Application of Adult-Learning Principles to Patient Instructions: A Usability Study for an Exenatide Once-Weekly Injection Device

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More than 23 million individuals in the United States have diabetes, and ~ 90% of those have type 2 diabetes. An important aspect of successful disease management for type 2 diabetes is effective use of the numerous pharmacological interventions that are available to target the metabolic defects contributing to the underlying pathology.[1] After lifestyle modification and metformin, clinicians may consider many factors when selecting additional therapies. These include efficacy, safety, side effects, treatment complexity (i.e., dosing, administration, and convenience), unique patient characteristics (e.g., physical and cognitive capabilities, understanding of disease, comorbidities, and self-care involvement), and cost. Importantly, patients' ability to initiate and continue using a prescribed therapy is heavily dependent on the education they receive about the disease and its recommended treatments.[2]

Self-Management of Chronic Disease

Self-management education is an integral component of diabetes care and is emphasized in the American Diabetes Association's Standards of Medical Care in Diabetes[3] and in the Chronic Care Model.[4,5] Data support the positive impact of self-management education on quality of life, glycemic control, and psychological factors.[6–9] Furthermore, self-management education raises patient awareness of the impact of poor disease management on the occurrence of disease-related complications, premature mortality, and morbidity.[10]

However, few patients are actually educated by trained professionals or have access to diabetes education training programs.[11–14] Often, patients must rely on sources such as the Internet, lay and promotional materials, and peers to supplement the education received from providers who must balance patient needs with severe time and resource constraints.[15] In addition, individual characteristics such as language, literacy, vision, comprehension of the need for a therapy, and willingness to try alternatives to managing the disease will influence understanding and subsequent use of any prescribed therapy.[16,17]

Education Principles

These education challenges also apply to the use of medical devices. Patients' appropriate use of a new device is contingent on their having sufficient knowledge about the device and adequate confidence in their ability to use the device. Building both knowledge and confidence requires consideration of human factors in the design of the device and incorporation of educational principles (learning concepts and cognitive theory) into the development of educational materials to support its use.

Cognitive theory holds that adult learners build schema (mental representations) as they learn.[18] Working memory is activated as learners construct new mental symbols. For example, how a patient with limited hand mobility will use a medication delivery device is an example of a human factor consideration. How well a person translates information from an instructional guide to actual device use is an example of mental modeling, a necessary component of active learning.[19] Even such factors as graphic design, use of analogies, choice of words, and physical placement of the instructional guide in the product package must be thoughtfully considered to promote successful initiation and continued use of a medication delivery device.

Exenatide Once-Weekly Device Patient Instructions for Use

Exenatide once-weekly, extended-release formulation, which is under development for the treatment of type 2 diabetes, is administered by subcutaneous injection. This formulation requires a custom injection device. Here, we report on the development and evaluation of patient instructions for use (PIU) for the exenatide once-weekly injection device. The objective of this study was to determine whether the PIU, which was created with attention to human factors considerations, were effective in instructing patients with type 2 diabetes to prepare and deliver a simulated dose using the exenatide once-weekly injection device in the absence of additional training, educational materials, or additional support.

Methods

PIU design

The exenatide once-weekly injection device requires users to manipulate a syringe, a vial, and a vial connector. The single-dose kit used in this study contained a syringe pre-filled with diluent, a vial containing the medication placebo (a dry powder), and a vial connector. Administration of a dose involved combining the powder and diluent, mixing the resultant suspension, filling the syringe, and injecting the dose. The PIU were designed with consideration to human factors and adult-learning principles such as *1*) readability and language, *2*) imitation and modeling, and *3*) schema construction and cognitive load theory (including continuity, coherence, and redundancy effects).

Readability and language. To address readability and language, the PIU were written at a seventh-grade reading level.[20] Attempts to reduce the reading level further were complicated by the medication name (i.e., exenatide) and device components (e.g., syringe, connector). Action-oriented language and colorful diagrams guided readers through the preparation process by segmenting the information into smaller steps or coherent parts.[21]

Imitation and modeling. The learning concepts of imitation and modeling were addressed through the use of diagrams to demonstrate the required action and to provide visual confirmation of the completed action.[22] Analogies were used to describe how to adequately mix the drug (e.g., "shake like salad dressing") and how to break off the syringe cap (e.g., snapping a twig).

