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Original Paper

# A Reinforcement Learning–Based Method for Management of Type 1 Diabetes: Exploratory Study

Mahsa Oroojeni Mohammad Javad<sup>1</sup>, PhD; Stephen Olusegun Agboola<sup>2,3</sup>, MPH, MD; Kamal Jethwani<sup>2</sup>, MPH, MD; Abe Zeid<sup>4</sup>, PhD; Sagar Kamarthi<sup>4</sup>, PhD

<sup>1</sup>Department of Information Technology and Analytics, Kogod School of Business, American University, Washington, DC, United States

<sup>2</sup>Department of Dermatology, Harvard Medical School, Boston, MA, United States

<sup>3</sup>Partners HealthCare, Boston, MA, United States

<sup>4</sup>Mechanical and Industrial Engineering Department, College of Engineering, Northeastern University, Boston, MA, United States

**Corresponding Author:**

Mahsa Oroojeni Mohammad Javad, PhD  
Department of Information Technology and Analytics  
Kogod School of Business  
American University  
Kogod School of Business Building  
4400 Massachusetts Ave NW  
Washington, DC, 20016  
United States  
Phone: 1 202 885 2698  
Email: [oroojeni@american.edu](mailto:oroojeni@american.edu)

## Abstract

**Background:** Type 1 diabetes mellitus (T1DM) is characterized by chronic insulin deficiency and consequent hyperglycemia. Patients with T1DM require long-term exogenous insulin therapy to regulate blood glucose levels and prevent the long-term complications of the disease. Currently, there are no effective algorithms that consider the unique characteristics of T1DM patients to automatically recommend personalized insulin dosage levels.

**Objective:** The objective of this study was to develop and validate a general reinforcement learning (RL) framework for the personalized treatment of T1DM using clinical data.

**Methods:** This research presents a model-free data-driven RL algorithm, namely Q-learning, that recommends insulin doses to regulate the blood glucose level of a T1DM patient, considering his or her state defined by glycated hemoglobin (HbA<sub>1c</sub>) levels, body mass index, engagement in physical activity, and alcohol usage. In this approach, the RL agent identifies the different states of the patient by exploring the patient's responses when he or she is subjected to varying insulin doses. On the basis of the result of a treatment action at time step  $t$ , the RL agent receives a numeric reward, positive or negative. The reward is calculated as a function of the difference between the actual blood glucose level achieved in response to the insulin dose and the targeted HbA<sub>1c</sub> level. The RL agent was trained on 10 years of clinical data of patients treated at the Mass General Hospital.

**Results:** A total of 87 patients were included in the training set. The mean age of these patients was 53 years, 59% (51/87) were male, 86% (75/87) were white, and 47% (41/87) were married. The performance of the RL agent was evaluated on 60 test cases. RL agent–recommended insulin dosage interval includes the actual dose prescribed by the physician in 53 out of 60 cases (53/60, 88%).

**Conclusions:** This exploratory study demonstrates that an RL algorithm can be used to recommend personalized insulin doses to achieve adequate glycemic control in patients with T1DM. However, further investigation in a larger sample of patients is needed to confirm these findings.

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**KEYWORDS**

type 1 diabetes mellitus; T1DM; diabetes treatment; machine learning; reinforcement learning; Q-learning; insulin dose prescription

## Introduction

### Background

According to the 2017 national diabetic statistics report, diabetes was the seventh leading cause of death in 2015 and a major cause of cardiovascular and renal diseases in the United States [1]. The Centers for Disease Control and Prevention reports that the number of Americans with diabetes is predicted to double or triple by 2050. In 2015, 30.3 million people in the United States (9.4% of the population) had diabetes. Of these, about 1.25 million were reported to have type 1 diabetes mellitus (T1DM) [2,3]. In T1DM, the beta cells responsible for producing insulin in the pancreas are deficient because of autoimmune destruction. T1DM patients depend on lifelong insulin therapy, delivered by injection or a pump, for glycemic control. Uncontrolled blood sugar can lead to serious short-term problems, such as hypoglycemia, hyperglycemia, or diabetic ketoacidosis [1,4-6], or chronic problems that can damage blood vessels supplying blood to important end organs, such as the heart, kidneys, eyes, and nerves [7,8]. Management of T1DM and its complications is achieved via pharmacotherapy, exercise, diet, and other lifestyle changes [9,10]. As individual patients have different physiological characteristics, they respond differently to treatments. Therefore, personalized treatment planning is likely to offer a more effective solution to managing glucose level and diabetes complications.

### Literature Review

Some studies analyzed diabetes data and built models to predict blood glucose level [11-13]. Breault et al (2002) applied a classification and regression tree on data from 15,902 patients with diabetes to predict blood glucose level [14]. Yamaguchi et al (2006) used data collected over a period of 150 days from patients with T1DM to predict next-day-morning fasting blood glucose. They considered metabolic rate, food intake, and physical conditions as predictor variables and concluded that the physical conditions were highly correlated with fasting blood glucose [15]. Bellazzi et al (1998) used a combination of structural time series analysis and temporal abstraction for interpreting historic blood glucose level to extract and visualize the trends and daily cycles of blood glucose level [16]. Bellazzi and Abu-Hanna (2009) applied a temporal abstraction and subgroup discovery algorithm for predicting the blood glucose level of diabetes for 2 types of patients: those who self-monitor their blood glucose level at home and those who were admitted to an intensive care unit [17].

Many studies have used computer-based systems, including open-loop and closed-loop control systems, to control the blood glucose levels of patients with diabetes. In the open-loop system, the patient or diabetologist is responsible for decision making regarding administration of each insulin injection [18]. On the other hand, the closed-loop system mimics the function of the pancreas to control blood glucose level [16-18]. A closed-loop system for T1DM includes either a model-free or a model-based method [19], which follows a cycle of steps: blood glucose measurement, insulin demand calculation, and insulin injection [18]. Many researchers attempted to use model-based control techniques to solve problems associated with diabetes [20,21].

Few studies applied a reinforcement learning (RL) algorithm for controlling blood glucose for type 1 diabetes.

Only a few studies have applied model-based RL algorithm for controlling blood glucose levels for type 1 diabetes. Vrabie et al (2018) proposed using RL for obtaining optimal adaptive control algorithms for dynamical systems using the mathematical models [22]. Ngo et al (2018) used an RL-based algorithm for optimal control of blood glucose in patients with type 1 diabetes using simulations on a combination of the minimum model and part of the Hovorka model [23]. Ngo et al (2018) proposed an RL algorithm for automatically calculating the basal and bolus insulin doses for type 1 diabetes patients using simulation on a blood glucose model with Kalman filter [24].

Currently, there are no effective algorithms to automatically control insulin delivery considering the blood glucose level feedback from the patient body. Only a few studies have attempted a data-driven approach to find a solution. Albisser et al (1974) applied a data-driven approach for developing artificial pancreas based on data from only 3 patients [25]. Javad et al (2015) proposed an RL approach for insulin dosage recommendation for patients with T1DM using an insulin pump based on the data from limited number of patients and states [26].

In this study, we use a data-driven approach where an RL agent learns the model from patient data. The main purpose of this paper is to explore an RL-based approach to recommend personalized treatment plan for managing glucose level to prevent diabetes-related complications and improve quality of life in patients with T1DM.

### Overview of Reinforcement Learning

RL discovers a policy to map a situation to an action to maximize a numeric reward, which takes into consideration not only the immediate rewards but also the possible subsequent rewards (delayed rewards) leading to an outcome such as a state where blood glucose is controlled. An RL agent determines which actions lead to the best reward through exploration of state space and exploitation of experience [27,28]. It has been applied successfully in different scientific fields such as robotics and control [29], manufacturing, and combinatorial search problems such as computer games [30,31]. In health care, using medical image and treatment regimen-related information from historical medical data, RL was used for cancer prediction, diagnosis, and prognosis [32,33].

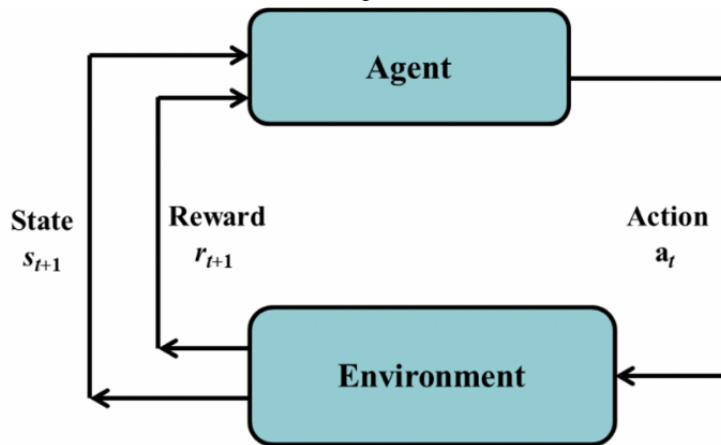
In RL, the learner or decision maker is called an *agent* (Q-learning in this application; it is described in the Methods section) that interacts with an *environment* (patient with T1DM in this application). Other 4 main subelements of RL include a *policy* (prescription medication level for a given patient condition in this application), a *reward function* (which estimates the reward, either positive or negative, depending on whether or not HbA<sub>1c</sub> level was controlled), a *value function* (Q-table in this application), and optionally, a *model* of the environment (not used in this application). In this application, let  $S$  be the set of all possible states of the environment (states of the T1DM patient) and  $A$  be the set of all possible actions (actions are the insulin levels prescribed to treat the T1DM patient). At each

sequence of discrete time steps  $t=0,1,2,3,\dots$ , the RL agent receives a representation of the environment's state  $s_t \in S$ . Considering available actions when environment is in state  $s_t$ , the agent takes an action  $a_t \in A$ , randomly at the early exploratory learning stage and more rationally exploiting the experience gained through data-driven learning in the advanced learning stage. The RL agent, depending on the consequence of its action at time  $t$ , receives a numerical reward  $r_t$  and changes the environment to state  $s_{t+1}$ . Normally, the merit of an action is quantified by the total amount of reward that the RL agent can expect to accumulate in the long run, considering the states that are likely to be visited in the transition. Over a series of learning

epochs, the RL agent learns an optimal control policy  $\pi^* : S \rightarrow A$ . At each time step time  $t$ , the optimal policy  $\pi^*(s_t)$  maps state  $s_t$  to a right action  $a_t$ , that is,  $a_t = \pi^*(s_t)$ . Figure 1 shows the agent-environment (agent-patient) interaction in RL. The optimal control policy is shaped through exploration in the early stages of learning and through experience in the mature stage of learning.

In this study, we apply a data-driven model-free RL method, known as Q-learning, that needs no previous knowledge of the environment to prescribe medication dose to treat T1DM patients considering their current HbA<sub>1c</sub>, body mass index (BMI), activity level, and alcohol usage.

Figure 1. The agent-environment interaction in reinforcement learning.



## Methods

This section describes Q-learning as applied to T1DM and its components including parameters that define state space and action space, reward function, training processes, training data, and evaluation function.

### Q-Learning

Q-learning is useful for finding optimal strategies for an environment for which neither the transition function nor the probability distribution of state variables is known [34]. Q-learning works by estimating a set of Q-values, which serves as the role of a value function. In the Q-learning algorithm, Q-values are estimated for each state-action  $(s_t, a_t)$  combination. Once the final Q-values are estimated, the only thing that needs to be known is the state of the environment (T1DM patient)  $s_t$  to determine a right action  $a_t$  (insulin dose).

Figure 2. Q-value update function.

$$Q(s_t, a_t) \leftarrow r_t + \gamma \max_{a_{t+1}} \{Q(s_{t+1}, a_{t+1})\}$$

Figure 3. Optimal policy function.

$$a_t = \pi^*(s_t) = \arg \max_{a_t} Q(s_t, a_t)$$

At the beginning of the algorithm, Q-values are initiated to an arbitrary real number. Subsequently, at each iteration  $t$ , for each combination of state  $s_t \in S$  and action  $a_t \in A$ , a reward value is calculated by the RL agent. At the core of the algorithm is the iterative process of updating Q-values as a function of the immediate reward  $r_t$  and Q-values of the next state-action pair  $Q(s_{t+1}, a_{t+1})$ . Figure 2 shows Q-value update function.

In the above formulation,  $\gamma$  is a factor that regulates the influence of the future rewards relative to the current reward. If  $\gamma=0$ , the reward only depends on the reward received in the current state; as  $\gamma$  approaches 1, the reward is maximized over the long run taking future rewards into consideration [27,28]. Over several iterations of learning, Q-values for state-action pair,  $Q(s_t, a_t)$ , converge to stable values and the RL agent is considered to have learned the optimal policy  $\pi^* : S \rightarrow A$ . At each time step time  $t$ , given state  $s_t$ , the right action  $a_t$  is determined from the formula presented in Figure 3.

## Q-Learning Applied to Type 1 Diabetes Mellitus

In this study, we study a Q-learning algorithm that prescribes medication level to a T1DM patient considering his or her state defined by HbA<sub>1c</sub>, BMI, activity level, and alcohol usage. The data for training Q-learning were obtained from electronic health records (EHRs) of patients admitted to the Mass General Hospital (MGH).

### Parameters That Define State Space

On the basis of American Diabetes Association report, several factors such as diet, medication adherence, alcohol usage, physical activity, BMI, stress, age, smoking status, and side effects from other medications can change the blood glucose level of diabetes patients [1]. To identify the factors that are crucial for developing an effective machine learning model to personalize diabetes treatment planning, we calculated the correlation coefficient matrix of potential variables recorded in the EHR and observed that only BMI, activity level, and alcohol

usage were strongly correlated with the blood glucose level measured in terms of HbA<sub>1c</sub>; other potential variables, such as age and smoking status, did not show significant correlation coefficients. Therefore, in this study, we defined a patient's state by the 4 factors that influence the patient's future HbA<sub>1c</sub>: current HbA<sub>1c</sub>, BMI, activity level, and alcohol usage.

We denote the set of HbA<sub>1c</sub> states at epoch  $t$  by  $\mathbb{H}_t = \{\mathbb{H}_{at} | a=1,2,3\}$ , the set of BMI levels by  $\text{BMI}_t = \{\text{BMI}_{bt} | b=1, \dots, 17\}$ , the set of activity levels by  $\text{activity\_level}_t = \{\text{activity\_level}_{ct} | c=1,2\}$ ; and the set of alcohol usage levels by  $\text{alcohol\_usage}_t = \{\text{alcohol\_usage}_{dt} | d=1,2,3\}$ . Table 1 presents the levels for HbA<sub>1c</sub>, BMI, activity level, and alcohol usage. The set of health states of a T1DM patient at epoch  $t$  is defined by  $s_t = (\mathbb{H}_{at}, \text{BMI}_{bt}, \text{activity\_level}_{ct}, \text{alcohol\_usage}_{dt})$ .

**Table 1.** Definitions of levels for glycated hemoglobin, body mass index, activity level, and alcohol usage.

Variable	Level 1	Level 2	Level 3	Levels 4 to 16	Level 17
Glycated hemoglobin	≤7: glucose level is well controlled	(7,9]: glucose level is moderately controlled	>9: glucose level is poorly controlled	NA <sup>a</sup>	NA
Body mass index distribution	[18.5,19)	[19,20)	[20,21)	[21,22) to [33,34)	(34,35]
Activity level	Active—engages in physical activity ≥2 times per week	Nonactive—engages in physical activity <2 times a week	NA	NA	NA
Alcohol usage	Mild to no alcohol consumption—consumption of alcohol <2 times a week	Moderate to high alcohol consumption—consumption of alcohol ≥2 times per week	Heavy consumption—consumption of alcohol few times a day	NA	NA

<sup>a</sup>Not applicable.

### Parameters That Define Action Space

Insulin is the mainstay of T1DM treatment and mostly administered through injections. The type of insulin that a T1DM patient needs depends on the severity of insulin depletion. There are different types of insulin used to treat T1DM. Normally, these insulin supplements are classified as short, rapid, intermediate, or long-acting. In this exploratory research, we focus only on the prescription of the most commonly prescribed long-acting insulin, that is, insulin glargine, which goes by the common brand name Lantus.

Lantus is usually injected once per day at the same time each day. Once injected, Lantus works for about 24 hours. This is similar to the action of insulin normally produced by the pancreas to keep a patient's blood sugar under control throughout the patient's daily routine. Adding rapid-acting insulin to the long-acting background insulin prevents increasing a patient's blood glucose right after eating a meal [7]. In the proposed Q-learning algorithm, actions represent the Lantus medication dosage levels recommended to the patients. Possible actions are coded based on 6 Lantus dosage ranges:  $a_{1t}=[6,15)$ ,  $a_{2t}=[15,20)$ ,  $a_{3t}=[20,30)$ ,  $a_{4t}=[30,40)$ ,  $a_{5t}=[40,50)$ , and

$a_{6t}=[50,100]$ ; these levels are referred to as Action 1, Action 2, ..., Action 6, respectively. The set of possible actions at epoch  $t$  is denoted by  $a_t = \{a_{kt} | k=1,2, \dots, 6\}$ , in other words,  $a_t = \{\text{Action 1, Action 2, } \dots, \text{Action 6}\}$ . Actions are taken at a discrete decision epoch indexed by  $t=1,2, \dots, T$ , where epoch  $t$  represents the time of the patient's visit to physician's office to get checkup and Lantus prescription. The patient's visits (approximately every 3 months) to their physician over 10 years are treated as decision epochs.

### Reward Function

In the proposed algorithm, the RL agent receives reward at each state comparable with the change in the state of HbA<sub>1c</sub>. At the beginning, the patient is in state  $s_1$  and takes treatment action  $a_1$ ; as a result, the agent receives reward  $r_1$  and the patient moves on to state  $s_2$ ; then the patient takes treatment  $a_2$ , the agent receives reward  $r_2$ , and the patient reaches state  $s_3$ ; and the procedure continues in this fashion. From a series of data-driven experiences, the RL agent learns the right action  $a_t$  (prescription of right Lantus dose) for a given patient state  $s_t$ . Figure 4 shows the reward function for the Q-learning algorithm.



Figure 4. Reward function.

$$r_t = \begin{cases} 10 & \text{if } HbA_{1c_{t+1}} - HbA_{1c_t} < 0 \\ 5 & \text{if } HbA_{1c_{t+1}} - HbA_{1c_t} = 0 \\ -5 & \text{if } HbA_{1c_{t+1}} - HbA_{1c_t} = 0 \\ -10 & \text{if } HbA_{1c_{t+1}} - HbA_{1c_t} > 0 \end{cases} \quad \text{and } HbA_{1c} = 1 \text{ or } 2 \\ \text{and } HbA_{1c} = 3$$

### Training Processes

In the training process, the Q-learning agent in this algorithm tries to learn the optimal treatment policy from the patient’s historical data in the EHR. At each iteration, the agent updates a table of Q-values for each combination of state and action. For example, each experience cycle  $(s_t, a_t, s_{t+1}, r_t)$  updates the value of  $Q(s_t, a_t)$  according to the Equation 1. In this implementation,  $\epsilon$ -greedy policy is applied for taking actions

during the training process. Implementing  $\epsilon$ -greedy policy helps the algorithm visit and explore different states by choosing random actions with small probability  $\epsilon$ , instead of always taking experience-driven promising actions all the time. In this method, at each time step  $t$ , the algorithm selects a random action with a fixed probability,  $\epsilon$ , based on the following formulation. Figure 5 shows the random action selection function, where  $0 \leq u_t \leq 1$  is a uniform random number drawn at each time step  $t$  [23,24].

Figure 5. Random action selection function.

$$\pi(s_t) = \begin{cases} \text{Random action } a_t \in A & \text{if } u_t \leq \epsilon \\ \arg \max_{a_t} Q(s_t, a_t) & \text{if } u_t > \epsilon \end{cases}$$

### Training Data

RL algorithm was trained and tested on the clinical data obtained from the MGH. The study was approved by the Partners Human Research Committee, the institutional review board that grants approval for such studies. In the dataset, most of the patients used Lantus compared with other types of insulin. So, this exploratory research focuses on only Lantus treatment planning for T1DM. Medical records of 87 T1DM patients enrolled at MGH from 2003 to 2013 were included in the training set. Only the patients who had complete data necessary for training the Q-learning agent were included in this analysis. Medical record data for each patient’s visits over a 10-year period were collected and processed for analyses. At each clinical encounter,  $HbA_{1c}$ ,

BMI, activity level, alcohol usage status, and Lantus medication dose were recorded. Table 2 shows a sample of patient data collected from each visit. In addition, we validated the trained Q-learning agent performance on another dataset with 60 MGH patients for whom complete data were available.

### Evaluation Function

Consider that  $(\hat{y}_{li}, \hat{y}_{ui})$  is the Lantus dose interval recommend by the RL agent for test case  $I$ , and  $y_i$  is the actual Lantus dose prescribed by the patient’s physician, and there are  $n$  number of cases in the validation set. The following equation was used for calculating the average error of RL agent predications. Figure 6 shows error function.

Table 2. Tracking the patients’ visits.

Visit	HbA <sub>1c</sub> <sub>t</sub>	Body_mass_index <sub>t</sub>	Activity_level <sub>t</sub>	Alcohol_usage <sub>t</sub>	Lantus_dose <sub>t</sub>
1	8.1	21.4	1	1	20
2	9.1	24	1	1	22
3	8	22	1	1	21

Figure 6. Error function.

$$e = \frac{\sum_{i=1}^n e_i}{n}, \quad \text{where } e_i = \begin{cases} 0 & \text{if } \hat{y}_{li} \leq y_i \leq \hat{y}_{ui} \\ 1 & \text{if } y_i < \hat{y}_{li} \text{ or } y_i > \hat{y}_{ui} \end{cases}$$

## Results

The average age of the study population was 53 years, 59% of the patients were male, 86% were white, and 47% were married. Table 3 shows demographics characteristics of patients included in the training data.

Table 4 shows demographics characteristics of patients included in the testing data. Table 5 presents the results of Q-learning algorithm for 60 test cases. For the 60 test patients, on average, in 53 out of 60 cases (88%) the physician-prescribed Lantus dose was within the dose interval recommended by the Q-learning algorithm.

**Table 3.** Summary of training data of patients (N=87).

Patient characteristics	Statistics <sup>a</sup>
<b>Age (years)</b>	
Mean (SD)	52.9 (15.7)
Median	54
<b>Race distribution, n (%)</b>	
White	75 (86)
Hispanic or Latino	7 (8)
Black	3 (3)
Asian	1 (1)
Not recorded	1 (1)
<b>Marital status, n (%)</b>	
Married or partnered	41 (47)
Single or widow	33 (38)
Divorced or separated	12 (14)
Widowed	1 (1)
<b>Gender, n (%)</b>	
Male	51 (59)
Female	36 (41)

<sup>a</sup>Due to rounding, the sum of the percentages shown is not 100.

**Table 4.** Summary of test data of patients (N=60).

Patient characteristics	Statistics
<b>Age (years)</b>	
Mean (SD)	50.4 (15.8)
Median	52
<b>Race distribution, n (%<sup>a</sup>)</b>	
White	53 (88)
Hispanic or Latino	5 (8)
Not recorded	2 (3)
<b>Marital status, n (%<sup>a</sup>)</b>	
Married or partnered	32 (53)
Single or widow	22 (36)
Divorced or separated	6 (10)
<b>Gender, n (%)</b>	
Female	34 (57)
Male	26 (43)

<sup>a</sup>Due to rounding, the sum of the percentages shown is not 100.

**Table 5.** Test results.

Test number	Hemoglobin A <sub>1c</sub> level	Body mass index level	Activity level	Alcohol usage	Actual Lantus Units dosage prescribed	Reinforcement learning agent–recommended Lantus Units dose interval	Comparison of actual Lantus dose with reinforcement learning agent–recommended Lantus dose interval
1	1	7	1	1	6	[6,15)	match
2	1	2	1	1	14	[6,15)	match
3	2	5	1	1	12	[6,15)	match
4	2	7	1	1	20	[6,15)	not match
5	2	4	1	1	14	[6,15)	match
6	2	5	1	1	10	[6,15)	match
7	2	6	1	1	12	[6,15)	match
8	2	8	1	1	20	[20,30)	match
9	2	4	1	1	20	[20,30)	match
10	2	11	1	1	25	[20,30)	match
11	2	10	1	1	25	[20,30)	match
12	2	8	1	1	13	[20,30)	not match
13	2	6	1	1	10	[6,15)	match
14	2	2	1	1	11	[6,15)	match
15	2	4	1	1	12	[6,15)	match
16	2	5	1	1	13	[6,15)	match
17	2	7	1	1	22	[6,15)	not match
18	2	4	1	1	8	[6,15)	match
19	2	4	1	1	6	[6,15)	match
20	2	4	1	1	9	[6,15)	match
21	2	5	1	1	10	[6,15)	match
22	2	5	1	1	14	[6,15)	match
23	2	8	1	2	15	[6,15)	match
24	2	14	1	2	20	[20,30)	match
25	2	8	1	2	18	[6,15)	not match
26	2	5	1	2	14	[6,15)	match
27	2	5	1	2	14	[6,15)	match
28	2	5	1	2	8	[6,15)	match
29	2	8	1	2	15	[6,15)	match
30	2	5	1	2	11	[6,15)	match
31	2	5	1	2	10	[6,15)	match
32	2	4	1	2	9	[6,15)	match
33	2	6	1	3	20	[20,30)	match
34	2	5	1	3	20	[20,30)	match
35	2	5	1	3	20	[20,30)	match
36	1	6	1	3	20	[15,20)	match
37	3	12	2	1	46	[30,40)	not match
38	1	5	2	1	15	[15,20)	match
39	1	7	2	1	20	[15,20)	match



Test number	Hemoglobin A <sub>1c</sub> level	Body mass index level	Activity level	Alcohol usage	Actual Lantus Units dosage prescribed	Reinforcement learning agent–recommended Lantus Units dose interval	Comparison of actual Lantus dose with reinforcement learning agent–recommended Lantus dose interval
40	1	5	2	1	15	[15,20)	match
41	2	8	2	1	25	[20,30)	match
42	2	10	2	1	30	[20,30)	match
43	3	13	2	1	50	[30,40)	not match
44	2	8	2	1	21	[20,30)	match
45	2	6	2	1	20	[20,30)	match
46	2	8	2	1	28	[20,30)	match
47	2	6	2	1	20	[20,30)	match
48	2	7	2	1	20	[15,20)	match
49	3	12	2	1	50	[50,100]	match
50	3	17	2	1	70	[50,100]	match
51	3	17	2	1	80	[50,100]	match
52	2	8	2	1	25	[20,30)	match
53	2	6	2	1	30	[20,30)	match
54	3	12	2	1	50	[30,40)	not match
55	3	11	2	1	36	[30,40)	match
56	3	11	2	1	38	[30,40)	match
57	2	8	2	1	21	[20,30)	match
58	2	9	2	1	23	[20,30)	match
59	2	9	2	1	23	[20,30)	match
60	2	7	2	1	20	[20,30)	match

## Discussion

### Principal Findings

Alcohol usage, physical activity, BMI, stress, and HbA<sub>1c</sub> level are crucial for developing effective models to personalize diabetes treatment planning [1]. In this study, a Q-learning agent that predicts personalized insulin dosages was formulated, trained, and tested considering patients' current HbA<sub>1c</sub>, BMI, activity level, alcohol usage to define the patient state at epoch  $t$ :  $s_t = \{HbA_{1c}, BMI_t, activity\_level_t, alcohol\_usage_t\}$ . In other words, a patient can be in any of the 306 possible states (number of HbA<sub>1c</sub> states\*number of BMI states\*number of activity level states\*number of alcohol usage status states=3 × 17 × 2 × 3). Each of these combinations represents a state. For example, if the patient is in state  $s_t$ , the dosage recommendation  $a_t$ , appropriate to state  $s_t$ , is suggested by Q-learning agent for that patient. Q-learning agent–recommended Lantus dose interval includes the actual prescription dose in 88% of the cases.

### Limitations

This research has several limitations. We did not include other important lifestyle information about patients' diet, stress, and medication adherence. These are well-known factors that

influence blood glucose levels but are infrequently documented in the medical records. We suggest considering these factors in future research for developing more effective blood glucose control. Another important limitation is the small training dataset. The main constraint to evaluating the model in a larger cohort of patients was the time it took to clean and extract these important but poorly documented factors. With adequate funding, we can apply more sophisticated natural language processing techniques to capture data from unstructured text or note from a larger sample of patients. Yet another factor is the limited generalizability of the study findings. Study data were from patients in a large academic medical center that has a diabetes center and access to other supportive lifestyle change programs that may not be available in community health centers. The fact that only 1 type of insulin (Lantus) was included broadly limits the application of this study. However, as a proof of concept, we demonstrated that this concept could potentially be used for other insulin regimen as well.

### Comparison With Previous Studies

Although in recent years, we have seen increased interest in applying machine learning methodologies in the study of personalize diabetes treatment planning, this study is the first of its kind that aims at finding the best insulin dosage for the T1DM for several reasons. First, this study involved the use of

crucial factors including alcohol usage, physical activity, BMI, and HbA<sub>1c</sub> level for finding the best insulin dosage for patients with type 1 diabetes. None of the earlier studies in the literature considered all of these important factors for developing effective models to personalize diabetes treatment planning. Second, 2 patients with the same BMI and HbA<sub>1c</sub> but different alcohol usage and activity level need different insulin dosages for managing their blood glucose level. Considering only BMI and HbA<sub>1c</sub> for insulin dosage recommendation may lead to suggesting the same dose of medication to patients with different insulin dosage needs. Finally, this study involved the use of a larger clinical dataset compared with other datasets used in other studies concerned with managing blood glucose level. Data gathered from clinical settings have an important and complementary role in the research outcomes. The suggested model-based approaches in the literature used mathematical models for simulating the function of pancreas. These model-based approaches did not consider patient's alcohol usage and physical activity level for the insulin dosage recommendation.

Yasini et al (2003) applied an agent-based simulation for managing blood glucose of patients with diabetes based only on blood glucose levels [19]. For each state of glucose level, their algorithm provided only 1 insulin dosage recommendation without considering the patient's BMI, activity level, or alcohol usage. Our proposed algorithm provides more precise insulin dosage recommendation considering the patient's current HbA<sub>1c</sub>, BMI, activity level, or alcohol usage. Vrabie et al (2018) and 2 studies by Ngo et al (2018) applied a model-based RL algorithm for controlling blood glucose for type 1 Diabetes [22-24]. We used a data-driven approach and considered the blood glucose level feedback from the patient body for training the Q-learning algorithm. In addition, our proposed Q-learning

algorithm considers not only the blood glucose of the patient for the insulin dosage recommendation but also the patient's current HbA<sub>1c</sub>, BMI, activity level, and alcohol usage. Javad et al (2015) applied data-driven approach on the limited number of patients and small dimension of problem with only 13 states for insulin dosage recommendation of type 1 diabetes, without testing the results [26]. Our proposed algorithm provides more precise insulin dosage recommendation based on the 306 possible patient states, and the results have been validated. RL algorithm was trained on the clinical data obtained from 87 T1DM patients enrolled at MGH from 2003 to 2013. Furthermore, the performance of the RL agent was evaluated on 60 test cases.

## Conclusions

Effective decision making about correct insulin dose may delay or prevent diabetes complications, such as heart attack, kidney disease, blindness, and amputation [2]. Study findings suggest that physicians may be able to use a Q-learning agent that considers patients' BMI, activity level, alcohol usage status, and current HbA<sub>1c</sub> level to recommend insulin doses. This machine learning model may help improve the timeliness of achieving an effective treatment dose rather than multiple dosage trials based on clinical acumen alone. In addition to improving treatment efficacy time, this has the potential to reduce patient stress (less clinic visits), reduce health care costs, and improve overall quality of life. Future research could extend this proof-of-concept Q-learning model to include other types of insulin and other types of diabetes medications and other state variables. The performance of the Q-learning model can be enhanced by considering finer categories and intervals for defining a patient state and action. It may also be worth exploring in patients with type 2 diabetes.

## Conflicts of Interest

None declared.

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**Abbreviations**

**BMI:** body mass index  
**EHR:** electronic health record  
**HbA<sub>1c</sub>:** glycated hemoglobin  
**MGH:** Mass General Hospital  
**RL:** reinforcement learning  
**T1DM:** type 1 diabetes mellitus

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Original Paper

# Experiences of Adults With Type 1 Diabetes Using Glucose Sensor–Based Mobile Technology for Glycemic Variability: Qualitative Study

Marilyn D Ritholz<sup>1,2</sup>, PhD; Owen Henn<sup>1</sup>, MSc; Astrid Atakov Castillo<sup>1</sup>, BA; Howard Wolpert<sup>1,3</sup>, MD; Stephanie Edwards<sup>1</sup>, MPH; Lawrence Fisher<sup>4</sup>, PhD; Elena Toschi<sup>1,3</sup>, MD

<sup>1</sup>Joslin Diabetes Center, Boston, MA, United States

<sup>2</sup>Department of Psychiatry, Harvard Medical School, Boston, MA, United States

<sup>3</sup>Department of Medicine, Harvard Medical School, Boston, MA, United States

<sup>4</sup>University of California, San Francisco, San Francisco, CA, United States

**Corresponding Author:**

Marilyn D Ritholz, PhD

Joslin Diabetes Center

1 Joslin Place

Boston, MA, 02215

United States

Phone: 1 6173094196

Fax: 1 617 713 3410

Email: [marilyn.ritholz@joslin.harvard.edu](mailto:marilyn.ritholz@joslin.harvard.edu)

## Abstract

**Background:** Adults with type 1 diabetes (PWDs) face challenging self-management regimens including monitoring their glucose values multiple times a day to assist with achieving glycemic targets and reduce the risk of long-term diabetes complications. Recent advances in diabetes technology have reportedly improved glycemia, but little is known about how PWDs utilize mobile technology to make positive changes in their diabetes self-management.

**Objective:** The aim of this qualitative study was to explore PWDs' experiences using *Sugar Sleuth*, a glucose sensor–based mobile app and Web-based reporting system, integrated with the FreeStyle Libre glucose monitor that provides feedback about glycemic variability.

**Methods:** We used a qualitative descriptive research design and conducted semistructured interviews with 10 PWDs (baseline mean glycated hemoglobin, HbA<sub>1c</sub>) 8.0%, (SD 0.45); 6 males and 4 females, aged 52 years (SD 15), type 1 diabetes (T1D) duration 31 years (SD 13), 40% (4/10, insulin pump) following a 14-week intervention during which they received clinical support and used *Sugar Sleuth* to evaluate and understand their glucose data. Audio-recorded interviews were transcribed, coded, and analyzed using thematic analysis and NVivo 11 (QSR International Pty Ltd).

**Results:** A total of 4 main themes emerged from the data. Participants perceived *Sugar Sleuth* as an *Empowering Tool* that served to inform lifestyle choices and diabetes self-management tasks, promoted preemptive self-care actions, and improved discussions with clinicians. They also described *Sugar Sleuth* as providing a *Source of Psychosocial Support* and offering relief from worry, reducing glycemic uncertainty, and supporting positive feelings about everyday life with diabetes. Participants varied in their *Approaches to Glycemic Data*: 40% (4/10) described using *Sugar Sleuth* to review data, understand glycemic cause and effect, and plan for future self-care. On the contrary, 60% (6/10) were reluctant to review past data; they described receiving benefits from the immediate numbers and trend arrows, but the app still prompted them to enter in the suspected causes of glucose excursions within hours of their occurrence. Finally, only 2 participants voiced *Concerns About Use of Sugar Sleuth*; they perceived the app as sometimes too demanding of information or as not attuned to the socioeconomic backgrounds of PWDs from diverse populations.

**Conclusions:** Results suggest that *Sugar Sleuth* can be an effective educational tool to enhance both patient-clinician collaboration and diabetes self-management. Findings also highlight the importance of exploring psychosocial and socioeconomic factors that may advance the understanding of PWDs' individual differences when using glycemic technology and may promote the development of customized mobile tools to improve diabetes self-management.



**KEYWORDS**

diabetes mellitus, type 1; educational technology; blood glucose self-monitoring; qualitative research

## Introduction

### Background

Following the results of the Diabetes Control and Complications Trial [1] and the start of intensive insulin therapy, clinicians have attempted to help persons with type 1 diabetes (T1D) keep their glucose values as close to the normal range as possible to delay the onset and slow the progression of long-term diabetes complications such as retinopathy, renal disease, neuropathy, and heart disease. Monitoring glucose levels is essential for achieving target glycemia and avoiding hypoglycemia. Continuous Glucose Monitoring (CGM) is a recent glucose monitoring device that assists with these aims.

CGM has been shown to improve glycemia without an increase in hypoglycemia for adults with T1D (PWDs) who wear it most days [2-6]. In addition, studies have reported positive psychosocial changes such as decreased partners' anxiety, vigilance and negative experiences surrounding hypoglycemia, and improved patients' mood and general quality of life [7-8]. Similarly, a recent survey of 22,697 T1D Exchange Registry participants (aged 1-93 years) found that CGM usage increased from 7% in 2010 to 2012 to 30% in 2016 to 2018 and glycated hemoglobin (HbA<sub>1c</sub>) levels were lower in CGM users than nonusers [9]. Furthermore, technology improvements include an increased use of mobile health (mHealth) technology to support achieving optimal glycemia. However, more studies are needed to understand how mHealth devices influence diabetes self-management and improve glycemia [10]. Thus far, studies have mostly explored patient opinions on helpfulness and satisfaction with mHealth devices using quantitative self-report measures [11]. Qualitative studies can allow for a more in-depth understanding of how an intervention may individually affect PWDs and what to target for future interventions [10].

### Sugar Sleuth Technology

In our pilot intervention study, PWDs used a new glucose sensor-based tool, the *Sugar Sleuth* system, a specially designed interactive mobile app and Web-based reporting software integrated with the FreeStyle Libre, a glucose sensor (Abbott Diabetes Care) that provides feedback about glycemic variability to the PWD and the study investigators [12]. Importantly, glycemic variability is reported to limit the ability of PWDs to reach their HbA<sub>1c</sub> targets without causing excessive hypoglycemia [13]. Furthermore, commercially available CGM devices inform the PWD when glucose levels are going up or down and acknowledge only patterns with no causes but *Sugar Sleuth* performs the unique task of asking why patterns are the way they are. In other words, this system was designed to identify the most prevalent causes of glucose excursions—highs, lows, and rapid rises—that contribute to variability and to provide reports in which the clinician and PWD can quickly understand the key problems that need to be addressed.

Therefore, *Sugar Sleuth* is a unique strategy for helping people to improve their diabetes self-management because it is able to provide context or organization to PWDs' out-of-range glucose levels, key barriers to target glucose levels, and actionable insights to perform. Thus, the aim of our study was to explore qualitatively PWDs' experiences using this integrated *Sugar Sleuth* technology to better understand how their experiences affected their diabetes self-management.

## Methods

### Design and Ethics

We used a qualitative descriptive research design to obtain in-depth information about PWDs' experiences using a mobile app for improving their diabetes self-management. We administered a one-on-one semistructured interview to a sample of PWDs naïve to CGM and following their participation in the *Sugar Sleuth* intervention at the Joslin Diabetes Center, which is an outpatient diabetes treatment and research center in the northeastern United States. The purpose of the intervention was to learn more about patient and clinician reactions to using a comprehensive mobile app linked to FreeStyle Libre. In short, participants attended 5 clinic visits over 14 weeks. Clinicians provided participants with the *Sugar Sleuth* system consisting of FreeStyle Libre, a wearable glucose sensor, and a mobile phone on which the *Sugar Sleuth* app was installed. Upon scanning the glucose sensor with the phone, the app displays the current glucose value as well as a trend arrow, which visually illustrates the direction and rate of change in glucose. In addition, the *Sugar Sleuth* app generates prompts for more information from the participant if a high, low, or rapid-rise episode is detected and provides a checklist of self-care issues that might have been the cause of the episode, for example, high carb meal or too much insulin. Thus, the app, Web-based report software, and glucose sensor provide an integrated, comprehensive system for detecting glycemic variability, specific problem identification, associated problem cause, plan for corrective action, and monitoring of intervention effects. Clinicians and participants collaboratively analyzed and reviewed collected data and devised specific self-care plans to address each event detected by *Sugar Sleuth*. Quantitative methods and results for this study were previously reported [12]. The Institutional Review Board at the Joslin Diabetes Center approved the protocol, and all participants provided written informed consent and received a small stipend.

### Study Participants

The study recruited 10 of the 30 participants who had completed the *Sugar Sleuth* intervention study for the qualitative interviews. Qualifications for the intervention study included T1D for at least 1 year, aged 25 to 75 years, treated with multiple daily injections or insulin pump, no previous use of CGM, not pregnant, no diagnosis of gastroparesis, no past bariatric surgery, and with HbA<sub>1c</sub> between 7.5% and 9.5%. All 30 participants



were contacted via email or by phone call and were asked to meet with the interviewer in the evenings or on weekends at the Joslin Diabetes Center. The first 10 participants who were able to meet with the interviewer at the available times were interviewed.

