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SYMPOSIUM

DiAs User Interface: A Patient-Centric Interface for Mobile Artificial Pancreas Systems

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Abstract

Background:

Recent in-hospital studies of artificial pancreas (AP) systems have shown promising results in improving glycemic control in patients with type 1 diabetes mellitus. The next logical step in AP development is to conduct transitional outpatient clinical trials with a mobile system that is *controlled by the patient*. In this article, we present the user interface (UI) of the Diabetes Assistant (DiAs), an experimental smartphone-based mobile AP system, and describe the reactions of a round of focus groups to the UI. This work is an initial inquiry involving a relatively small number of potential users, many of whom had never seen an AP system before, and the results should be understood in that light.

Methods:

We began by considering how the UI of an AP system could be designed to make use of the familiar touch-based graphical UI of a consumer smartphone. After developing a working prototype UI, we enlisted a human factors specialist to perform a heuristic expert analysis. Next we conducted a formative evaluation of the UI through a series of three focus groups with $N = 13$ potential end users as participants. The UI was modified based upon the results of these studies, and the resulting DiAs system was used in transitional outpatient AP studies of adults in the United States and Europe.

Results:

The DiAs UI was modified based on focus group feedback from potential users. The DiAs was subsequently used in JDRF- and AP@Home-sponsored transitional outpatient AP studies in the United States and Europe by 40 subjects for 2400 h with no adverse events.

Conclusions:

Adult patients with type 1 diabetes mellitus are able to control an AP system successfully using a patient-centric UI on a commercial smartphone in a transitional outpatient environment.

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Abbreviations: (AP) artificial pancreas, (BG) blood glucose, (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (DiAs) Diabetes Assistant, (IOB) insulin on board, (SC) subcutaneous, (UI) user interface, (UVa) University of Virginia

Keywords: artificial pancreas, DiAs, graphical user interface, type 1 diabetes

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Introduction

In health, the human pancreas secretes insulin and other hormones to maintain blood glucose (BG) at a safe level. A healthy endocrine system automatically responds to disturbances such as eating and physical exercise without requiring the person to exert any conscious control. Much of the burden of type 1 diabetes stems from the requirement that people with diabetes must actively manage their BG level through insulin injection, diet, and exercise. An ideal artificial pancreas (AP) system worn by a type 1 diabetes patient would have *no* user interface (UI). It would continuously measure BG and would inject insulin, and possibly other hormones, to maintain normoglycemia unobtrusively without requiring *any* attention from the user. This type of AP system does not yet exist. Nevertheless, the AP has made significant progress since the 1970s when the possibility for external BG regulation was first demonstrated by studies using intravenous BG measurement and intravenous infusion of insulin and glucose.[1–3] Although these systems resulted in excellent BG control, they were cumbersome and unsuitable for long-term or outpatient use.[4,5] With the advent of minimally invasive subcutaneous (SC) continuous glucose monitoring (CGM), increasing academic and industrial effort has been focused on the development of SC–SC AP systems, using CGM coupled with continuous subcutaneous insulin infusion (CSII). Following the pioneering work of Hovorka and coauthors[6] and Steil and coauthors,[7] the JDRF AP Project was initiated in 2006, sponsoring several centers in the United States and Europe to carry out closed-loop control research.[8] In 2008, the National Institute of Diabetes and Digestive and Kidney Diseases launched an AP initiative, and in 2010, the European AP@Home consortium was established. By 2010, the AP had become a global research topic engaging physicians and engineers in unprecedented collaboration. Key milestones of this development are described elsewhere.[9]

