HOME II meeting

Amsterdam 6-7 June 2011

Minutes

Attendees (in alphabetical order)

Number	Surname	First name	Country
1	Allsopp	Richard	UK
2	Aoki	Valeria	Brazil
3	Apfelbacher	Christian	Germany
4	Boers	Maarten	Netherlands
5	Bruijnzeel-Koomen	Carla	Netherlands
6	Bruin-Weller	Marjolein	Netherlands
7	Chalmers	Joanne	UK
8	Charman	Carolyn	UK
9	Cohen	Arnon	Israel
10	Dohil	Magdalene	USA
11	Flohr	Carsten	UK
12	Furue	Masutaka	Japan
13	Gieler	Uwe	Germany
14	Hooft	Lotty	Netherlands
15	Humphreys	Rosemary	UK
16	Ishii	Henrique Akira	Brazil
17	Katayama	Ichiro	Japan
18	Kouwenhoven	Willem	Netherlands
19	Langan	Sinead	UK
20	Lewis-Jones	Sue	UK
21	Merhand	Stephanie	France
22	Murota	Hiroyuki	Japan
23	Murrell	Dedee	Australia
24	Nankervis	Helen	UK
25	Ohya	Yukihiro	Japan
26	Oranje	Arnold	Netherlands
27	Otsuka	Hiromi	Japan
28	Paul	Carle	France
29	Roekevisch	Evelien	Netherlands
30	Rosenbluth	Yael	Israel
31	Saeki	Hidehisa	Japan
32	Schmitt	Jochen	Germany
33	Schram	Mandy	Netherlands
34	Schuttelaar	Marie-Louise	Netherlands
35	Spuls	Phyllis	Netherlands
36	Stalder	Jean-Francois	France
37	Svensson	Åke	Sweden
38	Takaoka	Roberto	Brazil
39	Thomas	Kim	UK
40	Wahlgren	Carl-Fredrik	Sweden
41	Weidinger	Stephan	Germany
42	Williams	Hywel	UK
43	Wollenberg	Andreas	Germany

Abbreviations

AD	Atopic Dermatitis
EASI	Eczema Area and Severity Index
EMA	European Medicines Agency
FDA	Food and Drug Administration
HOME	Harmonising Outcome Measures for Eczema
MCID	Minimum Clinically Important Difference
NESS	Nottingham Eczema Severity Scale
OMERACT	Outcome Measures in Rheumatoid Arthritis Clinical Trials
POEM	Patient-Oriented Eczema Measure
poSCORAD	patient oriented self assessment SCOring Atopic Dermatitis
QoL	Quality of Life
SASSAD	Six Area, Six Sign Atopic Dermatitis
SCORAD	SCORing Atopic Dermatitis
TIS	Three Item Severity score
VAS	Visual Analogue Scale

Background and Introduction

HOME stands for Harmonising Outcome Measures for Atopic Eczema. In 2010 a first meeting was organized by Hywel Williams and Jochen Schmitt. As a result of the overwhelming support from the international community of AD researchers expressed at the HOME I meeting, a HOME II meeting was held on 6th - 7th June, 2011 in Amsterdam, hosted by Dr. Phyllis Spuls from the Academic Medical Center in Amsterdam.

The aim of the HOME II meeting was to establish the core outcome domains and scales that might be used in all future eczema clinical trials (and clinical practice).

All those interested in eczema outcome measures and evidence-based dermatology including patient representatives, clinicians, methodologists, pharmaceutical company and regulatory agency representatives with a special interest in eczema, were invited. A total of 43 delegates from all over the world attended the meeting.

We were fortunate to welcome Maarten Boers to the meeting, a founding member of OMERACT (outcome measures in rheumatology), to help guide us along our venture.

Day 1: June 6th 2011 1.00 pm

Introduction and Aims

After a short welcome by Hywel Williams (HW), Jochen Schmitt (JS) and Phyllis Spuls (PS) all participants introduced themselves.

