ORIGINAL ARTICLE

Artificial Pancreas (AP) Clinical Trial Participants' Acceptance of Future AP Technology

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Abstract

Background: Artificial pancreas (AP) systems are currently an active field of diabetes research. This pilot study examined the attitudes of AP clinical trial participants toward future acceptance of the technology, having gained firsthand experience.

Subjects and Methods: After possible influencers of AP technology adoption were considered, a 34-question questionnaire was developed. The survey assessed current treatment satisfaction, dimensions of clinical trial participant motivation, and variables of the technology acceptance model (TAM). Forty-seven subjects were contacted to complete the survey. The reliability of the survey scales was tested using Cronbach's α . The relationship of the factors to the likelihood of AP technology adoption was explored using regression analysis.

Results: Thirty-six subjects (76.6%) completed the survey. Of the respondents, 86.1% were either highly likely or likely to adopt the technology once available. Reliability analysis of the survey dimensions revealed good internal consistency, with scores of >0.7 for current treatment satisfaction, convenience (motivation), personal health benefit (motivation), perceived ease of use (TAM), and perceived usefulness (TAM). Linear modeling showed that future acceptance of the AP was significantly associated with TAM and the motivation variables of convenience plus the individual item benefit to others ($R^2 = 0.26$, $P = 0.05$). When insulin pump and continuous glucose monitor use were added, the model significance improved ($R^2 = 0.37$, $P = 0.02$).

Conclusions: This pilot study demonstrated that individuals with direct AP technology experience expressed high likelihood of future acceptance. Results support the factors of personal benefit, convenience, perceived usefulness, and perceived ease of use as reliable scales that suggest system adoption in this highly motivated patient population.

Introduction

OUR CLINICAL TEAM AT Sansum Diabetes Research Institute (SDRI) (Santa Barbara, CA) joined with chemical engineers at the University of California Santa Barbara in 2004 to begin work on an artificial pancreas (AP) for people with type 1 diabetes mellitus (T1DM). Even with intensive

insulin treatment administered as multiple daily injections or via a continuous subcutaneous insulin infusion (CSII) pump, people with T1DM may experience significant episodes of hyperglycemia and hypoglycemia. The goal of an AP system is to combine continuous glucose monitors (CGMs) with CSII pumps to control insulin delivery automatically with a mathematical algorithm. This would potentially improve

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This article is dedicated to the memory of Richard Rubin, PhD, CDE, who dedicated his life to people with diabetes and making life with diabetes easier and who guided and encouraged this study.

long-term patient health and reduce the burden of daily management for people with T1DM.¹

Many preliminary AP studies were done at SDRI to lay the groundwork to develop a working AP/closed-loop system.²⁻⁸ Our first closed-loop study at SDRI was done in April 2007; several studies followed this initial closed-loop design with different controller designs but with the common theme of a fully automated closed-loop system.^{9,10} Additional AP studies are being conducted in many other settings, including across the United States, the United Kingdom, The Netherlands, Israel, France, and Italy.¹¹⁻¹⁵ Knowing the importance of human behavior in diabetes management, investigators are now looking at future acceptance of AP technology as well as behavioral and psychological considerations.^{16,17} In an interview and then follow-up survey development study by van Bon et al.,^{16,18} it was concluded that most patients who used

CSII pumps (technology), when provided a written description of an AP system, would likely adopt it.

As of 2004, in total, 49 subjects have volunteered in one or more of the SDRI AP studies. The purpose of this study was to investigate whether participants who have directly experienced AP technology expressed similar attitudes toward future acceptance as those examined in previous studies.^{16,17,19,20} We hypothesized that subjects with T1DM volunteer for AP studies because they believe that the technology will eventually help them achieve better (more stable and within a tighter range of 80–140 mg/dL) blood glucose control and therefore experience improved health and a life more like someone without T1DM. To test our hypothesis we measured current diabetes treatment satisfaction, dimensions of clinical trial participation motivation, and variables of the technology acceptance model (TAM).^{21,22} We chose to

