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Protocol of a scoping review of outcome domains in dermatology

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ABSTRACT

Introduction Core outcome sets (COSs) are agreed outcomes (domains (subdomains) and instruments) that should be measured as a minimum in clinical trials or practice in certain diseases or clinical fields. Worldwide, the number of COSs is increasing and there might be conceptual overlaps of domains (subdomains) and instruments within disciplines. The aim of this scoping review is to map and to classify all outcomes identified with COS projects relating to skin diseases.

Methods and analysis We will conduct a scoping review of outcomes of skin disease-related COS initiatives to identify all concepts and their definitions. We will search PubMed, Embase and Cochrane library. The search dates will be 1 January 2010 (the point at which Core Outcome Measures in Effectiveness Trials (COMET) was established) to 1 January 2024. We will also review the COMET database and C3 website to identify parts of COSs (domains and/or instruments) that are being developed and published. This review will be supplemented by querying relevant stakeholders from COS organisations, dermatology organisations and patient organisations for additional COSs that were developed. The resulting long lists of outcomes will then be mapped into conceptually similar concepts.

Ethics and dissemination This study was supported by departmental research funds from the Department of Dermatology at Northwestern University. An ethics committee review was waived since this protocol was done by staff researchers with no involvement of patient care. Conflicts of interests, if any, will be addressed by replacing participants with relevant conflicts or reassigning them. The results will be disseminated through publication in peer-reviewed journals, social media posts and promotion by COS organisations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Various databases and websites will be searched.
⇒ The scoping review will only include studies that were published in the English language.
⇒ The inclusion only of studies which relate to dermatological conditions limits the generalisability to other specialties.

INTRODUCTION

According to the Core Outcome Measures in Effectiveness Trials (COMET) initiative, a core outcome set (COS) is a standardised set of outcomes that are agreed on by experts and patients which should be measured and reported on, at minimum, in all clinical trials or practice related to a specific disease or condition.[1] The COMET Initiative further defines an outcome as any metric being measured to assess the effects of a specific treatment, such as risk or benefits. COSs exist across a wide range of medical specialties, including dermatology, dentistry, cardiology and others.[2 3] The process of developing and implementing COS includes defining both the *outcome domains* (subdomains) and the instruments (*outcome measurement instruments*) most suitable to measure these.[4] The reason for developing COS derives from evidentiary problems that have been documented by the Cochrane Collaboration and other entities that synthesise evidence.[5] Specifically, a barrier to developing synthesised evidence such as systematic reviews and meta-analyses is the heterogeneity in outcomes and outcome measurement instruments in clinical trials.[6 7] Multiple studies may study a similar condition, but each assesses different outcomes, or if they assess similar outcomes, they do so with different outcome measurement instruments.[8]

There has been a strong interest in COS development in dermatology for many years to meet the methodological challenges and reduce waste of research.[9] As COSs are being developed within this field, one concern has been that some outcomes maybe redundant and overlapping between different COSs, and some may be recapitulating the same concepts. Additionally, there is a worry that certain outcomes within varying COSs might inadvertently encompass the same fundamental notions, thereby raising questions about the need for such redundancies within the COS framework. Similar domains and subdomains may be implemented in slightly different ways, which adds to the confusion.

An example of a recurring outcome domain in dermatology is quality of life. While quality of life is one of the broadest concepts in health, it is of course applicable to all dermatological diseases. A COS published by the Harmonizing Outcome Measures for Eczema, one published by the Vitiligo Outcome Instruments and Consensus for Evidence, The Hidradenitis Suppurativa Quality of Life, and a COS for congenital melanocytic naevi list quality of life as a core outcome,[10–13] but with varying definitions. Another example is pain, which appears in both the COS for hidradenitis suppurativa as well as for incontinence-associated dermatitis, also with disparate definitions and associated measures.[14–16]

Another challenge is the level of complexity or granularity of outcomes within COSs. While some COSs contain core outcomes such as 'clinical signs',[17] other contain very specific clinical signs such as erythema.[11] Obviously, outcome domains and subdomains are on different hierarchical levels and there is uncertainty within dermatological COS development groups about at what level COS domains should be defined.[18] These challenges are not specific to dermatology and have been described for various COSs.[19] Classifications of outcomes are emerging[20 21] and recently the need for a dermatology-specific outcome classification has been demonstrated.[22] In order to develop such a discipline-specific classification, it is necessary to identify, to map and to define all outcomes that have been listed and/or proposed by COS initiatives. In addition, it will be helpful to better understand the information that is available regarding taxonomies for outcome, outcome subdomain and outcome domain in other disciplines.

Therefore, the main objective of this scoping review is to map all available outcome domains relevant to skin diseases and conditions.

