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

Jochen Schmitt[1], Christian Apfelbacher[2], Phyllis I. Spuls[3], Kim S. Thomas[4], Eric L. Simpson[5], Masutaka Furue[6], Joanne Chalmers[4] and Hywel C. Williams[4]

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).

[1]*Center for Evidence-Based Healthcare, University Hospital Carl Gustav Carus, Technical University Dresden, Dresden, Germany;* [2]*Medical Sociology, Institute of Epidemiology and Preventive Medicine, University of Regensburg, Regensburg, Germany;* [3]*Academic Medical Centre, Department of Dermatology, University of Amsterdam, Amsterdam, The Netherlands;* [4]*Centre of Evidence Based Dermatology, University of Nottingham, Nottingham, UK;* [5]*Department of Dermatology, Oregon Health & Sciences University, Portland, Oregon, USA and* [6]*Department of Dermatology, Kyushu University, Fukuoka, Japan*

Correspondence: Jochen Schmitt, Center for Evidence-Based Healthcare, University Hospital Carl Gustav Carus, Technical University Dresden, Fetscherstrasse 74, Dresden D-01307, Germany. E-mail: jochen.schmitt@uniklinikum-dresden.de

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.

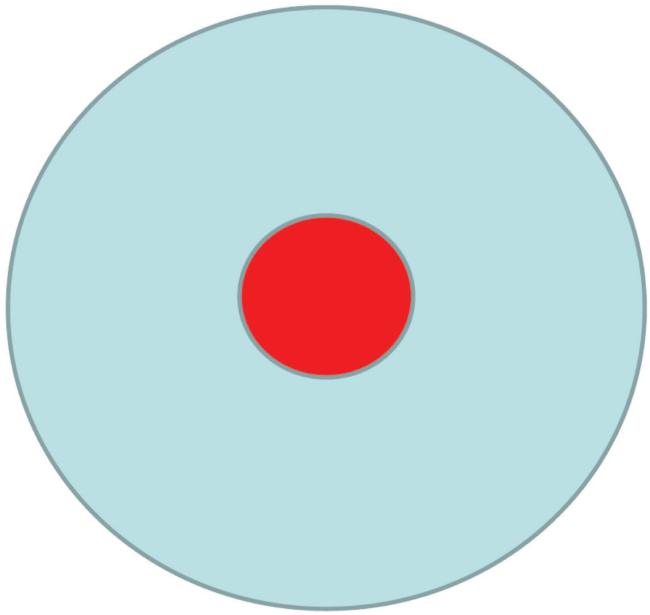

Figure 1. The concept of core outcome sets. The large blue circle symbolizes all outcome domains/measures that may be used. The small red circle symbolizes the core set of outcome domains/measures. The core outcome domains/measures constitute a consensus-derived evidence-based minimum set of domains/measures 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

