

POSITION PAPER

Towards global consensus on outcome measures for atopic eczema research: results of the HOME II meeting

Jochen Schmitt^{1,2}, Phyllis Spuls³, Maarten Boers⁴, Kim Thomas⁵, Joanne Chalmers⁵, Evelien Rookevisch³, Mandy Schram³, Richard Allsopp⁶, Valeria Aoki⁷, Christian Apfelbacher^{8,9}, Carla Bruijnzeel-Koomen¹⁰, Marjolein Bruin-Weller¹¹, Carolyn Charman¹², Arnon Cohen¹³, Magdalene Dohil¹⁴, Carsten Flohr^{15,16}, Masataka Furue¹⁷, Uwe Gieler¹⁸, Lotty Hooft¹⁹, Rosemary Humphreys²⁰, Henrique Akira Ishii²¹, Ichiro Katayama²², Willem Kouwenhoven²³, Sinéad Langan^{15,24}, Sue Lewis-Jones²⁵, Stephanie Merhand²⁶, Hiroyuki Murota²², Dedee F. Murrell^{27,28}, Helen Nankervis⁵, Yukihiro Ohya²⁹, Arnold Oranje³⁰, Hiromi Otsuka³¹, Carle Paul³², Yael Rosenbluth³³, Hidehisa Saeki³⁴, Marie-Louise Schuttelaar³⁵, Jean-Francois Stalder³⁶, Åke Svensson³⁷, Roberto Takaoka³⁸, Carl-Fredrik Wahlgren³⁹, Stephan Weidinger⁴⁰, Andreas Wollenberg⁴¹ & Hywel Williams^{5,42}

¹Centre for Evidence-Based Healthcare, University Hospital Dresden; ²Department of Occupational and Social Medicine, Technical University Dresden, Dresden, Germany; ³Department of Dermatology, Academic Medical Center, Amsterdam; ⁴Department of Epidemiology and Biostatistics, VU University Medical Center, Amsterdam, The Netherlands; ⁵Centre of Evidence Based Dermatology, University of Nottingham, Nottingham, UK; ⁶Astellas Pharma Europe Ltd, Lovett House, Staines, UK; ⁷Department of Dermatology, University of Sao Paulo, Sao Paulo, Brazil; ⁸Medical Sociology, Department of Epidemiology and Preventive Medicine, University of Regensburg, Regensburg, Germany; ⁹Department of Clinical Social Medicine, University Hospital Heidelberg, Heidelberg, Germany; ¹⁰Department of Dermatology, University Hospital Utrecht; ¹¹Department of Dermatology and Allergology, University Medical Center Utrecht, Utrecht, The Netherlands; ¹²Department of Dermatology, Royal Devon and Exeter Hospital, Exeter, UK; ¹³Department of Quality Measures and Research, Chief Physician Office, General Management, Clalit Health Services, Tel Aviv, Israel; ¹⁴Rady Children's Hospital, University of California, San Diego, CA, USA; ¹⁵St John's Institute of Dermatology, Guy's and St Thomas' Hospitals NHS Foundation Trust, UK; ¹⁶King's College London, London, UK; ¹⁷Department of Dermatology, Kyushu University, Fukuoka, Japan; ¹⁸Justus Liebig University Giessen, Giessen, Germany; ¹⁹Dutch Cochrane Centre, Academic Medical Center, Amsterdam, The Netherlands; ²⁰National Eczema Society, London, UK; ²¹Department of Mining Engineering and Petroleum, Polytechnic School of the University of São Paulo, São Paulo, Brazil; ²²Department of Dermatology, Osaka University, Osaka, Japan; ²³Dutch consumers organisation VMCE, The Netherlands; ²⁴Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London; ²⁵Department of Dermatology, Ninewells Hospital & Medical School, Dundee, Tayside, UK; ²⁶French Association of Eczema, Nantes, France; ²⁷Department of Dermatology, St George Hospital, Sydney, Australia; ²⁸University of New South Wales, Sydney, NSW, Australia; ²⁹Division of Allergy, Department of Medical Subspecialties, National Centre for Child Health and Development, Tokyo, Japan; ³⁰Department of Pediatrics, Division of Pediatric Dermatology, Erasmus MC-Sophia Children's Hospital, and Department of Dermatology, Maasstad Ziekenhuis, Rotterdam, The Netherlands; ³¹Japan Allergy Volunteer Association, Tokyo, Japan; ³²Department of Dermatology, Larrey Hospital, Paul Sabatier University, Toulouse, France; ³³Chief Physician Office, Clalit Health Services, Tel Aviv, Israel; ³⁴Department of Dermatology, The Jikei University School of Medicine, Tokyo, Japan; ³⁵Department of Dermatology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands; ³⁶Department of Dermatology, Nantes University Hospital, Nantes, France; ³⁷Department of Dermatology, University Hospital, Malmö, Sweden; ³⁸Department of Dermatology, School of Medicine, University of Sao Paulo, Sao Paulo, Brazil; ³⁹Department of Medicine Solna, Dermatology Unit, Karolinska Institutet and Karolinska University Hospital, Solna, Sweden; ⁴⁰Department of Dermatology, Allergology, and Venerology, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany; ⁴¹Department of Dermatology and Allergy, Ludwig-Maximilian-University, Munich, Germany; ⁴²Department of Dermatology, Nottingham University Hospitals NHS Trust, Nottingham, UK

