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REVIEW ARTICLE

A Review of User-Centered Design for Diabetes-Related Consumer Health Informatics Technologies

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Abstract

User-centered design (UCD) is well recognized as an effective human factor engineering strategy for designing ease of use in the total customer experience with products and information technology that has been applied specifically to health care information technology systems. We conducted a literature review to analyze the current research regarding the use of UCD methods and principles to support the development or evaluation of diabetes-related consumer health informatics technology (CHIT) initiatives. Findings indicate that (1) UCD activities have been applied across the technology development life cycle stages, (2) there are benefits to incorporating UCD to better inform CHIT development in this area, and (3) the degree of adoption of the UCD process is quite uneven across diabetes CHIT studies. In addition, few to no studies report on methods used across all phases of the life cycle with process detail. To address that void, the Appendix provides an illustrative case study example of UCD techniques across development stages.

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Introduction

Many health issues require active participation by an informed patient for the treatment to be successful. This is particularly true in the case of lifestyle issues related to chronic diseases, such as diabetes, which cannot be successfully treated without changing the patient's personal behavior and habits.[1] Thus consumer health informatics technology (CHIT) has emerged for self-managing chronic diseases. Consumer health informatics technology is expected to help health care consumers assume greater responsibility for managing their health; support the exchange of information among patients, caregivers, and health care providers; and facilitate the patient–provider partnership.[2,3] Furthermore, CHIT (e.g., social media and mobile devices) offers providers access to useful patient data that can be used in prevention and managing chronic disease as well as providing opportunities for empowering patients.[4] In fact, an assessment by Geisler and Wickramasinghe[5] emphasized the growing role for wireless technologies in supporting and facilitating diabetes self-care.

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Abbreviations: (CADA) Chinese Aged Diabetic Assistant, (CHI) consumer health informatics, (CHIT) consumer health informatics technology, (HCI) human–computer interaction, (UCD) user-centered design

Keywords: consumer health informatics, diabetes, literature review, software development, user-centered design

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Research to date indicates that CHITs tend to work best when they are user centered (i.e., take the needs, barriers, and design preferences of target users into account) and can be tailored to different types of users and across different contexts.[6] To date, we know of no study that has reviewed and synthesized (1) the user-centered design (UCD) efforts used in research to support developing or evaluating diabetes-related CHIT, (2) the results of these efforts, and (3) general recommendations for UCD specifically applied to diabetes self-management. In response, this study examines the state of research regarding using UCD methods and principles to design and evaluate CHIT to support diabetes self-management.

Background

Numerous technologies are available to assist with collecting, summarizing, and responding to the information needed for diabetes management, from clinical and lifestyle perspectives. Particularly, for optimal diabetes self-management, a person with diabetes needs timely information on his or her blood glucose levels, nutrition, physical activity, medications, medical examinations, and laboratory test results, among other things.[7] The potential positive effects of a CHIT intervention include the following: (1) better compliance with recommended care, (2) expanded knowledge of the disease, and (3) higher awareness and use of the social support network available to the patient. These intermediary effects should lead to improved clinical outcomes and enhanced patient satisfaction with care. In addition, some indirect positive effects of CHIT may include decreased psychological distress and satisfaction with patient–provider communication.

Although studies have shown positive results,[8–11] the usability of emerging disease and case management technologies is rarely addressed and reported.[12] Some estimate the failure rate of software development projects is as high as 60% due to human–computer interaction issues of poor functionality and usability, and hence low uptake.[13] Positive HCI is key to CHIT use quality and continued use.

Human–computer interaction (HCI) lies at the confluence of several fields, including computer behavioral sciences, and involves studying, planning, and designing interactions between people (users) and computers.[14] User-centered design is a modern HCI design philosophy and a multistage problem-solving process in which the needs, desires, and limitations of the end users of an interface are questioned and analyzed and assumptions of user behavior are transferred to prototypes and tested. The goal is to "tune in" to users' mental model before specifying and finalizing the design. User-centered design is well recognized as an effective human-factor engineering strategy for designing ease of use in the total customer experience with products and information technology that has been applied specifically to health care information technology systems.[15–17]

The UCD problem-solving process is typically characterized by activities that can be applied to one or more of the technology development lifecycle stages. Key stages (planning and feasibility, requirements, design, implementation, test and measure, and post-release) and UCD methods supporting these stages are provided in **Table 1**. Though there is natural progression of steps in designing a study, the stages presented in **Table 1** are more of a grouping of similar activities than a rigid representation of a lock-step timeline. A study may include one or more of the stages and one or more of the methods (activities). Various methodologies and approaches have evolved that select and sequence various methods in various ways. User-centered approaches such as Hartson and Hix's star life cycle,[18] Preece and coauthors' interaction design model,[19] and the Cognetics LUCID framework[20] provide examples of processes that focus on iteration and usability evaluation. The generally iterative nature of UCD (interplay between developers, users, and user context) ensures that feedback from users during evaluation (e.g., suggestions ranging from medications to the requirements and design of the product) is incorporated before the final product is implemented and tested.[18,21] In addition, the user-centered development process can be used to minimize extraneous functionality to concentrate on the core of the system.[21] The shift from "system-centered" to "user-centered" design has increased the effectiveness of software systems because the product is less likely to require major redesign after the final evaluation process is completed.[22,23]

However, cautionary understanding is needed in deploying UCD techniques. User-centered design is not a customer service exercise in which researchers and developers try to satisfy every target user suggestion or whim. Studies reveal

Table 1.
User-Centered Design Methods Used Across the Technology Development Life Cycle Stages[a]