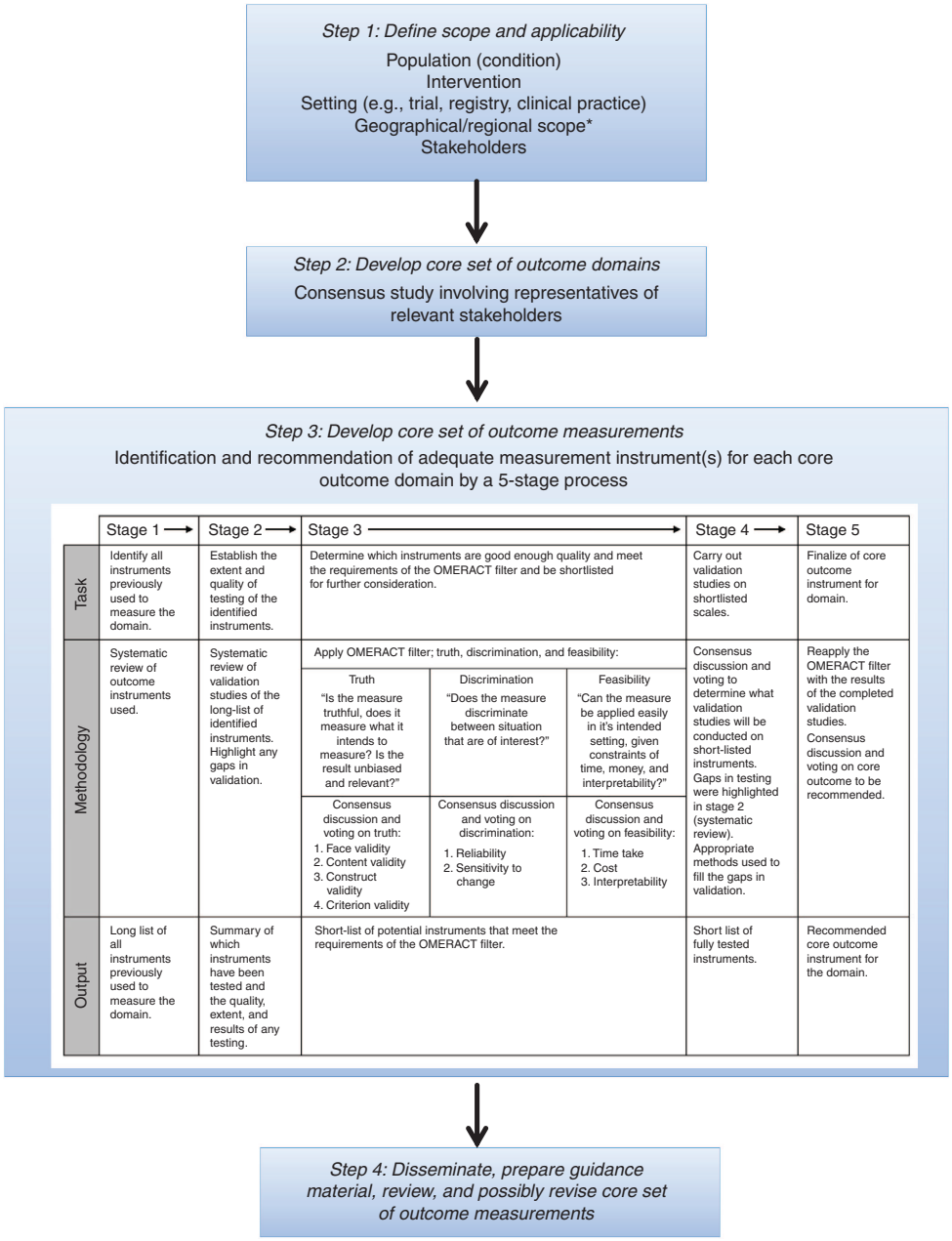

Figure 2. The Harmonizing Outcome Measures for Eczema (HOME) roadmap to develop core sets of outcome measurement instruments. *For trials the scope should generally be global.

stakeholder groups should be involved throughout the entire developmental process. For clinical trials we determined patients, health-care professionals, researchers, regulatory agencies, and pharmaceutical companies to be relevant stakeholders. We recommend keeping core outcome initiatives open to all interested parties, in order to form a diverse group in terms of viewpoints and talents. At least for COSs for trials the global perspective should be captured by involving stakeholders from all over the world. To achieve truly global representation of patients and health-care professionals, proactive approaches and possibly funding to enable participation in consensus meetings may be necessary.

Step 2: Define core set of outcome domains

The second step is the development of a core set of outcome domains by means of a consensus study. The Delphi method and the nominal group technique have been successfully applied to define COSs (Idzerda *et al.*, 2014; Schmitt *et al.*, 2011). The consensus study should be based on an *a priori* protocol. The protocol should include consensus rules, i.e., minimum requirements for a consensus within the panel. The HOME group defined that a consensus is reached if less than 30% of the voters disagree (Schmitt *et al.*,

Table 1. The two levels of core outcome sets: the concepts of core outcome domains and core outcome measurement instruments

