
Navigating the landscape of core outcome set development in dermatology



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The development of core outcome sets (COSs; ie, a minimum set of core outcomes that should be measured and reported in all trials or in clinical practice for a specific condition) in dermatology is increasing in pace. A total of 44 dermatology-related COS projects have been registered in the online Core Outcome Measures in Effectiveness Trials database (<http://www.comet-initiative.org/studies/search>) and include studies on 26 different skin diseases. With the increasing number of COSs in dermatology, care is needed to ensure the delivery of high-quality COSs that meet quality standards when using state-of-the-art methods. In 2015, the Cochrane Skin—Core Outcome Set Initiative (CS-COUSIN) was established. CS-COUSIN is an international, multidisciplinary working group aiming to improve the development and implementation of COSs in dermatology. CS-COUSIN has developed guidance on how to develop high-quality COSs for skin diseases and supports dermatology-specific COS initiatives. Currently, 17 COS development groups are affiliated with CS-COUSIN and following standardized COS development processes. To ensure successful uptake of COSs in dermatology, researchers, clinicians, systematic reviewers, guideline developers, and other stakeholders should use existing COSs in their work. (J Am Acad Dermatol 2019;81:297-305.)

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For most skin diseases and conditions, the outcomes that need to be measured in clinical trials, the clinical measures that can best aid patients, health care professionals, and commissioners make fully informed decisions about treatment options, is unclear. Even when the clinical trial outcomes that need to be measured are clear, the outcome measurement instruments available might be deficient in terms of validity, reliability, or feasibility or be just completely absent. Such a knowledge vacuum can result in chaotic nonuniformity of outcome measure reporting in dermatology clinical trials, which at best limits and at worst prevents meaningful meta-analysis and interpretation of trial evidence. This situation might also lead to selective outcome reporting, which can hinder comparisons of health care effects within and across health care organizations and benchmarking of health care quality¹⁻⁷ and hampers informed health care decision-making.¹

Continuing clinical trials without a focus on intra-discipline trial comparability can result in the failure to progress evidence-based medicine and is considered a serious waste in research.⁸⁻¹² Clinical trials can no longer be thought of as a means to an end, as most trials now typically have a second life in the form of systematic reviews that combine all relevant evidence, such as those conducted by Cochrane Skin.¹³

Thankfully, a solution has been found in the form of core outcome sets (COSs) as a means of standardizing outcome measurement and reporting in clinical trials. A COS is a minimum set of the most important outcomes that should be measured and reported in all clinical trials for a specific health condition,¹⁴ including definitions and the core outcome measurement instruments or methods used to measure the core outcomes. A core outcome does not have to be the primary outcome of a clinical trial and, as such, the COS can be measured in addition to other outcomes of interest. Although the primary emphasis of a COS is for clinical trials, they can also be used in routine clinical care, for clinical registries, for defining important outcomes in systematic reviews, or for funders of research to ensure that they are funding research that is measuring important aspects of the disease from the perspective of patients and health care professionals.

COSs hold great potential to improve rigor and relevance of clinical research; however, to ensure

COSs provide value, they need to be developed in a rigorous manner. Therefore, using reference standards is required for the preferred methods of COS development across disciplines and within a single discipline to account for subject-specific methodologic challenges. The purpose of this article is to discuss the landscape of COS development in medicine and, more specifically, the field of dermatology.

CAPSULE SUMMARY

- Core outcome sets must be developed with state-of-the-art methods.
- Cochrane Skin—Core Outcome Set Initiative provides methodologic support for dermatology-specific core outcome set initiatives to ensure high quality across core outcome sets in dermatology.

EARLY PIONEERS OF OUTCOME STANDARDIZATION IN MEDICINE

One of the first attempts to standardize outcome measures in clinical trials was done by the World Health Organization¹⁵ in 1981, when Miller and colleagues published recommendations

for standardized approaches to recording data for cancer patients. Since then, interest in standardization of outcomes research has grown and international initiatives on COS development have been launched in many medical disciplines. Since 1992, the initiative Outcome Measures in Rheumatology (OMERACT, <http://www.omeract.org>) has been the frontrunner in COS development in medicine. The uptake of this COS in rheumatoid arthritis clinical trials increased from 40% in 1995 to 81% in 2016.¹⁶ Furthermore, the rheumatoid arthritis COS is now required by the US Food and Drug Administration to be measured in clinical trials on rheumatoid arthritis.¹⁷ These trials are now more comparable, enabling meta-analysis of clinical trial data and improved health outcomes for patients.¹⁶ The development of COSs in health care research has rapidly grown over recent years, with 299 COSs published as of 2017.^{18,19}