1. Planning and feasibility	2. Requirements	3. Design	4. Implementation	5. Test and measure	6. Post-release
1.1. Stakeholder meeting	2.1. User surveys	3.1. Design guidelines[b]	4.1. Style guides	5.1. Diagnostic evaluation (may include think out loud)[b]	6.1. Post-release testing (alpha, pilot)[b]
1.2. Analyze context[b]	2.2. Interviews[b]	3.2. Paper prototyping[b]	4.2. Rapid prototyping[b]	5.2. Performance testing	6.2. Subjective assessment (satisfaction)[b]
1.3. ISO 13407	2.3. Contextual inquiry	3.3. Heuristic evaluation (interface and persuasive)[b]		5.3. Subjective evaluation[b]	6.3. User surveys[b]
1.4. Usability planning[b]	2.4. User observation[b]	3.4. Parallel design		5.4. Heuristic evaluation[b]	6.4. Remote evaluation[b]
1.5. Competitor analysis	2.5. Analyze context[b]	3.5. Task/workflow diagram		5.5. Critical incidence technique	6.5. Content analysis[b]
1.6. Literature review[b]	2.6. Focus groups[b]	3.6. Storyboarding		5.6. Pleasure	
	2.7. Brainstorming	3.7. Evaluate prototype[b]		5.7. Interviews (group and individual)[b]	
	2.8. Evaluating existing systems[b]	3.8. Wizard of Oz		5.8. Demonstration and feedback[b]	
	2.9. Card sorting	3.9. Interface design pattern		5.9. Systematic observation	
	2.10. Affinity diagramming	3.10. Role playing, walk-throughs, simulation		5.10. Expert panel review (user or health behavior expert)[b]	
	2.11. Scenarios of use[b]	3.11. User profiles[b]		5.11. Questionnaires[b]	
	2.12. Task analysis	3.12. User personas[b]		5.12. Test user scenarios[b]	
	2.13. Requirements meeting[b]	3.14. Cognitive task analysis (think out loud)[b]		5.13. Log file review[b]	
				5.14. Content analysis[b]	

[a] Adapted from http://www.usabilitynet.org/tools/methods.htm, *which includes further descriptions of methods.*
[b] Found representation of this technique in the literature reviewed.

that there is a chance that users may become disillusioned when suggestions are rejected, while designers may be forced to compromise on design specifications or guidelines to satisfy user demands.[24] The goal is to understand true user needs and requirements (some of which may not be directly explicated or understood directly by users) based on the users' mental models and performance. To this end, researchers and developers must be clear in their approach.

Given that health care is embracing numerous technology solutions to effect superior health care delivery, more attention to and understanding of HCI and related UCD philosophies, methodologies, and constructs are needed. Consumer health informatics technology must persuade health consumers to assume or continue health-enhancing behaviors and create health-enhancing contexts. Limited persuasive design considerations combined with technological constraints in sensing opportune moments for influence are thought to contribute to the failure of health applications in motivating people to change their health care behaviors.[25]

Diabetes is a chronic disease that is reaching epidemic proportions globally,[5] and in an attempt to better manage this disease, various CHIT solutions are being designed, developed, and implemented.[5] To realize the potential that modern technologies can have for patients with diabetes, we need to carefully assess and consider the challenges and needs of the target group to determine (1) the features and design of the technology platform, (2) the form and content of system messages, and (3) the means of message routing and effective opportunities for sharing and exchanging. User-centered design principles and methods align with these objectives to facilitate superior monitoring and management of the chronic disease diabetes using CHIT.

Methods

In response to the apparent void in the extant literature we identified earlier, we performed a literature review of current literature to examine the state of the field regarding using UCD methods and principles to design and evaluate CHIT to support diabetes self-management. The criteria for selection included adherence to *all* the following key criteria:

- Studies that focused on developing, evaluating, or testing diabetes interventions;
- Studies that focused on CHIT solutions, such as web-based portals/applications and mobile applications;
- Studies that explicitly focused on using UCD methods and principles to design and evaluate CHIT;
- Studies that were published between 2007 and 2013 (a study begun as a 5-year period and was extended to current); and
- Peer reviewed journal articles (used as an indirect proxy to indicate methodological rigor).

The following exclusion criteria were applied:

- Papers not written in English,
- Papers for which full text was not available, and
- Review articles.

The search parameters are further detailed in **Table 2**.

Table 2.
Search Parameters

Databases queried	ABI/INFORM Complete, PubMed, MEDLINE, Elsevier, World Wide Web, IEEE, ACM		
Keywords	Diabetes	AND one of these CHIT terms	AND one of these UCD terms
	Diabetes	Consumer informatics; consumer health information technology; CHIT; consumer health technologies	*General terms:* participatory design; user-centered design; user centered design; user-centred design; user centred design; human computer interaction; user mental model; usability *Secondary methods specific to UCD:* card-sorting; contextual inquiry; affinity diagramming; scenarios of use; task analysis; rapid prototyping; user persona
Selection criteria	1. Studies that focused on developing, evaluating, or testing diabetes interventions 2. Studies that focused on CHIT solutions, such as web-based portals/applications and mobile applications 3. Studies that focused on applying UCD methods explicitly or implicitly 4. Studies that were published between 2007 and 2012 5. Peer reviewed articles		
Exclusion criteria	1. Not written in English 2. Papers for which full text was not available 3. Review articles 4. Did not use true UCD methodology and conceptualization		

Finally, the UCD relevance of each publication was examined by reading the abstract and the whole text, if needed. Though many articles referencing usability were identified, several were excluded, as they measured some aspect of usability as part of an experiment,[11,26] clinical trial, or field test, but were not adopting a user-centered, participatory design or user-iteration approach. The following data were extracted from the final selected papers: indicative UCD term(s) used in paper, UCD method, UCD outcomes/areas of interest, platforms, study population, and main diabetes self-management purpose of the tool used or developed.

Results

Our search identified 18 papers meeting all the aforementioned criteria (see **Table 3**). The generally positive study results (linked to increasing knowledge regarding what constitutes user-friendly and useful end products) imply there are benefits to incorporating UCD into the development of CHIT. Despite these positive results, the sparse listing of recent papers reported in **Table 3** and the fact that we identified (and ultimately excluded) papers that assessed usability but did not adopt a UCD approach indicates that the degree of UCD method adoption is quite uneven across studies of CHIT focused on diabetes self-management.

As can be discerned from the summary of findings presented in **Table 3**, research studies often use multiple UCD techniques. Findings indicate that UCD activities have been applied across the technology development life cycle stages.

