Measuring atopic eczema symptoms in clinical practice: The first consensus statement from the Harmonising Outcome Measures for Eczema in clinical practice initiative

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Background: Measuring patient-centered outcomes in clinical practice is valuable for monitoring patients and advancing real-world research. A new initiative from the Harmonising Outcome Measures for Eczema (HOME) group aims to recommend what might be recorded for atopic eczema patients in routine clinical care.

Objectives: Prioritize outcome domains to measure atopic eczema in clinical practice and select valid and practical outcome measurement instruments for the highest-priority domain.

Methods: An online survey of HOME members identified and ranked 21 possible health domains. Suitable instruments were then selected for the top-prioritized domain at the HOME VI meeting, using established consensus processes informed by systematic reviews of instrument quality.

Results: Patient-reported symptoms was the top-prioritized domain. In accordance with psychometric properties and feasibility, there was consensus that the recommended instruments to measure atopic eczema symptoms in clinical practice are the POEM, the PO-SCORAD index, or both. The numeric rating scale for itch received support pending definition and validation in atopic eczema.

Conclusion: Following the first step of the HOME Clinical Practice initiative, we endorse using the POEM, the PO-SCORAD index, or both for measuring atopic eczema symptoms in clinical practice. Additional high-priority domains for clinical practice will be assessed at subsequent HOME meetings. (J Am Acad Dermatol 2020;82:1181-6.)

Key words: outcomes; outcome measures; instruments; atopic dermatitis; atopic eczema; eczema; Harmonising Outcome Measures for Eczema; HOME; clinical practice.

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INTRODUCTION

Atopic eczema (also known as atopic dermatitis) is a common chronic inflammatory skin disease[1-3] that causes a significant burden on the life of patients.[4-6] In daily practice, most clinicians assess their patients with a detailed history and physical examination. Although invaluable for the practicing clinician, such assessments do not quantitatively capture multiple domains of the disease over time. Adding outcome measurement using well-validated instruments to patient management, can be useful at the individual level for monitoring treatment response or assessing the disease burden. Some outcomes, such as patient-reported ones, can be collected outside of scheduled office visits, thus enhancing the understanding of the patient's disease in between office visits. A study in patients with cancer found that simply monitoring symptoms by using patient-reported outcome instruments imparted clinical benefit to patients,[7] even improving survival.[8]

CAPSULE SUMMARY

- The Harmonising Outcome Measures for Eczema group's new initiative aims to identify practical and valid instruments to measure atopic eczema outcomes in routine clinical practice.
- We recommend measuring atopic eczema symptoms in the clinic setting with the POEM, the PO-SCORAD index, or both.

Outcome measurements collected in clinical practice are also an important part of real-world data, collectively defined as the data relating to patient health status or the delivery of health care routinely collected from a variety of sources.[9] Real-world data have been gaining traction as a key resource for improving patient care by translating it into actionable information that benefits health care and patient outcomes,[10] for example, assisting in developing guidelines and decision support tools for use in clinical practice.

The past years have seen renewed interest in the use of real-world data to bridge the evidentiary gap between clinical research and practice.[11] Real-world research includes patients representative of diverse populations and evaluates interventions realistically.[10] Real-world data with outcome measurements can advance our understanding of the natural history and burden of disease, treatment patterns, compliance, persistence, and health outcomes of different treatments.[12] They can be applied to support clinical trial designs (eg, pragmatic clinical trials) and observational studies to generate innovative, new treatment approaches.[9] Last, outcome measurement can inform quality-of-care improvement projects, eventually leading to improved treatment of patients.

To our knowledge, there are currently no recommendations to guide the selection of instruments for measuring patient-reported outcomes in atopic eczema in clinical practice. To attain high-quality outcome measurement data, standardized and validated outcomes measurements are needed. This is critical for research initiatives, especially when data are aggregated across centers, meta-analyses are performed, or trends are analyzed at a population level. The Harmonising Outcome Measures for Eczema (HOME) group is a global initiative working toward standardization and validation of outcome measurement in atopic eczema. Since 2012, the group has focused primarily on clinical trials.[13-16] Because the needs and available resources in daily practice are different from those in clinical trials, an adaptation of the current HOME clinical trial initiative is needed to fill such a gap. The HOME Clinical Practice Set aims to identify instruments suitable for use in the clinical practice setting to measure domains of health in patients with atopic eczema.

