quality of life with the use of integrated systems. In observational studies, users have reported an increased sense of wellbeing, improved sleep, reduced worries for hypoglycemia and less burden of diabetes, when using integrated systems.[68,69] Although more studies are warranted, the significant reductions of hypoglycemia provided by integrated systems will probably render them cost-effective in most settings for at-risk populations with hypoglycemia unawareness. However, coverage remains low especially for hybrid loop technology, given that, until recently, they were only commercially available in North America. More ongoing studies will probably support its approval in other countries.[70]

Telemedicine

Telemedicine offers care at a distance. For diabetes, telemedicine has shown promising results offering continued support in ongoing treatments and education, reducing costs in medication and screening for diabetes retinopathy.[23,71–75]

Cons for this technology are: initial costs, coverage, data security issues, technical requirements and support. New technology solutions are under way to enable wider telemedicine coverage and facilitate their integration into healthcare systems for ongoing treatments and prevention of diabetes.[23,76]

Applications, wearables and smartphone technologies

Applications and smartphone technologies offer technological solutions for telemedicine, social interaction, exercise monitoring, and specific diabetes health platforms.

Diabetes health platforms have built a diabetes digital ecosystem by incorporating large amounts of real-world data. Applications like MySugr, Glooko, One Drop, Livongo or Social Diabetes

have achieved estimated HbA1c drops of −1.0% to −2.0%, reductions of hypoglycemia and low blood glucose indexes.[77–81] Gamification characteristics of some of these applications have shown to be of interest to promote user engagement and adherence.[77]

More applications for smart CGMs and decision aids in insulin dosing are being powered by machine learning.[82,83] Other trending areas within the diabetes technology research fields are for food recognition systems. Computer vision-based carbohydrate counting is being studied with promising results.[84]

Although it is unstoppable, the cons to mobile technology are mainly related to data security and personal data protection. A lot of these applications do not allow the user to limit the information they wish to share with the platform, and this may imply a privacy violation for some users.

Blogs, forums, social media and internet communities

Although these are not specific diabetes technologies, they allow for social interaction of people living with diabetes. An important sense of support may come from sharing experiences, connections or even technical support. As an example of this, social media use has shown an added value for self-management in chronic conditions, including diabetes.[85,86]

Do-it-yourself online communities, supported by engineers, bioinformatics and expert patients managed to get CGM on the Cloud. Self-reported benefits of real-world use include significant improvements of HbA1c and quality of life.[87] This patient-driven effort uses the slogan 'we are not waiting to reduce the burden of type 1 diabetes', and continues to work for more people to access integrated systems (openaps.org). The Juvenile Diabetes Research Foundation has called for research on do-it-yourself systems.

The main cons for the use of these technologies are safety, regarding information accuracy and data protection. However, online communities, blogs and social media are unstoppable and will continue to be sources of support and information for people living with chronic conditions. Ideally, clinicians should be able to guide patients towards trustworthy online information sources. Some scientific societies have recognized this and have undertaken the responsibility of emitting consensus guidelines for correct practices when sharing or obtaining information about diabetes on social media.[88]

Conclusion

Diabetes technologies can be used to empower patients and improve their self-care. The opportunities for empowerment offered by diabetes technologies include: safety, support, self-efficacy, and comfort. Cost and coverage are the most frequently encountered barriers reported by both clinicians and patients. Specific training and diabetes education for patients and healthcare provider teams, as well as an individualized approach to prioritize the needs of patients is required for the optimal use of these technologies. Cost-effectiveness results from the use of diabetes technologies depend on the particular device and technology, the setting, the endpoints and methodologies used, but in general, an optimal use of technologies is required to achieve benefits and cost-effectiveness. The use of technologies by people with diabetes is an unstoppable phenomenon given the opportunities they offer for improved self-care.

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Conflict of interest statement

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