METHODS

Eligibility criteria

Using the population, concept, and context approach,[23] we will use the following inclusion criteria: (1) subjects with any skin disease or condition classified as 'Diseases of the skin' according to the WHO International Classification of Diseases (ICD)-11[24] (population); (2) outcome domains or outcomes as effects of any health intervention (concept); an 'outcome domain' refers to a distinct category or thematic area within which various specific outcomes can be classified and assessed. An 'outcome' is a measurable and observable result that is the focus of investigation within a research study; and (3) COS development initiatives for clinical trials, registries and/or clinical practice, in particular, the so-called 'long lists' describing candidate outcomes for COSs (context). Articles will be excluded if they do not focus on a skin disease/skin diseases, or if they are published in any language other than English.

Information sources

Searches will be conducted in the electronic databases PubMed, Embase and Cochrane Library. Additionally, the COMET database, the C3 website, the IDEOM website and the ICHOM website will be searched for relevant published and unpublished work. Since we are seeking to include all outcomes, there will be no date limitations included in the search.

Search strategy

The keywords "outcome," "core domain," "core outcome," "instrument," "concept," "subdomain" and "skin," "hair," "nail," "mucous," "membrane, " or "dermatology," will be used (table 1). The search strategy for each database and website, developed after consultation with a medical librarian, is presented in table 1. The search dates will be 1 January 2010 (the point at which COMET was established) to 1 January 2024. We will also use the COMET database and C3 index of COS groups to identify COS groups that have published on outcomes relating to dermatology and query them regarding additional long lists of outcomes that may be in the process of development or otherwise unavailable. Lastly, we will consult with prominent COS researchers and experts and dermatology organisations to identify any additional outcomes which were not represented in our literature search. These stakeholders will be especially important in sourcing additional grey literature and unpublished outcomes. Any additional sources of outcomes that are found will be extracted in a manner similar to that of published articles.

Selection process

We will restrict our search to articles that provide consensus-based information on outcome domains and subdomains relevant to dermatology. Two raters independently will perform review of search results to select relevant articles and sources. Disagreements will be resolved by a third independent rater. After completion of the title and abstract screening, the two raters independently will conduct a full-text review of the remaining articles to select those which are suitable for inclusion in the scoping review. Each rater will also search the reference lists of relevant publications to identify additional references or sources to be included.

Data items

The following information will be extracted from each article or source by two extractors independently: title, year of publication, disease or condition, outcomes/outcome domains and definition for each outcome or outcome domain if available.

Data synthesis

For each outcome included, we will count the number of mentions in the source documents. In addition to this, the definitions and meanings of the outcomes will be provided and compared. If possible and if there is conceptual similarity according to the process proposed by Young *et al*,[16] certain outcomes may be combined. To ensure the integrity of thematic analysis, this process will involve independent thematic grouping by two researchers. Each researcher will identify potential themes, engage in a consensus-based

Table 1 Sources of information for scoping review along with inclusion and exclusion criteria

Information source	Search strategies	Inclusion criteria	Exclusion criteria
Electronic database	PubMed ► Search terms: ((core outcome set) OR (core outcome sets) OR (core domain) OR (core outcome) OR (outcome)) AND ((skin) OR (hair) OR (nail) OR (nails) OR (mucous) OR (membrane) OR (Dermatology)) Embase ► ('core outcome set'/exp OR 'core outcome sets'/exp OR 'core domain'/exp OR 'core outcome'/exp OR 'outcome'/exp) AND ('skin'/exp OR 'hair'/exp OR 'nail'/exp OR 'nails'/exp OR 'mucous'/exp OR 'membrane'/exp OR 'dermatology'/exp) Scopus ► ("core outcome set" OR "core outcome sets" OR "core domain" OR "core outcome" OR "outcome") AND ("skin" OR "hair" OR "nail" OR "nails" OR "mucous" OR "membrane" OR "Dermatology") Web of Science ► ((core outcome set) OR (core outcome sets) OR (core domain) OR (core outcome) OR (outcome)) AND ((skin) OR (hair) OR (nail) OR (nails) OR (mucous) OR (membrane) OR (Dermatology)) Cochrane ► (Core AND outcome AND set) AND (skin OR hair OR nail OR mucous OR membrane)	Subjects with any skin disease or condition classified as 'Diseases of the skin' according to the WHO ICD-11[24] (population); (2) outcome domains or outcomes as effects of any health intervention (concept).	Articles will be excluded if they do not focus on a skin disease/skin diseases, or if they are published in any language other than English.
Relevant websites and COS organisations	► COMET database ► C3 COS groups ► IDEOM publications list	Subjects with any skin disease or condition classified as 'Diseases of the skin' according to the WHO ICD-11[24] (population); (2) outcome domains or outcomes as effects of any health intervention (concept).	Articles will be excluded if they do not focus on a skin disease/skin diseases, or if they are published in any language other than English.
Other relevant stakeholders	► Dermatology organisations ► Patient representatives	Subjects with any skin disease or condition classified as 'Diseases of the skin' according to the WHO ICD-11[24] (population); (2) outcome domains or outcomes as effects of any health intervention (concept).	Articles will be excluded if they do not focus on a skin disease/skin diseases, or if they are published in any language other than English.

