Why Download Data: The Benefits and Challenges of More Diabetes Data

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IN BRIEF Diabetes care lends itself to interactions centered around data—counting carbohydrate for meals, calculating correction doses, viewing logbooks or device data, and discussing A1C levels—and digital technology has enhanced diabetes care through the improved collection and analysis of data from multiple sources. With these technological advancements have come great improvements in quality of life for people with type 1 diabetes. These technologies allow for more informed and immediate decision-making through better access to blood glucose data and sometimes allow the devices themselves to make decisions, removing the need for patients or clinicians to be involved in decision-making altogether. At the same time, these new technologies bring new challenges for both patients and health care providers, who must now analyze and make sense of more diabetes data.

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Diabetes care lends itself to interactions centered around data—whether counting carbohydrate for meals, calculating corrections doses, viewing logbooks or device data, or discussing A1C levels—and digital technology has enhanced diabetes care through the improved collection and analysis of data from multiple sources (1). In addition, the scope of connected health services has continued to grow, allowing for ongoing direct contact and data-sharing between people with di-

abetes and their health care providers (HCPs) mediated via phone, email, text messaging, video messaging, or a variety of software applications (apps). Connected health technologies use data as a tool, allowing both patients and HCPs to interact with diabetes data, both in real-time and retrospectively, and find patterns in glucose readings or identify areas for improvement (2). The technology to simultaneously view both retrospective and real-time data from multiple sources (e.g., blood glucose meters, insulin pumps, continuous glucose monitoring [CGM] devices, and wearable activity monitors) continues to improve and brings both new opportunities for patient and clinician learning and new challenges.

Data and Diabetes Care

Continuous subcutaneous insulin infusion, also known as insulin pump therapy, has been available commercially for more than 50 years, and the more recent integration of CGM systems has improved glycemic control for people with diabetes. U.S. Food and Drug Administration (FDA)-regulated insulin pumps that respond to sensor data (e.g., those that display CGM data on the pump screen, automate predictive suspension of insulin for low glucose, or are hybrid closed-loop systems that automate basal insulin delivery and deliver correction doses without disrupting the life of the user) are revolutionizing glucose management. With these technological advancements have come great improvements in quality of life for people with diabetes, allowing for more informed and more immediate decision-making through better access to glucose data such as summary reports that show glucose readings and insulin doses by time of day and proximity to meals. The ability to visualize pre- and post-meal and overnight glucose data allows for direct insights such as pattern identification that simply were not possible without the aid of such devices. Technological advancements are moving further toward allowing devices to make more direct decisions, removing the need for patients or clinicians to be involved in the decision-making altogether (2). At the same time, these new technologies bring new challenges for both patients and HCPs, who must now analyze and make sense of more diabetes data.

During clinic visits, HCPs have long relied on A1C test results and patients self-reported self-monitoring of blood glucose (SMBG) data in logbooks. A1C tests measure what percentage of hemoglobin is glycated (coated with sugar). A1C results reflect average glycemic control over a 2- to 3-month period and thus can only provide a limited view of glycemia, which can lead to a misinterpretation of titration needs and hinder pattern identification (3). Patient logbooks, on the other hand, run the risk of being misreported or manipulated (4). Even the most meticulously kept manual SMBG logs cannot compete with continuous data that include dozens or hundreds of blood glucose readings, carbohydrate equivalents, and insulin doses each day.

However, while the continued advancement of diabetes management technology has brought more opportunities for capturing such data points, the technology needed to view, visualize, and interpret these data has lagged behind. Even just a few years ago, it was nearly impossible to visualize insulin pump and CGM data simultaneously. The most enterprising clinicians would have had to print out reports from separate software systems and manually overlay them, perhaps holding them up to the light to see how they relate to each other. In contemporary clinical practice, patients can now download or directly synchronize their diabetes data from insulin pumps, CGM devices, and blood glucose meters to a variety of devices, including computers, tablets, smartphones, smartwatches, and other wearable devices and then send the data or give access to it to their HCPs electronically to get diabetes management guidance.