Though we do see representation of various methods across and even within studies, likely due to limitations in scope, it is the exception for one article to provide a detailed account of the multiple UCD methods employed across various phases. Thus, in summary, what we have identified (**Table 3**) is that, although studies may use multiple UCD methods, most of the published studies in our list do not subscribe to (or at least report) UCD methods across all stages of the UCD life cycle in a single study. The few that do seem to adopt methods throughout all phases[21,39,42] provide very limited representation of the flow and detail of activities. This limited use indicates that the full UCD approach has uneven adoption (or reporting) within studies of CHIT focused on diabetes management. To address this gap in the reported literature and provide clarity regarding UCD study design and the connection among stages across the UCD development process for the development of CHIT for diabetes, we provide a comprehensive UCD example in **Appendix A**.

Discussion of User-Centered Design Studies

Types of Applications Developed/Functionality

Table 3 illustrates that UCD has been used to assess functionality related to nutrition, exercise, lifestyle and education, blood glucose level, and medication management. Some CHITs have included functionality that supports electronic communication between diabetes patients and providers[21,31,38,40] and/or other diabetes patients[40] to assist one of more of the areas of self-management.

These functions have been spread across various platforms. In 2007, Nordfeldt and coauthors[39] conducted a research study using UCD methods in a pilot study to develop and test a personal-computer-based interactive diabetes simulator prototype for teenagers and their families. Fonda and coauthors[7,35] have been active in designing and testing Internet-based diabetes CHIT, particularly a diabetes personal health assistant consisting of a collection of flexible, reusable, small web applications called "gadgets" designed to be used within a portal-based website.

Mobile CHITs have received increasing UCD interest. In 2007, Arsand and coauthors[28] designed the interactive mobile tool Easy Health Diary (or eDiary), which includes a dictionary, daily tips, help function, sensor history, and nutrition recording. User-centered design efforts revealed that context sensitivity and tailoring need further attention in these tools. In addition, in 2008, Arsand and coauthors[28,29] focused UCD efforts on mobile applications that would allow data to be uploaded wirelessly from blood glucose monitors, sensors that measure physical activity, and user-generated records of routine eating habits.

Table 3.
Literature Search Findings[a]

First author	Key UCD term used	UCD method (see Table 1 for coding)	Outcome focus	Platforms	Study population	Nutrition	Physical activity	Lifestyle and education	Glucose	Medication management
Armstrong[27]	User-centered design	5.7, 6.1	Usability, most effective functionality, diabetes knowledge	Internet-based social networking	5 Diabetes patients			X		
Arsand[28]	Usability; participatory design	3.1; 3.2; 3.7; 5.7	Usability	Smartphone, mobile phone, website	32 Participants (12 type 2 diabetes patients and 20 non-diabetes patients); approximately 50 years old	X	X	X	X	
Arsand[29]	User-centred design; usability	2.4; 2.8; 3.1; 3.7; 3.14; 4.2; 5.7	Motivation; usability	Smartphone, desktop personal computer and mobile phone photo	6 type 1 diabetes patients and 3 type 2 diabetes patients; 18-56 years old	X				
Arsand[30]	Human computer interaction; usability	2.6; 2.2; 3.2; 4.2; 6.1; 6.2; 6.3; 6.4	Most effective functionality; motivation; lifestyle modification achieved; usability	Smartphone	12 type 2 diabetes patients (4 men and 8 women); 44–70 years old	X	X	X	X	
Biswas[31]	User driven innovation	6.1; 6.5	Determining provider and patient information needs, disease related outcomes (e.g., glycemic control, blood pressure, weight control)	Cell phone (short message service); integrated web-based personal health record	Type 2 Malaysian diabetes patients; overweight; within 5 years of diagnosis; their provider; their personal caregiver (thought partner)			X		
Cafazzo[32]	User-centered design; usability;	2.2; 2.6; 3.1; 3.3	Capture end user requirements; assess social networking to promote application use adherence; assess rewards to promote application use adherence; system satisfaction; usability; behavioral change (diabetes quality of life, self-care inventory, patient–provider interaction, frequency of blood glucose testing)	Personal digital assistant (iTouch) or iPhone with glucometer	20 type 1 diabetes patients; 12–16 years old (pilot and interview); personal caregiver/ parents (interview); providers (focus groups)				X	
Carroll[33]	Usability (data used to modify system before further study)	2.6; 3.7; 4.2; 5.3; 5.7; 6.1; 6.2	Usage; usability; relationship with provider and parent impact; performance (system bugs)	Cell phone with output integrated to website	10 type 1 adolescent diabetes patient; between ages of 13 and 18 years (focus group and pilot); their parents				X	

Table 3. Continued

First author	Key UCD term used	UCD method (see Table 1 for coding)	Outcome focus	Platforms	Study population	Nutrition	Physical activity	Lifestyle and education	Glucose	Medication management
DeShazo[34]	User-centred design; usability	2.6; 5.11; 6.1; 6.4	Usage; usability; verifying self-report of time spent with metric data; text communications and multiple choice effective for capturing critical user events	Smartphone games	Adult type 1 and type 2 diabetes patients; (11 participants in focus groups, 10 pilot and questionnaire)	X		X		
Fonda[35]	Usability; user-centred design	2.6; 3.2, 5.8,	Usability; most useful functions (e.g., "what if" analysis for glucose levels, mood indicator, glucose, medications); integration of multiple functions into one system and personal health record	Internet-based portal gadgets integrated with personal health record and biosensors	21 adult diabetes patients	X	X	X	X	X
Fonda[7]	Usability; user-centered design	2.6; 2.11; 2.13; 3.1; 3.7; 5.8; 5.11	Usability	Internet-based portal gadgets integrated with iGoogle and biosensors	11 type 1 diabetes patients and 10 type 2 diabetes patients; average age 63.8 years; 10 providers	X	X	X	X	X
LeRouge[36]	User-centered design; usability; mental model; participatory design	3.11; 3.12	Provide user profile and persona for diabetes patient population	Smartphone	Chinese diabetes patients; 60–80 years old; providers; personal caregivers	X		X		
Lin[37]	Usability	2.2; 2.5; 3.7; 3.14	Usability; improved counseling	ADAPT (Avoiding Diabetes Thru Action Plan) website	8 Pre-diabetes patients; 12 primary care providers for interviews; 2 primary care providers and 4 pre-diabetes patients; age 38–58 years			X		
Nijland[38]	Usability; participatory design	5.1 (with a think-out-loud component); 5.7 (in person and email); 5.11; 5.13; 5.14	Primary features of initial and long-term users; actual usage; barriers to adoption (lack of Internet access, poor user-friendliness, and selection of the "wrong patient", i.e., well-regulated patients not needing the system); nature of patient–provider communications using system	Web-based application, Diabetes Coach	50 type 2 diabetes patients			X	X	X