COMET, Core Outcome Measures in Effectiveness Trials; COS, core outcome set.

discussion to resolve any discrepancies and consult a third author if necessary. After that, the resulting meta-long list will be shared with a steering committee, which will consist of prominent COS researchers and experts who have previously published COS projects, or who hold leadership positions in COS organisations. To map the results, the Steering Committee will use a systematic approach involving nine steps: (1) each analyst will independently scrutinise the list to verify the accuracy and relevance of the themes identified; (2) notes and insights will be discussed among the team members, resulting in codes (thematic categories) that formed the basis of a preliminary codebook (list of codes and definitions); (3) the codebook will be used to systematically code the source documents line by line, with each document coded by a minimum of two analysts; (4) key themes will be identified and their importance rated to determine the most crucial factors; (5) discrepancies in coding will be resolved during group discussion, and the codebook refined when needed; (6) the coding will be done iteratively, with continuous reviews of additional source documents for further refinement of the codebook; (7) data obtained from coding later source documents will be compared with initial ones to identify the point of thematic saturation, where no new themes emerged; (8) following the coding of all documents, a final review will be conducted to ensure no themes were missed; (9) finally, the findings and themes derived from this comprehensive analysis served as the foundation for developing a conceptual model representing the spectrum of outcome domains in dermatology research.[22]

The planned start and end dates for the study are January–June 2024.

Implications for practice and research

This scoping review will be the first step in the creation of a taxonomy of commonly recurring outcomes in dermatology, which is an important and timely task that may expedite the development of COSs and their uptake while minimising resource use and research waste. A taxonomy may also facilitate future meta-analyses if clinical trials adapt to a standardised taxonomy of outcomes.

The scoping review will identify any gaps in the available literature on dermatological outcomes. It will direct the researchers to important research questions and areas for further investigation by identifying areas where comprehensive outcome sets are lacking, or specific outcomes are under-represented. This knowledge can help to shape future studies and research priorities. By prioritising outcomes that are meaningful to patients, the scoping review will promote patient-oriented research in dermatology. It will encourage researchers to engage with patients and incorporate their perspectives in outcome selection and study design. Patient involvement enhances the relevance and impact of research, leading to outcomes that better reflect patients' needs and preferences.[25]

After consolidating and disseminating a taxonomy of shared definitions for these commonly recurring outcomes and outcome domains, future research should focus on selecting, or developing and validating, a single measurement instrument for each critical outcome.

Some outcomes will be easy to group or combine and some will be difficult to group or combine. The classification scheme will need to be hierarchical, with different levels of specificity, and similar types of outcomes or concepts at the same level. For instance, clinical signs and symptoms may be a domain, and erythema may be a subordinate concept or outcome under this domain. A formal system for categorising outcomes may be used, with outcomes mapped to ICD-11. Domains and outcomes should be non-overlapping, and there may be multiple levels. Similar outcomes may be linked to each other or combined into one shared outcome. After outcomes have been combined and categorised, the steering committee will create a specific definition for each outcome, domain or other level of construct.

According to Young *et al*,[19] most of the studies that report or investigate COSs have a methodological lack of detail and difference in the numbers of outcomes reported which suggest a non-systematic approach in extracting the outcomes. To overcome this, we will systematically address the outcomes extraction and we wrote this protocol to provide the methodological details about the whole process in our scoping review. The findings of this review will ultimately contribute to the generation of high-quality evidence and the improvement of patient outcomes in the field of dermatology.

Strengths and limitations

The main limitation of this scoping review is that only studies published in the English language are included. Another limitation is the focus on outcomes and outcome domains which relate to dermatological conditions, which could limit the generalisability of the resulting taxonomy for COSs in other specialties. An additional limitation is that the quality of COS work can vary and will not be assessed in this study. Interestingly, if certain long lists are missed in the process of developing the meta-long list, this will not be particularly problematic since a high degree of redundancy in outcomes and outcome domains across long lists is expected .

Patient and public involvement

No patients were involved in the development of this protocol.

ETHICS AND DISSEMINATION

As this is not a human research study, institutional review board approval was not necessary. Conflicts of interest disclosures and information about relationships with industry will be obtained from all steering group members and coauthors at inception of the project. Individuals with a potential, significant conflict of interest will have their duties curtailed or reassigned, or if the conflict cannot be resolved, they will be disqualified from further participation in the project. Participants who are unconflicted at the

start of the project will be encouraged to not initiate involvement in activities that may constitute a conflict until the completion of the project, and they will be asked to promptly disclose conflicts if they do develop additional or new conflicts. An ethics committee review was waived, since this protocol was done by staff researchers with no involvement of patient care.

The final manuscript associated with the scoping review will be submitted for publication in an academic journal. Similarly, once the process of categorising these outcomes into a hierarchical taxonomy is completed, that taxonomy will also be submitted for publication. Additionally, both manuscripts will be disseminated through social media channels and websites of stakeholders. We will also ask major stakeholders in dermatology organisations and patient organisations to endorse and consider using the taxonomy. Furthermore, we will also communicate with individual editors of key journals in general internal medicine, dermatology, public health and COSs to encourage them to implement and potentially require the use of the taxonomy.

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