DEVELOPING STANDARDS FOR COS DEVELOPMENT

Two main organizations have emerged as leaders in the development of COSs globally. The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (<http://www.cometinitiative.org>) was established in 2010 and is an international umbrella organization that supports the development, dissemination, and implementation of COSs by establishing agreed upon COS development methods.²⁰⁻²³ COS development typically involves a range of methodologic techniques to identify all possible outcomes by means of systematic reviews and qualitative methods. Subsequently, consensus should be

Abbreviations used:

COMET:	Core Outcome Measures in Effectiveness Trials
COS:	core outcome sets
COSMIN:	Consensus-based Standards for the selection of health Measurement INstruments
CS-COUSIN:	Cochrane Skin—Core Outcome Set Initiative
HOME:	Harmonising Outcome Measures for Eczema
OMERACT:	Outcome Measures in Rheumatology

reached on the most important outcome domains and outcome measurement instruments. Finding consensus could include international e-Delphi consensus studies, face-to-face consensus meetings including small and large group discussions, presentations of evidence, and anonymized voting. Furthermore, the COMET Initiative maintains an international database for existing and ongoing work on COS development in health care that helps to reduce duplication of effort.²⁴ To date, the focus of the COMET Initiative has been to encourage groups to identify the most important outcome domains for clinical trials. Outcome domains may be thought of as the key aspects of a disease that need to be evaluated to determine the effectiveness of an intervention.²⁰ Examples of outcome domains include pain intensity, physical functioning, and fatigue.

In contrast, the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN, www.cosmin.nl) initiative focuses on the selection of instruments to measure the important outcome domains in the COS. To improve the selection of outcome measurement instruments, COSMIN has developed guidance on how to select instruments for outcomes included in a COS.²⁰ In 4 consecutive steps, COS developers are guided through the process of outcome measurement instrument selection, including finding the existing instruments by means of literature searches and systematic reviews and assessing the quality of these instruments (ie, evaluating the measurement properties and feasibility aspects). Furthermore, the COSMIN initiative has developed guidance on systematic reviews of patient-reported outcome measurement instruments²⁵ and guidance on the evaluation of the methodologic quality of studies on the measurement properties of outcome measurement instruments.^{26,27} COSMIN initiative methods can be used to inform the selection of the most suitable instruments to measure the core outcome domains.

In addition to COS development, the International Consortium for Health Outcomes Measurement (<http://www.ichom.org>), founded in 2012, aims to improve value-based health care by developing standard sets. Standard sets are similar to COSs but with a clear focus on clinical practice. To date, the International Consortium for Health Outcomes Measurement has developed 24 standard sets for some of the most prevalent diseases (eg, cardiovascular, neurologic, oncologic, and musculoskeletal disease areas), some specific to vulnerable populations,²⁸ but none of these are currently dermatology specific.

CORE OUTCOME SET DEVELOPMENT IN DERMATOLOGY

The longest-running COS initiative in dermatology is the Harmonising Outcome Measures for Eczema (HOME) initiative. Founded in 2008, HOME is a global initiative of patients, health care professionals, journal editors, regulatory authorities, and pharmaceutical companies with a mission to harmonize outcome measurement and reporting in atopic eczema clinical trials and clinical practice. In-depth research on outcomes and measurement instruments, followed by a series of successful consensus meetings, resulted in the recommendation of 4 core outcome domains to be measured in all atopic eczema clinical trials: signs, symptoms, long-term control, and quality of life.²⁹ The Eczema Area and Severity Index and Patient-Oriented Eczema Measure are the recommended outcome measurement instruments to measure signs and symptoms, respectively.³⁰⁻³² The HOME initiative has published a methodologic roadmap outlining the essential steps in the development of and implementation of COSs in dermatology.³³