Table 3. Continued

First author	Key UCD term used	UCD method (see Table 1 for coding)	Outcome focus	Platforms	Study population	Nutrition	Physical activity	Lifestyle and education	Glucose	Medication management
Nordfeldt[39]	User-centered design; participatory design	1.2; 2.13; 3.7; 4.2; 5.7; 5.10; 6.1; 6.2	Functional system; how to perform discussion groups and pilot testing with teens; usage; system improvements required	Personal-computer-based interactive diabetes simulator prototype, DiabIT	Type 1 diabetes patients; 13–17 years old; their parents	X	X		X	
Nordqvist[40]	User-centered design	2.13; 5.7; 5.12	Barriers and facilitators to adoption in clinical practice; provider attitudes toward their use and patient use; functionality that would be used; user satisfaction; need to educate clinicians regarding Web 2.0 resources; sense of community developed among those involved in design	Local Web 2.0 portal for child and adolescent diabetes care	20 clinicians treating type 1 diabetes patients under the age of 19 in Sweden (and patient sample for design phase)			X		
Tsai[41]	User centered design; usability	1.6; 5.1; 5.4; 5.7; 5.10; 5.12; 6.1	Satisfaction; usage; comfort in social settings; usability	Smartphone	Pre-diabetes patients (adults overweight)	X				
Waller[21]	Participatory design; user-centred design; usability; human computer interaction	1.2, 2.7; 2.13; 3.2; 3.11; 3.14; 4.2; 5.1; 6.1	Provides a participatory design methodology suited to young people with diabetes; system modifications to suit users based on usability testing; usability; sense of community among those developing system	Smartphone (text messaging)	Adolescents and their health professionals in alpha testing	X	X	X	X	X
Yu[42]	Usability; involving stakeholders in development	1.2; 1.4; 1.6; 2.5; 2.6; 3.7; 3.14; 4.2; 5.7; 5.12; 6.3	Barriers to adoption; diabetes self-efficacy; facilitators to adoption; knowledge of diabetes; lifestyle adjustment; usability	Web-based patient self-management intervention tool	Type-2 diabetes patients; over 25 years old			X		

[a] Lifestyle includes increased communications with medical providers.

Waller and coauthors[21] used UCD methods to develop a text message scheduling system for supporting young people with diabetes. Text messaging was thought to offer an ideal channel for delivering "push" support and facilitating reciprocal communication between the patient and the health professional.

User-Centered Design Methods Used

The most frequent stage of the UCD approach adopted in studies reported in the literature was related to requirements gathering and testing. This is understandable, as most research focused on design, development, and evaluations.

Four studies[21,39,41,42] used at least one planning and feasibility (stage 1) method. Twelve studies[7,21,29,30,32–35,37,39,40,42] subscribed to at least one UCD requirements-gathering (stage 2) method, with one study[7] subscribing to three different methods within this stage. The most common UCD technique in the requirements phase was focus groups (2.6 in **Table 3**; seven studies). For example, personal health application requirements were determined through a series of 90 min focus groups with patients with diabetes.[43] Work by Nordfeldt and coauthors[39,44] and Waller and coauthors[21] demonstrated that focus groups might also be an appropriate technique for the design and test stages. Additional requirements phase procedures that were demonstrated in multiple studies include requirements meetings (2.13 in **Table 3**; four studies) and interviews (2.2 in **Table 3**; three studies).

Twelve studies subscribed to Design methods (stage 3).[7,21,28–30,32,33,35–37,39,42] Seven of these studies subscribed to evaluate prototype methods (see 3.7 in **Table 1**). User-centered design implementation methods (stage 4) were present in six studies,[21,29,30,33,39,42] and when it was present, it was always represented by rapid prototyping (see 4.2 in **Table 1**). Participants were often observed and interviewed while using the prototypes under simulated conditions to elicit the participants' perceptions of the design strengths and weaknesses, ease of use, contexts of use, and potential utility in supporting the participants' diabetes management goals. In addition, various stages of prototyping were represented. For example, Waller and coauthors[21] used paper-based prototypes as a starting point to develop a functional web-based evolutionary prototype, which was modified and refined during the design session.

Test and measure (stage 5) activities were present in 12 of the studies,[21,27–29,33–35,38–42] with one study deploying five of the test and measure methods.[38] The most common methods used in the test and measurement stage were interviews (5.7 in **Table 3**; eight studies).

The post-release phase method (stage 6) was used in eight studies,[21,27,30,31,33,34,39,42] with pilot testing deployed in six of these studies (see 6.1 in **Table 1**).

Sometimes UCD methods are used in combination; one method is an extension to other methods or encompassed other methods. For example, Tsai and coauthors[41] demonstrated usability testing using single-participant session "think aloud" processes where providers performed standardized tasks and researchers observed how the providers approached these tasks and documenting verbalizations. The participants then gathered and participated in a group debriefing where they were asked to comment on 10 usability heuristics.