To cite this article: Schmitt J, Spuls P, Boers M, Thomas K, Chalmers J, Rookevisch E, Schram M, Allsopp R, Aoki V, Apfelbacher C, Bruijnzeel-Koomen C, Bruin-Weller M, Charman C, Cohen A, Dohil M, Flohr C, Furue M, Gieler U, Hooft L, Humphreys R, Ishii HA, Katayama I, Kouwenhoven W, Langan S, Lewis-Jones S, Merhand S, Murota H, Murrell DF, Nankervis H, Ohya Y, Oranje A, Otsuka H, Paul C, Rosenbluth Y, Saeki H, Schuttelaar M-L, Stalder J-F, Svensson Å, Takaoka R, Wahlgren C-F, Weidinger S, Wollenberg A, Williams H. Towards global consensus on outcome measures for atopic eczema research: results of the HOME II meeting. *Allergy* 2012; DOI: 10.1111/j.1398-9995.2012.02874.x

Keywords

atopic dermatitis; consensus study; measurement; outcome domain; study endpoint.

Abstract

The use of nonstandardized and inadequately validated outcome measures in atopic eczema trials is a major obstacle to practising evidence-based dermatology. The Harmonising Outcome Measures for Eczema (HOME) initiative is an

Correspondence:

Jochen Schmitt, Centre for evidence-based healthcare University Hospital Dresden, Dresden, Germany.
Tel.: +49 351 3177 447
Fax: +49 351 3177 236
E-mail: Jochen.Schmitt@tu-dresden.de

Anyone interested in contributing to the HOME project or working groups is welcome and should contact the HOME project manager (HOME@nottingham.ac.uk).

Edited by: Thomas Bieber

Accepted for publication 16 June 2012

DOI:10.1111/j.1398-9995.2012.02874.x

international multiprofessional group dedicated to atopic eczema outcomes research. In June 2011, the HOME initiative conducted a consensus study involving 43 individuals from 10 countries, representing different stakeholders (patients, clinicians, methodologists, pharmaceutical industry) to determine core outcome domains for atopic eczema trials, to define quality criteria for atopic eczema outcome measures and to prioritize topics for atopic eczema outcomes research. Delegates were given evidence-based information, followed by structured group discussion and anonymous consensus voting. Consensus was achieved to include clinical signs, symptoms, long-term control of flares and quality of life into the core set of outcome domains for atopic eczema trials. The HOME initiative strongly recommends including and reporting these core outcome domains as primary or secondary endpoints in all future atopic eczema trials. Measures of these core outcome domains need to be valid, sensitive to change and feasible. Prioritized topics of the HOME initiative are the identification/development of the most appropriate instruments for the four core outcome domains. HOME is open to anyone with an interest in atopic eczema outcomes research.