With so many different dermatoses, the need for standardization in outcome reporting in dermatology is imperative.* In 2015, the Cochrane Skin—Core Outcome Set Initiative (CS-COUSIN, www.cs-cousin.org) was established. CS-COUSIN is an international, multidisciplinary working group aiming to improve the development and implementation of COS in dermatology. CS-COUSIN is an umbrella organization to support dermatology-specific initiatives to develop their own COSS. Recently, the CS-COUSIN methods group conducted a systematic review to assess the concordance between efficacy outcomes in a random sample of 10 Cochrane Skin systematic reviews and the 220

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Table I. Overview of COS-related projects in dermatology, registered in the COMET Initiative database²⁴

No.	Skin diseases	No. projects	COS for clinical research	COS for clinical practice	COS for registry	Other
1	Acne vulgaris*	1	X			
2	Acne scarring	1	X	X		
3	Actinic keratosis	1	X	X		
4	Atopic eczema*	11	X	X	X	Systematic reviews, meeting reports, consensus reports, recommendations, guideline
5	Basal cell carcinoma*	1	X	X		
6	Congenital melanocytic nevi	1	X	X		
7	Cutaneous leishmaniasis	2	X	X		
8	Epidermolysis bullosa	1	X	X		
9	Facial aging*	1	X	X		
10	Facial structure and function postskin cancer excision	1	X	X		
11	Hair loss and nonscarring alopecia	1	X	X		
12	Head and neck lymphatic malformation	1	X			
13	Hidradenitis suppurativa*	1	X			
14	Hyperhidrosis	1	X	X		
15	Incontinence-associated dermatitis*	1	X			
16	Leprosy	1	-	-		Overview of literature
17	Melanoma*	1	X			
18	Melasma	1	X	X		
19	Nail psoriasis*	2	X			Systematic review, overview of literature
20	Postinflammatory hyperpigmentation	1	X	X		
21	Pressure ulcer*	1	X			
22	Rosacea*	1	X	X		
23	Scarring	1	X	X		
24	Squamous cell carcinoma	1	X	X		
25	Vascular malformations	1	X			Systematic review and consensus report
26	Vasculitis (small-vessel and ANCA-associated)	1	X			
27	Vitiligo*	4	X			Systematic review, consensus report, recommendations, guideline
28	Vulval skin disorders	1	X	X		Systematic review
29	Medical indications for laser treatments in dermatology*	1	X	X	X	
TOTAL		44				

ANCA, Antineutrophil cytoplasmic antibody; COMET, Core Outcome Measures in Effectiveness Trials; COS, core outcome sets.

*Supported by Cochrane Skin—Core Outcome Set Initiative.

dermatology clinical trials that the systematic reviews included.³⁴ The results showed a low concordance of outcomes between reviews and primary studies, and the authors concluded that standardization of outcome reporting could be improved by the development and implementation of COSs.

Since inauguration of the HOME initiative in 2008, the development of COSs in dermatology has fortunately started increasing in pace. A total of 44

dermatology-related COS projects have been registered in the COMET Initiative database;²⁴ these projects include studies on 26 different skin diseases, such as acne, atopic eczema, hidradenitis suppurativa, melanoma, nail psoriasis, rosacea, and vitiligo (Table I).²⁴ Most COSs are being developed for research and clinical practice purposes; 2 registered COS-related projects are focusing on the development of a core set of domains and domain items for

