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Original Research

Improved A1C Levels in Type 1 Diabetes with Smartphone App Use

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ABSTRACT

Objectives: Smartphones are a potentially useful tool in diabetes care. We have developed an application (app) linked to a website, Intelligent Diabetes Management (IDM), which serves as both an insulin bolus calculator and an electronic diabetes diary. We have prospectively studied whether patients using this app improved control of their glucose levels.

Methods: Patients with type 1 diabetes were recruited. There was a 4-week observation period, midway during which we offered to review the participants' records. The app was then downloaded and participants' diabetes regimens entered on the synchronized IDM website. At 2, 4, 8, 12 and 16 weeks of the active phase, their records were reviewed online, and feedback was provided electronically. The primary endpoint was change in levels of glycated hemoglobin (A1C).

Results: Of the 31 patients recruited, 18 completed the study. These 18 made 572±98 entries per person on the IDM system over the course of the study (≈5.1/day). Their ages were 40.0±13.9 years, the durations of their diabetes were 27.3±14.9 years and 44% used insulin pumps. The median A1C level fell from 8.1% (7.5 to 9.0, IQ range) to 7.8% (6.9 to 8.3; p<0.001). During the observation period, glucose records were reviewed for 50% of the participants. In the active phase, review of the glucose diaries took less time on the IDM website than using personal glucose records in the observation period, median 6 minutes (5 to 7.5 IQ range) vs. 10 minutes (7.5 to 10.5 IQ range; p<0.05).

Conclusions: Our smartphone app enables online review of glucose records, requires less time for clinical staff and is associated with improved glucose control.

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R É S U M É

Objectifs : Les téléphones intelligents sont des outils potentiellement utiles pour les soins aux diabétiques. Nous avons conçu une application (appli) liée à un site web, Intelligent Diabetes Management (IDM), qui sert de calculateur de bolus d'insuline et de carnet électronique de diabète. Nous avons étudié de manière prospective si les patients qui utilisaient cette appli amélioreraient la régulation de leurs concentrations de glucose.

Méthodes : Nous avons recruté les patients atteints de diabète de type 1. Il y a eu une période d'observation de 4 semaines au cours de laquelle nous avons offert à mi-chemin d'examiner l'enregistrement des données des participants. Ensuite, après le téléchargement de l'appli, les dosages du diabète des participants ont été synchronisés sur le site web IDM. À 2, 4, 8, 12 et 16 semaines de la phase active, notre équipe a examiné en ligne leurs enregistrements de données et a fourni leurs commentaires par voie électronique. Le critère de jugement principal était la modification des concentrations de l'hémoglobine glyquée (A1c).

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Résultats : Parmi les 31 patients recrutés, 18 ont complété l'étude. Ces 18 patients ont fait 572±98 entrées par personne sur le système IDM au cours de la période de l'étude (≈5,1/jour). Leur âge était de 40,0±13,9 ans, la durée de leur diabète était de 27,3±14,9 ans et 44 % utilisaient des pompes à insuline. La concentration médiane d'A1c est passée de 8,1 % (7,5 à 9,0, intervalle IQ) à 7,8 % (6,9 à 8,3; $p<0,001$). Durant la période d'observation, notre équipe a examiné les enregistrements de données de la glycémie de 50 % des participants. Dans la phase active, l'examen des carnets de glycémie prenait moins de temps sur le site web IDM que l'utilisation des enregistrements personnels de données de la glycémie au cours de la période d'observation, soit un temps médian de 6 minutes (5 à 7,5 intervalle IQ) vs un temps médian de 10 minutes (7,5 à 10,5 intervalle IQ; $p<0,05$).

Conclusions : Notre appli pour téléphones intelligents permet l'examen en ligne des enregistrements des données de la glycémie, exige moins de temps au personnel clinique et est associée à l'amélioration de la régulation de la glycémie.

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Introduction

Given all the innovations in diabetes care—continuous subcutaneous insulin infusion systems (CSII), insulin pump “wizards” and automatic bolus calculators, newer analogue insulins, faster glucose testing meters, continuous glucose monitoring systems (CGMSs), dietary measurements of carbohydrate intake—it is surprising that glycemic control, as measured by levels of glycated hemoglobin (A1C), has improved only modestly (1). A recent report indicated that the average A1C levels in specialized clinics in the United States was 8.4% despite the use of insulin pumps by 60% of the study participants (2). In the most controlled situations, the use of continuous glucose sensors and insulin infusion pumps, A1C levels averaged 7.5% in the study group (3), a level that is still above target. We clearly need better ways of using the wealth of data available (4,5).

