The Harmonizing Outcome Measures for Eczema (HOME) Roadmap: A Methodological Framework to Develop Core Sets of Outcome Measurements in Dermatology

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Core outcome sets (COSs) are consensus-derived minimum sets of outcomes to be assessed in a specific situation. COSs are being increasingly developed to limit outcome-reporting bias, allow comparisons across trials, and strengthen clinical decision making. Despite the increasing interest in outcomes research, methods to develop COSs have not yet been standardized. The aim of this paper is to present the Harmonizing Outcomes Measures for Eczema (HOME) roadmap for the development and implementation of COSs, which was developed on the basis of our experience in the standardization of outcome measurements for atopic eczema. Following the establishment of a panel representing all relevant stakeholders and a research team experienced in outcomes research, the scope and setting of the core set should be defined. The next steps are the definition of a core set of outcome domains such as symptoms or quality of life, followed by the identification or development and validation of appropriate outcome measurement instruments to measure these core domains. Finally, the consented COS needs to be disseminated, implemented, and reviewed. We believe that the HOME roadmap is a useful methodological framework to develop COSs in dermatology, with the ultimate goal of better decision making and promoting patient-centered health care.

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INTRODUCTION

Measurement has a central role in medicine. In everyday clinical practice we examine patients in order to diagnose, provide a prognosis, and monitor change over time. In clinical trials, outcome measurements are used to assess the safety and efficacy of the interventions being investigated. Researchers may choose from a great variety of different outcome measurements to use as primary and secondary end points in clinical trials. However, comparing data and pooling of clinical trial results in systematic reviews and for guideline development can only be carried out if the underlying clinical trials use the same outcome measurements.

In atopic eczema, we have previously identified more than 20 named measurement instruments to assess disease severity in clinical trials (Schmitt *et al.*, 2007a). Because these instruments differ in the items and domains they include and because most instruments have not been sufficiently validated (Schmitt *et al.*, 2013), treatment effects cannot be readily compared and meta-analyses are difficult, if not impossible (Schmitt *et al.*, 2007b). This situation is a significant threat to evidence-based health care, as clinical decision making depends on the summary of the best evidence available to balance the harms and benefits of treatments and therefore the comparability of trial data.

The global, multi-professional Harmonizing Outcome Measures for Eczema (HOME) initiative is an evidence-driven and evidence-generating outcomes research initiative that aims to standardize and validate a core set of outcome measurements for atopic eczema and increase the quality of outcomes research in dermatology (Schmitt and Williams, 2010; Schmitt *et al.*, 2012; Schram *et al.*, 2012; Schmitt *et al.*, 2013).

Despite the increasing significance of outcomes research and the development of core outcome sets (COSs), the methods to develop and implement COSs have not yet been standardized (Williamson *et al.*, 2012).

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Abbreviations: COMET, Core Outcome Measures in Effectiveness Trials; COS, core outcome set; COSMIN, Consensus-based Standards for the Selection of Health Measurement Instruments; HOME, Harmonizing Outcomes Measures for Eczema

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Influenced by, and in cooperation with, other international outcomes research groups such as the Outcome Measures in Rheumatology (Tugwell *et al.*, 2007), the Core Outcome Measures in Effectiveness Trials (COMET) (Sinha *et al.*, 2008), and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN; (Mokkink *et al.*, 2010b) initiatives, the members of the HOME executive board (the authors of this article) have developed a systematic process for developing a core set of outcome measurements. We believe that the HOME roadmap may serve as a methodological standard for developing COSs for other (skin) diseases such as skin cancer, psoriasis, acne, hand eczema, and chronic wounds.

As the research field of outcome domains and measures is developing, the HOME roadmap may evolve as new important developments emerge in the field. Core sets of outcome measurements reflect the best evidence at a time and can be revised or modified in light of new evidence.