TABLE 1. SURVEY QUESTIONS, CONSTRUCTS, AND RELIABILITY ANALYSIS

<i>Construct</i>	<i>Question</i>	<i>Cronbach's α</i>
Current treatment satisfaction	Prompt: How satisfied are you with your current diabetes medication?	
Satisfaction	Time it takes Convenient it is Easy it is to take medication Painful it is Easy it was to learn to use Easy it is to use Effective it is at minimizing hypoglycemia Effective it is at minimizing hyperglycemia	0.8636
Motivation to participate in clinical trials	Prompt: How much do the following motivate you to participate in an AP research study?	
Altruism	AP technology will benefit others with T1DM Improvement of medical knowledge about T1DM Improvement in health in order to take care of family Participating in research is the right thing to do To give back for good medical care received	0.5232
Monetary incentive	Financial compensation for participation	NA
Personal health benefit	AP technology will increase my quality of life AP technology will increase my lifespan Receiving care from an expert medical team Access to intensive monitoring	0.888
Convenience	Overall length (days) of study Amount of discomfort Location of study Time of day of study Total number of study visits	0.8261
TAM		
Intention to use	How likely are you to change your current diabetes medical management system? Prompt: Compared with current treatment my expectations of AP technology are:	NA
Perceived usefulness	Fewer episodes of hyperglycemia Fewer episodes of hypoglycemia Reduced number of doctor visits Increased quality of life Increased lifespan Improved blood glucose control My life will be more like someone without T1DM	0.8415
Perceived ease of use	Ease of use Reduced discomfort Requires minimal effort	0.7516

AP, artificial pancreas; NA, not applicable; T1DM, type 1 diabetes mellitus; TAM, technology acceptance model.

address these because (1) treatment satisfaction is a known barrier toward future adoption of advanced diabetes management technology,^{20,23} (2) considering the specific patient population relationships between future adoption and clinical trial participation was of interest, and (3) TAM is frequently used in health care as a model to predict the likelihood of a technology's future adoption.²⁰ Specifically, the TAM explains how patients might come to accept, and therefore adopt, novel tools or methodologies. Three key factors of the theory include subjects' perceived usefulness, perceived ease of use, and trust in the technology,^{19,20} and TAM has been used to assess future acceptance of an AP system previously.^{14,17,18} The study end points were completion of the questionnaires, compilation of the answers, and summary of the findings.

Subjects and Methods

Survey design

A questionnaire was developed to learn about variables that might associate with intention to use AP technology in a specific patient population, AP clinical trial subjects. Here the assumption was that intention to use, or technology acceptance, is thought to reliably predict actual use.^{21,22} The 34-item survey contained eight current treatment satisfaction questions,²³ 11 TAM questions,²⁰ and 15 questions assessing clinical trial patients' motivation.^{24,25} A 5-point Likert scale was used. Table 1 lists the 34 items. Patient demographics, self-reported anthropometric and biochemical data, and current diabetes treatment questions, including the use of CGM and CSII pumps, were also collected.

Participants

The study population was subjects with T1DM who participated in SDRI AP studies since 2004. All 49 clinical trial participants were called via phone. If contact was possible, subjects were invited to participate. Participants were explained the nature and purpose of the study, and each subject had the opportunity to ask questions. Those subjects who verbally agreed to take part, via an approved waiver of a formal informed consent process by the Cottage Health System Institutional Review Board, were e-mailed a link to complete the survey online.

Statistical methods

The statistical analysis was performed using the R Statistical and Rcmdr packages (www.r-project.org/). Frequencies or descriptive statistics were run for demographic information, anthropometric plus biochemical data, and current diabetes treatment. To test for gender differences, χ^2 tests were conducted. Questionnaire scales with three or more items were checked for reliability using Cronbach's α . When appropriate (Cronbach's $\alpha \geq 0.7$ threshold), the relationship of the factors and/or individual items to the likelihood of AP technology adoption was explored using multiple linear regression. Two-tailed values of $P \leq 0.05$ were considered statistically significant.

