

1 **Measuring atopic eczema symptoms in clinical practice: The First Consensus**
2 **Statement from the Harmonising Outcome Measures for Eczema in Clinical**
3 **Practice Initiative**

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41 **Abstract**

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

46 **Objectives:** Prioritize outcome domains to measure AE in clinical practice and select valid and
47 practical outcome measurement instruments for the highest-priority domain.

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

51 **Results:** Patient-reported symptoms was the top-prioritized domain. Based on psychometric
52 properties and feasibility, there was consensus that the recommended instruments to measure AE
53 symptoms in clinical practice are the Patient-Oriented Eczema Measure (POEM) and/or the Patient-
54 Oriented SCORing Atopic Dermatitis index (PO-SCORAD). The Numerical Rating Scale for itch
55 received support pending definition and validation in AE.

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

59 Introduction.

60 Atopic eczema (AE) (syn. atopic dermatitis) is a common chronic inflammatory skin disease¹⁻³ which
61 causes a significant burden on the life of patients.⁴⁻⁶ In daily practice, most clinicians assess their
62 patients using a detailed history and physical examination. While invaluable for the practicing
63 clinician, such assessments do not quantitatively capture multiple domains of the disease over time.
64 Adding outcome measurement using well-validated instruments to patient management can be
65 useful at the individual level for monitoring treatment response or assessing the disease burden.
66 Some outcomes, such as patient-reported outcomes (PROs), can be collected outside of scheduled
67 office visits thus enhancing the understanding of the patient's disease in between office visits. A
68 study in patients with cancer found that simply monitoring symptoms using PRO instruments
69 imparted clinical benefit to patients,⁷ even improving survival.⁸

70 Outcome measurements collected in the clinical practice are also an important part of real-world
71 data (RWD), collectively defined as the data relating to patient health status and/or the delivery of
72 health care routinely collected from a variety of sources.⁹ RWD has been gaining traction as a key
73 resource for improving patient care, by translating it into actionable information that benefits
74 healthcare and patient outcomes,¹⁰ for example assisting in developing guidelines and decision
75 support tools for use in clinical practice.

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

84 There are currently no recommendations to guide the selection of instruments for measuring PROs
85 in AE in clinical practice. To attain high-quality outcome measurement data, standardized and
86 validated outcomes measurements are needed. This is critical for research initiatives, especially
87 when aggregating data across centers, performing meta-analyses, or analysing trends at a
88 population level. The Harmonising Outcome Measures for Eczema (HOME) group is a global initiative
89 working towards standardization and validation of outcome measurement in AE. Since 2012, the
90 HOME group has focused primarily on clinical trials.¹³⁻¹⁶ Because the needs and available resources
91 in daily practice are different than in clinical trials, an adaptation of the current HOME clinical trial
92 initiative is needed to fill such a gap. The HOME Clinical Practice Set aims to identify instruments to
93 measure domains of health in patients with AE suitable for use in the clinical practice setting.

94 The HOME Executive Committee agreed that the HOME Clinical Practice Set should follow a similar
95 process as the original HOME Roadmap- a step-by-step process of identifying selected outcome
96 domains followed by systematically identifying the appropriate measurement instruments for these
97 domains.¹⁷ The Executive Committee also agreed that the Clinical Practice Set will not be a
98 mandatory core outcome set (COS) containing a predefined number of outcome domains and their
99 measurement instruments that need to be measured in all patients, as is the case with the clinical
100 trial COS. Instead, there is no limit to the number of domains identified to be important to measure
101 in the HOME Clinical Practice Set. While COS allow for complete and harmonized data sets, their
102 adoption in clinical practice is challenging due to time and budgetary constraints. Patient burden,
103 defined by PCORI as the time, effort, and emotional strain associated with completing a PROM,¹⁸ is
104 another limitation, and effort should be made to minimize this burden.

105 To further enhance flexibility, it was decided the HOME Clinical Practice Set will include all
106 instruments (not just one as in the core set for trials) that are considered feasible for use in clinical
107 practice and have sufficient validation. This allows a set or list of valid instruments from which
108 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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114 **Methods and Results**

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

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

118 **Step 2: Develop a prioritized set of outcome domains.** Utilizing an online survey of HOME members
119 (Supplementary 1a)¹⁹, we outlined and prioritized the outcome domains to guide the work ahead
120 (Fig. 2). Consistent with a previous HOME Delphi study,¹³ patient-reported symptoms was the
121 highest prioritized domain to measure in patients with AE.