The HOME Executive Committee agreed that the HOME Clinical Practice Set should follow a process similar to that of the original HOME Roadmap: a step-by-step process of identifying selected outcome domains followed by systematically identifying the appropriate measurement instruments for these domains.[17] The Executive Committee also agreed that the Clinical Practice Set will not be a mandatory core outcome set containing a predefined number of outcome domains and their measurement instruments that need to be measured in all patients, as is the case with the clinical trial core outcome set. Instead, there is no limit to the number of domains identified to be important to measure in the HOME Clinical Practice Set. Although core outcome sets allow complete and harmonized data sets, their adoption in clinical practice is challenging because of time and budgetary constraints. Patient burden, including the time, effort, and emotional strain associated with completing a patient-reported outcome measure[18] is another limitation, and effort should be made to minimize this burden.

To further enhance flexibility, it was decided the HOME Clinical Practice Set will include all instruments

Abbreviations used:

HOME:	Harmonising Outcome Measures for Eczema
POEM:	Patient-Oriented Eczema Measure
PO-SCORAD:	Patient-Oriented Scoring Atopic Dermatitis

(not just 1 as in the core set for trials) that are considered feasible for use in clinical practice, and have sufficient validation. This allows a set or list of valid instruments from which practitioners may choose (ie, a "pick-and-choose" list) to measure a particular domain.

This article summarizes the progress made following the HOME Roadmap for the HOME Clinical Practice Set and the recommendation on measurement of the most prioritized domain, symptoms in atopic eczema in clinical practice.

METHODS AND RESULTS

We followed the HOME Clinical Practice Set Roadmap steps (Fig 1). In brief, this included the following:

Step 1: define scope

The first step involves developing a set of the most suitable atopic eczema outcome measurement instruments to be used globally in clinical practice.

Step 2: develop a prioritized set of outcome domains

Using an online survey of HOME members (Supplemental material 1, A, available at doi: 10.17632/3bthdx6tz2.2),[19] we outlined and prioritized the outcome domains to guide the work ahead (Fig 2). Consistent with a previous HOME Delphi study,[13] patient-reported symptoms was the highest-prioritized domain to measure in patients with atopic eczema.

Step 3, stages 1 to 2: identify instruments used to measure symptoms in atopic eczema and establish their extent and quality

Based on previous systematic reviews to identify instruments for measuring symptoms of atopic eczema and their measurement properties[20,21] and applying an updated version of the latter