A large volume of literature exists discussing the key components of AP design: insulin pump,[10–13] CGM,[14–18] and various types of control algorithms ranging from relatively straightforward proportional-integral-derivative controllers[7,19] to complex model-predictive algorithms[20–25] and other techniques.[26] These methods have been described in extensive reviews.[27–30] Between 2008 and 2011, promising results from inpatient AP studies were reported by several groups.[19–21,23–26,31–33] Most of these studies pointed out the superiority of AP over standard CSII therapy in terms of (i) increased time within target glucose range (typically 70–180 mg/dl), (ii) reduced incidence of hypoglycemia, and (iii) better overnight control. Two of these studies[23,32] had state-of-the-art randomized crossover design but lacked automated data transfer—all CGM readings were transferred to the controller manually by the study personnel, and all insulin pump commands were entered manually as well.[34] Automated communication between CGM devices, insulin pumps, and control algorithms was made possible in 2008 when a research platform—the Artificial Pancreas System (APS)—was introduced.[35] The APS enabled several inpatient closed-loop control trials.[20,21,25,33,36] One outpatient study was reported where an AP system was taken into the ambulatory setting of a diabetes camp.[37] It is important to note, however, that none of these previous studies had an AP system suitable for outpatient use. The critical missing features were portability and UI designed to be operated by the patient.

The AP's transition to portability and ambulatory use began in 2011 with the introduction of Diabetes Assistant (DiAs), the first portable outpatient AP platform. Diabetes Assistant was developed by our group at the University of Virginia (UVa), and its design specifications were detailed in a patent application published in 2012.[38] In October 2011, DiAs was used in two pilot trials of portable outpatient AP done simultaneously in Padova, Italy, and Montpellier, France.[39] These 2-day pilot trials enabled a subsequent multisite feasibility study of ambulatory AP, which was completed at UVa, Padova, Montpellier, and the Sansum Diabetes Research Institute, Santa Barbara, CA.[40] A second randomized crossover trial testing the efficacy of the DiAs was reported at the 2013 American Diabetes Association Scientific Sessions.[41] These studies concluded that the DiAs is a feasible prototype for a portable outpatient AP. For the first time, the patient was put in charge of the communication with an AP system via a UI specifically designed for patient interaction.[42] In this article, we outline the interface development process and address the question of how to design an AP UI that allows the patient to think less about their diabetes while keeping them safe and in good glycemic control. We believe this is a central challenge for the transition of the AP to home use.

Method

Most modern AP systems include the following components:

- SC CGM devices,
- SC infusion pumps for delivery of insulin and other hormones,
- BG meter (for CGM calibration and meal boluses),
- Processing platform (control algorithm, communication, and storage), and
- UI.

The form that an AP system takes depends upon the details of its processing platform and the way in which it communicates with the other devices. Most current AP systems include SC CGM devices and pumps and use either a smartphone, tablet, or laptop computer as a processing platform. As AP systems transition out of the clinic and into home use, smartphones present a number of advantages over other processing platforms. They are inexpensive, highly portable, and power efficient and support a variety of wireless protocols suitable for device connectivity. Perhaps most importantly, the graphical, touch-enabled, software-driven UI of the modern smartphone is familiar to most people and provides the possibility of an AP UI that is fully functional while still being simple and safe. Regardless of the choice of processing platform all AP UIs need to

- Convey information that is understandable at a glance, presenting additional detail as required;
- Alert the user immediately to potentially dangerous conditions; and
- Present clear controls to start and stop operation, change operating mode, deliver insulin, and configure the system.

In this article, we focus on smartphone-based AP systems and use the example of the UVa DiAs platform to examine AP UI design choices, user reactions, and ways in which the UI may be improved.

Smartphone Operating System and Diabetes Assistant Platform

Diabetes Assistant is a *dedicated AP platform*, meaning that it is an AP system that happens to use a smartphone, rather than being a smartphone with AP "apps" installed. Diabetes Assistant is built atop the Android mobile operating system, and the open source nature of Android makes it possible to modify the behavior of the operating system to support this type of use. Smartphone functions not essential for AP operation are disabled or removed. The telephone, short message service messaging, application store, games, music, video, and web browser applications are disabled, and operating system internals have been modified to block loading of unapproved modules. The DiAs is a *platform* for AP development and testing rather than a complete AP system. **Figure 1** is a block diagram showing DiAs software as a network of task-specific modules, some of which are user replaceable such as the AP controller, constraint service, meal service, and safety module. Because of this configurability, the operation of an AP system built using DiAs will depend upon the characteristics of the particular AP controller and other user-replaceable modules installed.

