Reporting of Harmonising Outcome Measures for Eczema (HOME) Core Outcome Set Instruments in randomized clinical trials for systemic treatments in Atopic Dermatitis

Dear Editor,

The Harmonising Outcome Measures for Eczema (HOME) initiative established a core outcome set (COS) to standardize outcomes in clinical trials for atopic dermatitis.[1] In 2018, the HOME initiative published guidance for reporting results for continuous efficacy measures, specifying that at minimum, baseline and follow-up mean and standard deviation should be reported,[2] in keeping with CONSORT recommendations for continuous outcome reporting in all trials.[3] Standardized reporting of outcomes is essential for all relevant trial data to be included in meta-analyses of trial evidence, which are used to inform clinical practice guidelines. Our objective was to measure the proportion of randomized clinical trials (RCTs) of systemic immunomodulatory treatments for atopic dermatitis that adhere to HOME reporting guidelines, and to describe potential research waste associated with inadequate reporting.

We included RCTs with publicly available results in 2018 or after in our living systematic review and network meta-analysis (NMA) of RCTs of systemic treatments for atopic dermatitis.[4] For each included RCT, we evaluated data reported in trial registries, published conference abstracts, and peer-reviewed publications.

The HOME COS consists of four domains: i) clinical signs, ii) patient-reported symptoms, iii) quality of life, and iv) long-term control. Agreed upon outcome instruments for the four domains are, respectively: i) Eczema Area and Severity Index (EASI), ii) Patient-Oriented Eczema Measure (POEM) and 24-hour Peak Pruritus Numerical Rating Scale (PP-NRS), iii) Dermatology Life Quality Index (DLQI) suite of instruments, and iv) Recap of Atopic Eczema (RECAP) or Atopic Dermatitis Control Tool (ADCT).[1] We assessed

reporting for four HOME instruments (EASI, POEM, DLQI instruments, and PP-NRS). The recommended instruments for the fourth domain of long-term control (RECAP/ADCT) were published in 2019[5,6] , are not widely reported among currently published trials and were therefore not evaluated here.

We evaluated whether each of the four HOME instruments was: i) reported in any form including dichotomous reporting (‘any reporting’); ii) reported with enough detail to be included in quantitative synthesis ('adequate reporting’), which included adhering to HOME reporting recommendations but could also include alternatives such as change from baseline with a measure of variance including standard error or confidence intervals, or baseline mean plus percent change from baseline with a measure of variance (complete details on statistical analyses previously published);[4,7,8] or iii) reported according to HOME standards (‘proper reporting’), which involved reporting mean and standard deviation at baseline and the primary follow-up timepoint.[2]

We included 52 RCTs, 40 of which had a primary peer-reviewed publication. All were industry-sponsored. 24 (40%) RCTs included ‘any reporting’ for all four HOME instruments (EASI, POEM, DLQI suite, or PP-NRS), 18 (35%) trials had ‘adequate reporting’ for inclusion in NMA for all four instruments, and only 1 (1.9%) trial had ‘proper reporting’ for all four HOME instruments.

EASI was reported in some form (‘any reporting’) in 49 (94%), POEM in 31 (60%), DLQI in 33 (63%) and PP-NRS in 32 (62%) trials (table 1).

Of the 49 RCTs that reported some EASI outcomes, 9 (18%) trials, including data for 3,278 participants, could not be included in NMA due to inadequate reporting. All RCTs that reported POEM, DLQI suite, and PP-NRS outcomes in some form, had ‘adequate reporting’ to be included in their respective NMAs. However, 9 (17%) RCTs did not include ‘any reporting’ of POEM, DLQI suite, or PP-NRS outcomes, involving the data of 1290

participants. In RCTs with primary peer-reviewed publications, there was an overall increase in the proportion of adequate reporting for POEM, DLQI suite, and PP-NRS outcomes over time from RCTs reported between 2018 and 2022. However, the proportion of ‘adequate reporting’ for EASI outcomes decreased from 86% in 2018 to 55% in 2022.

‘Proper reporting' per HOME reporting guidance was low for each of EASI (8%), POEM (6%), DLQI (3%), and PP-NRS (3%) (table 1).

