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Measuring Atopic Eczema Control and Itch Intensity in Clinical Practice

A Consensus Statement From the Harmonising Outcome Measures for Eczema in Clinical Practice (HOME-CP) Initiative

Yael A. Leshem, MD, MCR; Joanne R. Chalmers, PhD; Christian Apfelbacher, PhD; Norito Katoh, MD, PhD; Louise A. A. Gerbens, MD, PhD; Jochen Schmitt, MD, MPH; Phyllis I. Spuls, MD, PhD; Kim S. Thomas, PhD; Laura Howells, PhD; Hywel C. Williams, DSc; Eric L. Simpson, MD, MCR; for the Harmonising Outcome Measures for Eczema (HOME) initiative

IMPORTANCE Measuring outcomes in clinical practice can aid patient care, quality improvement, and real-world evidence generation. The Harmonising Outcome Measures for Eczema (HOME) Clinical Practice initiative is developing a list of validated, feasible instruments to measure atopic eczema in clinical care. Prior work identified symptoms and long-term control as the most important domains to measure in clinical practice. The Patient-Oriented Eczema Measure (POEM) and the Patient-Oriented Scoring Atopic Dermatitis Index (PO-SCORAD) were recommended by consensus to measure symptoms in clinical practice, but a need for instruments to measure itch intensity specifically was recognized. The HOME group also previously decided that long-term control should be captured by repeated measurements of eczema control. Recommended instruments to measure eczema control in clinical practice have not been defined.

OBJECTIVE To recommend instruments to measure eczema control and itch intensity in patients with atopic eczema in clinical practice.

EVIDENCE REVIEW Available instruments to measure eczema control and itch intensity were identified through systematic reviews, informing a consensus process held at the HOME VIII virtual online meeting (October 6 and October 9, 2020). Feasibility aspects were highlighted to optimize instrument selection for the clinical practice. Consensus on an instrument was reached if fewer than 30% of the voters disagreed.

FINDINGS Of 7 identified instruments, the Recap of Atopic Eczema (RECAP) and Atopic Dermatitis Control Tool (ADCT) were the recommended instruments to measure eczema control (3 of 63 [5%] and 7 of 69 [10%] of voters disagreed, respectively). A single-question patient global assessment garnered support, but the current available instrument did not reach consensus. Six available itch-intensity instruments were identified. Of them, 3 instruments were recommended by consensus: a peak 24-hour numeric rating scale (NRS)-itch, and 1-week NRS-itch instruments from the Patient-Reported Outcomes Measurement Information System (PROMIS) Itch Questionnaire, measuring average and peak itch (11 of 63 [17%], 14 of 63 [22%], and 16 of 59 [27%] voters disagreed, respectively).

CONCLUSIONS AND RELEVANCE Clinicians and patients are encouraged to incorporate these well-validated, quick-to-perform, and easy-to-use instruments into their clinic, selecting the instruments that best fit their need. These assessments are meant to enhance, not replace, the patient–clinician encounter, and to support real-world research and health care improvement.

Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: HOME VIII meeting attendees are listed in Supplement 2.

Corresponding Author: Yael A. Leshem, MD, MCR, Division of Dermatology, Rabin Medical Center, Beilinson Hopsital, 39 Zabotinsky St, Petah Tikva, Israel (yael.leshem@gmail.com).

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Atopic eczema (AE, also known as atopic dermatitis) is a common, chronic, inflammatory, and burdensome skin disorder.[1-3] Treatment plans for AE are tailored on an individual basis, and the impact of disease plays a key role in guiding treatment decisions. In routine practice, clinicians usually evaluate patients via a history and physical examination. Most do not use quantitative measurement instruments to assess patient outcomes,[4] despite their potential benefits. On an aggregate level, measuring outcomes in routine clinical care can be valuable for real-world data generation and comparative effectiveness research. Outcome measures are considered an integral[5-7] or even the key component[8] of quality-of-care measurement by many organizations. The growing focus on value-based health care,[9] and specifically on patient-reported outcomes (PROs),[10] highlights the need for clinic-based outcome indicators for use in quality measurement programs. On an individual level, using measurement instruments can help monitor disease activity and inform therapeutic decision-making. Instruments measuring different domains of health can augment clinicians' insight on multiple aspects of a disease, raising issues that may not come up in the regular history and examination.[11] Measuring outcomes, especially with PRO instruments, can facilitate patient–clinician communication and promote shared decision-making.[12] Simply monitoring symptoms using PROs has even been reported to improve outcomes in some patients with cancer.[13,14] Also, PROs can be completed by patients at home, providing a comprehensive view of their condition.