Glucose control is facilitated by tracking glucose levels, care with food intake and judging the correct dose of insulin to administer. At clinic visits, healthcare providers often adjust the parameters for the various components of the regimen, including carbohydrate ratio, a correction system for current glucose and proposed activity, insulin on board and underlying basal insulin dose. Success in achieving excellent glycemic control requires not only the ongoing use of such algorithms but also repeated revision of the parameters on the basis of regular assessment of glycemic patterns and trends. Record keeping and routine reviews of such diaries allow recognition of patterns that prompt changes, but many with type 1 diabetes find these to be so challenging that they rely on their diabetes caregiver to suggest modifications at intermittent clinic review visits. Newer technologies involving Bluetooth connectivity allow entry of glucose data from meters into electronic diaries will facilitate record keeping, but only 10% to 12% of people with type 1 diabetes routinely download their capillary glucose testing results for review (2,6). Smartphone use is widespread, and the technology lends itself to use in diabetes care (7–9). Although bolus calculators are routinely built into insulin pumps, several stand-alone applications (apps) have bolus calculators (10). An easy-to-use combined electronic diabetes diary and bolus calculator may facilitate better glucose control.

We have developed a smartphone app and web repository to address these issues in diabetes care. The app allows participants to record their individual glucose levels, proposed carbohydrate intakes and planned activities. The app then uses the individuals' parameters to suggest the appropriate insulin doses. This insulin-dose calculator can be utilized by those using carbohydrate counting or insulin sensitivity correction systems and by those using fixed doses of insulin for mealtimes (with the option of varying the insulin for smaller or larger meals), together with an insulin grid system to adjust for differing glucose levels at that time or by those using any combination of these methods. Moreover, our app is linked to a website, Intelligent Diabetes Management (IDM) (<https://idm.ualberta.ca/>), which records this information and presents it in a personalized fashion for easy identification of patterns by the user or healthcare provider.

The purpose of this study was to determine the acceptability and user uptake of the app and associated IDM website by people with type 1 diabetes and to determine whether its use can lead to improved glucose control.

Methods

Study design

This pilot study consisted of 2 phases: an observation phase of 4 weeks and a subsequent active phase of 4 months. To establish a baseline, on enrollment, participants were asked to complete a detailed survey regarding their monitoring practices, adjustment patterns, frequencies of capillary glucose testing, recording practices, patterns of patient glycemic record review and frequencies of changes made to the insulin regimens. The A1C levels within the 3 months prior to the study were noted. For the observation phase the participants were asked to continue their present regimens of glucose monitoring and recording and were asked to review their records at least once weekly and make changes to their diabetes regimen settings as they saw fit. Patients were contacted at the middle of the observation period with an offer to review the glucose records so as to look for patterns and offer suggestions (i.e. modifications of their parameters) if appropriate. For the observation period, patients could either e-mail or fax their records. The time taken for these reviews was recorded.

For the active phase of the study, participants downloaded the app to their smartphones (either Android or iOS), and their current parameters were entered into the linked IDM website. They were asked to continue their current monitoring practices and to record the information on the app. They were taught how to review the data on the IDM website and use that website to change their insulin regimen settings. During the first week of this phase, the app records were used to obtain pre-meal and bedtime glucose values as recorded by the participants. After 2 weeks they were contacted via e-mail by a study investigator (JH or EAR) who had reviewed their glucose records using the IDM website and who offered suggestions, as appropriate, about changes in their insulin regimens. The time taken for these reviews was recorded. This review was repeated at 4, 8, 12 and 16 weeks of the study. At the end of the study, the A1C levels were measured, and 1 week of the IDM records were used to obtain pre-meal and bedtime glucose values. Using the formula provided by Nathan et al (11), the app also estimated the patients' A1C levels based on the glucose-monitoring records. Finally, we asked the participants to complete an exit survey regarding what they liked or disliked about the app and whether they wished to continue using it after the study's completion. One month after completion of the study, we checked to see how many were still using the app.