Atopic eczema (syn. atopic dermatitis) is very common in children and adults. It adversely affects quality of life of patients and their families and causes substantial financial burden (1–4). The course of atopic eczema is typically chronic or chronically relapsing (5). Itching is a major symptom (6); hence, atopic eczema is a leading cause of sleeping problems in children (7).

In recent years, outcomes research has been identified as an important unmet need in medical research (8,9). The standardized use of valid and reliable instruments that are able to measure changes in disease characteristics that are relevant for patients is a prerequisite for evidence-based health care (10).

In 2007, a systematic review critically appraised the validity, reliability and ease of use of all published measures to assess the severity of atopic eczema (11). This review concluded that only three of the 20 named scales [Severity Scoring of Atopic Dermatitis Index (SCORAD) (12), Eczema area and severity index (EASI) (13) and Patient-oriented Eczema Measure (POEM) (14)] had been adequately validated such that their use can be recommended (11). Although proactive treatment for flare prevention is currently a relevant strategy given that atopic eczema is a chronic disease (15), a recent systematic review highlighted there is no clear definition and validated measure of disease flares (16). The corollary of a lack of high-quality outcomes research is that current clinical trials face the possibility of overestimating, underestimating or completely missing the true effect of an intervention for atopic eczema.

We therefore launched an international initiative to aid the standardization of outcome measures for atopic eczema. The first stage was to conduct an online Delphi consensus exercise to suggest a preliminary core set of outcome domains that should be used in every clinical trial and in clinical record keeping (17). An outcome 'domain' is defined as a distinct aspect of disease, such as quality of life, clinical signs, symptoms or cost, and typically, each outcome domain can be measured by different instruments and/or scales. Our Delphi consensus exercise involved 46 individuals representing four

stakeholder groups (consumers, clinical experts, regulatory agency representatives and journal editors) from 13 countries and 4 continents (17). There was consensus from this Delphi exercise that measures for the domains symptoms, physician-assessed clinical signs and long-term control of flares should be assessed in every future atopic eczema trial, but there was no consensus whether or not health-related quality of life (HRQL) should be included in the core set of domains (17).

Following on from this Delphi exercise, two of the authors (JS and HW) set up an international and multiperspective group called the Harmonising Outcome Measures for Eczema (HOME) initiative with an overall purpose to derive core outcome measures for atopic eczema research and clinical record keeping through collaborative research.

The first meeting of the HOME initiative was a short exploratory workshop (HOME I) held during the International Symposium on Atopic Dermatitis/New Trends in Allergy meeting in Munich in 2010 (18). There was overwhelming support at this workshop amongst the international community to address atopic eczema outcomes research collaboratively as an open group, and it was agreed that a second meeting would be arranged in which the initial findings of the Delphi exercise could be built on. This second working meeting (HOME II) took place in July 2011, and the results are reported here.

Aims

The aims of the HOME II consensus meeting were to:

- Refine or confirm the preliminary core set of outcome domains for atopic eczema trials derived from the Delphi procedure
- Define minimum criteria for the recommendation of instruments to measure specific core outcome measures in clinical trials of interventions for atopic eczema
- Prioritize research into outcome measures for atopic eczema

Methods

Study design

We undertook an international multiprofessional consensus study involving patient representatives, clinicians, methodologists and pharmaceutical industry representatives. The study took place at a 2-day face-to-face meeting in June 2011, hosted by Dr Phyllis Spuls from the Academic Medical Center in Amsterdam. The HOME II study planning group consisted of Phyllis Spuls (PS), Jochen Schmitt (JS) and Hywel Williams (HW).

In contrast to our previous online Delphi exercise (17), to ensure the task was manageable, the group focussed exclusively on outcome measures for clinical trials in this study meeting. Core outcome measures for record keeping in clinical practice are equally important, and we plan to address these in future.