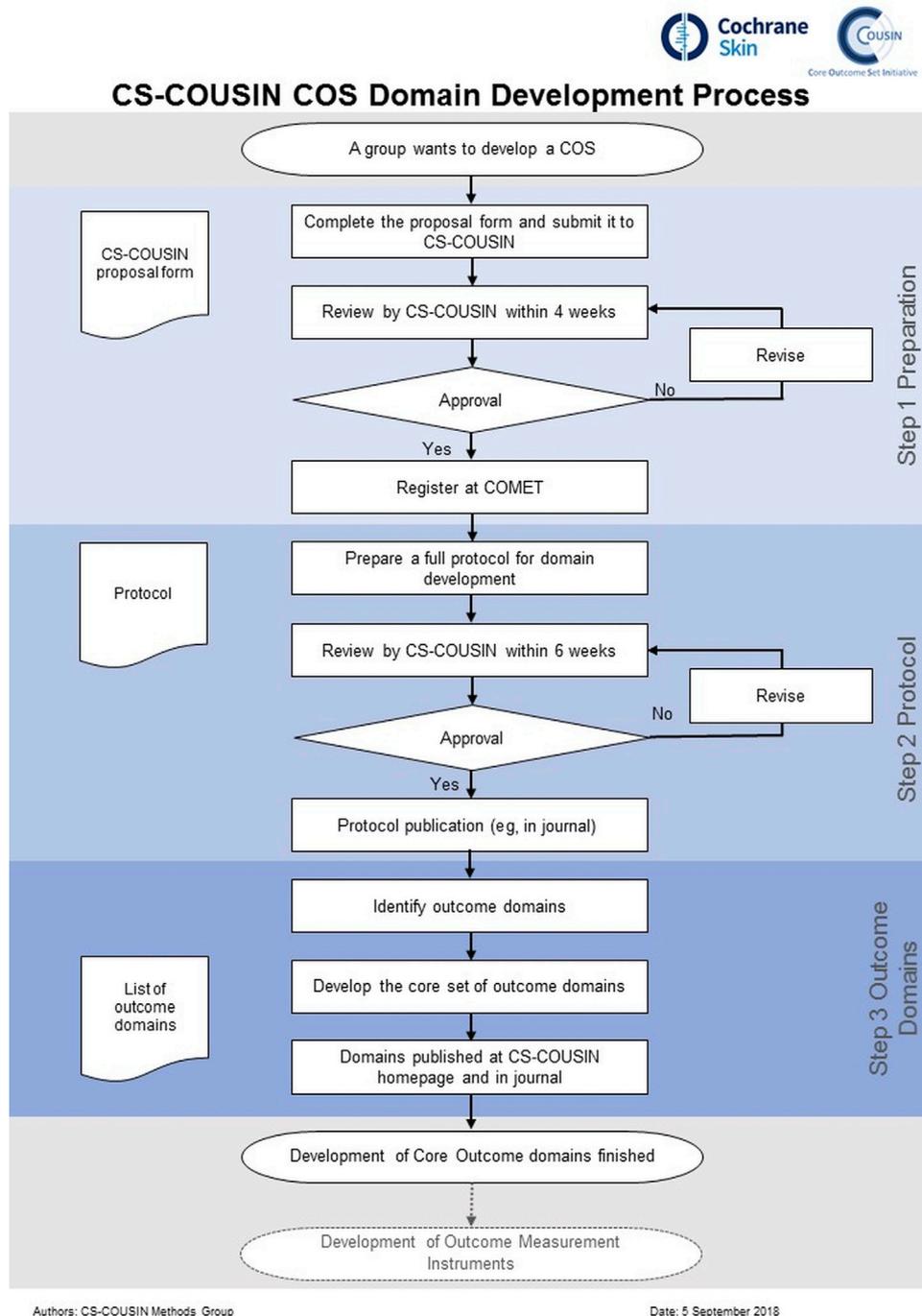


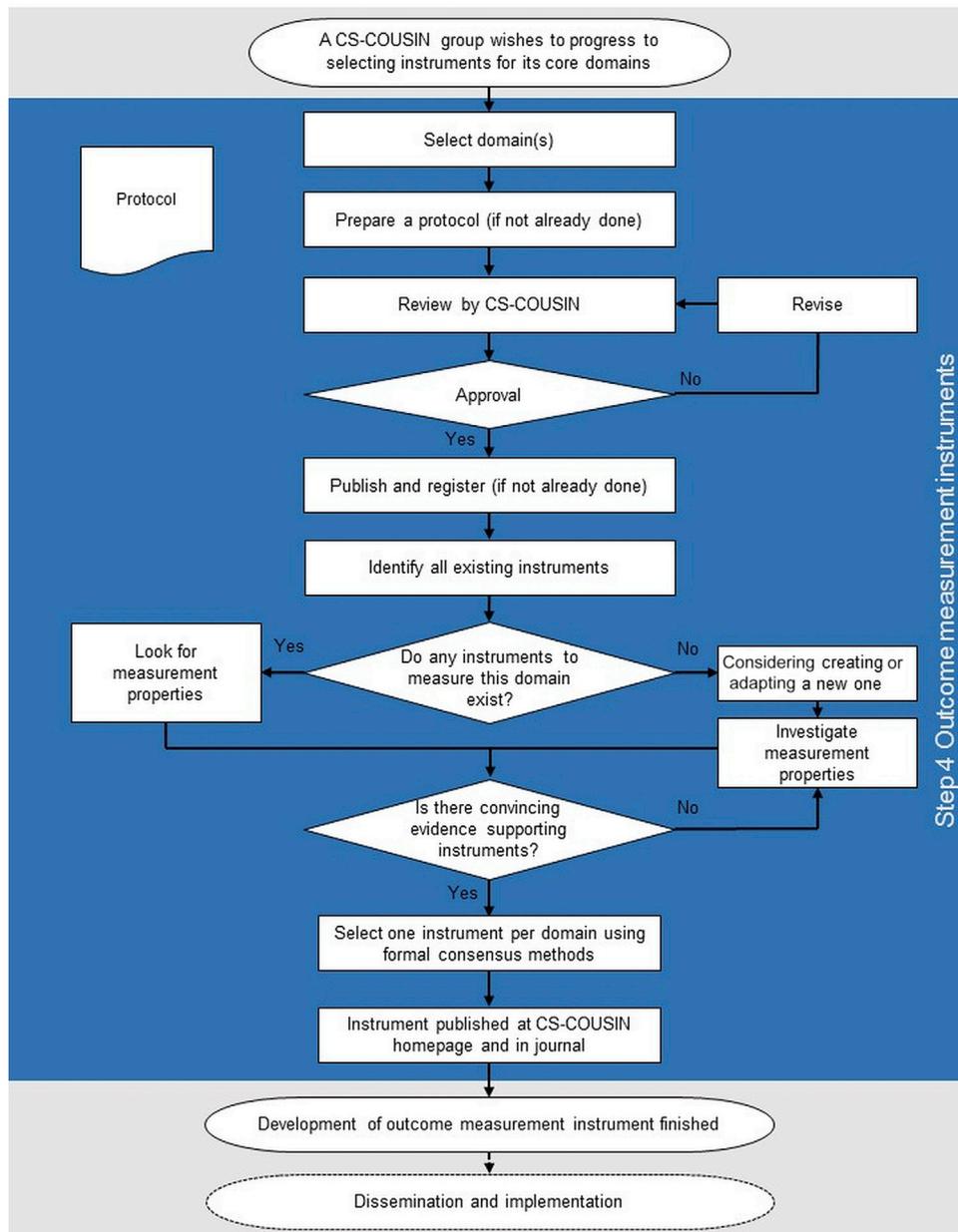
Fig 1. CS-COUSIN flow diagram for the domain development process. *COMET*, Core Outcome Measures in Effectiveness Trials; *COS*, core outcome sets; *CS-COUSIN*, Cochrane Skin—Core Outcome Set Initiative.

registry purposes, ie, the TrEatment of ATopic eczema Registry^{35,36} and the European Laser TrEatment Dermatology registry.²⁴

To achieve a similar level of success in dermatology as OMERACT has achieved in rheumatology,¹⁶ care is needed to ensure the delivery of high-quality COSs that meet quality standards when

using state-of-the-art methods.^{20,21,23,25,33,37,38} Using the HOME Initiative roadmap, the CS-COUSIN methods group has developed guidance for developing skin disease-specific COSs,³⁹ including a flow diagram for the domain development process and a diagram for outcome measurement instrument selection and development (Figs 1 and 2).

CS-COUSIN COS Outcome Measurement Instrument Selection/Development Process



Authors: CS-COUSIN group

Date: 5 September 2018

Fig 2. CS-COUSIN flow diagram for the outcome measurement instrument selection and development process. CS-COUSIN, Cochrane Skin—Core Outcome Set Initiative.

An important difference between CS-COUSIN and the COMET Initiative is that CS-COUSIN provides direct methodologic support for skin-related COSs and is embedded within the international Cochrane Skin group, thus ensuring speedy adoption of COSs within high-quality systematic reviews that are used by guideline developers.

To date, 17 COS initiatives have been supported by CS-COUSIN.⁴⁰ To ensure high-quality across COSs in dermatology, groups developing COSs are supplied with access to protocol templates and recommendations on best practices, and all are assigned a CS-COUSIN methods group representative who provides individual support for that group.