### Data Collection

A clinical psychologist (MDR), an experienced interviewer with extensive experience treating adult patients with T1D, conducted

the qualitative interviews. These interviews asked participants open-ended questions about their experiences using the *Sugar Sleuth* technology and also used directive probes to elicit additional information and clarify questions (Textbox 1). Interviews lasted 30 to 60 min and were digitally recorded and transcribed.

**Textbox 1.** Sugar Sleuth semistructured interview questions.

1. How did you expect the technology in this study to influence you as a person with diabetes?  
 Probe: What were your expectations of the technology's influence on your diabetes management?  
 Probe: What were your expectations of the technology's influence on your daily life?  
 Probe: Were your expectations realized? If so, how? If not, how?
2. What was positive in your experience of using the technology in this study?  
 Probe: How has the technology positively affected the way you manage your diabetes?  
 Probe: How has the technology positively affected the way you think about your diabetes?
3. What was negative in your experience of using the technology in this study?  
 Probe: How has the technology negatively affected the way you manage your diabetes?  
 Probe: How has the technology negatively affected the way you think about your diabetes?
4. What would you change about the technology to better support your diabetes management and everyday life?  
 Probe: How would these changes help you better manage your diabetes?  
 Probe: How would these changes improve your life with diabetes?
5. What were your concerns about using the technology in this study?  
 Probe: How do you feel about the amount of information the device supplies?  
 Probe: How do you feel about the technology's convenience/lack of convenience?  
 Probe: How did you cope with these concerns?
6. How did you feel about using the device?  
 Probe: What was most difficult and easiest about wearing the device?  
 Probe: How often would you want to wear the device? Explain.  
 Probe: How did you respond to the tracings?  
 Probe: What do you think and feel when viewing the tracings?  
 Probe: How do you utilize the tracings in your diabetes management?

### Data Analysis

The multidisciplinary research analysis team was diverse in terms of gender, disciplines, age, years of experience, and ethnic backgrounds. It included a woman senior clinical psychologist, a woman adult endocrinologist, a younger man researcher, and an experienced woman researcher, and 2 people with American English as a second language (ET and AAC). The team met over the course of 4 months to analyze data according to the principles of thematic analysis [14]. They independently read transcripts and coded the data by marking and categorizing key words and phrases and used an iterative approach whereby codes were continuously revised and refined throughout the analysis. Data analysis continued until data saturation for each theme occurred. After transcripts were coded and reviewed, one

member of the research team (OH) entered the marked transcripts into NVivo 11 (QSR International Pty Ltd) to further organize and group codes into themes. The group then met to agree on the final themes and to select quotations that represented each theme. An audit trail tracked the decision-making process and supported the dependability (reliability) of the data.

### Results

A total of 10 PWDs participated in the interviews. There were no demographic differences between those participants who were interviewed and those who were not interviewed (Table 1).

**Table 1.** Characteristics of interviewed versus noninterviewed participants. Student *t* tests were used to examine differences between those interviewed and not interviewed.

Demographic characteristics	Semistructured interviewed (n=10)	Not interviewed (n=20)	<i>P</i> value
<b>Gender, n (%)</b>			<b>.32</b>
Male	6 (60)	12 (60)	
Female	4 (40)	8 (40)	
Age (years), mean (SD)	52 (15)	56 (14)	.53
<b>Ethnicity, n (%)</b>			<b>.02</b>
Non-Hispanic	9 (90)	16 (80 <sup>a</sup> )	
Hispanic	1 (10)	1 (5 <sup>a</sup> )	
Duration of type 1 diabetes (years), mean (SD)	31 (13)	33 (17)	.75
<b>Insulin use, n (%)</b>			<b>.80</b>
Pump	4 (40)	9 (45)	
Multiple daily injections	6 (60)	11 (55)	
HbA <sub>1c</sub> <sup>b</sup> % baseline, mean (SD)	8.0 (0.45)	8.0 (0.60)	.78
HbA <sub>1c</sub> % end of study, mean (SD)	7.6 (0.50)	7.5 (0.50)	.38

<sup>a</sup>A total of 15% (3/20) did not answer.

<sup>b</sup>HbA<sub>1c</sub>: glycated hemoglobin.

## Emergent Themes

Qualitative analysis revealed 4 main themes that described participants' experiences with *Sugar Sleuth* and their diabetes self-management: *Empowering Tool*, *Source of Psychosocial Support*, *Approaches to Glycemic Data: Overview versus Narrow View*, and *Concerns About Use*. Transcript identifiers (age, sex, and years with T1D) are included with quotations.

### Empowering Tool

Participants described *Sugar Sleuth* as providing an empowering educational tool that informed their lifestyle choices and promoted their engagement in diabetes self-care tasks. *Sugar Sleuth* also fostered preemptive self-care actions as well as improved discussions with their clinicians. Furthermore, participants reported that *Sugar Sleuth* provided constant and immediate feedback that increased their understanding of the factors contributing to their glycemic excursions (variability) and how and when to address these excursions:

*Well just seeing where my blood sugars were going, and being able to keep track of everything in one location, what I was eating, my activity level, um, my insulin dosages, and then being able to see snapshots of where you went low when you went for a 2 mile walk and just compare it to a day where I sat at my desk all day.... It really helped me to understand how to better adjust my insulin dosages, to better reflect, or to have better control and fewer fluctuations. [54-year-old woman, T1D for 34 years]*

*...It's one thing to hear 'avoid being low it could kill you,' which hadn't been my experience with the first 40-50 years of management, but seeing it happen and nipping it in the bud, I could see a downward trend*

*or a fast downward trend, I could catch it before it became an issue, and the same on the high ends. Yeah it was definitely good to avoid the extremes. [65-year-old man, T1D for 59 years]*

In terms of lifestyle choices and behaviors, participants reported that *Sugar Sleuth* increased their awareness and understanding about appropriate food choices and thereby contributed to changes in their eating behaviors:

*It was probably making me more aware of what foods I was eating, what kind of effect it had on my body, where I sort of knew but didn't pay much attention to it. But seeing concrete information with what I had entered into the system with the clinicians looking at it, and charting those highs and lows, it really gave me more of an understanding. [60-year-old man, T1D for 32 years]*

*It gets me to look at more of what I eat, anything that makes me look at more of the nutritional factors on the back of the boxes or anything like that, that got me really to slow down, take a look at exactly what I'm eating and stuff like that, so that was a huge improvement. [40-year-old woman, T1D for 22 years]*

Finally, participants viewed *Sugar Sleuth* as empowering because it enhanced supportive and encouraging interaction between the patient and clinician and allowed the PWD to feel more actively engaged in their diabetes management:

*And it's also been really helpful when I have seen my doctor. Instead of just looking at a static list of blood sugars and insulin doses, to look at the graph and make adjustments. ...At my last visit... he (doctor) looked at the numbers first but then looked at the graph and then just said, "Actually I think you're*

*doing a great job because I'm not seeing the wild fluctuations that we would see before. There's still some tweaking, but this is great information and you're doing a great job." And that's the first time my doctor has ever said you're doing a great job. ... I think it's all because of just having access to more, more data points, more information. [54-year-old woman, T1D for 34 years]*

*I loved the technology. I loved the fact that I was focusing on entering in all the foods that I was eating, and I loved the fact that I could talk with Joslin (clinicians), and they were talking about some of my highs, when they occurred, what I had eaten, and it really got me more on track. [60-year-old man, T1D for 23 years]*

### Source of Psychosocial Support

Participants described *Sugar Sleuth* as offering relief from worry and as helping them cope more effectively with T1D. They perceived the constant information that *Sugar Sleuth* provided as making for less glycemic uncertainty; they and others worried less about whether or not they were hypo- or hyperglycemic. These feelings contributed to participants feeling more positive about their everyday lives with diabetes:

*And checking out this food and watching after the meal how's it going; and going out for exercise, beginning middle and end because it's there; I don't have to stab myself, I can see it.... I could show it to my friends – "see I'm normal you don't have to worry." That was a relief to me and a relief to them. [65-year-old man, T1D for 59 years]*

*It was a confirmation ... that I was in range more than I thought I was. And that was surprising because in the past when you only check your blood sugar every so many hours you get the feeling that you're always up and down, up and down, which I am a lot, but I was in range in parts of the day much more than I thought. That was a good feeling. That was reinforcement. [76-year-old woman, T1D for 37 years]*

Furthermore, participants described how *Sugar Sleuth* made living with T1D more manageable and thus less burdensome. For example, *Sugar Sleuth's* graphic information, unlike finger-stick numbers, made participants feel less powerless and more in charge of their T1D:

*The graphical presentation—because up until then all I had was 4 data points for an entire day and I had no idea what was going in between—not no idea, but that isn't what was really happening in real life. You get to see what is actually happening—it's the truth or as close as we're gonna get. [65-year-old man, T1D for 59 years]*

*I think it [Sugar Sleuth] just made it [diabetes] um, easier to manage; easier isn't really the right word, but it just, it just, it enhanced having it [diabetes]. I didn't think about it more. I didn't think about it less;*

*it just made dealing with it [diabetes] more pleasant. [50-year-old woman, T1D for 28 years]*

### Approaches to Glycemic Data: Overview Versus Narrow View

A total of 4 participants described utilizing an overview approach to their glycemic data, which included actively reviewing graphs and app information to better understand cause and effect regarding their glycemia and to plan for future self-care:

*I love the graphs, I love the longer time base thing. Day to day is one thing, but then you look at 2 weeks' worth of data and you can see maybe I wasn't as good as I thought and maybe I was better than I thought. The averaging and the probability-based parts of it were interesting. [64-year-old man, T1D for 25 years]*

*In terms of the suspected causes and the list that it had, I think that's something that's definitely helpful and if you take the time to sit down and locate what's consistently causing a rapid rise it helps you to figure that out and fix it going forward. [30-year-old man, T1D for 16 years]*

On the contrary, 6 participants described having a narrow view or focusing only on the immediate data and were reluctant to use the app or Web-based information to review data. However, they were still engaged with the app, that is, the app still prompted them to enter in the suspected causes of glucose excursions within hours of their occurrence. This narrow view suggests that the immediate information they received was sufficient, and they did not want or need to focus on past information and generally wanted to *move on*:

*In real life, I'm probably not gonna get up every morning and look all night long and say, "oh look I went up, I went down..." It's just not gonna happen...Maybe I don't get the use of all the data but just that arrow going up and down and telling you what's happening right now is enough to make you do stuff. [55-year-old woman, T1D for 47 years]*

*Once the episode was over I wasn't so much interested in hearing about it again. Maybe it was the ones that typically happened overnight when I wasn't aware—if I went high overnight—that was last night, today is today—let's move on. [65-year-old man, T1D for 59 years]*

### Concerns About Use

Only 2 participants reported negative perceptions about their use of the *Sugar Sleuth* system. They perceived the app as too demanding of information or as not attuned to the socioeconomic backgrounds of diverse populations. For example, one participant stated that the app's demand for information did not always fit with where he was in his glycemia. He noted how difficult it was to answer questions about the causes of his hypoglycemia while he was in the midst of a hypoglycemia episode:

*Like when I'm low I can't really say like yeah I didn't eat or I took too much insulin. Maybe like after I take*

*care of the low then I can go back and say oh yeah this is why I was low. [28-year-old man, T1D for 19 years]*

The second participant observed that the app's excessive demand for information did not fit well into the average person's life:

*Too much information. Like I said I did it just because I was in a study. So I did it. But your average Joe person is not gonna do that. People are just way too impatient; it's just how it is. As sad as it is, that's how it is. [40-year-old man, T1D for 22 years]*

Interestingly, this second participant was the only Hispanic person in the study. He voiced concern that it might be too difficult for PWDs from a lower socioeconomic or a different cultural background to adopt this technology because they do not have access to the same information or resources as those from the majority culture. He pointedly illustrated his concern when reporting how much it bothered him that he could not understand some of the choices offered by the app:

*Who really uses this [technology] in the overall general public? If there was somebody that's a severe diabetic and is in a low-income environment... they wouldn't know what this is... I'm also talking about other religions, cultures and stuff like that Hispanics, Blacks...they would not understand what this is.... ...the options that they had were kind of, I wasn't really, didn't really know exactly what they meant. So to me that was the thing that really got me." [40-year-old man, T1D for 22 years]*

## Discussion

### Principal Findings

In this qualitative study, participants described how the integrated *Sugar Sleuth* system empowered them as PWDs to make more informed food choices, to preemptively avoid glycemic excursions, to improve problem-solving discussions with their clinicians, and to have a greater awareness of cause and effect surrounding their glycemia. Furthermore, they described this system as providing comfort and reassurance and thereby serving as a source of psychosocial support. In addition, the results of the previously published quantitative study indicated a significant average reduction in HbA<sub>1c</sub> from baseline mean of 8.0% (SD 0.10%) to final mean of 7.5% (SD 0.09%;  $P < .01$ ) and in mean daily carbohydrate intake from baseline 235 (SD 21) grams to final 192 (SD 26) grams ( $P = .05$ ), which reflect the empowering qualitative experiences that participants described [12]. However, our study also found variability in PWDs' approaches to the use of glycemic information. All participants used the glucose information to improve their diabetes self-management but some benefited from the immediate feedback whereas others preferred retrospective data review.

Of note, 40% (4/10) of participants utilized retrospective review to help manage their diabetes both in the present and in the future. Alternatively, 60% (6/10) did not review their data and described finding it useful to focus solely on immediate numbers and trend arrows. This finding is of interest in the world of

diabetes treatment where retrospective review of Glucose Pattern Management (GPM) is often described as an essential ingredient for improving diabetes self-management [15]. The goal of GPM is to reduce the frequency of undesirable glycemic patterns to improve clinical outcomes and to lighten the burden of diabetes management for PWD [16], but studies have found that most CGM users never download data from their devices [17]. In fact, we do not really know if CGM users mostly rely on their current glucose value, glucose profile over the past few hours, or rate of change (trend) arrows to make insulin adjustment decisions [18]. Furthermore, although the recent study of T1D Exchange participants found increased use of CGM among its 22,697 registry participants, the downloading and retrospective review of the CGM data as part of diabetes self-management had not increased and there was no indication that HbA<sub>1c</sub> levels in the registry as a whole have improved over the 5-year period despite this increased use of CGM [9]. Thus, there appears to be a real need for increased education about how to utilize the CGM data offered to PWDs.

Moreover, the one Hispanic participant in our study wondered if *Sugar Sleuth* was appropriate for PWDs from a low socioeconomic or different racial or cultural background. The participant's comment suggests that *Sugar Sleuth* may require increased adaptation to the educational and cultural needs of diverse populations. In fact, in a recent review of studies on mHealth technology and underserved populations, the authors strongly note the importance of tailoring mHealth interventions in a culturally competent manner and of instituting curriculums at literacy levels appropriate to target populations to optimally utilize this technology [19].

Finally, our results suggest that the *Sugar Sleuth* system taught participants a meaningful way to use their glycemic data for diabetes self-management by helping them identify the causes of their glycemic excursions and guiding them to make appropriate diabetes self-management decisions. Interestingly, another recent study suggests that the discovery of cause and effect in diabetes for persons with type 2 diabetes can help improve their self-management strategies and that self-monitoring data can initiate personal discovery that may lead to sustainable behavior changes [20]. Although the results of our study support this finding, efforts are called for to further document this finding for T1D adults. Importantly, 2 participants also perceived the system as too demanding for information or as not attuned to lower socioeconomic and different cultural groups and addressing these perceptions may enhance the use of *Sugar Sleuth*. In addition, research needs to explore how technologies can be used to help PWDs solve specific diabetes self-management problems [21] and how to improve the integration of mobile technology into everyday life.

### Limitations

Study limitations include the use of a small, homogenous (eg, English-speaking, 90% non-Hispanic, with long-duration T1D) sample from a specialty diabetes clinic in the northeastern United States. Furthermore, the intervention is a short, single-arm, single-center study. Therefore, results cannot be attributed to one of the 3 interventions used: *Sugar Sleuth* app, educational module, and flash glucose sensor. Studies to



compare the benefit and long-term sustainability of results for the Sugar Sleuth app on its own versus all 3 combined components are needed. In addition, this qualitative study did not use an iterative data collection approach, which limits the inclusion of additional participants who might have expanded the description of the experiences studied. Future studies should include a larger sample using iterative data collection and data saturation so that the research question is more fully explored. In addition, our participants agreed to participate in this interview study and thus may have been more willing or motivated to perceive the benefits of *Sugar Sleuth* for their diabetes self-management than those who did not agree to participate. Finally, self-reported data are vulnerable to social desirability bias.

### Conclusions and Implications

The findings of this qualitative study have important implications for clinical care. Primarily, they suggest that a glucose sensor-based mobile technology can be an effective educational tool to enhance both patient-clinician collaboration

and diabetes self-management. These results suggest the clinical usefulness for evaluating the experience of diabetes mobile technology in a larger, more diverse population, given the demographic characteristics of our sample. Results also highlight the importance of exploring psychosocial factors such as cognitive processing, decision making, diabetes distress, depression, and anxiety that may advance the understanding of individual differences in PWDs' use of mobile technology to improve diabetes self-management. As the world of diabetes self-management moves increasingly toward mobile technology, diabetes researchers and clinicians need to understand better how each PWD's cognitive and emotional attributes influence his/her ability to use glycemic information for diabetes self-management. Importantly, this understanding may help avoid the too often made assumption in clinical care that one size fits all. Thus, customizing technological devices to meet individual cognitive and emotional needs and characteristics may provide more personalized mobile education tools for optimal diabetes management and allow not only for improved glycemia but also for improved quality of life for PWDs.

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### Conflicts of Interest

MDR, ET, and HW work at the Joslin Diabetes Center. The Joslin Diabetes Center has received research funding from Abbott Diabetes Care. LF has received compensation as a consultant from Abbott Diabetes Care.

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## Abbreviations

- HbA<sub>1c</sub>**: glycated hemoglobin  
**CGM**: Continuous Glucose Monitor  
**GPM**: Glucose Pattern Management  
**mHealth**: mobile health  
**PWD**: adult with type 1 diabetes  
**T1D**: type 1 diabetes

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Original Paper

# An Evaluation of Digital Health Tools for Diabetes Self-Management in Hispanic Adults: Exploratory Study

Leah Yingling<sup>1</sup>, BS; Nancy A Allen<sup>2</sup>, ANP-BC, PhD; Michelle L Litchman<sup>2</sup>, PhD, FNP-BC, FAANP; Vanessa Colicchio<sup>2</sup>, BSN; Bryan S Gibson<sup>1</sup>, DPT, PhD

<sup>1</sup>Department of Biomedical Informatics, University of Utah School of Medicine, Salt Lake City, UT, United States

<sup>2</sup>College of Nursing, University of Utah School of Medicine, Salt Lake City, UT, United States

**Corresponding Author:**

Bryan S Gibson, DPT, PhD

Department of Biomedical Informatics

University of Utah School of Medicine

421 Wakara Way #140

Salt Lake City, UT, 84108

United States

Phone: 1 801 582 1565

Email: [bryan.gibson@utah.edu](mailto:bryan.gibson@utah.edu)

## Abstract

**Background:** Although multiple self-monitoring technologies for type 2 diabetes mellitus (T2DM) show promise for improving T2DM self-care behaviors and clinical outcomes, they have been understudied in Hispanic adult populations who suffer disproportionately from T2DM.

**Objective:** The objective of this study was to evaluate the acceptability, feasibility, and potential integration of wearable sensors for diabetes self-monitoring among Hispanic adults with self-reported T2DM.

**Methods:** We conducted a pilot study of T2DM self-monitoring technologies among Hispanic adults with self-reported T2DM. Participants (n=21) received a real-time continuous glucose monitor (RT-CGM), a wrist-worn physical activity (PA) tracker, and a tablet-based digital food diary to self-monitor blood glucose, PA, and food intake, respectively, for 1 week. The RT-CGM captured viewable blood glucose concentration (mg/dL) and PA trackers collected accelerometer-based data, viewable on the device or an associated tablet app. After 1 week of use, we conducted a semistructured interview with each participant to understand experiences and thoughts on integration of the data from the devices into a technology-facilitated T2DM self-management intervention. We also conducted a brief written questionnaire to understand participants' self-reported T2DM history and past experience using digital health tools for T2DM self-management. Feasibility was measured by device utilization and objective RT-CGM, PA tracker, and diet logging data. Acceptability and potential integration were evaluated through thematic analysis of verbatim interview transcripts.

**Results:** Participants (n=21, 76% female, 50.4 [SD 11] years) had a mean self-reported hemoglobin A<sub>1c</sub> of 7.4 [SD 1.8] mg/dL and had been diagnosed with T2DM for 7.4 [SD 5.2] years (range: 1-16 years). Most (89%) were treated with oral medications, whereas the others self-managed through diet and exercise. Nearly all participants (n=20) used both the RT-CGM and PA tracker, and 52% (11/21) logged at least one meal, with 33% (7/21) logging meals for 4 or more days. Of the 8 possible days, PA data were recorded for 7.1 [SD 1.8] days (range: 2-8), and participants averaged 7822 [SD 3984] steps per day. Interview transcripts revealed that participants felt most positive about the RT-CGM as it unveiled previously unknown relationships between lifestyle and health and contributed to changes in T2DM-related thoughts and behaviors. Participants felt generally positive about incorporating the wearable sensors and mobile apps into a future intervention if support were provided by a health coach or health care provider, device training were provided, apps were tailored to their language and culture, and content were both actionable and delivered on a single platform.

**Conclusions:** Sensor-based tools for facilitating T2DM self-monitoring appear to be a feasible and acceptable technology among low-income Hispanic adults. We identified barriers to acceptability and highlighted preferences for wearable sensor integration in a community-based intervention. These findings have implications for the design of T2DM interventions targeting Hispanic adults.

**KEYWORDS**

type 2 diabetes; Hispanic; blood glucose self-monitoring; culturally appropriate technology; mobile app

## Introduction

### Type 2 Diabetes Among Hispanic Adults in the United States

Type 2 diabetes mellitus (T2DM) disproportionately affects racial and ethnic minorities and poses a significant risk of morbidity and early mortality [1]. Hispanic adults with T2DM, for instance, have higher hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels and rates of T2DM-related complications compared with non-Hispanic white adults [2,3]. Such disparities may be attributed to the unique barriers Hispanic adults face in achieving optimal T2DM management, including lower rates of health insurance coverage and language and literacy challenges [4].

### Diabetes Self-Management in Hispanic Adults

Effective long-term management of T2DM can be achieved with dedicated patient self-management, where individuals are actively engaged in their health-related behaviors and decisions. Components of T2DM self-management include physical activity (PA), tracking food intake and blood glucose levels, and taking medications, among others [5]. Hispanic adults with T2DM have difficulties engaging in T2DM self-management activities compared with non-Hispanic whites, and many struggle to meet the American Diabetes Association's self-management recommendations [6].

### Technology-Facilitated Type 2 Diabetes Mellitus Self-Management

Wearable sensors and mobile apps have shown promise for capturing both self-reported and objective measures of T2DM self-management (ie, continuous blood glucose levels, food intake, and PA) in the context of a patient's daily life. Although these devices are often explored separately [7], integrating data from multiple devices and data sources provides the potential to yield new knowledge and illuminate relationships between multiple health behaviors (eg, the effect of PA on blood glucose levels). Understanding the facilitators and barriers to using multiple self-monitoring tools for self-management may reveal opportunities to improve T2DM self-care behaviors and clinical outcomes, particularly for patient populations who suffer disproportionately from T2DM.

In this community-based participatory research (CBPR) pilot study, we assessed the minimally guided use of multiple digital health tools for T2DM self-monitoring by a Hispanic community-based population. We (1) evaluated the use of wearable sensors and mobile apps for capturing T2DM self-management behaviors; (2) investigated the facilitators and barriers of implementing technology-facilitated T2DM self-management interventions in a low socioeconomic status Hispanic community; and (3) identified opportunities for integrating these tools and their data into a future self-management intervention tailored to low-income Hispanic communities.

The purpose of this study was to evaluate the acceptability, feasibility and potential integration of wearable sensors and mobile apps for T2DM self-management among a Hispanic community-based population with self-reported T2DM.

## Methods

### Study Background

This study was part of a large 3-tiered Patient Centered Outcomes Research Institute-funded project. In tier I, a community advisory board (CAB) of Hispanic adults with T2DM was developed to identify potential technology solutions that would be useful and acceptable to a Hispanic population. In tier II, a larger sample of Hispanic adults with T2DM was surveyed about technology-related solutions that could support T2DM. This CBPR study was conducted following the survey to pilot test 3 different self-monitoring technologies and understand facilitators and barriers to use among Hispanic adults with self-reported T2DM. The University of Utah Institutional Review Board approved this study. All participants provided written informed consent.

### Study Population

Participants were recruited from August 2016 to September 2017 through outreach performed by members of our CAB and through community partnerships. Recruitment fliers were also distributed at local health clinics and with our nonprofit partners. Participants were eligible for this study if they were aged 19 to 85 years, had been diagnosed with T2DM, were willing to avoid acetaminophen during the study period because of its interaction with the RT-CGM sensor, provided informed consent, and possessed sufficient English language proficiency to carry out study tasks. Our study protocol did not require that participants have previous experience with technology. With this inclusion criteria, we aimed to recruit a diverse range of Hispanic adults with T2DM to reflect various types of technology users.

### Study Design

At study initiation, participants received 3 devices for T2DM self-monitoring: a Dexcom G4 real-time Continuous Glucose Monitor (RT-CGM; Dexcom Inc), Fitbit Surge (Fitbit), and an iPad (Apple) preloaded with health-related mobile apps, including Headspace, Fitbit, HealthWatch 360, EsTuDiabetes, Diabetes Detective, and Fooducate (see [Multimedia Appendix 1](#) for brief descriptions). Participants also received a blood glucose meter to collect finger-stick blood glucose measurements twice daily, required for RT-CGM calibration.

The wrist-worn PA monitor, a Fitbit Surge, collected accelerometer-based data on the amount and intensity of PA (eg, steps taken, calories burned, distance travelled, and floors climbed). The RT-CGM, a Dexcom G4 Platinum Professional Glucose Monitoring System, collected real-time continuous sensor glucose readings every 5 min during a sensor session (7 days) and communicated the reading and trends to the patient.

The system consists of 3 parts: a sensor, receiver, and transmitter. The sensor is inserted in the patient's subcutaneous tissue; this was performed by the study nurse. The transmitter, a gray chip connected to the sensor pod, communicates glucose readings between the sensor and the receiver; the receiver, a small handheld device, displays sensor glucose readings, trends, and direction and rate of glucose change. The tablet, an iPad, was preloaded with various T2DM self-monitoring and educational apps by the research team. The research team prepurchased a data plan for the iPad at study onset to allow for the use of the iPad apps when a wireless connection was unavailable to participants.

Participants were instructed to use the RT-CGM and activity tracker continuously (but unguided) for 7 days. They were also instructed to log their food intake using the Fitbit or HealthWatch 360 apps and were invited to explore other apps included on the iPad as needed or desired. A 30-min one-on-one training session explaining this protocol and specific instructions on device use (ie, calibrating the RT-CGM, self-monitoring blood glucose, logging meals on the iPad, and charging the devices) was conducted on the day of device distribution by a member of the research team. The industry instruction manual for each device (eg, Fitbit and Dexcom G4) and a device list were also provided to all participants at this time, both of which were written in English only (see [Multimedia Appendix 2](#)). Participants were also provided with the research team's contact information in case any questions arise.

After 1 week of T2DM self-monitoring (a testing period determined by the 7-day lifespan of the RT-CGM sensor) with the 3 devices, a semistructured interview ([Multimedia Appendix 3](#)) was conducted by a bilingual study nurse (to ensure questions were understood and accurately interpreted by participants) and a clinical informaticist. Participants also completed a questionnaire that captured sociodemographic information, T2DM-related information, and technology usage and preferences.

The outcomes of interest in our study were (1) feasibility of the wearable activity tracker and RT-CGM, as measured by days with self-directed device use and (2) acceptability of the system as measured by the results of semistructured interviews designed to elicit participants' feedback on the devices as standalone tools and prompt their suggestions for potential design improvements and opportunities for incorporating these tools in an integrated T2DM self-management intervention.

## Data Collection

During the 7-day monitoring period, participants synchronized their Fitbit device with the Fitbit app on the iPad through a Bluetooth connection. After a successful upload, the study investigators could access minute-level Fitbit data through the Web-based platform, Fitabase. If a participant did not synchronize their device during the study period, a member of the study team would synchronize the device with the participant on the final day of the study during the semistructured interview session. Data from the RT-CGM devices were collected at the end of each 7-day monitoring period by synchronizing each receiver to Dexcom Studio (Dexcom Inc) on a study laptop. Food intake data were exported manually from Healthwatch

360 and Fitbit at the end of each 7-day monitoring period by a study investigator.

A semistructured interview was conducted with participants to seek insight into their experiences using the RT-CGM, the wearable activity tracker, and the mobile apps provided on the iPad. Moreover, 1 study investigator, who acted as a moderator, led the interview. The interview moderator also probed for suggestions for integration of the devices and their data in a T2DM self-management intervention. A bilingual comoderator assisted with translation of language and complex concepts if needed. The moderator led the interview using a Moderator's Guide (see [Multimedia Appendix 3](#)), which included preselected questions and probes. The questions were adapted from the Moderator's Guide developed by Wallen et al used in a similar community-based technology pilot study [8].

Participants were remunerated with a US \$100 gift card for providing at least 1 day of reliable device data and for participating in the follow-up interview.

## Quantitative Data Analysis

Quantitative accelerometer-based data and 5-min blood glucose data were collected from all participants' devices. All quantitative analyses were performed in R version 3.3.2 (R Core Team).

Feasibility of the devices was assessed based on device usage (ie, the higher the number of participants engaging with the devices, the higher the feasibility). Device utilization frequency for both the activity tracker and RT-CGM was measured by the number of days with device-captured data. Usage of the food logging apps was measured by the number of days with self-logged meals and the number of meals logged.

Quantitative data included steps taken, minutes of activity intensity on a 0 to 3 scale (predefined by Fitabase: 0=sedentary, 1=light, 2=moderate, 3=very active), distance traveled (measured in miles), floors climbed, calories burned (measured in kilocalories), and heart rate. For those participants with more than 7 days of data, the first full 7 days of collected data were included in the analysis. The first day of data activity and RT-CGM data were omitted from the analysis, as this information represented only a partial day and was likely not representative of a typical full day's measurements. Days with no recorded PA data were considered *missing* and were not included when calculating average measures per day.

## Qualitative Data Analysis

Each semistructured interview was audio recorded, and the recording was translated (if needed) and transcribed by an independent Health Information Portability and Accountability Act-compliant translation and transcription service (TranscribeMe). The qualitative team comprised 4 investigators (LY, BG, ML, and NA). LY listened to the audio files to verify transcription, and all 4 members developed a codebook based on participants' responses. In addition, 2 teams of 2 coders independently reviewed the interview transcripts and evaluated each for the presence of the codes. NVivo (version 9.0) was used for further qualitative analysis. Discordance was discussed until consensus was reached. Main themes, subthemes, and

selected quotes that align with each theme are displayed in the tables to indicate important findings.

## Results

### Demographic and Clinical Characteristics

There were 21 individuals who participated in the self-monitoring period and 18 who participated in the subsequent semistructured interview and questionnaire. However, 3 participants chose not to participate in the follow-up interview and questionnaire. Participants could also choose not to answer certain sociodemographic questions (eg, income and employment). Among the participants, 76% (16/21) were female, the mean age was 50.4 (SD 11.0) years, all participants were Hispanic, and 82% (14/17) had an annual household income of <US \$40,000 per year. All patients had a self-reported

diagnosis of T2DM, and most (89%, 16/18) were treated with oral medications (ie, Metformin), some with insulin (17%, 3/18), and the others through diet and exercise. Demographic and clinical characteristics for the study population are presented in Table 1.

### Quantitative Data

#### Device Usage

Of the 7 possible full days of device usage, participants provided Fitbit activity readings for 6.14 (SD 0.8) days. Most participants (86%, 18/21) registered 6 days or more of activity data, with 14% (3/21) registering 3 days or less. Nearly all (95%, 20/21) participants provided RT-CGM readings, with 1 participant providing none. More than half (52%, 11/21) logged at least 1 meal in a diet tracking app, with 33% (7/21) logging meals for 4 or more days.

**Table 1.** Demographic and clinical characteristics.

Variable	Value
<b>Sex (n=21), n (%)</b>	
Female	16 (76)
Male	5 (24)
Age in years (n=18), mean (SD); range	50.4 (11.0); 36-74
<b>Ethnicity (n=21), n (%)</b>	
Hispanic	21 (100)
<b>Employed (n=17), n (%)</b>	
Full time	8 (47)
Part time	5 (29)
Retired	1 (6)
Unemployed	3 (18)
<b>Annual household income (US \$; n=17), n (%)</b>	
<40,000 per year	14 (82)
>40,000 per year	3 (18)
Years with T2DM <sup>a</sup> (n=18), mean (SD); range	7.4 (5.2); 1-16
Self-reported hemoglobin A <sub>1c</sub> (n=13), mean (SD); range	7.42 (1.8); 5.4-11.9
Body mass index, mean (SD); range	33.6 (6.2); 22.9-44.8
<b>T2DM treatment (n=18), n (%)</b>	
Medication, insulin	3 (16)
Medication, oral	14 (78)
Diet/exercise	10 (56)
<b>Type of T2DM care received (n=18), n (%)</b>	
Primary care provider	15 (83)
Specialist	7 (39)
<b>Has attended a T2DM education class (n=18), n (%)</b>	
Yes	13 (72)
No	5 (28)

<sup>a</sup>T2DM: type 2 diabetes mellitus.

### Objective Measurements

For the days on which steps were registered by the Fitbit, mean steps per day among participants (n=21) was 7822 (SD 3984) steps. Among participants, the maximum steps per day was 11,893 (SD 5478) steps and the minimum was 4147 (SD 4218) steps. For the days on which the RT-CGM registered real-time blood glucose levels, the mean value among participants (n=20) was 148.6 (SD 47.1) mg/dL (range of participant means 94.2-247.4 mg/dL). The minimum glucose value captured among participants was 43 mg/dL and the maximum exceeded 400 mg/dL (a value of *high* is recorded when a level exceeds 400 mg/dL).

### Technology Ownership and Usage

Nearly all survey respondents (17/18) owned a mobile phone. Of mobile phone owners, all but 1 owned a smartphone; 47%

owned an Android (8/17), 41% owned an iPhone (7/17), and 6% (1/17) owned a different type of smartphone. Table 2 describes additional technology ownership and usage among the 18 survey respondents.

### Qualitative Data

The results of the qualitative study provided insight about the benefits and challenges of wearable sensors and mobile apps for T2DM self-management among a Hispanic community-based population. The analysis resulted in 3 major themes that highlight the level of acceptability of these devices: (1) advantages of T2DM self-monitoring devices, (2) user design preferences, and (3) limitations to diabetes technology use in Hispanic populations. Several subthemes were also identified and described in Table 3.

**Table 2.** Technology usage and ownership among survey respondents (N=18).

Variables	Value, n (%)
Own a mobile phone	17 (94)
Own a tablet computer	7 (39)
Own a laptop or desktop computer	9 (53)
<b>Email account</b>	17 (94)
Daily	10 (59)
Weekly	4 (24)
Monthly	2 (12)
Never	1 (6)
<b>Facebook account</b>	17 (94)
Daily	15 (89)
Weekly	1 (6)
Monthly	1 (6)
Never	0 (0)
Food logging app	1 (6)
Activity tracker on phone or watch	2 (11)
Facebook for T2DM <sup>a</sup> support and education	6 (33)
Websites for T2DM support and education	7 (39)
Mobile app for T2DM support and education	1 (6)
Mobile app with glucose meter integration	1 (6)

<sup>a</sup>T2DM: type 2 diabetes mellitus.



**Table 3.** Semistructured interview themes and subthemes.

Themes	Subthemes
Advantages of self-monitoring devices	<ul style="list-style-type: none"> <li>• Device feedback supports behavior change</li> <li>• Device feedback supports increased awareness to enhance self-management</li> </ul>
User design preferences	<ul style="list-style-type: none"> <li>• Training</li> <li>• Tailoring</li> <li>• Comparison</li> <li>• Social support</li> <li>• Data sharing</li> <li>• Data integration</li> </ul>
Limitations to diabetes technology use in Hispanic population	<ul style="list-style-type: none"> <li>• Barriers to type 2 diabetes mellitus management</li> <li>• Barriers to technology use</li> <li>• Technology limitations</li> </ul>

## Advantages of Self-Monitoring Devices

### *Device Feedback Supports Behavior Change*

Individuals with T2DM felt that the near real-time feedback (eg, glucose levels, trends, alerts, step counts, and reminders) from the self-monitoring tools encouraged behavior modification. Most participants reported behavior modifications for selecting foods, but some participants also modified their PA behaviors or general health maintenance routine.

Most participants who reported modifying food behavior did so in response to the feedback on the RT-CGM. Examples of food behavior changes that took place included swapping a food item for a healthier choice, ending a meal prematurely if blood glucose levels were rising, or consuming carbohydrates if blood glucose levels were too low. One participant who swapped a food item for another in response to RT-CGM data noted:

*Of course I have to choose. Do I eat the two tortillas or...more rice? I'm not going to eat the rice if I'm eating the—you can choose because you know it's going to get high.*

Several participants reported that they stopped eating if they saw their blood glucose rising or if the RT-CGM was delivering a *high* alert. However, 1 representative quote includes:

*Sunday, we went to the buffet...I wanted to eat more to take advantage...but [the RT-CGM] didn't let me do it. It was ring, ring, ring, and vram, vram, vibrating...I tell my husband, "I'm not going to eat anymore because this is telling me that I'm high...so I have to stop it."*

Similarly, another participant noted:

*I decided to eat less or to avoid eating because my glucose level was high. Or, I was aware that I had gone too long without eating, and my glucose level was low.*

Although most participants reported food modifications, some also reported changes to PA behavior because of the device feedback. Although most PA behavior modifications were in response to feedback from the Fitbit, some participants reported increases to PA behavior because of feedback from the RT-CGM. However, 1 participant reported that it helped him

*make decisions to go to the gym to exercise*, whereas another reported that she chose to walk to the grocery store rather than drive when she saw that her blood glucose levels were rising on the RT-CGM receiver.

Interestingly, the feedback on the RT-CGM also encouraged participants to modify their general health maintenance and medication management regimen. Regarding the RT-CGM, 1 participant reported:

*It helped me a lot to remind me to take my pill...I did not have the habit of taking my pills...But this week with the device, I was taking them constantly*

Participants felt the daily use, and twice-a-day calibration of the RT-CGM was a passive reminder to meet other self-management needs. Furthermore, participants appeared most likely to modify behaviors based on the RT-CGM feedback than other devices. Patients attributed this to the novelty of the RT-CGM data and how it relayed information that they *did not already know*.

### *Device Feedback Supports Increased Awareness to Enhance Self-Management*

Participants expressed that device feedback (eg, glucose levels, trends, alerts, step counts, and reminders) illuminated previously unknown relationships between certain health behaviors and T2DM measures. Some previously unknown relationships included the relationship between stress and blood glucose as well as the relationship between HbA<sub>1c</sub> and glycemic variability.