Study participants

The HOME initiative is an international, multiprofessional group open to anyone interested in atopic eczema outcomes research. We invited participants from the Delphi consensus study (17), HOME I meeting attendees (18) and clinicians and methodological experts who had expressed interest in HOME or have recently published in the field of atopic eczema outcomes research. We also invited individuals who were involved in the development of specific atopic eczema outcome measurement (11) as well as representatives from the pharmaceutical industry. We invited Professor Maarten Boers (MB) as an external expert, who, as a founding member of the OMERACT group, has been involved in outcomes research in rheumatology since 1992 (19). The meeting was free of charge for all participants, and travel expenses for some of the patient representatives and researchers were covered by patient associations or academics.

Study procedures

There was a strong focus on evidence-based information before consensus voting. Group techniques and modified Delphi exercises were applied as described previously by the OMERACT group (9,19). Scientific information was provided in the form of presentations and handouts of key publications. Patient representatives additionally received plain language information material before the meeting that had been developed by one of the consumers (RH) and organizers (HW). To allow structured and effective group discussions, we divided the panel into two groups, assigned one moderator and one rapporteur to each group and applied nominal group technique methods. For consensus voting, an anonymous electronic keypad voting system was used. For further details concerning the study procedures, please refer to the HOME website (www.homeforeczema.org).

Statistical analysis

Based on his previous experiences from OMERACT meetings, MB proposed the following definition of consensus:

Consensus is reached if less than 30% of the voters disagree. None of the participants disagreed with this definition. There was 100% agreement that the whole group of participants voted as one without dividing it into stakeholder groups [as done in the previously published online Delphi exercise (17)]. For the purposes of sensitivity analyses, information on stakeholder groups (i.e. clinicians, consumers, others including pharmaceutical industry representatives and methodologists) was collected. Participants were asked to nominate which stakeholder group they were most closely related to.

For each question, counts and percentages of participants who 'agreed', were 'undecided', and 'disagreed' are presented.

Results

A total of 43 individuals from 10 countries participated in the HOME II consensus study. About half of the panel was female ($n = 20$; 47%) and male ($n = 23$; 53%), respectively. The majority of participants ($n = 30$; 71%) were from Europe (UK $n = 10$; the Netherlands $n = 10$; Germany $n = 5$; France $n = 3$; Sweden $n = 2$). The panel included six participants from Japan, three from Brazil, two from Israel, one from the United States and one from Australia. Clinical experts were the largest stakeholder group ($n = 29$; 67%). The panel included five consumers, five methodologists and one pharmaceutical industry representative.

Refinement of the preliminary core set of outcome domains for atopic eczema trials

During group discussions, both groups agreed that four domains should be included into the core set of outcome domains for atopic eczema trials: clinical signs, symptoms, a long-term measure that captures flares and remissions, and HRQL. It was noted that long-term disease control could be viewed as a derivative function of clinical signs and symptoms over time and not an independent item of source data. Some group members favoured generic HRQL measures, whereas others favoured disease-specific quality-of-life measures.

Both groups discussed the role of biomarkers, coping behaviour and treatment utilization as outcome domains for atopic eczema trials. Both groups agreed that biomarkers should not be added to the core outcome domains for now as blood tests might hamper recruitment to clinical trials, but that future research may identify adequate biomarkers for consideration. Neither group favoured including coping behaviour or treatment utilization into the core set of outcome domains.

The results of consensus voting on refinement of core outcome domains for clinical trials to investigate the efficacy of interventions for atopic eczema reflected the discussions and are summarized in Table 1.

