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Clearing up misunderstandings around core outcomes for atopic dermatitis

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We thank Professor Taieb for his comments on the report of the Third International Consensus Meeting to Harmonise Core Outcome Measures for Atopic Eczema/Dermatitis Clinical Trials (HOME III) in the December 2014 issue of the *BJD* (1). He promulgates a number of misconceptions about our work which we wish to respond to. First, he suggests that the Outcome Measures in Rheumatology (OMERACT) filter “truth, discrimination and feasibility” might not be applicable to outcome measurement instruments for atopic dermatitis (AD) (2). We maintain that ascertaining whether an instrument measures what it is supposed to measure (validity), whether it can distinguish between disease states of interest (reliability and sensitivity to change), and whether it can be used and interpreted easily, is every bit as applicable to AD as rheumatology or other diseases(3). He then questions whether signs and symptoms should be considered separately when evaluating AD outcomes. As agreed at previous HOME meetings (4) clinical signs should be considered as a separate domain as there are many instances where interventions cannot be blinded

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from participants, and having an objective blinded outcome meets the fundamental need to minimise information bias in such studies (5). Additionally, composite scales that combine domains such as signs and symptoms are frequently reported as a single score, making it impossible to evaluate the treatment effect on individual domains.

Despite the initial focus on the clinical signs domain in HOME, we agree with Taieb that patient-reported symptoms are of critical importance in AD. Working groups are currently undertaking systematic reviews to determine the best instruments to measure the *symptoms* domain which will be discussed at future HOME meetings. Professor Taieb then suggests that the design and rationale of SCORAD are frequently misunderstood or misquoted, especially in the HOME papers, but does not explain how or where we have misquoted its rationale. We fully understand how the various components of SCORAD were derived, and that a signs-only version (objective SCORAD) was developed which is exactly what we tested as the main alternative to EASI. We fully appreciate the hard work and innovative methods that went into the development of SCORAD which is reflected in the fact that objective SCORAD made it to the short-list of instruments for measuring clinical signs (6). However, EASI performed better in terms of content validity and intra-observer reliability despite its perceived less sophisticated development (7). A very clear consensus in favour of EASI was achieved at the HOME III meeting, including support from one of the original SCORAD developers, Prof. J-F Stalder (1).

Contrary to what Professor Taieb suggests, the HOME initiative did not take a long time to reach a decision in favour of the EASI scoring system. A four month systematic review of the evidence was followed by detailed group discussions and an unambiguous vote at HOME III. He asserts that the vote was achieved by a large “minority” of non-experts and excluded many experts but does not make it clear whom he considers experts. The development of a core outcome set should include a broad range of stakeholders and this consensus was achieved by dermatologists, patients and carers, industry experts and methodologists (8). The invitation to the HOME III meetings has always been open and exclusion of anyone is against the fundamental principles HOME (9).

Web-based voting systems may be convenient and were used by the HOME Group for initial phases, but as the COMET IV conference on core outcome measures identified, web-based voting may be less useful for critical decisions as they are susceptible to lack of qualified explanation to patient stakeholders. We agree with Prof Taieb that face to face discussion is the best way forward which is why anyone interested in core outcomes on AD is invited to attend our open HOME meetings, the next of which will be held in Malmo on 23rd-24th April 2015
<http://www.nottingham.ac.uk/conference/fac-mhs/medicine/home-iv-meeting-2015/index.aspx>.

As Dr Flohr rightly points out in his response to our meeting (10), it is not necessary to insist that *core* outcomes are *primary* outcome measures for future clinical trials, but simply that they are included so that sensible comparisons can be made across studies. Therefore there is still plenty of room for SCORAD and other AD outcomes to be used in AD trials providing that core outcomes are also included.

Medicine is moving out of an era of research that yields conclusions of unknown validity. Groups like OMERACT (www.omeract.org), COMET (www.comet-initiative.org) and COSMIN (Consensus-based Standards for the selection of health Measurement Instruments - www.cosmin.nl) have developed methods which will improve the quality of clinical research, reduce selective outcome reporting bias, increasing the validity of the conclusions, allowing better data synthesis, that will ultimately improve clinical decision-making. The HOME initiative is playing its small part in the field of AD research and all interested are welcome to join.

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