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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Word count:
- Abstract: 199
- Capsule summary: 50
- Text: 1625

Figures: 2
Tables:1

Funding: This article has no funding source

Keywords: outcomes, outcome measures, instruments, atopic dermatitis, atopic eczema, eczema, Harmonising Outcome Measures for Eczema, HOME, clinical practice.

Abstract

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 (AE) patients in routine clinical care.

Objectives: Prioritize outcome domains to measure AE 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. Based on psychometric properties and feasibility, there was consensus that the recommended instruments to measure AE symptoms in clinical practice are the Patient-Oriented Eczema Measure (POEM) and/or the Patient-Oriented SCORing Atopic Dermatitis index (PO-SCORAD). The Numerical Rating Scale for itch received support pending definition and validation in AE.

Conclusion: Following the first step of the HOME Clinical Practice initiative, we endorse using the POEM, the PO-SCORAD, or both for measuring AE symptoms in clinical practice. Additional high-priority domains for clinical practice will be assessed at subsequent HOME meetings.

Introduction.

Atopic eczema (AE) (syn. atopic dermatitis) is a common chronic inflammatory skin disease[1–3] which causes a significant burden on the life of patients.[4–6] In daily practice, most clinicians assess their patients using a detailed history and physical examination. While 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 outcomes (PROs), 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 using PRO instruments imparted clinical benefit to patients,[7] even improving survival.[8]

Outcome measurements collected in the clinical practice are also an important part of real-world data (RWD), collectively defined as the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.[9] RWD has been gaining traction as a key resource for improving patient care, by translating it into actionable information that benefits healthcare 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 RWD 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] RWD 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] RWD can be applied to support clinical trial designs (e.g., 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.

There are currently no recommendations to guide the selection of instruments for measuring PROs in AE 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 aggregating data across centers, performing meta-analyses, or analysing trends at a population level. The Harmonising Outcome Measures for Eczema (HOME) group is a global initiative working towards standardization and validation of outcome measurement in AE. Since 2012, the HOME group has focused primarily on clinical trials.[13–16] Because the needs and available resources in daily practice are different than 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 to measure domains of health in patients with AE suitable for use in the clinical practice setting.

The HOME Executive Committee agreed that the HOME Clinical Practice Set should follow a similar process as 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 (COS) 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 COS. Instead, there is no limit to the number of domains identified to be important to measure in the HOME Clinical Practice Set. While COS allow for complete and harmonized data sets, their adoption in clinical practice is challenging due to time and budgetary constraints. Patient burden, defined by PCORI as the time, effort, and emotional strain associated with completing a PROM,[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 (not just one 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 (i.e. a “pick and choose” list) to measure a particular domain.

109 This paper summarizes the progress made following the HOME roadmap for the HOME Clinical
110 Practice Set and the recommendation on measurement of the most prioritized domain – symptoms
111 in AE in clinical practice.

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Methods and Results

We followed the HOME Clinical Practice Set Roadmaps Steps (Fig 1.). In brief, this included:

Step 1: Define scope. To develop a set of the most suitable AE outcome measurement instruments to be used globally in clinical practice.

Step 2: Develop a prioritized set of outcome domains. Utilizing an online survey of HOME members (Supplementary 1a)[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 AE.

Step 3; stages 1-2: identify instruments used to measure symptoms in AE and establish their extent and quality.

Based on previous systematic reviews to identify instruments for measuring symptoms of AE and their measurement properties[20,21] and applying an updated version of the latter (Supplementary 1b[19]), 18 identified instruments were included. Based on best evidence synthesis, a recommendation for usage was provided for each instrument[20] (Table 1).

Table 1: 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 **two 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 one required quality criteria** 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.

Step 3; stages 3-5: Selection of recommended instruments

At the HOME VI meeting (Utrecht, the Netherlands, April 11th 2018), an international panel of 72 participants (11 patients/parents of children with AE, 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] Those with a conflict of interest for a specific instrument were asked to refrain from voting.