The day began with three presentations:

1. **Aims of the HOME initiative: Hywel Williams (HW)**

Hywel began by explaining that a set of core outcome measures for eczema research is desperately needed to improve the quality and comparability of research ultimately leading to better care for eczema patients. The only way that this can be done is through international co-operation and consensus, and by sharing of expertise. The principle that the project aimed to identify core outcome domains was emphasized. Once such core outcome domains are agreed on, every researcher should include them in future trials. Researchers would be free to also use additional outcomes relevant to their study as well as the core set.

2. **What can we learn from OMERACT?: Maarten Boers (MB)**

Maarten shared his experience with OMERACT, a similar initiative in rheumatology that started in 1992. Maarten is one of the founder members of OMERACT and so has a lot of experience in outcomes research, consensus exercises, and moderating similar meetings. Maarten introduced the OMERACT filter for outcome measures in rheumatology [1] which consists of:

1. Truth: validity
2. Discrimination: sensitivity to change, responsiveness
3. Feasibility: can we use this instrument at acceptable costs and time plus interpret results.

OMERACT has made a great impact not only in rheumatology, but in outcomes research in general. More information about OMERACT can be found at http://www.intermed.med.uottawa.ca/research/omeract./homepage.html

3. **"HOME- work" so far: Jochen Schmitt (JS)**

Jochen Schmitt presented an overview of the progress of HOME to date.

- In 2007 a systematic review on outcome measures for clinical signs and symptoms of eczema identified a great variety of different, non-comparable instruments most of which have never been adequately validated.[2]
- This was followed by an international Delphi consensus exercise to define preliminary core outcome domains for eczema in the settings "clinical trials" and "recordkeeping in routine practice".[3] The consensus panel included representatives of four stakeholder

groups (consumers, clinical experts, regulatory agency representatives, and journal editors) representing 13 countries. Consensus was achieved for inclusion of symptoms, physician-assessed clinical signs, and a measurement for long-term control of flares in the core set of outcome domains for eczema trials. There was no consensus on whether the domain "quality of life" should be included into the core set: While clinical experts and journal editors recommended adding the domain "quality of life" to the core set, the majority of patients did not. In order to achieve high level of external validity 6 representatives from eczema self-help groups from 5 countries representing 4 continents were included as patient representatives. The relevance of the domain "quality of life" was a major point of discussion after completion of the Delphi consensus study. For recordkeeping in daily clinical practice, consensus was reached to regularly monitor eczema symptoms in clinical practice.

- The first HOME meeting was held in Munich in 2010 (HOME I).[4] This two hour exploratory meeting highlighted a clear interest from the international community to form a working group that would collaboratively perform eczema outcomes research.

Whole Group discussion

All group members were then asked to raise any important issues concerning the goals of the meeting, their expectations, any critique, etc. Statements were listed on a whiteboard. A summary of key statements/points of the discussion is presented in Text box 1.

Text box 1 Points for discussion

General

- The need to agree on consensus rules.
- The focus of this meeting should be the setting "clinical trials" only. Identifying core domains for "Record-keeping" will be postponed for now.
- The need to make HOME a truly international initiative. Despite our efforts to directly approach colleagues from areas of the world including Africa and China, none were present at this meeting.

The previous Delphi exercise[3]

- Should the group build on the results of the previous Delphi exercise OR does the group want to start from scratch?
- How to deal with the variability between experts, patients, agencies and editors in the Delphi round?
- There are some worries about the Delphi round group-sizes. This is especially true for the subgroup of consumers.
- Should 'quality of life' (QoL) be added as a core outcome domain? What are the possible reasons that patients the Delphi exercise did not consider QoL relevant for the set of core outcome domains? Were they aware that QoL measure can be eczema or dermatology specific?