Results

Sample characteristics

Forty-seven of the 49 subjects (two subjects were lost to follow-up) since 2004 were contacted. All 47 agreed to par-

TABLE 2. SUBJECT CHARACTERISTICS

Variable	n	Mean $\pm$ SD or frequency count
Age (years)	36	46.6 $\pm$ 12.5
Gender	36	25 females:11 males
Education	36	11 some college, 1 AA, 18 BA, 3 MA, 3 Prof/Doc
Years with T1DM	35	28.5 $\pm$ 15.5
Employment	36	21 FT, 2 FT-H, 5 PT, 3 S/I, 5 R
IP use	36	32 yes/4 no
CGM use	36	15 yes/21 no
HbA1c (%)	33	7.1 $\pm$ 1.1
BMI [(lbs/in ²) $\times$ 703]	35	26.0 $\pm$ 7.6
PSP	36	29 yes/7 no

AA, associate's degree any kind; BA, bachelor's degree any kind; BMI, body mass index; FT, full-time; FT-H, full-time in home; HbA1c, glycosylated hemoglobin; IP, insulin pump; MA, master's degree any kind; Prof/Doc, professional or doctorate any kind; PSP, previous study participation other than AP Sansum Diabetes Research Institute clinical trials; PT, part-time; R, retired; S/I, student/intern; T1DM, type 1 diabetes mellitus.

ticipate and were sent an e-mail link to complete the survey. Thirty-six subjects (76.6%) completed the survey. Table 2 presents study participant characteristics. A χ^2 test revealed no significant gender differences, so all subsequent analyses were performed using the complete dataset (data not shown). Of note is that the majority of subjects used a CSII pump (86.4%, $n = 32$), and fewer than half or 40.5% ($n = 15$) used a CGM system as well.

Reliability of questionnaire

The reliability of the majority of scales was good. Table 1 shows Cronbach's α with scores >0.7 for all constructs except altruism ($\alpha = 0.53$) under the motivation model, although the monetary incentive variable could not be tested using Cronbach's α as it was represented by a single question. This was similarly true for the intention to use item; however, for other factors of TAM, perceived ease of use ($\alpha = 0.75$) and perceived usefulness ($\alpha = 0.84$) were tested and reflected good internal consistency. As expected, the scale for current treatment satisfaction was also reliable when all items were included ($\alpha = 0.86$) (Table 1), supporting the previous survey design study.¹⁸ Deletion of any item in each of the scales, where possible, did not improve the respective α values, and thus the scales were left unchanged.

Descriptive statistics of questionnaire items

Table 3 provides the mean $\pm$ SD values and 25% and 75% interquartile ranges for the three highest scoring scale items. Highest scoring here refers to items that were ranked by patients as the most positive or likely responses. Overall, findings were concordant with other qualitative and quantitative AP intention to use studies that considered different patient populations.^{16,17,19,20} The majority of AP clinical trial participants (86.1%) indicated they were either highly likely or likely to change their current diabetes treatment to AP technology once available.

Most patients were satisfied with their current diabetes treatment for all questions as summarized in Table 3. Subjects were surprisingly most content with how painful and easy to

TABLE 3. RANKED ORDER OF TOP THREE SCORING ITEMS FOR CURRENT TREATMENT SATISFACTION AND FACTORS OF BOTH CLINICAL TRIAL PARTICIPATION MOTIVATIONS AND TECHNOLOGY ACCEPTANCE MODEL

