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Evaluating Feasibility of Personal Diabetes Device Data Collection for Research

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Abstract

Background: Diabetes devices, like insulin pumps and continuous glucose monitors (CGM), capture and store patient adherence and utilization data that can be retrieved or downloaded providing objective information on self-management behaviors; yet, diabetes device data remain underutilized in research.

Objective: To examine the usability and feasibility of personal diabetes device data collected using a clinical download platform retooled for research purposes.

Methods: Investigators evaluated the feasibility of raw diabetes device data collection. One hundred eight preteens and adolescents with type 1 diabetes and their parents provided consent/assent.

Results: Data were successfully collected from the diabetes devices (insulin pumps and CGM) of 97 youth using a clinical download software adapted for research including data from all three commercially available CGM systems and insulin pumps brands, which contained all current and previous models of each insulin pump brand. The time required to download, mode of connection, and process varied significantly between brands. Despite the use of an agnostic download software, some outdated device brands and cloud-based CGM data were unsupported during data collection. Within the download software, dummy clinical accounts were created for each study participant, which were then linked back to a master study account for data retrieval. Raw device data were extracted into 7–8 Excel files per participant which were then used to develop aggregate daily measures.

Discussion: Our analysis is the first of its kind to examine the feasibility of raw diabetes device data using a clinical download software. The investigators highlight issues encountered throughout the research process along with mitigating strategies to inform future inquiry.

Conclusion: This study demonstrates the feasibility of raw data collection, from a wide variety of insulin pump and CGM brands, through the retooling of a clinical download software. Data from

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these personal devices provide a unique opportunity to study self-management behavior and the glycemic response of individuals in their everyday environments.

Keywords

continuous glucose monitor; diabetes mellitus; insulin pump; self-management

The use of diabetes monitoring and self-management devices has increased dramatically over the last several years, with the most significant increase seen in continuous glucose monitoring (CGM) utilization (Foster et al., 2019). The use of diabetes devices has been shown to improve outcomes across several studies in a recent review (Pease et al., 2020). However, despite the use of CGM among individuals with type 1 diabetes (T1D) climbing from 7% to 30% over the last 3 years, diabetes outcomes like hemoglobin A1C (HbA1c) remain unchanged (Foster et al., 2019). It is increasingly important to understand who is benefitting from diabetes devices, such as insulin pump and CGM therapy, and what specific self-management behaviors and patient characteristics are correlated with successful outcomes. Well-established links among knowledge, skill development, and outcomes in diabetes self-management underscore the importance of self-management science to inform patient selection and optimize patient device utilization (Beck et al., 2015; DAFNE Study Group, 2002; Elliott et al., 2015). Nevertheless, diabetes device self-management remains understudied (Matejko et al., 2013; Wilkinson et al., 2010).

Insulin pumps store patient adherence and utilization data that can be retrieved or downloaded providing objective information on self-management behaviors (e.g., frequency and timing of self-monitoring blood glucose [SMBG] testing; bolus insulin doses, advanced feature use; Driscoll & Young-Hyman, 2014). In much the same way, CGM devices capture real-time glucose with a recorded glucose reading every 5 min (up to 288 readings/day for patients with 100% CGM use). Many insulin pumps and CGM systems incorporate cloud-based platforms into the software allowing patient insulin pump data to be directly transferred and stored in large databases, resulting in a fertile source of diabetes self-management “big data.”

While personal diabetes device data are commonly downloaded and used in clinical practice, it is underused in research (Driscoll & Young-Hyman, 2014). Data from these personal devices provide a unique opportunity to study self-management behavior and the glycemic response of patients in their everyday environment (Corwin et al., 2019). Because the data were time-stamped, analysis can be targeted to examine how self-management behavior or glycemic control change over time, across segments of time (i.e., time of day, day of the week, season), or by setting (i.e., school, work, home; Corwin et al., 2019).