One barrier to incorporating measurement instruments in clinical practice is the lack of recommendations to guide the choice of instruments. The Harmonising Outcome Measures for Eczema (HOME) group is a global initiative focusing on standardization and validation of outcome measurement in AE. The HOME Clinical Practice (HOME-CP) initiative is aimed at providing patients, health care professionals, and other stakeholders with a vetted set of valid and easy-to-use instruments to measure outcomes in patients with AE that are suitable for the clinical practice setting. Different from the HOME core outcome set (COS) for clinical trials,[15-19] the HOME-CP set is not a mandatory minimum core set of instruments, but rather a "pick and choose" list. This provides the required flexibility for performing measurements in the clinical setting, tailored to the needs of the clinician, patients, or health system.

To guide the HOME-CP project, a domain prioritization survey identified that symptoms and long-term control were the most important domains for clinical practice.[20] At the 2018 HOME VI meeting in Utrecht, the Netherlands, consensus was reached that the Patient-Oriented Eczema Measure (POEM) and/or the Patient-Oriented SCORing Atopic Dermatitis index (PO-SCORAD) were the recommended instruments to measure symptoms in the clinical practice.[20] HOME members also agreed that a numeric rating scale (NRS) measuring itch intensity was needed. No AE-specific validated NRS-itch intensity instruments were available at the time, so none were selected.

This consensus statement describes the recent work of the HOME-CP initiative, culminating in the HOME VIII virtual consensus meetings, which aimed to reach consensus on recommended instruments to measure long-term eczema control and itch intensity in patients with AE in clinical practice.

Key Points

Question What instruments are recommended to measure eczema control and itch intensity in patients with atopic eczema in clinical practice?

Findings Based on a consensus process informed by systematic reviews, the Recap of Atopic Eczema (RECAP) and Atopic Dermatitis Control Tool (ADCT) were recommended to measure long-term control in eczema in clinical practice. Recommended itch-intensity instruments were a peak 24-hour numeric rating scale (NRS)-itch and peak and average 1-week NRS-itch instruments from the Patient-Reported Outcomes Measurement Information System (PROMIS) Itch Questionnaire.

Meaning Clinicians should consider using these simple, validated instruments when treating patients with atopic eczema, to support clinical care, real-world studies, and quality-of-care assessments.

Methods

The HOME-CP initiative follows a predefined road map.[20] Steps 1 and 2 have been completed and described elsewhere.[20] Step 3 of the road map—identification and recommendation of the most suitable outcome measurement instruments—is described herein. This report is in accordance with the revised Standards for Quality Improvement Reporting Excellence (SQUIRE) reporting guideline.[21]

Identifying Instruments and Establishing the Extent and Quality of Their Testing

Eczema Control Domain

Prior to identifying measurement instruments, long-term eczema control needed to be defined. This was based on work done for the HOME clinical trials COS. At the 2017 HOME V meeting in Nantes, France, it was agreed that long-term control should be captured by repeated measurements of eczema control. Extensive work has gone into conceptualizing the meaning of eczema control in AE. This includes a systematic review that identified several strategies to capturing eczema control in randomized clinical trials,[22] such as repeated measurement of outcomes, medication use, and AE flares and remissions. Additional qualitative research projects found that AE control is not limited to 1 aspect of the disease experience, but rather encompasses multiple domains (such as symptoms and quality of life).[23-25] Based on this body of work, consensus was reached at the HOME V meeting that the eczema control domain for clinical trials should include signs, symptoms, quality of life, and a patient global assessment.[26] Following this definition, a systematic review[27] identified all PRO instruments that capture eczema control and systematically assessed their measurement properties using the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) criteria.[28] This systematic review was the basis for the discussion and voting.