(Core) outcome domains

- Should there be a reduction of domains?
- Should we consider 'conceptual mapping of domains' as a HOME research project and should we add the domains: Quality of care? Serum markers/bio markers? Coping behaviour?
- Should we make better definitions of the domains? For instance, what is meant by global assessment of disease severity? Long-term flare control: how long is long-term? What is the definition of control?
- Long term control could be viewed as another way of looking at signs and symptoms; including it as a separate domain may be an overlap
- Should we focus on applicability of core domains for children?
- Should we group the domains: efficacy, harm/safety and applicability?
- Safety issues seem to be missing from current domains. Safety should be measured in all trials – the purpose of HOME is to define core efficacy measures.
- Measures should be simple and usable in clinical trials!

Group discussion (two groups)

Participants were divided into two groups and asked to discuss three key questions from the points of discussion that were raised earlier and listed in textbox 1. Each group was assigned one moderator and one rapporteur. The three key questions and group responses are summarized in Text box 2.

Text box 2 Questions for discussion

1. Should the following three domains defined by the previous Delphi exercise[3] be included in the core set of outcome domains for clinical trials on eczema? • **Symptoms** • **Physician-assessed clinical signs using a score** • **Long term control of flares**
Group 1 agreed that all three domains should be included in the core set. In addition to signs and symptoms, it was considered important that this chronic disease needs a chronicity measure i.e. a long-term measure that captures flares and remissions.
Group 2 agreed to include the three domains in the core set. Some group members indicated that measures of clinical signs should include both, disease extent and intensity. Also, some group members indicate that clinical signs do not necessarily need to be assessed by a physician, but may also be assessed by patients / caregivers. The point was made that long-term disease control may be viewed as a derivative of clinical signs and symptoms over time.
2. Should 'quality of life' (QoL) be added as core domain?
Group 1 were comfortable adding QoL as a core outcome domain.
Group 2 largely agreed that QoL should be included into the core set of outcome domains. Some group members favoured generic QoL measures, whereas others favoured disease-specific quality of life measures.
3. Should the following domains be considered to be included into the core set of outcome domains? • **Biomarkers** • **Coping behaviour** • **Treatment utilization**
Group 1 suggested biomarkers could perhaps be added as core domain in the future because reliable biomarkers are not yet available. The need to include blood tests in trials could impair recruitment of children for future trials. Coping should probably **not** be a core domain but may be taken into account within QoL assessment. For utilization of health care (number and type of clinical visits) there are still too many variables, and variations of healthcare systems both within and between countries, to tackle this issue at the outset.
Group 2 felt biomarkers should not be a core domain yet. Biomarkers usually mean blood tests which might impact on patient acceptability. Coping behaviour and treatment utilization were not discussed in this group due to time constraints.

A discussion among the whole group of participants followed about 'Treatment utilization' as a possible core outcome domain, which raised questions about definition. MB suggested adding it to the agenda.

Before moving on to vote on these discussions summarised above, two votes took place.

1. **Definition of consensus**

The following definition for establishing if consensus has been reached during this meeting was proposed by MB based on his previous OMERACT experience:

- ***Consensus is reached if fewer than 30% of the voters disagree.***
- ***Undecided/missing votes are counted in the agree group.***

All participants agreed with this definition.

2. **Establishing which stakeholder groups participants belonged to**

JS proposed that participants should vote on issues as a whole group i.e. not divide into stakeholder groups for voting as was done in the published online Delphi exercise[3]. All participants agreed with this proposal. Information on stakeholder groups was then collected for subsequent sensitivity analyses.

Initially, all participants indicated which of 5 subgroups they felt best described their role:

1	Clinicians	61%	22 votes
2	Consumers	11%	4 votes
3	Regulatory agencies representatives	3%	1 vote
4	Methodologists	22%	8 votes
5	Pharmaceutical industries representatives	3%	1 vote

Thereafter a second question followed in which sub groups 3-5 were combined. The results were as follows:

1	Clinicians	71%	29 votes
2	Consumers	12%	5 votes
3	Regulatory agencies representatives, Methodologists and pharmaceutical industries representatives	17%	7 votes

HOME II meeting voting session I – core domains:

The whole group the moved on to vote on the approval and / or refinement of the preliminary set of core outcome domains for eczema trials as defined in the previous Delphi study[3]. The results are summarised in Text box 3:

Text box 3: Results of voting session I:

Do you agree on 'clinical signs (physician)', 'symptoms' and 'long-term control of flares' as core domains?	Agree: 79%, Undecided: 8%, Disagree: 13% 1. Clinicians (A 82 % 23 votes, U 4% 1 vote, D 14% 4 votes) 2. Consumers (A100 % 5 votes, U 0% 0 votes, D 0% 0 votes) 3. Other (A 57% 4 votes, U 29% 2 votes, D 14% 1 vote)
Do you agree to add 'quality of life' as core domain?	Agree: 75%, Undecided: 15%, Disagree: 10% 1. Clinicians (A 69% 20 votes, U 17% 5 votes, D 14% 4 votes) 2. Consumers (A100% 5 votes, U 0% 0 votes, D 0% 0 votes) 3. Other (A 86% 6 votes, U 14% 1 votes, D 0% 0 votes)
Should 'coping' be considered for inclusion as core domain?	Agree: 9%, Undecided: 20%, Disagree: 71% 1. Clinicians (A 3% 1 vote, U 21% 6 votes, D 76% 22 votes) 2. Consumers (A 60 % 3 votes, U 20% 1 vote, D 20% 1 vote) 3. Other (A 0% 0 votes, U 14% 1 vote, D 86% 6 votes)
Should 'biomarkers' be considered for inclusion as core domain?	Agree: 10%, Undecided: 12%, Disagree: 78% 1. Clinicians (A 14 % 4 votes, U 10% 3 votes, D 76% 22 votes) 2. Consumers (A 0 % 0 votes, U 40% 2 votes, D 60% 3 votes) 3. Other (A 0% 0 votes, U 0% 0 votes, D 100% 7 votes)
Should 'treatment utilization' be considered for inclusion as core domain?	Agree: 15%, Undecided: 22%, Disagree: 63% 1. Clinicians (A 17 % 5 votes, U 21% 6 votes, D 62% 18 votes) 2. Consumers (A 20 % 1 vote, U 20% 1 vote, D 60% 3 votes) 3. Other (A 0% 0 votes, U 29% 2 votes, D 71% 5 votes)

Key: A= Agree, U= Undecided, D= Disagree

Conclusions from voting session I – core domains:

Using the agreed consensus criteria detailed above, the following was agreed:

- The refined core set of outcome domains for eczema trials is:
    1. Symptoms
    2. Clinical signs using a score
    3. Long term control of flares
    4. Quality of life
- Coping, biomarkers and treatment utilization should not be included into the core set of outcome domains.

Presentation

Sinead Langan then gave a presentation entitled "**Measures of flares and long term control of atopic eczema**". A number of possible measures for long term disease control were presented. The take home message was that there is currently no clear consensus on how flares should be defined in AD. Defining long term disease control was highlighted as an important research gap.

Whole group discussion on long term control outcome measures

There is a lack of a generally accepted definition of flares and long term control of eczema. The need for rescue medication may be an important aspect of a flare. A holistic view to assess flares was mentioned. There might be a problem with the word "flare". Often you don't have a flare, but the disease is just not managed right. Alternatively, the lack of management / adherence with therapy is the underlying cause of the "flare". Some investigators have used a threshold definition (a return <50% of baseline score). Flare could mean uncontrolled disease.

JS closed the discussion by summarizing that the current definitions are too different and non-comparable.

Presentation

JS presented the preliminary update of his systematic review on outcome measures for clinical signs and symptoms of eczema.

Close

HW closed the meeting for the day and summarized the phenomenal progress achieved in agreeing on four core domains for eczema/AD.