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

In the meeting, participants were presented with the remaining available instruments (ordered based on a pre-meeting prioritisation exercise, Supplementary 1c[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 as instruments for assessing symptoms in the clinical practice setting (Supplementary 2[19]). There was general agreement that while new-time users can take longer to complete the PO-SCORAD (up to 15 minutes), this improves with experience. The POEM takes 1 to 2 minutes to complete.[23]

There was also general agreement on the need for a simple measure of itch intensity. The numerical rating scale for itch (NRS-itch) was discussed as an acceptable and feasible instrument.[24] However, peer-reviewed validation studies for the NRS-itch in AE had not been published at the time of the meeting.[25] Another limitation is that the optimal NRS-itch instrument for patients with AE has not been defined, including the recall period (i.e. the time over which itch is recalled) and whether the assessment should ask about "peak" versus "average" itch. Consensus was reached that an NRS for

153 itch intensity should be included in the HOME Clinical Practice Set for assessing symptoms. The
154 specific instrument is yet to be defined and agreed upon. Of note, at the recent HOME VII meeting,
155 the HOME group voted for a peak NRS with a 24-hour recall period as the preferred instrument to
156 measure itch in clinical trials, as a validation study in AE is now available[26].

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Recommendation

Following a pre-defined 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 were selected as suitable instruments to measure symptoms in the clinical practice setting. The NRS-itch is a provisional instrument for measuring itch intensity, and will be addressed in future meetings as a validation study for an NRS-itch instrument in AE 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 “pick and choose” from in their daily clinical practice. We encourage clinicians and patients to apply at least one 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 the patient symptom burden. They could also be filled in as patients are waiting to be seen in a hospital or community clinic, providing essential information for the assessing health care professional, and engaging the patient/family in the consultation before they enter the room. Both the POEM and the PO-SCORAD are free of charge, they are available in multiple languages and have unrestricted mobile apps (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 be also collected and harmonized to provide for real-life research and quality improvement projects. Implementing PROs for the solo community practitioner may be challenging, however with dedicated resources and electronic medical record systems, large health systems have successfully implemented PROs into routine

primary care with the goals improving the patient experience and enhancing communication regarding their health status.[27,28] Future work includes progressing on the assessing an NRS-itch instrument and addressing additional domains, starting with the patient global assessment prioritized by the group.

Abbreviation and acronym list

AE: Atopic eczema

COS: Core outcome set

HOME: Harmonising Outcome Measures for Eczema

NRS-itch: Numerical rating scale for itch

PED-ISS: Pediatric Itch Severity Scale

PO-SCORAD: Patient-Oriented SCORing Atopic Dermatitis index

POEM: Patient-Oriented Eczema Measure

PROs: Patient-reported outcomes

RWD: Real-world data

200 References

201 1. Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data
202 from the 2003 National Survey of Children's Health. *J Invest Dermatol*. 2011;131(1):67-73.
203 doi:10.1038/jid.2010.251

204 2. Silverberg JI, Hanifin JM. Adult eczema prevalence and associations with asthma and other
205 health and demographic factors: A US population-based study. *J Allergy Clin Immunol*. October
206 2013. doi:10.1016/j.jaci.2013.08.031

207 3. Asher MI, Montefort S, Björkstén B, et al. Worldwide time trends in the prevalence of symptoms
208 of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three
209 repeat multicountry cross-sectional surveys. *The Lancet*. 2006;368(9537):733-743.
210 doi:10.1016/S0140-6736(06)69283-0

211 4. Drucker AM, Wang AR, Li W-Q, Sevetson E, Block JK, Qureshi AA. The Burden of Atopic
212 Dermatitis: Summary of a Report for the National Eczema Association. *J Invest Dermatol*.
213 2017;137(1):26-30. doi:10.1016/j.jid.2016.07.012

214 5. Dalgard FJ, Gieler U, Tomas-Aragones L, et al. The psychological burden of skin diseases: a cross-
215 sectional multicenter study among dermatological out-patients in 13 European countries. *J*
216 *Invest Dermatol*. 2015;135(4):984-991. doi:10.1038/jid.2014.530