Symptoms Domain/NRS-Itch Intensity

The instruments discussed in this domain were based on an updated systematic review[29,30] (search period up to 2019) of the measurement properties of PRO measures for pruritus. To identify

Table 1. Eczema Control Domain

Instruments	Categories of instrument recommendation		HOME VIII consensus voting results		Main meeting discussion points
	Evidence for sufficient content validity[a]	May have potential to be recommended but further validation studies needed	Recommended for the Clinical Practice Set	Disagreed with inclusion in the set, % (No. disagreed/ No. of votes)[b]	
RECAP[1,2]	Yes	No	Yes	5 (3/63)	Previously selected to measure eczema control in the HOME core outcomes set for clinical trials Free to use after a simple online permission request
ADCT[3,4]	Yes	No	Yes	10 (7/69)	Previously selected to measure eczema control in the HOME core outcomes set for clinical trials Limitation: lack of validation of in children Regeneron/Sanofi have set up a 1-click online licensing form for use in individual clinical practice
PtGA[6,7]	No	Yes	No	63 (44/70)	The phrasing of the instrument question may measure disease severity rather than disease control The limited response options (especially no "clear" option) and the lack of a defined recall period were a concern, although in the instrument content validation study (n = 8),[33] these were the patient preferences
PBI 2.0[5]	No	Yes	No	78 (53/68)	Considered to measure response to treatment rather than eczema control per se
AESEC[8]	No	Yes	No	93 (66/71)	Provides a comprehensive picture of the emotional consequences of eczema; however, too long for use in routine clinical practice; was not designed to capture eczema control
ISDL[9]	No	Yes	No	97 (69/71)	Unsuitable for the clinical practice set due to the instrument time requirement
ADS7[10]	No	Yes	No	90 (64/71)	Unsuitable for the clinical practice set due to limited validation in atopic eczema and instrument time requirement

Abbreviations: ADCT, Atopic Dermatitis Control Tool; ADS7, Atopic Dermatitis Score 7; AESEC, Atopic Eczema Score of Emotional Consequences; HOME, Harmonising Outcome Measures for Eczema; ISDL, Impact of Chronic Skin Disease on Daily Life; PBI, Patient Benefit Index; PtGA, Patient Global Assessment; RECAP, Recap of Atopic Eczema.

[a] At any level of quality of evidence.

[b] Consensus was achieved if fewer than 30% disagreed.

any new AE-specific validation studies of NRS-itch intensity instruments, we reviewed publications from January 2018 to July 2020 (not yet published). The measurement properties of the identified instruments were assessed applying criteria from a previous systematic review.[31] Due to time constraints, this review did not include an assessment of the methodological quality of included studies using the COSMIN risk-of-bias checklist. The findings of this review were also included in the discussion.

Selection of Recommended Instruments

An international meeting was held, aiming to achieve consensus on the recommended instruments for the eczema control and itch intensity domains for the HOME-CP set. Due to the COVID-19 pandemic, the meeting was held virtually. To encourage global participation, the meeting was split into 2 sessions, accessible to participants in different time zones.

During both meetings, participants were presented with the available instruments for both domains along with their psychometric properties. Feasibility concerns, which are critical in clinical practice settings, were emphasized (cost and access; time demands; available languages and electronic apps). Voting on each instrument followed small group and whole group discussions. When voting on instruments, those with a conflict of interest for a specific instrument were recorded and asked to refrain from voting.

The same consensus process was used as for previous meetings, reaching consensus if fewer than 30% of the voters disagreed.[32] To reach whole group consensus from 2 asynchronous sessions, we followed an a priori defined protocol: each session ended with voting on instruments. However, all participants, including the meeting moderators, were blinded to the voting results (except a vote-trustee, J.R.C.) to maintain an independent, nonbiased discussion in the second session. After both sessions were completed, the votes were numerically combined and the consensus criteria applied. As there is no limit to the number of instruments in the HOME-CP set, voting each instrument in or out of the set ended the consensus process, with no need for additional rounds. A patient/patient representative premeeting was held prior to the HOME meeting to acquaint patients with the HOME-CP initiative.