Schema construction and cognitive load theory. Cognitive load theory addresses the ability of the human brain to hold concepts in working memory and thus to build schema or mental representations.[23] Distracting diagrams, complex information, and disjointed design elements interfere with knowledge acquisition and can make learning to use a new device more difficult.

During the developmental process, a variety of techniques were incorporated into the PIU to decrease the burden of learning for patients. The device instructions delineated the steps needed to prepare and administer a dose. A small flip-book format was used to help users focus on each discrete instructional step, and a coil-bound design was used to keep the pages flat during use. Line drawings, a simple color palette, and abundant use of white space decreased visual clutter and kept patients focused on the important task of learning how to use the device.

Design of user study

The purpose of the user study was to evaluate the effectiveness of the PIU in training patients to prepare and deliver a simulated dose of exenatide once weekly in the absence of any other educational support. Participants were required to have a diagnosis of type 2 diabetes and to be 21–75 years of age.

Preestablished desired participant criteria were developed to ensure generalization of the study results to intended exenatide once-weekly users. The desired cohort criteria included > 75% injection naïve, ~ 25% current exenatide twice-daily users, ≥ 10% left-handed, 60% female, and no single age category to exceed 30% of the total sample, with no more than 20% of the sample to be > 71 years of age. Desired patients were to be racially and ethnically diverse (Caucasian, African American, Hispanic, and Asian) and were intended to be representative of the potential user population of the exenatide once-weekly formulation.

Study participants were expected to be able to speak, write, and read in English. To obtain a cross-section of educational backgrounds, at least 30% of participants were required to have a high-school degree or the equivalent, with a goal of including ~ 10–15% of participants who did not graduate from high school.

Participant reports of peripheral neuropathy, symptomatic arthritis, or hand weakness, which could affect their use of the once-weekly product, were noted. Subjects who reported being legally blind or had a functional loss of either hand (e.g., amputation or history of cerebrovascular event with paralysis) were excluded. All physical limitations, symptoms, and diseases were self-reported.

The study was conducted at four sites in large, urban areas (Boston, Mass.; Los Angeles, Calif.; Phoenix, Ariz.; and Atlanta, Ga.). One-on-one sessions lasting up to 45 minutes were conducted by facilitators trained to ensure uniform interaction with the participants across the study sites.

Subjects were given a single-dose product kit. The facilitator asked participants to use the PIU to prepare a dose of placebo and simulate an injection into an injection ball using the exenatide once-weekly device. The facilitator could not answer any questions or give further instruction to participants unless participants specifically indicated that they would contact the customer support center to ask a particular question. In such cases, the facilitator would verbally answer the specific question providing no physical assistance, and the request for assistance would be noted in the study data. Participants did not have access to any additional educational materials (e.g., starter kits or instructional videos).

The facilitator assessed participants' ability to complete each of the fundamental steps involved in the preparation and administration of a simulated dose using the exenatide once-weekly injection device. Subsequently, the facilitator used a standardized questionnaire to elicit feedback from participants regarding their satisfaction with the instructions, level of confidence in completing the task, and suggestions to improve the perceived usefulness of the PIU.

Results

Baseline demographics

Baseline demographics of the participants are presented in Table 1. Although Asian subjects were identified, completed screening for participation in the study, and were scheduled, these subjects did not attend the appointment and therefore were underrepresented in the study.

The study cohort was composed solely of individuals with type 2 diabetes; 78% of the subjects were injection naïve, 22% were current exenatide twice-daily users, 12% were left-handed, 21% reported physical limitations (5% neuropathy, 8% hand weakness, and 8% arthritis), and 79% reported that they required visual assistance (glasses or contact lenses). All study participants met the English-language literacy requirement. Less than 1% of subjects had an education level of less than a high school degree, 48% had less than a college degree, 34% had a college degree, and 17% had more than a college degree.

Facilitator observations

Most subjects (88%; $n = 90$) completed the fundamental steps necessary to prepare the medication placebo and deliver a simulated injection with the exenatide once-weekly device as shown in Table 2. Of the participants completing the steps, 72.6% ($n = 74$) completed the fundamental tasks without assistance; 15.7 % ($n = 16$) requested assistance by calling the simulated customer support line; and 11.8% ($n = 12$) of participants did not complete one or more of the fundamental steps.

