Qualitative Interviews with Psoriasis Patients Evaluating Paper to Electronic Migration of the Psoriasis Symptom Inventory

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INTRODUCTION

- Psoriasis is a symptomatic disease that significantly impacts health related quality of life (HRQoL) outcomes and Patient Reported Outcomes (PROs) can be used in clinical trials to support efficacy claims[1]
- Traditionally, PROs have been assessed using paper diaries or questionnaires
- Migration of PRO assessments from a paper version to an electronic version is considered to be an instrument modification[2] and requires evidence that the two modes of administration perform equally well
  - Minimal changes with migration to an electronic version can rely on cognitive interviewing to establish equivalence[3, 4, 5]
  - Equivalence is established by consensus among patients that the intent and meaning of items, response options, and instructions are the same for both modes of administration
- Migration of a paper PRO instrument into an electronic format with only minor modification have generally been successful with no negative impacts on instruments' psychometric integrity and with scores remaining equivalent across modes[3, 4, 5]

OBJECTIVE

- To evaluate and document the migration of the Psoriasis Symptom Inventory (PSI), a newly developed Patient Reported Outcome (PRO) instrument, from the existing paper format to an electronic daily diary format using qualitative interviews of patients with psoriasis

METHODS

Study Design

- Cross-sectional, qualitative interview study using a cognitive interview process to evaluate the equivalence of the PSI from paper format to electronic format (handheld PDA)
- Cognitive interview sessions in two waves of six patients each were conducted by trained interviewers
  - Interviews assessed consistency of patient comprehension across modes of administration, and the meaning and intent of instructions, items, and response options
  - Usability of the PDA was assessed with qualitative interview questions, descriptive survey questions, and observation of the patient's use of the by the interviewers

Study Population and Analysis Dataset

- Adult patients (age ≥ 18 years) with moderate to severe chronic plaque psoriasis
  - Likely candidate for systemic or phototherapy for psoriasis with percent body surface area affected (BSA) ≥ 10, psoriasis area severity index (PASI) score ≥ 12, physician global assessment (PGA) score ≥ 3
  - Patients could not be currently participating in another research study/clinical trial which includes the use of investigational or approved medications for Psoriasis
- Study conducted at sites in Seattle, WA and Longmont, CO

Cognitive Interviews

- The cognitive interview process used the PSI in both paper format and electronic format (Figure 1)
  - Questions were slightly reformatted to fit the screen for the electronic format
  - The electronic version presented 1 item per screen rather than multiple items on a page as in the paper version
  - No wording changes were made between the paper and electronic format
- The primary focus of the interview was to determine whether or not the patient understood the item on the initial mode of administration presented to them and whether their understanding of the question itself (including response options) was changed or altered by seeing the same item on the alternate mode of administration
- Half of the patients received the electronic version first followed by the paper version; the other half received the paper version first followed by the electronic version
- Patients were then interviewed with a series of semi-structured questions assessing:
  - Their perceived meaning for each item
  - response option clarity
  - whether or not the format change would affect the answer they would give for each item
- Interviews were taped and transcribed to construct Cognitive Summary Grids

Comprehension of Altered Format

- Assessment of comprehension of item in initial mode of administration
- Assessment of change in comprehension due to change in format of alternate mode of administration

Usability

- Interviewers observed the patients during completion of the PSI, and noted any difficulties observed with the completion of either format
- Patients completed an ease of use questionnaire for the electronic platform at the end of the session

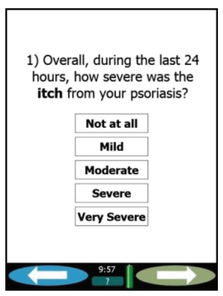
Data Analysis

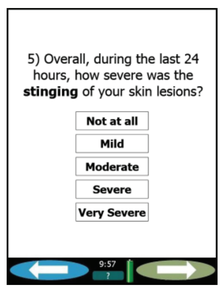
- Data was analyzed on an item-by-item basis
- Qualitative data from cognitive interviews was evaluated for evidence of successful migration from paper to electronic formats
- Descriptive data from demographics was summarized

Figure 1. PSI Format Examples

Example of Format for Paper and Electronic Versions:

For the following group of questions, the **"last 24 hours"** means from right now - back to yesterday at this same time.	Not at all	Mild	Mod-erate	Severe	Very Severe
1) Overal, during the last 24 hours, how severe was the **itch** from your psoriasis?					
5) Overall, during the last 24 hours, how severe was the **stinging** from your psoriasis?					