Results

Identifying Instruments and Establishing the Extent and Quality of Their Testing

Eczema Control Domain

The eczema control instruments systematic review[27] concluded that the Recap of Atopic Eczema (RECAP; https://www.nottingham.ac.uk/research/groups/cebd/resources/recap.aspx) and the Atopic Dermatitis Control Tool (ADCT; http://www.adcontroltool.com) had evidence for sufficient content validity (**Table 1**).[1-10,33]

Symptoms Domain/NRS-Itch Intensity

The PRO measures for pruritus systematic review[29,30] identified a single AE-specific validated NRS-itch intensity instrument with a

Table 2. Numeric Rating Scale (NRS)-Itch Intensity

Instruments	Categories of preliminary instrument recommendation		HOME VIII consensus voting results	
	Evidence for sufficient content validity[a]	May have potential to be recommended but further validation studies needed	Recommended for the Clinical Practice Set	Disagreed with inclusion in the set, % (No. disagreed/No. of votes)[b]
24-h Peak #1[34]	Yes	No	Yes	17 (11/63)
24-h Peak #2[35]	Yes	No	No	36 (23/63)
1-wk Average[36]	Yes	No	Yes	22 (14/63)
1-wk Peak[36]	Yes	No	Yes	27 (16/59)
24-h Average[37]	No	Yes	No	79 (50/63)
3-d[38]	No	Yes	No	85 (53/62)

[a] At any level of quality of evidence.

[b] Consensus was achieved if fewer than 30% disagreed.

24-hour recall period.[34] This instrument received a positive rating based on COSMIN criteria. Our additional review identified 5 new studies assessing 6 NRS-itch intensity instruments (eTables 1 and 2 in Supplement 1). **Table 2**[34-38] presents a preliminary rating of the degree of recommendation for the instruments.[31] All are NRS-11 instruments, ie, apply a 0 to 10 scale.

Selection of Recommended Instruments

The HOME VIII meeting (October 6 and October 9, 2020) included 79 participants from 18 countries, 12 of whom were patients or patient representatives. The amalgamated voting results from both sessions are presented in Tables 1 and 2.

Eczema Control Domain

Consensus was reached on including both the RECAP[39] and ADCT[40] as instruments for assessing eczema control in the clinical practice setting. The ADCT has 7 items, and the RECAP has 6; both take less than 2 minutes to complete and have previously been selected to measure eczema control in the HOME COS for clinical trials.[41]

The concept of a single-item patient global assessment was endorsed by many participants because it offers a quick, nonburdensome option for both patients and clinicians. However, the available AE-validated Patient Global Assessment (PtGA)[33,42] did not meet consensus criteria for inclusion.

Symptoms Domain: NRS-Itch Intensity

Three NRS-itch instruments were recommended by consensus: a peak 24-hour NRS-itch,[34] which is also included in the HOME COS for clinical trials[41]; and two 1-week NRS-itch instruments, both part of the Patient-Reported Outcomes Measurement Information System (PROMIS) Itch Questionnaire,[36] measuring average and peak itch (the PROMIS itch instruments are publicly available from https://www.healthmeasures.net/ for use in individual research, clinical practice, and educational assessment without licensing or royalty fees). The time to complete the 1-week itch intensity NRS[36] was assessed at less than 1 minute and assumed to be similar for all the NRS-itch intensity instruments.

The discussion regarding the NRS-itch intensity instruments centered on 2 main issues: defining the optimal recall period (24 hours to 1 week) and the type of itch intensity to measure (peak vs average).

The shorter the recall period, the lower the recall bias, promoting a 24-hour recall from a methodological standpoint. However, patients repeatedly voiced concerns that restricting recall to the previous 24 hours may fail to capture their true status, as AE itch can fluctuate on a daily basis (eg, "I'm better now, but you should have seen me 2 days ago"). Another possible disadvantage to 24-hour itch instruments is that they were designed for daily measurements with electronic diaries in clinical trials. Applied this way, they do provide a very precise picture of daily itch over time. However, a daily itch measurement may be burdensome to patients. It may also not be feasible for most clinical settings, although advances in digital health technologies, especially monitoring through mobile devices,[43] could increase feasibility.