Participants were able to complete the entire process (including opening the kit, reading the PIU, preparing the placebo medication, and administering the simulated injection) in a mean time of 11.8 minutes. Overall, 66% of participants completed the process in ≤ 12 minutes. Left-handed subjects completed the process more quickly than right-handed subjects, with a mean time of 8.7 versus 12.3 minutes, respectively, with all other factors being equal.

Age did not influence participants' ability to successfully use the PIU to complete the necessary steps to prepare the placebo medication and administer a simulated injection (89% of those ≤ 60 years and 87% of those > 60 years of age were successful).

Completion success was slightly affected by physical and visual limitations. Specifically, 72% of those with self-reported hand limitations (arthritis, neuropathy, or hand weakness) completed all of the steps compared to 92% of those without hand limitations. Similarly, 100% of those reporting normal vision completed all of the steps compared to 85% of those who required visual correction.

The facilitators also observed that 37% of participants did not keep the "Your Guide to the Parts" page folded out as instructed in the PIU. The number of subjects who skipped over pages (~ 30%) was similar to the number of subjects who required some assistance (with fundamental and nonessential steps) from the simulated call center. Only one subject was unsuccessful in performing

Table 1: Participant Demographics and Characteristics

Characteristics	Total ($n = 102$)
Female sex (%)	55
Age in years (%)	
21–30	2
31–40	12
41–50	25
51–60	31
61–70	26
71–75	4
Injection experience (%)	
Injection naïve	78
Current exenatide twice-daily users	22
Race/ethnicity (%)	
Caucasian	72
African American	23
Hispanic	6
Asian	0
Education level (%)	
Less than a high school degree	1
Less than a college degree	48
College degree	34
More than a college degree	17
Handedness (%)	
Left-handed	12
Physical limitations (%)	
Neuropathy	5
Arthritis	8
Hand weakness	8
Visual impairment (%)	
Wears glasses or contacts	79
Duration of diabetes in years (%)	
< 5	43
5–9	32
10–14	14
15–19	7
≥ 20	4

Table 2. Performance Data Using the Exenatide Once-Weekly PIU by Age and Physical Limitations

		Completed All Fundamental Steps			Incomplete (≥ 1 Fundamental Steps)
		Total	Assisted	No Assistance	
Total		88%	15%	73%	12%
Age	≤ 60 years	89%	12%	77%	11%
	> 60 years	87%	26%	61%	13%
Hand Issues	None	92%	15%	77%	8%
	Neuropathy, arthritis, or weakness	72%	22%	50%	28%
Requires glasses/ contacts	Yes	85%	17%	68%	15%
	No	100%	10%	90%	—

any of the steps outlined in the PIU; this was because of cognitive deficits unrelated to study performance that were not identified during study recruitment.

Patient feedback

Self-reported participant feedback is presented in Figure 1. More than 90% of participants reported confidence in their ability to prepare and deliver the injection at home with access to only the PIU (responding either "agree" or "strongly agree"). In addition, ~ 85% of participants found the PIU easy to use (responding either "agree" or "strongly agree").

Discussion

Acquisition of the skills required for self-management of diabetes therapies is a prerequisite for patient compliance. This study demonstrated that the exenatide once-weekly PIU, designed with key human factors and adult-learning principles proactively considered, enabled successful use of the exenatide once-weekly injection device by 88% of the study participants in the absence of individual training or other educational resources. Although most subjects (73%) who completed the fundamental steps did not require additional assistance, 15% obtained verbal assistance by simulating a call to a customer support center. Based on the one-time use of the exenatide once-weekly injection device, ~ 90% of study participants reported confidence in their ability to deliver a dose at home with this device using the PIU. In addition, first-time use of the exenatide once-weekly injection device by predominantly injection-naïve participants averaged ~ 12 minutes from start to finish when aided by the PIU alone. These results are consistent with previous observations that educational resources incorporating human factors and adult-learning principles lead to effective learning.[21]

Many patients are distressed about the use of an injection device.[24] Because the majority of patients with type 2 diabetes receive health care from primary care physicians,