This manuscript describes an evaluation of the usability and feasibility of research data collection from patients’ personal diabetes devices using commercially available software. We address the methodological question: Is it possible to harness data from patients’ personal diabetes devices for research in formats usable for research?

Methods

We examined the usability and feasibility of personal diabetes device data collected in the Self-Management Among Preteen and Adolescent Insulin Pump (SPIN) users study. SPIN is a mixed methods descriptive study investigating insulin pump self-management among preteens and adolescents (ages 10–18 years) with T1D. The study was conducted at the endocrinology clinics of a large Midwestern children's hospital. Table 1 provides eligibility criteria.

Measures and Instruments

Demographic information (age, race/ethnicity, sex, and years of education) and clinical characteristics (date of diabetes diagnosis, date insulin pump therapy initiated, hospitalization history) were collected from the participant's electronic health record (EHR) and questionnaires. Hemoglobin A1C from the coinciding endocrinology clinic appointment was obtained from the participant's EHR. Questionnaires were administered to assess family structure, socioeconomic status, and adolescent academic performance factors.

Insulin Pump Download

The youth's personal insulin pump was downloaded by the principal investigator (PI), a certified diabetes educator, and endocrinology nurse practitioner to retrieve the previous 28 days of data. Prior studies suggest that patients may increase pump adherence in the weeks leading up to their appointments; thus, 28 days of data were retrieved for analysis (Driscoll et al., 2016). Variables of interest from device download data are listed in Table 2.

We used Tidepool (Palo Alto, CA) clinical download software for the retrieval of raw personal diabetes device data. Tidepool provides clear visualizations of daily management and glycemic control features including blood glucose readings, basal rates, bolus doses, advanced feature use, and carbohydrate inputs all occurring in chronological order presented on individual daily graphics. The Tidepool software used for research data collection in this study is the same clinical software used commonly in endocrinology practice where patients' personal diabetes devices are often downloaded during clinic visits. Download platforms such as Tidepool are generally felt to accurately capture and display device data; however, companies do not routinely publish findings confirming accuracy. Tidepool is an agnostic download software allowing the retrieval and uniform presentation of data from all current commercially available insulin pump brands (e.g., Medtronic [Northridge, CA], Omnipod [Insulet Inc., Acton, MA], Tandem [San Diego, CA]) including all current and previous models of these brands. At the time this study was conducted, Tidepool could download all three commercially available CGM brands (e.g., Freestyle Libre [Abbott, Inc., Chicago, IL], Dexcom [San Diego, CA], Medtronic).

Sample

One hundred eight participants were enrolled with 8 participants declining participation (6.6%). The majority of those who declined had HbA1c > 9.0% and only 1 declining youth had an HbA1c < 7.5%. Seven ($n = 7$) youth were excluded after enrollment due to an inability to obtain device data which occurred for several reasons: errors occurred during the

downloading process ($n = 2$); insulin pumps or CGM devices were not supported by the software ($n = 3$); and data were unable to be retrieved from cloud-based CGM platforms ($n = 2$). Devices discovered during the download process to be incompatible with Tidepool software included an Animas insulin pump and Freestyle Libre CGM systems. Although both brands are listed as compatible in Tidepool specifications (Tidepool, n.d.), we found that these were not fully supported. In the case of the Freestyle Libre CGM system, only the Freestyle Libre reader can be downloaded whereas data cannot be retrieved from the Freestyle Libre smartphone app. This platform is utilized when individuals use their smartphone as their scanning receiver which is increasingly common. Once these limitations in data compatibility were realized, participants with these devices were excluded prior to enrollment. Data were successfully obtained from the personal diabetes devices of 97 youth. A full description of enrollment is provided in Figure 1.

All three commercially available insulin pumps and CGM devices were represented in the study along with multiple insulin pump models for each brand including Medtronic's 670G—the first commercially available hybrid close loop insulin delivery system.

