
Publishers page: http://dx.doi.org/10.1016/j.jval.2015.03.1066
<http://dx.doi.org/10.1016/j.jval.2015.03.1066>

Please note:
Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher’s version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See http://orca.cf.ac.uk/policies.html for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.
score distributions and indices of reliability and validity. **RESULTS:** The literature review and exhaustive list of PRO instruments indicates that a range of symptoms (e.g., pain, drainage, itchiness) and impacts (e.g., difficulty with movement and interference with sexual activities). These concepts were organized into a conceptual model to facilitate the construction of the questionnaires. Results from cognitive interviews indicated that both the HSIA and HSSA are easily understood by patients and characterize their condition well. Forty subjects completed the observational study (females = 58%, Caucasian = 65%, and age [mean] = 41 years). The HSIA and HSSA scores were well psychometrically sound with strong evidence of test-retest (ICC = 0.92 and 0.80, respectively) and internal consistency (alpha = 0.97 and 0.96, respectively) reliability and known groups (p < 0.001 and F < 0.006, respectively) and construct-related validity (via correlations between the questionnaire measures and other, concurrently administered tools). **CONCLUSIONS:** There is robust evidence supporting the HSIA and HSSA as content valid and psychometrically sound questionnaires for assessing symptoms and impacts in patients with HS.

**PSS30**

**SENSITIVITY OF FUNCTIONAL READING INDEPENDENCE (FRI) INDEX TO CHANGES IN SIZE OF GEOGRAPHIC ATROPHY**

Kapre A1, Bagwe K2, Copleymerman C2, Liffes C2, Kitchen H1

**OBJECTIVES:** The Functional Reading Independence (FRI) Index is a 7-item patient-reported measure developed for use in GA trials. This study examined the sensitivity of the FRI index to change in GA. **METHODS:** A pilot study approach was used to recruit 9 patients from MAHALO, a 2 phase 2 study of laspalumab, a complement factor monoclonal antibody fragment, for treatment of GA. For each reading activity performed in the past 7 days (e.g., writing checks or reading medicine labels), patients were asked the extent to which they required vision aids, adjustments in the activity, or help from another person. The FRI Index yields continuous mean scores (range 1-4) and ordinal mean change in FRI Index score (SD) from baseline for patients with more lesion size and age [mean] 65 years. **RESULTS:** At 18 months, the mean change in FRI index score (SD) from baseline for patients with more lesion size growth was 0.30 (0.5, n = 13) vs 0.17 (0.7, n = 42) for patients with less growth (p = 0.02). For patients with more growth, 36% declined ≥1 FRI Level vs 15% for less growth. Excluding patients at FRI Level 1 at baseline, 41% of patients with more growth (N=54) declined >1 FRI Level vs 18% with less growth (N=11). **CONCLUSIONS:** In MAHALO, the mean FRI Index score of 0.2 differentiated patients with more vs less growth of GA lesion size. FRI level scores were also sensitive to GA lesion growth. These results provide evidence that patient-reported functional independence as measured by the FRI Index is linked to GA lesion growth, an objective clinical measure of disease progression.

**PSS31**

**DEMONSTRATING CONCEPTUAL EQUIVALENCE: TRANSLATION OF THE URTRICARIA ACTIVITY AND IMPACT MEASURE (U-AIM) FROM ENGLISH INTO SPANISH**

Peri T1, Varni J1,4, Antonova EN2, Arnold B2, Perez B3, Zazzali I2

1FACTStrans, Embratur, IL, USA, 2Genentech, Inc., South San Francisco, CA, USA

**OBJECTIVES:** Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinationa randomized controlled trials. The U-AIM consists of 20 items that were developed in English for patients with chronic idiopathic urticaria and constitutes a disease-specific tool developed in English to assess the impact of chronic urticaria from the patient’s viewpoint. The objective of this work was to translate and linguistically validate the U-AIM from English to Spanish for use in the US. **METHODS:** The U-AIM was translated into universal Spanish according to industry standard methodology. After the translation was completed, five Spanish-speaking patients in the US diagnosed with chronic idiopathic urticaria completed the translated questionnaire and participated in a cognitive debriefing interview. Interviews were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity of the U-AIM was maintained for the Spanish version. **RESULTS:** Of the five patients (40% male), the mean age of four was 37 years [one patient did not report his age]. All U-AIM items were well understood and proved relevant to the patients in this sample. Of interest, terms such as, “urticaria,” “hives,” “angioedema” and “rapid swelling” were clearly understood as intended. **CONCLUSIONS:** The results indicate that the Spanish version of the U-AIM translation is conceptually equivalent to the English source version and easily understood by the target population in the US. We consider the translation to be acceptable for PRO assessment in research and clinical practice. Future research could include testing of the PRO in patients with other Spanish-speaking countries to confirm its acceptability beyond the US.

**PSS32**

**PATIENT REPORTED OUTCOMES IN GLAUCOMA A SYSTEMATIC REVIEW**

Agarwala S1,2,3, Caprioli L1,2, Kappareddy R1,2

1Medscape, Health Science Centre and Salford Royal NHS Foundation Trust, Salford, UK, 2AKIUS International, Manchester, UK, 3University of Manchester and Manchester Academic Health Science Centre, Manchester, UK

**OBJECTIVES:** A recent systematic literature review of randomized controlled dermatology-related trials showed that patient-reported efficacy outcomes (PROs) were measured in 37% of 1325 trials as a secondary outcome. Our research aimed to characterize the benefits of PROs in drug development in dermatology from the patient, prescriber, regulator, payer, and manufacturer perspectives using a real-world example of a new medical product. **METHODS:** The case studies were identified based on the use of PROs in pivotal clinical trials for the product. **RESULTS:** A target lifestyle review was conducted in PubMed from 2004 to 2014 for six products (Atopiclair for atopic dermatitis, Acitretin for psoriasis, etc.) and mentions. **CONCLUSIONS:** Patient-reported assessment of the treatment impact on disease during drug development has many benefits for all stakeholders.