To leverage future development efforts, the diabetes technology research and development community would benefit if the UCD deliverables resulting from various studies were readily available to interested community members. For example, LeRouge and coauthors[36] shared their user profile and personal deliverables from a study of Chinese elderly with diabetes that can be reused in other efforts interested in this user population. In addition, the research community may find specification of USD approaches (methodologies) deployed in a study to beneficial in providing guidance to future research design. Waller and coauthors[21] illustrated a participatory design approach to develop a text-message scheduling system for supporting young people with diabetes. Participatory design includes users as equal members of the design team, which can ensure more accurate task information, provides greater opportunities for users to influence the design, and gives users greater sense of ownership. In this model, users are involved in every level of the design process using exploratory, experience-driven activities.[21]

User Groups

Diabetes UCD includes participants of all ages, though certain modalities seem targeted toward specific age groups. Two of the studies[35,36] seemed to focus on an older population (60 years and over). In contrast, six of the studies, particularly those regarding mobile technologies, were focused toward adolescents.[21,32–34,39,40] In the 2006 Waller and coauthors[21] study, a broad set of usability requirements was identified by a large population of adolescents with diabetes during an initial brainstorming design session. To test the prototype, approximately 60,000 messages were sent to patients over the duration of the study, and 1400 messages were received by the system. Likewise, the Nordfeldt and coauthors[39] research study included 118 patients 13–20 years old (57 boys and 61 girls) with diabetes. In this study, four user group sessions were specifically focused on a personal-computer-based diabetes simulator design process, mostly in separate groups of teenagers and parents.

The Nordfeldt and coauthors[39] study also demonstrated that UCD data collection is not limited to patients with diabetes. Other studies have included a personal care giver as well as providers as participants.[31,32,36] This implies some appreciation that self-management is not a solo activity but part of a continuum of care that includes clinicians and patient support systems. User-centered design studies should recognize the continuum of care and support needed to self-manage this disease and thus access secondary users and other supporting "players" in the UCD process.

Usability Outcomes

General outcomes of interest (reported in **Table 3**) included those related to usability, assessment of knowledge gained, behavioral change, motivation, actual use, and clinical outcomes (glycemic control, blood pressure, weight control). In UCD studies, usability outcomes of interest almost always include recommendations for modifying existing technologies based on usability assessment related to design, function, and usage. **Table 4** provides a detailed list of usability issues and outcomes categorized by usability areas (design, function, and usage) identified across the literature reviewed.

Table 4.
Usability Areas of Interest

CHIT diabetes usability areas of interest		
Design	Function	Use
Content awareness[27,41]	Appropriate negative feedback[28,29]	Fit with lifestyle[27,28,31,32,41]
Organization/navigation[27]	Training required to use technology[17,41]	Usefulness[21,27,29,33,42]
Simple[28]	Reminders[7]	Short-term/periodic use patterns[28,29]
Reliable[28]	Motivation message/tip-of-the-day usefulness[28]	Long-term use patterns[38]
Input method[28]	Simple automated transfer glucometer reading[32]	Instructions easy to follow[33]
Automated as possible[30,35]	Linking educational attainment with score[34]	Facilitate decision making[32]
Size of phone[33]	Interactive learning[34]	Scores achieved[34]
Appropriate color[21]	Just-in-time information[7,29]	Paths taken through application[42]
Navigation ease[21]	Need for ad hoc information sharing[32]	Errors made[42]
Value of integrating multiple self-management tools into one system[28,29]	Fast, discrete transactions (analysis) on glucose testing[32,33,41]	Enjoyment[34]
Tailoring to user[34,37]	Use of prompts based on data[32]	
Effective information presentation format[21]	Not just data collection/decision support/ overcoming decision inertia[32,35]	
Conceptual model[41]	Emergency access[28]	
Gamification (time/variety)[32,34]	Rewards[32]	
Cost efficiency/feasible cost[21,34,35,41]	Allow users to update the frequent foods and activities lists[29,41]	
	Scaffolding (progressive levels of guidance through the system, as needed by the user)[34]	
	Engaging education[29]	
	Security[7,41]	

In reference to design, Waller's work demonstrates the benefits of collaboration between the computer developers and non–computing professionals, which resulted in an interface tempered by the developers' technical knowledge and the users' common sense garnered through feedback on the technology aesthetics regarding the color coding of some screen items and other cosmetic improvements.[21] Navigation ease,[27] content awareness,[27] and minimizing user effort through automation[30] are classic usability assessment items that are represented in studies of diabetes self-management technologies. A 2012 study found that the use of a CHIT for adolescent diabetes patients that incorporated the use of a social community and the concept of gamification (whereby routine behaviors and actions are rewarded in the form of iTunes music and applications) yielded high satisfaction among participants; it is of note that the daily average frequency of blood glucose measurement increased 50% in this study.[32] A 2010 study found gaming to also be an attractive design modality for adults.[34]

The number of studies in our list that use a mobile platform indicates that mobile phone technology is gaining ground as an interface for the health consumer and may be a worthy design consideration. Explicit and implicit reasons for the use of a mobile platform in those studies that used them include increasing ubiquity of this technology worldwide, access for patients who do not have or seldom use their computer, and anywhere access.

Some studies remind us that design is not just about looks or form; cost feasibility is an element to consider in design.[21,34,35,41] As a result of user feedback, one research team redesigned their prototype so that it did not have to rely on the use of advanced, high-cost, continuous biomonitoring devices; instead, CHIT gave users the choice to use automated devices or to do manual data entry.[35]

Usability related to function was also explored. Functional enhancements from a study by Arsand and coauthors[29] included the following: (1) the ability to download the resulting data to a personal computer to enable more detailed analyses, (2) the ability to delete or edit entries after they were submitted, and (3) the addition of negative and positive reinforcement cues in the graphical user interface (e.g., "frowny faces" and "smiley faces" as indicators of progress toward achieving goals). In contrast, in the Waller and coauthors[21] research, the UCD process did not result in adding functionality, but instead proved useful in minimizing extraneous functionality to allow concentration on the core of the system. In other cases, the results suggest reorganization rather than adding or minimizing functionality. One case in point is one where users who evaluated reusable, small web CHIT applications called "gadgets" within a portal-based website said the choice of which gadgets to use for diabetes management was confusing.[35] The participants' feedback led to two changes in the conceptualization of the gadgets: (1) the addition of a My Diabetes Data Tracker gadget to bring the different components of the prototype personal health application together under one system umbrella and (2) reconceptualization of the gadgets by topic areas originally defined by the American Association of Diabetes Educators for self-management (healthy eating, being active, medications, reducing risks, monitoring, and problem-solving/coping).