Item	n	Mean $\pm$ SD	25% IQR	75% IQR
Current treatment satisfaction				
Painful it is (satisfaction)	36	4.08 $\pm$ 0.81	3	5
Easy it is to use (satisfaction)	36	4.06 $\pm$ 0.71	4	5
Easy it was to learn to use (satisfaction)	36	4.06 $\pm$ 0.71	4	5
Motivation to participate in clinical trials				
Benefit others with T1DM (altruism)	36	4.89 $\pm$ 0.32	4	5
Improvement of medical knowledge (altruism)	36	4.72 $\pm$ 0.51	3	5
Improvement in health in order to take care of family (altruism)	36	4.72 $\pm$ 0.51	3	5
Increase lifespan (personal health benefit)	36	4.56 $\pm$ 0.61	3	5
Increase quality of life (personal health benefit)	36	4.56 $\pm$ 0.77	1	5
Receive care from expert (personal health benefit)	36	4.42 $\pm$ 0.87	1	5
Length of study (convenience)	36	4.03 $\pm$ 0.84	3	4
Number of study visits (convenience)	36	3.78 $\pm$ 0.80	2	4
Time of day (convenience)	36	3.75 $\pm$ 0.87	2	4
TAM				
Improved blood glucose control (useful)	36	4.64 $\pm$ 0.54	4	5
Increased quality of life (useful)	36	4.56 $\pm$ 0.61	4	5
Fewer episodes of hyperglycemia (useful)	36	4.50 $\pm$ 0.70	4	5
Likelihood of changing to AP (intention to use)	36	4.39 $\pm$ 0.80	4	5
Ease of use (ease of use)	36	4.36 $\pm$ 0.64	4	5
Requires minimal effort (ease of use)	36	3.83 $\pm$ 0.77	3	4
Reduced discomfort (ease of use)	36	3.53 $\pm$ 0.81	3	4

Answers were given on a 5-point Likert scale where 5 = completely satisfied, strongly agree, or highly likely and 1 = not at all satisfied, strongly disagree, or highly unlikely.

AP, artificial pancreas; IQR, interquartile range; T1DM, type 1 diabetes mellitus; TAM, technology acceptance model.

use their current diabetes management system is; 66.7% reported they were either completely satisfied or very satisfied, and 77.8% reported they were either completely satisfied or very satisfied with how easy their current treatment is to use. The two lowest scoring satisfaction variables related to blood glucose control, with 66.7% subjects responding with neutral input toward the ability of their current system to minimize episodes of both hyper- and hypoglycemia.

Overall, the clinical trial participation motivation items showed the most variance. Motivating variables tended to cluster together, with altruism and personal health benefit ranking the highest, followed by convenience and then monetary incentive (Table 3). These findings align with the literature.^{24,25} The two highest scoring questions for motivating factors were AP technology could benefit others and improve the T1DM medical knowledge, with 88.9% and 77.7% of subjects reporting they strongly agree, respectively. The lowest scoring motivators of clinical trial participation were measures of convenience. Subjects rated discomfort, with 11.1% responding they strongly agree that it is an influencer, and that time of day of the study impacts willingness to participate, with 16.7% of subjects strongly agreeing. This appears to support the responses from the current treatment satisfaction variables. Here, convenience (like pain) of clinical trial participation was ranked lower than other motivating factors, like personal health benefit. This is similar to the finding that subjects were more satisfied in the amount of pain related to, or difficulty of using, their current diabetes management system when compared with their reported satisfaction with the ability of their respective treatments to control episodes of hyper- and hypoglycemia.

Specific to the TAM, subjects ranked the perceived usefulness of AP higher than perceived ease of use (Table 3).

This aligns with the survey study of van Bon et al.,¹⁸ as well as the findings from the motivation and current treatment satisfaction variables. Table 3 shows that 66.6% strongly agree that an AP system will improve their blood glucose control and that 63.9% strongly agree that an AP system will improve their quality of life.

Linear modeling

Multiple linear regression was conducted using combined scale scores for all but the altruism construct. This was due to its calculated reliability of <0.7 . Individual altruism items were included in the model. Analysis showed that AP adoption is best fit by the TAM constructs of ease of use and usefulness plus and, surprisingly, the motivation construct of convenience plus the individual item benefit to others ($R^2=0.26$, $P=0.05$). By adding in CSII and CGM use, the model significance improved ($R^2=0.37$, $P=0.02$). The scales of personal health benefit and current diabetes satisfaction did not improve the R^2 value, nor did any additional altruism questions.