Core set of outcome domains	Core set of outcome measurement instruments
Definition	
Domain:	Outcome measurement instrument:
The concept to measure	Measurement method, items, and quantification of response
The ''what'' to measure	The ''how'' to measure the domain
Example: clinical signs of atopic eczema	Example: the Eczema Area and Severity Index (EASI)
Core set of outcome domains:	Core set of outcome measurement instruments:
Minimum set of outcome domains that should be assessed	Minimum set of outcome measurement instruments that should be assessed
Requirements	
Involvement of all relevant stakeholder groups	Involvement of all relevant stakeholder groups
Based on external evidence/systematic review and/or conceptual framework	Based on external evidence/systematic review
Developed by consensus study following an *a priori* protocol	Outcome measurement instruments should meet the requirements of validity, reliability, sensitivity to change, and feasibility
	Developed by consensus study following an *a priori* protocol

2012). The consensus panel should reflect the scope and applicability of the core set to be developed. Generally, as a minimum, patients (or their representatives), clinical researchers, and relevant clinicians should be considered as key stakeholders. Additional stakeholder groups such as regulatory authorities, industry, and health policy representatives may also be considered. The application of consensus methods such as the Delphi method or the nominal group technique is necessary to avoid dominance of individual panel members. For the same reason, it is useful to engage a moderator with experience in consensus studies to provide an independent oversight. Any consensus process needs to be based on evidence to inform decisions. Typically, a consensus process includes reviews, surveys, small group discussions, plenary discussions, and confidential voting at face-to-face meetings (Schmitt *et al.*, 2012).

Step 3: Define core set of outcome measurements: identify, validate, or develop an appropriate measurement instrument for each core outcome domain

The identification of appropriate instruments for each core outcome domain involves five stages. Ideally, *one best* instrument should be defined for each core outcome domain.

- *Stage 1*: All measurement instruments previously used to assess the domain in the setting of interest need to be identified using a systematic review methodology.
- *Stage 2*: For each outcome measurement instrument included in the list of possible outcome measurements, the extent and quality of testing and the measurement properties of the instruments need to be determined by means of a systematic review. Three important measurement properties that need to be assessed are validity (the degree to which an instrument measures the construct(s) it purports to measure), reliability (the degree to which the measurement is free from measurement error), and responsiveness to change (the ability of an instrument to detect change over time in the construct to be measured; Mokkink *et al.*, 2010b). A fourth domain that also needs to be assessed is ''interpretability''—that is, the degree to which one can assign qualitative meaning to quantitative scores (Boers *et al.*, 1998). Interpretability is not considered a measurement property but is nevertheless an important characteristic of measurement instruments. Interpretability encompasses examining the assessment of floor and ceiling effects as well as the minimal important change and clinical bandings according to the overall severity of disease.

Various criteria have been proposed to assess outcome measurement instruments. For instance, COSMIN initiative (www.cosmin.nl) has proposed quality criteria for measurement properties of health status questionnaires, in particular patient-reported outcomes (Terwee *et al.*, 2007; Mokkink *et al.*, 2010b). COSMIN also developed a checklist for the assessment of the quality of validation studies (the COSMIN checklist) and sensitive search terms for systematic reviews of validation studies that we recommend (Mokkink *et al.*, 2010a).

- *Stage 3*: The systematic review of measurement properties (stage 2) is used to inform the consensus process whether or not the individual outcome measurement instruments are suitable to assess the core outcome domain. All relevant stakeholders should be involved. Within the HOME initiative, we reached a broad international consensus among health-care professionals, patients, and clinical researchers that the Outcome Measures in Rheumatology-filter of ''Truth, Discrimination, and Feasibility'' (Boers *et al.*, 1998) should be met for outcome measurements to be recommended (Schmitt *et al.*, 2012). ''Truth'' means that the outcome measurement captures what it intends to, and thus corresponds to the measurement property ''validity''. ''Discrimination'' means that the outcome measurement discriminates between disease states in a reliable way, and therefore corresponds to the measurement criteria of ''reliability'' and ''sensitivity to change''. ''Feasibility'' captures important aspects of outcome

measurements beyond the classic psychometric properties such as interpretability (see above stage 2), cost, availability, time requirements, and practicability and clearly depends on the setting (Boers *et al.*, 1998). The output of stage 3 is a short list of instruments that may be considered as potential core outcome measurement instruments (Figure 2).

