Harmonizing Outcome Measures for Eczema

HOME XI Meeting

10th October 2023

Berlin, Germany

Meeting Report

List of Attendees

	Name	Stakeholder group	Country
1	Christian Apfelbacher	Researcher, Local Organiser	Germany
2	Arabella Baker	Researcher, Student	UK
3	Teresa Berents	Researcher or Healthcare Professional	Norway
4	Maria Bradley	Researcher or Healthcare Professional	Sweden
5	Elena Buñola-Hadfield	Healthcare Professional, student	UK
6	Isabel Buñola-Hadfield	Healthcare Professional, student	UK
7	Brian Calimlim	Industry Representative	USA
8	Barbara Kind	Researcher or Healthcare Professional	Germany
9	Jitske Dijkstra	Researcher	The Netherlands
10	Theresa Donhauser	Researcher, Student	Germany
11	Philipp Drewitz	Researcher, Local Organiser	Germany
12	Mike Lanigan	Student	USA
13	Lawrence Eichenfield	Healthcare professional	USA
14	Andrew Finlay	Healthcare professional	UK
15	Louise Gerbens	Healthcare professional	The Netherlands
16	Yuval Gilad	Researcher, Student	Israel
17	Tina Hadfield	Researcher or Healthcare Professional	UK
18	Luise Heinrich	Researcher or Healthcare Professional	Germany
19	Patrick Hoekstra	Researcher, Student	The Netherlands
20	Gaelle Le Bagousse-Bego	Industry Representative	France
21	Carolyn Jack	Researcher or Healthcare Professional	Canada
22	Michael Jacobson	Researcher or Healthcare Professional	USA
23	Emma Kristin Johansson	Researcher or Healthcare Professional	Sweden
24	Raquel Leão Orfali	Researcher or Healthcare Professional	Brazil
25	Katharina Piontek	Researcher or Healthcare Professional	Germany
26	Ayley Loh	Healthcare professional, Student	UK
27	Astrid Lossius	Researcher or Healthcare Professional	Norway
28	Tammi Shipowick	Patient Representative	Canada
29	Daniela Myers	Industry Representative	USA
30	Eric Simpson	Researcher or Healthcare Professional	USA
31	Kazuyoshi Okamoto	Industry Representative	Japan
32	Evangeline Pierce	Industry Representative	USA
33	Phyllis Spuls	Healthcare professional	The Netherlands
34	Åke Svensson	Healthcare professional	Sweden
35	Kaneyoshi Takahashi	Industry Representative	Japan
36	Henrique Teixeira	Industry Representative	USA
37	Kim Thomas	Researcher	UK
38	Takahiro Tsuchiya	Industry Representative	Japan
39	Amy Prestgaard	Industry Representative	USA
40	Laura Kobyletski	Healthcare professional	Sweden
41	Allison Fitzgerald	Patient Representative	Canada
42	William Romero	Industry Representative	UK

Attendees of the HOME XI meeting

Agenda

Time (CEST)	Topic	Speaker / Moderator
09:30	Meeting with patients, patient representatives and people new to HOME	Yael Leshem & Kim Thomas
10:30	Welcome coffee	
11:00	Opening and Reflection of HOME X	Eric Simpson & Christian Apfelbacher
11:20	Talks 1 - Implementation and Implementation Roadmap	Yael Leshem
	HOME core outcome set implementation in systematic reviews. How are we doing?	Isabel Buñola-Hadfield & Ayley Loh
11:40	Talks 2 - Stakeholder engagement Introduction	Yael Leshem
	Awareness, attitudes and utilization of the HOME core outcome set in atopic dermatitis clinical trialists – a survey	Yuval Gilad
12:05	Talks 3 - Universal Applicability Introduction	Kim Thomas
	Atopic Dermatitis Control Tool: Adaptation and Content Validation for Children and Caregivers of Children With Atopic Dermatitis	Gaelle Le-Bagousse-Bego
	Cross-Cultural Validation of the RECAP of Atopic Eczema Questionnaire in a Swedish Population	Laura von Kobyletzki
	Validating the use of Recap of atopic eczema (RECAP) instrument to measure eczema control of adult patients in an Asian clinical setting	Christian Apfelbacher

12:30	Talks 4 - Ease of use Introduction	Louise Gerbens & Phyllis Spuls
	How to use the HOME Core Outcomes set - a practical guide	Kim Thomas
	PROMs for Atopic Eczema: exploring feasibility and acceptability	Jitske Dijkstra
	The impact of weekly patient-reported symptom assessments on trial outcomes: results from an online randomised controlled trial in eczema	Arabella Baker
13:00	Short Poster Presentation	
13:15	Lunch Break and Posterwalk	

