Br J Dermatol 2023; **00**:1–9
https://doi.org/10.1093/bjd/ljad278
Advance access publication date: 7 August 2023

BJD
British Journal of Dermatology
Outcomes and Qualitative Research

The Harmonising Outcome Measures for Eczema (HOME) implementation roadmap

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Abstract

Background Core outcome sets (COS) are consensus-driven sets of minimum outcomes that should be measured and reported in all clinical trials. COS aim to reduce heterogeneity in outcome measurement and reporting, and selective outcome reporting. Implementing COS into clinical trials is challenging. Guidance to improve COS uptake in dermatology is lacking.

Objectives To develop a structured practical guide to COS implementation.

Methods Members of the Harmonising Outcome Measurement for Eczema (HOME) executive committee developed an expert opinion-based roadmap founded on a combination of a review of the COS implementation literature, the Core Outcome Measures in Effectiveness Trials (COMET) initiative resources, input from HOME members and experience in COS development and clinical trials.

Results The data review and input from HOME members was synthesized into themes, which guided roadmap development: (a) barriers and facilitators to COS uptake based on stakeholder awareness/engagement and COS features; and (b) key implementation science principles (assessment-driven, data-centred, priority-based and context-sensitive). The HOME implementation roadmap follows three stages. Firstly, the COS uptake scope and goals need to be defined. Secondly, during COS development, preparation for future implementation is supported by establishing the COS as a credible evidence-informed consensus by applying robust COS development methodology, engaging multiple stakeholders, fostering sustained and global engagement, emphasizing COS ease of use and universal applicability, and providing recommendations on COS use. Thirdly, incorporating completed COS into primary (trials) and secondary (reviews) research is an iterative process starting with mapping COS uptake and stakeholders' attitudes, followed by designing and carrying out targeted implementation projects. Main themes for implementation projects identified at HOME are stakeholder awareness/engagement; universal applicability for different populations; and improving ease-of-use by reducing administrative and study burden. Formal implementation frameworks can be used to identify implementation barriers/facilitators and to design implementation strategies. The effect of these strategies on uptake should be evaluated and implementation plans adjusted accordingly.

Conclusions COS can improve the quality and applicability of research and, so, clinical practice but can only succeed if used and reported consistently. The HOME implementation roadmap is an extension of the original HOME roadmap for COS development and provides a pragmatic framework to develop COS implementation strategies.

What is already known about this topic?

- Core outcome sets (COS) are standardized outcomes that should be measured and reported as a minimum in all clinical trials.
- COS can improve the reporting of patient-relevant outcomes and enable comparison and combination of results to inform patient care.
- COS will only be as effective as their uptake into clinical trials.
- COS implementation involves strategies to increase their uptake into trials.
- Practical guidance on COS implementation in dermatology is limited.

Accepted: 3 August 2023
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What does this study add?

- The Harmonising Outcome Measures for Eczema (HOME) implementation roadmap is a pragmatic guide to COS implementation, starting from COS development until completion.
- The HOME implementation roadmap is a starting point for a structured approach to COS implementation, to help fulfil the purpose of COS: the consistent use of relevant outcomes in clinical studies.
- This, in turn, enables and improves the quality of systematic reviews and meta-analyses to support therapeutic decisions.

What are the clinical implications of this work?

- COS permit clinical trial evidence to be compared and combined. The development of COS requires a lot of work in terms of evidence reviews and international consensus with patients and healthcare professionals.
- Such effort is of little value unless they are used.
- This article suggests an evidence-informed and practical framework to facilitate implementation of COS into routine so that patients can ultimately benefit from them.

Clinical trials have long shown a wide variation in their choice of outcomes.[1] Heterogeneity limits comparison and data harmonization in meta-analyses, and may introduce selective outcome reporting. Outcomes should be relevant to key stakeholders, most importantly patients, and be measured using validated instruments. Core outcome sets (COS), which are consensus-based standardized sets of the minimum outcomes to be measured and reported in clinical trials,[2] aim to address these concerns.[3]

