# Protocol for core outcomes consensus meeting- HOME V

## Title:

HOME V meeting

## Date:

1pm, Monday 12th June 2017 – 1pm Wednesday 14th June 2017

## Venue:

CCI Nantes, Nantes, France

Date of protocol: 15th May 2017

Local meeting organisers: Sebastien Barbarot, Jean-Francois Stalder

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## Abbreviations

| | |
|---|---|
| COMET | Core Outcomes for Effectiveness Trials |
| COS | Core Outcome Sets |
| HOME | Harmonising Outcome Measures for Eczema |
| OMERACT | Outcome Measures in Rheumatology |
| QoL | Quality of Life |

## Introduction

The Harmonising Outcome Measures for Eczema (HOME) initiative is an international group working together to agree a core outcome set (COS) for atopic eczema clinical trials. THE HOME initiative is coordinated from the Centre of Evidence based Dermatology, University of Nottingham.

All trials should include core outcome domains and instruments but the inclusion of core outcomes does not preclude the use of any other outcomes, scales or instruments. Participation in HOME is open to anyone with an interest in outcomes for atopic eczema.

The four core outcome domains for eczema trials are(1):

1. Clinician reported signs
2. Patient reported symptoms
3. Quality of Life
4. Long term control

The core outcome measures for clinician-reported signs and patient-reported symptoms have been established (EASI for measuring clinician-reported signs at HOME IV (2) and POEM for measuring patient-reported symptoms (3)). Work is ongoing to identify suitable instruments for quality of life and long term control to complete the core outcome set. These will be the focus of discussions at the HOME V consensus meeting.

The HOME initiative adheres to best current guidance on developing core outcome sets, including the HOME roadmap(4, 5).

## Aims

1. Long-term control domain:
    - To agree by consensus how to define the domain (roadmap stage 2).
    - To agree by consensus how to measure the domain (roadmap stage 3).
    - Agree whether any further studies are required and what these should be.
2. Quality of life (QoL) domain in children:
    - To progress towards a consensus on which instruments should be recommended for inclusion in the core outcome set for QoL in children.
3. Clinical Record Keeping:
    - To progress towards a list of validated instruments for recording key domains in routine care.

# Methods

## Study design

This is a face-to-face consensus meeting using presentations of up-to-date evidence, adapted nominal group techniques including whole group discussions, small group discussions and electronic voting.

## Participants

All members of the HOME initiative will be invited to this face-to-face consensus meeting. The HOME membership currently stands at 303 including clinicians, patients, methodologists, journal editors and pharmaceutical company representatives. Further invitations will be sent by members of the HOME initiative to other individuals particularly representative of pharma, journal editors and regulators who bring a specific perspective. Details of the meeting will be available on the HOME website(6).

Demographic data of those attending the consensus meeting will be collected and will include continent, country, stakeholder group, and trial experience.

## Meeting structure and methods

Two optional pre-meeting sessions will be offered; a patient session and a refresher/introduction session on core outcomes for non-patients. The purpose of these pre-meetings is to increase knowledge and understanding of those participating in the consensus meeting, in order to ensure meaningful engagement from all stakeholders, regardless of their experience of core outcome development or attendance at previous HOME meetings. Topics will include why core outcomes are important, methods used in COS development, lay summaries of findings to be presented at the main meeting and what is expected of meeting participants.

Members of the HOME Executive Committee and leads for the long-term control and quality of life Working Groups will chair each session, and a member of the Outcome Measures in Rheumatology (OMERACT) group will act as an independent moderator for the meeting overall. Background information and data will be presented to the group and also provided in handouts. A modified nominal group technique will be used to achieve consensus in which small-group discussions are used to ensure the opinion of all participants is taken into account in the consensus process and achieving consensus within each small group. Participants will be allocated *a priori* to their small groups to ensure a spread of stakeholder groups and geographical coverage in each.

## Consensus rules and voting

The voting rule to achieve consensus agreed at HOME II and subsequently used at HOME III and IV will be used at this meeting. Consensus is defined as having been reached when less than 30% of voters disagree (i.e. 70% agree or are unsure). Voting will be anonymous using electronic handsets and voting software, with real time results fed back to the group once voting is closed. All meeting participants will be permitted to vote (observers will be excluded from voting).

# Date and location

The consensus meeting will be held at the CCI Nantes, Nantes, France from 1pm, Monday 12th June 2017 until 1pm Wednesday 14th June 2017, with pre-meeting introduction sessions for patients and other stakeholders 10am-12pm on Monday 12th June.

# Programme

## Long-term control

The main focus of the meeting will be achieving consensus on how to define and measure the domain of 'Long-term Control'. Discussions will first focus on what is to be measured followed by more detailed discussions around the how to measure in clinical trials.