There was broad consensus that clinical signs, symptoms, long-term control of flares and quality of life should be used as core outcome domains for future atopic eczema trials. Each stakeholder group agreed on this core set of outcome

Table 1 Results of consensus voting about core outcome domains for clinical trials to investigate the efficacy of interventions for atopic eczema

Question	Total Votes	Agreement <i>n</i> (%)	Undecided <i>n</i> (%)	Disagreement <i>n</i> (%)
Do you agree on 'clinical signs', 'symptoms' and 'long-term control of flares' as core domains?	40	32 (80)	3 (8)	5 (13)
Do you agree to add 'quality of life' as core domain?	41	31 (76)	6 (15)	4 (10)
Should 'coping' be considered for inclusion as core domain?	41	4 (10)	8 (20)	29 (71)
Should 'biomarkers' be considered for inclusion as core domain?	41	4 (10)	5 (12)	32 (78)
Should 'treatment utilization' be considered for inclusion as core domain?	41	6 (15)	9 (22)	26 (63)

domains. Agreement between the group of consumers was 100% ($n = 5$).

There was also consensus that biomarkers, treatment utilization and compliance should not be added to the core set of outcome domains at the moment. Interestingly, three of five consumers favoured the inclusion of biomarkers into the core set of outcome domains.

Definition of quality requirements to recommend outcome measures

A series of presentations was given to the panel on instruments for measuring outcomes in eczema trials. JS presented a systematic review on named outcome measures for atopic eczema, in which reliability, validity, sensitivity to change and acceptability were used as criteria for recommendation of measurements (11). As examples for specific measures of core outcome domains of atopic eczema, data were presented on previous validation work and psychometric properties of EASI (13) (Carle Paul), SCORAD (12) (Jean-Francois Stalder), Six-Area Six-sigh Atopic Dermatitis Severity Score (SAS-SAD) (20) (Kim Thomas), Three Item Severity Score (TISS) (21) (Arnold Oranje) and POEM scores (14) (Carolyn Charman), as well as measures of flares/long-term control of atopic eczema (16) (Sinéad Langan), and methods of how to assess sensitivity to change and minimal clinically relevant change by means of atopic eczema scores (22) (Mandy Schram).

MB presented the 'OMERACT filter' (10), which defines three criteria necessary for outcome measures to be recommended:

- Truth: validity
- Discrimination: sensitivity to change, responsiveness
- Feasibility: ease of use, costs, time to perform and interpret

Group discussion indicated that the adoption of the OMERACT filter was generally favoured by the panel. Consensus voting resulted in absolute agreement (100%) of the panel that the necessary criteria to recommend an outcome measure for atopic eczema trials are truth, discrimination and feasibility as defined previously by the OMERACT group (10).

Prioritization of future atopic eczema outcomes research issues

Group discussions were used to identify important atopic eczema outcomes research topics. The following research

topics were considered important by both groups: Identification of adequate measurements for the four core outcome domains, measurement of quality of care, collapsing core outcome domains/conceptual mapping, biomarkers and definitions of disease severity (i.e. how does 'mild', 'moderate' and 'severe' atopic eczema translate into a score and vice versa). Additional issues indicated as important by members of one group were measurement of coping behaviour, self-efficacy, empowerment, illness perception, patient satisfaction and corticosteroid phobia. Definition of incident atopic eczema in prevention trials and definition of subtypes of atopic eczema were additional suggested issues for the future outcomes research agenda.

The results of consensus voting about the prioritization of future atopic eczema outcomes research are summarized in Table 2. The majority of panel members wanted to identify adequate measurements for the core outcome domains clinical signs, symptoms, and long-term control of flares. About half of the panel also considered the identification of adequate measurements for HRQL and how to define the severity of atopic eczema to be important. A minority prioritized the identification of biomarkers and measures for the domain 'quality of care' and the development of methods to explore whether several different core outcome domains could be further collapsed into one composite score (Table 2).

Discussion

Forty-three individuals from five continents representing clinicians, patients, methodologists and the pharmaceutical industry participated in the HOME II consensus study.

The previously described (17) core outcome domains of symptoms, clinical signs and long-term control of flares were confirmed by the panel. An additional core outcome domain of HRQL was identified with broad consensus. It thus appears that the four core outcome domains of symptoms, clinical signs, long-term control of flares and quality of life should be measured consistently in future atopic eczema trials. It is clear therefore that more than one of the currently available instruments will need to be included in the core outcome set as none cover all four domains (Table 3).