Furthermore, 1 participant, in particular, recognized that on days when she did not eat breakfast, she still experienced significant blood glucose escalations that she attributed to her stress. She noted:

*Yes, the stress, and I don't eat nothing in the morning. I don't eat nothing in the day, all day, and then "foo!" This is new for me. The emotion affect my diabetes.*

Other participants were made aware—primarily through the visualizations on the RT-CGM—of the relationship between the level and intensity of PA and changes in blood glucose levels. One participant noted that:

*Even 10 minutes of walking. It does make a difference [on my blood glucose levels].*

Participants who had a general knowledge of T2DM management and HbA<sub>1c</sub> levels recognized that although A<sub>1c</sub> values represent an average, they may be misrepresenting one's actual glucose levels and not reflecting daily glycemic variability. One participant, who self-reported an A<sub>1c</sub> value of 6.6 mg/dL, noted:

*I see my sugar, after eating, it went up and then really low...My A1C is 6.6--but something is going on because my sugar is getting up more than 200. So I know what happens with your organs if it is going up more than 200. So now I can explain to my doctor what's going on.*

## User Design Preferences

### Training

Many participants suggested that additional training and instructions would be needed for them to effectively use the self-monitoring tools in the future, especially the iPad and the food tracking apps. Many of those participants who did not use one of the devices (eg, the iPad) or used them minimally during the study reported a fear of being *nosy* or *breaking* it. Several participants reported fear of losing the iPad as the primary reason for minimal use. Despite receiving guidance and an introduction to the apps from a study coordinator, most participants were not comfortable exploring all the apps on the iPad and felt restricted to the diet tracking apps only. To alleviate this issue, participants suggested that the study coordinators should train people more extensively on *how to use [the iPad] so people know it can go not only on the food one [application] but on the other ones.*

### Tailoring

Participants felt that a future T2DM self-monitoring intervention leveraging these tools would be most effective if it was tailored to the individual patient. One participant felt that the diabetes technologies should be tailored differently to different members of the Hispanic community. He noted that:

*Because they speak the same language does not mean that they are the same. They value things differently...You want to say Hispanic community? Foreign-born or US born? 18-22 are totally different than 30-50.*

Similarly, participants raised the concern of delivering a technology-facilitated intervention to a population of varying technology and health literacy. One participant noted:

*Some are not literate enough that they could use a computer or even a cell phone to text. So not to expect a 70 year old, all 70 year olds to be at the same level. It's just not going to happen.*

In addition to tailoring to cultural and sociodemographic characteristics, most patients felt that they would be most likely to engage with a future intervention that was tailored to time and meal. For instance, 1 participant remarked positively about the time-based reminders on the Fitbit at mealtimes and after

long periods of sedentary time but would have preferred more specific advice or goals. An example she provided was:

*So it would be lunch time and [it could remind you] "Don't forget your salad! Don't forget your veggies!" You're like, "Oh my goodness. Need to do it."*

Other participants expressed that not all patients have the same needs, and some may require diabetes specialty providers who can provide more specific counseling related to nutrition or medication management. They felt that a technology-facilitated T2DM intervention should cater to these varying types and levels of support. One participant explained this in the following scenario:

*Look, I need more specialized help--like nutrition, or maybe an endocrinologist to look at [my data] to actually say, "this is what is happening to you." Maybe, my general doctor or physician might not be able to provide me good feedback [but an endocrinologist can].*

### Comparison

The Dexcom G4 visualizations are restricted to a small window that shows blood glucose trends for only a few hours at a time. Many participants expressed that the RT-CGM would have been most beneficial if they were able to compare their glucose over time, whether that was between days or weeks. One participant noted that:

*When I was checking the graphic, I thought I can scroll more for the next day, the day before and the day before and no. It's only for one day.*

Participants desired a comparison feature to ensure that any modifications they made while self-monitoring were leading to improved outcomes. One participant said:

*So what I want to do in myself is improvement. Compare one week and say, "This was the first week." But I need to see the change in the second week, and another progress in the third, like that...And at the end, keep those good habits...But I need to see the change.*

### Social Support

Use of the self-monitoring tools required a certain level of positive social support. Participants felt that the tools—as standalone devices—were not enough to promote behavior change. Rather, they desired peer, family, community, and medical support complementary to the devices. Most felt that, with support, the self-monitoring tools could aid in improving HbA<sub>1c</sub> levels. One participant noted:

*If you want to bring my A1c down from 8 to 5, and this would help me monitor my diet and everything, and I do it with medical support, and hopefully peer support, now that is pretty darn good. Now, you're talking about something that I am willing to do.*

Some participants also desired peer support specifically from others with T2DM, as they would have an *idea of what you can do or the type of activity that would require you to go from 200 to 160 mg/dL.*

The highest percentage of participants desired and relied on technical, emotional, and/or behavioral support from a spouse or family member. Several participants brought family members to the follow-up interviews, and most noted that a family member also engaged with the devices at some point during the study period. Several participants wanted the ability to share their data in real time with their spouse and felt that doing so was, at times, more important than sharing with a health professional. One participant noted:

*If [your spouse] knows, they are closest to you, they can support and/or correct whatever. It's a good thing.*

However, not all spouse support was positive. A few participants noted the emotional stress that self-monitoring tools can place on a spouse or family member. One participant shared:

*I can see a point of view that [the RT-CGM] can be really stressful. For my husband it was...He said, "You know what? Just turn it off. I don't want to hear it. I don't want to hear it if you have your sugar level up or down. Don't do it. It's making me crazy."...So I mean, I can see his point there.*

### Data Sharing

Participants expressed the need to have the ability to share their T2DM device data with health professionals or a health coach to receive interpretation of the data, guided feedback, or personalized advice through messaging. Many participants also expressed the need for controlling which data were shared and with whom. One participant noted:

*There are programs that have been developed that say, "I shared all my data with my doctor." But, I would only share this data with my [health] coach. Then, you, as my [health] coach can actually enter if you have my permission. You can go into the program and say, "Okay, you're doing great."...As a coach, if I'm working with 10 people, then I could have access to the information that they have agreed to provide me. Then I can provide better feedback on a constant basis. Then, I could text them.*

### Data Integration

Participants felt overwhelmed with multiple devices and multiple streams of data and expressed a need to view their data in one place. To alleviate this burden, 1 participant recommended that the study team consider the *consolidation of all the artifacts into 1 single place*. The recommended medium for visualizing the streams of data was on a smartphone. One participant commented:

*It's better if I can have [everything] in my phone. It's with me. I sleep with that.*

Participants desired a single device that was already part of their routine. Participants also recommended integrating different sources of data such as T2DM-related measures from the electronic health record. One participant commented that having health measures, such as recent HbA<sub>1c</sub> values, is *something ideal to be more in control*.

## Limitations to Diabetes Technology Use in Hispanic Populations

### Barriers to Type 2 Diabetes Mellitus Management

Our results revealed that T2DM knowledge, lifestyle, and willingness to engage in self-management, among others, existed as barriers to adequate T2DM management. Several participants did not understand the expected effect of medications such as Metformin. Some even mentioned taking Metformin to lower their blood glucose when they were experiencing hyperglycemia. One individual reported the following scenario:

*Last night, [the RT-CGM] was showing 189 after I ate the hamburger, so...I went home and I took the—I don't take too much medicine because I don't want it—so I took medicine, and then I want to take another one, my husband said, "No, don't take another one." Because it was 189. And [the RT-CGM] was ta-ta-ta-ta-ta.*

Other participants reported thinking that the RT-CGM was not working because they were not observing a change in their blood glucose trend on the RT-CGM after taking their prescribed dose. One participant stated, "I take Metformin medication ... and the [RT-CGM] does not reflect it." These quotes suggest a misunderstanding related to the mechanism of action of the medication and how that would be reflected in the CGM data.

In addition to T2DM-related knowledge, busy lifestyles remain a primary barrier to patients' T2DM behavior change. Some participants reported being parents with multiple children and holding several jobs and felt that making healthy food choices was difficult; therefore, they preferred options that were easy, inexpensive, and accessible. One woman recalled a recent scenario:

*I got to my house, I have broccoli, I bought a bunch of broccoli. I don't want it. I'm not in the mood for broccoli. I'm hungry. I'm shaking, I'm hungry. Yeah, quick, fast.*

Other participants expressed that motivation and willingness to self-manage one's T2DM are also likely barriers. One individual recounted:

*Before, I would not have been glad [to participate], because one wants to eat what one wants to eat. I am trying to educate myself [about diabetes], and that is why I liked [these tools] because I already have that in my mind.*

### Barriers to Technology Acceptance and Use

Most participants expressed that main barriers to use were fear, trust, calibration requirements, comfort, and cost. Participants were most fearful of the small insertion site for the RT-CGM. One participant commented:

*I talked...some of my co-workers and my family too, about the [RT-CGM] that I have. They said, "Oh, it's nice. I would like to have one of those, but I'm scared of [the insertion]."*



Other participants were fearful that the device would move while in use; therefore, they restricted their activity during the study period. One participant commented:

*I don't make exercise this week because I scared about [the CGM] moving or something...Only walking, that's it.*

Another participant raised the concern about trust. He experienced glucose fluctuations when comparing his self-monitoring of blood glucose (SMBG) level with the RT-CGM level when calibrating the device. As a result, he felt unsure about which value was accurate. He commented:

*Which one do I trust? This thing is plugged into my body, and I would think that the measurement of this item is more accurate than the one that I'm doing in my finger. Yet, the discrepancy between the two readings at times was quite significant. And, I thought, okay which one is correct. Here the machine says I'm good, but my finger says not.*

Calibration posed additional challenges for participants. Often, participants did not calibrate the device in 12-hour intervals twice a day as recommended. Some participants also reported forgetting the receiver during the day, which results in an inability to transmit data.

Comfort was also cited as a deterrent to the use of the self-monitoring tools, particularly irritation from the rubber wristband of the Fitbit and the adhesive on the RT-CGM. One participant whose sensor pod and transmitter became unattached to her insertion site reported discontinuing use of the RT-CGM during the study period because it *broke*. She said:

*The truth is, if it didn't break I would have used it every day, but it was very fragile. I don't believe it would have been able to break.*

Another participant discontinued RT-CGM use and removed the transmitter and sensor pod after 4 days due to discomfort at the insertion site.

When asked about the use of these tools for self-monitoring in the future, most participants cited cost as a barrier. Those participants without health insurance commented that these devices would be out of reach. However, after being told the cost, some participants were willing to purchase the device. One participant mentioned that if such a tool would prevent him from being on insulin, he would buy one. He commented:

*Before I go to insulin, do you think that I wouldn't be happy to pay \$300/month for 6 months [for sensors]? Oh, heck yeah. I don't want to get into insulin. If my doctor after seeing this says you need to get into insulin. Nope. Just simply, I won't. So, this would be a good way to say, "Okay, let's work together on this."*

### Technology Limitations

Certain technology limitations restricted the optimal use of the T2DM self-monitoring tools. These included proficiency with SMBG, insulin adjustments based on RT-CGM levels, and the

language offerings on the RT-CGM and the iPad apps (ie, lack of Spanish).

The RT-CGM required daily calibration and previous exposure to SMBG; however, a few participants were not accustomed to daily SMBG, and 1 participant had never practiced SMBG at all. This required extra training by the research team for participants to be prepared to calibrate the RT-CGM daily during the self-monitoring period.

Several participants felt that the user interface of the RT-CGM was specific to insulin-requiring diabetes and not to those who are not insulin requiring. They felt the options for inputting insulin dose and the number of carbohydrates consumed were confusing. One participant stated:

*So, this assumes that I take Insulin, but I don't. I take pills. So, that seems to me, one piece that is lacking.*

Furthermore, no apps or tools used in the study were offered exclusively in Spanish, posing a challenge for nearly all participants. The RT-CGM was limited to English only, making it more challenging for those who primarily spoke Spanish, limiting usability related to features that used the menu (ie, calibrations). Food logging was especially challenging. One participant noted that:

*There is a lot of Latino foods that you guys already have in there, but...you're missing a bunch.*

## Discussion

### Principal Findings

The objective of this study was to engage Hispanic community members with T2DM in the evaluation of the feasibility, acceptability, and potential integration of self-monitoring technologies and their data into a future self-management intervention. Both quantitative and qualitative findings revealed that the tools—used in a relatively unguided manner—successfully captured and communicated T2DM self-monitoring data (ie, food intake, PA, and blood glucose level) on most days. Although participants were inexperienced in using the 3 self-monitoring tools at baseline, nearly all used both the RT-CGM and the activity tracker to self-monitor, and more than half logged food intake on the iPad. Strengths and weaknesses of the T2DM self-monitoring devices and the user experience as well as preferences for integration and data sharing were identified and categorized into themes, which will inform the design of an acceptable, technology-facilitated T2DM self-management intervention targeting this group.

This study is among the first to explore the use and potential integration of multiple T2DM self-monitoring technologies in a community of low-income, primarily middle-aged Hispanic adults with T2DM. Our findings indicate that using a multimodal system (comprised a RT-CGM, a wearable activity tracker and a digital food diary) is not only feasible and acceptable but also educational, as it unveils previously unknown relationships between lifestyle and health and contributes to changes in T2DM-related behaviors among *both* insulin-requiring and noninsulin-requiring patients with T2DM (in clinical practice, RT-CGM is offered primarily for insulin-requiring patients).

Our findings also highlighted that a successful T2DM self-management intervention leveraging multiple devices and their data should be offered on a single device; should be accessible and actionable to patients, clinicians, and family members; and should be tailored to the unique needs of the individual user. In the community group targeted in this study, providing culture-specific content was also a critical need.

### **Multimodal System for Type 2 Diabetes Mellitus Self-Monitoring on 1 Device**

In an era characterized by the internet of things, sensors for capturing multiple health behaviors, exposures, and symptoms are ubiquitous [9]. Minimizing the burden of multiple sensors and devices in health interventions is critical for patient engagement. In our study, patients interacted more with the devices that required less user input—the RT-CGM and the Fitbit—and less with the tool that required more input—the iPad for diet tracking. This is consistent with studies on self-tracking, where tools that require additional time and attention see a lower level of engagement [10]. In our study, individuals noted that the iPad was burdensome to use outside the home because of its size and fear of losing it. Participants suggested consolidation of the tools and visualization of the device data, on a smartphone, for instance, as an avenue for minimizing user burden. Nearly all participants in this study reported owning a smartphone and cited a smartphone as a preferred platform for viewing self-monitoring data. Technology companies, such as Fitbit and Dexcom, are beginning to answer this need through partnerships and the integration of health apps on a single smartphone and smartwatch platform [11].

### **Interoperable System for Facilitating Support From Peer or Professional Care Team**

Although patients felt generally favorable about the standalone tools used in this study, they desired a data sharing feature to facilitate support from a family, peer, or professional care team. Health care partnerships have been cited previously as a key element for engaging and retaining users of self-monitoring digital health tools in the clinical setting [12,13]. Patients have reported a lack of confidence in their ability to synthesize various self-monitoring data streams and cite a care team as a missing piece of this puzzle for additional support [12].

An additional patient need, as identified in previous studies, also included control of access to self-monitoring data. Our participants desired functionality that allowed them to choose with whom they shared their data. Patient choice on *who* and *when* to share data with care partners has been cited as a critical consideration in RT-CGM data sharing [14]. Including a care partner in one's data sharing has been shown to enhance patients' perception of safety [14].

Although most of the literature point to data sharing with a health care team, our participants also highlighted the need for preferential data sharing with a peer health coach or community health worker. Previous work has shown that peer support interventions for patients with T2DM are most effective for those who have difficulty engaging with T2DM, have inadequate access to T2DM support, and have lower levels of health literacy [15]. In our study, patients desired to have a peer health coach

be the first line of support and provide them with access to certain data, reserving other data for providers to access. Peer support interventions, specifically those that involve community health workers, are not uncommon in diabetes care, and they have shown a clinically significant effect on glycemic levels and diabetes-related behaviors, knowledge, and self-efficacy among Hispanic with T2DM [16].

### **Actionable Insights and Feedback for Facilitating Behavior Change**

After just 7 days of device use, several patients found meaning in their data, which led to both increased awareness of how behaviors affect their blood glucose level and self-reported behavior change. In particular, participants reported the RT-CGM was helpful in making behavior changes related to food and exercise behavior. This supports findings in other CGM studies.

We did not provide participants with a priori instructions on actions to improve their glucose readings, but in a similarly designed study, participants took immediate actionable steps to solve blood glucose excursions without any self-management education [17]. The potential for CGM technology in individuals with T2DM to make clinically significant changes is great. After only wearing the CGM for 6 weeks over a 3-month period, participants had decreased their HbA<sub>1c</sub> level by 1%, and their HbA<sub>1c</sub> remained significantly decreased at 0.8% at 12 months [18,19]. Although participants in this study were not provided self-management education, individuals were able to draw on past experiences and receive insight from educational resources or trained professionals.

Although participants valued the device feedback, particularly that from the RT-CGM, they desired enhanced feedback that was actionable and contextual, such as built-in personalized advice on lowering blood glucose level in real-time or historical context comparing current state to a past state. As referenced in a similar study on digital health tools [12], this need for insight and context supports the theory of *sensemaking*, suggesting that people can make predictions on behavior change based on information gathered from past experiences and then derive meaning about their present actions and environment [20,21]. However, little is known about what (if any) RT-CGM features (eg, trend arrow, current glucose value, and profile from past few hours) guide decision making [22]. Studies have shown that patients are not using their downloaded RT-CGM data to make decisions, but rather using data presented on the RT-CGM device itself [23]. In our study, not all participants derived meaning from their data, and some who derived did not draw accurate conclusions.

These additional features that support sensemaking should be offered on self-monitoring devices in real-time to help patients understand their data and draw accurate conclusions that lead to behavior change and increased awareness. Recent work has shown that simulated data demonstrating the acute effect of PA on blood glucose may even be enough to change PA-related outcome expectancies and behavioral intentions among adults with T2DM [24].



## Cultural Tailoring

Our study is one of the first to explore the needs of Hispanic adults using T2DM self-monitoring technologies. To date, T2DM self-monitoring apps and devices targeting limited English proficiency Hispanic communities are lacking. Although all participants in our study were relatively proficient in English, nearly all preferred content on the devices be delivered in Spanish. Few apps on the iPad were available both in Spanish and at a recommended reading level for patient education, a finding consistent with the recent literature [25]. To overcome this barrier for food tracking, Fitbit offers different food databases from which participants can choose. Dexcom also offers content in Spanish (eg, user guide), although the G4 receiver used in this study was not available in Spanish for participants. Since our study, flash glucose monitors, such as the Freestyle Libre (Abbott Diabetes Care, Inc) and its integrated smartphone app, have joined the market and received Food and Drug Administration approval [26]. Flash glucose monitors are a sensor-based hybrid between RT-CGMs and glucose meters. They measure blood glucose levels throughout the day and provide access to the readings by scanning the sensor. This device suite may address the language barrier presented by the Dexcom, as it provides both a user guide and smartphone app available in Spanish. Despite the noted benefits, this 14-day flash glucose monitoring system does not provide real-time continuous access to glucose levels as the Dexcom suite does. To access glucose levels, the sensor *must* be manually scanned, and an iPhone app facilitating this process has recently been developed. Although a recent meta-analysis demonstrated that RT-CGM was effective at reducing the HbA<sub>1c</sub> level, the evidence to promote the effectiveness of flash glucose monitoring in individuals with T2DM was not conclusive [27]. The lack of significant HbA<sub>1c</sub> reduction may be the result of the lack of real-time data and alerts. However, the significant cost difference between the continuous glucose monitoring and the more affordable flash glucose monitoring suites may make this a target for future study in the Hispanic population.

## Strengths and Limitations

Strengths of this study include the use of T2DM self-monitoring tools targeting a low-income, racial and ethnic minority group, the incorporation of CBPR strategies, and the combination of both qualitative and quantitative data gathered during the pilot test. In addition, our study investigated primarily *unguided* use of multiple digital health tools, allowing us to determine likely barriers in the real-world rather than in an idealized setting. Most participants voiced a desire to use the RT-CGM and the Fitbit for longer periods of time, suggesting that the tools were valued and accepted and would observe similar success in a long-term study.

Limitations of this study must also be acknowledged. The study was limited to the 7-day lifespan of the RT-CGM sensor. This limited our ability to adequately test participant participation with the research protocol, engagement, and retention over time. Future work would benefit from a study 30 days or longer to understand how participant engagement changes over time,

although we believe that a 7-day study period was adequate to understand major facilitators and barriers to use. Generalizability may also be a concern. Our sample size consisted of 21 participants, all Hispanic and from different countries of origin, but now living in the same geographical region—a region to be targeted by a future T2DM intervention. This study sample is not an adequate representation of a particular foreign-born or US-born Hispanic population. Future work would benefit from extending this study to a larger and more diverse sample to better evaluate if country of origin or years in the United States contribute to certain aspects of T2DM self-management. In addition, individuals in this study had various experiences with T2DM. Ensuring that all participants have experience in SMBG in future work would aid in improving accuracy and ease of calibration of the RT-CGM. Finally, no standard score for measuring health literacy or average English proficiency was used. Future studies would benefit from standardizing these measurements to better characterize our population of interest.

Owing to our focus on the unguided use of these tools, training was limited. Future studies exploring these tools would benefit from in-depth training and direct contact during the 7 days to troubleshoot potential technological difficulties. A past community-based technology study has suggested creating a community point-person or *super user* who understands the technology and the needs of the community and can troubleshoot during the research period [8]. Including tools available in both English and Spanish would aid in uptake among the community, although in the case of any digital health study, researchers are limited by the availability and offerings of existing tools.

## Conclusions

Sensor-based tools for facilitating T2DM self-monitoring appear to be a feasible and acceptable technology among a low-income, Hispanic community-based population in Utah. Community-based methods, particularly pilot testing and semistructured interviews, aided in early identification of issues and user preferences for the future design of a technology-facilitated T2DM intervention. We identified barriers to acceptability and highlighted preferences for wearable sensor integration. These findings have implications for the design of T2DM interventions targeting racial and ethnic minorities. Additional work is needed to understand how to guide patients in decision making using their device data and visualizations. Although feedback from devices aids in enhancing an individual's awareness, insight that is actionable and personalized is likely needed to promote sustained behavior change. Of equal importance is understanding the implications of integrating T2DM self-monitoring tools and their data into the clinical setting. Although patients desire the integration of T2DM self-monitoring tools, careful consideration of a care team's needs will be critical to their success. Future work will investigate the use of T2DM self-monitoring data to drive a simulation-based, problem-solving intervention that highlights problem areas, suggests opportunities for improvement, addresses facilitators and barriers to behavior change and guides the participant in goal setting.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Mobile apps (with descriptions) offered on iPad.

[[DOCX File, 15KB - diabetes\\_v4i3e12936\\_app1.docx](#) ]

## Multimedia Appendix 2

Self-monitoring device guide.

[[DOCX File, 14MB - diabetes\\_v4i3e12936\\_app2.docx](#) ]

## Multimedia Appendix 3

Moderator's guide for semistructured interview.

[[DOCX File, 17KB - diabetes\\_v4i3e12936\\_app3.docx](#) ]

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## Abbreviations

- CAB:** community advisory board
- CBPR:** Community-Based Participatory Research
- HbA<sub>1c</sub>:** hemoglobin A<sub>1c</sub>
- PA:** physical activity
- RT-CGM:** real-time continuous glucose monitor
- SMBG:** self-monitoring of blood glucose
- T2DM:** type 2 diabetes mellitus

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Original Paper

# Acceptability of Mobile Health Interventions to Increase Diabetic Risk Factor Awareness Among the Commuter Population in Johannesburg: Descriptive Cross-Sectional Study

Alex Fischer<sup>1</sup>, BSc, MPH; Martha Chadyiwa<sup>1</sup>, BSc, MBA; Ndumiso Tshuma<sup>2</sup>, BSc, MBA, PhD; Vusumuzi Nkosi<sup>1,3,4</sup>, PhD

<sup>1</sup>Department of Environmental Health, Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa

<sup>2</sup>Best Health Solutions, Johannesburg, South Africa

<sup>3</sup>Environment and Health Research Unit, South African Medical Research Council, Johannesburg, South Africa

<sup>4</sup>School of Health Systems and Public Health, Faculty of Health Sciences, University of Pretoria, Pretoria, South Africa

**Corresponding Author:**

Alex Fischer, BSc, MPH

Department of Environmental Health

Faculty of Health Sciences

University of Johannesburg

John Orr Building

Doornfontein Campus, Doornfontein

Johannesburg, 2094

South Africa

Phone: 27 0737762705

Email: [afischer@wrhi.ac.za](mailto:afischer@wrhi.ac.za)

## Abstract

**Background:** Developing countries are experiencing a shift from infectious diseases such as HIV and tuberculosis to noncommunicable diseases (NCDs) such as diabetes. Diabetes accounts for more disability-adjusted life years than any other NCD in South Africa, and research has identified a number of preventable risk factors; however, there is not enough evidence from lower resource settings as to how best to disseminate this information to the population. Today, 90% of the world's population lives in mobile phone coverage areas, and this provides a unique opportunity to reach large populations with health information.

**Objective:** This study aimed to investigate how potential mobile health (mHealth) platforms should be paired with diabetes risk factor education so that at-risk communities are empowered with information to prevent and manage diabetes.

**Methods:** A Likert-style survey was distributed to commuters in the City of Johannesburg in July 2018 that explored participants' background characteristics as well as their knowledge and awareness surrounding diabetic risk factors (such as exercise, smoking, and hypertension) and their comfort level with various information delivery methods (such as WhatsApp, short message service, and email). The grouped variables from diabetic risk factors and information delivery methods were described with mean Likert scores and then investigated for relationships with Spearman Rho correlation coefficients.

**Results:** Background characteristics revealed that the self-reported prevalence of diabetes was twice as high in this studied commuter population than the national average. WhatsApp was the most favorable mHealth information delivery method and had a moderate correlation coefficient with diet and nutrition (0.338;  $P < .001$ ) as well as a weaker correlation with physical activity (0.243;  $P < .001$ ). Although not as robust as the WhatsApp correlations, each of the other information delivery methods also showed weaker, yet statistically significant, relationships with one or more of the risk factors.

**Conclusions:** The elevated self-reported diabetes prevalence reinforces the need for diabetes risk factor education in the studied commuter population of Johannesburg. The most feasible mHealth intervention for diabetic risk factor education should focus on WhatsApp messaging while also offering content across other mHealth and traditional platforms to remove barriers to access and enhance the user experience. The content should emphasize diet and nutrition as well as physical activity while also incorporating information on secondary risk factors.

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**KEYWORDS**

mHealth; diabetes mellitus; noncommunicable disease; South Africa

## Introduction

### Background

In developing countries, advances in maternal health and infectious disease treatments are causing a shift in the burden of disease from communicable diseases to noncommunicable diseases (NCDs). In South Africa, 5.5% of the population (2.28 million people) is affected by diabetes, and another 9.9% of the population is described as prediabetic [1,2]. The prevalence of diabetes in low-income communities is estimated to be 7.1%, as these communities are more susceptible to diabetes because of specific risk factors [3]. These risk factors include unbalanced diets because of food insecurity, cultural influence on food and body-image perceptions, lack of physical activity, as well as a general lack of knowledge surrounding diabetes [4,5]. These risk factors are often preventable and have been well defined in literature; however, there is very little information regarding how these communities comprehend the risk factors and how they would like more information on them.

With the recent advances in technology over the last two decades, developing countries are also experiencing a surge in mobile penetration; the cellular market in Africa is estimated at over 1 billion subscribers, and there are more mobile phone users in sub-Saharan Africa than the entire United States [6]. In South Africa specifically, mobile penetration has reached 68%, and up to 90% of smartphone users regularly use at least one app-based messaging service, such as WhatsApp or Facebook Messenger [7]. This provides a unique opportunity to distribute health information to large populations, and in 2015, the South African National Department of Health introduced the South African mHealth Strategy 2015-2019. This strategy was initiated as a way to promote and regulate the use of mobile health (mHealth) initiatives to strengthen health care [8]. Since then, many mHealth interventions have been successfully initiated; however, majority of the interventions support maternal health or HIV programs and very few of the interventions focus on NCDs [9-12].

There are, however, several diabetes-related apps available from Web-based stores such as Google Play, but the majority of apps focus on tracking blood sugar levels, with very little attention being directed toward prevention and education, as stressed by clinical guidelines [13,14]. Messaging and internet interventions have also been implemented, and evidence suggests that they might change behavior by promoting fruit and vegetable intake as well as increased exercise [15,16]. These apps and other mHealth platforms provide proof of concept, but many of these studies are pilot projects with small sample sizes or high elements of bias [17,18].

### Objectives

Despite successful mHealth interventions showing proof of concept in the local setting and diabetic mHealth interventions showing effectiveness elsewhere, there is not yet a strong enough body of evidence to guide the development of mHealth

interventions for South Africans at risk of diabetes [19]. To ensure that new mHealth interventions have high acceptability, these knowledge gaps must be filled, and this can be done by incorporating end users into the design process [20,21]. By surveying end users, this study aimed to investigate how potential mHealth platforms should be paired with diabetes risk factor education so that at-risk communities are empowered with information to prevent and manage the disease.

## Methods

### Setting

A descriptive cross-sectional study was conducted with a convenience sample of commuters from the City of Johannesburg. The public space surrounding the Noord Street Taxi Rank was selected as the venue for this venue-based intercept study because it is one of the busiest mini-bus taxi hubs in Johannesburg. This hub serves as a transfer station for commuters coming from nearby townships as well as the starting point for many residents of the Central Business District. The mini-bus taxi system is used primarily by individuals with lower socioeconomic status, as it is the most affordable means of transportation in the city. The commuter population was, therefore, studied because it offers an opportunity to engage with a high volume of low- and middle-income individuals on a neutral territory [22,23].

### Survey Design

Standardized surveys for diabetes risk factors are all associated with quantifying a persons' risks, not their perceptions or openness to learning about risks, so a new data collection tool was needed for this study. To explore participants' perceptions surrounding diabetic risk factor education as well as their comfort and openness toward using different information delivery methods, a new unvalidated survey was created by the authors. This new survey used groups of perception-based questions, which are utilized in human-centered design by many consulting firms such as IDEO [20,21]. This form of data collection is common practice in many industries, and in sub-Saharan Africa, digital financial services incorporate this into the development of mobile banking apps [24].

Categorical demographics questions were used to describe the sample population with self-reporting, whereas a Likert scale from 1 to 5 was used to explore perceptions surrounding diabetic risk factor education and information delivery methods by creating grouped variables from 3 to 4 related questions. The Likert scores for diabetic risk factor represented the participants' interest in learning about that topic, whereas the scores for information delivery methods represented the participants' willingness to use each intervention.

The complete list of variables is as follows: *demographics* (gender, age, ethnicity, marital status, education, employment, economic status, residence, household size, medication, diabetes [informed by doctor], high blood sugar [informed by doctor], risk of diabetes [informed by doctor], weight, and body type),

*diabetic risk factors* (diet and nutrition, physical activity, smoking, alcohol, hypertension, and medication use), and *information delivery methods* (television, radio, newspaper, short message service [SMS], WhatsApp, internet access, email, mobile apps, social media, and face-to-face). The complete survey is available as [Multimedia Appendix 1](#).

### Data Collection

Before data collection, the survey was reviewed by 2 public health specialists and a statistician and then pilot tested for usability. A sample size of 400 was required to obtain results with a maximum discrepancy of 5% and a CI of 95%. This was calculated by a statistician with a CI-based formula. Data collection was done by trained field workers who used convenience sampling to distribute the Likert-style survey to consenting individuals surrounding the Noord Street Taxi Rank between July 2, 2018, and July 6, 2018. Participants were included in the study if there were older than 18 years and provided informed consent, whereas participants were excluded if they were younger than 18 years or did not want to participate for any reason. The data were then entered into Microsoft Excel V16.16.2 (Microsoft Corporation), and an independent third party reviewed the entries for accuracy. SPSS Statistics V 21 (IBM Corporation) was used for data analysis, and after the data were imported, variables were created and divided into 3 categories: demographics, diabetic risk factors, and information delivery methods.

### Data Analysis

Descriptive statistics were used to analyze the demographic characteristics and explore them as categorical variables. Subcategories were then described with frequencies and percentages.

For diabetic risk factors and information delivery methods, grouped variables were initially tested for internal reliability with Cronbach alpha statistics, and groups were considered reliable with an alpha coefficient greater than .7 or a mean interitem correlation above 0.3 [25,26]. The medication use grouped variable from diabetic risk factors was not considered reliable, and in information delivery methods, the question "I have access to a cell phone" was also removed from the SMS original grouped variable, and a new variable, SMS, was created, which was reliable.

The internally reliable grouped variables were then explored with descriptive statistics to identify means and SDs. Spearman's Rho correlation coefficients were employed to identify relationships between each diabetic risk factor and each

information delivery method. A coefficient approaching 1 represents strong positive correlation between 2 variables, whereas a value of 0 represents no correlation at all [27].

### Ethical Consideration and Approval

The University of Johannesburg Research Ethics Committee granted approval on April 17, 2018, with the National Health Research Ethics Committee registration no: REC-241112-035. No incentives or compensation was provided to any of the study participants.

## Results

### Descriptive Statistics

A total of 364 predominantly black individuals completed the survey, and 230 (63.2%, 230/364) of these participants were male. The mean age was 35 years, and the participants' ages ranged from 18 to 65 years. The majority of respondents had completed at least grade 12, and one-quarter of all participants stated that they were unemployed. When asked to describe their economic status, 123 (33.8%, 123/364) self-reported as below average or poor, 190 (52.20%, 190/364) as average, and 51 (14.0%, 51/364) as above average or wealthy. Half of the participants were married or living with their partner, whereas 90.1% (328/364) stated that they share a household with at least one other person.

One-quarter of all participants stated that they took some sort of medications on a regular basis, and 51 (14.3%, 51/364) participants stated that they had been told that they were at risk of diabetes from their doctor. With respect to diabetes diagnoses, 45 (12.4%, 45/364) participants self-reported that were told by a doctor that they had diabetes, and 46 (12.6%, 46/364) participants stated that they were told by a doctor they had high blood sugar. When asked to self-report their described weight, 42 (11.5%, 42/364) participants were below average, 283 (77.8%, 283/364) were average, and 38 (10.4%, 38/364) were above average. Participants were also asked to self-report their described body types, and 161 (44.2%, 161/364) participants self-reported as skinny or small, 167 (45.9%, 167/364) as average, and 36 (9.9%, 36/364) as overweight or obese. A total of 18 (5.0%, 18/364) participants did not provide an age, and 4 (1.1%, 4/364) participants did not respond to whether they had been told by a doctor that they were at risk of diabetes. All other background characteristics had less than 1% missing data. [Table 1](#) summarizes the demographic characteristics of the study participants.

**Table 1.** Background characteristics of participants.

Characteristic	n (%) <sup>a</sup>
<b>Gender</b>	
Male	230 (63.2)
Female	134 (36.8)
<b>Age (years)</b>	
18-24	99 (27.2)
25-30	94 (25.8)
31-40	80 (21.0)
>41	73 (20.1)
Missing	18 (5.0)
<b>Ethnicity</b>	
Black	325 (89.3)
White	5 (1.4)
Colored <sup>b</sup>	23 (6.3)
Indian or Asian	4 (1.1)
Other	4 (1.1)
Missing	3 (0.8)
<b>Marital status</b>	
Single	156 (42.9)
Living with partner	75 (20.6)
Married	110 (30.2)
Divorced or separated	18 (5.0)
Widowed	4 (1.1)
Missing	1 (0.3)
<b>Education</b>	
No formal education	35 (9.6)
Grade 7	13 (3.6)
Grade 12	141 (38.7)
Certificate	101 (27.8)
Bachelor's degree	59 (16.2)
Higher degree	14 (3.9)
Missing	1 (0.3)
<b>Employment status</b>	
Unemployed	91 (25.0)
Casually employed	69 (19.0)
Self-employed	95 (26.1)
Salaried employee	108 (29.7)
Missing	1 (0.3)
<b>Economic status</b>	
Poor	53 (14.6)
Below average	70 (19.2)
Average	190 (52.2)

Characteristic	n (%) <sup>a</sup>
Above average	41 (11.3)
Wealthy	10 (2.8)
<b>Residence</b>	
Informal settlement	27 (7.4)
House (owned)	54 (14.8)
House (rented)	131 (36.0)
Apartment (owned)	43 (11.8)
Apartment (rented)	107 (29.4)
Missing	2 (0.6)
<b>Household</b>	
Living alone	35 (9.6)
Living with 2 people	71 (19.5)
Living with 3 people	93 (25.6)
Living with 4 people	101 (27.8)
Living with >5 people	62 (17.0)
Missing	2 (0.6)
<b>Takes medication</b>	
Yes	89 (24.5)
No	274 (75.3)
Missing	1 (0.3)
<b>Diabetic (told by doctor)</b>	
Yes	45 (12.4)
No	316 (86.8)
Missing	3 (0.8)
<b>High blood sugar (told by doctor)</b>	
Yes	46 (12.6)
No	316 (86.8)
Missing	2 (0.6)
<b>Risk of diabetes (told by doctor)</b>	
Yes	51 (14.3)
No	308 (84.6)
Missing	4 (1.1)
<b>Weight</b>	
Below average	42 (11.5)
Average	283 (77.8)
Above average	38 (10.4)
Missing	1 (0.3)
<b>Body type</b>	
Skinny	86 (23.6)
Small	75 (20.6)
Average	167 (45.9)
Overweight	25 (6.9)

Characteristic	n (%) <sup>a</sup>
Obese	11 (3.0)

<sup>a</sup>Percentages may not equal 100.0% due to rounding.

<sup>b</sup>“In South Africa, the term *Coloured* originated during the apartheid era to describe a distinct mixed ancestry community. The term is still used in South Africa as an official race group for census data and scientific research.” [28]

### Internal Reliability

The Cronbach alpha coefficients for each grouped variable are presented in Table 2. All grouped variables, except for medications, SMS original, and SMS were considered acceptable and reliable with a coefficient greater than the .7 limit.

For medication use, the mean interitem correlation of 0.307 was within the acceptable range of 0.3 to 0.5; however, the questions “I find it easy to manage my medications” and “I would like to be reminded when to take my medications” provided a very low value of 0.078. There was also a large inconsistency between the number of people who filled out the questions for this grouped variable (n=120) and the number of people who answered yes to the demographic question “Do you take any medications on a regular basis?” (n=89). Due to this discrepancy and the outlier from the interitem correlations, this grouped variable was not considered reliable and was removed from further analysis.

For SMS original, the mean interitem correlation of 0.262 was below the acceptable range. The question “I have access to a cell phone” was removed from the analysis, and the data were rerun to reveal a mean interitem correlation of 0.314, so a new variable titled SMS, containing the remaining 3 questions, was created and used for further analysis. Despite having a strong Cronbach alpha coefficient, it was determined that internet access did not appropriately address participants’ interest in receiving information, so it was removed from analysis as well.

### Mean Likert Scores

For diabetic risk factors, mean Likert scores closest to 5 represented the risk factors that participants were most interested learning about, whereas scores closest to 1 represented the risk factors that participants were least interested in. Diet and nutrition and physical activity had the highest mean Likert scores of 3.983 and 3.830, respectively, followed by alcohol use (3.314) and smoking (3.224). The lowest mean Likert score was 2.721 for hypertension. The mean Likert scores are presented with SDs in Table 3.

**Table 2.** Reliability coefficients of the grouped variables.

Outcome measure	Number of items	Test scale (alpha coefficient)	Mean interitem correlations (range)
<b>Diabetic risk factors</b>			
Diet and nutrition	4	.75	0.429 (0.288-0.608)
Physical activity	4	.756	0.437 (0.271-0.739)
Smoking	4	.828	0.546 (0.435-0.662)
Alcohol	4	.85	0.587 (0.440-0.798)
Hypertension	4	.769	0.459 (0.327-0.747)
Medication use	4	.636	0.307 (0.078-0.581)
<b>Information delivery</b>			
Television	3	.825	0.609 (0.538-0.725)
Radio	3	.867	0.686 (0.645-0.761)
Newspaper	3	.906	0.763 (0.700-0.820)
SMS <sup>a</sup> original	4	.582	0.262 (0.005-0.405)
SMS	3	.577	0.314 (0.247-0.405)
WhatsApp	4	.747	0.444 (0.200-0.829)
Internet access	3	.795	0.561 (0.444-0.791)
Email	4	.768	0.453 (0.320-0.652)
Mobile apps	4	.81	0.516 (0.347-0.720)
Social media	4	.793	0.486 (0.296-0.736)
Face to face	4	.78	0.476 (0.183-0.629)

<sup>a</sup>SMS: short message service.



**Table 3.** Mean Likert scores for diabetic risk factors and information delivery methods.

Outcome variables	n	Mean Likert score (SD)
<b>Diabetes risk factors</b>		
Diet and nutrition	361	3.983 (0.721)
Physical activity	362	3.830 (0.734)
Smoking	361	3.224 (1.116)
Alcohol	360	3.314 (1.159)
Hypertension	360	2.721 (1.028)
<b>Information delivery methods</b>		
Television	360	3.995 (0.933)
Radio	363	3.318 (1.060)
Newspaper	359	3.320 (1.172)
SMS <sup>a</sup>	359	3.356 (0.927)
WhatsApp	359	3.844 (0.917)
Email	361	2.757 (1.076)
Mobile apps	361	2.747 (1.044)
Social media	363	3.009 (1.070)
Face to face	364	2.732 (1.086)

<sup>a</sup>SMS: short message service.

For information delivery methods, mean Likert scores closest to 5 represented the interventions that participants were most receptive toward using, whereas scores closest to 1 represented the risk factors that participants were least receptive toward. Television and WhatsApp had the highest mean Likert scores of 3.995 and 3.844, respectively, followed by SMS (3.356), newspaper (3.320), radio (3.318), and social media (3.009). The lowest mean Likert scores were face-to-face interactions (2.732), mobile apps (2.747), and email (2.757). The mean Likert scores are presented with SDs in [Table 3](#).