### *Session One*

Data will be presented on different options for capturing long-term control based on the results of previously conducted research including:

i) A systematic review of long-term control in eczema trials – this review summarises methods for capturing long-term control in previously published eczema trials that were of 3-months' duration or longer(7).

ii) A survey of the HOME membership – this survey provides a summary of the views of the wider HOME membership (rather than just those able to attend the consensus meeting) in defining the concept of long-term control, and the considerations that need to be taken into account regarding the different approaches to capturing LTC.

iii) International online focus groups with eczema patients and parents of children with eczema – these qualitative studies provide detailed insights into the views of patients on what long-term control means to them.

All of the above research activities have been conducted by members of the HOME Long-term Control Working Group, and will be published separately.

Once all available evidence has been presented to the group, discussion amongst the whole group will take place, followed by small group discussions to elicit views on what the domain of Long-term Control is seeking to capture and whether all potential options for measuring long-term control have been identified. It is likely that these discussions will focus on whether or not long-term control is a measure of eczema severity and/ or the impact of eczema) over time, or whether the domain represents a separate construct that requires definition (e.g. flares or well controlled weeks). The relative important of different considerations of each method will be used to inform these discussions. The small groups will feedback their views to the whole group prior to voting to reduce the potential options. Results of voting at the end of Session One will inform the content and focus of Session Two, although preliminary voting at the end of Session One will not be taken as final until discussions are complete at the end of Session Two.

### *Session Two*

The second session will build on the discussions and decision from session one, and will focus on agreeing how best to measure long-term control. The specific content of this session will depend largely on the result of the vote on the definition of the long-term control in session one. It will Results of studies conducted by members of the HOME Long-term Control working group will be presented, along with other validation studies and methodological studies conducted independently of the HOME group including:

i. Systematic reviews of flare definitions that have previously been used (8)
ii. Validation studies of methods used to capture long-term control – flares (9) and Well Controlled Weeks plus any additional validation studies identified prior to the meeting
iii. Studies exploring frequency of data collection over longer-term studies

Presentation of evidence will be followed by whole and small group discussions as for Session One, with subsequent voting on key issues.

Topics that are likely to be covered during Session Two are:

i. *Repeated measurement over time of existing HOME domains (signs, symptoms and/or QoL)* - best instruments to use, frequency of data collection required, feasibility, and methods of analysis (to ensure efficient use of data at all time points).
ii. *New constructs for capturing long-term control (e.g. flares, well-controlled weeks, medication usage)* – definitions of constructs, methods of measurement, frequency of data collection, feasibility, and methods of analysis.

The provisional voting from session 1 will be revisited prior to voting on the chosen instruments and methods of capturing long-term control.

## Quality of Life in Children

Data will be presented from systematic reviews:

i) Systematic review of what QoL instruments have been used in eczema trials (ref).
ii) Systematic review of the measurement properties of paediatric QoL instruments (ref)

These systematic reviews have been conducted by members of the QoL working group.

A summary of the minimum validation requirements of instruments to be suitable for further consideration (as stated in the COSMIN/COMET guidance on instrument selection) will be presented for each instrument. Discussion amongst the whole group will take place, followed by small group discussions to determine the long list of potential instruments and to determine the face validity of each of the potential instruments identified in the systematic review. A long-list of potential instruments identified in order to identify and prioritise future studies. Depending on the outcome of those discussions, voting will take place to either i) recommend, as an interim measure, a shortlist of potentially suitable instruments until a single instrument is chosen at the next HOME consensus meeting or ii) recommend a single instrument for the COS.

## Other topics

Other topics that will be discussed more briefly during the meeting will be:

### *Clinical Record Keeping*

The overall aim of the HOME initiative is to recommend core outcomes for both clinical trials and routine care / clinical record keeping. However, at the HOME II meeting in Amsterdam April 2011, it was decided that the initial focus of the group would be clinical trials(10). Now that good progress has been made in establishing a core outcome set for clinical trials, we plan to start work on the clinical record keeping aspect. The results of a survey of the HOME membership on clinical record keeping will be presented and the group invited to discuss the results and agree how to move forward with this topic.

### *Symptoms*

At the HOME IV meeting, POEM was agreed as the core instrument for patient-reported symptoms. An update on the activities of this working group since that decision including ongoing validation studies POEM will be presented.

## Dissemination

A report of this meeting will be published in a peer reviewed journal as rapidly as possible after the meeting. Any consensus will be published as a separate statement. All members of HOME will be encouraged to disseminate the results widely and encourage others to implement. The HOME website will be updated with resources to support the use of agreed core outcome instruments.

## Funding

Delegates will be charged a fee as follows; Industry £150, Non-industry £50, Patients free of charge.

The meeting is supported by several donations and grants from the University of Nantes, University of Nottingham), Department of Dermatology CHU Nantes and French Society of Dermatology. Bioderma and Fondation Dermatite Atopique Pierre Fabre are meeting the costs of the meeting dinners.

There will be no commercial sponsorship of the meeting.

## Conflicts of interest

All participants will be asked to complete a written conflict of interest form prior to attending the meeting, and to declare any conflicts of interest regarding instrument development and income from outcome instruments at the start of the meeting.

# Acknowledgements

**Symptoms working group**

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