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

124 Based on previous systematic reviews to identify instruments for measuring symptoms of AE and
125 their measurement properties^{20,21} and applying an updated version of the latter (Supplementary
126 1b¹⁹), 18 identified instruments were included. Based on best evidence synthesis, a recommendation
127 for usage was provided for each instrument²⁰ (Table 1).

Table 1: Rating of symptoms instruments based on assessment of measurement properties²⁰

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.

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

129 At the HOME VI meeting (Utrecht, the Netherlands, April 11th 2018), an international panel of 72
130 participants (11 patients/parents of children with AE, 40 clinicians, 9 methodologists, and 12
131 pharmaceutical industry representatives) focused on selecting recommended instruments.

132 Consensus was reached if less than 30% of the voters disagreed.²² Those with a conflict of interest
133 for a specific instrument were asked to refrain from voting.

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

136 In the meeting, participants were presented with the remaining available instruments (ordered
137 based on a pre-meeting prioritisation exercise, Supplementary 1c¹⁹) with their quality and feasibility
138 attributes, followed by small-group (“whisper-technique”) and whole-panel discussions. Issues
139 pertinent to the clinical practice settings were highlighted: selecting instruments that could be
140 applied both by dermatologists and primary care providers; the importance of feasibility in the
141 constrained setting of the day-to-day practice (including cost, accessibility, availability in multiple
142 languages, and time to completion); and limiting the burden on patients.

143 Consensus was reached on including the POEM and PO-SCORAD as instruments for assessing
144 symptoms in the clinical practice setting (Supplementary 2¹⁹). There was general agreement that
145 while new-time users can take longer to complete the PO-SCORAD (up to 15 minutes), this improves
146 with experience. The POEM takes 1 to 2 minutes to complete.²³

147 There was also general agreement on the need for a simple measure of itch intensity. The numerical
148 rating scale for itch (NRS-itch) was discussed as an acceptable and feasible instrument.²⁴ However,
149 peer-reviewed validation studies for the NRS-itch in AE had not been published at the time of the
150 meeting.²⁵ Another limitation is that the optimal NRS-itch instrument for patients with AE has not
151 been defined, including the recall period (i.e. the time over which itch is recalled) and whether the
152 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 available²⁶.

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160 **Recommendation**

161 Following a pre-defined methodology delineated by the HOME Clinical Practice Set roadmap,
162 building on systematic reviews and culminating in a consensus process driven by an international
163 panel of multiple stakeholders including a significant contribution from patients, the POEM and the
164 PO-SCORAD were selected as suitable instruments to measure symptoms in the clinical practice
165 setting. The NRS-itch is a provisional instrument for measuring itch intensity, and will be addressed
166 in future meetings as a validation study for an NRS-itch instrument in AE has become recently
167 available.

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

180 Validated data on the symptom burden of patients can improve patient care from the individual
181 patient level to a clinic, hospital or national level. Data can be also collected and harmonized to
182 provide for real-life research and quality improvement projects. Implementing PROs for the solo
183 community practitioner may be challenging, however with dedicated resources and electronic
184 medical record systems, large health systems have successfully implemented PROs into routine

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

189

190 **Abbreviation and acronym list**

191 AE: Atopic eczema

192 COS: Core outcome set

193 HOME: Harmonising Outcome Measures for Eczema

194 NRS-itch: Numerical rating scale for itch

195 PED-ISS: Pediatric Itch Severity Scale

196 PO-SCORAD: Patient-Oriented SCORing Atopic Dermatitis index

197 POEM: Patient-Oriented Eczema Measure

198 PROs: Patient-reported outcomes

199 RWD: Real-world data

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

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

293

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 exercise¹³ 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