In dermatology, one of the first COS developed was the Harmonising Outcome Measures for Eczema (HOME) for atopic dermatitis (AD),[4] defining four domains (what to measure) as the minimum outcomes in AD clinical trials. HOME has agreed on a core set of instruments to measure these outcomes. Despite the success of the HOME COS development and its publication in major dermatology journals,[5–8] uptake and standardized reporting in AD clinical trials remain limited. In 2018, only about 60% and 20% of phase III/IV AD studies complied with HOME recommendations and used the Eczema Area and Severity Index (EASI) and the Patient-Oriented Eczema Measure (POEM) to assess signs and symptoms, respectively.[9] While the use of EASI and POEM in randomized controlled trials (RCTs) between 2018 and 2022 improved to 94% and 60%, respectively, lack of standardized reporting across studies still hinders evidence synthesis.[10]

Low uptake of COS is a universal problem.[11–13] Implementation research has broadened the understanding of the challenges facing COS implementation. Identified barriers include the level of understanding of the concept and purpose of COS, and awareness of the existence of a study-relevant COS.[11,12,14,15] COS that include domains but do not provide recommended instruments, or lack recommendations on how to apply these instruments, are harder to implement.[12] Concerns around patient burden from multiple outcome measurements, and triallists' own outcome preferences, are additional barriers. Implementation can be facilitated by making COS acceptable and easy to use. The wide-ranging research system can also increase COS uptake by influencing the adoption of COS in trials through stakeholders such as funding agencies and journal editors.[16] Conversely, conflicting recommendations across major stakeholders, such as regulatory agencies, can lead to confusion and reduce uptake.[12] At the 2021 HOME IX meeting,[17] the main themes that may explain the limited uptake of the HOME COS were identified as stakeholder awareness and engagement, universal applicability of the COS for different populations and administrative and study burden (ease of use). Upon launching the HOME implementation project in that meeting, the complexity of COS implementation became evident and with it a need for guidance. HOME previously designed a roadmap to guide COS development.[18] Here, we provide guidance on how to structure a COS implementation strategy in the form of an implementation roadmap.

Materials and methods

The HOME Executive Committee developed the roadmap in an iterative process based on a combination of literature searches, with expert and lay input on COS implementation processes. This committee has extensive experience in COS development,[4] and as clinical triallists and systematic reviewers (Y.A.L., H.C.W., L.H., L.A.A.G., P.I.S., J.S., K.S.T., C.A., E.L.S., N.K.), serving in trial funding bodies (H.C.W.), working with regulators, funding agencies and health technology assessment bodies (H.C.W., J.S., C.A., P.I.S.), and with the pharmaceutical industry (Y.A.L., J.S., C.A., E.L.S.).

The roadmap was developed as follows: (i) a selective PubMed search for publications on 'COS implementation' and 'COS uptake' was performed in December 2021, with key papers extracted. The reference list of a comprehensive 2022 review on COS implementation was reviewed for additional papers.[14] Additionally, we conducted an online search for websites with implementation resources and of the Core Outcome Measures in Effectiveness Trials (COMET) initiative website.[3] (ii) At the HOME IX (virtual, 2020)[17] and X (Montreal, 2021) multistakeholder meetings, HOME members identified HOME-specific implementation barriers and facilitators, and developed preliminary implementation strategies. (iii) Opportunities for influencing COS uptake were then mapped throughout the course of a clinical trial and its subsequent use in systematic reviews and guidelines (Figure 1). (iv) The data were integrated into the HOME implementation roadmap based on expert opinion.

