Title: 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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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 assessment[4] 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 the EASI and POEM are now included as core instruments in most large phase 2 and 3 clinical trials in AD, reporting of these endpoints is far from standardized. Investigators currently report an array of analyses for these endpoints, such as the mean change from baseline, the mean of the percentage change from baseline, and dichotomized results using various definitions of success versus no success (Supplementary Table 1). 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 CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement recommends that trials report a summary of outcomes for each study group, such as the mean and standard deviation at each time-point, as well as comparison between groups. For trials utilizing continuous variables, CONSORT recommends mean difference and 95% confidence interval (CI) when comparing groups. Additionally, CONSORT urges investigators to disclose all methods used to analyze 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 toward 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 percent change between groups may have limited use given the loss of power and difficulty pooling disparate results.[9, 10, 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 standard deviation (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 analyzed. 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. EASI-75) and represents a primary endpoint for regulatory approval in the European Union. Percent reduction or proportion of patients achieving a minimal important change (MIC) 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.

Implementation of the 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.

Table 1. Recommended minimum reporting standards for core outcome measurement instruments (EASI and POEM) 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)

SD=Standard Deviation

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