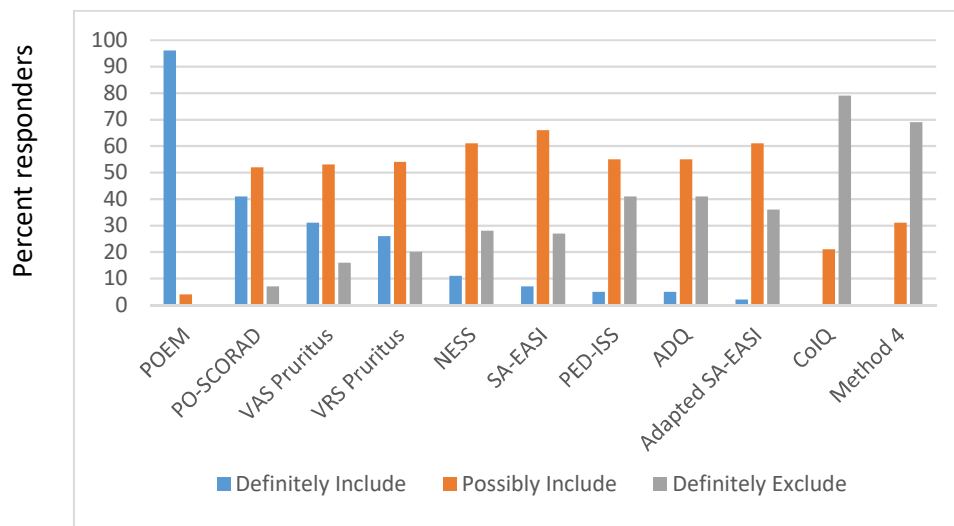
A systematic review has previously been published by the HOME symptoms group for the clinical trials COS (August 2015), evaluating 18 identified instruments.¹⁹ This review was updated for the HOME Clinical Practice Set in February 2018 (paper to be submitted). The updated review included six further 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