The Ohio State University institutional review board approved all study procedures. First, a business associate agreement was executed between the author's university and Tidepool. Tidepool is a secure HIPAA compliant software company. Next, special considerations and language were added to participant consents and assents addressing privacy and security measures surrounding the collection and storage of personal diabetes device data. Within the consents/assents, parents and youth were asked for permission to use their data, including diabetes device data, in future research inquiry. Serial numbers, which are considered protected health information and can be visualized in Tidepool's platform, were extracted along with raw data excel files and then removed during data cleaning.

Results

Participant Screening and Consent

Recruitment, consent, and data collection were conducted in a single encounter during participants' routine endocrinology clinic visits. The EHR daily census was screened by the PI 1 week prior to and on the day of clinic visits to identify youth meeting inclusion criteria. The PI first approached participants in the waiting room.

Diabetes Device Download

Downloads were performed by the PI who has experience with device downloads but had not previously used Tidepool's software; Tidepool's online tutorials provided training for software setup and device downloads (Tidepool, 2020). Additionally, the PI worked with Tidepool support staff to adapt the software for research. To facilitate the use of Tidepool for research data collection, dummy clinical accounts were created for each participant. A unique email address was necessary for each participant account. This was facilitated by creating a master account in Gmail and then adding a "+" and study number to individual participant addresses. In Gmail, anything after a "+" is ignored and forwarded to the master account, yet platforms like Tidepool recognize these addresses to be unique. The participant

email is then forwarded to the master account for authentication. Tidepool offers users the option of sharing their data with other entities including providers through a “share” feature. After data extraction, this share feature was used to connect individual accounts back to the master account.

Diabetes devices were downloaded using a free-standing app called Tidepool Uploader which is available for Mac and Windows PC (Tidepool, n.d.). To facilitate data extraction from multiple brands and models of diabetes devices, a variety of USB and cable connectors were required. Most connectors could be conveniently purchased, however, data extraction from Medtronic devices required the use of two distinct Contour Next (Bayer Inc., Leverkusen, Germany) linked meters which were more difficult to procure.

Time required for insulin pump data extraction varied significantly by device brand ranging from 2–15 min. CGM data were extracted by several mechanisms including directly from the insulin pump (for integrated systems), the CGM receiver, or the manufacturers cloud-based platform. The majority of participants who used Dexcom CGM connected their data directly to their smartphones eliminating the need for a freestanding receiver. In these cases, participants needed to grant Tidepool access to their cloud-based Dexcom data. Connecting the two accounts required participants to enter their Dexcom username and password into a Tidepool website portal. Because the username and password are not required for routine viewing of their CGM data, many parents or youth needed to retrieve their usernames or reset their passwords to facilitate access.

Confirmation of data capture could be viewed immediately within Tidepool’s website with the exception of cloud-based CGM data, which required a 1–3 hr window before visualization. The duration of data extracted could not be specified within Tidepool’s platform, meaning that while only 28 days of data was desired, in some cases up to > 2 years of data were extracted. Only Medtronic restricts the duration, limiting each download to the previous 30 days.

Although we did not encounter an inability to successfully extract available device data, there were significant missing CGM data associated with the natural wear patterns of youth in the study. Missing CGM data were attributed to: (a) an inability of the device to capture a glucose reading, typically because the value was above or below the threshold of detection (> 400mg/dl or < 40mg/dl); and (b) a failure to immediately insert a new sensor with sensor expiration often resulting in hours or days without CGM values. These large pauses or gaps in CGM data that naturally occur in daily wear should be anticipated and may present an analytic challenge for researchers.