The UI module is a DiAs system application that always has control of the touchscreen. Smartphones include one or more buttons for switching between applications or navigating the UI within an application. In order for the behavior of these buttons to "make sense" within the DiAs UI, we modified Android to disable the recent screens button and to change the operation of the home and back buttons (**Figure 2**, see orange rectangle at far right marked group 1) to bring the user to the DiAs Home Screen.

In addition to the graphical display, audio output is an important part of the AP UI. If the DiAs determines that a hypoglycemia event is imminent and cannot be prevented by halting insulin delivery, it illuminates the red hypoglycemia

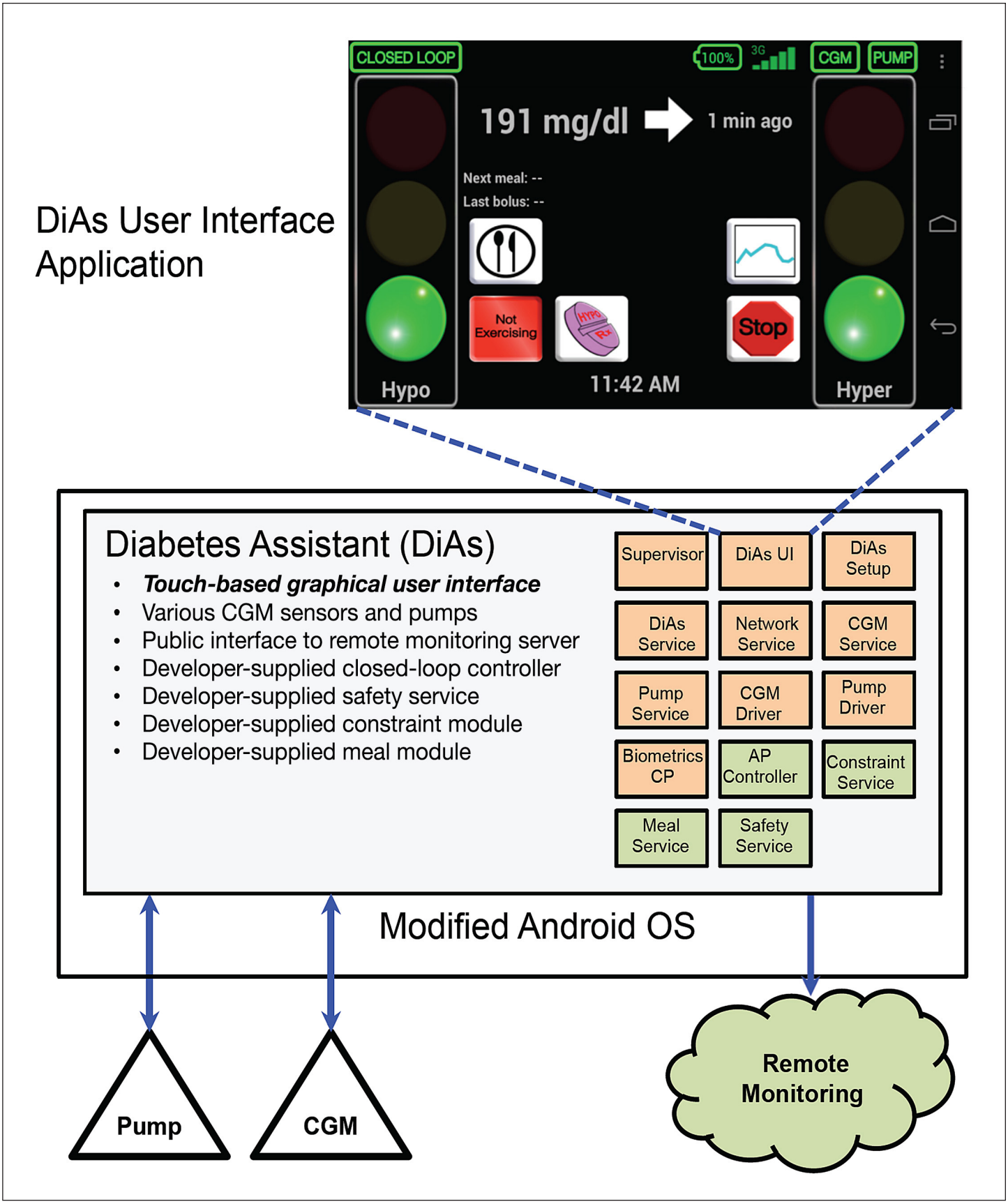

Figure 1. The DiAs software architecture. CP, content provider; OS, operating system.