217 6. Simpson EL, Bieber T, Eckert L, et al. Patient burden of moderate to severe atopic dermatitis
218 (AD): Insights from a phase 2b clinical trial of dupilumab in adults. *J Am Acad Dermatol*.
219 2016;74(3):491-498. doi:10.1016/j.jaad.2015.10.043

220 7. Basch E, Deal AM, Kris MG, et al. Symptom Monitoring With Patient-Reported Outcomes During
221 Routine Cancer Treatment: A Randomized Controlled Trial. *J Clin Oncol Off J Am Soc Clin Oncol*.
222 2016;34(6):557-565. doi:10.1200/JCO.2015.63.0830

223 8. Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported
224 Outcomes for Symptom Monitoring During Routine Cancer Treatment. *JAMA*. 2017;318(2):197-
225 198. doi:10.1001/jama.2017.7156

226 9. Commissioner O of the. Real-World Evidence. FDA. http://www.fda.gov/science-
227 research/science-and-research-special-topics/real-world-evidence. Published May 16, 2019.
228 Accessed July 27, 2019.

229 10. Cragg L, Williams S, Molen T van der, Thomas M, Sousa JC de, Chavannes NH. Fostering the
230 exchange of real world data across different countries to answer primary care research
231 questions: an UNLOCK study from the IPCRG. *Npj Prim Care Respir Med*. 2018;28(1):8.
232 doi:10.1038/s41533-018-0075-9

233 11. Corrigan-Curay J, Sacks L, Woodcock J. Real-World Evidence and Real-World Data for Evaluating
234 Drug Safety and Effectiveness. *JAMA*. 2018;320(9):867-868. doi:10.1001/jama.2018.10136

235 12. Mahajan R. Real world data: Additional source for making clinical decisions. *Int J Appl Basic Med*
236 *Res*. 2015;5(2):82. doi:10.4103/2229-516X.157148

237 13. Schmitt J, Langan S, Stamm T, Williams HC, Harmonizing Outcome Measurements in Eczema
238 (HOME) Delphi panel. Core outcome domains for controlled trials and clinical recordkeeping in

239 eczema: international multiperspective Delphi consensus process. *J Invest Dermatol*.
240 2011;131(3):623-630. doi:10.1038/jid.2010.303

241 14. Schmitt J, Spuls PI, Thomas KS, et al. The Harmonising Outcome Measures for Eczema (HOME)
242 statement to assess clinical signs of atopic eczema in trials. *J Allergy Clin Immunol*.
243 2014;134(4):800-807. doi:10.1016/j.jaci.2014.07.043

244 15. Spuls PI, Gerbens L a. A, Simpson E, et al. Patient-Oriented Eczema Measure (POEM), a core
245 instrument to measure symptoms in clinical trials: a Harmonising Outcome Measures for
246 Eczema (HOME) statement. *Br J Dermatol*. 2017;176(4):979-984. doi:10.1111/bjd.15179

247 16. Schmitt J, Williams H, HOME Development Group. Harmonising Outcome Measures for Eczema
248 (HOME). Report from the First International Consensus Meeting (HOME 1), 24 July 2010,
249 Munich, Germany. *Br J Dermatol*. 2010;163(6):1166-1168.

250 17. Schmitt J, Apfelbacher C, Spuls PI, et al. The Harmonizing Outcome Measures for Eczema
251 (HOME) Roadmap: A Methodological Framework to Develop Core Sets of Outcome
252 Measurements in Dermatology. *J Invest Dermatol*. 2015;135(1):24-30. doi:10.1038/jid.2014.320

253 18. The Design and Selection of Patient Reported Outcomes Measures for Use in Patient Centered
254 Outcomes Research. https://www.pcori.org/sites/default/files/The-Design-and-Selection-of-
255 Patient-Reported-Outcomes-Measures-for-Use-in-Patient-Centered-Outcomes-Research1.pdf.
256 Accessed July 13, 2019.