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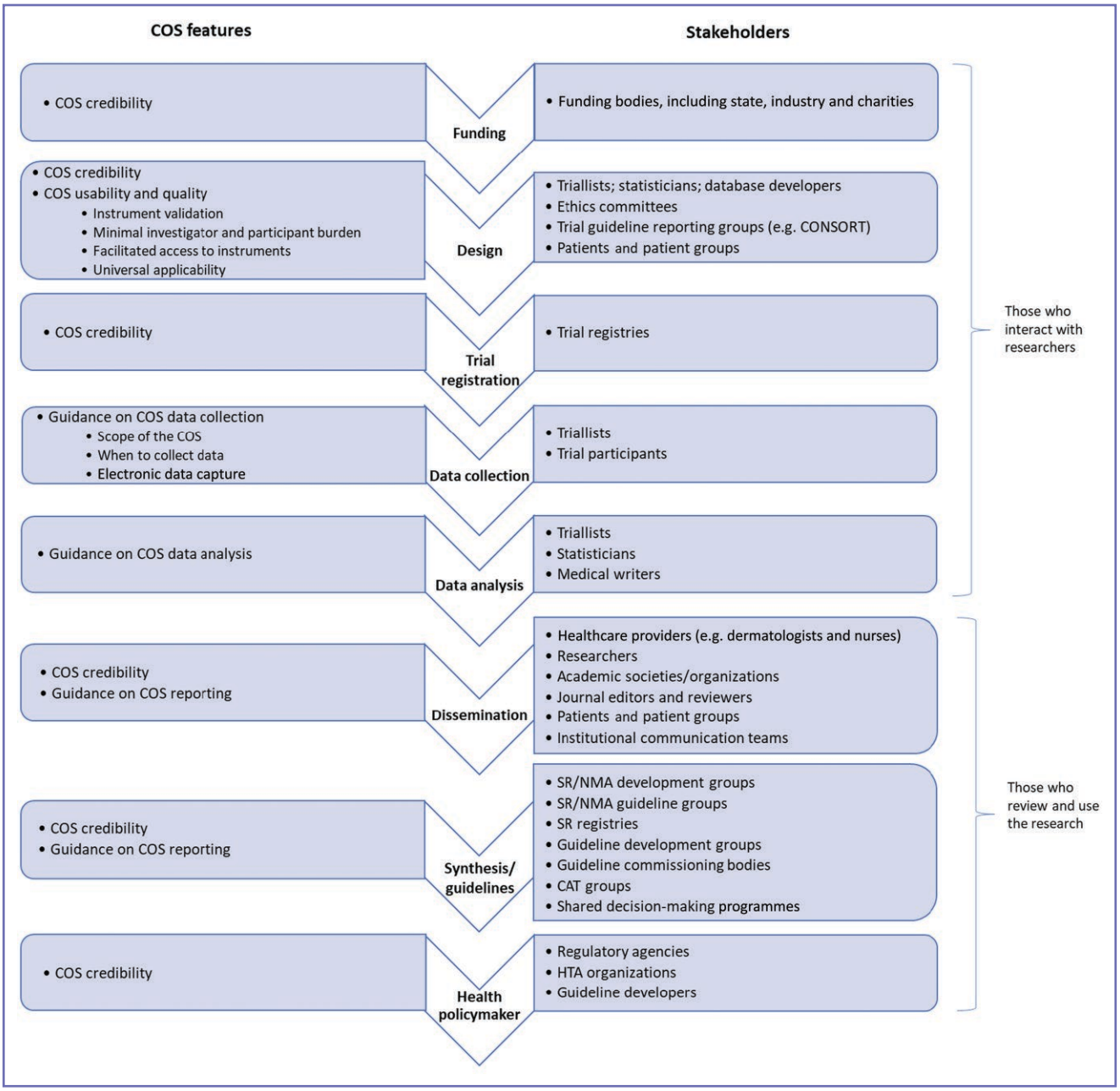

Figure 1 Implementation points of impact throughout the life of a clinical trial. CAT, critically appraised topic; COS, core outcome set; HTA, health technology assessment; NMA, network meta-analyses; SR, systematic reviews.

The roadmap was structured to follow the COS life cycle, guiding implementation efforts for each phase.

Results

The literature search and input from HOME meetings were synthesized into two themes that informed the development of the roadmap. Theme (a), 'Barriers and facilitators to COS uptake', was categorized to form the main implementation avenues: (i) stakeholder awareness and engagement; and (ii) features of the COS that are affecting uptake. Theme (b) was 'A science-based approach to implementation'. Key principles were identified to guide the roadmap: (i) implementation outcomes should be defined and evaluated intermittently; (ii) employ an empirical approach to designing interventions, building on scientific data; (iii) prioritize the interventions that will have the most broad-ranging and rapid effect; and (iv) design context-sensitive interventions[19] – avoid a 'one-size-fits-all' approach and tailor the intervention to stakeholders.

The HOME implementation roadmap is presented in Figure 2. Future implementation should be considered at the initiation of COS development, reflected in the first two stages of the roadmap. After the COS is developed, implementation methods and goals will evolve in an iterative learning process, illustrated in the third stage of the roadmap.

