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

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INTRODUCTION

Psoriasis is a chronic, inflammatory skin disorder that affects up to 3% of the world’s population. It is associated with significant physical and emotional distress, including depression and anxiety. Patients with psoriasis experience a range of symptoms, including skin lesions, arthritis, and nail involvement. The Psoriasis Symptom Inventory (PSI) is a validated instrument used to assess the impact of psoriasis on the patient’s quality of life. The PSI is a self-report measure that includes items evaluating the severity of skin lesions, joint pain, and other symptoms.

The PSI is typically administered in a paper format. However, with the increasing use of electronic health records and digital patient portals, there is a need to evaluate the feasibility and acceptability of migrating the PSI from paper to electronic formats. This study aimed to assess the comprehension of the PSI when administered in both paper and electronic formats, and to determine whether the two modes of administration perform equally well.

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 paper was assessed through qualitative interview questions, descriptive survey questions, and observation of the patient's use of the PDA.

Study Population and Analysis Dataset

Adult patients (age ≥ 18 years) with moderate to severe chronic plaque psoriasis were likely candidates for systemic therapy or phototherapy for psoriasis with percent body surface area affected (BSA) ≥ 10, psoriasis area severity index (PASI) ≥ 12, physician global assessment (PGA) score ≥ 3. Patients could not be concurrently participating in another research study or 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). Interviews were conducted at the beginning of the session.

Usability

- Interviewers observed the patients during completion of the PSI, and noted any difficulties observed with the completion of each format.
- Patients completed an ease of use questionnaire for the electronic format 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.

RESULTS

Examples from Cognitive Summary Grid

<table>
<thead>
<tr>
<th>Item Presented</th>
<th>Summary Comments - Wave 1</th>
<th>Summary Comments - Wave 2</th>
<th>Final Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSI Instructions - For each of the following questions, please mark (X) the box of 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 the same time.</td>
<td>Subjects seem to understand the instructions, and did not report any differences in cognition.</td>
<td>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.</td>
<td>One subject noted a formatting and sequence difference.</td>
</tr>
<tr>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSI Question 3 - The electronic format itself (including response options) was changed or altered by seeing the item on the alternate mode of administration. What made one or the other version more difficult or easy to use?</td>
<td>The electronic format itself presents no difficulty to patients. Subjects reported a preference for the electronic format of the PSI.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tabulated Results from Ease of Use Questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How easy/difficult did you find using the electronic questionnaire?</td>
<td>- Very Easy</td>
<td>9 (75)</td>
</tr>
<tr>
<td>The choices that were there to use when I answered the questions were:</td>
<td>- Easy to read on the screen/No Problem choosing my response</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Overall, did you find the electronic questionnaire acceptable to use?</td>
<td>- Yes</td>
<td>12 (100)</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- Patients reported that there was no change in their understanding of instructions, item language, and in response options between the two modes of administration.
- 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.

REFERENCES

1. Wilke, RJ, Burke, LB, and Erickson, P. Controlled Clinical Trials. 2004; 26:636-662.

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.
- Jon Nelsen PhD (Amgen, Inc.) provided medical writing support.

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