257 19. Leshem YA, Chalmers J, Apfelbacher C, et al. HOME in Clinical Practice Initiative Consensus
258 Statement on Symptoms-Supplementary, Mendeley Data, V3, doi: 10.17632/3bthdx6tz2.2.

259 20. Gerbens L a. A, Prinsen C a. C, Chalmers JR, et al. Evaluation of the measurement properties of
260 symptom measurement instruments for atopic eczema: a systematic review. *Allergy*.
261 2017;72(1):146-163. doi:10.1111/all.12959

262 21. Gerbens L a. A, Chalmers JR, Rogers NK, Nankervis H, Spuls PI, Harmonising Outcome Measures
263 for Eczema (HOME) initiative. Reporting of symptoms in randomized controlled trials of atopic
264 eczema treatments: a systematic review. *Br J Dermatol*. 2016;175(4):678-686.
265 doi:10.1111/bjd.14588

266 22. Schmitt J, Spuls P, Boers M, et al. Towards global consensus on outcome measures for atopic
267 eczema research: results of the HOME II meeting. *Allergy*. 2012;67(9):1111-1117.
268 doi:10.1111/j.1398-9995.2012.02874.x

269 23. Charman CR, Venn AJ, Williams HC. The Patient-Oriented Eczema Measure: Development and
270 Initial Validation of a New Tool for Measuring Atopic Eczema Severity From the Patients'
271 Perspective. *Arch Dermatol*. 2004;140(12):1513-1519. doi:10.1001/archderm.140.12.1513

272 24. Schoch D, Sommer R, Augustin M, Ständer S, Blome C. Patient-Reported Outcome Measures
273 in Pruritus: A Systematic Review of Measurement Properties. *J Invest Dermatol*.
274 2017;137(10):2069-2077. doi:10.1016/j.jid.2017.05.020

275 25. Patel KR, Singam V, Vakharia PP, et al. Measurement properties of three assessments of burden
276 used in atopic dermatitis in adults. *Br J Dermatol*. September 2018. doi:10.1111/bjd.17243

26. Yosipovitch G, Reaney M, Mastey V, et al. Peak Pruritus Numerical Rating Scale: psychometric validation and responder definition for assessing itch in moderate-to-severe atopic dermatitis. *Br J Dermatol*. February 2019. doi:10.1111/bjd.17744

27. Biber J, Ose D, Reese J, et al. Patient reported outcomes - experiences with implementation in a University Health Care setting. *J Patient-Rep Outcomes*. 2017;2:34. doi:10.1186/s41687-018-0059-0

28. Wu AW, Kharrazi H, Boulware LE, Snyder CF. Measure once, cut twice--adding patient-reported outcome measures to the electronic health record for comparative effectiveness research. *J Clin Epidemiol*. 2013;66(8 Suppl):S12-20. doi:10.1016/j.jclinepi.2013.04.005

Figure 1: The HOME roadmap for developing a set of outcome measurement instruments for clinical practice

Figure 2: Results of the HOME Clinical Practice Set prioritization exercise – Percent of responders who included the domain as a priority domain (of 5 domains selected by each responder)

Supplementary 1

a. HOME online survey for developing a prioritized set of outcome domains

During April-May 2017, an online survey was distributed to HOME members (membership is free and open to all) to characterize and prioritize the outcome domains for the HOME Clinical Practice Set. A list of relevant domains was adapted from the original HOME Delphi exercise[13] and additional domains were elicited from HOME members in response to a membership-wide email. In the survey, members were asked to rank their top 5 of 21 domains to prioritize for developing the Clinical Practice Set. Overall there were 47 responders (30 clinicians, 9 patient representatives, 4 methodologists, 3 pharmaceutical industry representatives, and one health economist). The results of this survey are depicted in Fig. 2. in the consensus paper.

b. Systematic review of the measurement properties of instruments for measuring symptoms of AE update