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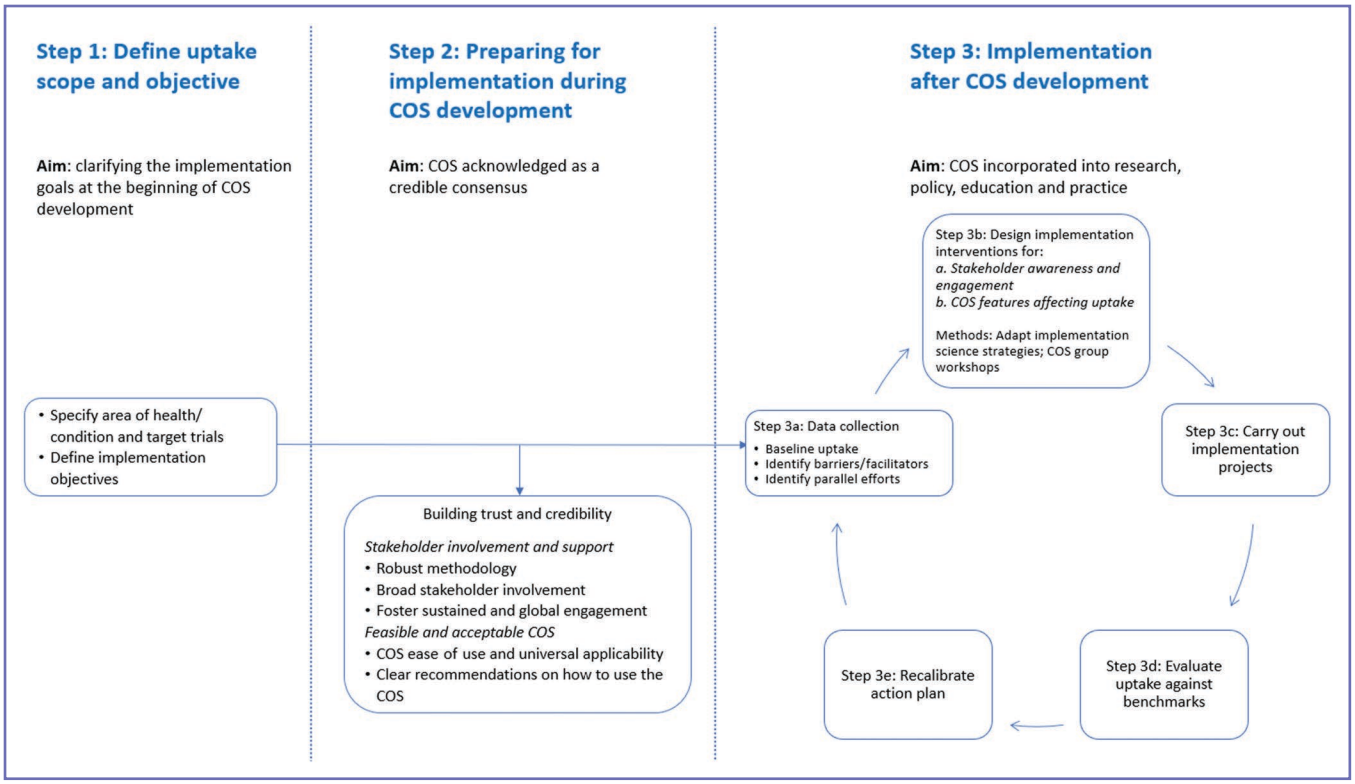

Figure 2 The Harmonising Outcome Measure for Eczema (HOME) implementation roadmap. COS, core outcome set.

Step 1: define uptake scope and objectives

Step 1 is focused on clarifying the implementation goals, to meet the roadmap principle of defining and evaluating uptake. The scope should specify the area of health/condition (e.g. AD) and the target trials specified by design (e.g. all clinical trials vs. RCTs) and settings.

Next, define implementation objectives using selected uptake indicators within a specified timeframe, for example to reach 80% use of the COS in interventional clinical trials within 8 years of its development. While adoption in trials is the intuitive indicator, there are other possible implementation indicators such as acceptability, penetration and user satisfaction.[20] Interim targets can also be defined to allow for adjusting implementation plans in real time, such as publication in leading journals or endorsement by a specific stakeholder.