There were conflicting voices on the preference of peak vs average itch, echoing prior studies that have shown that patients found both to be of relevance.[34,36] At the meeting, there were many proponents of measuring peak itch who thought this was the most significant aspect of itch, affecting sleep and quality of life and leading to scratching and skin damage. It is also cognitively difficult to average out symptoms or emotions, so the concept of "peak" can be easier to assess than "average." Others proposed there was a need for both measurements. It may also be that different instruments are appropriate for different disease severities. For example, inquiring about peak itch in patients with mild, well-controlled disease, but an occasional attack of severe itch, may provide responses skewed toward more severe disease.

There was concern that to our knowledge, no NRS-itch intensity validation studies had been published in children, except a 24-hour peak itch instrument from Eli Lilly,[35] validated in adolescents. However, another well-validated 24-hour peak NRS-itch instrument[34] is already part of the HOME-COS for clinical trials, which was ultimately considered a strong argument in its favor. During the meeting, it was noted that a PROMIS itch questionnaire for children just completed its development and validation. As the data were not published at the time of the meeting, it was not included in the instrument review and the voting.

Discussion

Measuring outcomes in patients with AE during routine care can provide diverse benefits. In relation to clinical care, such outcomes help to monitor disease activity, quantify and highlight the patient burden[11] to aid shared decision-making,[12] and support a treat-to-target approach based on indicators defined with outcome measurement instruments. Such outcome data also contribute to quality of care[5-8] where they can serve as quality indicators and support value-based health care decisions. Outcome measure use in routine care also provides valuable data for research. The HOME-CP

initiative aims to provide a list of valid and practical instruments to support these aims in the care of patients with AE. Following the initiative's predefined process[20] and applying an evidence-based consensus process with multiple stakeholders, most importantly patients, the HOME group recommended additional instruments for patients with AE for the clinical practice set: measuring eczema control using RECAP[39] and/or the ADCT[40]; and measuring itch intensity using the 24-hour peak NRS,[34] the PROMIS 1-week peak, and the PROMIS 1-week average NRS.[36]

Both the RECAP and the ADCT, while quick to fill in, are multi-item questionnaires. Many meeting participants supported a single-item patient global assessment. Such an assessment would be expected to be very quick to perform but lacks detail. The currently available single-question AE-validated PtGA[33,42] did not meet consensus criteria. During the meeting, concerns regarding this PtGA included the phrasing of the instrument question, which was considered by some to measure disease severity rather than disease control, and the limited choice of response options, especially the lack of a "clear" option. An additional constraint was the lack of a defined recall period, so that patients select their own time frame to consider when describing their eczema. In contrast, it was commented that the instrument development was based on patient preferences from the instrument content validation study (n = 8).[33] Striking the balance between applying instruments with few items, which can minimize assessment burden in routine care (eg, time constraints and respondent fatigue), with preserving a valid and reliable "enough" instrument is challenging. Studies of a single-item patient global assessment, which aim to bridge this gap, are needed.

The selection of 3 diverse NRS instruments to measure itch intensity highlights the debate surrounding the optimal recall period and itch type (peak vs average)[34,36] for this assessment. Peak itch was endorsed by some as the major driver of disease burden, directly affecting aspects such as sleep loss and quality of life. It may also be easier to assess cognitively than average itch. On the other hand, average itch may provide a more comprehensive picture of disease severity. It may be that there is a need for both measurements or that different clinical scenarios may call for a different instrument. To stress the complexity of itch measurement in AE, a patient participant described experiencing both types of itch—an underlying "baseline" itch coupled with severe bouts of scratch-inducing itch. Both are key to his experience and may not be captured by focusing on only peak or average itch assessments.

