



Original article

Development of a patient-reported outcome questionnaire for use in adults with moderate-to-severe plaque psoriasis: The Psoriasis Symptoms and Signs Diary[☆]

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Received 21 May 2015; accepted 14 July 2015

Available online 26 September 2015

Abstract

Background: Patients with psoriasis (PsO) suffer from a variety of symptoms. Tools are needed to assess PsO symptoms and signs from the patient's perspective.

Objective: To develop a patient-reported outcome (PRO) measure to assess symptoms and signs in individuals with moderate-to-severe PsO.

Methods: Face-to-face concept elicitation interviews were conducted with 20 subjects with moderate-to-severe plaque PsO. Results from the interviews, a literature review, and clinical input informed the development of the draft Psoriasis Symptoms and Signs Diary (PSSD). Three waves of face-to-face cognitive interviews ($n = 19$) were conducted to evaluate the clarity and relevance of the PSSD. Additional interviews ($n = 5$) were conducted to confirm its content.

Results: The PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) using 0–10 numerical ratings. Two versions with different recall periods (24 h and past 7 days) were developed. PsO patients found the PSSD to be clear and relevant.

Limitations: The sample had limited racial diversity.

Conclusion: The PSSD, developed according to the Food and Drug Administration PRO Guidance, assesses severity of symptoms and signs commonly associated with plaque PsO. Its measurement properties are currently being evaluated.

Abbreviations: BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; FDA, Food and Drug Administration; HRQoL, Health-Related Quality of Life; IRB, Institutional Review Board; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; PRO, Patient-Reported Outcomes; PsO, Psoriasis; PSSD, Psoriasis Symptoms and Signs Diary; US, United States.

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[☆] Preliminary data from this study were presented at the International Society for Pharmacoeconomics and Outcomes Research Annual International Meeting in Montreal, QC, Canada, May 31–June 4, 2014, and at the American Academy of Dermatology Annual Meeting in Denver, Colorado, March 21–25, 2014.

Peer review under responsibility of King Saud University.



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Keywords: Plaque; Psoriasis; Patient-reported outcomes; PSSD; Symptom; Sign; Diary; Questionnaire

1. Introduction

Psoriasis (PsO) affects 2–3.2% of the US adult population, (Stern et al., 2004; Kurd and Gelfand, 2009; Rachakonda et al., 2014) with around 20% considered to have moderate-to-severe PsO (Van Voorhees et al., 2009). Psoriasis has a significant impact on health-related quality of life (HRQoL) (de Arruda and De Moraes, 2001; Rapp et al., 2001; Weiss et al., 2002; Gelfand et al., 2004; Heydendael et al., 2004; Leino et al., 2014; Martinez-Garcia et al., 2014) and poses a significant humanistic and economic burden for patients and society (Javitz et al., 2002; Mustonen et al., 2014).

Evaluating symptoms, in terms of type and severity, is crucial in patient care (Mrowietz et al., 2014) and central to research on treatment efficacy, which often relies on measures of objective severity (versus subjective symptoms) as primary outcomes of interest (Brodell and Preston, 2012; Lajevardi et al., 2015; Molina-Leyva et al., 2014). Clinically-based measures of severity (e.g., Body Surface Area [BSA], the Psoriasis Area and Severity Index [PASI], and the Physician's Global Assessment [PGA]) (Berth-Jones et al., 2006; Puzenat et al., 2010) track changes in PsO severity from a clinician's perspective. Patient-reported outcome (PRO) measures (e.g., Dermatology Life Quality Index [DLQI] (Finlay and Khan, 1994), Skindex (Chren et al., 1996)) have been used in PsO research to evaluate symptoms and their impact on HRQoL, but were not developed exclusively for use in individuals with PsO. Additionally, these PRO measures were not developed in accordance with best practices to satisfy the requirements for product labeling claims, as described in the US Food and Drug Administration (FDA) guidance document for PRO Development (U.S. Department of Health and Human Services, Food and Drug Administration et al., 2009). Other PRO measures are somewhat limited in their scope and depth (Globe et al., 2009; Armstrong et al., 2012; Sampogna et al., 2012; Lebwohl et al., 2014), while still others are proprietary (Martin et al., 2011a, 2011b; Lebwohl et al., 2014). For these reasons, a new PRO measure, the Psoriasis Symptoms and Signs Diary (PSSD), was developed to assess symptoms and patient observable signs in individuals with moderate-to-severe plaque PsO.

2. Materials and methods

The steps involved in the development of the PSSD included a literature search, concept elicitation interviews,

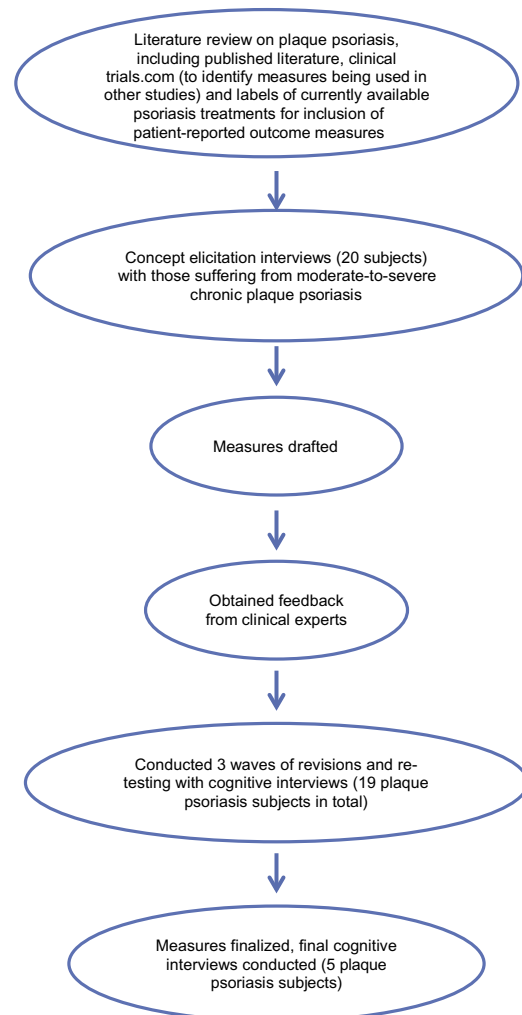


Figure 1. Development process.

drafting of initial items, and three waves of cognitive interviews to refine the instructions, items, and response options (Fig. 1).

2.1. Literature review and concept elicitation interviews

A literature review was conducted to better understand plaque PsO and identify existing PRO instruments that could potentially be used or modified for use in future PsO studies. No existing measure was identified that was available and appropriate for use with plaque PsO, so the decision was made to develop a new measure. As a first step

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