Step 2: preparing for implementation during core outcome set development

In the COS development stage, the implementation aim is to have the COS acknowledged as a credible and feasible consensus by a wide group of stakeholders. This stage corresponds to the main implementation avenues, as they manifest during COS development:

1 Stakeholder involvement and support
   a *Conduct a scientifically robust development process* and adhere to a predefined methodology [e.g. HOME roadmap,[18] COS-STAndardised Protocol Items/STAndards for Development/STAndards for Reporting,[21–23] COMET Handbook[24] and OMERACT Handbook,[25] or collaborate with the C[3] methods Group (Consortium for Harmonizing Outcomes Research in Dermatology and the Cochrane Skin COS Initiative)].[26] To prevent redundant efforts and to engage with potential contributors, registration in the COMET database is helpful (https://www.comet-initiative.org/studies).
   b *Involve key stakeholders in COS development* to contribute to credibility and create future advocates. Lack of key stakeholder involvement, especially patients, in COS development is a barrier to COS implementation.[12] It is important to involve key opinion leaders so that everyone has a voice at consensus meetings. HOME included patients, clinicians, researchers, methodologists, a regulator and industry representatives.
   c *Foster sustained and global engagement.* COS development is a lengthy process. Holding consensus meetings in different countries, disseminating interim results in meetings, high-impact journals and through social media are all important for encouraging sustained global uptake.[5–8,27]
2 Features of the COS: feasibility and acceptability for future large-scale use.
   a *Consider ease of use and universal applicability* during COS development. For example, HOME stakeholders recommended a maximum of four domains to achieve a user-friendly COS.

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Other feasibility considerations are the time to complete the COS, avoidance of overlapping domains or instruments, and the cost and availability of instruments. There may be advantages to recommending instruments that are in the public domain or owned by academia. In the case of copyrighted instruments owned by commercial entities, it is important to ensure their availability to all triallists, regardless of their affiliation. The universal applicability of the COS to different populations is another key consideration.

b *Minimize uncertainty in COS use* by providing recommendations on how to measure and to report outcomes using the COS instruments. Lack of clear recommendations hampers uptake.[12] For example, HOME published a recommendation on standardized reporting of the EASI and the POEM.[28]

Step 3: implementation after core outcome set development

The implementation aim at this stage is to incorporate the COS into research, policy, education and practice. Work in this stage was guided by the key roadmap principles: assessment-driven, data-centred, priority-based and context-sensitive. We suggest a pragmatic approach that is iterative in nature and broadly follows the plan–do–check–act (PDCA) cycle, a four-step framework for carrying out change.[29] The PDCA cycle should be repeated for continuous improvement. Similarly, implementation efforts involve repeated cycles of planning, executing, assessing and recalibrating based on the results.

Step 3(a): data collection and analysis

This step explores current COS uptake status, adhering to the implementation principle of using scientific data as a foundation for implementation efforts.

Baseline uptake. Assess baseline COS uptake by looking at the outcome domains and instruments used in target trials.[9] Trial registry data can efficiently provide current information,[30] as relying only on published papers may provide outdated information.[31]

It is useful to map COS uptake by stakeholders other than triallists. Uptake in this context means a requirement or an encouragement that triallists interacting with these stakeholders use the COS. Some stakeholders have a significant impact on outcomes selection by triallists and can serve as an effective means of enhancing COS adoption. Examples include funding bodies requiring COS use by applicants (e.g. UK National Institute for Health and Care Research or German Research Foundation);[32,33] regulatory bodies guidelines aligned with COS (e.g. the Food and Drugs Administration and European Medicines Agency guidelines on rheumatoid arthritis);[34] reporting guideline groups that recommend COS use for trial outcome selection (e.g. SPIRIT);[35] trial registries that guide triallists to use COS when registering their trials (e.g. ISRCTN);[36] patient groups that encourage participation in trials that use COS; and professional journals requiring COS use in clinical trial publications (e.g. the *Journal of the American Academy of Dermatology* and the *British Journal of Dermatology*).[30,31] Mapping uptake in these stakeholders can be performed by an online search of organizational guidelines and policy documents, or direct communication. We broadly prioritized the main stakeholders based on their anticipated uptake impact (Figure 3).

Identification of implementation barriers and facilitators. Understanding why people are not using the COS (barriers) and how to encourage them to use it (facilitators) is key to planning interventions for improving uptake.[14] Conceptual frameworks within implementation science,[37] such as the Consolidated Framework for Implementation Research,[38] can help guide the identification of factors that influence COS implementation.