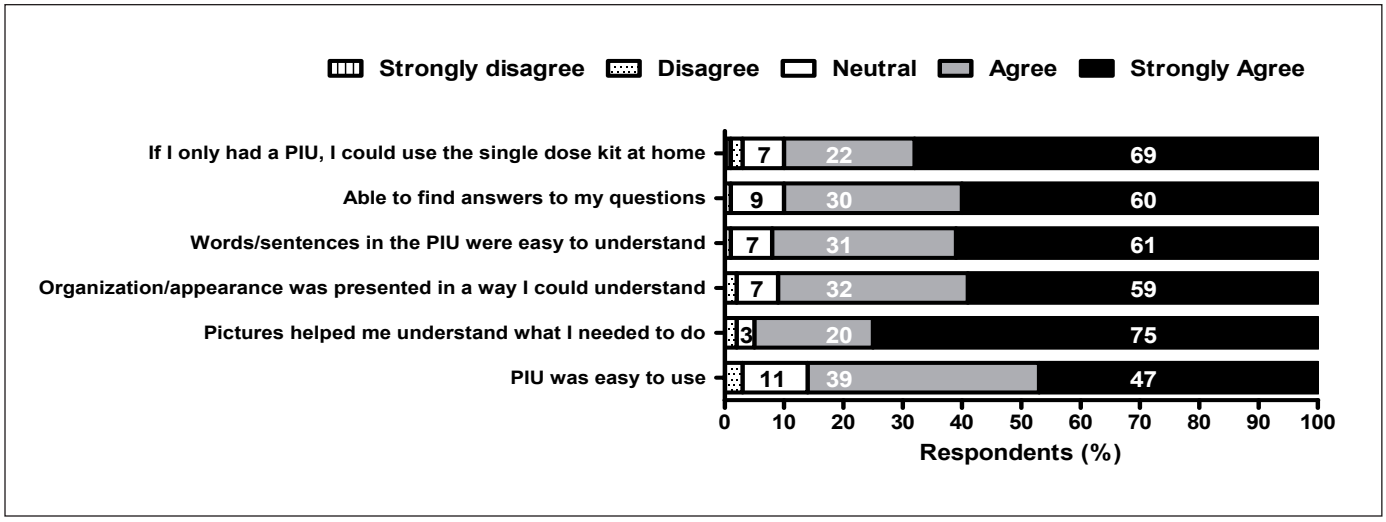

Figure 1. Participant post-use survey of PIU.

and diabetes education is generally not available, ease of use may facilitate medication adherence in these patients.[17,25,26] In this study, we demonstrated that minimal education beyond the PIU was required to learn how to correctly use the exenatide once-weekly device.

The data presented were collected from four major U.S. cities and may be generalizable to injection-naive patients and current exenatide twice-daily patients with type 2 diabetes. Although the majority of patients in this study (88%) were successful in using the PIU and the exenatide once-weekly injection device, issues that were common to participants who were not successful included *1*) skipping pages in the PIU, *2*) skipping over information on a page of the PIU, and *3*) not completing a step because a previous step was incomplete.

Study limitations

A limitation of this study is that the population did not match the desired recruitment plan; the Asian population is underrepresented. Also, the study attempted to include individuals who had not graduated from high school, but despite specific recruitment efforts to enroll 10–15% participants with less than a high school education, fewer subjects from this population were enrolled. This study was designed to assess the ability of the PIU to provide adequate information to ensure accurate use of the device by people who were naïve to the exenatide once-weekly product. Therefore, the study did not address the effect of repetitive use of the instructions or the device. However, one would expect that repetition may improve performance.[27]

Conclusion

This usability study demonstrated that the PIU were effective in guiding the preparation and administration of a simulated injection using the exenatide once-weekly injection device. The success rate (88%) of type 2 diabetic subjects who were able to complete the fundamental steps required to prepare and administer a dose using the PIU as the sole educational intervention may be attributed to instructions that were designed to incorporate adult-education learning principles and human-factors principles.

Although it is highly desirable for patients to be formally educated by diabetes educators when initiating a new medication, practical constraints (e.g., insufficient time, limited insurance coverage) and lack of access to education support are realities for many. This study demonstrated the ability of the PIU to provide adequate instruction in the absence of face-to-face training or any other educational resource to ensure the appropriate use of this new device for administration of once-weekly exenatide.

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