Novel Interactive Cell-Phone Technology for Health Enhancement

David L. Katz, M.D., M.P.H.,[1] and Bjorn Nordwall, B.A.[2]

Abstract

Self-care is essential in chronic disease management; however, adherence to self-care plans is often far from optimal. Advances in technology can facilitate self-management of chronic disease through patient empowerment and timely feedback. The Confidant system is a novel wireless remote patient monitoring and response system, centered around mobile phone technology, that translates scientifically supported knowledge for chronic disease management into action by providing easily followed daily coaching using the patient's own data. Daily provision of interactive, informative messages removes the burdens of recall, record keeping, decision making, scheduling, and data analysis. A pilot-controlled clinical trial evaluated the feasibility and efficacy of the Confidant system in the management of type 2 diabetes in 15 patients utilizing the cell-phone technology and 15 individuals in a control group (standard type 2 diabetes care). The study demonstrated improved levels of glycosylated hemoglobin, positive changes in diabetes management self-efficacy, and diabetes self-care activities among intervention group patients. A larger trial is now in development to demonstrate the clinical benefit of using the Confidant system among type 2 diabetic patients. This article describes the novel technology and applications of the Confidant system.

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Introduction

Long a disease of great public health importance, type 2 diabetes is now considered epidemic in both children and adults in the United States, due largely to an underlying epidemic of obesity.[1,2] In the United States, it affects 18.2 million people or 6.3% of the population.[3] From 1996 to 2001, diabetes has climbed from the seventh to the sixth leading cause of death,[4] with an increasing number of deaths occurring per year across age and race categories.[5–11] Estimated health care expenditures associated with diabetes include $91.8 billion in direct and $39.8 billion in indirect costs as of 2002.[12] The cause of such high morbidity, mortality, and costs can be mostly attributed to long-term, chronic diabetes-related complications, such as renal disease, coronary heart disease, blindness, and neuropathy.[13]

Lifestyle practices and adherence to prescribed interventions have enormous potential to ameliorate the

course of chronic diseases. Rich and colleagues[14–16] and others[17,18] have shown the clinical and financial benefits of a case management system in congestive heart failure. Similar benefits have been seen with case management in other chronic diseases, such as asthma[19,20] and diabetes.[21,22] The most cost-effective approach to enhanced chronic disease management is improved self-care.[23,24] Chronic diseases associated with unhealthy behavior are prevalent, and medical care is becoming more participatory. In addition, new technology expands what people can do for themselves.[25] Given the costs of care, self-care is becoming the disease management option of choice; however, empowering patients to engage in high-quality self-management has been a largely elusive goal to date.

The prevention of type 2 diabetes complications is substantially dependent on diabetes control. According to the American Diabetes Association, diabetes self-management is an integral component of diabetes care.[26] Improved glycemic control (hemoglobin A1c <7%) has been shown to minimize microvascular complications by decreasing the rates of nephropathy, retinopathy, neuropathy, and cardiovascular disease.[27] Blood glucose can often be controlled by following a careful diet and exercise program, losing excess weight, and taking oral medication.[26] In addition, self-monitoring of blood glucose is imperative in diabetes self-care; these data allow for adjustment in therapy to meet glycemic goals.[27] Maintaining a blood pressure of 130/80 or less can reduce cardiovascular disease by approximately 33 to 50% and can reduce microvascular disease (eye, kidney, and nerve disease) by approximately 33%.[26] Lifestyle modification (exercise, diet control, weight loss, smoking cessation) and nutritional counseling, as well as pharmacologic interventions, can lower blood pressure levels as part of a diabetes self-management plan. The same interventions can help manage cholesterol and lipid levels.

Despite the benefits of adhering to a disease management program for diabetes, national compliance to such programs is not optimal. In 2000, the levels of preventive-care practices among diabetes patients were lower than the national objectives for 2010.[28] A large-scale study determined that half (51.5%) of diabetes patients "always" self-tested as recommended, and only 11.8% completely adhered to a recommended diet. Because self-efficacy is considered a significant predictor of adherence to management plans,[29,30] increasing confidence in self-managing diabetes may be necessary to improve diabetes self-care adherence.