The OMERACT filter (10) as a quality requirement to recommend outcome measures by the HOME group has been adapted with full consensus of the HOME II panel. In order to be recommended, outcome measures need to be valid, need to discriminate between different disease states and need

Table 2 Prioritization of future atopic eczema outcomes research issues (*n* = 35 participants voted)

Atopic eczema outcomes research topic	Highest priority <i>n</i> (%)	NOT highest priority <i>n</i> (%)
Identify/validate measures for core outcome domain 'clinical signs'	28 (80)	7 (20)
Identify/validate measures for core outcome domain 'symptoms'	24 (69)	11 (31)
Identify/validate measures for core outcome domain 'long-term control of flares'	30 (86)	5 (14)
Identify/validate measures for core outcome domain 'quality of life'	17 (49)	18 (51)
Identify/validate measures for domain 'quality of care'	6 (18)	29 (82)
Identify/validate adequate biomarkers	4 (12)	31 (88)
Collapsing core domains and conceptual mapping	9 (26)	26 (74)
Definition of disease severity (i.e. mild, moderate, severe atopic eczema)	20 (57)	15 (43)

to be feasible in terms of ease of use, costs, performance and interpretation.

The HOME initiative will continuously review new and emerging outcome measures as they are published, such as the

EASIdig, a recently published digital tool for the digital assessment of severity and extent of atopic eczema, that has been shown to correlate with SCORAD and EASI scores (23).

The panel highlighted the need to design and/or validate adequate instruments that meet the OMERACT filter to measure the four core outcome domains symptoms, clinical signs, long-term control and quality of life.

Study strengths and limitations

Following systematic research (11, 16, 24–26), an international online Delphi consensus study on core outcome domains (17) and an exploratory meeting (HOME I) that resulted in the formation of the HOME group (18), the study presented here was the first extended 2-day meeting in which patient representatives, clinicians, methodologists and pharmaceutical industry representatives with an interest in atopic eczema outcomes research from various parts of the world met, worked together and formed an active working group. A significant strength of HOME is the close links with the OMERACT group, a similar initiative in Rheumatology that started in 1992 (19) (<http://www.intermed.med.uottawa.ca/research/omeract/>). MB, a founding member of OMERACT, guided us throughout the HOME II consensus study and proposed the use of the OMERACT filter (10), which has been successfully used in rheumatology. The HOME group also has strong links

Table 3 Presence of domains (clinical signs, symptoms, a long-term measure of control) in atopic eczema scores, adapted from the study of Schmitt et al. 2007 (11). Quality of Life is measured by different scores

Score	Full name of score	Clinical signs	Symptoms	Long-term measure of control of disease
ADAM	Atopic Dermatitis Assessment Measure	✓	✓	
ADASI	Atopic Dermatitis Area and Severity Index	✓	✓	
ADSI	Atopic Dermatitis Severity Index		✓	
BCSS	Basic Clinical Scoring System	✓		
EASI	Eczema Area and Severity Index	✓		
FSSS	Four Step Severity Score	✓		✓
IGADA	Investigator Global Atopic Dermatitis Assessment	✓		
Leicester index	N/AP	✓		
NESS	Nottingham Eczema Severity Score	✓	✓	✓
OSAAD	Objective Severity Assessment of Atopic Dermatitis	✓		
POEM	Patient-oriented Eczema Measure		✓	
RL score	Rajka & Langeland Score	✓	✓	✓
SA-EASI	Self-administered Eczema Area and Severity Index	✓	✓	
SASSAD	Six-Area Six-sigh Atopic Dermatitis Severity Score	✓		
SCORAD	Severity Scoring of Atopic Dermatitis Index	✓	✓	
SIS	Skin Intensity Score		✓	
SSS	Simple Scoring System	✓	✓	
TBSA	Six-Area Total Body Severity Assessment	✓		
TISS	Three-item Severity Score			
WAZ-S	Atopic Dermatitis Severity Score (in Polish)	✓	✓	

with other interdisciplinary outcomes research initiatives included in Core Outcome Measures in Effectiveness Trials (27).