Examples for projects to improve understanding of these factors include (i) identifying characteristics of trials with low COS uptake and temporal trends in uptake in relation to major events such as publication of the COS or regulatory body guidelines supporting COS;[9,34] (ii) surveying key stakeholders for their knowledge and attitudes regarding the COS;[11] and (iii) discussing implementation barriers/facilitators within your COS group.[17,39]

Identification of parallel implementation efforts and collaborations. To minimize research waste and broaden implementation efforts, identify ongoing projects that may impact on COS implementation. Methods include surveying the COS group members, reaching out to partner groups (e.g. COMET and C^3) and other COS groups for collaborative work with major stakeholders (e.g. approaching regulators to endorse COS use in drug approval trials). Collaborations with professional groups can increase awareness of COS (e.g. incorporating outcome research into resident educational programmes).

Step 3(b): develop implementation interventions

Building on the data gathered in the prior steps, develop implementation strategies. This step emphasizes the design of priority-based and context-specific interventions, in line with the key implementation principles.

Implementation research has identified different strategies, such as conducting educational meetings, intervening with patients to enhance uptake and developing educational materials.[40] Methods for matching and adapting strategies to the identified barriers and facilitators have also been described, including concept mapping, group model building, conjoint analysis and intervention mapping.[41] It is unknown which strategies and strategy-tailoring approaches are most effective.[42]

COS group workshops can advance the design and feasibility of implementation projects.[14,39] For example, group discussions at the HOME IX meeting identified leading implementation themes, with corresponding working groups formed and advanced at the HOME X meeting.[17]

The interventions developed in this stage target barriers/facilitators of COS adoption by the main implementation avenues.

Stakeholder awareness and engagement. Mixed methods for stakeholder engagement are needed and include targeted information and use of social media. Behavioural

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science-based approaches for increasing COS uptake are under development,[43] building on behaviour change frameworks such as the behaviour change wheel.[44]

Stakeholder engagement projects should preferably focus on stakeholders with broad impact to maximize COS uptake, in line with the implementation principle of priority-based interventions (Figure 3). However, efforts should be weighed up against potential benefits. For example, while regulators are very impactful stakeholders, gaining their endorsement can be complex and resource demanding. Some stakeholders have global reach, such as trial registries and reporting guideline groups. However, many impactful stakeholders are region-specific (e.g. national/regional regulatory agencies, funding bodies and patient groups). Galvanizing the COS community and its diverse regional representation, and identifying local champions in different geographical areas, may improve local uptake and support equality in health care.

Even when stakeholders endorse the use of COS, monitoring adherence to these endorsements is needed. Adherence monitoring can include projects like periodic assessments of trial registries for outcome selection, proactively approaching triallists to consider using COS and encouraging peer reviewers to request justification of outcome selection.

Features of the COS.

- Universal applicability: users of the COS require reassurance that the recommended instruments are applicable to people of different ages, cultures, skin tones and ability to understand the concepts being addressed. Additional content validity and cross-cultural validity studies may be required to ensure applicability to different age groups and cultural settings.[45] Widescale use also requires the availability of approved translations that conform to minimum standards, to ensure accuracy of translation and interpretation. A centralized repository of data from previous studies for different subgroups of people can support the relevance to and responsiveness of different target populations, and can help inform trial design and sample size calculations.[46]
- Ease of use: thinking through the feasibility of using the COS and how it impacts on different types of trial and stakeholder recommendations is key to acceptability and uptake. Different methods can be used to minimize the burden (time and effort) and optimize the use of COS. Guidance is the starting point; information on how to best access the COS (including administration costs and approval for using instruments), organize data capture, and collect, analyse and interpret COS data is essential. A practical guide, an infographic, an education video for patients and up-to-date information on a website may prove useful. Reducing overlap between instruments and/or the frequency of conducting questionnaires is another means of reducing COS burden. The question 'Is the COS easy to use?' can be evaluated by a feasibility study. This includes not only the time needed to complete the COS, but also its acceptability for patients and clinicians.

Step 3(c): carry out implementation projects

Given limited resources, prioritize the planned implementation projects, which includes establishing a timeline. The HOME initiative found that the allocation of leads and a team project manager can be instrumental in moving this stage forward.