stoplight and plays an audible alarm in order to get the attention of the patient. In a standard smartphone, an audio alarm can effectively be disabled either by turning the volume key all the way down, by adjusting the sound settings, or by plugging a headset into the audio output port. Again, having open access to the Android source permitted us to disable all of these means of blocking audio output in the case of a hypoglycemia alarm, ensuring that the alarm is played when needed to attract the attention of the patient.

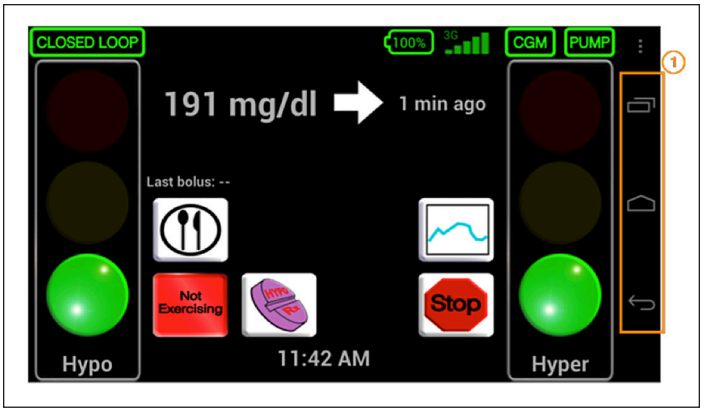

Figure 2. DiAs home screen, closed loop.

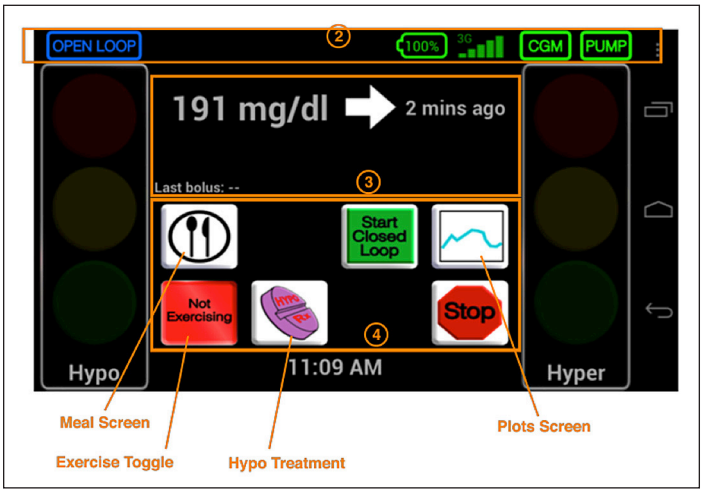

Figure 3. DiAs home screen, open loop.

Diabetes Assistant User Interface Overview

The DiAs UI main screen (**Figures 2** and **3**) displays

- Subject information such as CGM, current hypoglycemic and hyperglycemic risk, and the most recent bolus and
- System status, including AP mode, CGM value and time since last reading, pump status, phone battery level, and current time.

The UI main screen accepts input through smartphone buttons (**Figure 2**, see orange rectangle marked group 1) and touchscreen buttons in the central panel (**Figure 3**, see orange rectangle marked group 4), which become available based on CGM and pump device connectivity and the *mode*. The DiAs is always in one of five modes as indicated by color coded icons:

- Stopped (red): no insulin delivery
- Open loop (blue): insulin delivered based on CSII basal profile
- Closed loop (green): insulin delivered based on recommendations of AP controller
- Safety only (purple): insulin delivered based on CSII basal profile but may be attenuated based on hypoglycemic risk
- Sensor only (yellow): no insulin delivery, CGM data are received

The mode depends upon the status of the external CGM and pump devices and user commands. Any mode involving insulin delivery (open loop, closed loop, safety only) will require pump connectivity while other modes require recent CGM data (closed loop, safety only, sensor only) in order to be active. The system will always begin in stopped mode, and the user can switch to stopped mode from any other operating mode. The control button section of the screen (**Figure 3**, group 4) displays buttons effecting all permissible mode transitions. In **Figure 3**, the AP is in open-loop mode and CGM data are available, so it is possible for the user to switch to closed-loop or stopped mode.