The diversity of devices, operating systems, and data-capturing systems is also a challenge, however. Proprietary software is sometimes recommended for patients to use at home or their providers to use in the clinic to download and display data from their devices. Issues with device compatibility and integration may further complicate patients' and HCPs' ability to analyze and review data in a comprehensive and meaningful way.

It is vital that HCPs have access to abundant electronic data to effectively treat their patients—data that are legible and legitimate and can be analyzed by a variety of methods such as filtering by time of day, bolus calculations, and other factors. No matter what devices patients use and regardless of whether their data are downloaded at home or in clinic, the goals for HCPs are largely the same: to understand how patients are managing their diabetes and to find ways to help patients improve their health and quality of life.

Benefits of More Data

Regular retrospective review of diabetes data is necessary to adjust insulin therapy and evaluate the cause-and-effect relationships among factors such as physical activity, dietary changes, and medications. However, several studies suggest that patients use retrospective functions of their devices less often than they do real-time functions (5–7). Real-time data functions on devices such as CGM systems and insulin pumps help patients make more immediate care decisions based on their glucose levels, and studies have indicated that users of mobile and digital diabetes technologies demonstrate greater improvement in glucose management than those who do not use digital diabetes technologies (8). Whether in real time or retroactively, the ability for busy medical practices to quickly and easily access patients' diabetes device data creates opportunities to teach patients how to identify trends and more effectively avoid ad-

verse events such as diabetic ketoacidosis or severe hypoglycemia.

Downloading data from diabetes devices helps people with diabetes gain a more comprehensive, holistic understanding of glucose management and, with that deeper understanding, an opportunity to more fully benefit from decision support and coaching (i.e., through "teachable moments"), basic device training, and optimization of device settings.

Decision support and coaching involves looking at data patterns and relationships, allowing people with diabetes to perform tasks such as identifying trends or analyzing variability of basal rates (9). For example, eating the same meal of yogurt and granola for breakfast with the same dose of insulin might yield different glycemic outcomes on different days; using a digital platform that captures real-time, continuous device data, it is possible to view changes and patterns more holistically and identify other factors that may be in play, such as sleep quality, physical activity levels, travel, or menstrual cycles. Building a better understanding of diabetes data can also help with more informed planning and regulation of insulin regimens for future events such as training for a race or maintaining health during pregnancy.

Providing basic training for devices such as blood glucose meters, insulin pumps, and CGM systems is an important part of helping patients manage their diabetes. Although most insulin pumps, infusion sets, and other insertion devices share basic attributes, there are differences that may affect patients' experiences. By analyzing the device data, HCPs can help patients explore whether a device is an effective addition to their glucose management and perhaps whether there are issues with compatibility or a need for additional training. For example, a patient may be operating with an insulin pump infusion set that has a cannula or needle length that is not as effective for his or her body. Analyzing the data and patient behavior can help an HCP isolate the source of the problem more quickly.

Data analysis is a key component to optimizing device settings. After viewing a patient's blood glucose trends and patterns, it might become clear that a change to the individual's insulin therapy is required. For example, basal insulin requirements vary by individual, and improper basal insulin programming may cause undesirable glucose levels between meals, during sleep, or while exercising (8). Clearly visualizing glucose excursion events allows patients and HCPs to better analyze the association between basal dosage and glucose outcomes and to eliminate other possible confounding factors.

Challenges of More Data

One major limitation of downloading digital data is that a significant portion of the data captured by patients (e.g., glucose meter readings) is never transferred to HCPs for review (10). Whether through device incompatibility, software limitations, institutional information technology policies, or provider preference, data may be collected by patients but not analyzed by their HCP.