Step 3(d): evaluate uptake against benchmarks

Uptake assessments need to be regularly assessed using consistent methodology to allow comparison over time. A useful way of periodically reviewing COS uptake is to assess their use in living systematic reviews and network meta-analyses of intervention trials.[10,47–49] Uptake can be assessed on multiple levels: Are the COS domains being (partly or completely) measured (e.g. signs)? Are the COS instruments being used to measure these domains (e.g. EASI)? Are the results reported as recommended

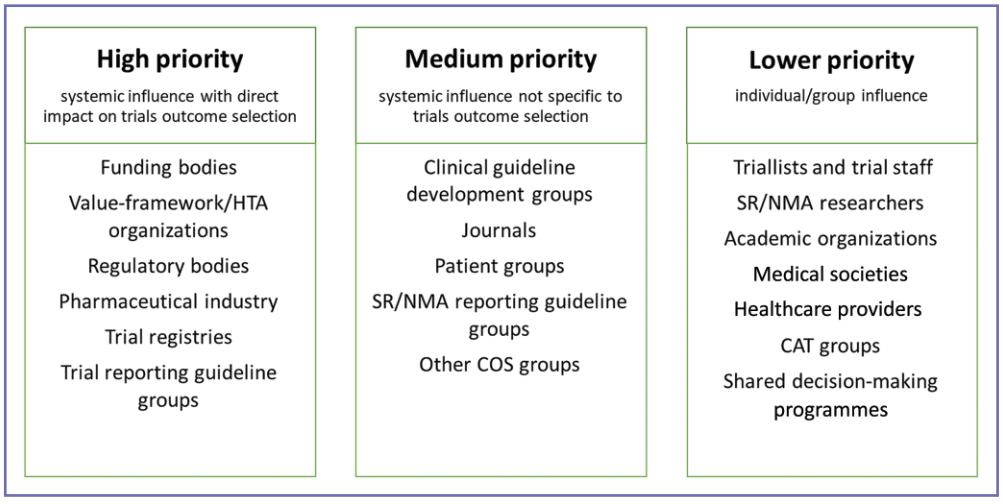

Figure 3 Prioritization of main stakeholder groups by anticipated impact. CAT, critically appraised topic; COS, core outcome set; HTA, health technology assessment; NMA, network meta-analysis; SR, systematic review.

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[e.g. baseline and end of treatment mean (SD) EASI for individual randomized groups]?[28]

Step 3(e): recalibrate the action plan

Implementation efforts may need to be recalibrated periodically. Some things will work better than others, and some might fail at the first hurdle, so an iterative learning process is needed.

Discussion

The implementation of COS in clinical studies is a difficult task that requires multistakeholder acceptance and engagement. The goal of this roadmap is to offer pragmatic guidance on *how* to implement COS throughout their development. Several key aspects of COS implementation are highlighted in this roadmap. Firstly, we strongly recommend identifying implementation needs right at the start of COS development when the focus typically centres around research and development of the COS. Secondly, there is a need for COS teams to be aware of the two main implementation avenues: methods for stakeholder awareness/engagement and features of the COS that affect uptake, such as ease of use and universal applicability. Considering these avenues can help in constructing implementation projects. Thirdly, after the COS is developed, implementation efforts should be viewed as an iterative process, subject to evaluation and modification.

The HOME implementation roadmap promotes the design of implementation interventions based on scientific data, such as an examination of uptake barriers and facilitators.[14] It can complement the formal use of implementation frameworks in bridging the gap between scientific findings and their application – the 'know–do' gap.[37,50] However, traditional data-driven approaches can be time consuming and inflexible. Current trends towards semi-formalized and expert-based means to knowledge production may offer a quick and agile alternative.[51]

Implementation requires COS developers, who are often academic researchers, to step out of the comfort zone of data- and analytics-based research to domains such as behavioural change, communication and marketing. It can be advantageous to involve people with these skills early in the COS development process.

The HOME implementation roadmap, like the COS itself, is very much a work in progress as with all iterative projects. It is still unclear if our approach is superior to common implementation approaches,[14] which HOME implementation projects are effective and whether such projects are generalizable to other fields of health care. This roadmap is a starting position that helps to structure the process and allows us to start thinking about the practicalities of the implementation pathway within a finite resource envelope that complements the HOME roadmap for COS development nicely.[18]

In summary, we hope this HOME implementation roadmap will help guide implementation efforts and improve COS uptake more generally beyond the field of AD, and complement established resources on COS implementation from the COMET group (https://www.comet-initiative.org) and on COS in dermatology from the C3 group (https://www.c3outcomes.org).