The central portion of the screen can display additional panels, including plots of CGM and infused insulin (**Figure 4**) and a meal bolus calculator (**Figure 5**). The UI occupies the entire screen in landscape (horizontal) mode in order to maximize the size of the hypoglycemia and hyperglycemia traffic lights indicating the subject's current level of risk. The risk estimates are calculated by the DiAs safety module based on CGM data and insulin infusions. The traffic lights are always visible during normal operation and are illuminated in closed-loop, safety only, and sensor only

modes when the system has access to CGM data. They are intended to permit the patient to determine at a glance whether any user intervention is necessary:

- Green: Risk low—no user intervention required
- Yellow: Risk moderate—in closed-loop modes, the system is modulating insulin delivery
  - Hypoglycemia: if in closed-loop or safety only mode, the insulin infusion rate is reduced
  - Hyperglycemia: if in closed-loop mode, insulin infusion is increased
- Red: Immediate risk—user intervention is required
  - Hypoglycemia: if in closed-loop mode, insulin infusion has been stopped but hypoglycemia is unavoidable, treat immediately
  - Hyperglycemia: check the insulin pump and infusion site.

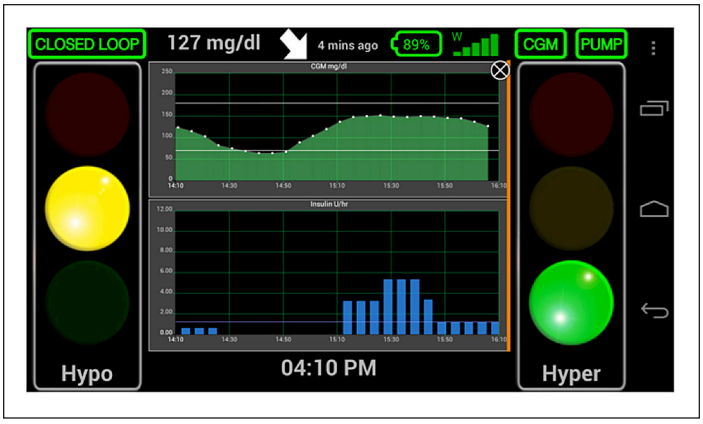

Figure 4. DiAs plots screen.

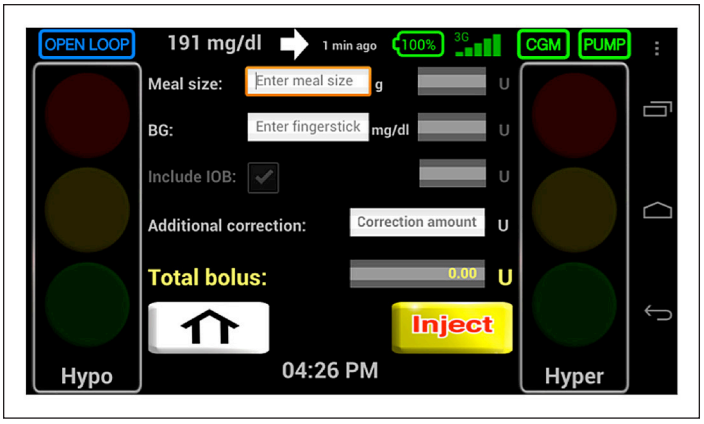

Figure 5. DiAs meal screen.

At the top of the main screen (**Figure 3**, group 2) is a status bar showing AP mode, smartphone battery level, wireless data connectivity (for remote monitoring and data collection), CGM status, and pump status. The CGM indicator light is green if CGM data have been collected recently, and the pump light is green if a pump is connected and ready to receive an insulin delivery command. The pump indicator displays the word "busy" in yellow while the pump is in the process of delivering insulin. The AP mode determines how the DiAs AP will respond to inputs and what control action—if any—it will attempt. Below the status indicators (**Figure 3**, group 3), the DiAs UI displays the most recent CGM value, a trend arrow, and how long ago the value was received. Also in the upper center of the screen is an indication of the most recent bolus (nonbasal insulin) delivered by the system. At the bottom center of the screen is the current time.

