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Preference-Based Assessments

Development of a Disease-Specific Version of the EQ-5D-5L for Use in Patients Suffering from Psoriasis: Lessons Learned from a Feasibility Study in the UK

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ABSTRACT

Objectives: The EuroQol five-dimensional (EQ-5D) questionnaire is a generic measure widely used for the assessment of health status. Research has suggested that it may be insensitive to the burdens associated with particular conditions. This study was designed to explore the feasibility of developing and valuing a disease-specific “bolt-on” version of the EQ-5D questionnaire for use in psoriasis.

Methods: A series of steps were undertaken to develop, test, and evaluate dimensions for a psoriasis-specific version of the EQ-5D questionnaire (hereafter referred to as the EQ-PSO questionnaire). Candidate dimensions were explored through a review of published literature, in-depth qualitative interviews with patients, and consultation with a clinical expert. A psychometric validation exercise was then undertaken to establish how well dimensions functioned. Two dimensions were selected for inclusion in a draft measure alongside the existing EQ-5D questionnaire dimensions: “skin irritation” and “self-confidence.” Last, a time trade-off valuation exercise was

conducted with 300 members of the UK general public to derive utilities for health states described by the measure. **Results:** The psychometric analyses indicated that the two new candidate dimensions captured additional variance over and above the existing five dimensions. Data from the valuation exercise were analyzed by using different models. A collapsed random effects model was put forward as a parsimonious and accurate approach. Based on this model, estimated utilities ranged from 0.98 ± 0.02 for state “111111” to 0.03 ± 0.29 for state “555555.” **Conclusions:** This study has developed the EQ-PSO questionnaire to support future psoriasis research and has informed the development of future bolt-on versions of the EQ-5D questionnaire.

Keywords: disease-specific, economic evaluation, EQ-5D, health-related quality of life, instrument development, psoriasis, utilities.

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Introduction

The EuroQol five-dimensional (EQ-5D) questionnaire is a standardized generic instrument used for describing and valuing health status, which is scored as a single index ranging from 1 (full health) to 0 (dead) and below 0 for states worse than dead [1]. The single index is used to estimate quality-adjusted life-years for cost-effectiveness analysis [2]. The original EQ-5D questionnaire was designed as a generic instrument with dimensions relevant to all patient groups and the general population. Five dimensions describe health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). For some conditions, however, important aspects of a disease or symptom may not be captured by these core dimensions of health and as such the EQ-5D questionnaire may be insensitive in these conditions.

Research has been undertaken in different therapy areas to explore the validity or sensitivity of the EQ-5D questionnaire

[3–6]. In summary, this research has demonstrated limitations with regard to vision, hearing, and some psychological disorders. This has been recognized in the latest version of the National Institute for Health and Care Excellence guidance for methods of technology appraisal, which states, “In some circumstances, evidence suggests that using the EQ-5D may not be valid (for example in certain mental health conditions related to psychosis, mania or cognition, or in conditions affecting sensory functions like vision or hearing)” [7].

One solution that has been proposed to improve the validity of the EQ-5D questionnaire is the inclusion of additional dimensions that are designed to capture important elements of the condition [8]. These so-called bolt-on measures would include the standard EQ-5D questionnaire five dimensions with the addition of one or more condition-specific dimension to address the particular disease. Such an approach has the potential advantage of retaining the core dimensions of the EQ-5D

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questionnaire while also achieving greater sensitivity within specific health conditions. It should also help to retain the strengths of the current version of the EQ-5D questionnaire.

There has been relatively limited research so far on the development of the EQ-5D questionnaire bolt-on measures. Some work has been undertaken in cognitive problems, sensory impairments, and difficulties related to sleep [9–11]. The present study team also considered that there is inconclusive evidence for the effectiveness of the EQ-5D questionnaire for use in dermatological conditions [12,13]. Research into the impact of psoriasis has shown that it can have a very significant impact on patients' health-related quality of life. One study reported that patients were willing to accept a 40% shorter life expectancy to avoid uncontrolled disease [14]. The nature of the specific burden traditionally associated with psoriasis (skin lesions, itch, embarrassment, etc.) may not be reflected in the EQ-5D questionnaire descriptive system and as such it may be an appropriate candidate for the development of an EQ-5D questionnaire bolt-on module.

The EuroQol Group has an interest in the potential for the development of bolt-on versions of the EQ-5D questionnaire. The project reported here was designed to develop a psoriasis-specific version of the EQ-5D questionnaire (the EQ-PSO questionnaire). In addition, the project was designed to explore the feasibility of methods for the development of bolt-on measures.