Table II. Overview of core outcome set projects supported by Cochrane Skin–Core Outcome Set Initiative

No.	Skin disease	Core outcome set initiative	Program acronym or name
1	Acne vulgaris	Acne Core Outcomes Research Network	ACORN
2	Atopic eczema	Harmonising Outcome Measures for Eczema	HOME
3	Basal cell carcinoma	Core outcome set for clinical trials in Basal Cell Carcinoma	IMPROVED
4	Chronic spontaneous urticaria	Core Outcome Measures in Chronic Spontaneous Urticaria	-
5	Chronic wounds	Developing a Core Outcome Set for Chronic Wounds	-
6	Facial aging	Core Outcome Set for the Appearance of Facial Aging	IMPROVED
7	Hand eczema	Development of a Hand Eczema Core Outcome Set	HECOS
8	Hidradenitis suppurativa	Development of a Core Outcome Set in Hidradenitis Suppurativa	HISTORIC
9	Incontinence-associated dermatitis	Core Outcome Set in IAD Research project: development of a core set of outcomes and measurement instruments for Incontinence-Associated Dermatitis research	CONSIDER
10	Laser treatment	European Laser TrEAtment Dermatology Registry	LEAD
11	Melanoma	Developing a Core Outcome Set for Melanoma trials	-
12	Nail psoriasis	Development of a Core Outcome Set in Nail Psoriasis	-
13	Pressure ulcer	The Outcomes for Pressure Ulcer Trials project	OUTPUTs
14	Rosacea	Core Outcome Set for Rosacea	IMPROVED
15	Vascular malformations	Development of a Core Outcome Set for Vascular Malformations	OVAMA
16	Vitiligo	International Initiative for Outcomes for vitiligo	INFO vitiligo
17	Congenital melanocytic nevi	Core Outcome Set for Congenital Melanocytic Nevi	OCOMEN

In addition, CS-COUSIN organizes annual meetings whereby knowledge, ideas, and issues with regard to COS development are exchanged and debated among CS-COUSIN members and external experts from the COMET Initiative, COSMIN initiative, and OMERACT.^{5,41} An overview of COS projects supported by CS-COUSIN is provided in Table II and detailed information about these COS projects can be found on the CS-COUSIN website.⁴⁰

Another initiative in dermatology (that is not affiliated within the COMET Initiative or CS-COUSIN) is International Dermatology Outcome Measures (<http://dermoutcomes.org>); this initiative seeks to develop and validate dermatology outcome measurement instruments throughout dermatology with an initial focus on psoriatic disease.⁴²

It is important to ensure and increase international cooperation and collaboration between different COS initiatives in dermatology. It is therefore recommended that present and future COS projects are embedded within CS-COUSIN, to ensure quality standards for COS development. The embedding of COS projects within CS-COUSIN facilitates the exchange of cutting-edge knowledge in an international community of COS developers and methodologists that supports COS development and uptake on a global level. CS-COUSIN is open

to everyone with an interest in outcomes research and evidence-based dermatology and with enthusiasm for developing and implementing COSs in dermatology.

CS-COUSIN encourages COS developers to have a clear focus on patient-centeredness and embraces the importance of the involvement of patient research partners in steering committees and throughout the entire course of the COS development process. Standardization of patient-centered outcome reporting enables synthesizing clinical trial results in a meaningful way. This significantly improves the patient-value of evidence acquired from research and clinical practice and enables delivering value-based health care.⁴³

Future directions of COS development could include innovative new generic outcome measurement instruments involving item response theory and computerized adaptive testing. These new outcome measurement instruments have recently become available and measure aspects of health more precisely and in a more tailored way than standard previous outcome measurement instruments that are based on classical test theory.⁴⁴⁻⁴⁷ The HOME Initiative, for example, is currently exploring the possibility of implementing Patient-Reported Outcomes Measurement Information

System instruments in the COS for atopic eczema. In addition to research, the possibility to use COSs for the evaluation of dermatologic clinical practice should also be developed further.

THE CHALLENGE TO UPTAKE OF COSs

Global uptake of COSs is crucial to overcome the problem of nonuniformity in outcome reporting. One way of ensuring early adoption into clinical trials is to ensure early engagement with regulatory agencies, such as the Food and Drug Administration and European Medicines Agency. To ensure a successful uptake of the various COSs in dermatology, it is important that researchers, clinicians, systematic reviewers, and other stakeholders adhere to the COS in their own research and work. In doing so, all stakeholders can be reassured that they are measuring important aspects of the disease in the most reliable, valid, and responsive ways and are contributing to a reduction in wasted research efforts and improving patient care.

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