Data Extraction and Cleaning

Raw device data were extracted into individual participant excel files. Each file contained multiple standardized excel sheets. Insulin pump data were stored on seven individual sheets (e.g., device, events, basal, wizard, bolus, SMBG, upload, pump settings) with an additional eighth sheet for CGM data. All data were then imported, cleaned, and merged in STATA 15.0 statistical software. Participant files were merged into a single-subject file at which time individual data points (i.e., SMBG glucose, CGM glucose, bolus doses, carbohydrate

entries) were used to develop aggregate daily measures (i.e., time-in-target, SMBG/day, bolus/day, percent bolus calculator use, carbohydrates/day, percent CGM use). Inaccuracy of the insulin pump device times was an important consideration noted during data cleaning. A valid time stamp is also provided in the Excel files and is calculated based on the time of download. However, these data are delivered in Coordinated Universal Time (UTC) and therefore must be aggregated to account for time zone and daylight savings time. Tidepool's clinical platform was used to validate the accuracy of cleaned data and aggregate measures. Data were not directly usable but required thoughtful aggregation and combination as derived variables. Data cleaning exemplars for select study variables are provided in Table 3.

Discussion

This brief report highlights the feasibility and usability of raw diabetes device data collection in research using a commercially available clinical download software. Despite the use of an agnostic download software, some outdated device brands and cloud-based CGM data were discovered to be unsupported during data collection. Given the rapidly changing diabetes technology landscape and need for contract negotiations between download software companies and device companies, the inability to connect with some devices should be anticipated and planned for accordingly in proposed sampling. Data access issues included the unforeseen inability to regulate the amount of data extracted from participant devices. While only 28 days of data were used for analysis, up to 2 years of data were available for viewing in the download software. The inability to anticipate, in many cases, the amount of data that would be extracted should be disclosed to patients and regulatory bodies. An additional consideration is the limited data available for Medtronic devices which restricted downloaded data to 30 days. This could be a limitation for future research interested in examining durations beyond this limit.

Our results demonstrate the feasibility of raw data extraction. The majority of recent studies utilizing device downloads have relied on manual extraction of data visualized within the clinical platform (Faulds et al., 2019; Matejko et al., 2013; Westen et al., 2019; Wilkinson et al., 2010). There are several advantages to using these clinical platforms for research data extraction including access to rich data visualization, no additional software cost, able to avoid many data cleaning and management issues present in raw data extraction, and readily available pool of clinic patient data. Despite these advantages, manual extraction of data from these platforms is laborious and prone to data entry errors. In addition, clinical platforms provide only aggregate measures of variables like CGM glucose, which limits analytic strategies.

Diabetes device data provide an alternative or adjunct means of studying objective measures of self-management rather than relying solely on self-report measures that have been found to have a high degree of misreporting (Chae et al., 2014; Given et al., 2013; Wilson & Endres, 1986). A systematic review found that only 50% of adult self-monitoring blood glucose logbooks can be considered accurate and reliable (Given et al., 2013). Attention to misreporting is especially important when studying vulnerable populations such as children and adolescents with type 1 diabetes (T1D) who show remarkably high rates (40%–70%) of misreporting self-management behaviors (Chae et al., 2014; Wilson & Endres, 1986),

making the use of objective measures imperative in the future analysis of adolescent self-management.

Conclusion

This study demonstrates the feasibility of raw data collection, from a wide variety of insulin pump and CGM brands, through the retooling of a clinical download software. The ongoing use of raw device data as opposed to manual data extracted from downloads should be considered as the standard for the study of diabetes self-management.

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The study was approved by the Nationwide Children's Hospital institutional review board.

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Figure 1.
Enrollment

Table 1

Inclusion and exclusion criteria

Inclusion criteria	Exclusion Criteria
<ul style="list-style-type: none">• Diagnosis of type 1 diabetes• 10–18 years of age• Currently uses insulin pump therapy• Duration of 6 months of pump therapy• At least 28 days of data available in pump	<ul style="list-style-type: none">• Significant learning disability• Self-reported pregnancy• Inability to read and write English (completion of questionnaires)