Day 2: June 7th 2011 9.00am

Introduction and Aims

HW introduced the day and indicated that it was not the intention to rush the scientific process needed to choose the most appropriate instruments that would best measure the domains selected on the previous day. Much more research and briefing would be needed. Instead, the aim of day 2 of the meeting was to introduce some of the most promising candidate instruments currently available to measure clinical signs and symptoms of eczema in order to better understand their structure, strengths, and potential drawbacks.

Potential Instruments for Core Outcome Measures

Five presentations were given to provide and overview of candidate instruments for signs and symptoms:

Clinical signs of eczema:

1. **E**czema **A**rea and **S**everity **I**ndex (EASI): Carle Paul
2. **SCOR**ing **A**topic **D**ermatitis (SCORAD): Jean- Francois Stalder
3. **S**ix **A**rea, **S**ix **S**ign **A**topic **D**ermatitis (SASSAD): Kim Thomas
4. **T**hree **I**tem **S**everity Score (TIS): Arnold Oranje

Symptoms of eczema:

5. **P**atient-**O**riented **E**czema **M**easure (POEM): Carolyn Charman

A further two presentations were made:

6. Sinead Langan presented on **flares / long term control** of eczema and pointed out that there currently is a lack of a accepted definition of flares and long term control of eczema and no clear candidate instrument to measure this and gave a brief summary of possibly meaningful items / definitions of flares/long term control of eczema/AD based on her published review of this topic.
7. Mandy Schram presented the methods of her study investigating the **minimal clinically important difference** and **responsiveness** of the EASI, (objective) SCORAD and POEM. The take home message was that minimal clinically important difference and the responsiveness of an outcome measure should be formally calculated in order to be able to confidently use the measure for clinical trials and further research was needed in this area.

Whole group discussion

During and after the presentations a discussion took place that involved all of the group attendees. Key points that arose from the discussion were:

Assessing skin dryness

Assessment of dryness of the skin is difficult and may be assessed best by patients themselves. Dryness is an important feature of AD and should not be assessed in eczema lesions.

Missing features in existing tools

MB asked the presenters Carle Paul, Jean- Francois Stalder, Kim Thomas and Carolyn Charman what specific features of the other tools they would like to have in the tool they presented on?

- Carle Paul: Minimal clinically important difference is missing for the EASI. Richard Allsopp added that itch is not measured by EASI and many Astellas studies have used the modified EASI to address this issue which may prove to be a conflict.
- Jean- Francois Stalder: In the SCORAD it may be difficult to select the "average affected area". Masutaka agreed and pointed out that they select most severely affected area in Japan.
- Kim Thomas: Oedema and population has been shown to be important to patients.

In general, inter/intra-observer reliability may be low for each instrument, especially when used by non-trained investigators. However, there seem to be important data about this subject published in Japanese. Masutaka kindly agreed to send an English translation to the group.

Correlation between patient-oriented and objective scales

In which subgroup of patients poSCORAD and SCORAD do not correlate well? Jean-Francois Stalder responded that analyzing the outliers will be the next step in the research about the poSCORAD. JS speculated that high poSCORAD and lower SCORAD may indicate significantly impaired QoL or prevalent depression.

Composite scores

Composite scores may have a nonlinear distribution. Clinical meaning may be lost when using composite scores. The SCORAD measures acute and chronic clinical signs, extent, and symptoms. It is possible to focus on one subunit of the SCORAD. It is very important to ask about pruritus and sleep loss, although quantification is very difficult and is perhaps more meaningful on an "within-patient" basis. An advantage of composite scales is that they measure many different aspects that are important for AD. If scales are split, more scores are needed which may exacerbate the problem of selective reporting.

Different elements could be measured separately with view to then making composite scales of the best items. This was done for the POEM by regression analysis: The items that discriminated best were selected for the final scale.

Lessons from rheumatology

MB recommended that we should focus on the construct to be measured. Think of every item that could be in that construct. Then look what is most relevant. Some will be important, but are not possible to measure reliably. Not everything that is important should/could be incorporated into an outcome measurement.