Discussion

In this pilot study we developed a questionnaire to assess potential predictors of likelihood of AP technology adoption among a motivated patient population that had directly experienced an AP system. Specifically, the AP Motivation and Satisfaction Survey (APMSS) was partially developed using theory presented by van Bon et al.^{16,18} These researchers detailed adapting the TAM^{21,22} to investigate attitudes about perceived usefulness and perceived ease of use regarding AP technology, as well as trust in the system. APMSS also uses current treatment satisfaction questions from the Diabetes

Medication System Rating Questionnaire survey developed by Peyrot et al.²³ For the AMPSS motivation questions, factors favoring participation in clinical trials were identified.^{24,25} Factors shown to influence participation in clinical trials were grouped into four themes: altruism, personal health benefit, monetary reimbursement, and convenience.

We found that subjects ranked items associated with altruism, including volunteering in order to benefit others, potential for improvement of personal health in order to take care of family, and advancing medical knowledge, as the highest ranked motivators for participation in AP clinical trials. Monetary incentives and convenience were not ranked as important, although convenience was a key aspect of linear modeling. These findings support other motivation research that demonstrate monetary incentive and overall convenience of research study participation are not perceived by subjects as important influencers.^{22,23} Although the altruism scale was not found to be reliable, the question of benefit to others was significant in linear modeling. This suggests that future directions of patient-based research regarding adoption of an AP system include specific altruism items. Another interesting finding was that satisfaction with current diabetes treatment was not predictive of AP technology adoption by any measure.

Subjects ranked perceived usefulness of an AP higher than perceived ease of use. This has implications for acceptance of an AP system and long-term use. Users will need to be educated about the system and its limitations; expectations will need to be realistic, especially as the system is being developed. If subjects perceive that the system will be of use for blood glucose control and improved health, they may be willing to be more engaged and trained on the system rather than having a system, which is simply “easy to use.” If patients can be shown the effectiveness of an AP system, then acceptance of the technology may be easier. It will be important to assess the effect of an AP system on the quality of life and the degree of trust in the AP. Relinquishing of diabetes management control to an automated system will be a significant hurdle to adoption of an AP.²⁰

The best predictors of AP adoption were variables of TAM. No current diabetes treatment satisfaction items and many motivations to participate in clinical trials questions were significant in our linear model. In summary, a combination of scales, or groupings of questions, was the best predictors of AP adoption, and these included questions related to the TAM items of ease of use and usefulness plus motivation questions related to convenience, as well as the individual item of benefit to others. Insulin pump and CGM use improved the model prediction. This is not an unexpected finding because subjects were a motivated group of individuals, with the majority having other direct technology experience of using CSII and CGMs. Identifying patient populations most likely to benefit from an AP system will be an important consideration; previous studies have demonstrated that correct technology implementation is a barrier to use of technology and thus achievement of improved blood glucose control.²⁶ Aligning with this observation includes findings specific to the convenience scale. Although not ranked as a strong motivator for clinical trial participation, it was significant in linear modeling. Thus, the convenience of an AP system should be addressed for both development of the technology and as an important point of discussion with potential users.

A strength of our study was that almost all of our subjects are familiar with the components of an AP system, such as CSII and CGM, and during the in-clinic closed-loop trials they were able to experience aspects of what an AP would look and feel like. The main limitations of this pilot study were small sample size and nonvalidated operational constructs. In addition, our subjects tend to be highly motivated and to have fairly well controlled diabetes. It will be useful and beneficial to recruit subjects who are not as highly motivated, or as well controlled, and more representative of the general T1DM population to gain their perspective on an AP system. Another limitation of our study is that subjects who chose not to participate in AP studies were not included, and these subjects may help us to understand why people with T1DM would not adopt an AP system. These limitations will be addressed in the future. We also plan to validate and refine our questionnaire for use in future AP trials. For example, questions related to current diabetes treatment satisfaction will be removed. It is encouraging that more closed-loop AP studies are considering the impact of psychology and behavior on the success of an AP system.

Conclusions

Patient decisions about adopting and using new technologies are rarely based solely on objective benefits, and this has led to a limited understanding of important psychological and behavioral factors that are related to successful use of new technology, such as an AP. Questionnaire studies are useful for the identification of people who will be most compliant and successful with new technology, those who will benefit most from this technology (such as people with hypoglycemia unawareness), which factors are most important, and how to develop training and support tools.

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