Tailored Diabetes Disease Management

Several tailored, technologically advanced disease management programs for diabetes have been studied and met with moderate success. Glasgow et al.[31] compared an online peer support group and an information-only group (with computer access to relevant articles) to a tailored self-management training (TSM) group that worked with an online "coach" who tailored strategies for each individual to reach dietary goals. Patients could also enter and receive graphical feedback on their blood glucose levels for different times of the day. All groups received Internet-based automated goal setting based on assessment results, identification of barriers and supports, updated diabetes information, and quarterly follow-ups, which produced improvements on behavioral, psychosocial, and biological outcomes from baseline. There was no significant difference between groups, although trends favoring TSM on several outcomes were apparent. Tailoring methods differed somewhat in the German M2DM project, which successfully implemented telemonitoring for physicians; telecare (including message exchange between doctor and patient and physician-supervised care for self-management); remote information access, which allowed providers and patients access to all information in the clinical database; and knowledge management and decision support through tailored alarms and reminders transmitted through cellular phones or email for both providers and patients. Patients participating in the program showed clinical improvement after 6 months of use.[32]

Tailored reinforcement was also used by Durso et al.,[33] who implemented the Personal Diabetes Management Program (PDMP), using cellular phones and the Internet. At predetermined times, the PDMP contacted patients with tailored interactive recorded messages (based on individual needs), which included reminders for performing self-care activities, prompting a call to the provider for medical advice if any symptoms or problems occur, providing health education, and recording personal health data, accomplished by entering the values on a telephone keypad. Data were transferred to a Web site to be reviewed by the provider. A nurse reviewed data provided by the patients and contacted them with feedback and diabetes management changes, if necessary. All participants reported increased awareness of impact of diet, activity, and medication on their diabetes management and some increased daily physical activity levels. Although results were encouraging, several limitations were noted, such as brevity of the study, small number of patients (7), self-reported data, and lack of a control group.

There has been increasing interest in the potential of mobile technologies, such as personal assistants and cell phones, to enhance self-management.[34] Gammon and co-workers[35] showed that a mobile system used to send child blood glucose monitoring data to parents was integrated into their daily activities and reduced parental anxiety. Mobile technologies are able to fulfill many of the same educational and interactive behavioral goals as desktop computers, but because of their ability to use "push" strategies, their unobtrusive nature, and their potential for integration into individual lifestyles and habits, mobile technologies may show greater appeal, feasibility, and utility for patients compared to desktop programs. While much research is needed on the development and testing of mobile technologies, there is agreement that they have great promise to facilitate self-management behaviors.

Description of Confidant Technology

The Confidant system is a novel wireless remote patient monitoring and response system, centered around mobile phone technology, that translates scientifically supported knowledge for chronic disease management into action by providing easily followed daily coaching using the patient's own data. Daily provision of interactive, informative messages removes the burdens of recall, record keeping, scheduling, and data analysis.

The Confidant system collects data from a range of supported home-monitoring devices. Data are collected from the supported devices and sent to a central database server, using standard wireless technologies. Upon receipt of newly submitted patient data, the Confidant server software will generate and send one or more feedback messages directly to the patient's cell phone. The feedback messages are selected by the system based on the patient's currently submitted and recent historic data.

Confidant currently supports several models of glucose meters, a noninvasive blood pressure cuff, and a weight scale. Additional functions include manual entry of daily step count and display of customized questions and collection of patient responses.

The Confidant system consists of two software modules—the collector and the server—and a single hardware module (the connector), which is used to communicate with monitoring devices through a serial data interface.

The Confidant connector is a proprietary hardware component that connects to a supported measurement device using a serial data cable. Data received from the measuring device are converted to the Bluetooth protocol and transmitted wirelessly to the patient's cell phone.