In rheumatology, the "responder index" is used to inform the clinician about the level of improvement for an individual patient. Multiple primary outcome measures can be calculated into ESR-20. The ESR-20 assembles all the different measures into one measure and was widely used within the past 3 years.

There are additional data about outcome measures in Japanese that will be translated and then included in future systematic review updates by the HOME group.

The time dimension

Disease severity over time is also important, e.g. as a baseline characteristic or inclusion criterion in trials. The Rajka & Langeland scale (or it's derivate the Nottingham Eczema Severity Scale, NESS) is a measure that includes time course over a longer period.

Arnold Oranje indicated that the 3 items of clinical signs included in the TIS are the most important items when there is a flare and match the signs that have been shown to correlate best with disease severity reported by patients (bother).

Darker skin types

The question how to handle pigmented skin came up. Carolyn Charman: Darker skin types were included when designing the POEM.

Severity versus frequency

JS raised the question if patients should better score the severity/intensity of symptoms (e.g. VAS itch and sleep loss as in SCORAD) instead of the frequency of occurrence as done by the POEM. Carolyn Charman: Most patients find it difficult to rate the severity of the item, but not the number of days of experiencing it. Hywel pointed out that subjective scales might be more discriminative than objective measures. Paradoxically subjective measures often show more reliability/validity than the so called objective outcomes.

Role of regulatory agencies

The EMA has a preference for global assessment of disease severity. FDA has a team on outcome measurement for chronic disease. We will keep trying to involve representatives of regulatory agencies in future HOME projects. Previously, the FDA declined to contribute.[3]

Identifying and prioritising future research priorities

Group discussion (two groups)

The group of participants was again divided into two groups. The goal was to discuss which research topics would be interesting for HOME. Besides the standard eight research area items (see Table 1), each participant was asked to suggest research topics of interest. See Textbox 4 for suggestions from the groups.

Text box 4a Possible research topics and prioritization

Group 1

Proposed research topics:

- Trials in different age groups
- Definition of flare
- Flare/eczema prevention
- Applicability of trials
- Coping behavior/time off school/ work performance
- Self-efficacy overlap with empowerment
- Disease definition/definition atopy
- Psychological health
- Coping & Illness perception
- Co-morbidity associated with eczema
- Treatment adherence
- Defining Phenotypes/subgroups
- Splitting point 5 (clinical record keeping/ quality of care)
- Defining severity
- Implementation research
- Patients satisfaction
- Corticosteroid phobia in relation to treatment effect/adherence

Prioritization of research projects

- Long term control received the most votes. Signs were also considered a priority, with disease severity, QoL and symptoms all considered roughly equal priority.

Group 2

Proposed research topics:

- Definition of disease severity: mild, moderate, severe
- Disease modification

Prioritization of research projects

Identify adequate measures for the core outcome domains

1. Clinical signs
2. Symptoms
3. Long-term control
4. Define disease severity

The research project clinical signs is achievable, and therefore should be a priority for the HOME project. The QoL research project is complicated. We have to identify unmet variables.

In the discussion that followed, MB stated the process should be to first identify the domain, then the instrument, then features of the instrument: applicability, minimal clinically important difference, interpreted the outcomes. Also, we should be mindful of the time-lines.

PS mentioned that induction and maintenance of remission is used in psoriasis trials and queried whether this should be included in HOME. HW suggested we may include it in the voting.

There was suggestion that it might be more logical to have a "short term control" group and a "long term control" group OR a signs and symptoms group to avoid overlap as long term control is essentially the same as signs and symptoms, just a difference in timescales.

The group then voted **on which research projects should take priority** for HOME.

Firstly, each participant was asked through the voting system to state which stakeholder group they belong to, but this was not used to prioritize.

Participants were asked to consider from the list of potential domains which they consider to be their 3 personal favourite research topics. Then all participants were asked to rate each topic as either:

- **Very important:** defined as "*Should be ready for HOME III in 2 years time*" or
- **Important:** defined as "*To be done when manageable to do so*"

For the results of the voting, see Table 1.