The exercise button (**Figure 3**, group 4) is a toggle switch that can be used to indicate to the system that the user is involved in physical exercise. Pressing this button causes a marker to be set indicating time intervals during which the subject is exercising. This information may be used as an input to the AP controller, safety service, or other user-replaceable modules. The hypoglycemia button is pressed to indicate that the patient has treated themselves for a hypoglycemia event. This also sets a time stamp in the database that informs the behavior of other system modules.

Pressing the plots button causes the center portion of the screen (**Figure 3**, groups 3 and 4) to be replaced by plots of CGM and infused insulin. The control buttons are covered by the plots, but the most recent CGM value, trend arrow,

and delivery time appear, reduced in size, at the top of the display. The upper plots panel shows a trace of the most recent CGM trace in milligrams per deciliter with a fill color that corresponds to the AP mode at the time that the CGM value was received. The lower panel shows the recent insulin delivery history with basal insulin shown as blue bars. In **Figure 4**, basal insulin delivery has been modulated by the AP controller and the safety system in order to respond to high and low values of BG, respectively. The CSII basal profile for the displayed time period appears as a horizontal line near the bottom of the display.

Pressing the meal screen button from the DiAs main menu triggers a customizable screen that permits the patient to request the delivery of meal insulin. **Figure 5** shows a version of this screen that provides a calculator enabling the user to calculate a total meal bolus by considering grams of carbohydrate, current BG as measured by a meter, insulin on board (IOB), and an additional relative correction that may be positive or negative. When the user presses the inject button, the bolus is passed to the DiAs safety system for evaluation prior to being sent to the pump for delivery.

Results

After developing the prototype DiAs UI, we conducted an expert heuristic analysis in order to identify obvious shortcomings. This evaluation resulted in a number of modifications to layout, appearance, and operation, including

- Making the back button work in a consistent and logical fashion,
- Making the CGM text larger,
- Switching to dark text on light background where possible, and
- Requiring confirmation after pressing buttons to eliminate undesired actions.

With a new version of the UI that incorporated the most pressing recommendations from the heuristic evaluation, we conducted three focus groups. There were a total of $N = 13$ type 1 diabetes patients, 11 females and 2 males, aged 29 to 64 years, with a time since diagnosis ranging from 4 to 28 years. All participants wore insulin pumps, and 10 were using a continuous glucose monitor at the time of the focus group. Each group was directed by a moderator who read a common introduction, after which the participants were free to ask questions at any time. A second moderator then read a description of planned outpatient clinical trials, after which the moderator made a visual presentation describing all features of the system and asked some targeted questions. Finally, the participants filled out a brief questionnaire that asked for demographic information, a rating of different aspects of the system, and final comments.

Rating Summary and Analysis

Table 1 summarizes responses to the written questions and indicates that although the participants generally liked the AP UI, they felt that it lacked needed features and functionality. The responses to questions from the moderator resulted in a number of feature requests and functionality changes that were incorporated into the DiAs UI, including

- Displaying the current time on all screens,
- Increasing the maximum bolus size,
- Displaying CGM value and trend at all times (even in stopped mode),
- Making exercise and hypoglycemia treatment buttons available in all modes,
- Displaying IOB on the meal screen rather than on the main screen,
- Never displaying a negative IOB (relative to expected IOB from basal delivery),

- Clarifying how the meal screen performs its bolus calculations,
- Adding a lock screen feature to prevent inadvertent button pushes, and
- Adding a confirmation dialog prior to sending bolus.