User-centered design may be used to assess system use, use patterns, and/or conditions of use (particularly through pilot testing). A 2007 study found that instant feedback by automatic updating and menus with standard meals and activities seemed to reduce thresholds for use of a simulator prototype.[39] Regarding frequency of use, a study led by Arsand and coauthors[28] determined that use of the eDiary tested would probably not be daily, but in periods. In a 2008 study to test and design a mobile dietary management support technology, five of the six participants stated that they would be likely to use this tool routinely if given the ability to personalize the goals and recording categories.[29] Concerning continued use, a longitudinal study found the following factors to be barriers to long-term use: (1) the absence of "push factors" or reminders, (2) promotion to patients that are already well regulated and do not need the CHIT, (3) a ceiling effect (I am now doing well and do not need the technology any more), (4) absence of tailoring to the patient's needs (e.g., do not provide education that a particular patient does not need), (5) a complex interface, and (6) integration of stand-alone functionality into one system.[38] This study also found that personalized feedback and interactive elements appeared to be two of the most promising features for long-term use by both patients and providers. The advantages of personalization is further supported by work by Armstrong demonstrates that use of the CHIT needs to fit with the user's lifestyle.[27]

Some studies have identified social and affective outcomes of UCD studies. DeShazo and coauthors[34] assessed users' level of enjoyment through use of a CHIT that incorporated gaming and found that all reported the gaming aspects were at least somewhat enjoyable. Two studies noted a sense of community emerging as a result of the UCD study.[21,40] Cafazzo and coauthors[32] indicate that a reason for fast transactions for glucose testing is so that diabetes patients can avoid embarrassment.

Though the findings from the identified studies provide a foundation, additional UCD work is needed to provide deeper understanding of usability in design, functional, and use areas. To illustrate, multiple studies indicated that, to increase adherence to self-management goals, technology should have push factors such as feedback mechanisms and triggers (i.e., reminders).[7,27,45,46] Future studies may build on this foundation by investigating what kind of technology features or cues would trigger users (words, images, or sounds) and what form (text messaging, email) is most suitable to various diabetes patient user groups.

Regarding analysis of the rigor applied in these studies and the degree to which we can attribute positive results to the use of UCD, we can only make qualitative observations from the limited detail of methods reported in the literature that the use of aspects of UCD in the studies were applied with appropriate rigor (hence our bias toward peer-reviewed publications) and helped to enhance the final outcomes and address the purpose of the studies. We cannot offer qualitative assessment of efficiencies resulting from the use of UCD, as the authors of the papers reviewed did not generally report whether the UCD approach actually led to savings in development time and costs.

Conclusion

With the advancement of CHIT, such as smartphones and Web 2.0, we have the tools to provide patients with more sophisticated self-care. Given the challenges and trends in today's health care environment, CHI will inevitably expand. Given this context, designing and developing appropriate and sustainable technology solutions are important. Moreover, CHI is not just about the technology, but also and most importantly about the people (users) and context. User-centered design is concerned with users' expectations of how something should work and what it should do, how users interpret the clues that a particular device or technology provides about its functioning and content, and how users interpret feedback from the device or technology.[47] User-centered design efforts can help prevent costly design and change management errors (and associated rework).

This study contributes to the existing literature by examining the use of UCD methods for CHIT related to diabetes self-management as reported in peer-reviewed publications. Results indicate that multiple UCD methods have been used to design and assess functionality related to nutrition, exercise, lifestyle, and blood glucose level self-management. These functions have been spread across various platforms. Although multimethods may be used, to our knowledge, no study within the scope of this review has demonstrated the multistage use of UCD across the UCD life cycle with a detailed accounting of process. **Appendix A** provides a contribution to the existing literature by addressing this gap.

User-centered design activities are admittedly time-consuming. However, the referenced studies generally indicated that the UCD methods used (and thus time invested) provided positive results and/or facilitated answering their research questions. Furthermore, the time invested can be offset by post-release success and the realization that the findings, data collection tools (e.g., surveys), and resulting UCD deliverables (e.g., profiles) can be repurposed in other research and development activities involving the same or similar target user groups or contexts. At this time, one can only hypothesize the resulting impact and cost/benefit if methods across all stages of the UCD life cycle are incorporated into studies or what the optimal mix of methods is to suit the purpose of the study. This situation provides an opportunity for future research.

However, UCD is not a silver bullet for universal system success. Although development efforts may take into account consumer input and produce positive design and functionality outcomes, CHIT may not be for everyone. Appropriate CHIT "fit" to a situation or user may be dictated by not only by alignment with the user's mental model, but also costs, whether the consumer owns a computer, Internet access, and self-motivation.[7,35]

In summary, our review of the literature strongly supports that incorporating UCD methods with appropriate rigor and choice of methods not only is prudent, but also facilitates true and faithful capture and delivery of what is quintessentially important within the domain of CHI—the users' mental model.

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Appendix A. Comprehensive Study Example

The Chinese Aged Diabetic Assistant (CADA) project proposed to design and prototype an age-appropriate and culturally appropriate interactive diabetes self-management support system on smartphones for a robust (independent in activities of daily living) elderly population with diabetes in urban and rural China. The focus was older (aged between 60 and 80 years) patients with diabetes, including patients who were taking insulin or oral medications or both. Three concepts underpinned this project: (1) sociotechnical, (2) user centered, and (3) systemness (meaning the applications needed to work within the continuum of care). The sociotechnical nature of the health care context and a UCD approach is well supported by an interdisciplinary team. In this case, various phases of the project included medical providers, information systems specialists, computer scientists, a health psychologist, and human factors engineers as project team members. The design consisted of three phases and multiple data collection methods as illustrated in **Figure 1**. We highlight various UCD methods and deliverables in the following sections.