Although individuals from all areas of the world were invited, colleagues from Africa, China or India were not able to attend this particular meeting and only one US invitee was able to attend. Also, a more equal representation of some stakeholders groups, such as the regulators, pharmaceutical industry and patients with a range of disease severity or in remission, could enhance the representativeness of our findings and recommendations. We intend holding the next HOME meeting (HOME III) in the USA in 2013 to attract a wider range of participants (see www.homeforeczema.org for details).

Conclusions/next steps

The core outcome domains identified by the international panel should be included in all future atopic eczema trials. The standardized use of these outcome domains will help to permit adequate interpretation of clinical trials and indirect comparisons between different interventions by means of meta-analyses. The standardized application of these core outcome domains is an important step towards evidence-based dermatology. However, it is important to point out that the core set of outcome domains is always preliminary. The core outcome domains do not necessarily need to be the only or the primary endpoints in clinical trials, and other outcomes that are particularly important for particular research questions can of course be included in addition to the core domains.

The formation of working groups to collectively address the research topics prioritized at HOME II is currently underway, and anyone with an enthusiasm for working in the field of atopic eczema outcomes research is welcome to get involved. To find out more, contact us at HOME@nottingham.ac.uk or visit the website at www.homeforeczema.org.

References

- Lewis-Jones S. Quality of life and childhood atopic dermatitis: the misery of living with childhood eczema. *Int J Clin Pract* 2006;**60**:984–992.
- Carroll CL, Balkrishnan R, Feldman SR, Fleischer AB Jr, Manuel JC. The burden of atopic dermatitis: impact on the patient, family, and society. *Pediatr Dermatol* 2005;**22**:192–199.
- Williams HC. Epidemiology of atopic dermatitis. *Clin Exp Dermatol* 2000;**25**:522–529.
- Schmitt J, Schmitt NM, Kirch W, Meurer M. Outpatient care and medical treatment of children and adults with atopic eczema. *J Dtsch Dermatol Ges* 2009;**7**:345–351.
- Bieber T. Atopic dermatitis. *N Engl J Med* 2008;**358**:1483–1494.
- Williams HC, Burney PG, Hay RJ, Archer CB, Shipley MJ, Hunter JJ et al. The U.K. Working Party's Diagnostic Criteria for Atopic Dermatitis. I. Derivation of a minimum set of discriminators for atopic dermatitis. *Br J Dermatol* 1994;**131**:383–396.
- Smaldone A, Honig JC, Byrne MW. Sleepless in America: inadequate sleep and relationships to health and well-being of our nation's children. *Pediatrics* 2007;**119**(Suppl 1):S29–S37.
- Tugwell P, Boers M. Developing consensus on preliminary core efficacy endpoints for rheumatoid arthritis clinical trials. OMERACT Committee. *J Rheumatol* 1993;**20**: 555–556.
- Tugwell P, Boers M, Brooks P, Simon L, Strand V, Idzerda L. OMERACT: an international initiative to improve outcome measurement in rheumatology. *Trials* 2007;**8**:38.
- Boers M, Brooks P, Strand CV, Tugwell P. The OMERACT filter for outcome measures in rheumatology. *J Rheumatol* 1998;**25**:198–199.
- Schmitt J, Langan SM, Williams HC. What are the best outcome measurements for atopic eczema? A systematic review. *J Allergy Clin Immunol* 2007;**120**:1389–1398.
- Severity scoring of atopic dermatitis: the SCORAD index. Consensus Report of the European Task Force on Atopic Dermatitis. *Dermatology* 1993;**186**:23–31.
- Toft SJ, Graeber M, Cherill R, Omoto M, Thurston M, Hanifin JM. Eczema area and severity index (EASI): a new tool to evaluate atopic dermatitis. *J Eur Acad Dermatol Venereol* 1998;**11**(Suppl 2):S197.
- Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure:

Author contributions

All named authors played an active role in the research meeting, contributing to discussions and voting procedures and consensus recommendations. Jochen Schmitt, Phyllis Spuls, Evelien Roekevisch, Mandy Schram and Hywel Williams were responsible for the HOME II planning and organization.