### Correlations

To detect relationships between diabetic risk factors and information delivery methods, nonparametric correlations were explored with Spearman Rho correlation coefficients. The strongest correlations were between the risk factor diet and nutrition and the information delivery methods WhatsApp and

television, with moderate correlation coefficients of 0.338 ( $P<.001$ ) and 0.312 ( $P<.001$ ), respectively. Physical activity also had weaker correlations with the same information delivery methods; WhatsApp had a correlation coefficient 0.243 ( $P<.001$ ) and television had a correlation coefficient of 0.294 ( $P<.001$ ).

Diet and nutrition also had weak correlation coefficients with email (0.145;  $P=.006$ ) and face-to-face interactions ( $-0.258$ ;  $P<.001$ ), whereas physical activity also had a weak correlation with email (0.157;  $P=.003$ ). Smoking also had weak correlations with television (0.152;  $P=.004$ ), radio (0.190;  $P<.001$ ), newspaper (0.210;  $P<.001$ ), mobile apps (0.160;  $P=.002$ ), and social media (0.116;  $P=.03$ ). Alcohol only had 1 weak correlation with newspaper (0.174;  $P=.001$ ), whereas hypertension had 2 weak correlations with newspaper (0.161;  $P=.002$ ) and mobile apps (0.107;  $P=.04$ ). A complete list of all correlation coefficients is presented in [Table 4](#).

**Table 4.** Spearman Rho correlation coefficients for risk factors and delivery methods.

Information delivery methods	Diabetic risk factors															
	Diet and nutrition			Physical activity			Smoking			Alcohol			Hypertension			
	$\rho$	<i>P</i> value <sup>a</sup>	N	$\rho$	<i>P</i> value	N	$\rho$	<i>P</i> value	N	$\rho$	<i>P</i> value	N	$\rho$	<i>P</i> value	N	
Television	<i>0.312</i> <sup>b</sup>	<.001	361	<i>0.294</i>	<.001	362	<i>0.152</i>	.004	361	0.091	.08	360	0.045	.39	360	
Radio	0.050	.35	361	0.060	.25	362	<i>0.190</i>	<.001	361	0.049	.35	360	0.072	.17	360	
Newspaper	0.009	.86	361	0.025	.64	362	<i>0.210</i>	<.001	361	<i>0.174</i>	.001	360	<i>0.161</i>	.002	360	
SMS <sup>c</sup>	0.006	.91	361	0.048	.36	362	0.103	.05	361	0.058	.27	360	0.027	.61	360	
WhatsApp	<i>0.338</i>	<.001	361	<i>0.243</i>	<.001	362	-0.081	.12	361	0.019	.71	360	-0.048	.36	360	
Email	<i>0.145</i>	.006	361	<i>0.157</i>	.003	362	0.065	.22	361	0.057	.28	360	0.070	.19	360	
Mobile apps	-0.050	.35	361	0.053	.31	362	<i>0.160</i>	.002	361	-0.020	.71	360	<i>0.107</i>	.04	360	
Social media	-0.042	.42	361	-0.015	.78	362	<i>0.116</i>	.03	361	0.005	.92	360	0.002	.99	360	
Face to face	-0.258	<.001	361	-0.079	.13	362	0.069	.19	361	-0.098	.06	360	0.029	.58	360	

<sup>a</sup>Two-tailed significance.

<sup>b</sup>Statistically significant correlations are presented in *italics*.

<sup>c</sup>SMS: short message service.

## Discussion

### Principal Findings

This research described the studied commuter population from the City of Johannesburg and their perceptions toward diabetic risk factors and information delivery methods. Although the national prevalence of diabetes in South Africa is 5.5%, the prevalence in this studied commuter population was greater than twice as high, at 12.4% [1], which reinforces the need for risk factor education, especially in the studied commuter population.

This study also provided the commuter population in Johannesburg with an opportunity for input, to ensure that new diabetic mHealth interventions have the greatest potential for acceptability and usability with the targeted end users. When the mHealth interventions were investigated for relationships with diabetes risk factors, WhatsApp showed the strongest correlations. WhatsApp had a moderate correlation with diet and nutrition as well as a weaker correlation with physical activity. This suggests that the most feasible mHealth intervention for diabetic risk factor education should feature WhatsApp to provide content focusing on diet and nutrition as well as physical activity.

Many of the other mHealth interventions had correlations with risk factors as well, and although these relationships were not as robust as the WhatsApp correlations, they were still statistically significant. This introduces the prospect of a multifaceted mHealth approach that does not solely rely on 1 information delivery method, and this combined approach could allow for a tailored experience, where end users may interact with different platforms to obtain information. This varied approach has already been implemented by other successful mHealth platforms in South Africa. Some interventions use messaging services as the backbone, but by offering information across different platforms, they removed barriers to access while

also providing users with the possibility for enhanced interactions [12].

For traditional information delivery methods, television had a moderate correlation with diet and nutrition as well as weaker correlations with physical activity, whereas all of the others except for face-to-face interactions also had weak but statistically significant correlations. These findings suggest that the combined approach can also be extended to traditional media as participants were receptive toward receiving information on these platforms. Traditional media, however, is often more expensive than mHealth interventions and only offers 1-way communications; so, they should be used as a way to create awareness and push users toward the interactive mHealth platforms [29].

The digital landscape is very dynamic and always changing, so certain platforms will come and go based on network capabilities and consumer demand. The combined mHealth approach also ensures that end users are engaged on platforms they are comfortable with now, while also introducing new platforms to ensure that the interventions stay current and in line with digital trends [30]. Another advantage of mHealth interventions is the possibility of tailoring messages to specific subdemographics of interest [29]. Although the exploration of subdemographics is beyond the scope of this study, future research should focus on defining higher risk subdemographics within the studied commuter population and creation of specific messages catered to their specific circumstances.

### Limitations

Our study presented some limitations. This was a new survey that had not been validated, and convenience sampling of the targeted commuter population may have introduced a selection bias. The survey was only offered in written English, which may have excluded some of the population. The background statistics about socioeconomic status; being told by a doctor they were diabetic, had high blood sugar, or were at risk of

diabetes; as well as the questions about body weight and type were all self-reported by the participants, and no measurements were taken to validate these statements. This use of nonstandardized questions may affect the external validity of the survey.

Of the 400 surveys that were collected, 36 surveys had at least five (6.7%) questions left blank and were considered spoiled. These spoiled surveys were not used in the data analysis, and no further tests were done on them. There were also discrepancies between the number of people who answered yes to the question about regular medication use in the demographic section and the diabetic risk factor section (120 vs 89), which may have been caused by inadequately defining the words *regular* and *medication* in the survey. This, combined by the lack of internal reliability of this variable, prevented further analysis of medication use. It was also discovered that the section pertaining to internet access in the information delivery systems did not appropriately address participants' interest in receiving information, so it was removed from analysis as well.

## Conclusions

The prevalence of diabetes was twice as high in the studied commuter population than the national average, and this

reinforces the need for innovative interventions that focus on prevention and management of diabetes. The South African mHealth Strategy 2015-2019 provides a backbone for creating mHealth interventions to address the diabetes epidemic; however, the body of evidence is not great enough to provide a tested blueprint for these interventions. The aim of this study was to investigate the feasibility and acceptability of mHealth interventions that increase awareness of diabetic risk factors among the studied commuter population in the City of Johannesburg to provide a starting point for future mHealth interventions.

Building from the combined-intervention approach found in the other successful mHealth programs and the statistically significant results in this study, the most practical mHealth intervention disseminating diabetes risk factor information to the studied commuters in the City of Johannesburg has been identified. This intervention should focus on WhatsApp messaging but offer content across other mHealth and traditional platforms to remove barriers to access and enhance the user experience. The content should emphasize the primary risk factors such as diet and nutrition as well as physical activity while also incorporating information on secondary risk factors such as smoking, alcohol use, and hypertension.

## Authors' Contributions

AF and VN designed the study. AF and NT were responsible for data collection. AF, MC, and VN were responsible for data cleaning and analysis. AF wrote the initial draft. All authors critically reviewed and approved the final draft.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Data collection survey.

[PDF File (Adobe PDF File), 331KB - [diabetes\\_v4i3e12600\\_app1.pdf](#)]

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**Abbreviations****mHealth:** mobile health**NCD:** noncommunicable disease**SMS:** short message service

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Original Paper

# Designing Online and Mobile Diabetes Education for Fathers of Children With Type 1 Diabetes: Mixed Methods Study

Anastasia Albanese-O'Neill<sup>1</sup>, PhD; Desmond A Schatz<sup>1</sup>, MD; Nicole Thomas<sup>1</sup>, BA; Jay M Bernhardt<sup>2</sup>, PhD; Christa L Cook<sup>3</sup>, PhD; Michael J Haller<sup>1</sup>, MD; Angelina V Bernier<sup>1</sup>, MD; Janet H Silverstein<sup>1</sup>, MD; Sarah C Westen<sup>4</sup>, PhD; Jennifer H Elder<sup>5</sup>, PhD

<sup>1</sup>College of Medicine, University of Florida, Gainesville, FL, United States

<sup>2</sup>Moody College of Communications, University of Texas at Austin, Austin, TX, United States

<sup>3</sup>College of Nursing, University of Central Florida, Orlando, FL, United States

<sup>4</sup>Department of Clinical and Health Psychology, University of Florida, Gainesville, FL, United States

<sup>5</sup>College of Nursing, University of Florida, Gainesville, FL, United States

**Corresponding Author:**

Anastasia Albanese-O'Neill, PhD

College of Medicine

University of Florida

1699 SW 16th Avenue

Gainesville, FL,

United States

Phone: 1 352 273 9297

Email: [aalbanese@ufl.edu](mailto:aalbanese@ufl.edu)

## Abstract

**Background:** Fathers make unique and central contributions to the health of their children. However, research in type 1 diabetes (T1D) education largely ignores the needs of fathers, including during the development of online and mobile educational materials.

**Objective:** The purpose of this study was to solicit and incorporate input from fathers of children with T1D into the design, content, and infrastructure of a suite of online diabetes self-management education and support (DSMES) resources.

**Methods:** The study took part in three phases: (1) exploratory research, (2) website and subdomain development, and (3) evaluation. Fathers of children with T1D (n=30) completed surveys and semistructured qualitative interviews. Thematic content analysis was used to identify fathers' content and design preferences. An online DSMES website (T1DToolkit.org) and a separate mobile subdomain targeting fathers (Mobile Diabetes Advice for Dads, or mDAD) were developed. A prototype of the site for fathers was evaluated by 33 additional father participants. End user feedback was elicited via survey.

**Results:** Participants in the exploratory phase were enthusiastic about the online diabetes resources. Preferences included high-quality design, availability via mobile phone and tablet, brief text content supplemented with multimedia and interactive features, reminders via text or email, endorsement by medical professionals, and links to scientific evidence. The mDAD subdomain received high usability and acceptability ratings, with 100% of participants very likely or likely to use the site again.

**Conclusions:** The development of eHealth educational platforms for fathers of children with T1D remains an unmet need in optimizing diabetes management. This study incorporated fathers' feedback into the development of a suite of online diabetes education resources. The findings will serve as the basis for future research to assess the clinical efficacy of the website, its subdomain targeting fathers, and additional subdomains targeting unique populations.

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**KEYWORDS**

type 1 diabetes; mobile health; fathers; stakeholder participation

## Introduction

Type 1 diabetes (T1D) is one of the most commonly diagnosed chronic childhood conditions. Despite significant advancements in glucose monitoring and insulin delivery technology over the past two decades, only a small percentage of children with T1D in the United States meet glycemic targets set forth in clinical guidelines [1-2]. In 2016, the American Academy of Pediatrics published its second clinical report on fathers, emphasizing the unique and central contributions they make to the health of their children and highlighting the cultural and structural barriers fathers encounter as caregivers [3]. Fathers' engagement in their children's T1D management has been linked to improved glycemic outcomes for the child with T1D and improved quality of life for all family members [4]. However, fathers of children with T1D are less likely than mothers to attend clinic visits with their children. As such, fathers are often absent when diabetes education is provided and likewise often miss opportunities to participate in research [5-6]. Few studies have targeted fathers' diabetes-specific educational needs, and there remains no tailored mobile or Web-based diabetes education available to fathers [7].

The available data reveal that fathers' knowledge trails that of mothers, fathers report insufficient knowledge to avoid common errors, and fathers' retention of diabetes knowledge diminishes over time [8-9]. Mothers and fathers alike have reported never mastering diabetes management skills and express a gap between desired knowledge and actual competencies [10]. While health care providers often focus on the mechanics of disease management, in particular glucose control, families indicate a need for assistance in responding to diabetes life challenges, adaptation to the diagnosis, and linkage to social support [11]. Fathers of children with T1D have reported diverse learning needs, with fathers of teenagers indicating more substantial knowledge requirements and skills training to guide their involvement in their children's care [7,11-14]. However, qualitative studies suggest that fathers can feel lost or left out during clinical appointments because they lack the disease-specific knowledge, vocabulary, or conceptual framework to confidently participate in the conversation with the care provider [15].

Paradoxically, as children become teens and fathers' diabetes-specific educational needs increase, paternal attendance at clinical visits decreases, falling to 14% of visits for fathers of children ages 13 to 17 years [5]. This is due in part to cultural and health care system barriers such as lack of time off and inconvenient clinic hours, but research also suggests that the diabetes care team may inadvertently discount paternal attendance at clinic visits [3,16]. Fathers themselves may not perceive clinic visits as a positive learning environment or opportunity to improve adaptation to and engagement with their children's diabetes management [17]. Regardless of the cause, the decline in paternal attendance during adolescence has been correlated with a longitudinal decline in regimen adherence and glycemic control, particularly if the child has low perceived diabetes-specific self-efficacy [18-19]. Collectively, these studies suggest that clinics might not be the best place to provide Diabetes Self-Management Education and Support (DSMES)

for fathers. It remains imperative, however, to enhance fathers' knowledge and involvement in their children's care to mitigate the decline in diabetes self-care behaviors and glycemic control that typifies adolescence with T1D [1,20].

Parents of children with T1D search for information online [21]. As of October 2018, a search for "diabetes education" in the Google search engine identified over 239 million results and entering "diabetes" into the iTunes App Store search field yielded over 1000 unique results [22]. Despite these voluminous options, there is only a small amount of scholarship in the scientific literature to describe how these diabetes education websites or apps were developed or if their effect on clinical and psychosocial outcomes has been validated [23]. Recent studies have solicited end user feedback to inform other facets of diabetes care, including the development of Web-based decision aids, coping skills training, eHealth behavioral programs, and the use of simulation in diabetes education [24-28]. A particularly promising study evaluating an online coping skills training program has shown improved clinical outcomes [29]. However, many pilot studies using mobile phone and text messaging to assist with diabetes management, track blood glucose, and provide motivation that have shown preliminary feasibility and acceptability have lacked sufficient sample sizes, have had brief intervention duration, or have had other flaws, limiting their generalizability [23,30].

To summarize, fathers of children with T1D have unmet educational needs, and traditional, clinic-based diabetes education delivery may be unsuccessful in meeting these needs due to low clinic attendance [5,7]. Leveraging mobile technology to deliver DSMES to fathers outside of the clinical setting is an important step toward improving their self-efficacy with regard to their children's care. Currently available diabetes-related mobile apps and websites have not incorporated fathers' feedback. The purpose of this study was to solicit end user input from fathers of youth with T1D, incorporate their preferences into the design and content of a DSMES website and prototype subdomain targeted to fathers, and beta-test the subdomain with fathers of youth with T1D to ascertain preliminary usability and acceptability.

## Methods

### Design and Methods by Phase

This multiyear, mixed-methods study was conducted in three phases by an interdisciplinary team including certified diabetes educators (CDEs), pediatric endocrinologists, nurse practitioners, dietitians, psychologists, Web designers, graphic designers, videographers, artists, parents of children with T1D, and people living with T1D. The study design was informed by the small but growing field of literature on best practices in eHealth tool development [23-29, 31-34]. In phase 1, data were collected via one-on-one semistructured interviews and an online survey from fathers of children with T1D. In phase 2, the DSMES website ([www.T1DToolkit.org](http://www.T1DToolkit.org)) and subdomain targeting fathers (mDAD: Mobile Diabetes Advice for Dads) were developed. In phase 3, participants evaluated the mDAD prototype and provided feedback via survey. All phases of the study were approved by the University of Florida institutional

review board, and informed consent was obtained from all participants prior to participation. The study team conducted recruitment, obtained informed consent, and performed data collection and related analyses.

### Phase 1: Exploratory Research

Fathers of children aged 6 to 17 years with T1D were recruited from the University of Florida pediatric diabetes clinic, at JDRF (formerly the Juvenile Diabetes Research Foundation) events, and via flyer. Participants completed surveys that included closed and open-ended questions and took part in a semistructured, one-on-one interview. All surveys and interviews were conducted in English. The quantitative survey results, published elsewhere [7], revealed that fathers of children with T1D had unmet diabetes education needs, including on topics in basic management such as managing hyperglycemia and hypoglycemia and calculating insulin doses, and more nuanced knowledge requirements, including managing diabetes at school, information on emerging diabetes technologies, and finding help for diabetes challenges. There was a high level of interest in online and mobile access to diabetes education resources [7]. The semistructured interview guide ([Multimedia Appendix 1](#)) was designed to elicit detailed information on the educational needs and design preferences of participants. Each participant was offered a \$40 gift card at the completion of the survey and interview.

Interviews were digitally recorded and immediately transcribed by a professional transcription service. Transcripts were reviewed for accuracy, and names and other identifiers were removed. The content analysis of the responses to open-ended survey questions and interview transcripts began immediately following the first interview and proceeded until saturation was reached. Thematic content analysis was used to characterize participant knowledge requirements and identify benchmark product preferences for the mobile diabetes education website and tailored subdomain. Transcripts were initially coded line by line by two study team members, and these codes were consolidated into themes [35,36]. As themes emerged, the data were reviewed in an iterative process to reach consensus by study team members and the university's Qualitative Data Analysis Group, a group of faculty and graduate students with expertise in qualitative research methods in health science research who provide consultation and review on qualitative projects.

### Phase 2: Website and Mobile App Development

The curriculum from a recognized diabetes education program affiliated with a university-based pediatric diabetes clinic served as the baseline website content. The curriculum covers basic management topics, including pathophysiology; insulin therapy (injection and pump); glucose monitoring, glucose targets, and pattern management; management of hyper- and hypoglycemia; emergency Glucagon administration; sick days and ketone monitoring and treatment; exercise and activity; nutrition and meal planning; social support and psychosocial aspects of care; safety; insurance coverage and financial support; managing diabetes at school; diabetes technology basics; and screening and prevention of chronic diabetes complications. In addition to the study team, the website design team comprised 5

professionals who worked on a part-time/contractual basis and included a Web designer, graphic designer, artist, and videographer to assist with design, animations, and video production. The overall site design was informed by user-centered and sociotechnical design principles [37]. This approach weighs the characteristics and preferences of the product's target population and integrates user perspectives into product design to increase usability and acceptability. Exploratory findings were used to develop and refine the DSMES website, [www.T1DToolkit.org](http://www.T1DToolkit.org) ([Figure 1](#)).

Based on guidance from the American Medical Association and National Institutes of Health, content on the website and subdomain was written at the 6th grade level; readability was confirmed by separate analysis [38]. All content was presented in English. A video or narrated animation was developed for each major educational topic or skill to ensure accessibility for users of all literacy levels. This necessitated the creation of a YouTube channel to house the video content, which could then be easily embedded and cross-purposed within various pages/posts on multiple sites/subdomains as desired. The YouTube channel is branded with the T1D Toolkit logo. Its content can only be accessed via password and the channel is routinely monitored by the study principal investigator. Push technology capability (the ability to push links to educational material to the end user via text or email) was facilitated via inclusion of a plug-in to automate this process. Content was informed by the phase 1 qualitative analysis and quantitative data on fathers' educational needs and technological preferences reported elsewhere [7].

The DSMES site content was organized into the following categories: (1) T1D 101 (topically sorted into basic skills, basic knowledge, support and connections, newly diagnosed, diabetes definitions); (2) Age-Related Topics (topically sorted into developmentally specific information for children with T1D during preschool, school age, teens, and young adult years); (3) Technology (topically sorted into glucose monitoring, insulin delivery, emerging technology, living with technology); and (4) Research. This grouping of topics reflects exploratory findings as well as iterative feedback obtained during website development. The site was designed to serve as a library for the subdomain targeted to fathers, with the capacity to support other tailored subdomains for babysitters, grandparents, siblings, school personnel, etc. T1D Toolkit-branded social media platforms were established on Facebook, Instagram, Twitter, and LinkedIn to facilitate dissemination of information and increase reach. The T1D Toolkit online infrastructure with current and potential subdomains can be seen in [Figure 2](#).

Video scripts were written by a clinical website development team including nurses, registered dietitians, CDEs, nurse practitioners, and physicians, reviewed by medical personnel, and then recorded, postproduced, and rendered. When possible, members of the diabetes care team, children/adults with diabetes, or parent caregivers were featured in the videos to improve relevance and create an opportunity for peer learning. It was agreed that the site would remain free from commercial influence to enhance trustworthiness. A "Not what you were looking for?" link was added to each page that could be



completed by visitors who did not find the information they sought.

The mDAD subdomain's content is drawn from the DSMES website but can be rebranded specifically for the target audience. The architecture of this subdomain reflected the priorities identified by father participants in the exploratory phase, with an emphasis on delivering information about diabetes technology and T1D research findings. Screenshots of the mDAD subdomain optimized for mobile devices can be seen in Figure

3. Separate logos were developed for the mDAD site and YouTube channel. The mDAD subdomain is a mobile website optimized for handheld devices such as mobile phones and tablets; it is not an app. Unlike apps, a mobile website can be kept up to date by the developer and does not rely on the end user to download updates. Moreover, mobile websites do not use data storage space on the end user's mobile device and do not collect identifying information from the end user. The mDAD subdomain has its own mDAD-branded social media platform.

Figure 1. T1D Toolkit website and YouTube channel.

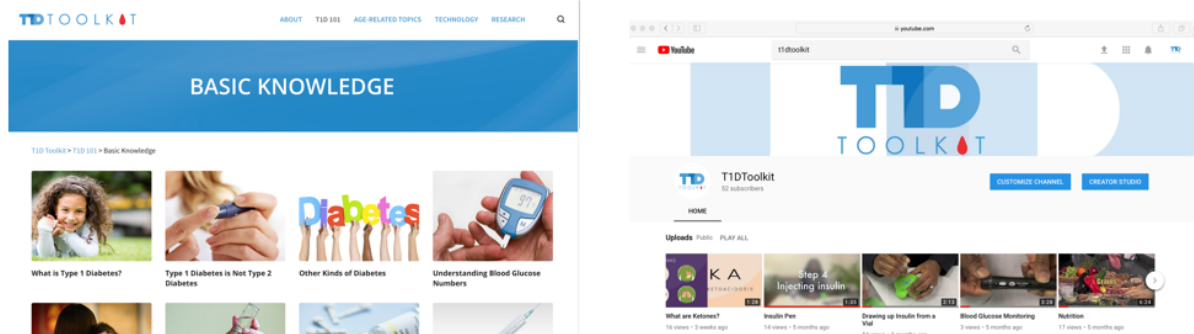


Figure 2. T1D Toolkit online architecture.

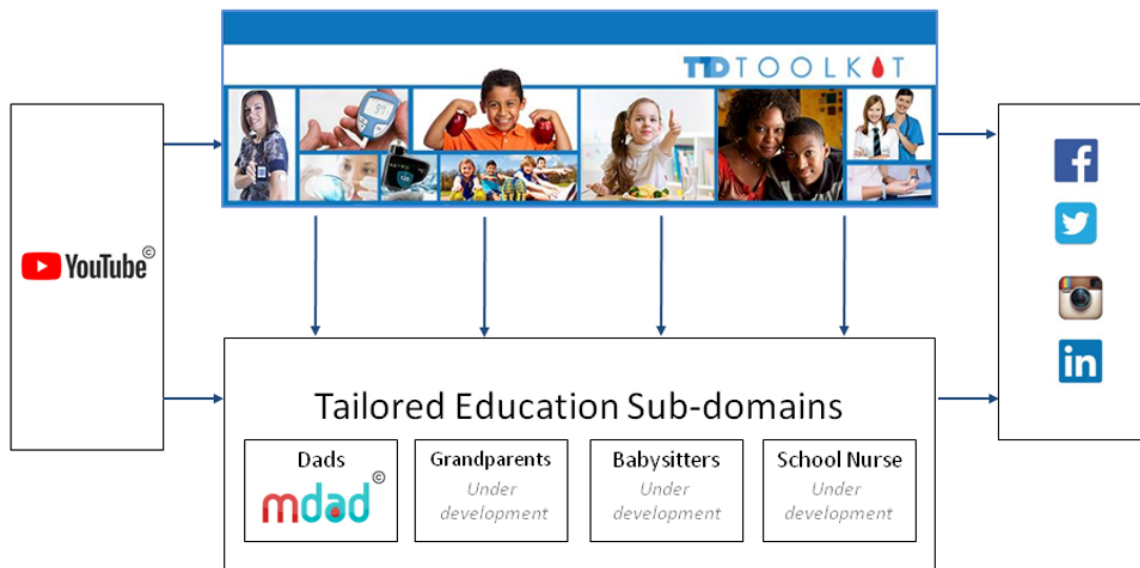
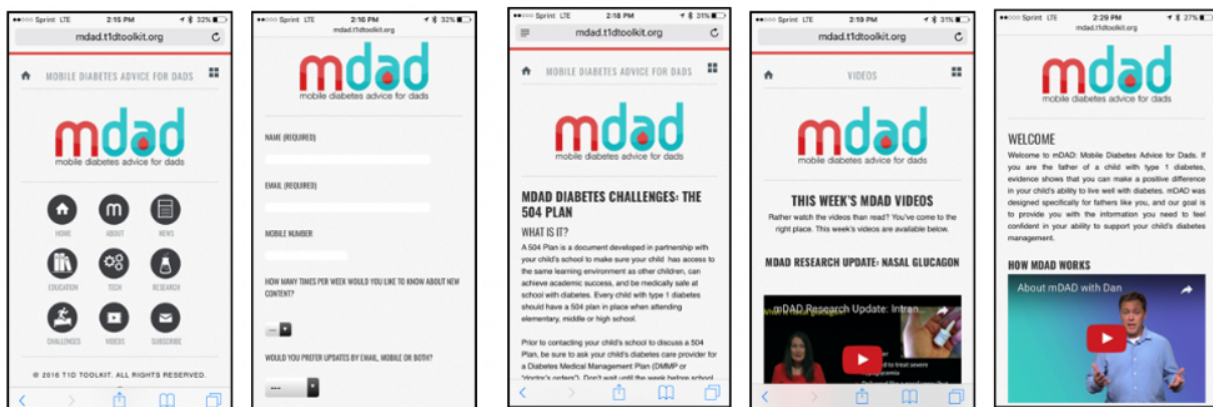


Figure 3. Screenshots of subdomain mDAD: Mobile Diabetes Advice for Dads.



### Phase 3: Evaluation of the Mobile Diabetes Advice for Dads Subdomain's Usability and Acceptability

Thirty-three fathers of children with T1D who did not participate in the exploratory phase were recruited during their attendance at the Children with Diabetes Friends for Life Conference in Orlando, FL, to evaluate the mDAD subdomain (mDAD.T1DToolkit.org). Participation was voluntary, and no compensation was provided. Following consent, participants were advised to explore the mDAD site on a mobile device (tablet or mobile phone) and then complete an anonymous survey that included 18 closed-ended and 2 open-ended questions about the site's usability, design quality, and content. Responses to closed-ended questions were measured using a 5-point Likert-like scale, with a total possible 90 points; higher

scores indicated higher levels of usability (ability to access the site, review content, and navigate the site), and acceptability (quality of content and design). Descriptive statistics were generated using SPSS Statistics (IBM Corp) software.

## Results

### Phase 1: Exploratory Research

Thirty fathers of children aged 6 to 17 years with T1D participated in phase 1 of the study (Table 1). The mean age of fathers was 47.7 (SD 8.5) years, mean child age was 12.5 (SD 3.4) years, and mean diabetes duration was 6.5 (SD 4.1) years. Analysis of the qualitative interview transcripts revealed three themes that would guide the development of the online diabetes education resources.

**Table 1.** Demographics of study participants (N=30).

Characteristics	n (%)
<b>Race/ethnicity</b>	
Black/African American	2 (7)
Hispanic/Latino	2 (7)
White	25 (84)
Asian	0 (0)
Other	1 (3)
<b>Highest education obtained</b>	
Some high school	0 (0)
High school graduate/General Education Development	4 (13)
Some college but no degree	4 (13)
Associate's degree	1 (3)
Bachelor's degree	10 (30)
Master's degree	6 (20)
Professional degree or doctorate	6 (20)
<b>Household income</b>	
Less than \$29,999	1 (3)
\$30,000 to \$49,999	2 (7)
\$50,000 to \$74,999	4 (13)
\$75,000 to \$99,999	3 (10)
\$100,000 to \$149,999	6 (27)
Over \$150,000	12 (40)
<b>Employment status</b>	
Employed, full-time	27 (90)
Employed, part-time	2 (7)
Retired	1 (3)

### Theme 1: Perceived Value of Online Diabetes Education Resources

Overall, participants expressed a high level of acceptability for receiving diabetes education online, particularly via mobile phone or another mobile device. Of particular interest were the

ability to review information at their own pace, convenience of not having to be in a fixed location, and freedom from judgment conferred by a private learning environment. A minority of participants noted they preferred in-person/clinic or group-based diabetes education. While all participants said they made the effort to attend clinic visits with their children, many were



unable to do so due to scheduling conflicts. A positive relationship with their diabetes care team was nearly universal; however, some participants indicated that routine appointments were not a venue where problems were solved or new information was obtained, and others noted they sometimes felt uncomfortable asking questions during clinical visits and/or worried they were being judged for their lack of knowledge. For fathers who did not attend visits, some viewed the child's mother as becoming a gatekeeper for diabetes knowledge and disease management. One father who was able to attend only

some of the visits put it this way, "I hate it when she goes to the doctor and I don't because I don't like feeling like I didn't hear the whole story." Fathers of female adolescents noted that both they and their daughters felt uncomfortable talking about puberty-related topics that invariably came up at visits (menstruation, birth control, physical development, etc), perhaps contributing to a decline in paternal attendance. A summary of the benefits of online diabetes education enunciated by father participants, along with illustrative quotes, can be found in [Textbox 1](#).

**Textbox 1.** Fathers' perceived value of online diabetes education resources.

On my time:

- "Online is, obviously, easier. Online, where you can jump in on your schedule, and jump out on your schedule is better for me."

Lower perceived value in clinic visits:

- "The doctor visits aren't solution based. They're just visits to see that you're managing it."
- "I know—I know for a fact, after talking with a lot of other parents, that they are reluctant to ask that question, for fear of sounding or looking dumb, so they let it go."

Concerns about judgment:

- "I don't know as much about it as I should know about it. I already feel crappy about that. I didn't want to go and interface in a set of circumstances where I'm going to feel like somebody's being judgmental about what I don't know."

Learning independently:

- "I'm more focused on learning on my own."
- "I've been through too many groups, and they get so easily distracted that it becomes a lot of—a lot of crybabies and whining. I don't like groups."
- "For me, group settings just drain the energy out of me."

### ***Theme 2: Website and Subdomain Content Priorities***

Although the average diabetes duration of the participants' children was 6.5 (SD 5.1) years, all participants noted a need to review basic diabetes knowledge and skills, particularly those that they did not use routinely. They advised that online information should be organized by age and tailored to the child's developmentally specific diabetes needs (eg, toddler versus teenager versus young adult). They sought guidance during developmental transitions often complicated by diabetes, including starting school, middle school, puberty, driving, leaving home, and going to college. They asked for expert advice on current and emerging diabetes technologies; not only what was available but how to use it effectively (eg, information

about brands and models of currently available continuous glucose monitors and guidance on how to access and interpret continuous glucose trend data). All father participants in the study desired information on current research that was presented in a way they could understand, and many looked for information about risks for chronic diabetes complications, had questions around health insurance, and worried about diabetes discrimination. Participants indicated they wanted to choose topics specific to their individual interests. As one participant explained, "I don't think just getting random bits of information that may or may not be tailored to somebody's specific, individual needs is particularly helpful." A summary of the desired content priorities identified by father participants, along with illustrative quotes, can be found in [Textbox 2](#).

**Textbox 2.** Website and subdomain content priorities.

<p>Basic management:</p> <ul style="list-style-type: none"> <li>• “It would be nice to have answers that were easily accessible to the kinds of questions that I have, like, [chuckles] what is a ketone? Why should I care? What the hell should I do about it?”</li> <li>• “It’s more just needing just basics...”</li> </ul> <p>Organized by age:</p> <ul style="list-style-type: none"> <li>• “Break it into the different stages, your child, teen, adult.”</li> <li>• “Different age groups, what’s good for toddlers? What’s good for growing young boys and girls to teenagers?”</li> </ul> <p>Guidance on transitions:</p> <ul style="list-style-type: none"> <li>• “These transitions. Middle school, high school, driving.”</li> <li>• “Puberty, what’s puberty going do to him?”</li> <li>• “It’d be nice to have—to be able to ask other families how they’ve dealt with the diabetes once their kid goes to college.”</li> <li>• “I have to let go. She’s going to a college 100-plus miles from home.”</li> </ul> <p>Technology:</p> <ul style="list-style-type: none"> <li>• “I would want to know more about the technology, number one...”</li> <li>• “If I had something that...—was a gold standard that I could turn to and get the state of the art on continuous glucose monitor or the best meter or the best pump or what to try, what to stay away from.”</li> </ul> <p>Research:</p> <ul style="list-style-type: none"> <li>• “I’d like to know more about the research and what’s going on and long-term to find a cure, and what the different types of approaches that they’re looking at.”</li> </ul> <p>Other:</p> <ul style="list-style-type: none"> <li>• “Long-term health and insurance coverage.”</li> <li>• “Is there any discrimination against diabetics? Are people going to treat my daughter differently because she’s diabetic?”</li> </ul>
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**Theme 3: Design Recommendations**

Participants clearly enunciated their design preferences, prioritizing high quality design and multimedia features including a combination of videos, images, animations, illustrations, interactive features, links to other resources/evidence, infographics, and downloadable reference sheets (PDF). Many participants acknowledged that brief videos would be optimal to convey information, particularly for fathers with lower educational attainment. Video content was also valued regarding skills training, especially for invasive or emergency skills. As one father noted, “I don’t think that without visualization you can really apprehend what it is that you’ve got to do.” Participants repeatedly stated that the information provided should be brief and concise, contain links to more in

depth information and evidence, should be curated by the diabetes care team, and should be pushed to them in a structured way via email, text, or social media. There was an underlying concern that the information should be trustworthy, up to date, free of commercial influence, and reflect evidence rather than opinion. One father commented, “Once I learned facts versus seeing only horror stories online, I steered away from looking online at stuff.” Most fathers said that they would be more likely to trust online information if it were endorsed by medical experts, had a direct connection to clinical practice, or was recommended by the child’s pediatric endocrinologist or CDE. A summary of the design priorities identified by father participants, along with illustrative quotes, can be found in [Textbox 3](#).

**Textbox 3.** Design recommendations.

## Videos and animations:

- “For skills like administering glucagon, I don’t think that without visualization you can really apprehend what it is that you’ve got to do.”
- “Being in education though, especially for people who are visual and who are not able to read and write, [video] is so important. Because we assume that people can read and write, which they can’t.”
- “I’m a visual learner. Obviously, I think YouTube is an awesome medium for learning.”

## Concise:

- “Things that are targeted. Bullet points, as opposed to long articles.”
- “I’m better in smaller doses because I don’t have a lot of time.”

## Push technology:

- “If it’s new information or updated information—I would want a reminder or a notice.”
- “I would like the idea of pushing it to us rather than going and looking for it because that’s sometimes complicated.”

## Up to date:

- “Something you could make sure you’re on top of everything and you’re up to the latest on all the diabetes news that’s coming down the line.”
- “Of course, as you know with diabetes, the information and the—it’s changing that [snaps fingers] quick.”

## Mobile:

- “I like it on my phone, because I pretty much have that with me everywhere. I look at it more if it’s on my phone. If it’s on the computer, it’s not as convenient.”

## Credible, endorsed, attractive:

- “I think an app’s a great idea. Everybody wants everything at their fingertips. I think the important thing is how it’s laid out, how did they get the information, and can the dad trust it?”
- “Then, they’ve also got to be right—because there’s so much misinformation or partial information. You want to know the answer to your question, and you want it to be actionable, where the response is accurate.”
- “That the information’s accurate, that the information is true.”
- “If you’ve got a poorly designed webpage covered with advertisements, I’m not likely to trust it.”

**Phase 3: Evaluation of the Mobile Diabetes Advice for Dads Subdomain’s Usability and Acceptability**

Thirty-three fathers of children with T1D who did not participate in phase 1 of the study were enrolled in phase 3 to evaluate the mDAD subdomain. The phase 3 feedback survey had a potential range of 18 to 90 points. Phase 3 participants reported high levels of usability and acceptability, with an average score of 85.6 points (range 78 to 90 points). All participants reported they would be very likely or likely to visit the site in the future; 97% (32/33) rated the overall quality of the site as excellent or very good; 91% (30/33) reported they strongly agreed or agreed that the information on the site was useful to them; 97% (32/33) strongly agreed or agreed the site was well organized; 100% (33/33) reported the overall layout and design of the site was attractive; 85% (28/33) reported they were always able to view the videos; and 91% (30/33) reported they never or rarely got lost when looking for information. The results of the product evaluation can be found in [Multimedia Appendix 2](#).

**Discussion****Principal Findings**

Few eHealth apps or websites solicit and incorporate end user perspectives into design and content decisions, and fewer still are validated by a rigorous design and development process. This study represented a first step in incorporating end user feedback into the design and content of a suite of online diabetes education resources for children with diabetes and their parent caregivers. Exploratory phase feedback was used to develop the online diabetes education resources [www.T1DToolkit.org](#) and [mDAD.T1DToolkit.org](#). In the evaluation phase, participants reported high levels of acceptability for mobile delivery of diabetes education and skills training. This study is particularly novel because it demonstrated it was possible to successfully recruit father participants, thereby facilitating meaningful input from a population that is typically left out of pediatric research. Of note, recruitment largely took place outside of the clinical setting where the accompanying parent is often the mother, suggesting that paternal recruitment may be more successful when conducted at diabetes conferences, via flyers, and through diabetes volunteer organizations.

As noted above, mothers have typically been the parent most directly involved in their children's care after a child's diagnosis with T1D. Likewise, mothers have most often participated in diabetes education research, and maternal feedback has been used to inform the diabetes education process and related resources over time. However, fathers' engagement in their children's T1D management has been correlated with improved adherence, better psychosocial adjustment, and improved overall family health, and fathers are becoming more involved in their children's care [3,18-19,39-42]. As such, fathers should be welcomed as integral diabetes caregivers as recommended by the American Academy of Pediatrics [3]. Creating a paradigm of care to help fathers avoid cultural or systemic barriers (eg, inconvenient office hours, lack of direct access to diabetes education, mother as gatekeeper) to participation in their children's care should be a priority for pediatric diabetes practices. Solutions to this problem include online education and skills training, flexible office hours, and the use of telemedicine to augment traditional clinic visits. Fathers who cannot attend clinic visits should have direct access to diabetes education, which necessitates the development and availability of validated online resources. Diabetes education that is available online or via mobile technology improves paternal access to diabetes knowledge and skills training and mitigates the gatekeeper role of mothers. This study contributes to our understanding of how to develop and sustain validated online and mobile diabetes education resources available outside of the clinic setting.

Although there is a low level of trust in the information found online, parents of youth with T1D report frequent use of the internet and online diabetes forums to acquire knowledge [20]. Our study confirms earlier findings that parental trust in online information about diabetes is enhanced by a commercial-free environment, links to evidence, and endorsement by an accredited diabetes clinical team [43]. Not only did our participants enthusiastically support the delivery of diabetes education via mobile and push technology, they cited unanticipated benefits, including the opportunity to acquire knowledge in a safe, private environment without fear or embarrassment. This concept of empowerment derived from the use of eHealth tools has been recommended as an important consideration in the development of T1D apps in systematic reviews [32].