With more diabetes data available now than ever before, analyzing all of the information has become more challenging. Previously, clinicians were viewing perhaps 40 manually logged glucose data points at a patient visit, along with an A1C test result. Now, with improved digital data collection encompassing insulin pumps, CGM systems, and blood glucose meters, HCPS might be viewing 150,000 data points for a patient over the same 3-month period. This deluge of available data has immensely increased the amount of work required of clinicians and their staff, while patients' expectations that their HCP will analyze their data have remained the same. The challenges of siloed systems and the limited uptake of interoperability and open device protocols further serve as a hindrance to viewing and analyzing patient data in a meaningful way.

A key element in successful insulin therapy is for HCPs to teach individuals with diabetes how to identify patterns in their blood glucose readings to determine whether changes are needed to optimize their glucose control (6). The more advanced the insulin therapy technology is, the more important it is for individuals with diabetes to engage in retroactive pattern review. Visualizations such as daily, weekly, and monthly trend reports, as well as the percentage of time spent in the blood glucose target range are valuable in helping patients make more meaningful decisions regarding insulin dose calculations and lifestyle behaviors. However, patients' discomfort with interpreting and acting on glucose patterns without the presence of a clinician may hamper their success. Furthermore, the burden of managing multiple devices may contribute to patients choosing not to adopt new technologies. With more real-time data available through digital technologies, individuals with diabetes may focus on compensating for the glucose values of the moment while failing to analyze patterns retroactively and correct patterns in the long term (10). Hybrid closed-loop technology, while still in its infancy, may alleviate some of this burden, as these devices adapt to real-time glucose levels by modulating insulin delivery as often as every 5 minutes.

Siloed Systems and Interoperability

Device interoperability and freedom of choice for both patients and clinicians allow for the use of the software best suited to each person's needs. Device interoperability refers to the ability of devices to connect and exchange data, as well as interpret and use data that have been shared. The lack of adoption among device makers of modern, secure authentication and authorization techniques, protocol standards, open protocols, and open

TABLE 1. Comparison of Diabetes Devices Compatible With Tidepool and Glooko

	Tidepool Only	Glooko Only	Tidepool and Glooko
Insulin pumps			
Medtronic	Minimed 523, 723, 530G (551/751), Veo (554/754), 630G, 640G, 670G.		
Animas			OneTouch Ping, Vibe
Tandem			t:slim, t:slim G4, t:slim X2, t:flex
Insulet			OmniPod
Roche		Spirit, Spirit Combo, Accu-Chek Insight	
ViCentra		Kaleido	
Ypsomed		mylife OmniPod	
CGM systems			
Abbott		FreeStyle Navigator II	FreeStyle Libre
Dexcom			G5 Mobile, G5 Mobile (Dexcom online), G4 Platinum
Senseonics		Eversense CGM Transmitter	
Blood glucose meters			
	A complete list is available on Tidepool's website at tidepool.org/users/devices	A complete list is available on Glooko's website at www.glooko.com/compatibility	

data repositories such as Apple Health are factors proving to be a challenge for the creation of a more connected diabetes ecosystem. Device makers, sometimes stoked by concerns over cybersecurity, create environments that fear interoperability rather than embrace it. Lack of interoperability likely limits the expansion of diabetes device functionality and slows innovation. Data platform interoperability would empower people with diabetes and clinicians to choose the devices and reports that work best for them. Platforms such as Tidepool and Glooko combine and display diabetes data from multiple devices in a uniform, user-friendly manner with the goal of increasing the benefits of viewing the data and decreasing the difficulty of analyzing it.

Tidepool is a Cloud-based software platform that was built to address the lack of data interoperability among diabetes devices. It collects data from multiple device vendors and allows third-party software apps to be built on the platform and use the data in a device-agnostic manner. The principal premise of the nonprofit organization is to simplify the process of data acquisition from multiple devices and make data more accessible and actionable. With support from JDRF, Tidepool's software is provided for free to clinicians and people with diabetes.