The manuscript was drafted by Jochen Schmitt, Phyllis Spuls, Kim Thomas, Joanne Chalmers and Hywel Williams. All remaining authors reviewed and commented on the manuscript.

Funding

Study participants funded their own travel and accommodation. Some patient representatives' costs were covered by academic colleagues (Professors Furue, Takaoka and Williams). Venue, voting system and catering costs were covered by Dr Spuls, Academic Medical Centre, Amsterdam.

The HOME initiative is partially supported through an independent research programme commissioned by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10177). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Commercial competing interests

Richard Allsopp is Associate Director, Medical Affairs Dermatology, Astellas Pharma. No other commercial competing interests.

Ethical approval

Not required.

- development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. *Arch Dermatol* 2004;**140**:1513–1519.
15. Schmitt J, von Kobyletzki L, Svensson A, Apfelbacher C. Efficacy and tolerability of proactive treatment with topical corticosteroids and calcineurin-inhibitors for atopic eczema: systematic review and meta-analysis of randomised controlled trials. *Br J Dermatol* 2011;**164**:415–428.
 16. Langan SM, Thomas KS, Williams HC. What is meant by a "flare" in atopic dermatitis? A systematic review and proposal. *Arch Dermatol* 2006;**142**:1190–1196.
 17. Schmitt J, Langan S, Stamm T, Williams HC. Core outcome domains for controlled trials and clinical recordkeeping in eczema: international multiperspective delphi consensus process. *J Invest Dermatol* 2011;**131**:623–630.
 18. Schmitt J, Williams HC. Harmonising Outcome Measures for Eczema (HOME). Report from the first international consensus meeting (HOME 1), 24 July 2010, Munich, Germany. *Br J Dermatol* 2010;**163**:1166–1168.
 19. Tugwell P, Boers M. OMERACT conference on outcome measures in rheumatoid arthritis clinical trials: introduction. *J Rheumatol* 1993;**20**:528–530.
 20. Berth-Jones J. Six area, six sign atopic dermatitis (SASSAD) severity score: a simple system for monitoring disease activity in atopic dermatitis. *Br J Dermatol* 1996;**135**(Suppl 48):25–30.
 21. Wolkerstorfer A, de Waard van der Spek FB, Glazenburg EJ, Mulder PGH, Oranje AP. Scoring the severity of atopic dermatitis: three item severity score as a rough system for daily practice and as a pre-screening tool for studies. *Acta Derm Venereol* 1999;**79**:356–359.
 22. Schram ME, Spuls PI, Leeftang MM, Lindeboom R, Bos JD, Schmitt J. EASI, (objective) SCORAD and POEM for atopic eczema: responsiveness and minimal clinically important difference. *Allergy* 2012;**67**:99–106.
 23. Tremp M, Knafla I, Burg G, Wuthrich B, Schmid-Grendelmeier P. 'EASIdig'—a digital tool to document disease activity in atopic dermatitis. *Dermatology* 2011;**223**: 68–73.
 24. Charman C, Chambers C, Williams H. Measuring atopic dermatitis severity in randomized controlled clinical trials: what exactly are we measuring? *J Invest Dermatol* 2003;**120**:932–941.
 25. Charman C, Williams H. Outcome measures of disease severity in atopic eczema. *Arch Dermatol* 2000;**136**:763–769.
 26. Charman CR, Venn AJ, Williams HC. Measurement of body surface area involvement in atopic eczema: an impossible task? *Br J Dermatol* 1999;**140**:109–111.
 27. Williamson P, Blazeby J, Altman D, Clarke M. *BMJ blog: The Comet initiative*. http://blogs_bmj_com/bmj/2010/03/08/the-comet-initiative/.