Table 1.
Responses to the Questionnaire Provided to the Participants

Question	Lowest	1	2	3	4	5	Highest	Mean
1. Overall, how satisfied are you with the AP system?	Very dissatisfied			1	1	11	Very satisfied	4.77
2. How would you describe the "look and feel" of the AP system?	Very clunky					13	Very professional	5.00
3. How would you describe the "features/ functions" of the AP system?	Limited features	1	2	1	2	7	Fully featured	3.92
4. How would you describe your "understandability" of the AP system?	Not clear			1	2	10	Always clear	4.69
5. How would you describe the "readiness for clinical trial" of the AP system?	Needs change	3	1	1	1	7	Ready to go	3.62

Discussion

In the initial stages of this project, we developed a prototype portable AP system—DiAs—based on a smartphone computational platform. In late 2011–2012, DiAs became the first portable AP used in outpatient trials of closed-loop control. So far, two pilot studies have been completed. These studies enrolled 40 patients with type 1 diabetes who logged over 2400 h of DiAs use in a closed- and open-loop mode of action. The accumulated data not only proved that a contemporary smartphone can run closed-loop control, but contributed to technology refinement and enabled the ongoing planning of a larger multicenter trial of control-to-range at home. A critical element of this progress was the design of a patient-oriented UI. The lessons learned during the design process and from our communication with focus groups and DiAs users reveal some recurring themes regarding AP devices in general and AP UIs in particular:

1. "It needs more features."

There were many requests for features that were prefaced with the statement "My pump/CGM already does this." The expectation seems to be that since the AP includes both a CGM and a pump, it should function like a "super remote control" that consolidates the UIs of each device. Although a smartphone UI could certainly provide this level of functionality, it is also one of the goals of the AP to work *automatically* in order to reduce the burden of diabetes management. The challenge from a UI perspective is to provide a clean and functional AP UI while reassuring early adopters that they are still in control. Which leads us to the next point.

2. "I don't really trust it to control my insulin delivery."

Many of the feature requests were for detailed information about the minute by minute functioning of elements of the system such as the control algorithm, e.g., "How much is the system boosting/attenuating my basal rate at this moment?" Many participants asked the question "How do I know that the AP system is working properly?" This is a natural and quite reasonable question to ask of such a new and still largely unproven technology. Developers of AP systems will need to strike a balance between the "need to know" of people who have been intensively managing their BG for years and the goal of providing a UI that is not so complicated as to be unusable.

3. "I want to consolidate all of my diabetes-related information in one place."

Many patients are trying to keep track of CGM data, insulin pump history, BG meter readings, food journals, and exercise logs, and a smartphone-based AP could be the place to consolidate all this information. Additionally, a smartphone capable of running AP algorithms should be able to provide a better way to estimate meal insulin requirements. This suggests the possibility of the smartphone-based AP as a more general software platform with an ecosystem of diabetes management applications capable of tapping into local and global data from the patient in order to provide a coherent way to manage diabetes-related information.

The focus group feedback makes it clear that while the participants are excited about AP systems and want to be able to make use of this technology, they already have workable methods of managing diabetes in their lives. Designers of AP systems, and their UIs, need to find ways to provide the undeniable benefits of AP technology—such as overnight safety and control—while allowing patients the degree of control that will help them to be safe and comfortable.

One potential way to achieve such a balance is to create a number of UIs with different styles for the same AP device, ranging from minimalist to fully configurable in order to match user preferences. Another possibility is to permit the user to enable or disable certain nonessential UI elements. This level of configurability is common in smartphone applications but is less common in medical-grade software. As more medical applications such as AP systems are developed for smartphones and other portable devices, techniques will need to be developed that simultaneously satisfy the safety and efficacy requirements of medical systems and the consumer's demands for flexibility and choice.

Conclusions

Most current portable AP systems are based on a SC CGM sensor and insulin pump and a smartphone processing platform. Because smartphones are widely used by most adults and also support software-defined UIs, they are a nearly ideal venue for the rapid development of a new generation of AP UIs. Although there will be resistance from those who say that consumer electronics are not suitable for medical applications, we can expect market forces to drive rapid adoption of mobile medical platforms for AP use. As technological developments continue, major portions of AP systems will be absorbed into infusion pumps and other devices, but UIs will continue to require graphical displays. In the short term, this means that smartphones will most likely continue to be used for AP UIs, but smart watches and even eyewear will begin to provide alternative UI platforms.

Experience with the DiAs AP UI has shown that patients can effectively control a smartphone-based portable AP system. Developers of AP UIs are now faced with the challenge and the opportunity of learning from patients what they need in order to make effective use of these promising systems.

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