Participants in our study also identified shifting priorities associated with their children's evolving developmental imperatives, underscoring the complexity of parenting a young child with T1D through adolescence into adulthood and the need for guidance on how to cope with the day-to-day challenges presented by T1D in real-life situations [11]. Our participants repeatedly expressed the need for anticipatory guidance specifically related to their children's developmental stage and life transitions, including attending school for the first time, going through puberty, surviving middle school, going to

college, and moving away from home. The importance of social support and the opportunity for peer learning should be strongly considered when educational interventions, both online and in person, are developed.

Diabetes education is poorly reimbursed and typically only provided comprehensively at diagnosis. In addition, families may not attend clinic-based education-focused visits because they are not a covered service and are costly to the family, require additional time off from work or school, or require the family to travel a long distance at a personal cost. The ubiquity of mobile phone technology makes the possibility of online diabetes education a reality, but only if it is presented in an accessible way and with reliable scientific evidence to support specific recommendations.

### Limitations

This study had several limitations. All fathers and stepfathers in the exploratory phase lived with their children in two-parent homes, and the majority had obtained a college degree. In addition, demographic data were not collected during the beta test. Additional research is required to ascertain the learning needs of minority fathers, single fathers, same-sex male couples, and fathers with lower incomes and less formal education. The usability and acceptability measures used in the study were not standard tools for assessing these constructs; future studies should use a standard usability tool in addition to study-specific measures. Observational data regarding how participants navigated and viewed the site were not collected. Finally, despite the use of rigorous processes to limit bias during qualitative data analysis, there still exists the inherent risk that study investigators may not have effectively bracketed their preexisting presuppositions.

### Conclusions

The publicly available website, [www.T1DToolkit.org](http://www.T1DToolkit.org) along with its subdomain targeted to fathers and future subdomains targeted to additional audiences have the potential to complement and supplement diabetes education provided in the clinical setting, with the ultimate goal of contributing to improved diabetes outcomes. The parent website has been integrated into the clinic's diabetes education paradigm, and the subdomain targeting fathers is being modified based on feedback obtained in this study. Future studies will solicit input from a diverse sample of end users to refine the suite of eHealth online resources. This will be followed by a clinical trial to determine the potential of these resources to contribute to improvements in the glycemic control of children with T1D and improvements in diabetes knowledge and psychosocial outcomes for all family members, including those who cannot routinely attend clinic visits. The promise of technology to reduce cost and improve diabetes outcomes will only be realized by placing evidence behind mobile diabetes websites and apps that can then be easily and cost-effectively incorporated into clinical practice.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Qualitative interview guide.

[[PDF File \(Adobe PDF File\), 14KB - diabetes\\_v4i3e13724\\_app1.pdf](#)]

## Multimedia Appendix 2

Survey responses for usability and acceptability of the Mobile Diabetes Advice for Dads subdomain.

[[PDF File \(Adobe PDF File\), 82KB - diabetes\\_v4i3e13724\\_app2.pdf](#)]

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## Abbreviations

**CDE:** certified diabetes educator

**DSMES:** Diabetes Self-Management Education and Support

**mDAD:** Mobile Diabetes Advice for Dads

**T1D:** type 1 diabetes

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Original Paper

# Digital Person-Centered Self-Management Support for People With Type 2 Diabetes: Qualitative Study Exploring Design Challenges

Robyn Schimmer<sup>1</sup>, MSc; Carljohan Orre<sup>2</sup>, PhD; Ulrika Öberg<sup>3</sup>, RN, PhD; Karin Danielsson<sup>1</sup>, PhD; Åsa Hörnsten<sup>3</sup>, RN

<sup>1</sup>Department of Informatics, Umeå University, Umeå, Sweden

<sup>2</sup>Department of Computer Science and Media Technology, Malmö University, Malmö, Sweden

<sup>3</sup>Department of Nursing, Umeå University, Umeå, Sweden

**Corresponding Author:**

Robyn Schimmer, MSc

Department of Informatics

Umeå University

MIT Building

Umeå, 90187

Sweden

Phone: 46 733834222

Email: [robyn.schimmer@umu.se](mailto:robyn.schimmer@umu.se)

## Abstract

**Background:** Self-management is a substantial part of treatment for patients with type 2 diabetes (T2D). Modern digital technology, being small, available, and ubiquitous, might work well in supporting self-management. This study follows the process of developing a pilot implementation of an electronic health (eHealth) service for T2D self-management support in primary health care. The use of digital health, or eHealth, solutions for supporting self-management for patients with T2D is increasing. There are good examples of successful implementations that can serve as guides in the development of new solutions. However, when adding person-centered principles as a requirement, the examples are scarce.

**Objective:** The objective of this study was to explore challenges that could impact the design of a person-centered eHealth service for T2D self-management support. The study included data collection from multiple sources, that is, interviews, observations, focus groups, and a Mentimeter (interactive presentation with polling) survey among stakeholders, representing various perspectives of T2D.

**Methods:** A user-centered design approach was used to exploratively collect data from different sources. Data were collected from a workshop, interviews, and observations. The different data sources enabled a triangulation of data.

**Results:** Results show that user needs related to an eHealth service for person-centered T2D self-management support are multifaceted and situated in a complex context. The two main user groups, patients and diabetes specialist nurses, express needs that both diverge and converge, which indicates that critical design decisions have to be made. There is also a discrepancy between the needs expressed by the potential users and the current work practice, suggesting more attention toward changing the organization of work to fully support a new eHealth service.

**Conclusions:** A total of three overarching challenges—flexible access, reducing administrative tasks, and patient empowerment—each having a significant impact on design, are discussed. These challenges need to be considered and resolved through careful design decisions. Special attention has to be given to the patient user group that could greatly impact current work practice and power structures at the primary care unit. A need for further studies investigating patient needs in everyday life is identified to better support the implementation of technology that does not give specific attention to organizational perspectives but instead approach design with the patient perspective in focus.

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**KEYWORDS**

eHealth; diabetes mellitus, type 2; informatics; nursing; patient-centered care; self-management

## Introduction

### Background

Using electronic health (eHealth) services as self-management support for people with type 2 diabetes (T2D) is, in many ways, a promising way to reduce costs, increase availability of care, and empower patients [1-3]. T2D is a common diagnosis and demands a high level of self-management. In Sweden, 4% to 6% of the population is estimated to suffer from diabetes, although approximately 4% is diagnosed and whereof approximately 90% is T2D [4,5]. However, as most people are diagnosed at an age of 60 years and above, the prevalence of T2D is much higher in the older age groups [6]. In the group of people aged 65 years and older, the prevalence is reported to be approximately 12% to 18%, with higher percentage among men [7]. The illness is complex and demanding as the basic treatment is dietary changes and increased physical activity besides the pharmaceutical treatment and blood sugar testing. It also commonly involves comorbidities such as hypertension, hyperlipidemia, and obesity and leads to severe complications such as stroke and heart disease, kidney dysfunction, blindness, and other problems if not sufficiently treated and self-managed by patients [8].

The context of this paper is Swedish primary health care, which is responsible for treating people with T2D. Basic medical treatment as well as nursing, prevention, and rehabilitation that do not demand special competences are offered in primary health care. Patients with chronic illnesses as T2D visit the primary health care center on a regular basis. General practitioners, primary health care nurses with special responsibility for diabetes clinics, physiotherapists, and occupational therapists often work in teams at primary health care centers. Majority of them are connected to the public health welfare program.

Studies have shown that patients see a potential in using eHealth services to support self-management [9,10]. The development of such eHealth services has been ongoing for many years and with various outcomes. In a systematic review from 2013, Pal et al [11] show that although internet-based interventions for diabetes self-management have limited effects on glycemic control, mobile phone-based interventions demonstrated more promising results. In a more recent study, Murray et al [12] report improvements in glycemic control through a Web-based self-management program.

The variety of outcomes reported in different studies implies a challenge in how eHealth services for self-management support should be designed, implemented, and evaluated. Reviewing the supply of available apps for diabetes management, Huang et al [13] conclude that “apps could play an important role in complementing multifaceted diabetes care” and also highlight the importance of being context-specific and adaptive to specific user’s needs. When addressing, for example, specific context and user needs, it is important to clearly describe how these perspectives are applied in design and implementation processes. Discussing the potential of self-management eHealth interventions for social support, Vorderstrasse et al [14] conclude that many studies lack detailed descriptions about how social support has been designed, implemented, and evaluated.

It is, therefore, hard to determine the factors that have impact on social support.

### Person-Centered Care and Electronic Health

The American Diabetes Association recommends [8] that person-centered care (PCC) approaches should be applied in self-management support. There are benefits of adding PCC functionality to eHealth services, both for patients and health care organizations [15]. Digital devices that capture personal data and behaviors can be utilized to develop more personalized and timely services [16]. However, going through current literature, there are still few examples of eHealth services for T2D self-management support that also incorporate PCC. Wildevuur et al [17] present a set of preconditions for information and communications technology-enabled PCC and also conclude that this is a relatively new research area. They also point out the need for more research on design of technology that integrates a person-centered approach with attention to the context of use and user experience.

In this paper, we address these challenges related to design and technology for PCC. Design of eHealth services, as with all information technology (IT), is not a matter of solving simple problems but rather finding a possible composition that meets the requirements. Exploring challenges faced in a design situation of an eHealth service that includes PCC principles is, therefore, crucial for future work integrating them into the design of new eHealth services. The study is a part of our work with an ongoing pilot implementation study to develop a person-centered eHealth service for T2D self-management support. The aim of this study was to explore possible challenges that could impact the design of a person-centered eHealth service for T2D self-management support in Swedish primary health care.

## Methods

### General Approach

This particular study is part of a larger project with the aim of exploring the prerequisites for and developing a person-centered eHealth service for support of self-management in T2D. The project has already published several part studies [10,18,19]. In this study, data are collected from multiple sources, that is, interviews, observations, focus groups, and a Mentimeter (interactive presentation with polling) survey among stakeholders, representing various perspectives of T2D. Identifying design challenges requires a broad approach where user requirements and needs are supplemented with an understanding of the context of use, current organization, and work practice. The choice of data sources for this study was made with this systemic view in mind, where each data source provided insights into different aspects of the whole.

### User-Centered Design

Due to the focus on PCC, we wanted to move beyond a solely health care perspective where organizational needs are prioritized. Instead, we wanted to have a more holistic viewpoint where the patients and their needs were foremost. We, therefore, chose to adopt a user-centered design (UCD) approach. The strength of the user-centered approach is that it is founded on



the principle of designing based on studying user's practice [20], which fits well with the purpose of adopting person-centered principles into the eHealth service. A design approach is also well suited for exploring complex problems [21] and context of use [22,23].

UCD can beneficially be used to focus on important aspects such as *multiple stakeholders*, *current practice*, and *future needs* [20,24,25]. These three aspects formed the foundation for data collection where different data sources were used to gather data that helped us explore these aspects.

### **Multiple Stakeholders**

Understanding the users and other stakeholders is an essential part of design [26]. A complex context often includes multiple users and stakeholders that require to be assessed to identify user needs and organizational constraints.

The two main user groups identified for this study were patients with T2D and diabetes specialist nurses. These two groups are the main actors in most of the current Swedish primary health care practice. As most patients manage their own health in everyday life, with help and support from family members, it makes them important stakeholders too. Beyond these groups, there are also other user groups and stakeholders involved such as managers and physicians at the primary care unit and representatives from higher organizational levels. However, no stakeholders on higher organizational levels than the regional primary care director were participating in our studies. Furthermore, researchers and system developers were also seen as stakeholders important for the design and development of eHealth service.

### **Current Practice**

Understanding the context of use is an important part of the design process. With the patient and the diabetes specialist nurse as the two main user groups, there are two distinctly different contexts of use: one situated in the patients' everyday life and the other that is situated at the primary care unit and the work of the diabetes specialist nurse. Together, they form a complex context that is necessary to understand to design an eHealth service that is adapted for the individual's use in everyday life; nurses' caring, treatment, and administrative aspects of work; and interaction between these two user groups.

Current practice is an aspect related to the context and focuses on the processes and activities in the current situation. For the design process, exploring current practice is an important part of making decisions, whether certain activities should be supported by the new system or whether it is necessary to make adjustments in the routines [27]. Within this context, current practice involves activities of the individual in everyday life and activities more closely related to the processes at the primary care unit. For this study, we choose to focus primarily on the primary care unit context and the interactions between patients and diabetes specialist nurses. The assumption was that these interactions between patients and nurses were likely to reveal challenges and tensions that were important in guiding design decisions.

### **Future Needs**

Design involves creating something that is not yet there [28]. An important part of design is, therefore, to establish the users' future needs. Identifying future needs is done through careful investigations into the current work practice and requirements expressed by future users. Users are, however, often limited in their ability to fully express what a new system should include [29].

Understanding and establishing future needs is not only an empirical inquiry into current practice and contexts that connects requirements and wishes expressed by future users but also an analytical activity where the results of the inquiry are analyzed in relation to available technology and other factors. Together with other relevant material, future needs form the foundation for important design decisions [23,28] by setting out the desired direction for the new design.

### **Data Collection and Participants**

Data collection from multiple sources, that is, interviews, observations, focus groups, and a Mentimeter survey among stakeholders, representing various perspectives of T2D, was performed.

### **Interviews and Observations**

Study participants for the interviews and observations were recruited through contacting the regional primary care director who appointed 1 health care center as a possible choice. The manager of this health care center accepted their participation and mediated contact with their diabetes nurses. The manager and 1 diabetes nurse both had many years of work experience within primary health care and T2D care. All interviews and observations were made by the first author.

Repeated interviews (n=4) with 1 diabetes specialist nurse and 1 primary care unit manager (n=2) revolved around work process, routines, and known organizational constraints and challenges. The purpose of this data collection was to gain insights into opportunities and constraints related to the organization and professional self-management support. All interviews were audio recorded and transcribed verbatim for analysis.

Nonparticipatory observations (n=4) of nurse-patient consultations were conducted at the health care center using video (GoPro cameras) to record the sessions. The purpose of the observations was to gain a deeper understanding of the preconditions for interaction between the diabetes specialist nurse and the patient.

### **Workshop Procedures**

Informed by the interviews and observations and to address the multifaceted perspectives of multiple stakeholders, we chose to design a workshop where we invited a broad sample of stakeholders somehow involved in T2D care. The recruitment began by listing potentially important stakeholders and participants who were invited based on personal contacts and snowball sampling. The purpose of the workshop that was held in 2016 was to explore expectations, wishes and needs, and concerns related to self-management support in T2D care and digitalization. The list of participants is presented in [Table 1](#).



**Table 1.** Workshop participants (N=26).

Participant	Value, n (%)
Patients	5 (19)
Spouses	2 (8)
Diabetes specialist nurses	9 (35)
Physician and regional primary care director	1 (4)
Researchers	6 (23)
System developers	3 (12)

### Focus Groups and Mentimeter Surveys

For focus group discussions during the workshop, the participants (n=26) were divided into 4 focus groups of 6 to 7 people. Participants were divided so that there were 1 to 2 patients and/or spouses per group and 2 to 3 diabetes specialist nurses per group. The other participants, including researchers, were distributed evenly into the 4 groups. The idea of using mixed groups was to let different perspectives be expressed and shared to explore both mutual and divergent expectations and opinions.

To support group discussions, each focus group worked with two canvases. On the basis of the idea of business canvases [30], these were designed to cover different aspects of self-management and digitalization. Additional material, multicolored post-it notes, pens, and markers were available and used by the participants to document the discussions.

Mentimeter questions had been prepared to cover questions on concept definitions (eg, *what does self-management mean to you?*) and user technology. The participants used smartphones or tablets to answer the questions individually, and the answers could then be presented anonymously to further inspire group discussions.

### Analysis

Nonparticipatory observations of nurse-patient consultations were conducted using video to record the sessions—focus lays on preconditions for and outcome of interaction between the diabetes specialist nurse and the patient. Video recordings from the observations were viewed in sequence, using memos to annotate important activities and situations [31]. The recordings and memos were then discussed, analyzed, and interpreted by the authors. Themes (*increased use of checklists, avoiding one-sided communication, and prioritizing among administrative tasks*) were identified, which suggested that changes were needed to make patients more involved.

Repeated interviews, conducted individually and in pair, were performed with 1 diabetes specialist nurse and 1 primary care unit manager. Interview guides were used that covered areas such as work processes, routines, and organizational constraints and challenges for T2D care. The purpose of this data collection was to gain insights on opportunities and constraints related to the organization and routines in care and care processes. All interviews were audio recorded and transcribed verbatim for analysis.

All text data were then analyzed using qualitative content analysis [32]. The texts were read through several times, and meaning units responding to the aim were identified in the interview data. In the next step, all texts in meaning units were coded and organized based on similarities and dissimilarities. The codes were sorted and abstracted into themes, illustrating emergent concerns expressed by the participants. Data on various levels were discussed between the authors to gain consensus and reach trustworthiness regarding the interpreted themes (*access governed by needs, developed teamwork, relevant IT training, assessing patients' individual needs, and counteracting shallow patient interaction*).

Focus group discussions in 4 groups were conducted during the workshop (2×45 min). The first session revolved around personal needs and possible improvements related to both everyday life and care. Questions raised were as follows: needs that are not satisfied today, what patients and spouses expect from care, and possible future improvements. The second sessions revolved around perceptions and expectations on eHealth and digital self-management support. Questions raised were as follows: negative expectations and fears toward digitalization, advantages with digitalization, and digital solutions and functions that could improve life with diabetes. Data from focus group discussions comprised canvases, multicolored post-it notes, pens, and markers that were used by the participants for self-documentation that was analyzed through systematic text condensation [33]. In addition, field notes made by the first author who moved around in the room observing and listening to all focus groups were analyzed together with the self-documented data (*striving for disease control and balanced life, practicing PCC, facing limited resources, and increasing number of contact channels*).

Mentimeter questions had been prepared in advance to cover questions related to concept definitions (eg, *what does self-management mean to you?* and *what does eHealth mean to you?*). Using smartphones or tablets, the participants answered the questions, and the results were displayed collectively (without revealing individual respondents). The purpose was to further inspire the discussions and create common understanding of key concepts. The data collected were added to the focus group discussion dataset and field notes for analysis. The analyzed Mentimeter survey data were about self-management (*improved responsibility and self-care, lifelong learning needs, and promoting independency*).

Data from all data collections were discussed and analyzed between the authors. Qualitative content analysis was used to

sort data on various levels into 7 themes (*improved access, resource efficiency, reduced administrative tasks, continuous training and support, tailored care, strengthened communication, and patient empowerment*).

### Ethics

Ethical approval was given by the regional ethics board in Umeå for all patient involvement (Registration number 2016/375-32). All patients were informed about the aim of the study and accepted participation in the study and expressed no doubts.

## Results

### Themes and Subthemes

The aim of this study was to explore challenges that could impact the design of a person-centered eHealth service for T2D self-management support. The design process included data collection from multiple sources, for example, interviews, observations, focus groups, and Mentimeter survey among stakeholders, representing various perspectives of T2D.

The analysis revealed 7 critical factors, or challenges, expressed as the following themes: improved access, resource efficiency, reduced administrative tasks, continuous training and support, tailored care, strengthened communication, and finally, patient empowerment (Table 2).

### Improved Access

Getting in contact with the caregiver was an emergent theme among the patients participating in the workshop. They requested increased number of contact channels to establish contact with the caregiver in an easier and quicker way. One of the patients expressed that it should be “Easy to get in contact, e.g., getting advice and new prescriptions.” Questions or issues could emerge at any given time, and it is not always meaningful to wait to raise this issue, for example, acute hypoglycemia, until the next regular meeting with the nurse or the physician (which could be 6 months away). Even if the issue is of temporal importance, getting a quick answer and support could strengthen the overall service experience and support patient learning.

This is, however, not reflected in what was seen at the primary care unit; there was no simple way for patients to interact directly with their diabetes specialist nurse without going through the generic booking or contact routine, as access must be governed by needs. This routine comprises contacting the primary care unit reception either by phone or using the existing Web-based system for bookings or requests. The request is evaluated and redirected to someone at the primary care unit that is considered appropriate (or has the time) to answer the request. Then, the patient is contacted later over phone, which could lead to a discrepancy between the urgency of the issue and the time of being contacted.

### Resource Efficiency

Being efficient with limited resources was brought up by both patients and caregiver representatives but with slightly different meaning. Patients were concerned with unnecessary waiting time. One of the patients at the workshop concluded that “Making contact over phone takes time.” Being put on hold or needing to elaborate with work hours to visit the primary care unit can be seen as compromising with an individual’s time.

From a caregiver perspective, there is a clear concern about being efficient with the limited economical resources that are available. The high costs associated with treating T2D and other chronic illnesses became clear in the interviews with the management representative who expressed the importance of finding efficient work processes and right resources being allocated to the right needs. In the current work practice, the diabetes specialist nurse faces the challenge of limited resources alone as the diabetes care is mostly organized around the nurse and to a lesser extent the physician responsible for diabetes care at the unit. The interviews revealed that there were ambitions toward dealing with this issue through more developed teamwork at the primary care unit. Through involving more professions at the unit, for example, dietitians and physiotherapists, the individual needs of the patient are expected to be met in a better way. Moreover, the diabetes specialist nurses attending the workshop also expressed a similar concern about resource allocation, saying that if resources were distributed wisely, there would have been “More time for those who need it more.”

### Reduced Administrative Tasks

Seen from a caregiver perspective, administrative tasks are seen as a source of frustration. The observations and the interviews at the primary care unit revealed a work process surrounded with administrative, sometimes manual, tasks. The overall experience is that they are forced to prioritize among administrative tasks. Much of the work is also governed by an increased use of checklists that takes up time from other tasks. The IT support is, however, poor. For example, there is currently no automated system support for the diabetes specialist nurse to schedule appointments for patients for their biannual visits at the primary care unit. Instead, this is a cumbersome process, keeping track of the list of patients when it is time for the next visit, and there is always a risk of forgetting a patient or even that a patient gets accidentally delisted. Making appointments can also include managing other resources at the primary care unit, for example, when a patient needs to take blood samples in advance and, therefore, needs to visit the laboratory unit. After a patient consultation, there are also the necessary tasks of reporting the visit in the electronic patient record and making notes in the Swedish National Diabetes Register. There is no integration between these two systems, resulting in registering the same data at two places.

**Table 2.** Themes and subthemes over challenges for design of a person-centered electronic health service for type 2 diabetes self-management support.

Themes	Subthemes
Improved access	Increased number of contact channels; access governed by needs
Resource efficiency	Facing limited resources; developed teamwork
Reduced administrative tasks	Prioritizing among administrative tasks; increased use of checklists
Continuous training and support	Responding to lifelong learning needs; relevant information technology training
Tailored care	Assessing patients' individual needs; practicing person-centered care
Strengthened communication	Avoiding one-sided communication; counteracting shallow patient interaction
Patient empowerment	Improved responsibility and self-care; striving for disease control and balanced life; promoting independency

### Continuous Training and Support

Technical problems and complicated interfaces are a reoccurring concern among both patients and health care personnel. Although participants at the workshop see a great potential in more digital support, there is also a fear that this might be a complicated and cumbersome transition. One of the patients during the workshop questions if the eHealth service will be "Hard to handle, hard to learn?". Similar concerns can be seen throughout the workshop participants, independent of background. There is an awareness that T2D patients are a diverse user group and that there are older people and people without much experience of digital tools. What is wanted is something that is "simple to use " and comes with "simple support ," thus responding to lifelong learning needs and accounting for differences in skill and previous knowledge.

Another problem related to learning new systems was revealed in the interviews at the primary care unit. Training is seen as important, but there are also expectations for it to be relevant. However, training is often given through Web-based course packages where the user is supposed to watch instruction videos. The videos are often long, and it is, therefore, hard to find suitable time for sitting down and watching during an ordinary workday. Due to these obstacles, there is a great risk that the training will be fragmented or even ignored. There is also a lack of opportunities for revised and more in-depth training for experienced users.

### Tailored Care

The workshop revealed a strong wish and expectation for more individualization when using eHealth solutions. A patient emphasized that "I am unique! Individual treatment." There was an overall awareness among the participants that T2D was an individual experience, and there was no *one-size-fits-all* solution for everyone. Patients clearly express the need for more personalized treatment and alertness for individual needs.

Caregivers shared the patients' aim for more personalization and expressed an expectation that the eHealth technology should provide better tools for assessing patients' individual needs. A nurse pointed out that it would be good with a "Tailored profile, what the patient should work towards." Availability of more and more easily accessible data was brought up as a promising enabler. This orientation toward personalization can also be seen in the interviews at the primary care unit, with the active aim toward practicing PCC through new routines and by

including more professions into the T2D care based on patients' individual needs.

### Strengthened Communication

Observations at the primary care unit showed that nurse-patient communication had a tendency to be one-sided. The nurse was leading the conversation, and the patient was passively listening and responding to direct questions. In one of the interviews, the specialist diabetes nurse commented on this and pointed out that it was hard to enable an open dialogue during these consultations. There are many things to go through during the visit, such as reviewing test results and medication, and there is, therefore, limited time for more open discussions. However, the nurse also pointed out that this varied depending on the individual patient. A patient with good self-management skills requires less time for standard activities, which leaves more time for dialogue.

The problem with communication was also brought up during the workshop. The caregiver representatives had high hopes for future eHealth solutions, and one of the nurses expressed that this could provide "more efficient communication which will save both time and money for patients and caregivers." However, from the caregiver perspective, the main objective for better communication seems to be connected to resource efficiency. The patient representatives at the workshop expressed a different perspective on communication, suggesting that a change of perspective might help avoid one-sided communication. This required more attention to issues that are important for them. One of the patients stated that it was important to "speak about feelings, fears and anxiety," which stood in strong contrast to the focus on practical checkpoints, as revealed in the observations.

### Patient Empowerment

Throughout the workshop, the participating nurses expressed a wish that future eHealth services would help patients improve responsibility and their self-care capability. Their expectations are that an eHealth service will provide patients with tools for being more engaged in their disease management and that increased involvement will promote increased independency among the patients. Moreover, highlighting the importance of involving relatives, one of the nurses said that the aim should be to "make oneself redundant—to be able to work in a way that makes patients and relatives flourish." More involvement and independence were not exclusive for the caregiver perspective. The patients participating in the workshop had

similar aims, expressing a strive for disease control and balance in life, and this could be achieved through eHealth services that supported independent and engaged self-management. One of the patients expressed the aim “to be able to handle ‘everything’ on my own without help, make everyday life easier.”

## Discussion

### Emergent Design Challenges

The 7 themes presented in the Results section were further discussed and abstracted by the authors and found to be bridged by three overarching concepts representing emergent design challenges. Challenges similar to these are suggested to have a large impact on the final design, and depending on the decisions made, one group of stakeholders might be favored at the expense of another group.

### Flexible Access: Critical Changes in Work Organization

Better and easier access to care was a prominent wish among patients. This can be supported in a new eHealth service, for example, through technology-enhanced communication such as instant messaging and video calls [34-36], thus offering an increased number of contact channels, and can also be achieved by changing current work processes at the primary care unit by making it easier for the patients to get in contact with the diabetes specialist nurse when needed. From a person-centered perspective, this would likely enhance the partnership between patient and nurse and support better physical and psychosocial well-being [17] for the patients by avoiding that small, but important, concern of being neglected.

However, promoting patients' access to care will have implications for health care personnel. Easier access and more direct ways of communication require changes in the current work process to handle patient contacts. Today's work practice involves gatekeeping patient contacts to support easier work planning and changing toward a more patient-initiated access will require primary care units to allocate resources to handle patient requests. This could also result in higher costs as some overstaffing can be required to handle unexpected peaks in the process flow.

We argue that to properly and fully address the person-centered perspective in design, the needs of the patient must come first. As pointed out, this will result in challenges for the health care organization when it comes to resource allocation; economy; and, which was evident in the results, resource efficiency. Overall, this can be seen as frustration with the current situation, when available resources do not match the actual need.

It could, however, be possible to find efficient ways of meeting patient needs through digital technology that does not necessarily require the patient to contact a person at the primary care unit. If we, for example, could better adapt the eHealth service to anticipate and react to user (patient) needs, for example, through data mining technologies [37], and automatically respond accordingly [38], some of the direct interaction with the primary unit could be avoided. This would benefit both the patient, through quick and accurate support,

and the primary care unit that needs to allocate fewer, and also more appropriate, resources to this activity. However, to further explore this possibility, we need to pay closer attention to the everyday experience of the patients to better understand when critical questions occur and how we can respond. This includes gaining better understanding of the types of communication that have to be strengthened.

### Reducing Administrative Tasks: A New Division of Labor

In the Result section, administrative work and efficiency were mainly brought up by the diabetes specialist nurses and other stakeholders associated with the health care system. Given the current practice with many different IT systems and sometimes the necessity of registering the same data several times into different databases and records, it is easy to sense the frustration. Bringing up the idea of a new eHealth service brings forth anxiety that new systems equal more administration, and it is therefore brought up as a concern (cf [19]). Designing for this need would require close attention to current practices and routines and adequate support through automation. Moreover, integration between the new and existing systems should be provided.

The aspect of administration is, however, not well represented among the patients. There are concerns about avoiding unnecessary tasks and wasting time (eg, waiting on hold) but not to the extent of what is expressed by the health care personnel. We argue that this is not a sign of unimportance but rather that the participants lack a relevant point of reference to formulate an opinion. Introducing a new IT system (eg, an eHealth service) into an organization will, in almost all situations, affect work organization and the division of labor [39]. How people work and who is doing what work tasks will, intended or not, change. The practical implication of this will be the continuous training and support that were an expressed need among the health care personnel. To cope with the changes that new IT brings to an organization, users need to be trained properly to both being able to interact with the new system and getting accustomed to changing work tasks and processes. In the end, on an organizational level, this becomes a question of management, where work tasks can be distributed to a new group of workers, for example, to unlock other important resources. Therefore, when designing the organization, this becomes a clear and important delimiter.

However, when bringing in the person-centered perspective, the organization does not work as a delimiter of use. The new system is brought into a context comprising both the health care organization and the everyday life experience of the patients using it. This might result in a situation where tasks normally performed by nurses and other health care personnel are redistributed to the patient. More, and perceived unnecessary, work adds to the complexity of using the design and goes against the basic design principles of accessibility and usability [40] and might become a barrier for using the system, implying an increased need for relevant training and support also for patients.

We argue that this reduction of administrative tasks should be carefully considered in light of this extended context of use. This also creates a venue for asking questions about what



patients consider as administrative tasks and what will be accepted. Again, this calls for closer attention to the everyday life experience of patients to better understand the potential impact of a new eHealth system and what administrative tasks can be acceptable.

### Patient Empowerment: Roles Are Changing

The results show that patients want independence and that the diabetes specialist nurses express that they want to support the patient in being more self-sustained. This is, however, not reflected in the current work process. Care is structured in such a way that it does not support independence, and the consultations mainly revolve around control; checking patient laboratory results; and the nurse leading the discussion, overall making the patient passive.

From a design perspective with focus on person-centered principles, a new eHealth service must focus on supporting patients and strengthening nurses in supporting the patients. Following the guidelines suggested by Wildevuur et al [17], this would include designing for shared decision making, mainly through enhancing communication and strengthening the partnership. Critical design decisions will have to be made that have a great impact on the role of the diabetes specialist nurse. The new eHealth service, if supporting person-centered perspectives and patient empowerment, will require the health care organization to initiate substantial changes in the organization, and the diabetes specialist nurses will have to adapt to this change and fine-tune their own work practice accordingly. This accommodates the expressed need for more tailored care, in which the nurse takes on a coaching role providing individualized support to the patient [14]. In addition, this would include a change in communication patterns, inviting the patient into a more in-depth interaction with the diabetes specialist nurse.

Implementing digital technology, for example, through a new eHealth service, will often have impact on power structures [39]. We argue that these power structures must receive closer attention and that the potential change of roles [41,42] when

designing person-centered eHealth services for T2D self-management should also be implemented. Digital technology has the potential to either help in restructuring power, that is, changing the roles, or act to preserve existing structures. Proper design decisions have to be made to achieve the wanted effects and with an awareness and readiness that this will have a substantial impact on work organization at the primary care unit.

### Methodological Discussion

The methods used performed well in highlighting user needs from different perspectives and supporting an understanding of the current context and practice. It also worked well with the intended focus on patient-nurse interaction and the challenges that emerged. It does, however, not shed sufficient light on patient's everyday experience and is, therefore, not enough for fully establishing the user needs for the patient group. To fully cover the patient perspective, the method needs to be adapted for that specific context.

### Conclusions

The aim of this study was to explore challenges that could impact the design of a person-centered eHealth service for T2D self-management. The results highlighted challenges or areas of concern that were seen as important and in which critical decisions have to be made. These challenges greatly affect both patients and health care personnel (diabetes specialist nurses in particular) and are essential points to be accounted for when designing a new eHealth service. To design in line with person-centered principles, the patient perspective needs to be favored, which in turn will have an impact on how work is organized and implemented at the primary care unit. Technology could possibly mitigate some of the impact on the organization, but to avoid a preponderance toward a primary care perspective, this would require more insights on how patients should be supported in everyday life, implying the use of other methods for exploring that particular context of use. This requires further research as it is not covered in this study.

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### Authors' Contributions

RS, CO, UÖ, and ÅH designed the study. RS collected the data. RS, CO, KD, UÖ, and ÅH participated in data analysis. All authors contributed to writing the paper and provided input.

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### Conflicts of Interest

None declared.

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## Abbreviations

**eHealth:** electronic health  
**IT:** information technology  
**PCC:** person-centered care  
**T2D:** type 2 diabetes  
**UCD:** user-centered design

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Original Paper

# Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study

Alain Giordanengo<sup>1,2</sup>, MScIT; Eirik Årsand<sup>2,3</sup>, PhD; Ashenafi Zebene Woldaregay<sup>1</sup>, MScIT; Meghan Bradway<sup>2,3</sup>, MBA; Astrid Grottnland<sup>2</sup>, BSc; Gunnar Hartvigsen<sup>1</sup>, PhD; Conceição Granja<sup>2</sup>, PhD; Torbjørn Torsvik<sup>2,4</sup>, MSc; Anne Helen Hansen<sup>5,6</sup>, PhD

<sup>1</sup>Department of Computer Science, UiT The Arctic University of Norway, Tromsø, Norway

<sup>2</sup>Norwegian Centre for E-health Research, Tromsø, Norway

<sup>3</sup>Department of Clinical Medicine, UiT The Arctic University of Norway, Tromsø, Norway

<sup>4</sup>Department of Neuroscience, Norwegian Electronic Health Record Research Centre, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway

<sup>5</sup>Department of Community Medicine, UiT The Arctic University of Norway, Tromsø, Norway

<sup>6</sup>Centre for Quality Improvement and Development, University Hospital of North Norway, Tromsø, Norway

**Corresponding Author:**

Alain Giordanengo, MScIT  
Norwegian Centre for E-health Research  
Siva Innovation Centre Breivika  
Sykehusveien 23  
Tromsø, 9019  
Norway  
Phone: 47 95805841  
Email: [alain.giordanengo@ehealthresearch.no](mailto:alain.giordanengo@ehealthresearch.no)

## Abstract

**Background:** Introducing self-collected health data from patients with diabetes into consultation can be beneficial for both patients and clinicians. Such an initiative can allow patients to be more proactive in their disease management and clinicians to provide more tailored medical services. Optimally, electronic health record systems (EHRs) should be able to receive self-collected health data in a standard representation of medical data such as Fast Healthcare Interoperability Resources (FHIR), from patients systems like mobile health apps and display the data directly to their users—the clinicians. However, although Norwegian EHRs are working on implementing FHIR, no solution or graphical interface is available today to display self-collected health data.

**Objective:** The objective of this study was to design and assess a dashboard for displaying relevant self-collected health data from patients with diabetes to clinicians.

**Methods:** The design relied on an iterative participatory process involving workshops with patients, clinicians, and researchers to define which information should be available and how it should be displayed. The assessment is based on a case study, presenting an instance of the dashboard populated with data collected from one patient with diabetes type 1 (in-house researcher) face-to-face by 14 clinicians. We performed a qualitative analysis based on usability, functionality, and expectation by using responses to questionnaires that were distributed to the 14 clinicians at the end of the workshops and collected before the participants left. The qualitative assessment was guided by the Standards for Reporting Qualitative Research.

**Results:** We created a dashboard permitting clinicians to assess the reliability of self-collected health data, list all collected data including medical calculations, and highlight medical situations that need to be investigated to improve the situation of the patients. The dashboard uses a combination of tables, graphs, and other visual representations to display the relevant information. Clinicians think that this type of solution will be useful during consultations every day, especially for patients living in remote areas or those who are technologically interested.

**Conclusions:** Displaying self-collected health data during consultations is not enough for clinicians; the data reliability has to be assured and the relevant information needs to be extracted and displayed along with the data to ease the introduction during a medical encounter. The prestudy assessment showed that the system provides relevant information to meet clinicians' need and

that clinicians were eager to start using it during consultations. The system has been under testing in a medical trial since November 2018, and the first results of its assessment in a real-life situation are expected in the beginning of next year (2020).

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## KEYWORDS

dashboard; self-collected health data; diabetes; mHealth; decision support system

## Introduction

Personal health information, such as data generated by sensors or data collected by patients themselves through their diaries, contains important information regarding the people's daily lifestyle. Previous studies have shown that clinicians can use these patient data to provide tailored medical services, especially for patients with chronic diseases [1-3], and that 60% of the patients are open to providing real-time access to their self-collected health information [4]. The use of self-collected data is especially relevant for patients with diabetes, because they often have to adhere to complex treatment regimes. If, for example, a patient is treated with insulin, the dosage has to be adjusted in concordance with not only the calorie intake, but also other factors such as physical exercise [5] and undercurrent disease [6]. Patients with diabetes and physicians have traditionally relied on analog diaries, but as personal computers and smartphones have become commonplace, there has been an explosive increase in the use of digital diaries and wearables [7,8]. In addition, several research projects and private companies are providing solutions to allow clinicians to consult data collected by the patients themselves [2,9]. However, none of these solutions are widely used, mainly because they are proprietary and require specific hardware and software to collect and access the data. This makes it difficult to provide fluid integration between such devices and the physicians' existing tools and constitutes an important barrier of acceptance for the introduction of these types of data [10].

This paper is part of the "Full Flow of Health Data Between Patients and Health Care Systems" project, which focuses on integrating self-collected health data into consultations in Norway using diabetes and Fast Healthcare Interoperability Resources (FHIR) as a case.

Major health care actors such as Epic Systems Corporation and Cerner propose application programming interfaces relying on FHIR standards [11,12]. Open source projects such as OpenMRS and Open mHealth also provide access to FHIR resources [13,14], and studies propose to use FHIR to improve the health care sector [15]. Norwegian electronic health records (EHRs) are currently working on implementing FHIR standards in their respective solutions [16], but none of them are ready to manage FHIR resources today, as they are not able to receive and display FHIR data. We therefore provided clinicians with a standalone dashboard (ie, view providing key performance indicators) displaying the patients' self-collected health data to be used as an addition to their current EHR.

Even if self-collected data could be seamlessly integrated, user acceptance is not guaranteed. Patients with diabetes can collect

large amounts of data. If the data cannot be presented in an efficient way, it cannot be efficiently comprehended, severely diminishing its usefulness [17-20]. Many physicians struggle to obtain an overview of constantly expanding EHRs. The introduction of a potentially large amount of new data that the physicians are not used to utilizing must therefore be handled with great care, as even minor ill-considered implementation details can have a huge negative impact [18-20]. Optimal presentation of health data depends on the information needed by the clinicians. There is no optimal way of presenting clinical data, because these needs vary a lot [21-25].

This paper presents the design of a dashboard for displaying the self-collected health data from patients with diabetes and describes how the user interface attempts to meet the clinicians' information needs. Furthermore, the paper presents the prestudy assessment of the dashboard by clinicians.

## Methods

### Phases

In the two main phases of the study, we used different methodologies: iterative dashboard design and prestudy assessment (Figure 1). The iterative design phase supported the conception and implementation of the dashboard, while the prestudy assessment was used to collect the clinicians' experiences with the developed dashboard as well as their recommendations.