The primary endpoint was changes in A1C levels, which were measured in the local hospital laboratory. Secondary endpoints

Table 1

Baseline data of those who completed the study

Number M/F	5/13				
Weight kg	76.8±12.5				
Smoker Y/N	1/17				
Age (years)	40.0±13.9				
Duration of diabetes (years)	27.3±14.9				
Highest education achieved					
High school/college	1/17				
Insulin regimen					
CSII/MDI	8/10				
Carbohydrate counting	13				
Correction formula	14				
Self-monitoring frequency, times per day	5.9±2.5				
Daily dose of insulin units/kg	0.61±0.27				
Frequency of regimen review over 2 weeks					
Daily	Every few days	Weekly	Every 2 weeks	Never	
N	6	4	3	3	2
Frequency of regimen changes over 2 weeks					
Daily	Every few days	Weekly	Every 2 weeks	Never	
N	2	2	2	10	2
Smartphone comfort level					
Very comfortable	Comfortable	Neutral	Uncomfortable	Very uncomfortable	
N	8	4	2	1	3

Note: Data are presented as the number or the mean ± SD.

included the investigators' time spent reviewing records, mean glucose levels at pre-meal times at the beginning vs. the end of the study, the relationship of measured A1C levels vs. the calculated A1C levels based on the monitoring glucose data, the frequency of participants' record reviews, the frequencies of insulin regimen changes, the acceptability of the system, agreement with insulin dose suggestions by using a Likert scale of 0 to 10 (0 for "dislike a lot" to 10 for "like a lot") and, finally, continued app use 1 month following completion of the active period.

The app and IDM website are available for iOS and Android platforms on the Apple and Android Play Stores. Details of using the app and IDM website are provided in the Appendix.

Statistics

Results are expressed as mean ± SD or median and 25th and 75th interquartile range (IQR). We used the Student t test to assess differences between groups and a signed rank test when the normality test failed. Proportions were assessed using the z test, and all analyses were performed using Sigma-Stat (Systat Software, San Jose, California, USA).

Results

Participants

We recruited 31 participants with type 1 diabetes, 28 of whom were recruited from our local university hospital clinic and 3 by word of mouth from other centres. The diagnoses of type 1 diabetes were inferred, given the average ages of onset of 11.8±6.9 years. All were treated with insulin within 5 weeks of the diagnoses, 14 had histories of at least 1 episode of diabetic ketoacidosis and 30 were lean at diagnosis. All but 2 were Caucasian. Of the participants, 13 did not complete the study based on fewer than 200 provided entries, fewer than 10 weeks of participation or lack of A1C level determination at the end of the study. The characteristics of the patients who completed the study are provided in Table 1. In terms of age, use of CSII vs. Multiple Daily Insulin regimen (MDI), level of education, comfort with smartphone use or type of operating system used (Apple or Android), there was no difference between those who completed the study or dropped out. Details of all participants' current insulin regimens were recorded as were the highest levels

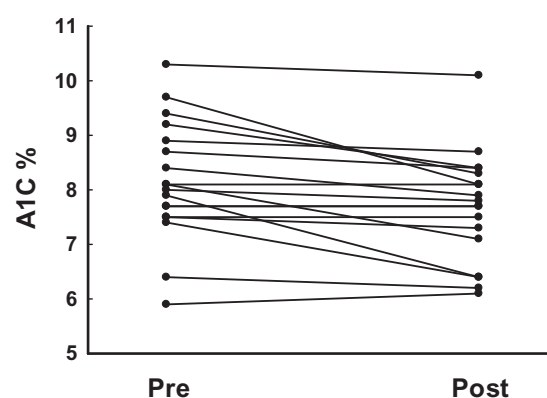


Figure 1. The A1C levels pre- and post-study in those who completed the study (n=18) improved significantly. Two patients are superimposed in the plot because they had identical starting and finishing A1C levels.

of education achieved and the comfort levels of use of smartphones. All participants gave written informed consent, and the study was approved by the Research Ethics Board of the University of Alberta. The study was registered at ClinicalTrials.gov (NCT02214719).