The collector module is a software program that runs on the patient's cell phone. It receives data from the connector (or directly from Blue Tooth-enabled home-monitoring devices) and transmits it to the server over a cellular data (General Packet Radio Service) network. The collector also provides the user interface for operating the system and viewing graphical and text responses sent from the server.

The server module is a software program that runs on standard Web server hardware. The server module receives data sent to it by the collector module and generates customized responses in both graphical and text forms (**Figure 1**). The Confidant server has an Internet (World Wide Web) user interface. Authorized users with a user name and password may view measurement data collected from the medical devices. The patient also has the ability to review prior messages received from the system. Combining these two elements allows the patient to better understand how well they are self-managing their disease.

Messages from the Confidant server to the user are normally sent to the mobile phone as a response to data collection so that each time the user sends collected data to the server, s/he receives a message back within seconds based partially on that data. Messages from the Confidant server to the doctor are sent as an email to an address configured for him/her (note that because many mobile phones take email, the email may be delivered to a phone with this feature or to a more traditional email client) (**Figures 2 and 3**).

All data storage and access conform to U.S. Health Insurance Portability and Accountability Act regulations concerning the privacy and protection of data.

The Evaluation

Phase I of the evaluation, called *Novel Interactive Cell-phone technology for Health Enhancement*, was a controlled clinical trial evaluating the feasibility and efficacy of the Confidant system in the management of type 2 diabetes.[36] Phase I evaluated this innovative technology in a community health center setting. As described previously, 30 subjects participated in the study: 15 in the group who used cell-phone technology (intervention) and 15 in the control group utilizing standard care for
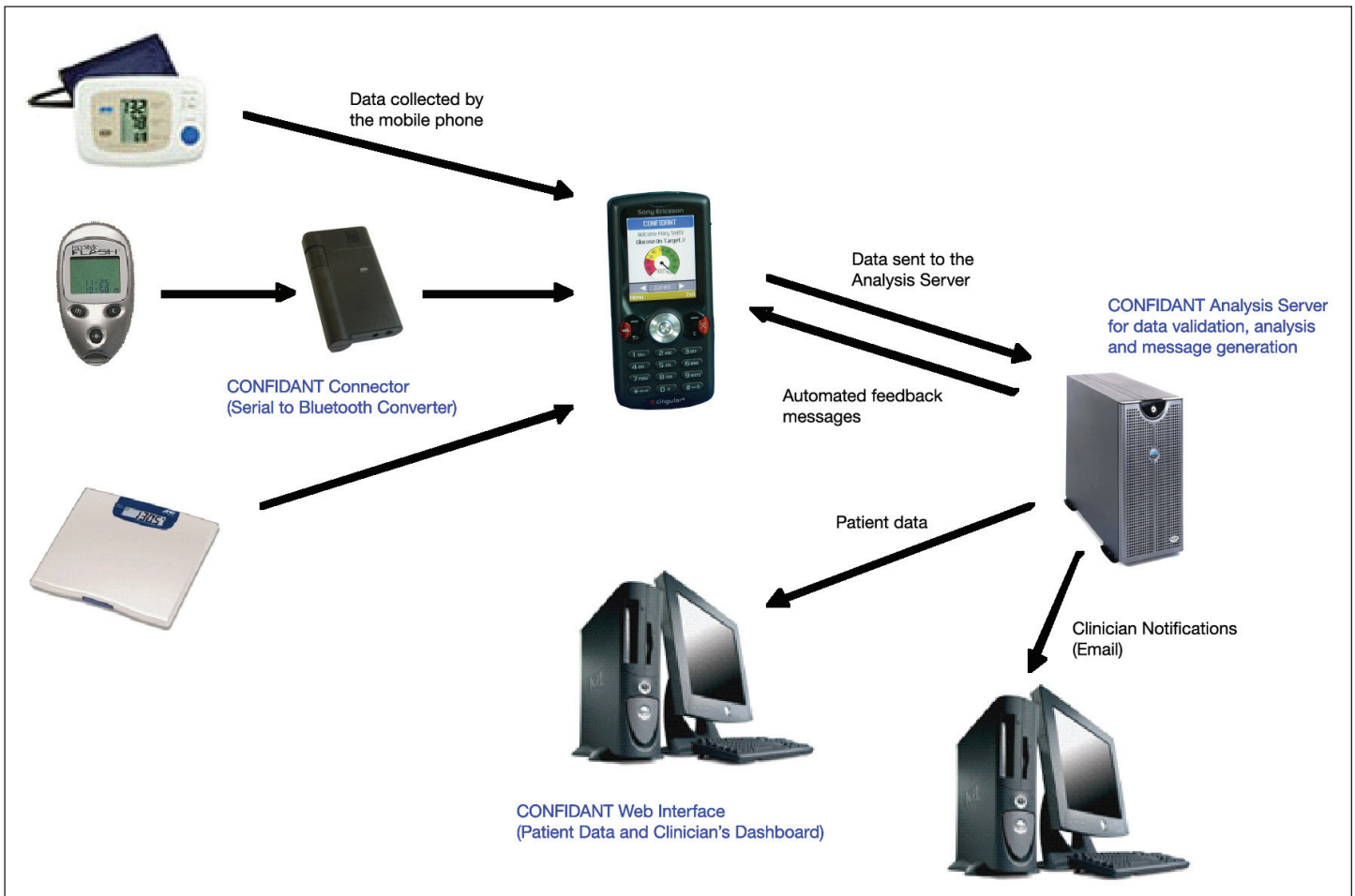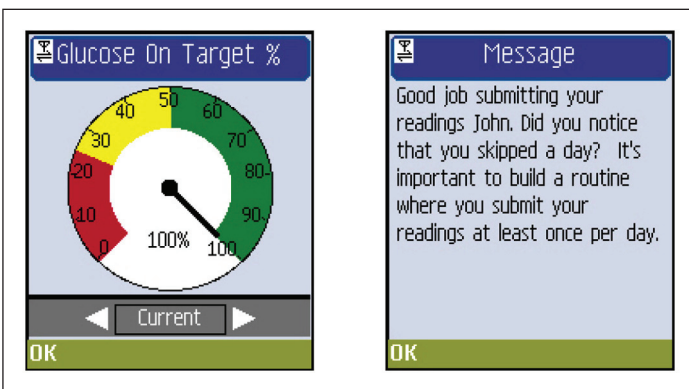
Figure 1. Confidant system.
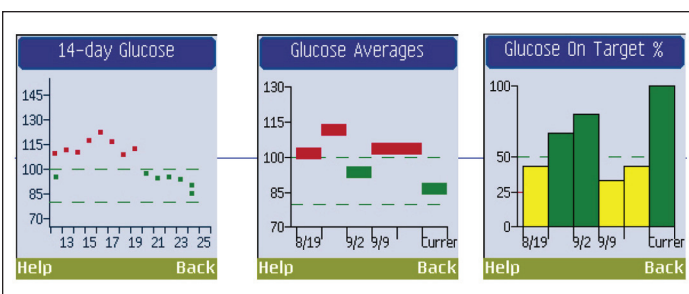

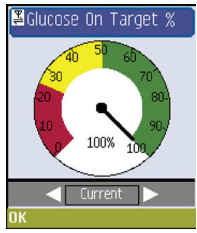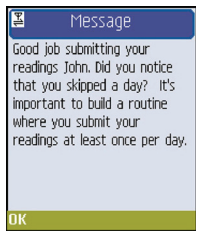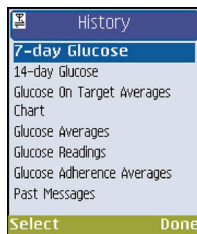**Figure 2**. Examples of automated feedback.