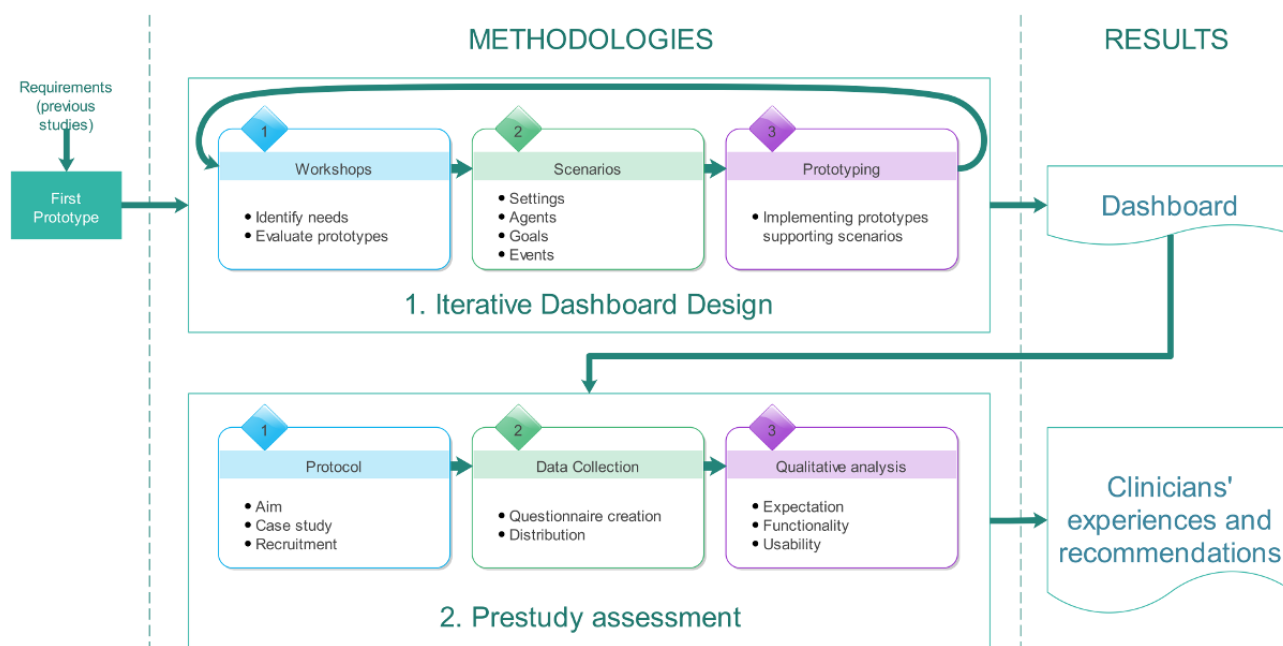
Based on previous studies by the authors [26,27], we created the first prototype of the dashboard to be used as a first input for the iterative design process. The information collected from the studies [26,27] was used to identify the data required during diabetes consultations and to define the requirements for the graphical user interface (GUI) of the dashboard.

### Iterative Dashboard Design

The development of the dashboard followed a three-step iterative process to approach the following primary objectives: (1) identify the needs of both patients and clinicians regarding information with clinical relevance during a consultation, information suitable to be collected by patients, and how to present the information in the GUI in order to improve its usability during consultations; (2) evaluate early prototypes and propose adjustments; and (3) develop prototypes based on the proposed adjustments identified in step two.

To achieve these objectives, we organized facilitated workshops, supported by open-ended discussions, to approach specific tasks in rapid development cycles.



**Figure 1.** The two main phases of the study, with their components and results.

### Facilitated Workshops and Open-Ended Discussions

Facilitated workshops are sessions bringing users, stakeholders, and partners together to define and evaluate product requirements [28].

We organized two facilitated workshops using a participatory design approach [29] involving four of the authors (AGi, AGr, EÅ, and AH), four clinicians (two nurses and two doctors who have worked with patients with diabetes), and two patients with diabetes. The clinicians and patients were recruited by our partner—the University Hospital of North Norway. Different methodologies were used during these workshops, namely, brainstorming, idea storms, and go-rounds, to balance creativity and problem-solving tasks and to reduce the pressure on the patients by allowing everyone to speak in turn. The facilitated workshops lasted 3 hours each, and participants were invited to use their own experiences to contribute to the workshops' primary objectives. The majority group decision-making technique was employed during these sessions.

In addition to the facilitated workshops, we organized a total of 11 sessions with open-ended discussion—three focused on mathematical models to use for medical and statistical calculations and involved two computer scientists; four focused on targeting the GUI usability, namely, the information to be displayed, which was attended by one computer scientist and one GUI expert; two focused on a first assessment regarding the medical relevance of the information displayed, which was joined by a computer scientist and a general practitioner; and two focused on the evaluation of the dashboard prototype against the requirements and involved four of the authors (AGi, AGr, EÅ, and AH).

### Scenarios

We used a simulation-type scenario approach to model real-life situations and narratives [30]. The modelling process relied on

a taxonomy containing four elements that were used for each scenario. These elements were as follows:

1. Settings: the context and the situation of the scenario
2. Agents: those who participate in the scenario
3. Goals: the functional targets of the scenario
4. Events: the actions taken by the agents during the scenario

The detailed information concerning the three main scenarios was defined together with the participants during the first facilitated workshop. We chose to use a scenario approach because it facilitates the cooperation of the participants during the facilitated workshops, who can see themselves in the situations and evoke their own experiences, and it simplifies the design process of the dashboard by providing concrete and flexible situations [31].

### Prototyping

The prototyping phase consisted of implementing the dashboard to support the given scenarios by using computer-generated data that express the data requirements for the scenarios.

The dashboard was then built to achieve the objectives described in the scenarios. An agile development process [32] was exclusively used for this task, as evolution, changes, and adaptability were necessary, considering the continuous inputs provided by the workshops. The implementation relied on Java Enterprise Edition 8, Java Server Faces 2.2, and Glassfish 5. The developed prototypes were assessed during the workshops and improved during each iteration of the design process.

Once the authors and participants in the workshops decided that the dashboard was satisfactory to be used in a real situation, we stopped the iterative design process and selected the last prototype for a prestudy assessment by different clinicians.



## Prestudy Assessment of the Dashboard by Clinicians

### Protocol

The design of the prestudy assessment was guided by the Standards for Reporting Qualitative Research checklist to enhance the organization and reporting of this study [33]. The aim of the prestudy assessment was to evaluate the pertinence of the functionalities presented in the dashboard GUI and its usability prior to a medical trial.

We used a case study approach, organizing a total of five workshops in health care offices (hospital and general practitioner [GP] office), each involving one to four clinicians, accounting to a total of 14 clinicians, and one or two researchers. The 14 clinicians were recruited through our partner, the University Hospital of North Norway, or by direct contact initiated by us; none participated in the dashboard design and all are currently participating in the medical trial. We were limited in the number of participants to include due to external factors (eg, time constraints and unavailability of further participants).

During the workshops, we presented the FullFlow system, which included the last prototype of the dashboard, by using the self-collected health data from one in-house researcher who has type 1 diabetes (an exemption was obtained from the local ethics committee: Ref 2018/719 [34]), hereafter referred to as Research Patient. We extracted these data from the Research Patient's Diabetes Diary to fill the FullFlow system, using the Diabetes Share Live solution to transmit the data in a way similar to that used in a previous study [27]. The use case presented in the workshops was based on the Research Patient's real-life diabetes data (ie, insulin intake, carbohydrate intake, blood glucose values, physical activities, weight, medication, and personal aims) and is similar to one scenario created in the dashboard design process. The Research Patient participated in all workshops, where he could explain the different values displayed in the dashboard and answer questions regarding his lifestyle and the recorded values.

### Data Collection

During the workshops, we distributed a paper-based questionnaire to the participants after presenting the system and letting the clinicians test it. We then collected the questionnaires at the end of the session. The first and second (AGi and EÅ) authors designed a specific questionnaire based on the System Usability Scale [35] and the Computer System Usability Questionnaire [36].

We decided to use a custom questionnaire, as the assessment did not permit inclusion of important usability factors due to a lack of clinical context such as patient-clinician relationships. Given that the questionnaire was administered to the participants before the study, we wanted to provide open-ended questions to obtain important feedback for this iterative process before starting the medical trial. The questionnaire contained four questions about the system and the role of the user (eg, nurse):

- Q1a: Do you think the system will be useful during consultation? Q1b: Potential comments.

- Q2a: Would you like to have more information delivered by the FullFlow system? Q2b: Potential comments.
- Q3a: Would you like to remove or hide information currently delivered by the FullFlow system? Q3b: Potential comments.
- Q4: Do you have any feedback you would like to offer?

### Qualitative Analysis

The first author (AG) performed a qualitative analysis based on three keywords: *expectation*, *usability*, and *functionality*. In our context, we defined *expectation* as a general belief that positive or negative outcomes could occur in clinical settings by using our proposed system. The use of this term was inspired by the work of Bialosky et al [37]. We used the seven notions provided by Vázquez-García et al [38] to define *usability*: knowability (user can understand, learn, and remember how to use the system), operability (capacity of the system to accommodate users with different needs), efficiency (capacity of the system to produce appropriate results), robustness (capacity of the system to resist error), safety (capacity of the system to avoid risk), and satisfaction (capacity of the system to generate interest in users). We used the definition proposed by Salleh et al [39] to describe *functionality*: a set of functions and their specified properties. We then used the feedback to improve the system before starting the medical trial. We used the feedback obtained in order to improve the system before starting the medical trial.

## Results

### Overview

From previous studies, we identified eight relevant data types for diabetes consultation—blood pressure, calories, carbohydrates, heart rate, blood glucose, insulin, weight, and physical activity (Figure 2 A)—and relevant medical calculations such as insulin-to-carbohydrate (I:C) ratio and basal insulin to bolus insulin ratio (Figure 2 C). As a requirement for the GUI, we identified the need to present the data in different time frames (per hour, per day, per week, and for the complete period [Figure 2 B]) and the use of a color scale to illustrate data ranges (Figure 2 D).

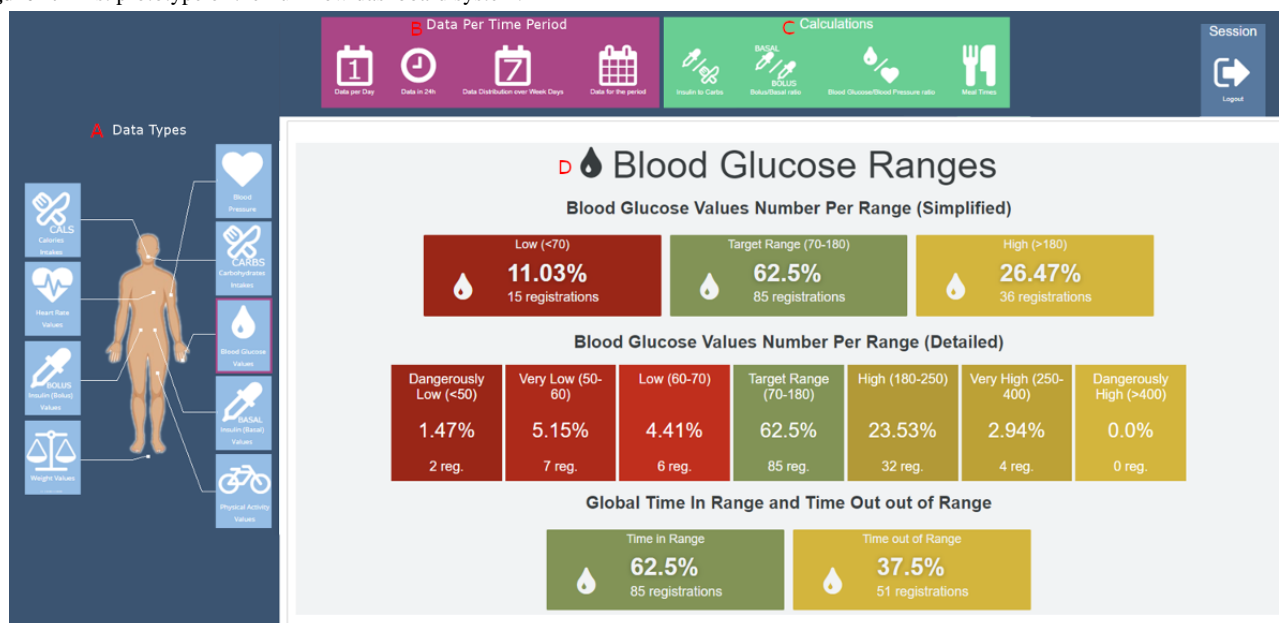
### Iterative Dashboard Design

#### Facilitated Workshops and Open-Ended Discussions

The first prototype was presented to the participants in the first facilitated workshop. Based on this prototype and their own experiences, the participants suggested improvements to both data, functionalities, and GUI. The suggested improvements were translated into requirements and implemented in the prototype presented during the second workshop. The improvements suggested during the second workshop were used as requirements during the development of the final prototype. The requirements identified are summarized in Table 1.

#### Scenarios

We created three main scenarios (Table 2); this was considered a manageable number of scenarios for the workshops and open-ended discussions while still allowing diversification of the situations.

**Figure 2.** First prototype of the FullFlow dashboard system.**Table 1.** Summary of the requirements defined based on suggestions from the participants in the facilitated workshops and their description.

Requirements	Description
R1: Displaying data collected by patients	At least blood glucose, blood pressure, insulin (bolus/basal), medication, carbohydrates, calories, and physical activity. Being able to accept new data types (eg, menstruation, ketones, and polypharmacy) would be a plus. The system shall inform clinicians if the patients register life goals (eg, what they are focusing on in their daily self-management).
R2: Quantify data collected by patients	The system will notify which data have been collected by the patients and quantify them.
R3: Displaying data collection period	The system will provide clinicians the length of time during which patients collected their data.
R4: Variabilities in the patients' data values	The system will be able to present a variability value for all data types to indicate how much these values diverge.
R5: Medical calculations	The system will be able to provide medically relevant information (eg, insulin-to-carbohydrate ratio and insulin sensitivity).
R6: Grading data reliability	The system will permit clinicians to know immediately if the data collected by the patients are reliable (ie, worth their time consulting the data).
R7: Hiding eA <sub>1c</sub> <sup>a</sup>	Removing eA <sub>1c</sub> from the graphical user interface.
R8: Reduce complexity of blood glucose ranges	The system will use the simplified (3 levels) blood glucose range.
R9: Consulting all self-collected health data at once	The system will present all self-collected health data at once in a graph.
R10: Pattern recognition	The system will ease identifying patterns in patients' lifestyle per day, per week, and for the whole period (eg, hyperglycemic events each day after dinner).
R11: Bridge to existing data	The system shall provide information clinicians can assess by comparing existing data to the self-collected health data.
R12: Overview of the patients' situations	The system will be able to inform clinicians about what the patients struggle with, what they manage, etc.
R13: Visual helper	The system will provide information about which data are in and out of range.

<sup>a</sup>eA<sub>1c</sub>: estimated hemoglobin A<sub>1c</sub>.

**Table 2.** Scenarios created to support the user requirements. Settings: the context and situation of the scenario. Agents: actors in the scenario. Goals: targets of the scenario. Events: the actions taken by the agents during the scenario.

Taxonomy	Scenario 1	Scenario 2	Scenario 3
Settings	Patient has nightly hypoglycemic events. The patient has an appointment with a diabetes nurse to discuss his situation and therefore collected health data for 1 month prior to the appointment. The patient uses finger pricks and an insulin pen.	Patient struggles with carbohydrate counting and always ends up in hyperglycemia after meals, despite using a hybrid closed-loop system (continuous glucose monitor and a pump). Patient also reaches hypoglycemic levels after the insulin action (“yoyo” effect). Patient has an appointment with a dietitian after having collected 1 week of data.	Patient always has high fasting blood glucose levels, despite being on medication and following cooking courses. Patient has a meeting with his general practitioner after collecting 2 weeks of data.
Agents	Patient with type 1 diabetes and diabetes nurse	Patient with type 1 diabetes and dietitian	Patient with type 2 diabetes and general practitioner
Goals	The system should show the hypoglycemic events and identify the nightly trends. The system should show the insulin dosages and the carbohydrate intakes to help the nurse identify possible points of action.	The system should show the relationship between meal intakes, insulin-on-board levels, and blood glucose levels.	The system should show the high glucose situations, the calorie intakes that are above the recommended levels, the patient’s lack of physical activity, the high blood pressure, and that the patient sometimes forgets to take his medication.
Events	<p>Patient registers, on an average, per day:</p> <ul style="list-style-type: none"> <li>• 10 blood glucose values,</li> <li>• 4 carbohydrate intakes,</li> <li>• 6 insulin injections (2 basal, 4 bolus), and</li> <li>• 10 minutes of physical activity.</li> </ul> <p>Nurse discusses the patient’s hypoglycemic events with him and consults the data using the FullFlow dashboard.</p>	<p>Patient registers, on an average, per day:</p> <ul style="list-style-type: none"> <li>• 288 blood glucose values,</li> <li>• hourly insulin bolus dosage, and</li> <li>• 5 carbohydrate intakes.</li> </ul> <p>Dietitian discusses with the patient his “yoyo effect” after meals and consults the self-collected health data using the FullFlow dashboard.</p>	<p>Patient registers, on an average, per day:</p> <ul style="list-style-type: none"> <li>• 1 blood glucose value,</li> <li>• 2 medication intakes, and</li> <li>• 5 calorie intakes.</li> </ul> <p>Patient also has:</p> <ul style="list-style-type: none"> <li>• 2 weight registrations,</li> <li>• 1 blood pressure registration, and</li> <li>• 3 physical activity registrations (&lt;10 minutes).</li> </ul> <p>General practitioner discusses the situation with the patient and uses the FullFlow system to get an overview of his situation.</p>

### Final Prototype

We provide an example of the dashboard based on the self-collected health data obtained from the Research Patient, which was similar to the use case presented to clinicians in the preassessment study. The proposed dashboard contains six main sections accessible from a menu displayed at the top of the page (Figure 3):

1. The *Overview* contains information regarding the data reliability, the data collected, the patients’ personal goals, and a list of noticeable events and their potential causes. It is the landing page of a FullFlow report.
2. The *Combined Data* displays all the quantifiable data sent by the patients in combination with the calculated information for the whole period in a unique graph.
3. The *Daily Distribution* distributes all quantifiable data per hour in multiple graphs (one graph per data type).

**Figure 3.** Dashboard menu.



Overview

Combined Data

Daily Distribution (24h)

Daily Evolution

Time Period

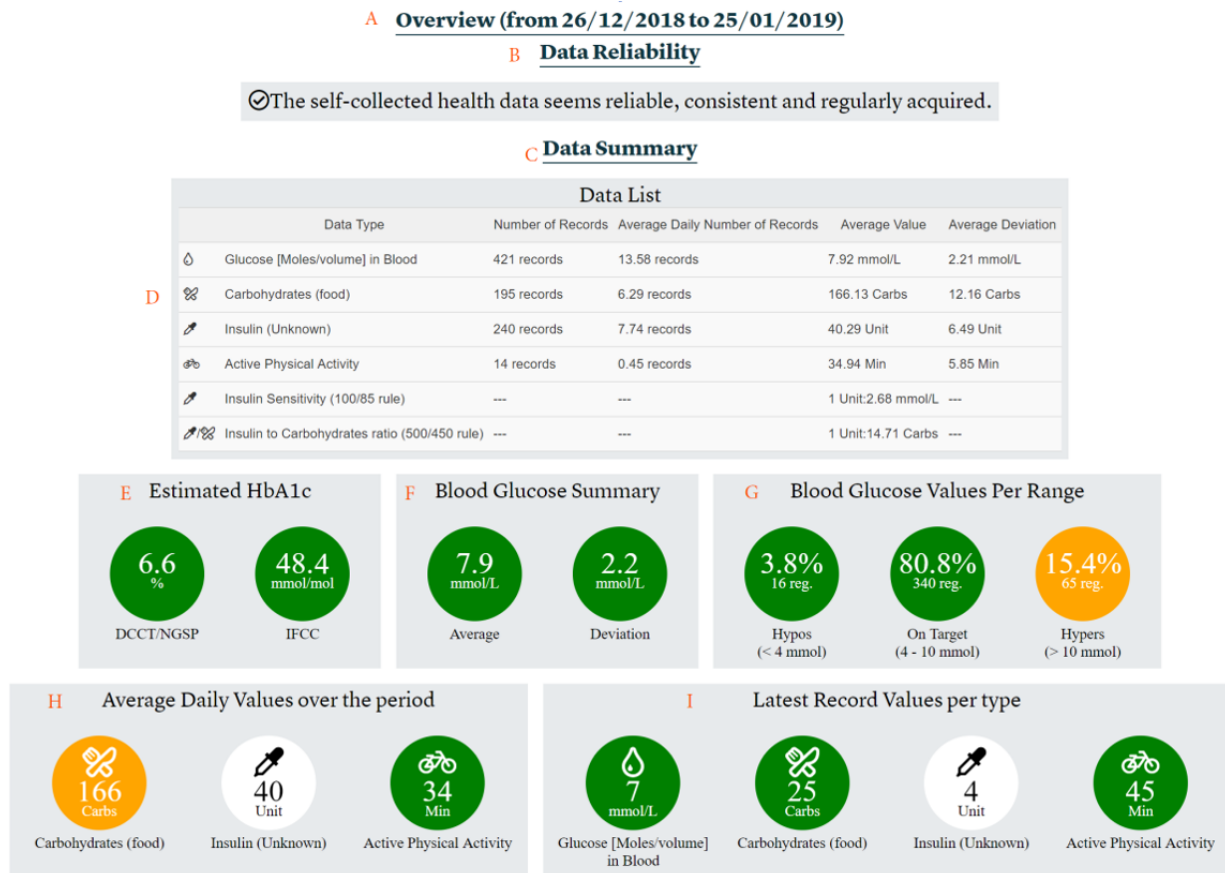
Data List

4. The *Daily Evolution* summarizes the data per day in multiple graphs (one graph per data type).
5. The *Time Period* displays the data for the whole period in multiple graphs (one graph per data type).
6. The *Data List* lists all the data collected by the patients in a table.

### Overview Section

The Overview section provides a summary of all data collected by the patients and the results of the FullFlow analyses (Figures 4 and 5). The objective of this section is to provide an overview of the patients’ situation and the medically related events found to be important to discuss or address, without the need to consult the whole data set. The first data displayed are the time period (Figure 4 A), determined by the first and last FHIR artefacts ordered by date. This addresses the requirement R3 (Table 1).

**Figure 4.** Overview section, part 1. (A) Title and period of time. (B) Data reliability. (C) Summary of the data. (D) List of all the data collected by the patients. (E) Estimated hemoglobin A1c. (F) Blood glucose summary. (G) Time in range and time out of range for blood glucose registrations. (H) Average daily values of data collected by the patients for the period. (I) Latest values for each type of data collected by patients.



The second dataset displayed is related to the reliability of the patients' self-collected health data (Figure 4 B). A knowledge-based module (KBM) grades the reliability of the self-collected health data based on the presence or absence of registered data, potential errors in data values, inconsistencies between data sources, the number of data registrations, and the regularity of the registrations made by the patients. This service addresses the requirement R6 (Table 1) by providing clinicians information about the quality and reliability of data at an early stage of consultation. In this example, the system graded the data as reliable. The system provides a list of issues if the data are graded as not reliable. We explained and illustrated this system in a previous article [40].

The next subsection, the Data Summary (Figure 4 C), first contains a table (Figure 4 D) listing all the patients' self-collected health data with important calculations for diabetes patients, such as insulin sensitivity and insulin to carbohydrates ratio (I:C), if the data collected permit the calculation of these components. These values are displayed side by side with the ratios submitted by the patients, if available, permitting a simple comparison. The table contains the number of registrations and the average daily number of registrations per day for all types of data collected. The table also provides the average of all the values as well as the pooled SD per data type (called "average deviation" for the clinicians, see Discussion). The pooled SD is calculated using the formula:



...where  $n_k$  represents the number of registrations for a day and  $\sigma_k$  represents the variance for a day. We used the same approach for appropriate data types (eg, not used for blood pressure where the system considers only the latest registered value per day). The table also contains specific diabetes rules, such as the 100/85 rule for estimating the insulin sensitivity (also called "correction factor") [41] or the 400 rule for estimating the insulin-to-carbohydrate ratio [42]. Patients can also provide this information, and in this case, both collected and calculated values will be listed one above the other for easy comparison. This table addresses requirements R2, R4, and R5 (Table 1).

The next dataset provided is the estimated hemoglobin  $A_{1c}$  ( $eA_{1c}$ ) value (Figure 4 E), calculated from the average blood glucose value of all blood glucose registrations, based on the formula proposed by Nathan et al [43]:  $eAG_{\text{mmol/L}} = 1.59 * A_{1c} - 2.59$ , where  $eAG$  is the estimated average glucose level in mmol/L and  $A_{1c}$  the hemoglobin  $A_{1c}$  value. The system calculates the  $eA_{1c}$  only if there are at least 3 blood glucose registrations a day and 21 blood glucose registrations in total. This system provides two standards for the  $eA_{1c}$  value—National Glycohemoglobin Standardization Program (NGSP; %) and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (mmol/mol)—considering that Norway



replaced NGSP with IFCC in 2018 [44]. To convert NGSP to the IFCC value [44], we use the following formula:



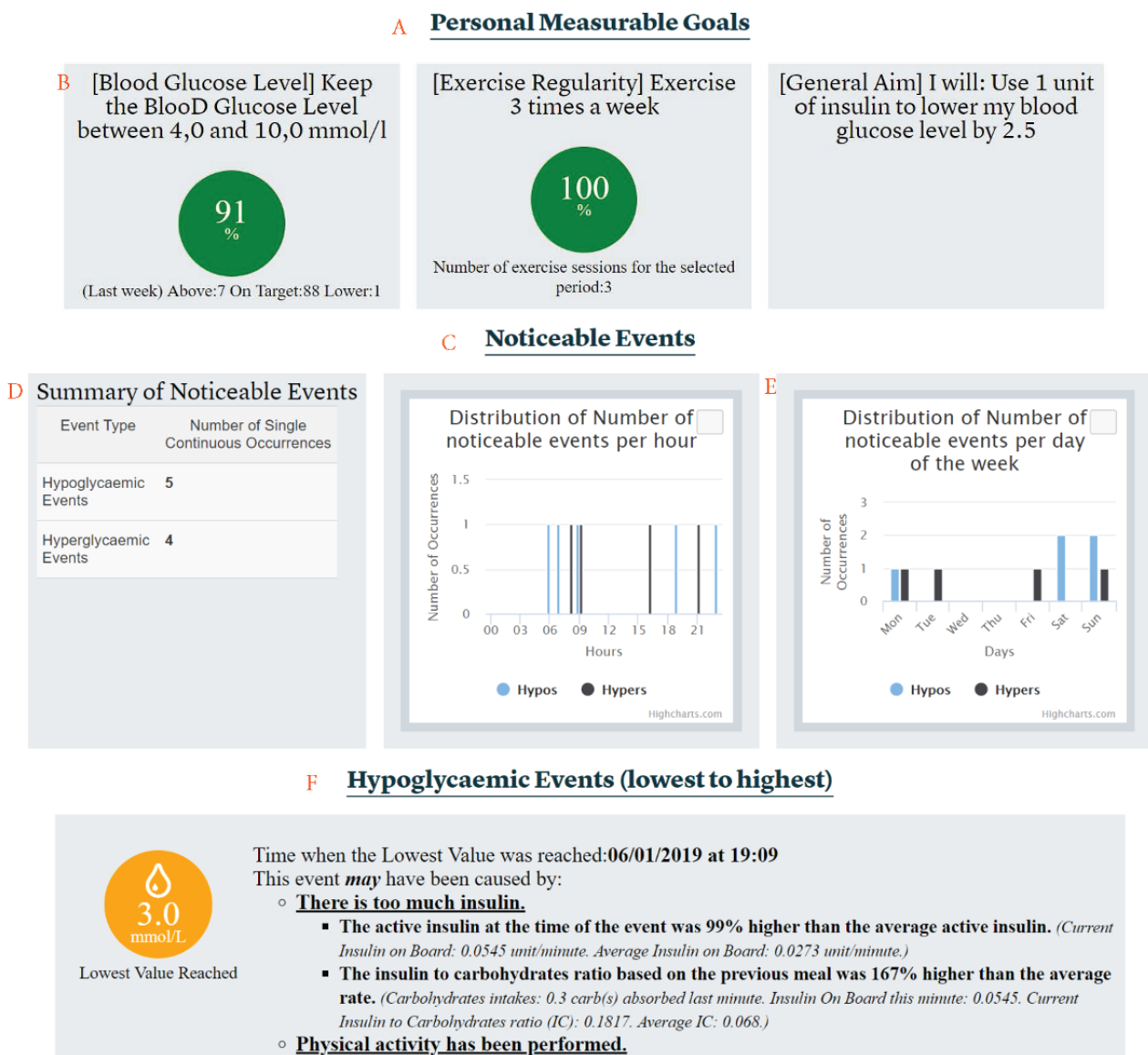
This service addresses the requirement R11 (Table 1) by providing a possible comparison between self-collected health data and laboratory results. However, it also conflicts with the requirement R7 (Table 1). Therefore, we decided to hide these values during the medical trial.

The blood glucose summary (Figure 4 F) displays the average blood glucose value and the pooled SD (same values as in Table 1). The blood glucose values per range (Figure 4 G) display the number of registrations and their percentages per range (low, on target, or high), which are defined as per the standards [45,46]. This addresses requirement R8 (Table 1).

The average daily values (Figure 4 H) display the average of all collected data when appropriate (same values as in Table 1). The final dataset displayed is the last value for each data type the patients have registered (Figure 4 I).

FullFlow grades each piece of information presented in Figure 4 E-I and provides four background color states: green, orange, red, and white. These colors have different meanings: green indicates that the value is in the recommended range, orange indicates that the value is slightly above or under the recommended range, red indicates that the value is out of range, and white indicates that a value is not graded because of a lack of standards or that the value depends heavily on context. The visual representation is inspired by the work of Sim et al [47], who are using a similar grading system, and the work of Diagliati et al [48], who used traffic lights. This grading addresses requirements R13 and R12 (Table 1).

**Figure 5.** Overview section, part 2. A: List of personal goals defined in the patients’ diary. B: Example of a personal goal. C: List of noticeable events based on the collected data. D: List of events detected organized by type. E: Distribution of event types per day and per hour. F: Example of a noticeable event.



Next, the overview section contains personal goals (Figure 5 A) defined by the patients with or without clinician involvement.

Personal goals can be measurable (eg, keeping your blood glucose level between 4 and 10 mmol/L [Figure 5 B]) or



nonmeasurable (eg, more proactive). FullFlow provides progress and description for measurable goals. Displaying personal goals addresses requirement R1 (Table 1).

The next section provides information about noticeable events (Figure 5 C). Noticeable events are important events that clinicians and patients should address to improve the health situation of the patients. FullFlow identifies them using KBM in combination with the patients' self-collected health data and statistical calculations. FullFlow first summarizes the noticeable events by displaying the number of occurrences (Figure 5 D) and distributing the events during the day and the day of the week based on the time, to potentially identify trends (Figure 5 E). Subsequently, FullFlow displays one event at a time, ordered from the most to the least serious, and provides potential causes and explanations for them (Figure 5 F). This section includes other medical conditions related to blood pressure or sleeping pattern in addition to hypoglycemic and hyperglycemic events shown in Figure 5. We described the KBM in detail in a previous article [40]. Noticeable events address requirement R12 (Table 1).

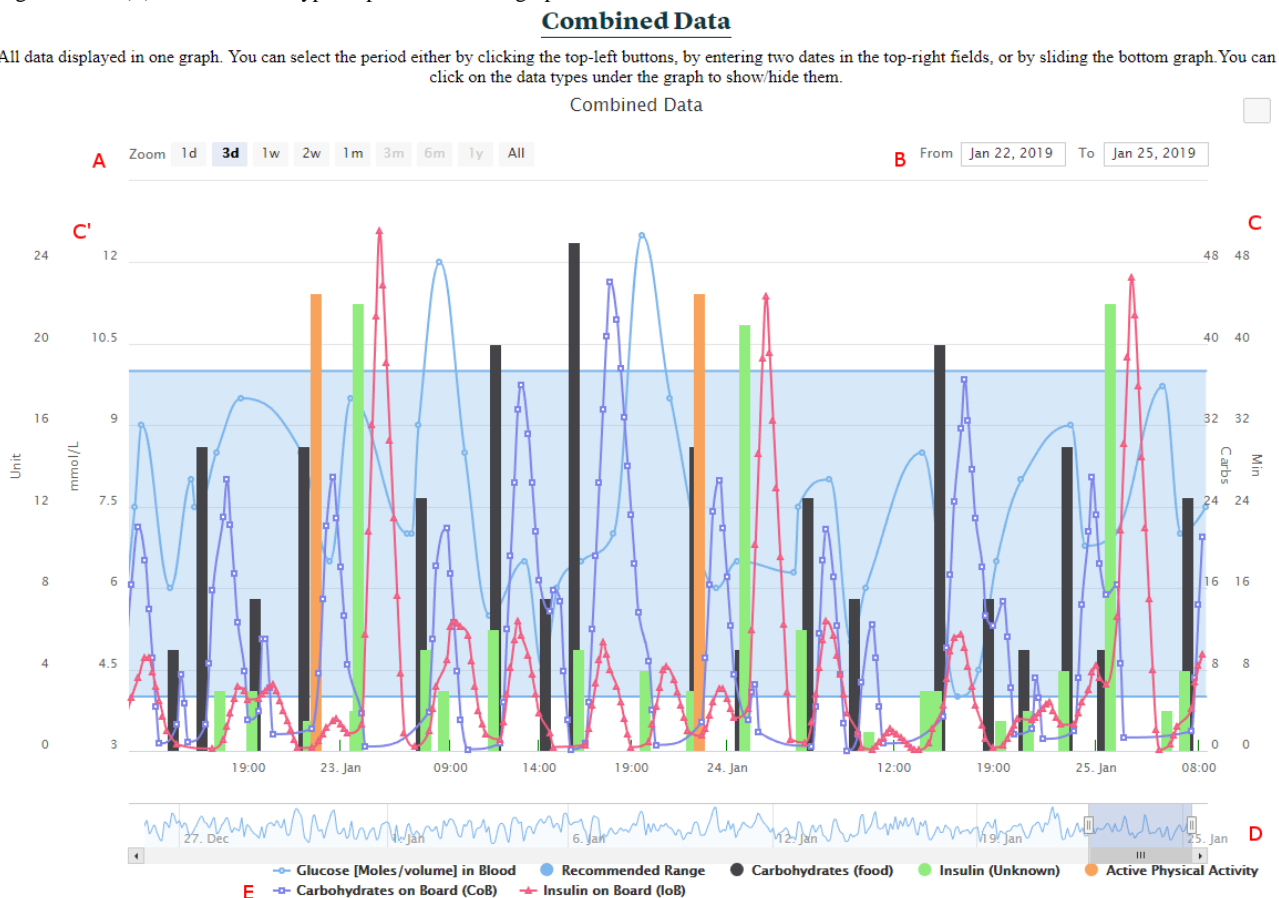
### Combined Data Section

The combined data section presents all the quantifiable data available in FullFlow (self-collected health data and

calculations), as shown in Figure 6. This graph is based on the Highstock library [49] and addresses requirement R9 (Table 1).

Clinicians can change the timeframe by selecting a start and an end date (Figure 6 B) and selecting a predefined time length such as 3 days or 1 week (Figure 6 A) or by sliding, extending, or narrowing the data range selector (Figure 6 D). Clicking on a data type in the lowest part of the graph hides or shows the data type in the center of the graph, allowing clinicians to focus on what they would like to analyze (Figure 6 E). The vertical axes are built automatically (either left or right, Figure 6 C and 6C') depending on the data type available. The frequency of measurements or the data type extracted from Logical Observation Identifiers Names and Codes or the Systematized Nomenclature of Medicine Clinical Terms contained in FHIR artefacts define the data representation in the graph. Series represent data types having at least 20 registrations per day or being of a specific type, such as blood glucose, while bars represent the rest. Areas represent the reference range of the FHIR artefacts (eg, in-range for blood glucose values) linked to a data type. A mouse hovering above a point shows the exact time and value for all data types with the exact same time. We used the OpenAPS approach to calculate the insulin on board (IoB) [50] and the work of Dana Lewis [51] to calculate the carbohydrates on board (CoB).

**Figure 6.** Combined data. (A) Period selection by predefined time length. (B) Period selection by dates. (C, C'): Multiple y-axes. (D) Period selection by range selector. (E) List of all data types represented in the graph.



### Daily Distribution Section

The daily distribution section distributes all the available data in a single day to help clinicians identify daily patterns

(requirement R10 in Table 1), such as hypoglycemic events during the nights or hyperglycemic events during the afternoon. This section proposes one graph per data type (Figure 7), which

displays all the blood glucose measurements available in a single day. In this example, only finger prick registrations are shown. In addition to displaying the data, FullFlow calculates a moving average of all the values. FullFlow uses either a simple moving average or a weighted moving average, depending on the data type and how patients have collected them (see Discussion for more details). This type of graph also contains reference ranges when provided.

#### **Daily Evolution Section**

The daily evolution section simply presents the sum, the average, or the latest data per day for the whole period, depending on the data type (Figure 8). For instance, blood glucose values are averaged per day, insulin amount values are summed per day, and the latest of the blood pressure values of the day are used for each day. This type of graph also contains reference ranges when provided. Each data type has its own graph.

#### **Time Period Section**

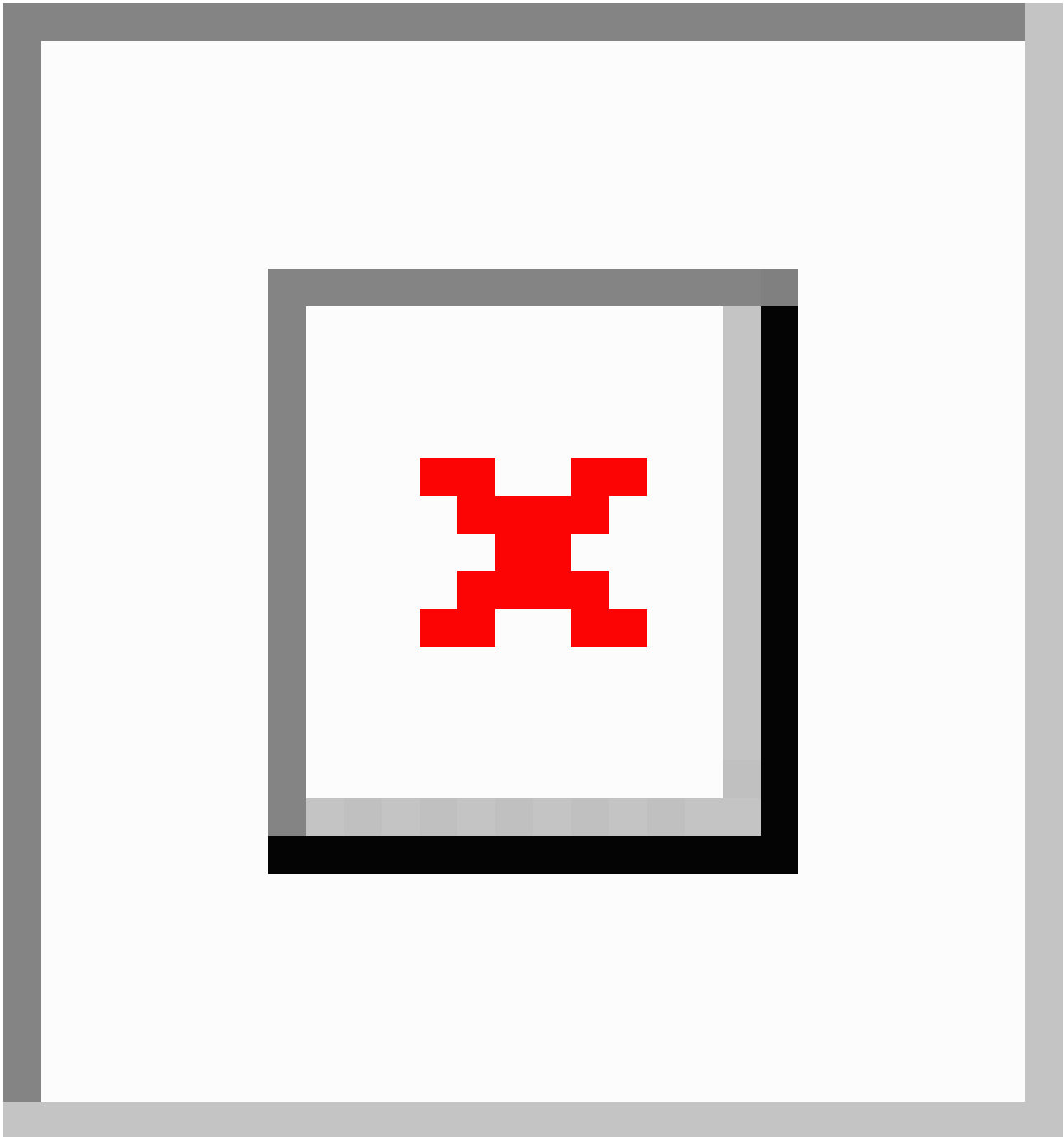
The time period section shows all data available for the whole period by using the same approach as the combined data, except that one graph contains only one data type (Figure 9).