The participants' demographics were typical for type 1 diabetes but included more women (72%), more college-educated people (95%) and fewer smokers (n=1) (Table 1). For the insulin regimen, essentially the same number used CSII as used MDI; 2 patients were using CGMSs, and about three-quarters were using formal carbohydrate ratios for mealtime insulin and had a formula to assist in calculations of correction doses. Two participants were already using a diabetes app. The 18 who completed the study had 572±98 entries per person on the IDM system over the course of the study (~5.1 entries per day).

The median A1C levels fell from 8.1% (7.5 to 9.0, IQR) to 7.8% (6.9 to 8.3; p<0.001) over the study period (Figure 1). The median A1C levels fell 0.4% (0.2 to 1.3, IQR) in the MDI users while it was unchanged in the CSII group (p=0.047). There was no significant difference in the mean glucose levels pre-meal or at bedtime from the start of using the app vs. the end (Table 2). Although all participants were offered the opportunity to have their glucose records reviewed during the observation period, only 50% sent in records for the study team to review. During the study, our team reviewed

Table 2

Glucose values at beginning and end of study (mmol/L)

Pre-breakfast		Pre-lunch		Pre-supper		Pre-bedtime	
Beginning of study	End of study	Beginning of study	End of study	Beginning of study	End of study	Beginning of study	End of study
8.5±0.6	8.7±0.5	8.2±0.5	8.1±0.5	9.2±0.5	9.4±0.8	9.9±1.0	8.4±0.7

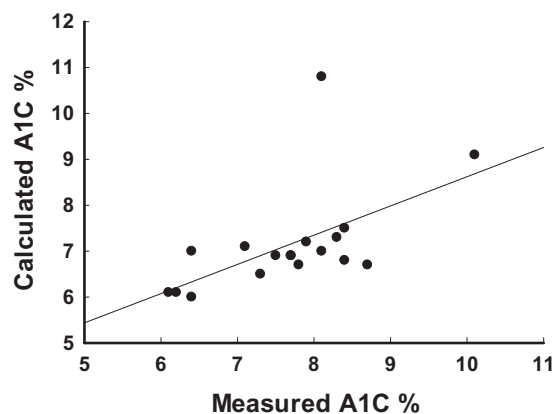


Figure 2. The relationship of the measured end-of-study A1C levels with the A1C levels derived from the glucose monitoring data using the report of Nathan et al (11). The calculated A1C levels were significantly correlated with the measured values at the end of the study period; $R=0.6$; $p=0.015$.

the records for all the patients online, and feedback was provided. The mean time for the diary record reviews by the study team was 5.7 ± 0.4 minutes per person, based on each patient's last review. The time to review records during the observation period was longer than for the same participants during the study period: 10 minutes (7.5 to 10.5, IQR) vs. 6 minutes (5.0 to 7.5, IQR; $p < 0.05$). The frequencies of blood glucose reviews by the patients and insulin regimen changes were not altered by the use of the app. The IDM website has a built-in A1C level calculation based on glucose monitoring data; its computed values correlated with the end-of-study measured A1C levels ($R=0.6$; $p=0.015$) (Figure 2).

Our exit survey found the following: 1) patients found the app simple to use with a score of 8.0 (7.0 – 9.5 IQR) on the Likert scale (0 – 10) about the app's ease of use; 2) they agreed with the bolus calculator-suggested insulin dose: 8.0 (7.0 to 9.0 IQR); and 3) they found that it helped with glucose control: 8.0 (7.5 to 9.5 IQR). One month after the study's end, 66% were still using the system. The IDM website allowed participants to review their records online, and 61% often availed themselves of this opportunity, but 17% never did. The “badges” motivational feature was used by 17% regularly, while 50% never used it.

There was no difference in the above parameters in those who continued on the study vs. those who dropped out. Drawbacks or issues mentioned were: 1) the need to enter the values on the phone manually; 2) early problems with some of the buttons on the iOS version (which have since been corrected) and 3) the fact that those on pumps already had bolus calculators.

Discussion

Our results show that patients who used our smartphone app and the IDM system had improved A1C levels, and this was particularly evident in the MDI users. While it could be argued that this was simply a study effect, it is fair to say that the system

facilitated the reviews and adjustments of the participants' diabetes regimens. In the month-long observation period prior to using the app, only 50% of the patients availed themselves of the opportunity to send in their records for review, whereas during the study, the records were always available online.