Patient Characteristics

	N = 12
Age (years), mean (SD)	49.7 (11.1)
Sex (male), n (%)	8 (66.7)
Race, n (%)	
White	10 (83.3)
Asian	1 (8.3)
Mixed	1 (8.3)
Height (inches), mean (SD)	69.0 (5.2)
Weight (pounds), mean (SD)	207.2 (57.2)
PASI, mean (SD)	19.2 (6.0)
BSA (%), mean (SD)	25.2 (11.9)
PGA, n (%)	
3 - moderate	2 (16.7)
4 - Severe	8 (66.7)
5 - Very Severe	2 (16.7)

SD, standard deviation; PASI, psoriasis activity severity index; BSA , body surface area affected; PGA, physician global assessment

RESULTS

Examples from Cognitive Summary Grid

Item Presented	Summary Comments - Wave 1	Summary Comments - Wave 2	Final Decision
PSI Instructions - For each of the following questions, please mark ( ) the box of one answer that best describes your experience. In the questions below, the phrase "skin lesions" refers to the areas of your skin affected by your psoriasis. For the following group of questions, the "last 24 hours" means from right now-back to yesterday at this same time.	Subjects seem to understand the instructions, and did not report any differences in cognition One subject suggested that the paper version targeted the time frame earlier than the electronic version. One subject noted the differing sizes of the formats.	One subject had a preference for the electronic format.	Instructions retained without modification
PSI Question 1 - Overall, during the last 24 hours, how severe was the **itch** from your psoriasis? Did you have any difficulty with the response options? Does the appearance of the two formats affect how you understand the response options? If so how?	One subject noted a formatting and sequence difference.	One subject noted that the format of the questions looked different, but indicated that that difference would not affect how they responded to the question.	Item was retained without modification
PSI Question 2 - Overall, during the last 24 hours, how severe was the **redness** of your skin lesions? Did you have any difficulty with the response options? Does the appearance of the two formats affect how you understand the response options? If so how?	One subject noted that on the paper version, one has the ability to look at the symptoms that will be covered, whereas on the electronic version, one must focus on one symptom at a time.	Subjects did not report any substantial differences in the meaning or appearance of the question, or to how they would think about the question.	Item was retained without modification
What made one or the other version more difficult or easy to use?	The electronic format itself presents no difficulty to patients. Subjects reported a preference for the electronic format of the PSI.		Electronic version retained without modification

For PSI question 3 to 8, subjects did not report any substantial differences in the meaning or appearance of the question, or to how they would think about the question in the differing formats and no difficulty with the response options was reported.

Summary of Cognitive Results

- Patients reported that there was no change in their understanding of instructions, item language, and response options between modes of administration
- There were no differences in comprehension nor in the responses patients selected between the two modes, nor were there differences between those completing the paper version first versus the electronic version first
- Some patients offered comments about one item on the screen at a time potentially causing them to focus on single symptoms rather than seeing all items at once
  - However, this difference did not affect their understanding of the item itself

Tabulated Results from Ease of Use Questionnaire

Question	Response	n (%) N = 12
How easy/difficult did you find using the electronic questionnaire?	- Very Easy - Quite Easy	9 (75) 3 (25)
The choices that were there to use when I answered the questions were:	- Easy to read on the screen/ No Problem choosing my response	12 (100)
Overall, did you find the electronic questionnaire acceptable to use?	- Yes	12 (100)

- All patients reported that the electronic version of the diary was acceptable and easy to use
- All patients indicated that the screen was easy to read
- None of the patients reported any problems choosing a response
- Many patients offered spontaneous comments expressing a preference for the electronic mode of administration over the paper

SUMMARY OF RESULTS

- Patients reported that there was no change in their understanding of instructions, item language, and in response options between the two modes of administrations
- Patients who received the paper version first versus the electronic version first showed no difference in their understanding of the items and concepts presented
- The patients' ability to successfully use the electronic version, as well as the consistent confirmation that the format changes did not impact the way patients comprehended the PSI indicated that the migration of the PSI from paper to electronic administration was successful

CONCLUSIONS

- The results of this analysis indicate a successful migration from the paper format to the electronic format of PSI was achieved

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CONFLICTS OF INTEREST

- MM and TC are employees of Health Research Associates Inc., which received funding for this study from Amgen, Inc.
- DC and HV are employees and shareholders of Amgen, Inc.

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