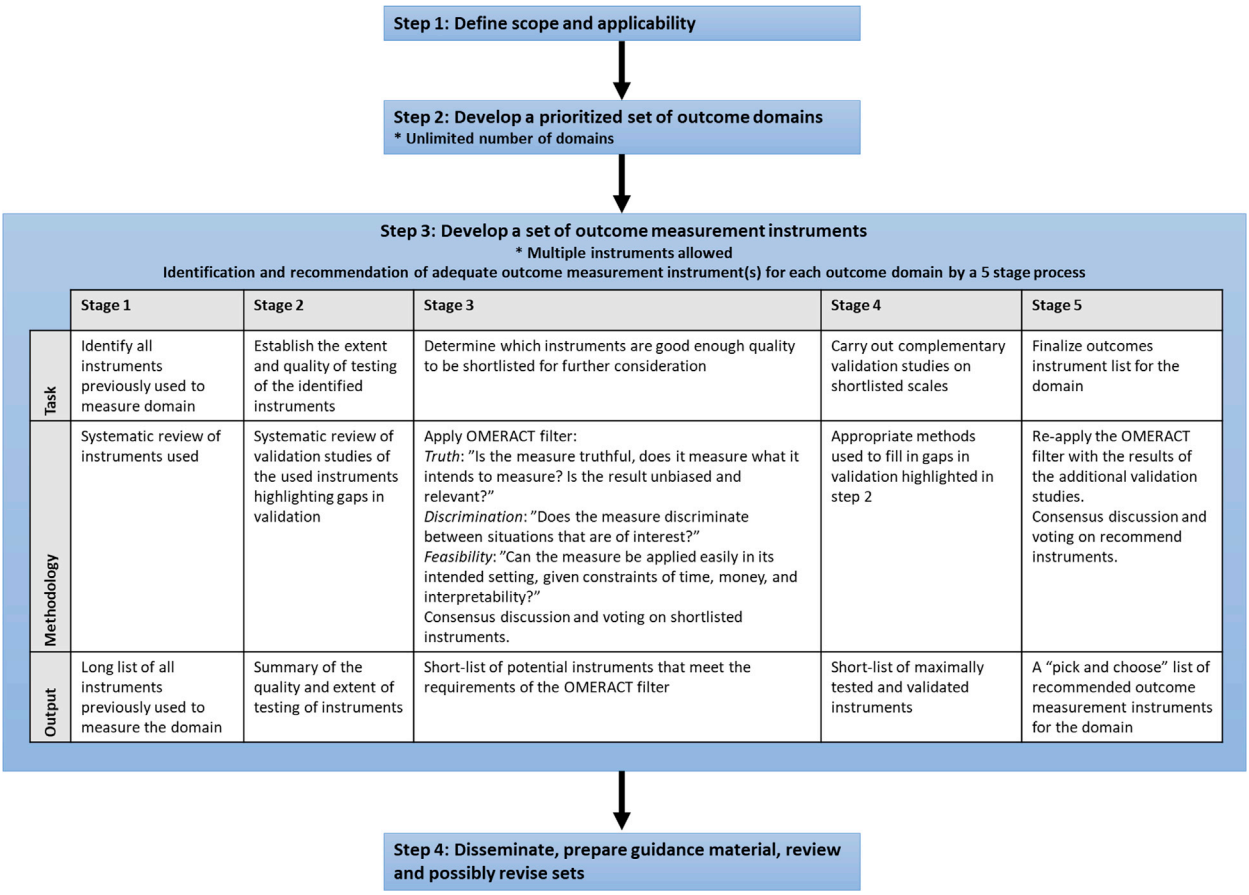

Fig 1. The HOME Roadmap for developing a set of outcome measurement instruments for clinical practice. *OMERACT*, Outcome Measures in Rheumatology.

