

The Harmonization of Outcome Measures in Eczema (HOME) amendment to the HOME roadmap for development of an outcome set for clinical practice/recordkeeping in atopic eczema

Introduction

Measuring outcomes in a valid way provides useful information for clinicians and their patients in evaluating response to treatment in the clinical setting. Patient outcome measurement also represents a key component of health care quality assessment and quality improvement projects in a clinical practice setting. Although HOME's mission does not include developing quality measures (which cover outcomes such as safety, care co-ordination, and patient experience), one of HOME's original goals was to develop a core outcome set for atopic eczema for use in the clinical setting above and beyond the core outcome set for clinical trials.

The HOME roadmap provides a step-by-step process for the development of a core outcome set for all eczema trials.¹ This process involves the following steps: Step 1) identify the scope of the instrument set (i.e. which population will be measured and in what setting), Step 2) using a stakeholder Delphi process, find consensus on which domains are relevant to be measured (i.e. what should be measured), Step 3) identify which instruments are best-suited for measuring these domains (How to measure), using systematic reviews of the quality of the instruments, filling validation gaps by primary validation research followed by consensus voting, and Step 4) disseminate the results.

Step 1 and 2 of the HOME roadmap have been completed for the development of an outcome set for clinical practice.² However, because of unique features of this setting, a few adjustments to the original HOME roadmap are deemed necessary for the efficient development of an outcome set for clinical practice. In the daily clinical practice, it is impractical to measure multiple outcomes in every patient encounter and the tools to measure outcomes need to be rapid and easy to perform. HOME aspires to build a prioritized list of outcomes with a list of easy-to-use measurement instruments for clinicians to "pick and choose" from in their daily clinical practice. This "pick and choose" model differs from the clinical trial setting, where all outcomes defined in the core outcome set were recommended to be measured.

This document outlines proposed amendments to the original HOME roadmap that should guide and facilitate the efficient development of a set of AE outcome instruments for use in clinical practice. They are organized by the original steps outlined in the original roadmap.¹

Step 1: Scope and applicability

Atopic eczema patients of all ages and severity, acute and chronic stages in the clinical practice setting.

Step 2: Developing a set of outcome domains³

2.1. The discovery of domains

An introductory email will be sent to the HOME members, including a brief explanation of the HOME outcome set for clinical practice and a preliminary suggested list of domains, derived from the original HOME Delphi exercise.² Members will be invited to submit additional domains to enhance the preliminary list.

2.2. Determining the most important domains and ranking

The domains suggested by the members will be consolidated to generate a preliminary list of possible domains to be measured in clinical practice. This list will be distributed via e-survey to the membership asking them to rank the top 5 domains they would like to prioritize for clinical practice.

For each domain, the mean rank and whole (absolute) rank will be calculated as well as Kendall's coefficient of concordance (W). If strong consensus is achieved ($W \geq 0.7$) polling will stop. If a weak agreement is reached ($W \leq 0.3$) we will perform a second round of polling via e-survey. For moderate agreement, the trade-off between the practicality and the potential gain from another polling round will be assessed, taking into account the number of respondents.

Should another round of polling occur domains which were not selected by over 50% of the respondents in the first round will be eliminated from the poll to enhance consensus. Participants will be provided data from the previous round: the mean rank and percentage of respondents who mentioned each domain, and Kendall's W for the second polling round. Continued polling will be based on the logic described above.

Step 3: Develop a set of outcome measurement instruments for the 5 top-ranked domains

HOME will focus its efforts on the 5 top-ranked domains. This does not preclude independent studies on other domains of interest from researchers.

1. In HOME V meeting and afterwards, we will conduct a consensus discussion on the top-ranked domains and we will agree upon the research plan moving forward.
2. For domains which have been previously assessed in HOME for clinical trials we will extract relevant data (identification of all instruments previously used to measure domain and their level of validation) and consider their suitability as clinical practice measures or whether additional research is needed. Domains not previously assessed will be open for examination using the HOME Roadmap protocol with systematic reviews used to identify potential instruments and their validation properties.

The suitability of instruments will be based on their quality rating, tested against pre-defined adequacy criteria for measurement properties. For domains previously reviewed in the clinical trials COS, we will use the adequacy criteria defined in these reviews.⁴⁻⁶ For other domains, the adequacy of measurement properties will be based on the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) group recommendations.⁷ In addition, the feasibility of the measurement instruments (time to complete and cost) will be addressed, with acceptable filters for the clinical practice setting discussed and agreed upon at HOME V.

3. A shortlist of relevant instruments based on consensus voting after evaluation of quality and feasibility data will be compiled. Additional studies can be completed, if needed.

Step 4

Efforts will be made through conferences, publications and mailing to recommend various the optimal instruments for measuring domains in clinical practice. The list will be a recommended list of instruments that the clinician can select from, not a core outcome set.

Reference

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- 4 Schmitt J, Langan S, Deckert S, *et al.* Assessment of clinical signs of atopic dermatitis: A systematic review and recommendation. *J Allergy Clin Immunol* 2013. doi:10.1016/j.jaci.2013.07.008.
- 5 Heintz D, Prinsen C a. C, Deckert S, *et al.* Measurement properties of adult quality-of-life measurement instruments for eczema: a systematic review. *Allergy* 2016; **71**:358–70.
- 6 Gerbens L a. A, Prinsen C a. C, Chalmers JR, *et al.* Evaluation of the measurement properties of symptom measurement instruments for atopic eczema: a systematic review. *Allergy* 2017; **72**:146–63.
- 7 Terwee CB, Bot SDM, de Boer MR, *et al.* Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007; **60**:34–42.