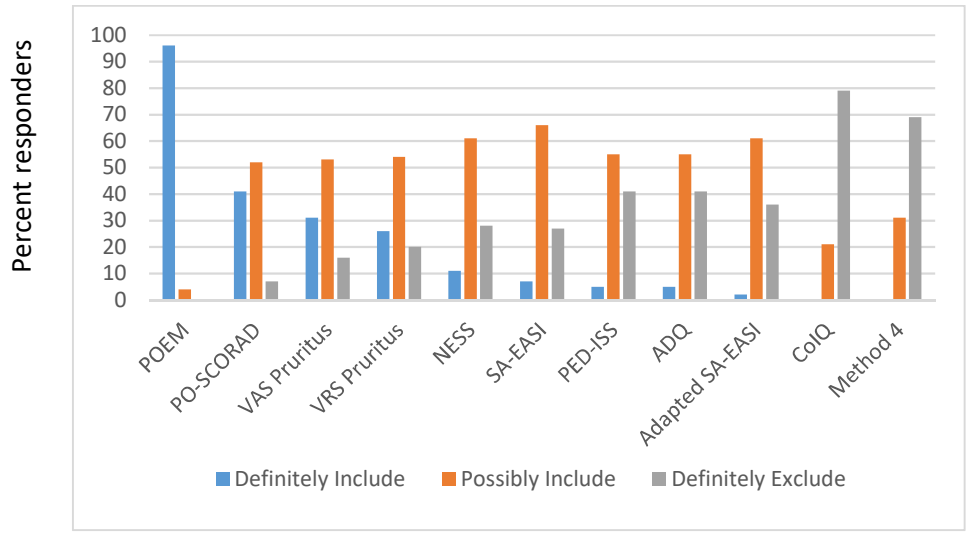
A systematic review has previously been published by the HOME symptoms group for the clinical trials COS (August 2015), evaluating 18 identified instruments.[19] This review was updated for the HOME Clinical Practice Set in February 2018 (paper to be submitted). The updated review included six further validation studies (for POEM, Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) and the pediatric Itch Severity Scale (PED-ISS)). While the PED-ISS improved its rating on several aspects of methodological quality and the POEM displayed poorer performance in some features, there was no change in the overall degree of recommendation for each of the 18 instruments from the original review.[19]

c. Pre-meeting online prioritisation exercise

For all category B and D instruments, HOME VI meeting registrants were provided with a copy of the instrument and a summary of its properties. Each registrant was asked to classify each instrument as i) definitely include, ii) possibly include or iii) definitely exclude from the Clinical Practice Set. A total

of 46 out of 73 registered for the meeting (63%) completed the task. The results of the vote are depicted in Supplementary table 1.

Supplementary table 1: Results of the pre-meeting task



* The subjective SCORAD, which was inadvertently not included in the pre-meeting voting, was added to the discussion in the meeting.

Figure 1: The HOME roadmap for developing a set of outcome measurement instruments for clinical practice

Step 1: Define scope and applicability

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Step 2: Develop a prioritized set of outcome domains
*** Unlimited number of domains**

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Step 3: Develop a set of outcome measurement instruments
*** Multiple instruments allowed**
Identification and recommendation of adequate outcome measurement instrument(s) for each outcome domain by a 5 stage process

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Task	Identify all instruments previously used to measure domain	Establish the extent and quality of testing of the identified instruments	Determine which instruments are good enough quality to be shortlisted for further consideration	Carry out complementary validation studies on shortlisted scales	Finalize outcomes instrument list for the domain
Methodology	Systematic review of instruments used	Systematic review of validation studies of the used instruments highlighting gaps in validation	Apply OMERACT filter: *Truth*: "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?" *Discrimination*: "Does the measure discriminate between situations that are of interest?" *Feasibility*: "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?" Consensus discussion and voting on shortlisted instruments.	Appropriate methods used to fill in gaps in validation highlighted in step 2	Re-apply the OMERACT filter with the results of the additional validation studies. Consensus discussion and voting on recommend instruments.
Output	Long list of all instruments previously used to measure the domain	Summary of the quality and extent of testing of instruments	Short-list of potential instruments that meet the requirements of the OMERACT filter	Short-list of maximally tested and validated instruments	A "pick and choose" list of recommended outcome measurement instruments for the domain