14:15	Small Group Discussions including coffee break	
	Stakeholder Engagement and awareness	Yael Leshem
	Universal Applicability	Eric Simpson
	How to use the HOME COS (Ease of Use)	Kim Thomas
16:00	Plenary Feedback Session • Results of Small Group Discussion • Strategy for 2024	Christian Apfelbacher
16:45	Wrap Up and Closing Statements	Eric Simpson & Christian Apfelbacher

Posters for session during lunch

Planning and initial testing of a nationwide e-health platform for atopic dermatitis patients and the use of patient related outcome measures	Laura von Kobyletzki
Assessing language variation and age suitability of RECAP: an international content validity study	Arabella Baker
Patient-centred development and validation of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure	Allison Fitzgerald
Psychometric Evaluation of Three Patient-Reported Outcome Questionnaires Assessing the Symptoms and Impacts of Atopic Dermatitis in Adults and Adolescents	Brian Calimlim
Further validation of Family Reported Outcome Measure (FROM-16): a simple practical measure of major hidden disease burden	Andrew Finlay
Measurement properties of quality-of-life outcome measures for children and adults with eczema: A systematic review update 2.0	Theresa Donhauser
Implementation of HOME core outcomes in a mobile health app for eczema management and shared decision making.	Isabelle Thibau

Tuesday 10th October 2023 (09:00 – 17:00)

Aims of the meeting

- To focus on implementation of the HOME core outcomes set (COS)
- To identify projects, resources or activities that can support uptake of the HOME COS

Participants

The meeting was attended by 42 delegates from 11 different countries. 10 (24%) were patients, patient representatives or students, 22 (52%) were healthcare professionals or researcher, 10 (24%) were from the pharmaceutical industry.

Structure of the meeting

The meeting was structured into three session.

SESSION 1: INTRODUCTION TO HOME (09.00 to 10.00)

This session introduced the HOME initiative and outlined the key activities and aims of the upcoming meeting. It was an opportunity for patients, patient representatives and people new to HOME to become familiar with the project and to ask questions in supportive environment prior to the main meeting.

SESSION 2: ORAL PRESENTATIONS (11.00 to 13.00)

This session allowed people to present updates on HOME-related projects that were ongoing or recently completed. The sessions focussed on topics relevant to the three implementation working group topics of:

- Stakeholder engagement
- Universal applicability
- Ease of use

A brief status update for each working group was provided followed by relevant submitted abstracts.

Plenary sessions included showcasing of key implementation projects and resources:

- HOME Implementation Roadmap (see: https://academic.oup.com/bjd/advance-article/doi/10.1093/bjd/ljad278/7238063?login=true)
- Showcasing of the HOME infographics package for supporting dissemination activities (http://www.homeforeczema.org/resources.aspx)

- Practical tips on how to use and report the HOME COS (paper under review)
- Survey of HOME membership to identify barriers / facilitators to uptake

Details of all submitted abstracts are provided in Appendix 1 (oral presentations and poster presentations).

Evidence presented during the meeting suggested that implementation efforts should focus on addressing some of the known barriers for implementation and gaps in our knowledge. These include:

- Consideration of the time burden of completing the COS and the need for overlapping or repetitive instruments (e.g itch captured in multiple ways)
- Clearer guidance on how to present trial reports and ensure clear and transparent reporting
- More detailed guidance and better photographs to support making EASI clinical signs assessments in people with darker skin tones.

SESSION 3: Workshop activities (14.15 to 16.45)

Participants were able to choose from one of three workshops during the afternoon session.

- Workshop A: Engagement and awareness
- Workshop B: How do we improve the HOME website to support 'universal applicability'?
- Workshop C: How to use the HOME COS (Ease of Use)

Outputs from workshops

Workshop A: Engagement and awareness

AIMS OF THE SESSION:

- To encourage attendees to feel empowered to be advocates for HOME
- To familiarize attendees with HOME advocacy
- To consider ways to broaden the HOME COS reach

ANTICIPATED OUTPUTS:

- Participants feel more empowered to be advocates for HOME
- Suggestions for future resources to be created
- Share HOME infographics and explain how they can be used
- Open discussion about how to make these available to people
- Are there innovative ways in which they can be used?
- How to use on social media?

METHODS:

Working in pairs delegates were asked to explain to each other:

- •What is a Core Outcome Set?
- •Why are they important?
- •What is the HOME COS?

This exercise was followed by open discussion:

- Shared what bits they struggled to explain or nice phrases / analogies used
- Open discussion about what other resources would be helpful for others to share info about HOME
- What social media platforms are people on? Which should we use for HOME?