Methods

The study comprised two main phases: the development and psychometric testing of the bolt-on instrument and a subsequent valuation exercise.

Phase 1: Development of the EQ-PSO Questionnaire Bolt-On Instrument

The EQ-PSO questionnaire was specifically designed to retain all the current five-level EQ-5D questionnaire (EQ-5D-5L) dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), which would be supplemented with additional disease-specific dimensions. The five-level version of the EQ-5D questionnaire was chosen as the basis because it was hypothesized that this would permit easier interpretation of the study findings in the context of future research. To develop a condition-specific version of the EQ-5D questionnaire, we sought to initially identify important issues and concerns for patients with psoriasis through review of the available literature, and interviews with clinicians and patients.

Literature review and clinician interview

Rather than undertaking a full systematic review, a more focused literature review was conducted to understand the symptom and treatment burden associated with psoriasis. The literature search incorporated Medline, Embase, and other specialist databases and was conducted by using OVID in March 2010. Articles were restricted to those published in English between 1990 and 2010, with particular attention paid to the identification of articles that used qualitative research methods to further examine patient perspectives on the experience of psoriasis.

The literature review provided evidence regarding how psoriasis affects physical, psychological, and social well-being. Psoriatic lesions are frequently itchy, but patients also experience burning, stinging, pain, and bleeding [15]. Skin lesions may further lead to disrupted sleep and can restrict the use of the hands [16]. The skin lesions associated with psoriasis can also be large in area, raised from the normal surface of the skin, and visually obvious. Studies have reported rates of depression in patients with psoriasis ranging from 10% to 58% [17], with the severity of

depression linked to the degree of skin area affected by psoriasis [18]. People with more severe psoriasis are more likely to report feeling anxious, hopeless, or ashamed [19]. Social contacts with family, friends, and neighbors; physical activities; group activities; going out socially; and going to public places can also be limited by psoriasis [20]. Skin disease is additionally noted as leading people to feel physically unattractive and/or sexually undesirable [21]. Previous research has noted a genetic component to the susceptibility of individuals to developing psoriasis [22].

An interview was conducted with a US-based dermatologist who has experience of working with patients with psoriasis. An interview discussion guide was developed on the basis of findings from the literature. The dermatologist was asked to characterize the nature of difficulties experienced by patients with respect to their symptoms and in managing their disease.

The dermatologist described the impact of psoriasis in terms of physical, social, and psychological difficulties, and how these varied in terms of the extent and visibility of the disease. The clinician described very common problems of skin irritation including itching, which can lead to further irritation. The psychosocial consequences of the condition could be severe, with patients often reporting anxiety and/or depression due to their skin complaints. The dermatologist also described how patients often worried about the prospect of further disease outbreaks or flare-ups.

Patient interviews

To identify candidate dimensions for the psoriasis module, a series of in-depth semi-structured qualitative interviews were conducted in the United Kingdom ($n = 8$) with individuals with self-reported psoriasis at varying degrees of severity. The interviews were recorded and transcribed for qualitative analysis by using the Atlas.ti (Scientific Soft., Berlin, Germany) software package. A summary of the themes and typical quotes are presented (Table 1); see also Lloyd et al. [23].

Psoriasis was reported as having a widespread effect on the lives of patients with psoriasis. Most individuals experienced a significant degree of pain or discomfort directly attributable to their condition. Frequent and often nonconscious scratching could serve to aggravate lesions, resulting in soreness and bleeding. This could result in sleep disturbance and daytime fatigue from inadequate rest. The prescribed skin care routine of some individuals was described as bothersome.

Some individuals reported an unwillingness to engage in social activities in which their psoriasis would be more visible (e.g., swimming, sunbathing, or visiting hairdressers). Psoriasis often resulted in embarrassment for patients, which affected self-confidence and self-esteem. Most participants also reported anxiety and/or depression because of their psoriasis as well as feelings of frustration due to their inability to successfully control the disease.

Two of the participants were diagnosed with psoriatic arthritis. These patients experienced arthritic problems of pain and loss of mobility. They did however report experiencing similar concerns related to their skin (although these were of secondary importance when compared with the very severe consequences related to arthritis).

Identification of candidate dimensions

The findings from the literature review and interviews were used to draft four new dimensions: skin irritation (including itching), skin appearance (e.g., redness, dry skin, and flakiness), self-confidence, and social/relationship difficulties (e.g., embarrassment, relationship problems). These dimensions reflected the findings from the qualitative research. New dimensions were chosen to minimize any overlap with existing EQ-5D questionnaire dimensions. The language of new dimensions and their

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