Many developments in diabetes care have led to overall improved outcomes, but documenting the benefits of individual components is more challenging. Insulin analogues result in less hypoglycemia, though not necessarily lower A1C levels (1,12,13). Newer insulin delivery means using pens with ultrafine needles or CSII that can provide very exact doses of insulin while providing modest drops in A1C levels of only 0.6% (14,15). Dietary carbohydrates indicating prediction of insulin need show only borderline benefits (16), perhaps confounded by other elements, such as the glycemic index of the food, the concomitant fat/protein intake (17) and the accuracy of carbohydrate counting by the person with diabetes. Even using a closed-loop system delivered A1C levels of 7.5%, still above target (3). CGM use is associated with A1C levels of 7.7%; this is lower than levels without CGM, but it is above target (18). Patients using CGM prefer to rely on the real-time data rather than reviewing downloads (18), but such an approach is always reactive rather than the proactive style facilitated by a tool (like ours) that can analyze records for trends. It is likely that continual insulin regimen adjustment is needed for success. Smartphones may help in this regard.

A plethora of diabetes diary apps are available to assist people with type 1 diabetes, most of which are glucose-recording apps; that is, they are simply a way of keeping a glucose diary or record log. About half of the available apps reviewed provide bolus calculators; i.e. they help to derive a suggested dose of insulin, a feature typically built into the insulin pumps on the market. A recently published systematic review of bolus calculators by Huckvale (10) looked at 46 bolus-calculating apps and found that 91% had no numeric input validation, 59% allowed calculations to proceed even if there were missing numbers and only 30% showed documentation of the calculations. Most studies of bolus calculators have been tied to insulin pump use (19–21) or linked to telemedicine supports (22), and only the latter showed a significant drop in A1C levels, which a subsequent report suggested was likely due to study effect (23). Shasaj (21) showed that a bolus calculator used by the pediatric population lowered the pre- and post-meal glucose levels but not the A1C levels. Gross et al (20) found that a bolus calculator could achieve similar postprandial glucose levels with less supplementary insulin boluses in CSII users, but A1C levels were not measured. Likewise, patients using the CSII bolus calculator did not show improved A1C levels (19). Our finding of decreased A1C levels is, therefore, important.

The app in this study is suitable for use with variety of regimens, including pumps, insulin scales and food insulin dosage based on grams of carbohydrates or simply size of meal. Although the data can be viewed on the phone, we suggest using the IDM website because that makes it easier to see the information using various filters, meaning the user can see just a minimalist record of glucose levels alone or can see everything, including meal size, carbohydrate intake, activity, real time, related text tags or any combination thereof. At the end of the study, the estimated A1C levels derived from the glucose monitoring data were related to the observed A1C levels, though differences between calculated and observed A1C levels are well recognized (11,24).

Our study has some weaknesses, including the high dropout rate, an issue many diabetes apps face. Two dropouts were due to personal issues that prevented the people from getting the end-of-study A1C measurements. Others found having their pump bolus calculator and an app bolus calculator confusing. Although the app facilitated review of the records by the clinical team, it is unclear whether participants would have reviewed the numbers of their own accord; some of the benefit resulted simply from being in a study. Our earlier Apple version of the app had problems because the positioning of the Next button was too close to the top of the screen, which caused frustration; this issue has now been fully corrected. Finally, some users expected all the trends to be evident on the phone screen, but the complexity and richness of the data render this a challenge. The webpage makes it easy to see summary profiles of changes over adjacent meals, e.g. plotting the glucose values for lunch to supper over a range of days by whether the glucose levels are high, normal or low. This means that users can easily see the trends and decide whether the current parameters for the carbohydrate ratio or corrections system are effective. To deal with the high dropout rate, we have released a new version that includes both IDM Tracker, used just for tracking glucose profiles, and IDM Bolus, which provides a bolus calculator as well as the IDM Tracker. Further refinements will be made on an ongoing basis to help negate the dropout rate.