KEY TAKE HOME MESSAGES/ACTIONS (WORKSHOP A)

1. **HOME Infographic publicity materials**
   Suggested amendments included:
   - Long term control add *: for studies of 3 months or longer
   - Symptoms in blue: not so clear
   - Perhaps make the 4 core domains as windows of a house, in the roof mention atopic eczema (population is currently missing).
   - Add QR-code

2. **Social media**: instagram, facebook, LinkedIn, tiktok, youtube.
   - Two medical students (Isabel and Ayley) volunteered to develop a strategy and start a social media campaign for HOME.
   - Videos of 10-20 seconds, photos, patients/physician/nurse/pharma experiences and photos are necessary for social campaigns to succeed. Build up a repository of small posts.
   - Examples of key messages that we could use: “HOME is where the COS is”, “B’COS it matters”, “Talk with your doctor about..”, “Quality research brings quality care”
   - Use skin influencers, ask patients to participate.
   - Global skin tag? For support.
   - Use a broader scope: EASI collection of the day, QoL, itch, sleep loss, sexual, ask random people, patient involvement in HOME, parts of Hywell Williams videos, new projects, linked projects (e.g. TREAT), instruments (or new instruments).

   Important side note: check how the content will be reviewed and if consent is necessary.

3. **HOME COS should be mentioned at all important/relevant conferences:** ETFAD, ISAD, IEC, PeDRA, SPIN, SUMMIT (Drug development in dermatology (all drug developers and small companies are present) --> Follow up with Henrique Texeira).
   - Provide standard slide deck about HOME COS. For presentations of RCTs, SRs, guidelines, registries.

4. **Educational programs** for medical students, residents, dermatologists, nurses, pts, pt organisations: increase awareness among doctors. Also online courses. E.g. at the EADV summer course 2023 Kim Thomas presented COS development.

   As SPIN webinar we have a presentation of Kim Thomas and Jo Chalmers on COS/HOME COS.

5. **Other ways for more engagement/awareness:**
    - Connect with e.g. manuscript central: for journal reviews a checkbox could be added --> COS used yes/no
    - Work with clinical trial registries to ensure COS are requested at point of registering trials – either as primary or secondary endpoints. Strat with Clin trials.gov and ISRCTN (other will hopefully then follow)
    - Check if COMET has worked on implementation already in WHO trial registries.
    - More videos needed: Mike Lanigan volunteered to do a "patient story" video: to tell the story why it is important that we have a COS for eczema (see example trial registration video from years ago).
    - Connect with pipeline product developers to inform them about HOME COS.
    - Connect with funders: NIH (in US) (possibly via Larry Eichenfield?), NIHR in UK
    - Connect with Cochrane skin – they already support using COS in their review protocols
    - Connect with guideline groups AAD. In the EDF guideline, HOME COS is mentioned. AAD Chu topicals mentioned HOME.
    - Make it easier to find COS: not easy on the COMET database, not easy on the C3 website.
    - Reporting guidelines EQUATOR website docs: can COS be included on this website?
    - Difficult to explain to regulatory agencies what COS are and why they are important. Highlight measurement properties/make more visible how the COS instruments show MCID.
    - Explain more why it is important for patients/pt organisations: they need to talk to their physicians about it. For shared decision docs COS are important (no blood tests are available). How do treatments perform?

    - Create more branded materials: COS store: t-shirt, mug, tile, mouse pad, ...consider sustainability issues when choosing items

Workshop B: How do we improve the HOME website to support 'universal applicability'?

AIM OF THE SESSION:
To update the HOME website and make sure it meets our implementation needs

ANTICIPATED OUTPUT:

- Summary of key changes needed to the HOME website
- Improved understanding for delegates of what is currently on the HOME website
- Improved understanding of what additional information is needed

METHODS:

Participants were briefly shown the website and were asked to identify how it aided and/or hindered the implementation efforts of the HOME initiative. Emphasis was placed on the structure and content of the website. Comparisons to similar and/or related websites such as that of the COSMIN initiative and the University of Nottingham were made. An open discussion followed whereby potential solutions to concerns deemed both of great importance and feasible to address by the group participants were brainstormed.