Table 2

SPIN Phase 1 Concepts, Variables and Measures of Interest

Aim	Concept	Variable	Measure
Aim 1	Adherence and use	• Mean number SMBG/day entered into the pump [daily]	• Insulin pump download (28-day)
		• Mean number of boluses/day [daily]	
		• Frequency of bolus calculator use per bolus [daily]	
		• Basal/bolus ^I insulin ratios/day [daily]	
		• Total daily dose (TDD) [daily]	
		• Grams of carbohydrates consumed/day [daily]	
		• Time spent using temporary basal insulin rates [28-days]	
		• Frequency of extended bolus use [28-days]	
Aim 1	Glycemic control	• Mean blood glucose [daily]	• A1C
		• Blood glucose standard deviation [daily]	
		• Glucose variability (time-in-target 70–180mg/dl) [daily]	
		• Rates and severity of hypoglycemia [28-days]	

Note. SMBG = Self-monitored blood glucose.

^IBOLUS score is calculated by giving participants 1 point for a mealtime bolus occurring between 0600–1000, 1100–1500 and 1600–2200 with a high score of 3.0 points possible per day.

Table 3

Cleaning of Device Data for Select Variables

Variable	Data file	Raw data element	Process
Percent wear CGM	cgm	<ul style="list-style-type: none"> Type (appears cbg[continuous blood glucose] when CGM value is present) time (time/date variable delivered in UTC*) 	1 Formulate string variable into recognizable time/day
			2 Formulate EST* with daylight savings
			3 Current device time – 14400000 (4 hr in milliseconds)
			4 Generate count variable for type if cbg by date
			5 Multiply count variable by 5 (cgm provides reading every 5 min)
			6 Multiplied count variable/1440 (number of minutes in day)
			7 Convert to percentage
TDD	basal bolus	<ul style="list-style-type: none"> duration (appears in milliseconds) rate (appears in units/hr) normal (contains bolus dose) time (time/date variable delivered in UTC) 	1 Complete steps 1–3 above
			2 Divide rate by 3600000 (creates units/millisecond)
			3 Multiply units/millisecond by duration
			4 Generate basal per day with sum total basal by day
			5 Generate total bolus with sum normal (bolus dose) by day
			6 Generate TDD with sum total bolus and total basal
Percent basal	basalbolus	<ul style="list-style-type: none"> duration (appears in milliseconds) rate (appears in units/hr) normal (contains bolus dose) time (time/date variable delivered in UTC) 	1 Complete steps 1–6 above
			2 Total basal day/TDD
			3 Convert to percentage
Time in target	cgm	<ul style="list-style-type: none"> value (cgm glucose appears as mmol/L) time (time/date variable delivered in UTC) 	1 Complete steps 1–3 in cell 1
			2 Convert mmol/L to mg/dl
			3 Current cgm value multiplied by 18.018018
			4 Generate categorical variable for cgm glucose
			5 Categorical glucose = 1 if glucose <70mg/dl
			6 Categorical glucose = 2 if glucose 70mg/dl and 180mg/dl
			7 Categorical glucose = 3 if glucose >180mg/dl
			8 Drop missing glucose values
			9 Generate percent time in target
			10 Sum categorical glucose = 2/cgm count variable (cell 1 step 4) by day
			11 Convert to percentage
Time above target	cgm	<ul style="list-style-type: none"> value (cgm glucose appears as mmol/L) time (time/date variable delivered in UTC) 	1 Complete steps 1–8 above
			2 Generate percent time above target
			3 Sum categorical glucose = 3/cgm count variable (cell 1 step 4) by day

Variable	Data file	Raw data element	Process
			4 Convert to percentage
Time below target	cgm	<ul style="list-style-type: none"> value (cgm glucose appears as mmol/L) time (time/date variable delivered in UTC) 	<ul style="list-style-type: none"> Complete steps 1–8 in cell 4 Generate percent time below target Sum categorical glucose = 1/cgm count variable (cell 1 step 4) by day Convert to percentage

Note. cgm = continuous glucose monitor; UTC = Coordinated Universal Time; EST = Eastern Standard Time, TDD = Total Daily Dose