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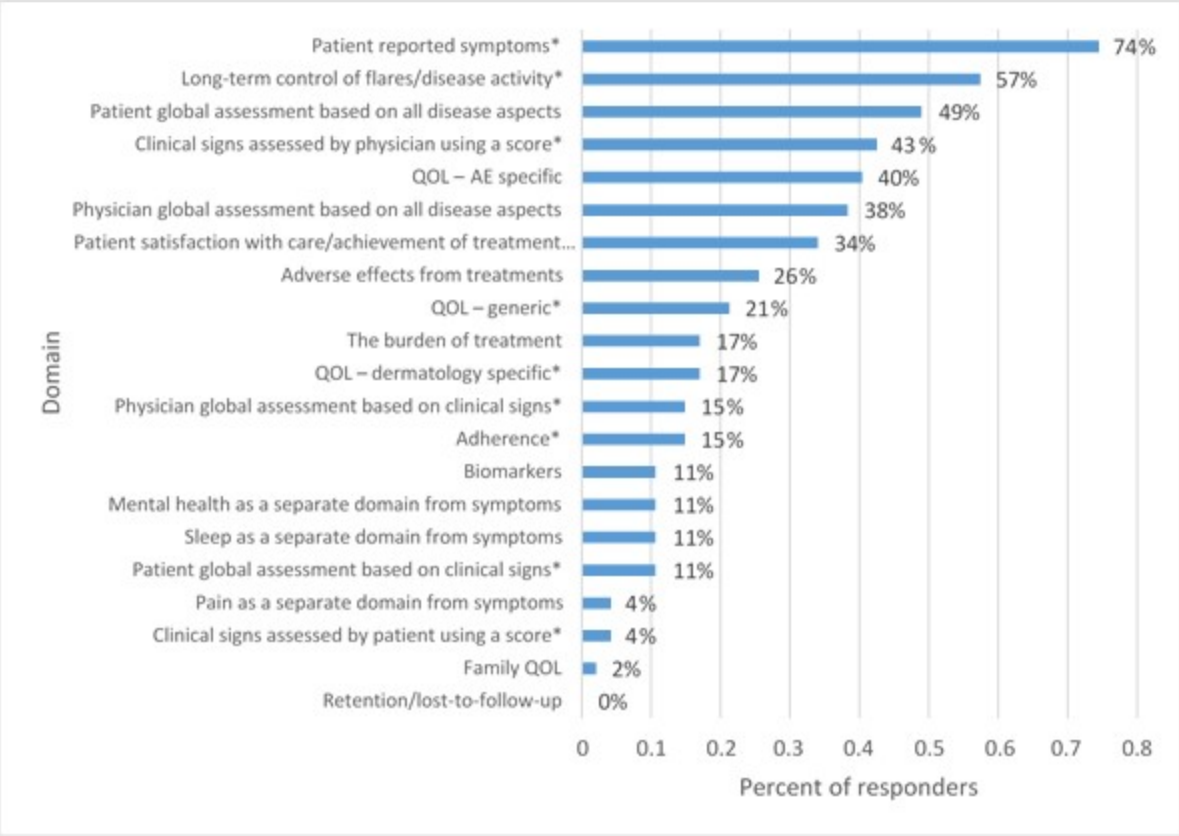
Step 4: Disseminate, prepare guidance material, review and possibly revise sets

Figure 2: Results of the HOME Clinical Practice Set prioritization exercise – Percent of responders who included the domain as a priority domain (of 5 domains selected by each responder)



* Domains adapted from the original HOME Delphi process.[13] The remaining domains were elicited from HOME members.

AE: Atopic eczema; QOL: Quality of life