Acknowledgements

We thank all the participants in the HOME IX and HOME X meetings and premeeting surveys for their valuable contributions to and perspectives on the implementation of the HOME COS.

Funding sources

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflicts of interest

Y.A.L. has received honoraria or fees from AbbVie, Sanofi, Genentech, Regeneron, Pfizer and Dexcel Pharma, an independent research grant from AbbVie and has – without personal compensation – provided investigator services for Eli Lilly, Pfizer and AbbVie, all unrelated to this study. E.L.S. reports personal fees from Advances in Cosmetic Medical Derm Hawaii, AbbVie, Amgen, AOBiome, Arcutis Biotherapeutics, Arena Pharmaceuticals, Aslan Pharma, Boehringer Ingelheim USA, Boston Consulting Group, Bristol Myers Squibb, Collective Acumen (CA), CorEvitas, Dermira, Eli Lilly, Evelo Biosciences, Evidera, ExcerptaMedica, FIDE, Forte Bio RX, Galderma, GlaxoSmithKline, Incyte, Janssen, Johnson & Johnson, Kyowa Kirin Pharmaceutical Development, LEO Pharma, Medscape, Merck, MauiDerm, MLG Operating, MJH Holding, Pfizer, Physicians World, PRImE, Regeneron, Revolutionizing Atopic Dermatitis, Roivant, Sanofi-Genzyme, Trevi Therapeutics, Valeant, Vindico Medical Education and WebMD. He also reports grants (or serves in a Principal Investigator role for) from AbbVie, Acrotech Biopharma, Amgen, Arcutis, Aslan, Castle Biosciences, CorEvitas, Dermavant, Dermira, Eli Lilly, Incyte, Kymab, Kyowa Kirin, National Jewish Health, LEO, Pfizer, Regeneron, Sanofi and Target RWE. These potential conflicts of interest have been reviewed and managed by Oregon Health & Science University. C.A. has received institutional funding from the Dr Wolff Group and Bionorica, and consultancy fees or honoraria from the Dr Wolff Group, Bionorica, Sanofi, LEO Pharma and RHEACELL. He was also involved in the development and testing of one of the HOME core outcome instruments [Recap of atopic eczema (RECAP)]. P.I.S. has received departmental independent research grants for the TREAT NL registry from pharma since December 2019; is involved in performing clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of, for example, psoriasis and atopic dermatitis, for which financial compensation is paid to the department/hospital; is Chief Investigator of the systemic and phototherapy atopic eczema registry (TREAT NL) for adults and children; and was involved in the development of one of the HOME core outcome instruments (RECAP). K.S.T. was involved in the development and testing of one of the HOME core outcome instruments (RECAP). J.S. reports institutional grants for investigator-initiated research from the German Federal Joint Committee (G-BA), the Federal Ministry of Health (BMG), Federal Ministry of Research and Education (BMBF), European Union, Federal State of Saxony, Novartis, Sanofi, ALK and Pfizer. He has also participated in advisory board

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meetings as a paid consultant for Sanofi, Eli Lilly and ALK. L.H. has received consultation fees from the University of Oxford on an educational grant funded by Pfizer, unrelated to the submitted work, and was involved in the development of the RECAP instrument. N.K. has received honoraria as a speaker/consultant for Sanofi, Maruho, AbbVie, Eli Lilly Japan, Mitsubishi Tanabe Pharma, Janssen Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, Kyowa Kirin, Celgene Japan and LEO Pharma; and has received grants as an investigator from Maruho, Eli Lilly Japan, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, Boehringer Ingelheim Japan, Kyowa Kirin, Jansen Pharma, Boehringer Ingelheim Japan, A2 Healthcare, AbbVie and LEO Pharma. H.C.W. chaired the HOME core outcome set initiative from 2008 to 2021 and was involved in the development of the Patient Oriented Eczema Measure (POEM). H.C.W., K.S.T. and L.H. are employed at the research centre where the POEM was developed. The University of Nottingham owns copyright to license POEM – chargeable for commercial users. L.A.A.G. and M.E.J. declare no conflicts of interest.

Data availability

The data underlying this article are available in the article.

Ethics statement

Not applicable.

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