#### **Data List Section**

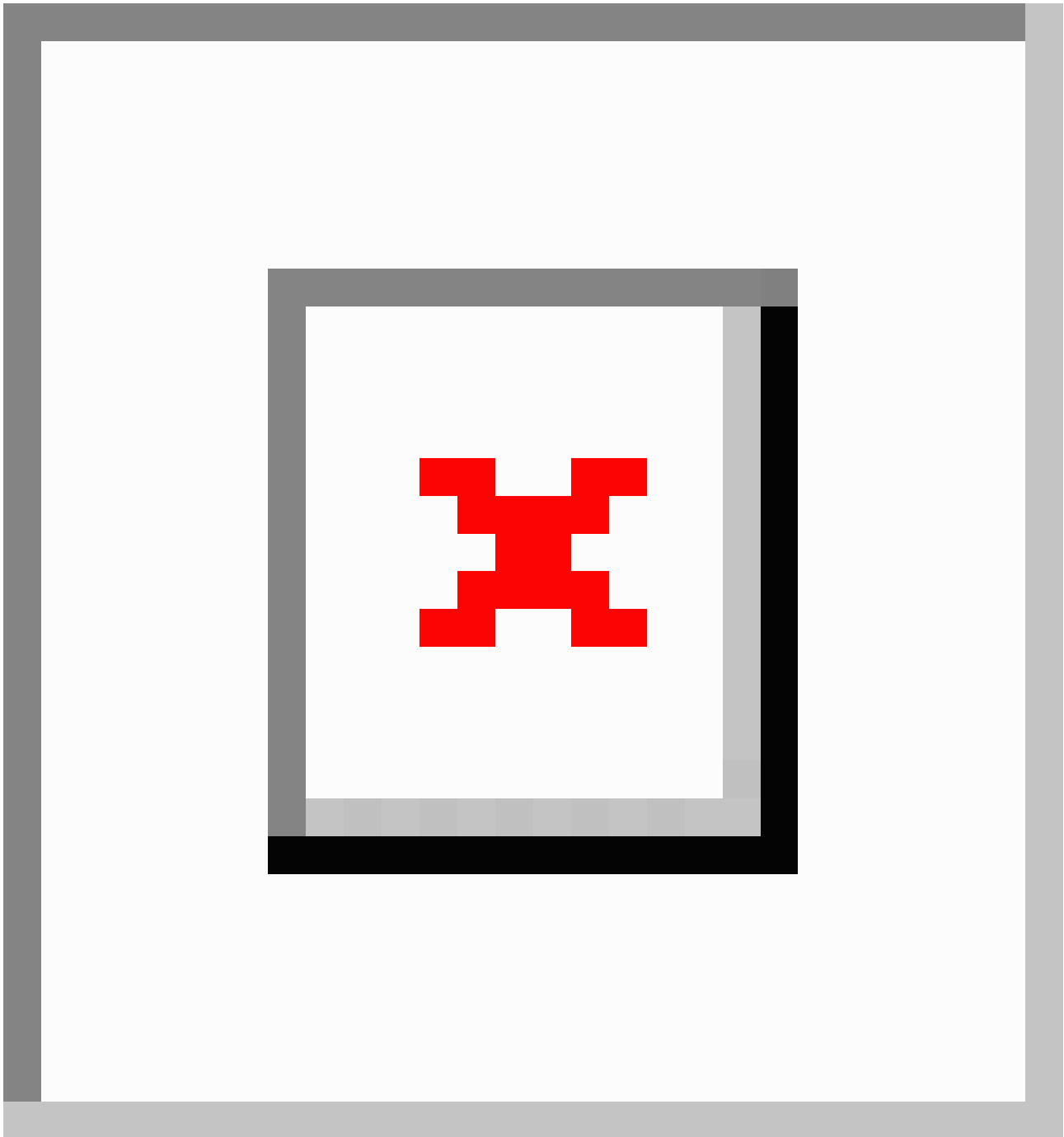
The data list section presents extracted information from all health data self-collected by patients in a list, without the calculated values of the FullFlow, as shown in Figure 10. The section displays the number of registrations made by the patients and shows the date, data type, value, unit, and comment for each entry. Clinicians can order the table by clicking on the head of a column (eg, ordering data per data type) or look up specific registrations using the search field (top right in Figure 10).

The different sections in this dashboard permit the display of any type of data collected by the patients and addresses the requirement R1 (Table 1).

**Figure 7.** Daily distribution of blood glucose values.



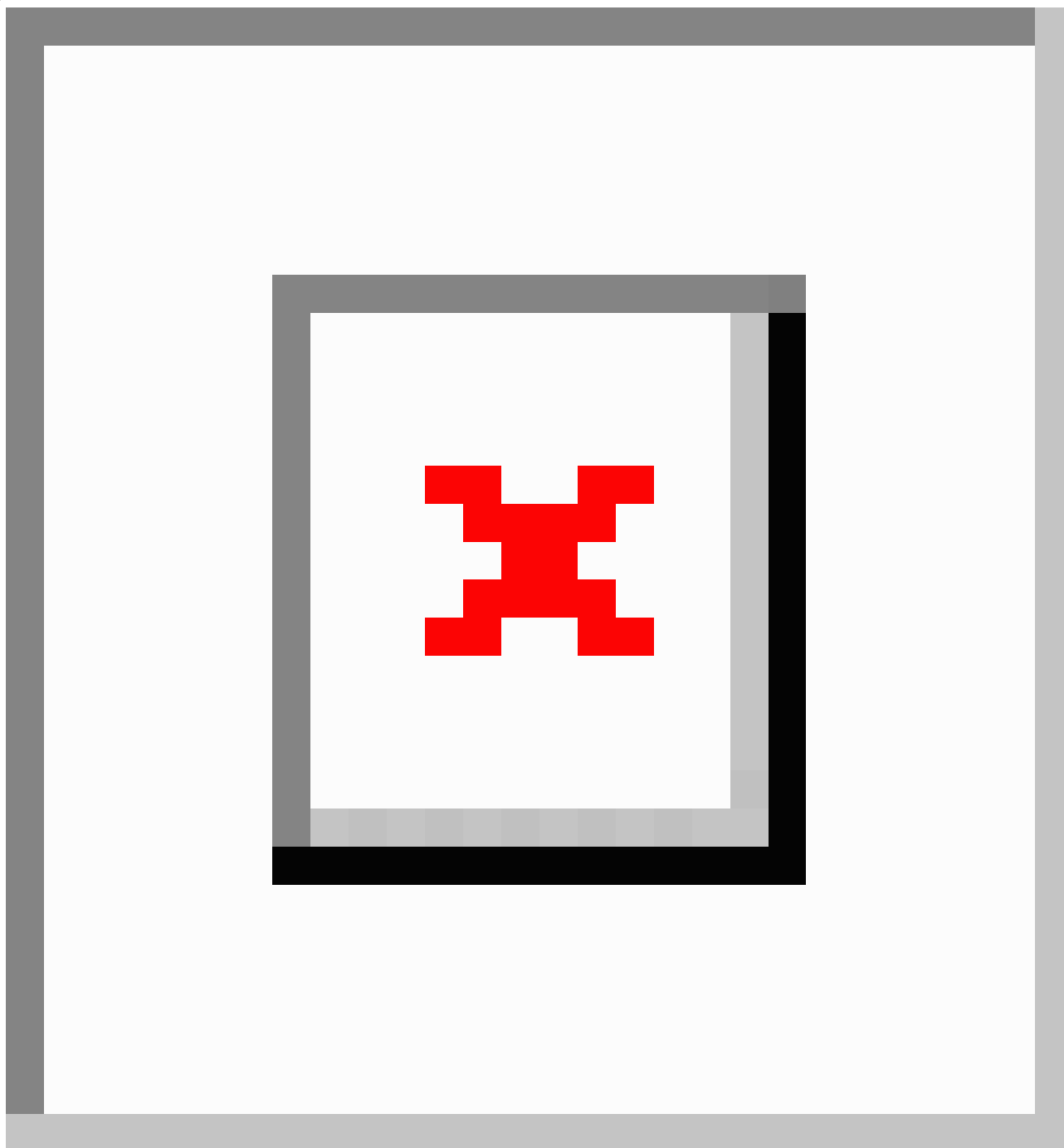
**Figure 8.** Daily evolution of the blood glucose for the whole period.



**Figure 9.** Time period for blood glucose values.





**Figure 10.** Data list section.

### **Prestudy Assessment of the Dashboard by Clinicians**

This section presents the assessment of the full system (a combination of the Diabetes Diary [52], Diabetes Share Live [27], and FullFlow) by clinicians, following the approach described in the Methods section. As mentioned in the previous section, the graphical interface was presented without the  $eA_{1c}$  value displayed in Figure 4. Multimedia Appendix 1 contains the transcribed answers to the collected questionnaires. The following subsections present the results of the analyses of the questionnaires organized using the taxonomy defined in the Methods section (Data Collection subsection) and concerning the FullFlow system only (the Diabetes Diary and Diabetes Share Live are outside the scope of this study).

### **Participants**

Fourteen clinicians participated in the prestudy assessment: nine (64.3%) were GPs, four (28.6%) were diabetes nurses, and one (7.1%) was a dietitian.

### **Pertinence of the Functionalities Provided by the FullFlow System**

Regarding the relevance of the functionalities provided by the system, the overwhelming majority of the participants (9/14, 64.3%) considered them relevant and would like to keep the system in the current state, without adding or removing any functionalities, as shown in Table 3. Five (35.7%) participants would have liked to add or remove one or more functionalities in the system. Although the majority of the primary health care

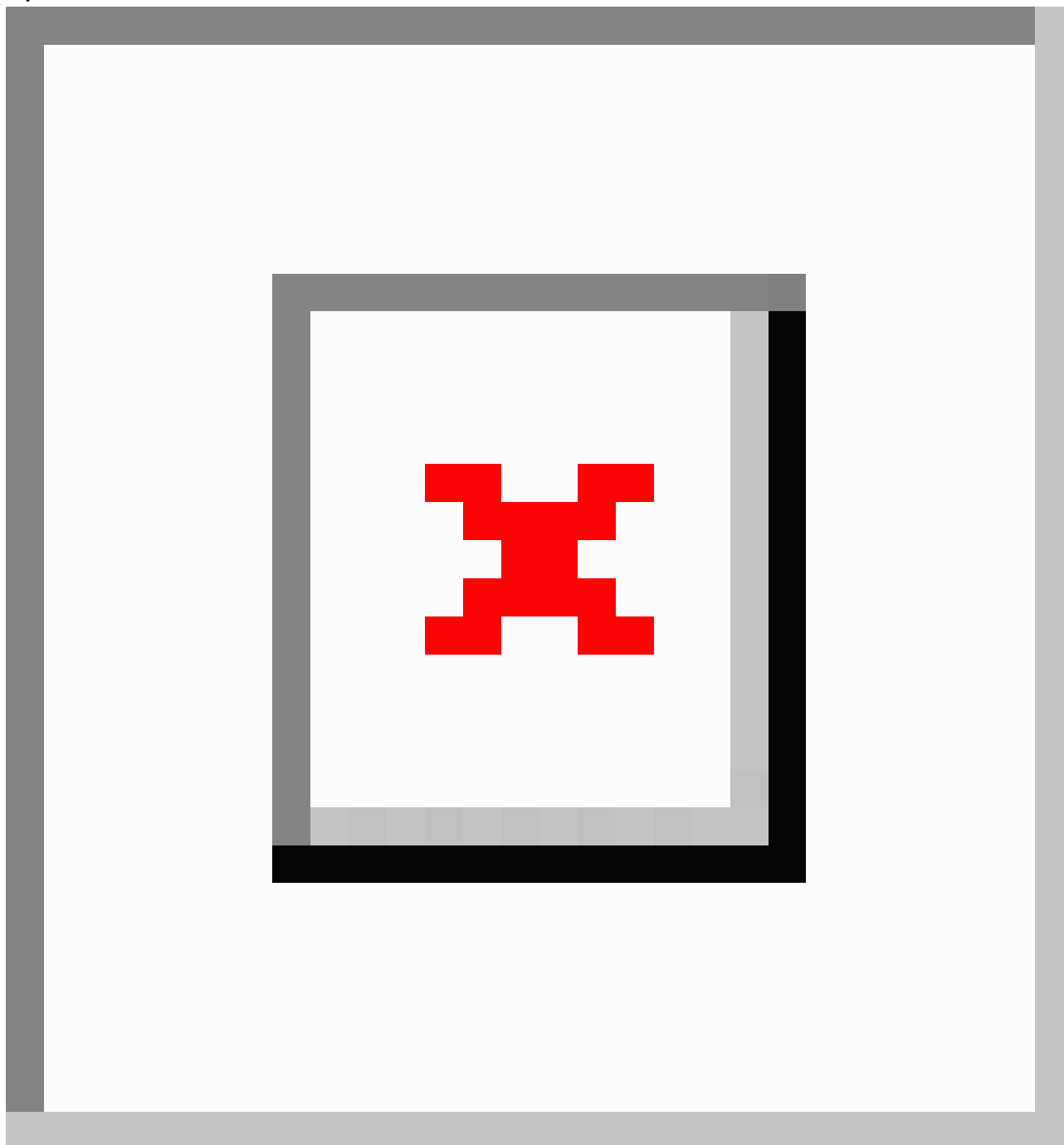
personnel (GPs) were satisfied with the information available in the system (7/9 or 77.8% would like to keep the system in its current state, while 2/9 or 22.2% would like to alter it), the situation was less clear for the secondary health care personnel (nurses and dietitian), with three (of 5, 60%) clinicians wanting

to adjust functionalities and the other two (40%) not wanting to change the system. Regarding functionality alterations, five clinicians proposed 11 points to improve the system and offer more pertinent data (Figure 11).

**Table 3.** Clinicians' evaluations of potential required adjustments to FullFlow, categorized by the results of the evaluation (to keep or adjust functionalities) and by clinical role (general practitioner, diabetes nurse, and dietitian).

Role	General practitioner, n	Diabetes nurse, n	Dietitian, n	Total, n (%)
Adjust functionalities	2	2	1	5 (36)
Keep functionalities	7	2	0	9 (64)

**Figure 11.** Sankey diagram of the functionality adjustments proposed by the clinicians. Each color corresponds to a specific type of adjustment. Orange: new service; lilac: new data type; light green: remove functionality; green: add functionality; dark green: proposed functionality adjustment. The numbers represent the number of times an adjustment was mentioned. BG: blood glucose; IoB: insulin on board; CoB: carbohydrates on board; I:C: insulin to carbohydrate ratio.



Of the eleven functionality adjustments proposed, nine (of 11, 81.8%) were related to adding new functionalities and the other two (18.2%) were related to removing functionalities. Proposals for adding new functionalities were divided into two subgroups: new services (n=4) and new data types (n=5). New data types would require adding data types not available in the system when they were presented to the clinicians, while adding new services would mean creation of new functionalities using the data currently available in the system. Of the suggested new data types, insulin type (eg, slow or fast acting) was mentioned twice by clinicians, with the suggestion that it be available in both the overview section and the graphs. The other data types

suggested were blood pressure, plasma glucose, and lipids. Of the suggested new services, clinicians twice expressed the desire to enter goals and notes directly into the Diabetes Diary of the patients through the FullFlow system. Another clinician requested more detailed blood glucose ranges such as high hypoglycemia in the overview section, and a second suggested displaying I:C values by time of the day (eg, fasting, morning, afternoon, and night). Depending on the situations of the patients, these new data types and services could “help provide more tailored advice” and “facilitate cooperation with the patients,” according to the clinicians. Of the functionalities suggested for removal, one clinician proposed removing IoB

and CoB from the graphical interface, suggesting that “they will not have time to investigate this data.”

Figure 12 shows the correlation between the suggested adjustments and clinical roles. The data show that adjustment needs were disjointed between the primary and secondary health care personnel: The former group expressed the need to add blood pressure, plasma glucose, and lipids to the functionalities of the FullFlow system (mentioned once each), while the latter group did not need them. The secondary health care personnel proposed adjusting the services available in FullFlow, while the GPs focused only on new data types.

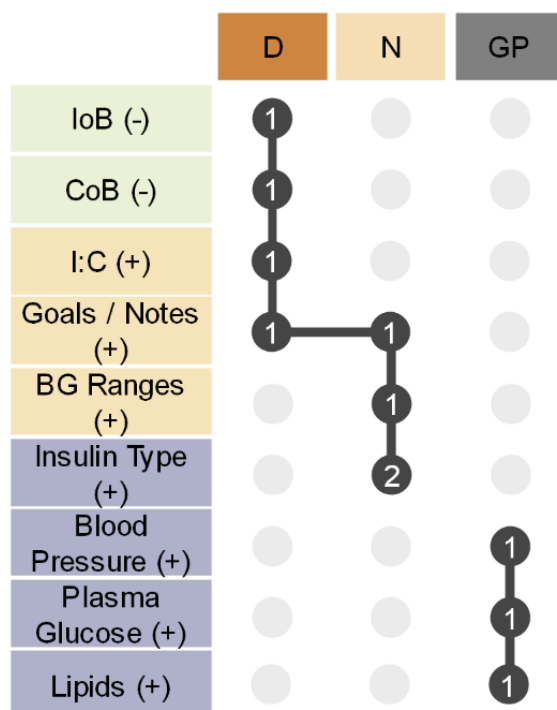
The needs of the dietitian and diabetes nurses intersected, with the proposal of writing goals and notes directly in the Diabetes Diary of the patients via the FullFlow system (mentioned once per group). The nurses proposed recording the insulin type

(mentioned twice) and a more detailed blood glucose range (mentioned once) in the FullFlow system. The dietitian was the only clinician to suggest removing features from the FullFlow system (IoB and CoB) and displaying the I:C values by time of the day.

**Usability of the FullFlow System**

One clinician pointed out the possibility of the system being time consuming during consultation, which could reduce its efficiency. Querying the robustness of the FullFlow system, one participant noted that insulin and carbohydrate intake times should be matched in the Combined Data graph. A bug resulting in movement of registrations on the time axis (x) when hiding or showing data types (Figure 6 E) was corrected, and registrations having the same time were shown close to each other.

**Figure 12.** Matrix presenting the correlation between the suggested adjustments and clinical roles (general practitioner, diabetes nurse, and dietitian). The columns represent the clinical roles and use the same color coding as the previous figures (D/orange: dietitian; N/beige: diabetes nurse; GP/grey: general practitioner). The rows represent the adjustments proposed by the clinicians and follow the same categorization and color coding as the previous figure (light green: remove functionality; beige: new service; lilac: new data type). (-) denotes a proposed functionality removal, while (+) denotes a proposed functionality introduction. The dark grey circles represent a suggested adjustment by a specific clinical role and the number of times it was mentioned by that role. The vertical lines represent logical sets, while the horizontal lines denote the intersections of the logical sets, like a Euler diagram. BG: blood glucose; IoB: insulin on board; CoB: carbohydrates on board; I:C: insulin-to-carbohydrate ratio.



**Expectations and Summary**

All the participants (14/14, 100%) expected that the presented system—a combination of the Diabetes Diary, Diabetes Share Live and FullFlow—would be useful during their daily consultations. They forecast that the system would be good for all patients, but particularly effective if patients enter enough data regularly in their diaries.

They predicted that three types of patients would be interested in this solution: (1) patients who are interested in technology and self-management; (2) patients concerned about their diabetes and quality of life; and (3) patients living in remote areas, where

the usage of the system could support remote consultations and avoid patients travelling several hours for a single face-to-face consultation. One participant mentioned that several patients already use self-management apps, which would ease the introduction of this system.

Overall, the system was very well received by the participants and they were eager to start using it during consultations. However, the participants mentioned that experience using the system will be needed to validate their expectations and clarify the system’s usability and functionality.

## Discussion

### Principal Results

This paper presented a dashboard for displaying patients' self-collected health data during consultations, using diabetes as a case example. The graphical interface was implemented using continuous feedback from clinicians and patients to minimize possible future user resistance by providing relevant information to meet clinicians' needs. We limited the potential increase in time consumption due to the usage of this solution by proposing information related to the quality of self-collected health data (identifying whether the data are worth consulting), displaying an overview of the situation of a patient, and identifying important medical events without the need to consult the complete data set.

The prestudy assessment showed that the solution could be effective during consultations, especially if patients live in remote areas or are interested in either mobile technologies or improving their life conditions. The majority of clinicians were satisfied with the current state of the graphical interface, and all clinicians were eager to start using it.

The prestudy assessment also showed that the needs of primary and secondary health care personnel are disjointed: GPs do not need the same data and services as diabetes nurses or dietitians. However, due to the limitations of the Diabetes Diary (see below), their wishes cannot be fulfilled.

### Dashboard Functionalities and Graphical User Interface

The information provided by the KBM module, namely, the grading of the self-collected health data (Figure 4 B), the identification of trends (Figure 5 C-E), and the identification of potential causes of medical events (Figure 5 F) address two of the main barriers of acceptance of introducing self-collected health data into consultation, namely, the distrust of this source of data [53-56] and a time increase in consultation.

The calculations presented in the overview table (Figure 4 D) can facilitate diabetes management [57-60] for both patients and clinicians. We chose to use a table for representing this information, considering that clinicians are accustomed to using tables for visually representing data, which can surpass graphs in certain conditions [61]. We used a standard pooled deviation for illustrating the variability of data type, considering that diabetes, as a chronic disease, is a day-to-day management disease and that a routine (ie, less variability of medical values) can improve the condition of patients drastically [62,63]. For instance, a low glucose variability is more important for diabetes patients than having an in-range hemoglobin A<sub>1c</sub> for preventing complications [64]. Therefore, providing an indication about how much patients are able to stabilize their blood glucose values during each day is important for them. Although previous studies proposed several methods for measuring glucose variability using SD, coefficient of variability, mean amplitude of glycemic excursion, or continuous overall net glycemic action with CGM, there is a lack of consensus on which method should be used [64,65]. Moreover, these methods have drawbacks when using self-monitoring blood glucose values due to a lack of

sufficient and regular number of measurements. Since our system uses available data either from CGM, self-monitoring of blood glucose, or a combination of the two, we are looking for a generic model that can work for all types of available data from the patient. It is quite optimistic to assume that patients self-register data regularly every day, because it reminds them that they are sick [66]; we used pooled SDs to weight the average of each day's SD. This weighting gives larger groups (days with more registrations) a proportionally greater effect on the overall estimate of the variability [67] and allows us to increase the robustness of statistical calculations. Clinicians agreed to use this approach. Another point to discuss is our decision to use the more accessible term "average deviation" instead of "pooled SD." We believe that this term will prevent patients and clinicians from being exposed to mathematical concepts in order to understand the value. However, the complete definition, with the formula and explanations of the term, is presented to users if they hover the mouse over the "average deviation" term. Moreover, we expect feedback on this taxonomy from the medical trial.

We decided to use the eA<sub>1c</sub> functionality, although its use is contested by some authors [68,69] for allowing clinicians to compare the eA<sub>1c</sub> with the hemoglobin A<sub>1c</sub> results of the laboratory tests, since previous studies showed that there is a correlation between the hemoglobin A<sub>1c</sub> and eA<sub>1c</sub> values [70]. An important deviation between these two values could indicate a poor quality and reliability of the self-collected health data due to, for example, an insufficient number of registrations per day and can therefore be used as one of the indicators of the quality and reliability of the self-collected health data. Today, due to technical restrictions, the FullFlow system cannot integrate EHRs' data and display the hemoglobin A<sub>1c</sub> value side by side with the eA<sub>1c</sub>. Clinicians can consult the hemoglobin A<sub>1c</sub> values in their EHRs and use FullFlow for consulting the eA<sub>1c</sub>. In addition, this approach is used by the American Diabetes Association [71] and MySugr [72] and is cited in the NGSP's website [73]. However, we decided to hide the eA<sub>1c</sub> value, considering that clinical workers were concerned that this value can confuse patients in Norway. Nonetheless, the system will still collect the value, allowing us to compare the calculated values against the laboratory test results or the hemoglobin A<sub>1c</sub> values reported through questionnaires, to determine how this approach fits real situations. The dashboard containing the eA<sub>1c</sub> may be of interest to clinicians, patients, researchers, and computer scientists.

Regarding the grading of each piece of information (Figure 4 E-I), the system uses different approaches depending on the type of data. For instance, the FullFlow relies on medical standards given by the Norwegian Directorate for Health [74] and international public entities [75] (eg, hemoglobin A<sub>1c</sub> values) or values we defined during our workshops (eg, grades for the blood glucose in-range values). Some values are not graded, such as the daily amount of insulin used, because each patient follows tailored insulin therapy, depending on physiological conditions such as weight as well as lifestyle factors such as meal times and physical activity [76].



Displaying the patients' personal goals in the overview section (Figure 5 A) before the noticeable events will help the patients steer the medical consultation toward what they would like to discuss with their clinicians, as some of them are too shy to interrupt the clinicians directly, according to the feedbacks collected in the workshops.

The moving average and weighted moving average used by the daily distribution section (Figure 7) further facilitate the visual detection of patterns by clinicians, which can be useful for improving patients' lifestyle [77,78]. We are aware of other types of moving averages such as the exponential weight moving average [79] or the Hull moving average for reducing lag [80]. However, we decided to use a simple weighted moving average in the first version of the FullFlow. The decision regarding the usage of a weighted or simple moving average relies on the analysis of the FHIR artefacts. For instance, a blood glucose value obtained from a finger prick has twice the weight of a blood glucose value measured with a CGM, considering that finger pricks are more accurate than the CGMs, which require calibration [81]. The window size for calculating the moving average is set to five registrations to suppress the sheer power the CGM readings have over the self-monitoring blood glucose measurements (ie, five registrations maximum are used for calculating one value of the weighted moving average). This fact remains true even though the CGMs are becoming more accurate [82] and some do not require calibration at all [83].

### Comparison with Previous Studies

The dashboard we proposed differs from others such as MySugr [84], the dashboard of Diagliati et al [48], Carelink by Medtronic [85], the clinical decision system by Sim et al [47], the system proposed by Martinez-Millana et al [86], and the platform proposed by Fico et al [87]. The main differences are listed below:

1. FullFlow does not limit the integration of data to specific companies or types of sensors: finger pricks, CGMs, insulin pens or insulin pumps can all be used by the patients.
2. FullFlow analyzes the data and proposes recommendations regarding potential causes of medical situations.
3. FullFlow provides indicators regarding the reliability of the self-collected health data.
4. FullFlow empowers patients by introducing their personal goals in the medical consultation.

### Limitations

The first limitation is the size of the sample for the design and prestudy assessment phases, in which 18 clinicians and 2 patients participated. Although the sample did not permit involvement of all types of clinical roles to identify their needs and evaluate the graphical interface according to their preferences, it was sufficient for determining that the dashboard is ready to enter a medical trial.

During the prestudy assessment, one of the clinicians mentioned that (s)he was afraid that the system could be time consuming. Although the KBM can, in theory, address this issue, as we explained in a previous article [40], we fear this challenge will greatly impact the medical trial due to the technical solutions chosen.

We know that the chosen patient platform, the Diabetes Diary, is not the optimum app for all diabetes patients, as it lacks important features such as the insulin type, blood pressure, polypharmacy, and integration into glucometers and physical activity trackers for automatic data transmission. These missing features might result in a degradation of the reliability of the data and experience for the patients as well as for the clinicians, who would like to have access to these missing data, as specified in the Prestudy Assessment section. Moreover, the Diabetes Share Live solution platform, which requires many steps to be performed during consultation for viewing the self-collected health data, could degrade the experience of the users. This platform requires eight steps to share the data: (1) patients open the Diabetes Diary, (2) patients wait for the application to give a unique identification code, (3) clinicians open an Internet Navigator, (4) patients give clinicians the unique code, (5) clinicians enter the code on the Webpage, (6) clinicians choose a time period, (7) patients acknowledge the time period given by the clinicians and select the data they want to share, and (8) clinicians consult the FullFlow.

However, the FullFlow system itself is not affected by these limitations and can accept data from several applications and several operating systems. For example, while the insulin type will not be displayed during the medical trial (the system displays "Insulin Unknown"; Figure 4 D and 4 H), the FullFlow differentiates types of insulin and treats them differently when such information is available. Figure 13 shows an example of different insulin types for data collected using the MySugr app, where bolus and basal insulin types are treated as separate entities and combined to calculate the IoB by using different profiles [50]. Multimedia Appendix 2 shows an instance of the dashboard populated with other data types and demonstrated that the system is able to display any FHIR data.

Nevertheless, the medical trial will still allow us to conduct research on the relevance of the information displayed, its potential impact on medical services, and the relevance of the KBM. Although the approach and business rules of the KBM are trusted by the clinicians who were involved in its creation, the medical trial will measure trust in the system during its usage, which will depend on the situation of the patients and the data collected by them. It could also be suitable for remote consultation.

The last limitation concerns the integration of EHR data into FullFlow, which, while planned, is not yet available. Therefore, FullFlow cannot directly show EHR data, such as hemoglobin A<sub>1c</sub>, and clinicians will have to use both systems during consultations. However, while not reaching its maximum potential, FullFlow will still permit the study of the integration of self-collected health data into consultations.

### Future Research

The graphical interface can still be improved in different ways: The table in the Data Summary section could contain information related to the in-range values of each data type and be visually graded like the rest of the overview page (green, orange, red, and white). Shortcuts to the combined graph from a noticeable event could be made, with automatic selection of data to display or hide. It may also be possible to see

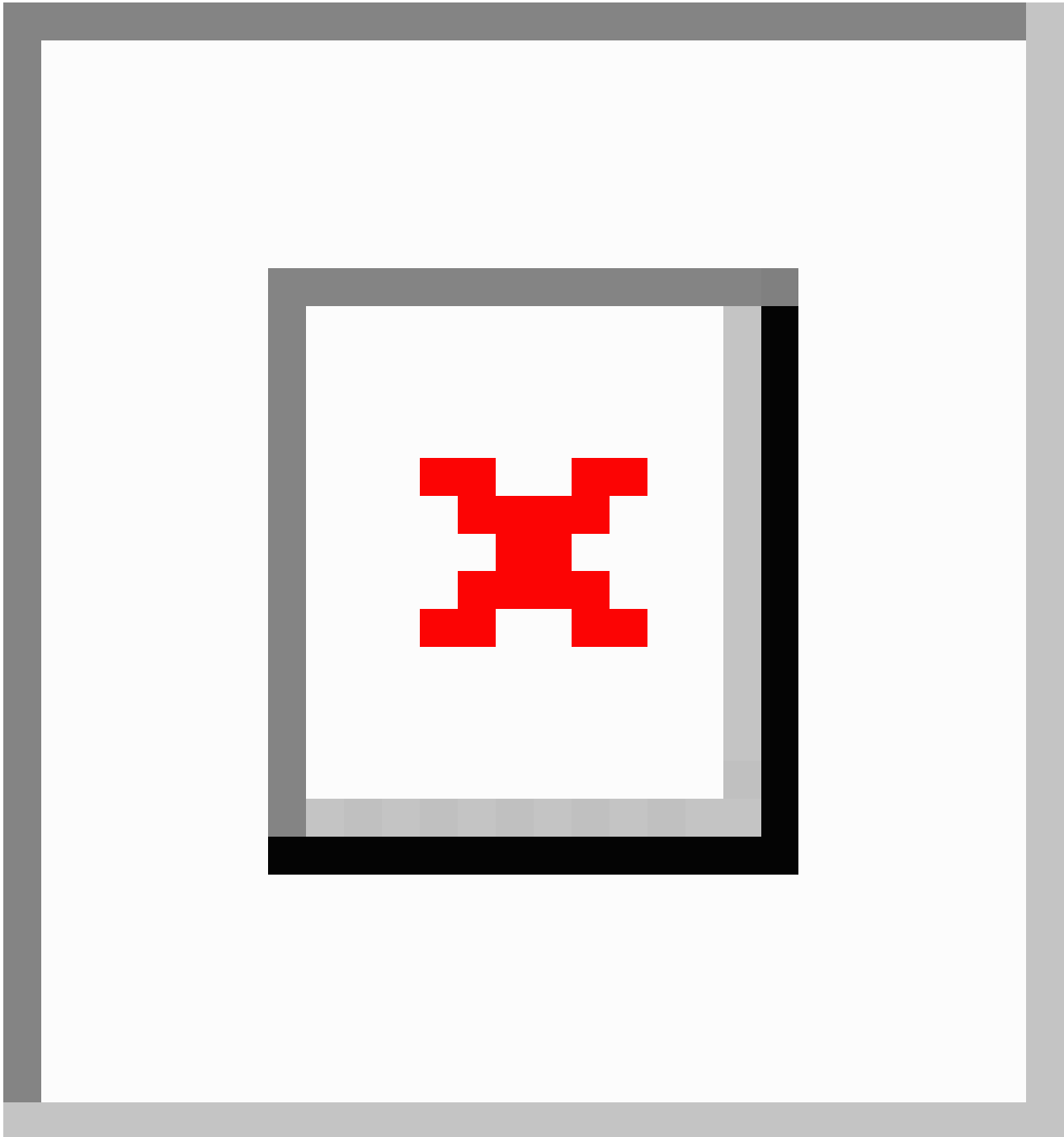
self-collected health values day by day, with the current day values displayed in a large graph at the top of the page and all other days' values listed under this graph as smaller graphs, one per day; we could also add daily computational glucose variability using SDs to the top of the overall graph.

We believe that the results from the medical trial, in which clinicians use FullFlow in their daily consultations, are necessary to assess what information is useful to add or remove, before changing the graphical interface. Nevertheless, we believe that the proposed dashboard is a viable temporary solution, and ensuring interoperability of the data using standards and

terminologies will allow the independence of the EHRs and permit users to display the information in the ways that benefits most of their users.

The graphical interface could also be improved by adding dual signaling for visually impaired people. For instance, the data summary table in the overview section could integrate visual cues, such as equals signs or arrows pointing up or down, to indicate whether values are in range or out of range. These signs could be added below the values displayed in circles in the overview section or even used as texture.

**Figure 13.** Example of data list and combined data with different types of insulin.



In addition, reports do not contain information regarding the patients themselves (eg, names or identity numbers). This is

due to the usage of the Diabetes Diary and Diabetes Share Live. It will not affect the medical trial, given that clinicians and

patients use the system in real time together and clinicians can export the reports to their EHRs, where the patient will already be selected. Notably, clinicians would like to write goals or notes directly into the patients' apps using the FullFlow system, which is outside the scope of the study at this stage; we would suggest that patients use their mobile apps themselves to directly create the goals defined in collaboration with their clinicians during consultation.

Although the system can read and display any data types as long as they are in an FHIR format, it will use only "registered" data types for advanced services (eg, blood glucose, insulin, blood pressure, and menstruation), such as grading data reliability or exploring potential causes of medical events. The registered data types are listed in another article [40]. We plan to add new business rules for new data types in the future, such as lipids (as requested by a clinician) or foot temperature for early detection of injuries due to diabetic neuropathy.

[Multimedia Appendix 2](#) shows an example of the graphical interface containing lipids as "unregistered" data type and six registered data types.

## Conclusions

The designed dashboard could ease the introduction of self-collected health data during medical consultation by providing relevant information about the situation of the patients, the reliability of the data, and important medical events without the need to consult the data in details. Moreover, the designed dashboard could be an effective solution for face-to-face and remote consultations.

A medical trial, started in November 2018, will provide medical context and document user experience and medical outcomes through usage logs, interviews, and surveys and will help us adjust and improve the dashboard in terms of its graphical interface and functionalities. The results are expected in the beginning of 2020.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Transcribed answers to the collected questionnaires.

[\[PDF File \(Adobe PDF File\), 73KB - diabetes\\_v4i3e14002\\_app1.pdf\]](#)

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## Multimedia Appendix 2

Example of the graphical interface with different data types.

[\[PDF File \(Adobe PDF File\), 149KB - diabetes\\_v4i3e14002\\_app2.pdf\]](#)

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## Abbreviations

**CGM:** continuous glucose monitor

**CoB:** carbohydrates on board

**eA<sub>1c</sub>:** estimated HbA<sub>1c</sub>

**EHR:** electronic health record

**FHIR:** Fast Healthcare Interoperability Resources

**GP:** general practitioner

**GUI:** graphical user interface

**I:C:** insulin-to-carbohydrate ratio

**IFCC:** International Federation of Clinical Chemistry and Laboratory Medicine

**IoB:** insulin on board

**KBM:** knowledge-based module

**NGSP:** National Glycohemoglobin Standardization Program

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Original Paper

# Small Data and Its Visualization for Diabetes Self-Management: Qualitative Study

Sally Jane Burford<sup>1</sup>, PhD; Sora Park<sup>1</sup>, PhD; Paresh Dawda<sup>1</sup>, BS, Med

News & Media Research Centre, Faculty of Arts and Design, University of Canberra, Canberra, Australia

**Corresponding Author:**

Sally Jane Burford, PhD

News & Media Research Centre

Faculty of Arts and Design

University of Canberra

College St

Canberra, 2617

Australia

Phone: 61 62015958

Email: [sally.burford@canberra.edu.au](mailto:sally.burford@canberra.edu.au)

## Abstract

**Background:** As digital healthcare expands to include the use of mobile devices, there are opportunities to integrate these technologies into the self-management of chronic disease. Purpose built apps for diabetes self-management are plentiful and vary in functionality; they offer capability for individuals to record, manage, display, and interpret their own data. The optimal incorporation of mobile tablets into diabetes self-care is little explored in research, and guidelines for use are scant.

**Objective:** The purpose of this study was to examine an individual's use of mobile devices and apps in the self-management of type 2 diabetes to establish the potential and value of this ubiquitous technology for chronic healthcare.

**Methods:** In a 9-month intervention, 28 patients at a large multidisciplinary healthcare center were gifted internet connected Apple iPads with preinstalled apps and given digital support to use them. They were invited to take up predefined activities, which included recording their own biometrics, monitoring their diet, and traditional online information seeking. Four online surveys captured the participants' perceptions and health outcomes throughout the study. This article reports on the qualitative analysis of the open-ended responses in all four surveys.

**Results:** Using apps, participants self-curated small data sets that included their blood glucose level, blood pressure, weight, and dietary intake. The dynamic visualizations of the data in the form of charts and diagrams were created using apps and participants were able to interpret the impact of their choices and behaviors from the diagrammatic form of their small personal data sets. Findings are presented in four themes: (1) recording personal data; (2) modelling and visualizing the data; (3) interpreting the data; and (4) empowering and improving health.

**Conclusions:** The modelling capability of apps using small personal data sets, collected and curated by individuals, and the resultant graphical information that can be displayed on tablet screens proves a valuable asset for diabetes self-care. Informed by their own data, individuals are well-positioned to make changes in their daily lives that will improve their health.

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## KEYWORDS

mobile health; type 2 diabetes; health data; mobile tablet devices; self-management

## Introduction

### Background

It is commonplace for individuals to supplement their healthcare professional's advice with information that is widely available on the web. The web presents a vast repository of detailed health information that is available to people with chronic diseases,

and much of that information is presented as text and static diagrams and is supportive of the self-management of disease [1]. It informs its consumer about symptoms, treatments and prognoses of disease, while varying in accuracy, authority and usefulness. Global information retrieval systems, such as Google, assist in locating specific health information [1].

The mobile phenomenon, initiated by the prolific uptake of smartphones and mobile tablet devices in tandem with expanding wireless networks, creates new opportunities for individuals to contribute to the management of their own health. The mobile device provides an access point to health information in new and varied contexts [2]. It also presents opportunities in the form of the proliferation of mobile apps developed for healthcare and made available by services such as the iTunes store [2].

Embedded in apps is the potential for personal data storage, modelling and presentation for health self-management. Apps with embedded algorithms to collect, manage, analyze and present small, personal, health data sets are widely available at little or no cost to the user. Isolated, small data sets are simple to curate and to manipulate. In contrast, attention to the phenomenon of big data is prominent in society currently. Big data refers to data collections that are vast and complex. It arises in health contexts as the aggregation of data from large populations, which is then used to establish trends, outcomes and predictions.

This article reports a longitudinal mobile health intervention for people with type 2 diabetes and reveals new ways in which individuals can use mobile technology for the self-management of their health. Discussed within is the use of personal health data recording, modelling, and depictions in dynamic diagrams, charts and graphs to support the self-management of disease.

### Previous Studies

The World Health Organization's Global Observatory for eHealth provided a definition of mobile health as:

*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices [3].*

Mobile health was first enabled by the smartphone, its functionality and corresponding apps. A decade of research [4,5,6] positioned the smartphone as a valuable device in healthcare initiatives that encourage weight loss, smoking cessation and depression treatment.