While the HOME-CP set offers well-validated and feasible instruments to measure patient care in clinical practice, implementation can be challenging. Some health care settings and initiatives that are natural candidates for using HOME-CP set instruments have already adopted other instruments. For example, some health systems require certain outcome measurement instruments to be used for reimbursing advanced therapeutics (eg, the Eczema Area and Severity Index and Dermatology Life Quality Index for dupilumab approval in the UK),[44] guiding the instrument selection in clinical care in these countries. While clinicians can still opt to use additional instruments, using many instruments can negate the principle of minimizing assessment burden in clinical care. A major uptake challenge will be encouraging clinicians to adopt recommended instruments into their daily clinic and quality projects. Local and global education as well as publications of consensus decisions in high-impact journals may aid in increasing uptake. Increasing the practicality of use of these instruments may also enhance uptake—for example, developing electronic forms or mobile apps that can upload to the electronic health records, so that the instruments can be implemented in a time-efficient manner, eg, having patients fill them out while waiting for their appointments or at home.

Limitations

While we aimed to maximize international participation in this consensus process and conducted separate meetings to accommodate different time zones, the vast majority of attendants were from Europe and North America. This may limit the generalizability of the findings to low-income countries and to skin of color. We also recognize that outcome measurement research is a dynamic field, and other instruments may become attractive candidates in the future. An example is the PROMIS itch questionnaire for children, recently validated in this patient population,[45] that was not available at the time of the meeting. The HOME-CP set is open to change, and additional instruments may be added following the HOME-CP road map.

Conclusions

This HOME-CP initiative process resulted in evidence-informed recommendations that reflect consensus among a group of patients, clinicians, methodologists, and industry representatives with an interest in AE for measuring 2 key domains for patients with AE in clinical practice: measuring eczema control using the RECAP and the ADCT; and measuring itch intensity using the 24-hour peak NRS,[34] the PROMIS 1-week peak, and the PROMIS 1-week average NRS.

The HOME-CP set is a "pick and choose" list of well-validated, feasible-to-use instruments that clinicians can use in their daily practice. These instruments can supplement, not replace, the thorough interpersonal medical encounter. The instrument a clinician chooses, and how to use it, depends on the domain and the objectives of the measurement, which can vary from patient baseline assessments and monitoring to quality improvement and real-world evidence generation.

While there is evidence that incorporating outcome measures into clinical practice can benefit patient care, quality improvement projects, and research, this needs to be evaluated specifically in patients with AE to further support the use of the HOME-CP set. Additional work includes agreeing on the optimal frequency and timing of eczema control assessments to capture long-term control; expanding the HOME-CP set to additional domains of interest, including a single-question patient global that was supported by many participants; promoting representation of diverse populations in outcome research; and supporting and appraising the uptake of the HOME-CP set in clinics. HOME is an open, international group, and we invite anyone with an interest in AE to join us and contribute.

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Author Affiliations: Division of Dermatology, Rabin Medical Center, Petach-Tikva, Israel (Leshem); Sackler School of Medicine, Tel-Aviv University,

Tel-Aviv, Israel (Leshem); Centre of Evidence Based Dermatology, School of Medicine, University of Nottingham, Nottingham, United Kingdom (Chalmers, Thomas, Howells, Williams); Institute of Social Medicine and Health Systems Research, Otto von Guericke University Magdeburg, Magdeburg, Germany (Apfelbacher); Lee Kong Chian School of Medicine, Nanyang Technological University Singapore, Singapore (Apfelbacher); Department of Dermatology, Kyoto Prefectural University of Medicine, Kyoto, Japan (Katoh); Department of Dermatology, Amsterdam UMC, Academic Medical Center, University of Amsterdam, Amsterdam Public Health, Infection and Immunity, Amsterdam, the Netherlands (Gerbens, Spuls); Center for Evidence-based Healthcare, Medical Faculty Carl Gustav Carus, TU Dresden, Germany (Schmitt); Department of Dermatology, Oregon Health and Science University, Portland, Oregon (Simpson).

Author Contributions: Dr Leshem had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Leshem, Chalmers, Apfelbacher, Katoh, Gerbens, Schmitt, Thomas, Williams.
Acquisition, analysis, or interpretation of data: Leshem, Chalmers, Apfelbacher, Katoh, Gerbens, Spuls, Howells, Williams, Simpson.
Drafting of the manuscript: Leshem, Katoh, Thomas.
Critical revision of the manuscript for important intellectual content: Chalmers, Apfelbacher, Katoh, Gerbens, Schmitt, Spuls, Howells, Williams, Simpson.
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