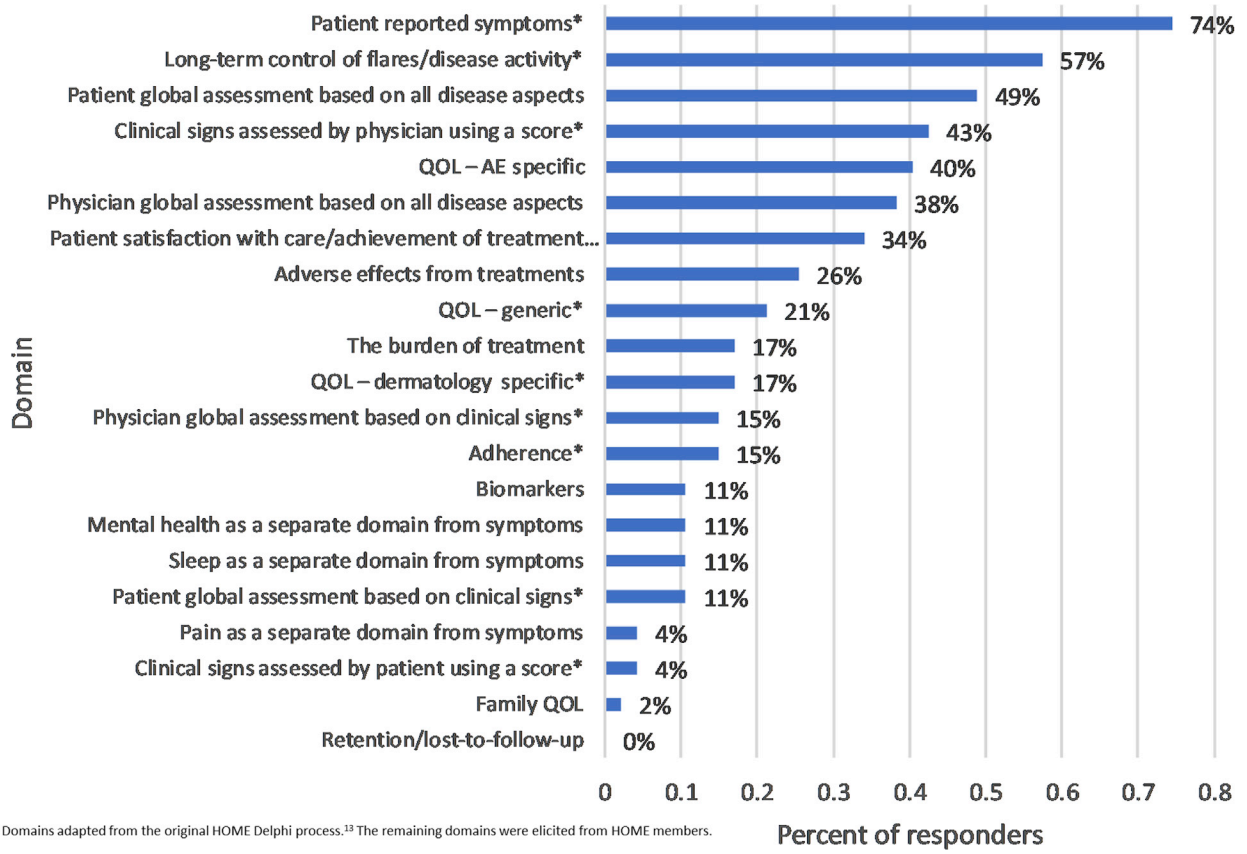

Fig 2. Results of the HOME Clinical Practice Set prioritization exercise: percentage of responders who included the domain as a priority domain (of 5 domains selected by each responder). *AE*, Atopic eczema; *QOL*, quality of life.

(Supplemental material 1, B[19] available at doi: 10.17632/3bthdx6tz2.2), 18 identified instruments were included. Based on best evidence synthesis, a recommendation for usage was provided for each instrument[20] (Table I).

Step 3, stages 3 to 5: selection of recommended instruments

At the HOME VI meeting (Utrecht, the Netherlands, April 11, 2018), an international panel of 72 participants (11 patients/parents of children with atopic eczema, 40 clinicians, 9 methodologists, and 12 pharmaceutical industry representatives) focused on selecting recommended instruments. Consensus was reached if less than 30% of the voters disagreed.[22] Individuals with a conflict of interest for a specific instrument were asked to refrain from voting.

Consensus was reached that category C instruments (ie, those that were shown to be low quality in at least 1 required quality criterion) (Table I) should be excluded from consideration.

In the meeting, participants were presented with the remaining available instruments (ordered in accordance with a premeeting prioritization exercise [Supplemental material 1, C available at doi: 10.17632/3bthdx6tz2.2][19]) with their quality and feasibility attributes, followed by small-group ("whisper-technique") and whole-panel discussions. Issues pertinent to the clinical practice settings were highlighted: selecting instruments that could be applied both by dermatologists and primary care providers, the importance of feasibility in the constrained setting of the day-to-day practice (including cost, accessibility, availability in multiple languages, and time to completion), and limiting the burden on patients.

Consensus was reached on including the POEM and PO-SCORAD index as instruments for assessing symptoms in the clinical practice setting (Supplemental material 2 available at doi: 10.17632/3bthdx6tz2.2).[19] There was general agreement that although first-time users can take longer to complete the PO-SCORAD index (up to 15 minutes), completion times improve with experience. The POEM takes 1 to 2 minutes to complete.[23]

Table I. Rating of symptoms instruments based on assessment of measurement properties[20]

