

Standardized reporting of the Eczema Area and Severity Index (EASI) and the Patient-Oriented Eczema Measure (POEM): a recommendation by the Harmonising Outcome Measures for Eczema (HOME) Initiative

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DEAR EDITOR, Several organizations from multiple fields of medicine are setting standards for clinical research including protocol development,¹ harmonization of outcome reporting,² statistical analysis,³ quality assessment⁴ and reporting of findings.¹ Clinical research standardization facilitates the interpretation and synthesis of data, increases the usability of trial results for guideline groups and shared decision making, and reduces selective outcome reporting bias.

The mission of the Harmonising Outcome Measures for Eczema (HOME) initiative is to establish an agreed-upon core set of outcomes to be measured and reported in all clinical trials of atopic dermatitis (AD). Following a systematic approach involving reviews of best evidence and consensus voting,⁵ our group identified two well-validated instruments to measure the core domains of signs and symptoms of AD.^{6,7} The Eczema Area and Severity Index (EASI) measures physician-reported signs,⁶ and the Patient-Oriented Eczema Measure (POEM) measures patient-reported symptoms.⁷

The objective of this letter is to provide recommendations for the minimum reporting of EASI and POEM scores in AD clinical trials with the goal of minimizing bias, improving the quality of data synthesis, and facilitating study interpretation by patients, clinicians and other stakeholders.

While EASI and POEM are now included as core instruments in most large phase II and III clinical trials in AD, reporting of these end points is far from standardized. Investigators currently report an array of analyses for these end points, such as the mean change from baseline, the mean of the percentage change from baseline, and dichotomized results using various definitions of success vs. no success (examples available from the authors). While general trial reporting recommendations exist, the lack of EASI- and POEM-specific guidelines hinders communication and effective data aggregation for AD trials.

There are several generalized reporting recommendations for clinical trials. The widely accepted Consolidated Standards of Reporting Trials (CONSORT) 2010 statement recommends that trials report a summary of outcomes for each study group, such as the mean and SD at each time point, as well as comparison between groups. For trials utilizing continuous

variables, CONSORT recommends reporting the mean difference and 95% confidence interval when comparing groups. Additionally, CONSORT urges investigators to disclose all methods used to analyse data to increase transparency and minimize reporting bias.¹ With the advent of online publication, investigators are no longer constrained by space and are encouraged to include all data and explanations in their reports. Thus, trial reporting is trending towards full disclosure of data on an individual participant level.⁸

Recommendations of what to avoid in trials with continuous variables also exist. Dichotomization of continuous outcomes and comparing percentage change between groups may have limited use given the loss of power and difficulty pooling disparate results.^{9–11} These two methods appear frequently in reporting of EASI scores, likely because they can be easily understood by patients or clinicians, and because of historical trends in reporting.

Based on the above literature, we recommend the following EASI- and POEM-specific reporting recommendations (Table 1). As a minimum, all investigators using these instruments should include a baseline mean and SD and an end-of-treatment mean and SD for individual randomized groups (or median and quartile range for skewed data),¹ along with the associated number of participants analysed. For maximal data transparency, these data would also be reported for each time point. For guidance on reporting differences between groups we recommend referencing CONSORT.¹

Although guidelines recommend against dichotomizing continuous outcome variables into binary results, this has become common in AD literature (e.g. $\geq 75\%$ improvement in EASI) and represents a primary end point for regulatory approval in the European Union. The percentage reduction or proportion of patients achieving a minimal important change may be clinically useful as well.¹² Including additional ways of reporting EASI and POEM scores such as these is acceptable provided the minimum reporting described in Table 1 is also met.

Table 1 Recommended minimum reporting standards for core outcome measurement instruments (Eczema Area and Severity Index and Patient-Oriented Eczema Measure) in atopic dermatitis trials

Baseline mean and SD for individual randomized groups (or median and quartile range for skewed data)
End-of-treatment mean and SD for individual randomized groups (or median and quartile range for skewed data)

Implementation of EASI and POEM is becoming standard in AD trials, thus improving the ability to pool and compare results in meta-analyses. These reporting recommendations will further facilitate standardization in outcome reporting, more accurate data synthesis and more valid data interpretation in all AD trials moving forward.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Table S1 Sample of Reporting of Eczema Area and Severity Index (EASI) and Patient-Oriented Eczema Measure (POEM) in randomized controlled trials (RCTs) for the Investigation of Systemic Therapies for Atopic Dermatitis.

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Supplementary Table 1. Sample of Reporting of Eczema Area and Severity Index (EASI) and Patient-Oriented Eczema Measure (POEM) in randomized controlled trials (RCTs) for the Investigation of Systemic Therapies for Atopic Dermatitis.

Reference	EASI	POEM
Beck et al., 2014	Proportion of patients achieving EASI-50 or EASI-75 <u>Mean</u> score at baseline <u>Mean percent change</u> from baseline with SE	
Kim et al., 2016	<u>Mean</u> score at baseline <u>Mean</u> score at end of treatment	
Schram et al., 2011	<u>Mean</u> score at baseline with SD <u>Mean</u> reduction of score with SD	<u>Mean</u> score at baseline with SD <u>Mean</u> reduction of score with SD
Simpson et al., 2016	Proportion of patients achieving EASI-50, EASI-57 or EASI-90 <u>Mean</u> score at baseline Quartile ranges at baseline <u>Mean percent change</u> with SE	<u>Mean</u> score at baseline with SD Quartile ranges at baseline <u>Mean percent change</u> with SE
Thaci et al., 2016	<u>Mean</u> score at baseline with SD <u>Mean</u> score at follow up with SD <u>Mean percent change</u> with SE	
Wolff et al., 2005	<u>Mean</u> score at baseline with SD <u>Mean</u> reduction from baseline with SD	