- *Stage 4*: The absence of evidence on measurement properties does not mean that a measurement instrument is inadequate. Depending on the results of stages 2 and 3, validation studies of outcome measurement instruments included in the short list may be necessary to clarify whether or not outcome measurement instruments meet the requirements of ''Truth, Discrimination, and Feasibility'' (Boers *et al.*, 1998). It may be necessary, or preferable, to develop a new instrument if existing measurement instruments are found to be inadequate. If one or more suitable measurement instruments have been identified then stage 4 is not necessary.
- *Stage 5*: The evidence from the validation studies (stage 4) and the results of the systematic review on measurement properties (stage 2) inform a consensus process on whether or not the individual measurement instruments are suitable to assess the core outcome domain. Finally, consensus voting involving the relevant stakeholder groups (please refer to step 2) determines whether or not a specific measurement instrument is included in the core set of outcome measurements.

Stages 1–5 need to be completed for each core outcome domain. Once an outcome measurement instrument has been recommended for each core outcome domain, the *core set of outcome measurement instruments* is complete.

Step 4: Dissemination, preparation of guidance material, review, and possibly revision of the core set of outcome measurement instruments

The dissemination and implementation of the core set of outcome measurements are of utmost importance. The goal is that all stakeholders in the target field and area comply with it. Therefore, dissemination should involve publications in leading journals (e.g., by consensus statements, supplemented by editorials and/or commentaries), presentations at relevant meetings, and dissemination to journal editors and reviewers as well as to all other relevant stakeholders. Core sets of outcome measurements for clinical trials should also be disseminated to the pharmaceutical industry and to regulatory authorities. The development of guidance material is recommended to facilitate dissemination and application of the COS. Guidance material may include training manuals on instrument use, guidance on interpretation of scores and what constitutes a minimal important clinical change, summaries of the distribution of scores in different populations to inform sample size calculations, and suggestions for the presentation of study results.

The use of the recommended core set of outcome measurements should be monitored to be able to detect possible barriers to the implementation and to optimize the implementation strategy. Core sets of outcome measurements reflect the best evidence at the time and can be revised or modified in light of new evidence. Any revision or modification should be carried out by consensus in accordance with the methods outlined in the HOME roadmap (Figure 2).

DISCUSSION

Failure to assess the most important aspects of a disease and the use of outcome measurement instruments with unclear validity or reliability have been increasingly recognized as important barriers toward practicing evidence-based medicine (Chalmers and Glasziou, 2009). This has led to the development of COSs in various fields of medicine over the past years (Ruperto *et al.*, 2003; Taylor, 2005; Schmitt *et al.*, 2011).

Despite the increasing interest in outcomes research and the broad recognition of the benefits of COSs (Tugwell *et al.*, 2007; Mokkink *et al.*, 2010b; Sinha *et al.*, 2012; Idzerda *et al.*, 2014; Macefield *et al.*, 2014), general guidance on how to develop a COS is still missing. The HOME roadmap provides this guidance and was developed through our experience in atopic eczema outcomes research. We believe that this roadmap is widely applicable to the development of COSs for all (skin) diseases and hope that others performing outcomes research will benefit from our experiences.

The development of evidence-based core sets of outcome measurements for clinical trials, clinical registries, record keeping, and quality assurance in routine care is a major task and requires significant resources and a multi-professional team of health-care professionals, patient representatives, and clinical researchers. On the basis of our experience, the development of a core set of outcome measurement instruments in accordance with the HOME roadmap requires many years of work. Encouraged by a systematic review on named outcome measurements for atopic eczema (Schmitt *et al.*, 2007a), and a preliminary Delphi consensus study (Schmitt *et al.*, 2011), the HOME initiative was founded in 2010 as a global multi-professional evidence-driven and evidence-generating initiative dedicated to outcomes research in atopic eczema (Schmitt and Williams, 2010). After the definition of the core set of outcome domains for atopic eczema trials in 2011 consisting of clinical signs, symptoms, quality of life, and long-term control of flares, we established a working group for each of these core outcome domains to identify appropriate measurement instruments (Schmitt *et al.*, 2012). Following the HOME roadmap we completed the selection of the core outcome measurement instrument for the domain clinical signs in 2013. Systematic reviews indicated that from various different instruments to quantify the severity of clinical signs of atopic eczema only the EASI and the objective Scoring Atopic Dermatitis Index fulfill the criteria to be included in the list of possible instruments (Schmitt *et al.*, 2013). In an international consensus study, 56 individuals from 10 countries including Asia, Europe, South America, and the United States representing stakeholders such as consumers, dermatologists, nurses,

