A REVIEW OF PATIENT REPORTED OUTCOMES (PROs) IN PSORIASIS ACCORDING TO THE FOOD AND DRUG ADMINISTRATION (FDA) PRO GUIDANCE CRITERIA

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BACKGROUND

Psoriasis is a chronic inflammatory skin condition that affects an estimated 4.5 to 7.5 million people in the United States.¹ For many patients, this condition can impact their quality-of-life (QoL) and well-being.² Due to the functional and psychosocial impact of psoriasis, clinician-assessments and dermatologic-specific patient-reported-outcomes (PROs) are often used in clinical practice.³ Numerous clinical trials have been conducted in psoriasis, many of which have included clinician-reported dermatologic or psoriasis-specific patient outcomes (PROs) as study outcome measures.⁴

In 2009, both the FDA's PRO Guidance⁵ and ISPOR Good Research Practices Task Force Fost⁶ provided recommendations on how PROs should be created to support claims in approved medical product labeling.⁷ The FDA has suggested PROs in psoriasis trials include the Psoriasis Quality of Life Questionnaire (PQoL-12), Dermatology Life Quality Index (DLQI), Skindex, Psoriasis Disability Index (PSI), Psoriasis Disability Inventory (PSID), and Psoriasis Quality of Life (PQoL).⁸ This study assessed how well the development and validation processes of these PROs align with the 2009 FDA PRO Guidance criteria.

METHODS

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RESULTS

The PRO-12 (⁹) is a self-administered 12-item, psoriasis-specific PRO with a recall period of the past month. It assesses a broad range of issues, including emotional issues, body image and social acceptability issues, overall psychosocial well-being, day-to-day activities, and day-to-day physical function.

The DLQI (¹⁰,¹¹) is a self-administered 10-item PRO, applicable to patients with any skin disease with a recall period of the last week. It assesses symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment-related distress as related to the patient’s skin condition.

The Skindex-29 (¹²) is a self-administered 29-item PRO, applicable to patients with any skin disease with a recall period of the last week. It assesses symptoms, emotions, and functioning as related to the patient’s skin condition.

The PQOL-12 (¹³) is a self-administered 15-item, psoriasis-specific PRO with a recall period of the past month. It assesses psoriasis-related stress including the psychosocial impact of psoriasis.

The PSI (¹⁴) is a self-administered 8-item psoriasis-specific PRO with a recall period of the last 7 days. It assesses itching, redness, scaling, burning, stinging, cracking, flaking, and pain.

Table 1 presents the gap analysis of each PRO as assessed according to the 2009 FDA PRO Guidance Report.

LIMITATIONS

PROs and studies were identified from publicly available sources. All relevant materials that are not currently available for review were not included.

Authors of articles may have included all the data pertaining to instrument development as assessed in this gap analysis. Published articles may have included detailed sections on a literature review; however, the background sections of most articles provided a brief summary. Conceptual frameworks are also rarely published in detail.

This analysis did not include the review of the dimensionality and scoring of the PROs.

This review does not apply to regulatory guidelines outside the US.

CONCLUSIONS

The only psoriasis-specific PRO measure that has met the recommendations of the FDA’s PRO Guidance is the Psoriasis Symptom Inventory. However, this PRO focuses solely on symptoms.

Although the gaps for meeting the FDA’s Guidance criteria for these PROs are variable, the PROs reviewed have undergone somewhat extensive psychometric evaluations. Only the PSI met all the criteria as specified by the FDA’s Guidance Report.

Internal consistency reliability of all PROs has been well documented. Four of the PROs did not have evidence of saturation in concepts during concept elicitation research or a published conceptual framework.