Phase 1: Planning/Feasibility and Requirements

The objective of phase 1 was to provide a detailed design profile of the targeted population for the CADA project reflecting targeted user needs, preferences, and capabilities. Functionality explored included blood glucose monitoring, potential learning messages, and ways to enhance the patients' support system. The UCD methods used in phase 1 directly involving the target population consisted of patient focus groups and direct observation of elderly patients with diabetes in exercise and leisure activities to explore and better understand current diabetes knowledge, self-management process, technology capabilities, design preferences and possibilities, and situations where smartphone applications could be helpful. In accordance with systemness, we also recognized the potential influence of context and the patient's caregiving system in designing the technology and assessing the adoption process. The team felt it important to leverage existing strengths and recognize gaps in the care continuum that applications could address. Therefore, UCD data collection activities included viewing the CHIT in light of the care continuum via (1) interviews with health care professionals and care facility administrators who supported diabetes management programs and (2) through a literature review and content analysis of publicly available documents to better understand the enactment and specification of chronic care model components in China.

Findings from the focus groups, interviews, and literature review provided source data to develop patient and provider surveys administered at urban and rural locations. Patient surveys further explored such areas as patient support systems, health attitudes and behaviors, design preferences, the potential for system adoption, and factors influencing adoption. Provider surveys explored patient support using smartphone applications, assessment of patient capabilities, the providers' adoption potential of information provided by such applications, and patient needs.

The findings from phase 1 efforts resulted in system design guidelines and functionality possibilities and requirements. The UCD products also included barrier analysis of health care technology use in general and specifically diet management and activity-level functions. In task flow models, data were used to understand and model strategies and tasks that 18- to 44-year-olds perform to assist with lifestyle management.

Phase 2: Design Phase

Requirements, task flow, and barrier analysis are not the only deliverables that can result from phase 1 activities to assist with the design process. In this study, phase 1 activities provided data to develop a World Health Organization Innovative Care for Chronic Conditions framework for China and a multilevel technical architectural design that guided system design. Aggregated results from phase 1 activities also resulted in the development of user profiles and personas that guided the remaining phases of the study. "UCD techniques such as user profile and user persona are structured ways of typifying a group of users in text and pictorial formats (i.e., conceptually modeling the end users). User profiles and personas go well beyond demographics, as they attempt to 'capture' the user's mental model comprising of their expectations, prior experience and anticipated behaviour."[36]

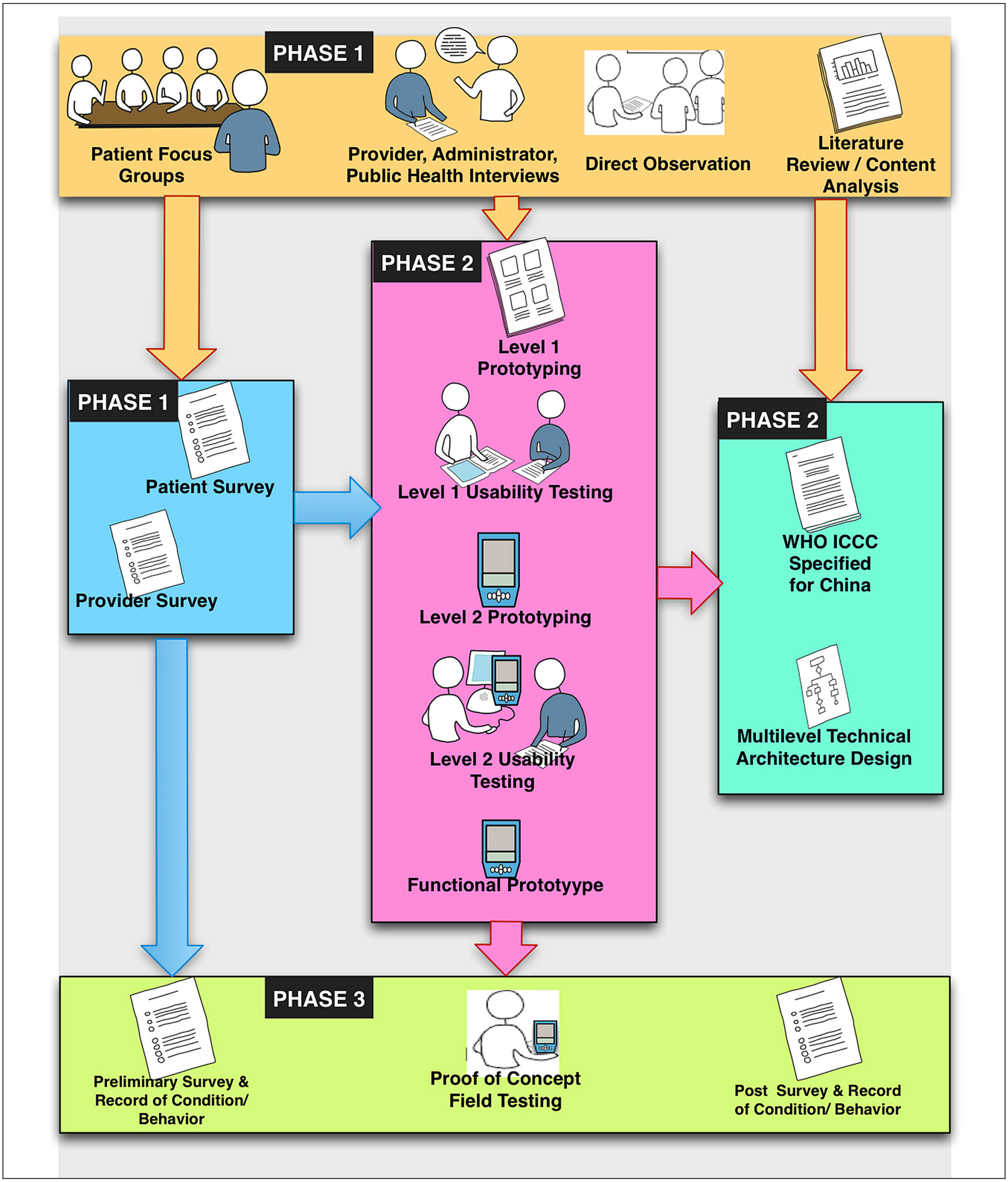

Figure 1. Chinese Aged Diabetic Assistant study design update to highlight phases as described. WHO ICCC, World Health Organization Innovative Care for Chronic Conditions.