clinical researchers, methodologists, and pharmaceutical industry representatives agreed that EASI is the preferred core instrument to measure clinical signs in future atopic eczema trials. Details of the meeting and consensus process can be found elsewhere (Chalmers et al., 2014). The selection of core outcome measurement instruments for the domains of quality of life, symptoms, and long-term control of atopic eczema flares is ongoing (www.homeforeczema.org).

Important outcomes research groups with focus on COSs and clinimetric properties of measurement instruments are the COMET and the COSMIN initiatives. The COMET initiative provides a database of planned, ongoing, and completed core sets of outcome domains for clinical trials and makes this information accessible (www.cometinitiative.org). The COSMIN initiative provides criteria to assess the quality of validation studies (Mokkink *et al.*, 2010a), guidance on systematic reviews on measurement properties (de Vet *et al.*, 2011), and consented definitions of these measurement properties (Mokkink *et al.*, 2010b). The HOME initiative is represented in the Core Outcome Measures in Effectiveness Trials database and applied the definitions and guidance material on systematic reviews on measurement properties developed by the COSMIN group.

COSs do not preclude the use of other measures of interest to investigators but identify the minimum standard that should be present in all studies. They should be based on the best evidence available at the time of consensus agreement but can be revised in the light of new evidence or developments.

COSs have been introduced in clinical trials to minimize selective outcome–reporting bias, to increase clinical interpretability, and to enable valid pooling of results across studies. The majority of the coordinating editors of the Cochrane Review Groups indicated that a COS for effectiveness trials should be used routinely for a Summary of Finding table in their Cochrane Reviews (Kirkham *et al.*, 2013b). Funding bodies are increasingly asking for COSs to be included in the trial-funding applications (e.g., this is now a requirement for the National Institute for Health Research Health Technology Assessment programme in the United Kingdom (http://www.nets.nihr.ac.uk/programmes/hta).

To date, COSs have been almost exclusively developed to standardize outcome assessment across clinical trials in a specific condition. However, the concept of COSs may also be applied in other settings such as record keeping, observational studies, clinical registries, or quality assurance in health care. Ideally, similar outcomes should be assessed in trials and in daily practice to enable the translation of trial evidence into clinical care (Schmitt *et al.*, 2011).

In dermatology, a lot of work has been carried out to develop new instruments for the assessment of different aspects of skin disorders. However, many of the existing outcome measurement instruments in dermatology have not been validated appropriately, and through their application we may underestimate, overestimate, or completely miss the true effects of an intervention (Spuls *et al.*, 2009; Nijsten, 2012; Vrijman *et al.*, 2012; Schmitt *et al.*, 2013). General, overarching studies to define which aspects of skin disorders are of such importance that they should be regularly assessed by means of defined, suitable instruments in every trial or other study are still very scarce in dermatology. Investigators should therefore focus more on the development of COSs and develop new outcome measurement instruments preferably in the context of multi-stakeholder and multi-perspective outcomes research initiatives. Another example from dermatology concerning the development of a core set of outcome measures is vitiligo. Following a systematic review of existing outcome measures for vitiligo and a survey of the most important outcomes for patients and clinicians (Eleftheriadou *et al.*, 2012), a Delphi study has been conducted to define a core set of outcome domains for vitiligo trials.

We encourage investigators and advocates from various fields within dermatology to pursue the development of COSs. For many other skin diseases with multiple and disparate outcome measures, such as psoriasis, acne, skin cancer, chronic wounds, and hand eczema, a core set of outcome measurement instruments is required, and we hope that the HOME roadmap will serve as guidance in this process.

CONFLICT OF INTEREST

The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health. The authors state no conflict of interest.

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