There is a natural tendency for patients to accept the status quo, a form of “clinical inertia,” as long as they are not having undue hypoglycemia (25). Although ongoing analysis and adjustment of an insulin regimen is hard work, it is needed to help patients achieve good glycemic control effectively. However, the majority of people with type 1 diabetes do not review their records formally (6,18). Current smartphone apps like ours and others (8,22,26) help in this task, but there are risk management issues, such as those that occur if the user makes the wrong modifications (10,27,28). Machine learning has the potential of producing an insulin adjustment app that is based on a large dataset of earlier patients and can use that evidence to advise particular persons with diabetes about how best to adjust the insulin regimen parameters on an ongoing basis; we and others are working toward this goal (29–31). DreaMed’s Pump Advisor is directed to insulin pump users, while Sanofi’s My Star Coach and Glooko’s Mobile Insulin Dosing System focus is patients with type 2 diabetes; IDM will work for either CSII or MDI users, but all these approaches share similar goals. In the meantime, apps such as the one we have developed will assist people with diabetes and their teams in managing individuals’ diabetes while at the same time accumulate the data needed to train an effective machine learning app. In time, such machine learning apps need to have proven benefit, a risk-management strategy, algorithm documentation and a global data base and must stimulate innovation (28). Such an app could have widespread appeal and minimal cost and could deliver advice on an ongoing basis, a program of continuous insulin-regimen adjustment.

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Author Contributions

EAR planned the study, monitored the patients, analyzed the data and wrote the manuscript; JH monitored the patients; ES helped

plan the design of the study and the app; BB helped design the app; SAB helped recruit and follow participants; HL helped with the maintenance of the app; PS contributed to the design of the study; RG helped plan the study and the app and website. All authors reviewed and contributed to the writing of the manuscript.

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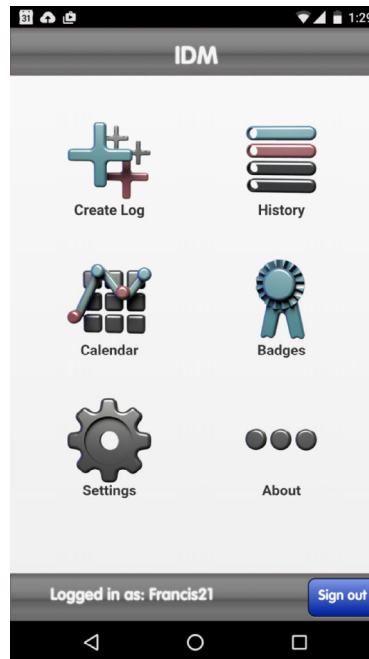
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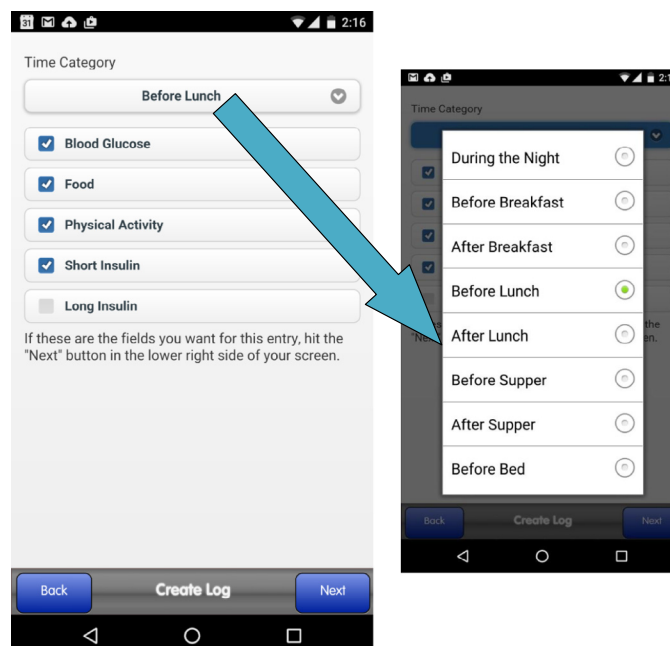
Appendix

The current version of the app can be downloaded from either the Apple or the Android Play Stores; the Android version is used for this example. The Intelligent Diabetes Management (IDM) app uses a manual entry system to create a log accessed by tapping Create Log on the opening screen. Tapping Create Log opens up the screen for creating glucose diary entries.

Opening Screen



The default screen reflects the expected time category window relative to food, e.g. Before Lunch in the shown example, but it can be changed to the appropriate relative time to a meal the entry actually reflects.



Hitting the Next button brings one to the current time and date and main entry screen. The date/time can be modified if the entry is a postdated addition.