Similarly, the Glooko device system was designed as a device-agnostic, unified platform for diabetes management to aid people with diabetes and their HCPs. Glooko's data management software synchronizes with more than 160 different devices, including glucose meters, insulin pumps, CGM systems, and activity trackers. Glooko's software packages for clinics and for people with diabetes are provided with subscription fees (11).

Diabetes devices that are compatible with Tidepool and Glooko are listed in Table 1.

American Association of Clinical Endocrinologists and American College of Endocrinology guidelines recommend that insulin pump and CGM data should be downloadable on the same platform and displayed in the context of meals, exercise, illness, and insulin boluses (7,12). While the technology to connect different diabetes devices and platforms continues to advance, there is still no software application that completely integrates data from all brands of glucose meters, insulin pumps, and CGM devices. More innovations are needed in the standardization of diabetes devices and reporting metrics, as well as the regulatory and approvals process.

The FDA has long needed a more efficient regulatory oversight of software-based medical devices to introduce newer, safer software-based medical devices into the market in a timelier manner. In September 2017, it launched the Software Precertification (Pre-Cert) Pilot Program, which aims to determine a regulatory process that provides a reasonable assurance of safety and effectiveness for a software product before its introduction to the market, as compared to the traditional paradigm. Tidepool was one of nine companies selected to participate in the Pre-Cert Pilot Program, along with Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phos-

phorus, Roche, Samsung, and Verily (13). The Pre-Cert Pilot Program has the potential to create new opportunities for innovation and remove existing barriers to data standardization and sharing.

Downloading Multiple Data Sources to a Single Format

The potential impact of improved data-sharing and visualization is significant because effective diabetes management depends in large part on robust and reliable data-sharing (14) While analysis of data from individual insulin pumps, CGM systems, and blood glucose meters can be extremely helpful, independent analysis does not take advantage of the relationship between glycemic control and insulin delivery. The value in using diabetes-management software is that it provides access to more data and insights that can help individuals with diabetes and their HCPs optimize blood glucose management and insulin therapy based on individual needs. Seeing synchronized CGM and insulin pump data and gathering the disparate data points through digital platforms provides much needed data continuity for people with diabetes.

The Future of Diabetes Data

Enabling the ability to view data from different devices in one place was the first step toward achieving more continuity for patients and HCPs. The next step will be to explore more ways to connect with electronic health records (EHRs). The term "EHR integration" can mean different things depending on which clinician or clinic is asking about it. Some clinicians want to use their institution's EHR for platform authentication. Others want an API (application program interface) to pull all device data directly from their diabetes software platform of choice and store data in the EHR. Still others are looking to have the same functionality of diabetes software platforms (e.g., visualizations such as daily view and trends view) to be replicated and embedded within the EHR. Tidepool, for example, provides a "copy to text" function, allowing HCPs to get device settings from patients' connected Tidepool accounts and copy and paste into their institution's EHR. This has eliminated the laborious process of manually typing insulin pump settings into the EHR for many of Tidepool's clinician users.

Additional functionalities and integrations are being explored, as the needs and legal requirements of clinics are varied. Viewing data from different devices for patients and sharing the reports on different EHR systems for clinicians will no doubt take on many iterations in the quest for standardized experiences. Crucial to this quest will be for diabetes software platforms to continue to protect the privacy of all users (15).

Duality of Interest

B.A., H.L., and C.S. are full-time employees of Tidepool. L.M. is a contractor with Tidepool. H.L. owns publicly traded shares in Dexcom. B.A. owns publicly traded shares in Dexcom and Abbott Diabetes Care. No other potential conflicts of interest relevant to this article were reported.

Author Contributions

B.A., H.L., and C.S. contributed to the discussion and reviewed/edited the manuscript. L.M. researched data and wrote the manuscript. H.L. is the guarantor of this work and takes responsibility for the integrity and accuracy of the information provided.

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