Figure 3. Examples of summarized patient-specific data.

type 2 diabetes. The intervention phase was 3 months long. Phase I was able to establish levels of compliance using the Confidant system and reasons for any problems; satisfaction with the technology based on clinician and patient feedback; and utility of the Confidant system in enhancing diabetes management based on improved levels of glycosylated hemoglobin, positive changes in diabetes management self-efficacy, and diabetes self-care activities among participating patients. Because phase I was pivotal in establishing feasibility and utility of the Confidant system, all the necessary improvements were done to the system in preparation for a phase II trial.

Improvements to the Confidant System

In response to results of the phase I study and in preparation for a phase II trial, Confidant Inc. has made modifications and additions to the system. **Table 1** outlines problems identified in the system through phase I paired with changes that have now been made to the technology and associated procedures.

Table 1.
Improvements to the Confidant System

Problem areas identified by phase I	Improvements in the Confidant system
1. The accelerometer device was very difficult to use: a. The user interface was ungainly b. The batteries did not last very long c. The device tended to pop out of its case and get lost	1. The accelerometer device used in the phase I trial is not being used in the new product. For phase II, a good quality pedometer will be used. The daily step count will be entered by the patient manually.
2. The message(s) did not contain enough useful information: a. They were rudimentary and unintuitive b. The messages only commented on patient compliance with using the system c. Clinicians did not have the ability to provide subjective questions for patients to answer	2. (a and b) The message display interface has been redesigned. It now presents the following three feedback screens: 1. Graphical response screen A graphical response screen displays average reading and adherence values. 2. Text messages Text messages provide customized informational and motivational feedback. 3. History Several views of patient's historic data are now available. (c) Confidant now provides customizable questions that can be configured by the clinician and displayed to the patient during the data collection process. The patient's responses are transmitted to the server for storage, along with monitoring data.

Table 1. (continued)

Problem areas identified by phase I	Improvements in the Confidant system
3. The product was available in English only.	3. The product in phase II will be translated into Spanish, both linguistically and culturally.
4. The Confidant connector device was too large	4. Confidant has redesigned the connector. The new device is significantly smaller and fits inside a typical soft case that can also hold the glucose meter and supplies. The cable is smaller and less obtrusive.

The phase II trial also has the following quality control features built into the design of the intervention. (1) *Problem solving of technological issues*: patient and clinician guides to using the system, a toll-free number to a technician available at convenient times to patients and clinicians 7 days a week, and a Web site with information for the Confidant system are provided. (2) *Clinician–patient interaction*: Confidant's server has always had a Web-based interface allowing the clinician to set patient regimens, reminders, and threshold values for caregiver alerts. A new practice management component (the clinician's dashboard) has been added that provides clinicians with a short list of "problem patients." The dashboard can be customized by the clinician to display patients that are either noncompliant in their self-management or have readings that are consistently outside of preset thresholds. This allows a clinician to quickly discover the few patients that require a more active intervention. By identifying patients that have not been submitting data on a regular basis, the dashboard will also help identify patients that may be experiencing technical problems. (3) *Interaction between Confidant and patients*: When notified by the clinician, Confidant staff will contact patients who have been identified as possibly having technical problems. (4) *Interaction between Confidant staff and clinicians*: Confidant staff will be in ongoing communication with participating clinicians regarding problem solving for any problems or concerns that arise with the system. (5) *Data quality*: Confidant staff will conduct data checks on uploaded data to validate it and make appropriate changes.

In summary, the aim of this technology is to enable the population to benefit from advice tailored specifically to them, without the inconvenience and time constraints involved in personal disease management counseling. Participants utilizing Confidant technology are provided with information about changes that can be made to

improve their diabetes management and receive tailored information based on information received from the Confidant system. Participants' ability to modify their health behaviors has the potential to be enhanced significantly by reducing their risk of diabetes-related complications. The impact of the improvements made in the technology will be examined in a phase II clinical trial now in development.

Disclosures:

David L. Katz is the chief medical officer and chair of the medical advisory board of Confidant, Inc. and Bjorn Nordwall is the president and CEO of Confidant, Inc.

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