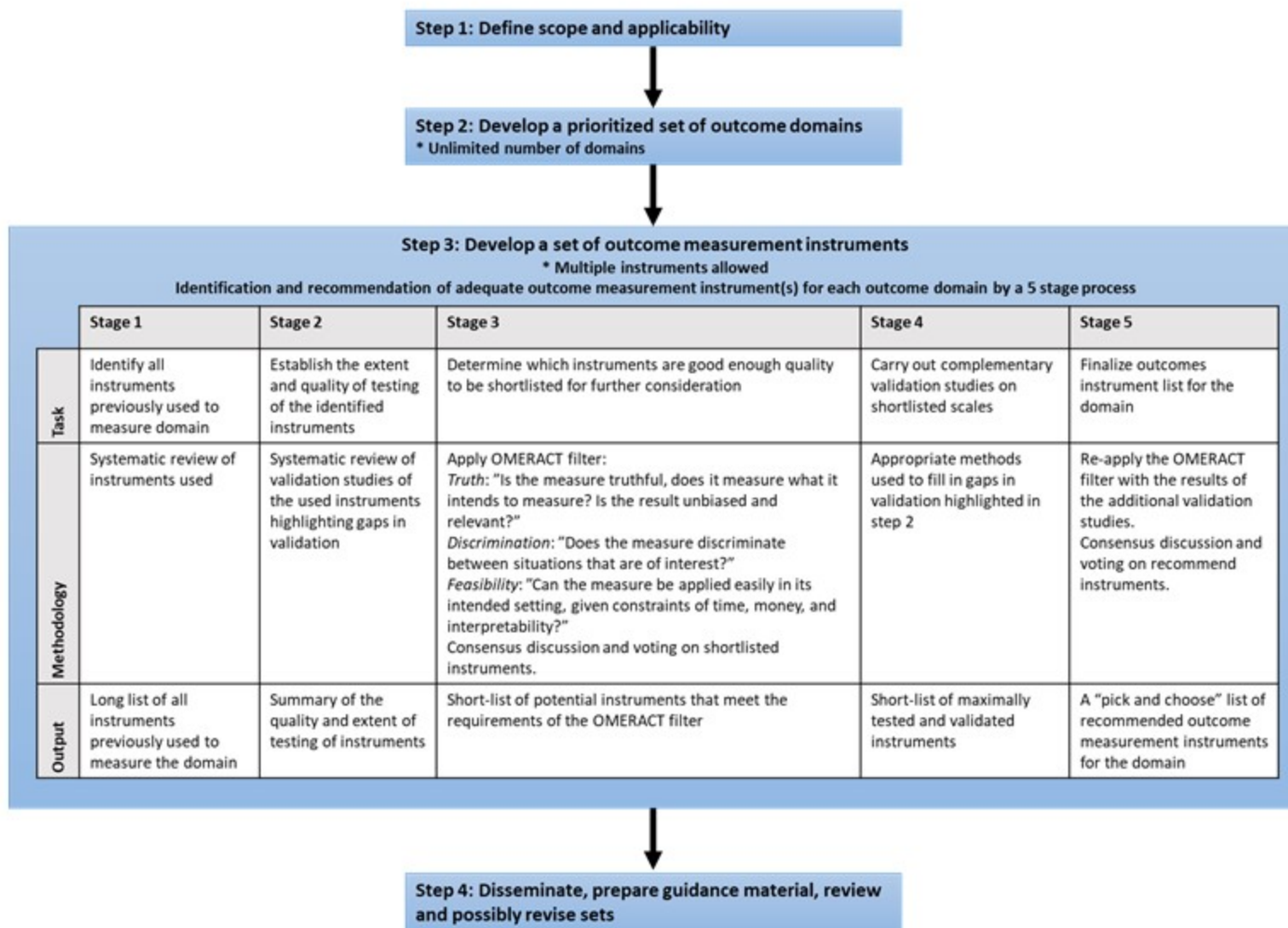
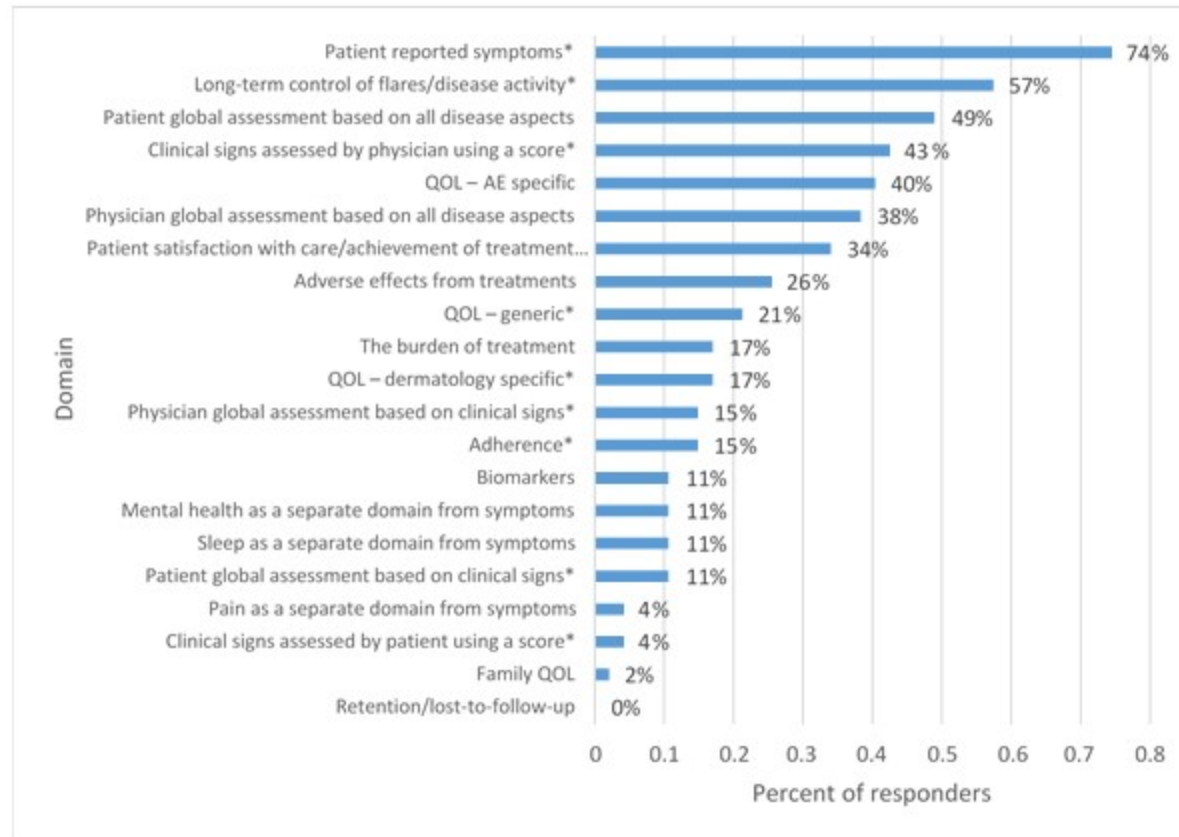


Figure 2: Results of the HOME Clinical Practice Set prioritization exercise – Percent of responders who included the domain as a priority domain (of 5 domains selected by each responder)



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

AE: Atopic eczema; QOL: Quality of life