Limitations of this study include insufficient statistical power to examine factors associated with reporting quality, including funding source. Trials published early in our inclusion window may have been designed and their reports drafted prior to the publication of HOME reporting recommendations; we did not see an improvement in reporting in later years.

In summary, we found that few RCTs of systemic treatments for atopic dermatitis adhered to HOME and CONSORT minimum reporting guidelines. Almost all trials reported EASI scores in some fashion but 18% of trials reporting EASI outcomes could not be included in NMA, wasting data from over 3,000 RCT participants. Over 17% of trials did not report POEM, DLQI suite, or PP-NRS scores at all.

Uptake of the HOME initiative has been encouraging, but implementation gaps still exist. RCT sponsors, investigators as well as journal editors and reviewers should promote its use and standardized reporting to enable robust evidence synthesis and to reduce research waste.

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Conflicts of interest: PS received departmental independent research grants from pharmaceutical industries since December 2019 for the TREAT NL registry, is involved in performing clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of e.g. psoriasis and atopic dermatitis, for which financial compensation is paid to the department/hospital and, is Chief Investigator (CI) of the Dutch photo- and systemic therapy atopic eczema registry (TREAT NL) for adults and children and member of the executive committee of the HOME initiative.
YAL is a member of the executive committee of the HOME initiative. She has also received honoraria or fees from AbbVie, Sanofi, Genentech, Regeneron, Pfizer, and Dexcel Pharma, an independent research grant from Abbvie, and has, without personal compensation, provided investigator services for Eli Lilly, Pfizer, and AbbVie, all unrelated to this study.
LG is one of the chief investigators of the Dutch photo- and systemic therapy atopic eczema registry (TREAT NL) for adults and children and member of the executive committee of the HOME initiative.
KST is a member of the executive committee of the HOME initiative, was involved in development and testing of one of the HOME core outcome instruments (Recap of atopic eczema (RECAP)), and works at the research centre where the Patient Oriented Eczema Measure (POEM) was developed. The University of Nottingham owns copyright to license Patient Oriented Eczema Measure – chargeable for commercial users.

Abbreviated abstract

The HOME initiative has successfully completed a core outcome set for atopic dermatitis trials, and most trials now include the core set instruments. However, to enable evidence synthesis of all relevant trials, reporting must be standardized as well. In this study, we evaluate reporting of the core outcome set instruments in atopic dermatitis systemic treatment trials included in a living systematic review and network meta-analysis. We found that even though the core instruments were measured in most trials, they were often not reported sufficiently to enable inclusion in network meta-analysis.

Figure legends

Table 1. Reporting of HOME recommended instruments for total trial data and for primary peer-reviewed publications only

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	EASI	**POEM**	**DLQI**	**PPNRS**
All trial data				
Proportion of trials that reported the instrument in any form, N/total trials (%)	49/52 (94.2%)	31/52 (59.6%)	33/52 (63.5%)	32/52 (61.5%)
Proportion of trials with adequate reporting to be included in NMA among those that reported the instrument in any form, n/N (%)	36/49 (73.5%)	29/31 (93.5%)	32/33 (97.0%)	31/32 (96.9%)
Proportion of trials with proper reporting according to HOME guidance among those that reported the instrument in any form, n/N (%)	4/49 (8.2%)	2/31 (6.5%)	1/33 (3.0%)	1/32 (3.1%)
Primary peer-reviewed publication				
Proportion of publications that reported the instrument in any form, N/total peer-reviewed publications (%)	39/40 (97.5%)	23/40 (57.5%)	23/40 (57.5%)	28/40 (70.0%)
Proportion of publications with adequate reporting to be included in NMA among those that reported the instrument in any form, n/N (%)	31/39 (79.5%)	20/23 (87.0%)	19/23 (82.6%)	25/28 (89.3%)
Proportion of publications with proper reporting according to HOME guidance among those that reported the instrument in any form, n/N (%)	2/39 (5.1%)	1/23 (4.3%)	1/23 (4.3%)	1/28 (3.6%)

DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; HOME: Harmonizing Outcome Measures for Eczema; NMA: Network Meta-Analysis; POEM: Patient-Oriented Eczema Measure; PP-NRS: Peak Pruritus Numeric Rating Scale