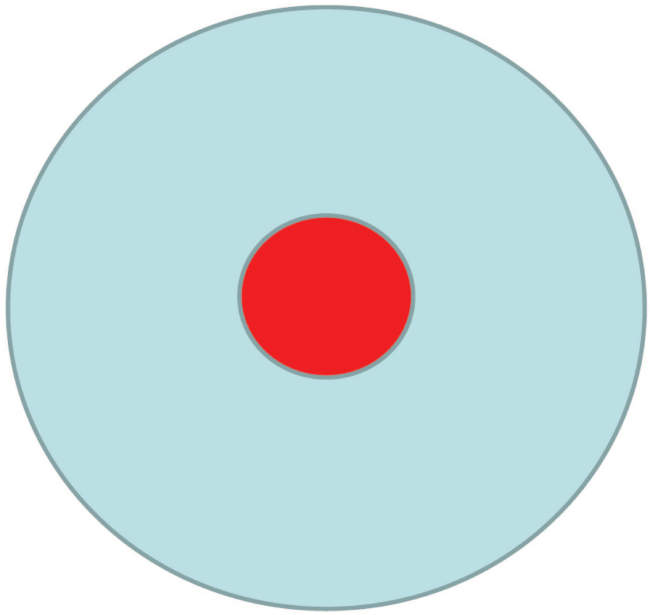

Figure 1. The concept of core outcome sets. The large blue circle symbolizes all outcome domains/measures that may be used. The small red circle symbolizes the core set of outcome domains/measures. The core outcome domains/measures constitute a consensus-derived evidence-based minimum set of domains/measures to be assessed. It is important that all investigators include the core outcome set to allow comparisons of the results of different trials. A core outcome domain/measure can be included as a primary or a secondary outcome.

THE CONCEPT OF COSs

A COS is a consensus-derived minimum set of outcomes to be assessed in a specific situation in clinical research or clinical care. The concept of COSs has been developed to standardize outcomes across trials to allow comparisons of the results of different trials in a given condition (Kirkham *et al.*, 2013b). A core outcome can be included as a primary or a secondary outcome. Many more outcomes can be measured in addition to the core outcomes as indicated in Figure 1. In rheumatology, the Outcome Measures in Rheumatology group has over 20 years of experience in developing COSs (Tugwell and Boers, 1993), and the majority of trials in rheumatoid arthritis now include the COS (Kirkham *et al.*, 2013a). This example indicates that COSs have the potential to standardize and improve clinical trial methodology and thus improve the overall quality of the evidence base for health-care decision making.

Two different levels of COSs need to be differentiated—core sets of outcome domains and core sets of outcome measurement instruments (Table 1).

Core sets of outcome domains (concepts to be measured) constitute an agreed minimum set of outcome domains to be measured. Outcome domains are aspects of disease, such as health-related quality of life, symptoms, clinical signs, productivity loss, or disability. Outcome domains relate to ''what'' should be measured. The aim of a core set of outcome domains is to consistently assess the essential features or aspects of health for a given condition.

Core sets of outcome measurement instruments constitute an agreed set of measurement instruments to assess the core outcome domains. Outcome measurements relate to ''how'' to measure an outcome domain (measurement method, items, and quantification of response). In dermatology, examples of outcome measurement instruments frequently used for assessing clinical signs (domain) include the Psoriasis Area Severity Index for psoriasis and the Eczema Area Severity Index (EASI) or the objective Scoring Atopic Dermatitis index for atopic eczema. To meet the requirements of evidence-based health care, outcome measurement instruments need to be valid, reliable, and sensitive to change and should also be feasible in their application (Mokkink *et al.*, 2010b).

THE HOME ROADMAP

The development of a core set of outcome measurements requires an integrated process of systematic reviews, consensus studies, validation studies, and consensus voting. The team to develop a core set of outcome measurements should include all relevant stakeholders (Williamson *et al.*, 2012) and should include researchers with experience in both qualitative and quantitative outcomes research. Following the HOME roadmap, the development of a core set of outcome measurements consists of a four-step process (Figure 2).

Step 1: Define scope and applicability

The first step in the development of a core set of outcome measurement instruments is to define its scope and applicability. This includes the population (i.e., disease or stage of disease), the setting (e.g., trial, record keeping, clinical registry, and quality assurance), and the geographical scope. All relevant