More recent studies expanded mobile health to include the use of mobile tablet devices. Zarghom et al assessed the usability of the touchscreen of tablet devices for patients in a Canadian family health clinic and reported that 94% of all participants regarded the device as easy to use [7]. Hunt, Sanderson and Ellison explored the use of iPads in type 2 diabetes self-management and required 17 participants to log their self-management behaviors [8]. They found that an individual who logged their behaviors using iPad apps had an increased awareness and participation in self-management [8]. The healthcare professional is also helped when a tablet device is embedded in their work, especially when that work is traditionally mobile in its nature [9].

### Self-Management and Empowerment

Individual self-management of diabetes is desirable from a national health care perspective. Recognizing the burden that diabetes presents to the country, a recent Australian consultation

paper to the government recommended a strategy of reduction of complications by increased emphasis on people with diabetes being active participants in their own care [10]. To maximize their health, self-management is important to an individual with type 2 diabetes. Coyle, Francis and Chapman outlined some of the activities of self-management, which include blood glucose testing, taking medication, and following a regular eating and exercise plan [11]. They also noted the need for individuals to be knowledgeable about their disease and respond capably to problems. Funnell and Anderson claimed that for successful outcomes, "a self-management plan has to fit patients' goals, priorities, and lifestyle as well as their diabetes" [12] and that pre-determined health care plans cannot accommodate the complexity of daily life and the myriad decisions that must be made.

Self-management is accompanied by a model of care that moves away from a traditional medical model based on acute, symptom-driven approaches [12]. Meetoo and Gopaul described an empowerment model of healthcare in which:

*people with diabetes are empowered when they have the necessary knowledge, skills, attitudes and self-awareness to influence their behaviour and that of others in order to improve the quality of their lives [13].*

While health care professionals are able to create a climate in which a patient desires to be empowered, it is always an individual's choice to become empowered [13,14]. Menon holds that individual empowerment is an experience of power and that having power leads to an experience of a sense of control [15]. Samoocha et al established the potential of the internet and eHealth to provide empowering opportunities for patients to make choices and take charge of their health [16], while Burford et al applied health locus of control theory to the intervention reported in this article and reported an increased sense of responsibility for health among research participants [17]. Gimbel et al used the construct of patient activation to design a study that levered mobile technologies for the self-management of type 2 diabetes [18]. They described activated patients as motivated, confident, skillful, and capable of changing their behavior [18].

### Collecting and Using Health Data

Mayer-Schonberger and Cukier reflected on the phenomenon of big data, noting that the scale of digital data that human society has collected and stored has resulted in the potential to "extract new insights or create new forms of value" [19]. They emphasized that big data is not just about the volume of data, but about patterns and predications that can be revealed [19]. Big data is found in many contexts, including the healthcare sector. Keen contested the increasing build of data in healthcare, suggesting that a centralized "bureaucratic data processing model" [20], such as national electronic patient records, is at odds with frontline, distributed and networked health care services. Keen noted that for health, big data processing is favored over more agile systems that might better serve the health care professional and the nature of their work [20].



The Finnish government offered a blueprint, MyData, to shift control of personal data away from businesses and governments and to place it in the hands of the individuals who are the subjects of the data. MyData idealistically challenges the power and infrastructures of big data and gives each individual the right to choose how their personal data are used [21]. Hakkila et al explored the use of wearable sensors connected to smartphones to collect personal activity and health data for wellness and suggested that these data should be stored within the MyData schema [22]. In this way, they envisioned the necessary information and awareness for individuals to pursue healthier lifestyles with personal data under their control.

However, Choe et al signaled that individuals may have difficulty in data integration and interpretation when personal data sets are collected using mobile technologies [23]. Choe et al examined the experiences of individuals wearing sensors to collect and track personal data, such as sleep patterns, heart rate and location. They report that managing, visualizing and interpreting this data is a significant barrier to its usefulness [23]. With a concern for making sense of health data, Katz et al investigated the use of apps on smartphones for diabetes self-management. They found that apps on smartphones did not support the cognitive load needed to make comparison between data and to reflect its meaning [24]. They surmised that the limited screen size of the smartphone prevented data visualization for deep engagement and sense-making [24]. Lyons et al combined the technologies of wearable monitors and mobile tablet apps in an intervention with the focused goal of increasingly physical activity in older adults [25]. They concluded that when accompanied by brief phone counselling, small increases in physical activity resulted and that there was potential for a behavior change when these technologies were merged for specific intent [25].

The literature, however, is silent on the value of small personal data sets that are manually collected, stored and manipulated in apps, and then displayed graphically on the screens of mobile tablet devices for self-management of chronic disease. Therefore, the value that this may present in the self-management of chronic disease is also unknown. The research question for this study thus asks:

*Are mobile devices and associated apps useful tools for type 2 diabetes self-management?*

## Methods

### Research Design

This study was conducted in a large Australian integrated primary healthcare clinic which houses an interdisciplinary team of health professionals that includes physiotherapists,

radiologists, and dieticians all in one physical location. All aspects of the project have the full approval of the Human Research Ethics Committee at the University of Canberra (approval number 14-85). Digital activities for diabetes self-management were designed at a participatory design workshop attended by healthcare professionals and researchers [26]. Two of the six activities that were suggested to the research participants in the form of invitations were: (1) to record their biomeasures such as blood glucose level (BGL), weight, and blood pressure; and (2) to use diet apps to plan and record their food intake. Responses to these two invitations are discussed in this article. Apps that supported these two activities (*Glucose Wiz* for recording biomeasures, and *Food Switch, Easy Diet Diary* and *iCookbook Diabetic* for dietary management) were preinstalled on the iPads given to participants. However, the participants were also able to download apps of their choice from the App Store. The choice and quality of the apps was not a focus of the study. It was important to rule out lack of digital skill as a cause for nonengagement in the program. All participants attended an initial workshop where Wi-Fi and 3G enabled iPads with 16GB were distributed. The goal of this workshop was to ensure basic digital establishment and literacy. Participants were supported in setting up an email address, obtaining an Apple ID, downloading apps from the Apple store and 3G subscriber identity module (SIM) card activation. Individual consultations and online support, which included the use of the device and apps, were participant-directed. They were offered for as long as the participants perceived a need.

### Recruitment

The gifting of iPads to research participants and the intensive digital support that was made available for the duration of the study meant sample size was set at approximately 30 to conform with the project budget. Participant recruitment started on August 6, 2014 and the quota were filled by August 22, 2014. Because diabetes patients visit their General Practitioner (GP) at two-month or three-month intervals and the recruitment window would therefore not reach the full spectrum of available patients, the recruitment strategy was twofold. Firstly, there was advertising in the clinic waiting room and the ability to self-nominate. Secondly, on health professional's recommendation, nurses could invite patients to participate by phone. Three of the initial participants, learning more about the commitment needed in the program, withdrew in the early weeks and several more patients were recruited to take their place. The final number of people with type 2 diabetes participating in the study was 28, and no specific inclusion or exclusion criteria were used in selecting participants. A summary of the demographics of participants is provided in Table 1, revealing a diverse range of socioeconomic and educational backgrounds.



**Table 1.** Demographic summary of participants (N=28).

Demographics	n (%)
<b>Gender</b>	
Male	16 (57)
Female	12 (43)
<b>Age (years)</b>	
30-39	1 (4)
40-49	4 (14)
50-59	10 (36)
60-69	9 (32)
70-79	4 (14)
<b>Education</b>	
High school	9 (32)
Diploma or associate degree	12 (43)
Bachelor's degree	3 (11)
Postgraduate degree	4 (14)
<b>Diagnosis</b>	
< 6 months	8 (29)
6 months to 2 years	3 (11)
2-9 years	9 (32)
10+ years	8 (29)

## Data Collection and Analysis

Using online questionnaires as the main method of collecting data from participants, both quantitative and qualitative data were sought. Quantitative data were collected in order to measure and establish demographics, trends and preferences, and qualitative data were collected in order to gain insight into, and understanding of, the human experience. All four online survey tools were developed iteratively and were informed by established measures of health behavior, digital literacy and digital engagement.

This article reports a secondary analysis of a subset of the data obtained in the larger study described above. It draws from the analysis of qualitative data obtained via open-ended written responses across four online surveys that were conducted over the nine-month intervention. Open-ended questions elicited information about the participants' use and perception of the mobile device, their digital literacy, their use of apps for self-care, perceived change in their health, changes in biomeasures and the ways in which all of this was enacted.

Thematic analysis, used in this study, captures a level of patterned meaning within the data [27] and provides a theoretical freedom to approach a complex body of data and reveal themes and insights without pre-existing expectations. It is inductive in nature and "has a long tradition of use" in applied health research [28]. The qualitative data in this study, resultant of the open response survey questions, existed in structured textual form and were coded across all questions. In an iterative approach, analysis took place at the conclusion of each of the

four surveys and emerging thematic concepts informed the design of the next survey. Following the coding of each survey and tentative theme construction, the four survey responses from each individual were re-examined to gain an alternate view of the data and further insight into the emerging themes. The coding was performed by a single researcher for consistency and the research team met periodically to discuss the emerging constructs.

## Results

### Overview

Results are presented as themes, which are constructs indicated by a detailed analysis of the data rather than found in the data itself [29]. The following themes emerged from the analysis of data collected in this study and reveal a logical sequence of digital engagement for self-management of diabetes. Accustomed to measuring and recording biological measures such as BGL and blood pressure, many of the research participants used the tablet device and its apps to record these measures, building a small personal data set over time. The data were then used to model and graphically display personal information that was, in turn, interpreted by participants by comparing it with other self-care data, such as dietary intake, which they had recorded using the tablet device. Throughout this article, pseudonyms are utilized when data provided by participants is used to illustrate themes and inform the reader.

## Recording Personal Data

Self-management of type 2 diabetes typically includes measuring and recording BGL, weight, and blood pressure as part of a routine of self-care [11]. The iPad proved a useful tool to support these activities:

*The iPad has helped me to record blood glucose levels, diet and exercise, all of which are important for managing diabetes. [Ruth]*

One participant outlines the simplicity of the process:

*I use this app to record my glucose readings 3 times a day. It's very simple to use - just enter the reading and it records it for you. [Lily]*

**Table 2.** The number of people using the pre-installed apps (N=28).

Pre-installed app name	n (%)
Glucose Wiz	12 (43)
iCookbook Diabetic	11 (39)
Food Switch	7 (25)

Medication times and dates were less commonly recorded; however, one participant, Tristan, reports that medication times and dates were his main use of the tablet in an environment where “the iPad stays on the table to remind me to take the medication.” This countered a pattern of Tristan having “missed [his] medication at least once or twice a fortnight.”

## Modelling and Visualizing the Data

With a small data set in place, the modelling capacity of the apps was discovered by participants. They were self-taught in producing varied models of their own data, which could be graphically displayed. One participant said that:

*Glucose Regulator is an easy and quick app to record and graph my BGL's and makes the trends in my levels so clear. [Rachel]*

Participants could look at their history and patterns with ease:

*There are two functions that I particularly like - once recorded you can look at your readings in a graph format over a period of days, plus it will also give you an average reading - which is great for your doctor to view too! [Lily]*

Claire valued the time and period of the day that was stamped with her granular BGL data:

*The Glucose Wiz app ties each reading to a time and the appropriate period eg. before a meal, a random mid period reading, after a meal etc. In addition it shows the averages for before meals, after meals.*

In combination with the recording and modelling capability of the apps, the visual, graphical representation of data was extremely beneficial to participants, with Ruth saying:

*I like the clarity of the BGL graph.*

“Visual feedback, which I have found most useful,” was important to Raymond. His results were much clearer to him in diagrammatic form. Extremely appreciative of the data

Leah reports that she “now takes accurate information to her doctor all the time.” She compares her recordkeeping before the iPad:

*Before I had the iPad and the apps, I was trying to keep records on paper, spreadsheets on the computer, it was a mess, I would lose the paperwork, forget to record on my desktop. [Leah]*

At the conclusion of the program, 79% of participants were using an app to record their BGL data. It was the most frequent purpose for using apps. Table 2 shows the number of people using the pre-installed apps [30].

visualization capability of her chosen app, this participant reports:

*This app makes charts of blood pressure fluctuations, with upper and lower parameters with colour warnings. As well, this app records the time, the measurement, the arm used, body position, recent meal, weight, height, BMI, body fat, cholesterol, LDL, HDL and water consumption. It is easy to use and the charts are just like magic. [Madelyn]*

Charts, tables, averages and trends were shared with health professionals, the mobile tablet being acclaimed by participants for its portability and visual display of data, with Ruth saying:

*It has also been beneficial for my Dr to see my levels at a glance.*

## Interpreting the Data

Ryan adopted regular recording of his BGL on Glucose Wiz and “where an anomaly occurred, [he] was able to determine what [he] was eating to correct the issue.” With a baseline for BGL presented as graphical information, he could watch for spikes and consider what he had eaten at that time. In this way, Ryan reported a reduction in BGL, weight loss and increased fitness at his next consultation with his healthcare professional.

Participants reported that monitoring the data was an important activity in self-management and when irregularities were noted, explanations were sought. Raymond monitors his circumstances:

*The visual feedback I get from Glucose Wiz enables me to keep track of my progress.*

Keith looks for changes in his BGL data and maps them to his diet for the day

*I am able to record by BGL test on the iPad, track the test over a week to a month, see what I have been eating that day and what I need to move on.*

This monitoring was made easier by the visualization of the data. Another participant reported being able to customize her own meals to avoid insulin spikes by mapping her BGLs to a record of food eaten.

The mobile tablet device presents self-management data with graphical clarity. It provides chronological and accurate records for diabetes self-management for this participant:

*While you may have an idea of how you are managing your diabetes, the graphical information presented in the app clearly shows how well you are in fact managing. [Anna]*

The personal data sets and visualizations make for realistic assessment and decisions by an individual. For Raymond, his own data collected via apps “helps me to keep on track, and to get back on track when I need to.” Keith notes improved self-management and its outcomes:

*I check my BGL more, I check my weight more, monitor my diet better. My blood levels are staying more normal than over a year ago.*

The following participant describes an improvement in self-management that has developed over time and increased his knowledge and routine:

*When I first used the device to record sugar level, I kept monitoring my levels frequently to get my level down. I feel over time, I have developed a routine of diet and exercise. [Jackson]*

Jackson says that he has learned a lot in this way, and that “it has changed the way that I live.” Emily has been assisted with “more tools at my disposal and a greater ability to track various things.” Because participants were invited to engage digitally rather than required to participate in any specific way, the uptake of the iPad as a management tool varied from minimal to a comprehensive engagement such as Madelyn’s:

*I track as many of my metabolic markers as I can, using various apps. I can see in my charts how my BGL fluctuates throughout the day or the month and also heed warnings about hypertension.*

### Empowering and Improving Health

The iPad and apps were regarded as empowering tools that enabled a sense of control over the participants’ health. Kaylee said that:

*I feel more in control with the help of the apps in the iPad in managing my diabetes.*

Menon claimed that a sense of control is an essential component of health empowerment [15]. According to one participant, Claire:

*The greatest feeling of good management is the feeling of well-being and energy you get when blood sugars are at acceptable levels and weight is under control.*

Recognizing from the depiction of his BGLs that his diabetic management was “not up to scratch” on a recent cruise, Ryan discussed managing diet when travelling and the importance of portion size with his doctor and was able take control once more.

Cause and effect are demonstrated to Raymond and he becomes more aware of the consequences of his choices:

*The graphical picture on charts from Glucose Wiz enabled me to see that good results do happen, when you are doing the right thing.*

Rachel makes notes on her app “if I do have any unusual results.” With an existing diagnosis of type 2 diabetes, she noted that her BGLs were increasing in spite of her vigilant lifestyle and monitoring. Using the iPad to research her symptoms, she suggested to her doctor that she should be tested for a rare form of diabetes. She was tested and found to have latent autoimmune diabetes in adults and was treated accordingly.

Madelyn reported that her visits to the doctor were more interesting with the records that she had made. She displayed BGLs, blood pressure, weight, BMI (body mass index), body fat percentage, hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) and hydration “in impressive chart form of chronological order.” Madelyn’s self-management using her personal small data brought about change in her health:

*My weight is now around 69kg [from 125kg], my BGL are in the normal range and I have an iPad which has a complete record of the transformation.*

Using the Glucose Wiz app to record her weight, medication and BGLs, Leah was feeling very unwell and dramatically losing weight, and she said that “my BGLs were unpredictable and rising from week to week.” Leah could see a contradiction between her strict diet and her BGLs. She handed her data set to her GP:

*I gave my iPad to the doctor, it was due to my iPad that I was diagnosed with type 1 diabetes and sent to a specialist.*

Leah continues to monitor her biomeasures on the iPad in the management of her newly diagnosed condition. For most participants who adopted mobile management, however, the shift in their health was less dramatic. Jackson describes his health situation having adopted the iPad as a self-management tool as “close to normal BGL and normal blood pressure – Doctor was happy.”

## Discussion

### Principal Findings

This article reports successful personal health data collection, curation, visualization and use by research participants, which is counter to the studies of personal data collection by Choe et al who reported small individual data sets captured by wearable monitors as difficult to manage and to understand [23]. We suggest that the point of difference of our study to that of Choe et al is the individual’s purposeful measurement and recording of each item of data. Measures were taken and entered into apps that support data storage and display. This differs from tracking devices that automatically read and store a large amount of data that proves more difficult to interpret and convert to information that is useful to its owner.

This study also sits in contrast to the big data phenomenon that is prevalent in many societal contexts including health. Big data can be unstructured data in a variety of formats such as video and audio and is produced in vast and rapid streams. It is complex data that is used to establish trends and solve complex, population-wide problems [19]. As society grapples with the extent of a digital revolution that is both ill-defined and full of potential, it is important to not ignore the small, personal, isolated, yet beneficial collections of data. This study is novel in its attention to small independent digital data sets, collected by individuals for self-care of chronic illness and adds nuanced and humanistic knowledge to digital health.

This intervention places data-driven modelling and resultant visual output in the hands of an individual, empowering their management of their own disease. With a small, personal data set in place, participants in this study engaged in the modelling capability of their apps, producing averages over varying time periods, trends and patterns.

Participants embraced the app functionality that allowed them to visualize their data in graphs and charts with embedded alerts for any extremes in the data. Data visualization is a form of visual communication that seeks to improve human comprehension of granular data [31]. Uyan Dur added that the value of data visualization is that it is based on measurable statistical data, that it provides a picture of numeric data that could otherwise be difficult to comprehend [31].

Data visualization allows its viewer to more readily interpret the data and to integrate it into problem solving activities. "Visualization of information ensures the ability to see events and connections between them in new and different ways and to reveal other invisible patterns" [31]. This was evident with the participants in this study as their BGL graphs revealed the effect of inadvisable dietary intake. Importantly for several participants, the visualization of their data led to them questioning all of the available information about their condition. Anomalies were noticed to the extent that individuals contacted their doctor and new diagnoses and treatment plans were made. The benefit of data visualization was improved cognition, and at times a corresponding shift in behavior.

The iPad tablet screen size is considered ideal for manipulating data and is of a quality that is easily viewed and comprehended. It was preferred by the participants to an iPhone with identical apps because its size supported the dexterous and visual capability of its user. This is in keeping with the study of Katz et al who found a smartphone too small for the sensemaking of health data in diabetes self-management [24]. The apps, both pre-populated and chosen by participants, provided intuitive use and participants moved through recording, modelling, visualizing and interpreting their data without barriers. Individuals were empowered to produce varied models of their behaviors and biomeasures and immediate feedback was available via visual display of patterns, trends and scenarios.

The result of this was improved participant cognition and discernment, with Ruth saying:

*Being able to record my blood glucose levels and see them on a graph, or in red if they are high, has made me want to keep them within normal limits.*

Choe et al [23] described the ideals of personal health informatics thus:

*That through knowledge of one's data, it becomes possible to reflect on one's activities, make self-discoveries, and use that knowledge to make changes.*

This study exposes the potential of mobile tablets and apps as tools for the establishment, visualization and interpretation of small personal data sets for diabetes self-management.

Clinicians are increasingly looking to enhance consumer enablement in chronic conditions such as diabetes mellitus [32]. The use of mobile tablet devices as in this study is likely to facilitate an increased enablement of individual consumers, which means an improvement to the extent to which they understand their health conditions and have the confidence, skills, knowledge and ability to manage their health and wellbeing. This in turn may translate into improved clinical outcomes and experience of care.

This article reports a qualitative research approach that examines human behavior in a complex intervention of technology, digital engagement, primary health care and self-management of chronic disease. It contributes to the health of society by delivering a rich, theoretical description of successful use of mobile devices in diabetes self-management from a humanistic perspective [33]. The study could be recontextualized and applied in similar settings and with other chronic illnesses.

The limitations of this study include the collection of qualitative data via an online survey tool. This approach was taken because of the longitudinal nature of the study that collected data on four occasions. Yet, it prevented an interaction between researcher and participant that could have probed deeper into some of the questions that were asked with follow-up queries.

## Conclusion

This article draws attention to the potential of mobile tablet devices for the self-management of type 2 diabetes. It illuminates the concept of small, personal health data and its collection and management by an individual to improve their health. Once proficient with measuring, entering, and storing biomeasures that support self-management, individuals turn their attention to the modelling, visual display and interpretation of their own health data. In this, an accessible tablet device provides a superior output screen for diagrammatic health information. Personal digital health activities shift from the consumption of text and static diagrams to dynamic data visualization of personal measures, from which insight results and behavior can change.



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## Conflicts of Interest

None declared.

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## Abbreviations

- BGL:** blood glucose level
- BMI:** body mass index
- GP:** general practitioner
- HbA<sub>1c</sub>:** hemoglobin A<sub>1c</sub>
- PDA:** personal digital assistant
- SIM:** subscriber identity modules

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Original Paper

# A Digital Diabetes Prevention Program (Transform) for Adults With Prediabetes: Secondary Analysis

Meshari F Alwashmi<sup>1</sup>, BN, MSc; Gerald Mugford<sup>1</sup>, CMH, BSc, PhD; Waseem Abu-Ashour<sup>1</sup>, PharmD, MSc; Misa Nuccio<sup>2</sup>, MPH

<sup>1</sup>Memorial University, St. John's, NL, Canada

<sup>2</sup>Blue Mesa Health, New York, NY, United States

**Corresponding Author:**

Meshari F Alwashmi, BN, MSc

Memorial University

St. John's Campus, Health Sciences Centre

300 Prince Philip Drive

St. John's, NL, A1B 3V6

Canada

Phone: 1 7096910728

Email: [mfa720@mun.ca](mailto:mfa720@mun.ca)

## Abstract

**Background:** The prevalence of diabetes is increasing among adults globally. Research has demonstrated that a diabetes prevention program (DPP), which focuses on developing and maintaining health-promoting lifestyle modifications, can prevent or delay the onset of type 2 diabetes among at-risk individuals. The implementation of a digitally adapted DPP has the potential to prevent prediabetes on a national and global scale by using technology and behavior change science.

**Objective:** This study aimed to investigate the effects of a novel digital therapeutic DPP (Transform) on weight loss, body mass index (BMI), exercise frequency, and work absenteeism.

**Methods:** This study was a secondary analysis of retrospective data of adults with prediabetes who were enrolled in the Transform DPP from December 2016 to December 2017. The program incorporates interactive mobile computing, remote monitoring, an evidence-based curriculum, behavior tracking tools, health coaching, and online peer support to prevent or delay the onset of type 2 diabetes. The analysis included data that were collected at baseline and after 4 months of the Transform DPP.

**Results:** The sample (N=273) comprised people with prediabetes who completed 4 months of the Transform program. Participants included 70.3% women, with a mean age of 54.0 (SD 11.2) years. On average, participants decreased their weight by 13.3 lbs (6.5%) and their BMI by 1.9 kg/m<sup>2</sup>. On average, participants increased their exercise frequency by 1.7 days per week, and absenteeism was reduced by almost half a day per month.

**Conclusions:** These results suggest that the digital therapeutic DPP (Transform) is effective at preventing type 2 diabetes through a significant reduction in body weight and an increase of physical activity. A prospective, controlled clinical study is warranted to validate these findings.

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**KEYWORDS**

mhealth; diabetes; DPP; diabetes prevention program; digital health; diabetes

## Introduction

**Background**

Diabetes imposes a significant economic burden on society in the form of higher medical costs, lost productivity, premature mortality, and additional costs in the form of disability-adjusted life years [1]. Diabetes is largely attributed to modifiable

lifestyle factors such as diet, physical activity, and sleep [2]. There is a need for those at risk of developing type 2 diabetes to engage in health-promoting behaviors to reduce their risk. Specifically, individuals can utilize lifestyle modification programs to reduce weight and increase physical activity [3]. Several published studies suggest that smartphones can deliver effective behavioral interventions among various age groups and for different diseases [4-6]. The purpose of this study was

to investigate the effects of a novel digital therapeutic diabetes prevention program (Transform) on weight loss, body mass index (BMI), exercise frequency, and work absenteeism.

In 2017, the International Diabetes Federation (IDF) [7] estimated that, worldwide, approximately 425 million adults, aged 20-79 years, were living with diabetes. By 2045, this number is expected to increase to 629 million. In the United States, it is estimated that more than 30 million adults are living with diabetes [7]. Lin et al [8] projected that the number of adults diagnosed with diabetes in the United States would significantly increase to almost 40 million in 2030 and to more than 60 million in 2060. Based on 79,535 death certificates, diabetes was the seventh leading cause of death in the United States in 2015 [9].

Diabetes imposes a significant economic burden on society. The American Diabetes Association estimated that the total cost of diagnosed diabetes has increased to US \$327 billion in 2017 from US \$245 billion in 2012 in the United States alone [10]. Indirect costs linked to diabetes in the United States include increased absenteeism (US \$3.3 billion) and reduced productivity while at work (US \$26.9 billion) [10].

Diabetes is a complex, chronic illness requiring ongoing medical care. It is managed by multifactorial risk-reduction strategies that go beyond glycemic control. Diabetes is caused by several factors including modifiable health behaviors and, in many cases, it is preventable. At-risk individuals can use lifestyle modification programs to reduce weight and increase physical activity [3]. A recent systematic review concluded that lifestyle modifications among individuals with prediabetes reduced the incidence of diabetes development more than standard treatment [11].

### **Mobile Health**

The ubiquity of smartphones and tablets has led to the widespread adoption of mobile health (mHealth). The Global Observatory for eHealth of the World Health Organization defines mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices” [12]. A mobile health intervention can include the use of home tracking medical devices that are compatible with smartphones and integrate with a health care professional. The significance of mHealth is outlined by its ability to deliver timely care irrespective of the geographical location of the patient and provider. Researchers and clinicians can utilize mHealth to conduct studies aimed at improving the quality and efficiency of health care delivery, enhancing the quality of life, and reducing the overall burden on the health care system. Although mHealth is a nascent industry, it is already showing its potential by significantly enhancing treatment outcomes while mitigating health care costs [13,14].

Several published studies indicate that smartphones can deliver effective interventions [4-6]. Mateo et al [15] conducted a systematic review and meta-analysis to compare the efficacy of mobile phone apps and other approaches that promote weight loss and increase physical activity. They concluded that mobile phone app-based interventions may be useful tools for weight

loss [15]. Researchers are proposing mHealth apps for many health conditions such as diabetes, dementia, autism, and dysarthria [16-18]. Research has shown that innovations in health technology demonstrated positive behavior changes among patients with type 2 diabetes [19,20].

### **The Diabetes Prevention Program**

Knowler et al [21] conducted a multicenter clinical research study to assess whether moderate lifestyle modifications in the form of dietary changes and increased physical activity could prevent or delay the onset of type 2 diabetes [21]. They concluded that the lifestyle intervention was almost twice as effective at reducing the risk of developing type 2 diabetes as the pharmacological treatment [21]. The results of the study provided a clinical foundation for DPP programs. A study by Hamman et al [22] stated that for every kilogram of weight loss, there was a 16% reduction in type 2 diabetes risk among individuals with prediabetes. Following these findings, the Centers for Disease Control and Prevention (CDC) launched the National Diabetes Prevention Program (NDPP), which includes a lifestyle modifications curriculum that can be delivered setting or online.

The NDPP curriculum consists of an intensive 16-week intervention that uses an evidence-based curriculum, health coaching, social support, and self-monitoring tools to initiate and sustain health behavior changes [23]. The 16-week high-frequency core intervention is followed by 8 months of complimentary maintenance programming to sustain the new lifestyle modifications.

In community-based programs, small groups of at-risk individuals meet on a weekly basis to engage in the curriculum, and work with a trained DPP educator who facilitates the program. The small group setting gives participants the opportunity to express empathy, offer support, and seek support, which are crucial components to behavior change. The group dynamic enables flexibility and tailorability to make the program relevant to each participant. Social support also creates a sense of accountability to others in the group.

The first 8 weeks of the 16-week core curriculum focus on basic tenets of healthy eating and physical activity, while the second half of the core 16-week CDC curriculum focuses on the environmental and social triggers that impact health behavior [24]. Participants are asked to track their food and physical activity daily using paper-based tools and measure their weight weekly at each class. Throughout the 16 weeks, participants aim to lose 5%-7% of their body weight and engage in at least 150 minutes of moderate physical activity each week [24]. The CDC's NDPP [23] has established a clinical basis for implementing lifestyle interventions in individuals with prediabetes as a reliable and sustainable method of preventing, reversing, or delaying the onset of type 2 diabetes [25].

### **Transform—A Digital Diabetes Prevention Program**

Blue Mesa Health, a global digital health company based in New York City, adapted the CDC's DPP to a digital model to enable a scalable, convenient, and flexible delivery of the evidence-based program. Transform integrates interactive mobile computing (eg, smartphone app), wearable tracking

devices (eg, activity tracker), remote health monitoring hardware (eg, digital scale), and professional health coaches to effectively address the complex factors that impact behavior. Transform is a 12-month intervention that uses the same two-phase program structure as the CDC's program: a 16-week high-frequency core

intervention followed by 8 months of complimentary maintenance programming to support the new health behaviors. The program components are described in detail below and outlined in Figure 1.

**Figure 1.** Transform components: a smartphone app with an interactive curriculum, digital tracking and communication tools, a wireless scale, a professional health coach, a private peer community, and an activity tracker.



### ***Personalized Health Coaching***

The program leverages the power of interpersonal connection by matching individuals with DPP-certified health coaches who motivate and guide participants to reach their health goals. Health coaches are trained in diabetes prevention education and use constructs from the Health Belief Model [26] to empower participants to adopt new health behaviors and create long-lasting lifestyle modifications [27]. Through high-frequency interactions and tailored communication, individuals receive empathy and support from their coach as they incorporate new habits into their lives.

Health coaches serve an important moderating and facilitating function by communicating with participants via private messages or calls. They keep participant discussions on track, provide personalized feedback on food logs and physical activity progress, and conduct individualized coaching sessions using specialized techniques such as motivational interviewing.

### ***Diabetes Prevention Program Curriculum***

The DPP curriculum is presented in a digital format via a smartphone app and includes survey questions, quizzes, and free-response questions. One lesson per week is “unlocked” each Sunday morning in the first 16 weeks, and participants are encouraged to complete the lessons at their convenience within the week. Quiz responses and free responses are shared with the health coach. Lessons are considered complete once a participant completes the quiz.

### ***Digital Tracking Tools***

In addition to a wearable tracking device and a digital scale, a photo-enabled food diary facilitates tracking of eating behaviors. Participants are asked to track their food intake by taking a picture of each meal, snack, or drink and uploading it to the app. The health coach reviews the tracking weekly and provides feedback. Food tracking enables participants to learn new information and tools to guide their eating patterns and plan meals. Over the course of the program, participants are encouraged to make each meal resemble MyPlate [28].

### ***Group Support***

To recreate the experience of a group dynamic, which is a core component of the in-person DPP, participants are placed into private chat groups within the smartphone app. An in-app group discussion allows participants to post questions, reply to comments, and share their experience and progress. This component of the Transform program is informed by constructs from Social Cognitive Theory, which empowers participants to improve self-efficacy, increase engagement, and influence behavior [27].

Group discussion is asynchronous, rather than live, to make the intervention more flexible and convenient.



## Objectives

In this study, we aimed to examine the effectiveness of a novel digital DPP (Transform) on weight, BMI, exercise frequency, and work absenteeism in a sample of adults with prediabetes.

## Methods

### Design and Setting

The study is a secondary analysis of data collected via the Transform DPP. Deidentified data that were collected at baseline and 4 months were analyzed. Transform participants were recruited via a marketing channel partner. Participants completed an online eligibility survey that was adapted from the CDC prediabetes screening survey [23]. Eligible participants completed a baseline questionnaire and a 4-month follow-up questionnaire. The questionnaires were adapted from the World Health Organization Health and Work Performance Questionnaire [29] and the National Health and Nutrition Examination Survey [30]. The end of the fourth month was a relevant time point because it marked the end of the first phase (core) of the 12-month DPP.

### Eligibility Criteria

Participants were eligible for the study if they met the following inclusion criteria: score  $\geq 9$  on the online survey adapted from the CDC prediabetes screening tool [23] or indication of prediabetes diagnosis through a recent blood test (within the last 12 months); BMI  $\geq 25$  kg/m<sup>2</sup> or  $\geq 23$  kg/m<sup>2</sup> if self-identified as Asian; age  $\geq 18$  years; indication of readiness to change based on additional survey questions [31]; and completion of the 4-month follow-up survey and record of body weight during week 16 of the Transform program.

Participants were excluded from the study if they had a BMI  $< 25$  kg/m<sup>2</sup>; were  $< 18$  years of age; failed to meet at least one of the following criteria: (a) screened as high-risk according to the American Diabetes Association [32] or CDC prediabetes screening tool [23] or (b) self-reported as positive for prediabetes, according to a blood test within the last 12 months; or did not consent for their data to be used for research.

### Measures

Once the participants were accepted into the program, they completed an online baseline health behavior survey to assess their current physical activity, diet, sleep, work performance, and general health status. Participants received a series of onboarding emails and were mailed packages to introduce them to the program. The packages included a wireless scale by

BodyTrace, Inc, and a wearable activity tracker by Fitbit, Inc (model: Flex 2). Weight was measured by the wireless scale and height was self-reported; weight and height were both used to calculate BMI. After 4 months, participants completed an online follow-up survey. Four outcomes were assessed: weight, BMI, exercise frequency, and work absenteeism. Work absenteeism was adapted from the World Health Organization Health and Work Performance Questionnaire [29]. Subjects answered the following question: "Think of your work experience over the past 4 weeks (28 days). In the space provided below, type the number of entire workdays missed because of problems with your physical or mental health." Each measure was calculated as the difference between scores at baseline and 4 months. Participants did not receive an incentive to complete the follow-up survey.

### Ethics

Solutions Institutional Review Board, an independent ethics review company (Little Rock, AR and Yarnell, AZ), reviewed and approved this study.

### Statistical Analysis

Descriptive statistics (mean and SD for continuous variables; frequency and percentage for categorical variables) were used to describe participant demographics. Four paired-samples *t* tests were used to compare the baseline mean BMI, exercise frequency, and work absenteeism with the means at the 4-month follow-up. Analyses were conducted using IBM SPSS Statistics, version 23 (IBM Corp, NY). A *P* value  $< .05$  was considered statistically significant for all tests.

## Results

### Demographics

Of the 1183 individuals who enrolled in the Transform program and completed the baseline survey, 27 participants did not give consent for their data to be used for research purposes. From the participants' interaction with their coach data, 10.5% (124/1183) of the participants were lost to follow-up. Approximately 23% ( $n=273$ ) of the participants completed the online follow-up survey at 4 months. This response rate is consistent with other studies using online surveys [33].

The current analysis included all participants that completed the 4-month follow-up survey. A total of 273 subjects were included in the analysis. Of these, 70.3% were female. The mean age of the sample was 54.01 (SD 11.33) years. Participants were primarily white (74%; Table 1).



**Table 1.** Participant demographics (N=273).

Characteristic	Value
Age in years, mean (SD)	54.0 (11.3)
Sex (female), n (%)	192 (70.3)
<b>Ethnicity, n (%)</b>	
White	202 (74)
Asian	16 (5.9)
Black	14 (5.1)
Other	41 (15)

## Outcomes

### Weight

We observed that the average weight declined by 6.5%. Participants' mean weight was 205.1 lbs (SD 46.5) at baseline and 191.79 lbs (SD 39.6) at 4 months. There was a statistically significant mean decrease of 13.3 lbs ( $P<.001$ ).

### Body Mass Index

The number of participants with a recorded BMI at 4 months was 272. There was a significant difference in BMI scores from baseline (mean 32.9 kg/m<sup>2</sup>, SD 6.4 kg/m<sup>2</sup>) to 4 months postintervention (mean 31 kg/m<sup>2</sup>, SD 7.3 kg/m<sup>2</sup>). This was a mean decrease of 1.9 kg/m<sup>2</sup> ( $P<.001$ ).

### Exercise Frequency

Data on exercise frequency were available for 202 participants. There was an increase of 1.7 days per week in exercise frequency from baseline (mean 2.4 days, SD 1.8 days) to 4 months (mean 4.1 days, SD 1.7 days;  $P<.001$ ).

### Work Absenteeism

Work absenteeism data were available for 167 participants. There was a significant difference in the scores from baseline (mean 0.9 days, SD 1.2 days) to 4 months (mean 0.5 days, SD 1.1 days;  $P<.001$ ). On an average, participants decreased their work absenteeism by almost half a day per month.

## Discussion

### Principal Findings

This secondary analysis demonstrates that adults with prediabetes who used a novel and individualized digital diabetes prevention program had significant reductions in BMI, weight, and work absenteeism. They also demonstrated a significant increase in exercise frequency at the end of the 4-month study period. This strongly suggests that the Transform digital DPP is an effective tool to drive positive changes in lifestyle behaviors associated with prevention of diabetes.

The Finnish National Diabetes Prevention Program implemented its DPP program in-person through clinics [34]. They were able to achieve an average weight loss of 1.2% among 919 participants, which is less than the weight loss recorded in our study. Although this study supports the findings of other digital interventions targeting diabetic patients [35,36], the current

study utilizes a comprehensive digital DPP targeting adults with prediabetes.

Among participants with prediabetes using the Transform DPP, the mean weight declined by 6.5%. This amount of weight loss can be interpreted as a clinically significant reduction in diabetes risk. According to Knowler et al, 5% to 7% of body weight loss reduces the risk of developing type 2 diabetes by 58% in adults with prediabetes and by 71% for people over 60 years old [21]. Additionally, Hamman et al [22] stated that for every kilogram of weight loss, there was a 16% reduction in diabetes risk. Colditz et al [37] noted that loss of 1 kg of weight was associated with a 10% reduction in diabetes risk.

### Limitations and Strengths

This study was observational and not experimental. It lacks a control group, which may help in addressing possible confounders. This study does not investigate the individual contribution of each program component on the outcome variables. Another limitation was the reliance on self-reports of exercise frequency and work absenteeism. Bias in self-reported physical activity can be avoided in the future by using data from an activity tracker.

The main strength of this study is that it is a secondary analysis of real-world implementation of the intervention. Participants did not receive an incentive to complete the follow-up survey. A benefit of real-world evidence is the generalizability of the outcomes.

### Future Research

Data on outcome sustainability after 4 months were not collected in this analysis. Future studies should examine 12-24 months of follow-up data to address the sustainability of behavior change following the intervention. Future research should include an experimental study to assess possible confounding variables including ethnic origin, education, socioeconomic factors, gender, and other factors related to the outcomes such as reduction in hemoglobin A1c levels. Future research would benefit from the inclusion of an economic analysis of the impact of the Transform DPP and should consider both the direct and indirect costs.

### Conclusions

Transform, a digital DPP adapted from the National Diabetes Prevention Program, was developed to prevent or delay the onset of type 2 diabetes in adults with prediabetes. Transform incorporates interactive mobile computing, remote monitoring,

health coaching, evidence-based curriculum, behavior tracking tools, health coaching, and online peer support to prevent or delay the onset of type 2 diabetes. We observed that the Transform DPP significantly reduces BMI, body weight, and work absenteeism and increases exercise frequency. The study findings highlight the effectiveness of the Transform program.

### Conflicts of Interest

Blue Mesa Health funded this study. MN is a full-time employee and has equity in Blue Mesa Health. MN was not involved in the analysis or reporting of the data. MA, an independent scientific consultant, was provided with the raw deidentified data to perform statistical analyses.

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## Abbreviations

- BMI:** body mass index
- CDC:** Centers of Disease Control and Prevention
- DPP:** diabetes prevention program
- IDF:** International Diabetes Federation
- mHealth:** mobile health
- NDPP:** National Diabetes Prevention Program
- PDA:** personal digital assistant

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