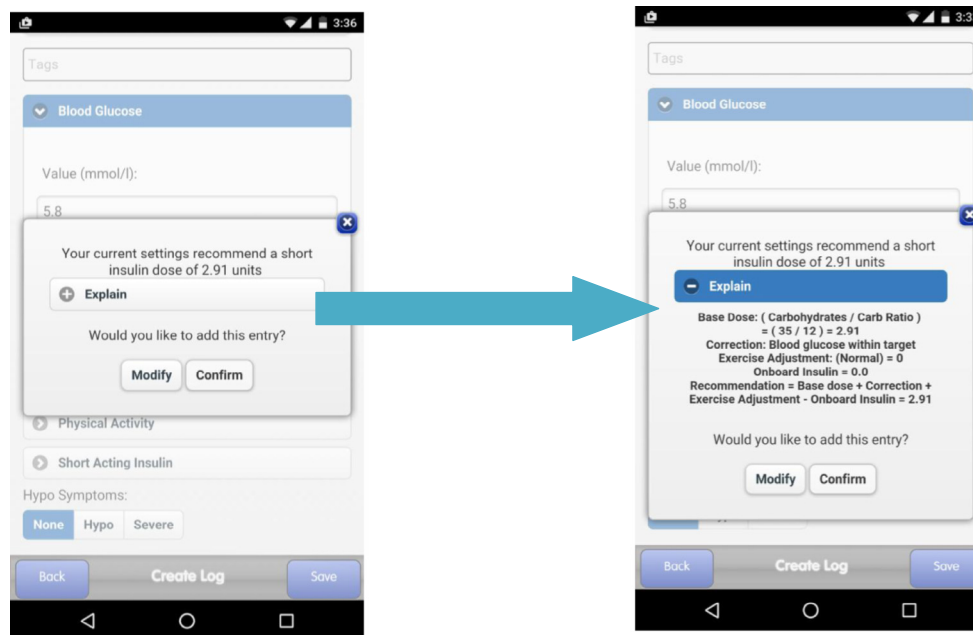
Below the Time category is a Tags dialogue box that allows any notes to be filled in relative to that entry.

Blood glucose level is entered.

Food is entered in terms of grams of carbohydrate if, in setup, carbohydrate counting has been chosen; if carbohydrate counting has not been selected, then meal size is entered in terms of Normal, Large or Small.

Physical activity may then be entered in terms of Less than Normal, Normal, Active or Very Active. Hypo Symptoms are entered as None, Hypo or Severe. The default for these is Normal or None, as appropriate.

Then Save is pressed, leading to the suggested dose of insulin based on the algorithm loaded in IDM. An explanation of the dose calculation is available. This suggested dose of insulin can be Modified or Confirmed and, once finalized, the data are synched to the IDM website.



Other buttons on the app Opening screen are a History button, for a log of previous entries that can then be edited; a Calendar button, for a simple graphic rendition of results; A Badges button, for self-motivational accolades based on results; a Settings button, to allow review of current settings; and, finally, an About button with a disclaimer and help section.

IDM site

On signing in, the current glucose diary log page is presented (https://idm.ualberta.ca/demo/diary_sheet). The format of this page is adjustable to show a minimum of information, e.g. just the glucose results or incremental data as clicked on in the Display option box, including Glucose, Short-acting insulin, Long-acting insulin if being used; carbohydrate intake; meal size if not carbohydrate counting; activity; occurrence of hypoglycemia, the time, if required; and any notes entered in the Tag line on the app. If the patient is using an insulin pump, the basal rate dose can be displayed.

At the bottom of the diary page, the median for each meal time for the displayed page and the median for all the values in the system are provided together with the 25th to 75th interquartile ranges. The calculated A1C levels and the number of low glucose values (<3.5 mmol/L) are given.

Last, a summary table is available, the time interval window being adjustable (https://idm.ualberta.ca/demo/diary_summary_sheet). The medians for each period relative to meals and the number of glucose values under 3.5 mmol/L are readily seen. To facilitate pattern recognition, there is a table of values that are linked in sequence, e.g. Breakfast to Lunch or Supper to Bedtime, divided into groups of starting values >8.0 mmol/L, 4.5 to 8.0 mmol/L and <4.5 mmol/L, so that it is evident how many values were above 8.0 mmol/L at a given meal time and whether these elevated values trended back to normal or not.