The primary phase 2 aim focused on creating mock-up prototypes of the CADA software application based on insights from phase 1, collecting patient assessment of usability and acceptance of the mock-ups. This iterative application development process included three levels of prototypes, leading to a functional CADA software application. The levels of prototyping were as follows:

Low-Fidelity Paper Prototype and Usability Testing

The "3 x 3" (three designs x three screens deep) prototyping methodology allows designers to explore alternatives early in designing an interface rather than diving into a single solution and driving toward implementation without first validating the solution with users. Three alternative models were developed using variations of low-fidelity/paper prototypes; each was developed to a level of three screens deep. The three prototypes were tested with three patients with diabetes to determine if the users understood and appreciated the design metaphor and how well the planned functionality supported users in completing their tasks. A "human computer" manipulated the prototypes to reflect the software's reactions to the user input actions. Based on collective user feedback, the two best models were selected for a second round of evaluation with three patients. Good features of the washed-out model were integrated into the remaining ones. Based on collective user feedback from the second round, the best model was selected as a starting place for mid-fidelity prototyping. A mid-fidelity prototype, consisting of sophisticated screen rendering and limited navigation functionality, was rendered at the end of the 3 x 3 process.

Mid-Fidelity Prototype and Usability Testing

Nine Chinese patients evaluated the mid-fidelity prototypes that reflected the visual treatment as most appealing, most appropriate, and most supportive of users' tasks based on earlier steps. Intended users attended an individual session in which they were asked to perform a series of task walk-throughs while a moderator noted any difficulties the individual encountered. Users were encouraged to verbalize what they were doing and why they were doing it. They were also timed on how long it took them to complete tasks as a measure of efficiency. A final, fully functional model was rendered at the end of the mid-level usability testing that addressed user issues and improvements and efficiency gains based on usability testing.

High-Fidelity Prototype and Usability Testing on the Smartphone (Fully Functional System)

Eighteen China-based Chinese patients were recruited to evaluate the high-fidelity prototypes that reflect which visual treatments and functionalities were most appealing, appropriate, efficient, and supportive of users' tasks based on earlier steps. Intended users were invited to attend a session individually in which they were asked to walk through a series of tasks while a moderator noted any difficulties the individuals encountered. Users were encouraged to verbalize what they were doing and why they were doing it. Testing was conducted in a usability-testing laboratory that facilitated researcher observation.

Quantitative and qualitative data were generated to evaluate the prototype. Three broad categories of usability metrics were collected: effectiveness, efficiency, and satisfaction. Observational data, measurements during usability testing, participant details, and time on task were entered. Participants were asked to provide feedback to the research team through a paper-and-pencil questionnaire. A final prototype was rendered at the end as inputs to phase 3 of this study.

Expert Panel Discussion

Expert panels are used to systematically solicit, organize, and structure collective judgments and opinions on a particularly complex subject matter from an authoritative group. We assembled an expert panel of four representative primary care providers to collect user evaluations of the CADA system for the secondary user group. Empirical studies in health care indicate that a "well-designed expert panel can closely reflect the views of practicing physicians" and incorporate a range of views.[36]

Phase 3: Test and Measure

Phase 3 used a proof-of-concept field evaluation adopting a quasi-experiment design (comparative cases) as performance testing. There were two primary user groups of the CADA application: elderly patients with diabetes (direct users) and their providers (indirect users). The field test consisted of 12 cases (participants) randomly assigned to three groups: (1) intervention 1 (smartphone application), (2) intervention 2 (paper-based application), and (3) the control group. Interventions 1 and 2 formed the experimental groups in this field test. A paper-based intervention (paper version of some of the smartphone application features) was used to test the results of the form of intervention (i.e., paper versus technology). Patients varied in the length of time they had been diagnosed as well as their location (urban or rural/country) to allow for various user scenarios.

Several activities were planned to interact with patient participants at three points of the 6-week field test: pre, mid, and post. Subjective assessment procedures via survey and interview were conducted with the patients. The pretest survey included sections on diabetes management and the potential for technology adoption. The pretest interview focused on the patients' current goals and challenges in diabetes self-management. After the patients had trained on and used the technology for 3 weeks, a midpoint subjective evaluation included the patient meeting with the provider to verbally answer open-ended survey questions to discover and document any challenges using the interventions and any additional burden to diabetes self-management created by the interventions. Each patient and his or her supervising provider also discussed how the intervention system had been used, how often it was used, in what aspects it had been helpful or not helpful (critical instance technique logic), and if anyone else in his or her personal network used the system. After completing the field test, each patient participant filled out a post-test patient survey with two primary sections on diabetes management and technology assessment using various heuristics and perceptions of usefulness, ease of use, potential continued use, barriers, design issues and recommendations, and reflections on the gaming approach.

Providers also assessed their patients' use and the providers' own use at three points of the 6-week testing. The pretest survey was a subjective assessment of use and included sections on diabetes management and the potential for technology adoption for themselves, their patients, and their perceived roles. At the midpoint of the field test, providers completed an open-ended midpoint provider survey for each patient based on their interaction and observation of the patient. Their assessment as a medical professional helped to document any additional burden to diabetes self-management created by the intervention system, how often it had been used, in what aspects it had been helpful or not helpful, and if anyone else in the patient's personal network used the system. After completing the field test, each provider participant also completed a post-test provider survey similar to the patient survey except that the providers reflected on their use and their patient's use. Follow-up, open-ended retrospectives in the form of critical instance techniques were conducted with providers in follow-up to some of the surveys and reports collected to clarify what the providers felt were critical features of the software being evaluated. After completing the field test, provider participants also completed a post-test patient report for each patient to document any improvements over 5 weeks and additional issues in using interventions and/or in diabetes self-management in general.

In addition to the user reports, various system metrics on usage, success in completing tasks, efficiency, and such were collected via the smartphone device.