Table 1: Results of voting session II:

Research topic	Personal favourites (*n* of participants)	Very important (%)	Important (%)
1. Symptom domain	10	69%	31%
2. Sign domain	20	80%	20%
3. Long-term control domain	40	86%	14%
4. QoL domain	6	47%	53%
5. Quality of care	3	18%	82%
6. Collapsing core domains and conceptual mapping	9	26%	74%
7. Biomarkers	3	12%	88%
8. Define disease severity	9	56%	44%

Conclusions from voting session II – research priorities:

- The four core domains symptoms, signs, long-term control and quality of life are very important HOME-research projects and will be prioritised. We will form a working group for each of these projects. Additionally, a working-group on the definition of disease severity appears to be very important.
- There is nothing stopping smaller groups with particular interests to pursue the research topics that were voted less important above, provided that the top projects are prioritized. HW announced that anyone willing to lead or contribute to one of these working groups should please contact HW or JS.
- Research domains are not mutually distinctive domains, so HOME working groups will need to work closely together. It was also suggested that project based groups might be better than domain based groups because of the considerable overlap.

Adopting the OMERACT-filter

The group was asked to vote on whether we should we adopt the OMERACT filter[1] as a quality requirement to recommend measures by the HOME group? The OMERACT filter consists of:

- Truth: validity
- Discrimination: sensitivity to change, responsiveness
- Feasibility: can we use this instrument at acceptable costs and time plus interpret results

Results of voting session III:

Accept/not accept: 100/0 (%).

Conclusions from voting session III - OMERACT-filter:

HOME will adopt the OMERACT filter.

Closing remarks

This meeting was attended by 43 delegates from all over the world, including clinicians, patients, methodologists and representatives from industry. Consensus was reached over the core domains to be included in future eczema trials (eczema signs, eczema symptoms, long-term control and quality of life). Several work packages were identified for development prior to the HOME III meeting, and these will now be led be specific project teams.

HOME III (date and venue to be confirmed) will concentrate on achieving consensus over the best instruments to be used when measuring the core outcome domains.

Summary of Key Points and Decisions

Processes

- Focus initially on core outcome measures for clinical research (clinical practice later)
- Consensus was reached in the voting if fewer than 30% of the voters disagree. Undecided/missing votes are counted in the agree group.
- The group voted as a whole (i.e. voting was not divided it into stakeholder groups).
- The OMERACT-filter[1] was adopted as a quality requirement.

Key decisions

Four core domains were identified and agreed:

- The three domains identified in the Delphi exercise:
    1. Symptoms
    2. Clinical signs using a score
    3. Long term control of flares
- Plus an additional domain:
    4. Quality of life
- A number of other domains (coping, biomarkers and treatment utilization) were considered for inclusion but rejected, whilst recognising their importance.

Identification and prioritisation of research projects:

- All four core domains (signs, symptoms, long-term control and quality of life).were voted as "very important" for research and take priority.
- Research to permit discussion around the selection of appropriate instruments should be completed prior to HOME III in 2013.
- A working group will be established to lead the research into each core domain.
- Other projects (including definition of disease severity which was also voted as very important) could proceed if there was sufficient interest but will not be a priority.

Action required

- Anyone willing to contribute to core domain working parties should contact HW or JS.
- Any project of relevance to the HOME initiative should be submitted to HW or JS.

Publications

- Jochen to draft a brief meeting summary in a peer reviewed journal.
- Hywel, Jochen & Phyllis draft statement on core domains, get comment from whole group, including any absent from HOME II. Submit for publication in several journals.

References

1. Boers M, Brooks P, Strand CV, Tugwell P. The OMERACT filter for Outcome Measures in Rheumatology. *J Rheumatol.* 1998;**25**:198-9.

2. Schmitt J, Langan SM, Williams HC. What are the best outcome measurements for atopic eczema? – A systematic review . *J Allergy Clin Immunol* 2007;**120**:1389-98.

3. 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**:623-30.

4. 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**:1166-8.