Rating	Criteria	Instruments
A	Meets all required quality items and is recommended for use	None
B	Meets 2 or more required quality items and has the potential to be recommended in the future, depending on the results of further validation studies	Paediatric ISS, POEM, PO-SCORAD, SA-EASI, adapted SA-EASI
C	Has low quality in at least 1 required quality criterion and therefore is not recommended to be used any more	ADAM, EIQ, adult ISS, LIS, SDQ, ZRADSQ
D	Has (almost) not been validated. Its performance in all or most relevant quality items is unclear so that it is not recommended to be used until further validation studies clarify its quality	ADQ, CoIQ, Method 4, NESS, subjective SCORAD, VAS itch, VRS itch

ADAM, Atopic Dermatitis Assessment Measure; *ADQ*, Atopic Dermatitis Quickscore; *CoIQ*, Web-based Characteristics of Itch Questionnaire; *EIQ*, Eppendorf Itch Questionnaire; *ISS*, Itch Severity Scale; *LIS*, Leuven Itch Scale; *NESS*, Nottingham Eczema Severity Score; *POEM*, Patient-Oriented Eczema Measure; *PO-SCORAD*, Patient-Oriented Scoring Atopic Dermatitis index; *SA-EASI*, Self-administered Eczema Area and Severity Index; *SCORAD*, Scoring Atopic Dermatitis index; *SDQ*, Skin Detective Questionnaire; *VAS*, Visual Analogue Scale; *VRS*, Verbal Rating Scale; *ZRADSQ*, Zheng-Related Atopic Dermatitis Symptom Questionnaire.

There was also general agreement on the need for a simple measure of itch intensity. The numeric rating scale for itch was discussed as an acceptable and feasible instrument.[24] However, peer-reviewed validation studies for this instrument in atopic eczema had not been published before the meeting.[25] Another limitation is that the optimal numeric rating scale for itch instrument for patients with atopic eczema has not been defined, including the recall period (ie, the time over which itch is recalled) and whether the assessment should ask about "peak" versus "average" itch. Consensus was reached that a numeric rating scale for itch intensity should be included in the HOME Clinical Practice Set for assessing symptoms. The specific instrument has yet to be defined and agreed on. At the recent HOME VII meeting, the HOME group voted for a peak numeric rating scale with a 24-hour recall period as the preferred instrument to measure itch in clinical trials, because a validation study in atopic eczema is now available.[26]

RECOMMENDATION

Following a predefined methodology delineated by the HOME Clinical Practice Set Roadmap, building on systematic reviews and culminating in a consensus process driven by an international panel of multiple stakeholders, including a significant contribution from patients, the POEM and the PO-SCORAD index were selected as suitable instruments to measure symptoms in the clinical practice setting. The numeric rating scale for itch is a provisional instrument for measuring itch intensity and will be addressed in future meetings, because a validation study for a numeric rating scale instrument for itch in atopic eczema has become recently available.

This is the first step in the HOME Clinical Practice Set effort, to build a prioritized list of outcome domains with easy-to-use outcome measurement instruments for clinicians to choose from in their daily clinical practice. We encourage clinicians and patients to apply at least 1 of the recommended instruments in their clinical practice, stressing that they should complement, not replace, a thorough history and physical examination. These instruments may be even more valuable when used in between visits to provide a broader view of disease control and patient symptom burden. They could also be filled in as patients are waiting to be treated in a hospital or community clinic, providing essential information for the assessing health care professional, and engaging the patient or family in the consultation before they enter the room. Both the POEM and the PO-SCORAD index are free, are available in multiple languages, and have unrestricted mobile applications (http://nottingham.ac.uk/research/groups/cebd/resources/poem.aspx; https://www.poscorad.com), all of which can facilitate their use.

Validated data on the symptom burden of patients can improve patient care from the individual patient level to a clinic, hospital, or national level. Data can also be collected and harmonized to provide for actual research and quality improvement projects. Implementing patient-reported outcomes for the solo community practitioner may be challenging; however, with dedicated resources and electronic medical record systems, large health systems have successfully implemented patient-reported outcomes into routine primary care, with the goals of improving the patient experience and enhancing communication in regard to patients' health status.[27,28] Future work includes progressing on

assessing a numeric rating scale instrument for itch and addressing additional domains, starting with the patient global assessment prioritized by the group.

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