KEY TAKE HOME MESSAGES/ACTIONS (WORKSHOP B)

1. **HOME website-structure**
   - Recommendations focused on a theme of approaching the website structure from a user's perspective.
     - Users tend to come for solutions to specific problems
     - Content is currently organized by category (e.g. publications, HOME-CP, meetings, etc.) rather than issue (e.g. how to use the COS)
   - Other structural concerns were the use of clicked links and the balance of professionalism vs. approachability

2. **HOME website-content**
   - Participants envisioned the HOME website as a one-stop shop for all things COS. Content improvements included
     - Explaining a raison d'etre for the COS and the individual instruments
     - Addressing prominent problems with the instrument (e.g. skin of colour with the EASI)
     - Providing translations or easy access to translations as well as tools to promote the translation of instruments
     - Acknowledging current limitations of the COS/instruments
     - Increased training/educational materials

3. **Publications / presentations section**
    - Should we encourage C3 to make a website template for all COS groups or HOME just do it?
    - Organise website like COSMIN based on scenario of what looking for? Questions that help guide the user to relevant materials
    - Consider making region specific? Links to national societies etc
    - Show publications where COS is used

4. **Training section**
    - Need more training materials
    - Courses
    - Educational materials
    - EADV Taskforce for experience
    - Guidelines for assessing BSA, diagnostic criteria

5. **Patients**
    - Patient involvement

6. **EASI**
    - Replace all mentions of erythema with language appropriate for skin of colour
    - Need EASI translations into different languages

7. **Skin of colour**
    - Include its own section in menu
8. **Language**
    - Is the HOME PRO content sufficient?
    - Is the language too high level?
    - What is the target audience?

UoN POEM and RECAP sites are good examples of accessible websites.

Workshop C: How to use the HOME COS (Ease of Use)

AIM OF THE SESSION

To help people understand how the COS is intended to be used and address practical difficulties that people have encountered in using them.

ANTICIPATED OUTPUT:

- Participants have a clearer idea of how the HOME COS should be used and what resources are available to help.
- Suggestions for areas that still require more information/clarity.

METHODS:

A whole group activity to brainstorm challenges faced by people wanting to implement the HOME COS identified areas to be addressed in future guidance or research projects. This was followed by small group discussions to identify which aspects were most important to address as a priority. Delegates were each encouraged to vote for their top 3 priority topics.

SUMMARY OF KEY MESSAGES (WORKSHOP C)

Items that received the most votes as being highest priority to resolve:

1. **Redundancy of items / overlap between different instruments (6 votes)**
    - Are the items equivalent and don't need to be asked multiple times?
    - Can we streamline the COS?

    POSSIBLE RESEARCH IDEA: look at existing dataset to establish equivalence/ redundancy of different items

    NOTE: there is a small project underway looking at this, but could be expanded (currently a student project in Nottingham).

2. **Electronic / remote data collection (6 votes)**
    - Does it need to be identical to paper?
    - How to deal with mandatory fields?
    - Are eCRFs the same as paper?
    - Can you ask over the telephone?

    SOLUTIONS DISCUSSED: provide some HOME guidance based on existing guidance / evidence.

    POSSIBLE RESEARCH IDEA: comparison of paper, eCRF and telephone

3. **When is it best to complete PROMS? Before or after visit? (6 votes)**

4. **When is it best to complete PROMS? Before or after visit? (6 votes)**

5. **Questions about EASI (5 votes)**
    - Need an electronic version
    - Ease of use in clinical practice?
    - Training in how to assess it
        - Need materials to support skin colour assessment
        - How do you know if sufficiently trained
        - What experience do assessors need?
        - How to deal with remote assessment of skin skigns e.g tele-dermatology. Is it possible to assess based on photos or is face-to-face visit needed? Would welcome a HOME statement on this
        - What is the impact of light / quality of photos

6. **How to interpret the scores – bandings (3 votes)**
    a. Controlled / not controlled
    b. At what point should you trigger treatment?

7. **When and why should we use the COS in clinical practice? (3 votes)**
    a. Treatments decisions e.g when to start systemic treatment
    b. Tracking over time
    c. Standardisation across HCPs

    SOLUTIONS DISCUSSED: Need training materials, possibly country-specific and in different languages

    POSSIBLE RESEARCH IDEA: Could do an e-Delphi study to explore this and understand what people are doing around the world

8. **What order should the questionnaires be completed in and does this affect outcomes? (2 votes)**

    SOLUTIONS DISCUSSED: at least group outcome instruments according to recall period (i.e last 24 hours or last week)

9. **Age issues: (2 votes)**
    a. Validation for different ages
    b. What happen if change age category during the trial?
    c. Combining results from different ages
    d. What to do if different care giver completes the questionnaires at different visits?
    e. When to encourage self-completion versus proxy
    f. Concern raised about ADCT adaptation presented during the meeting – it the child version has fewer response categories, how can these be combined with self-complete responses of older participants?

10. **Time burden (1 vote)**
    a. How long does it take to complete al
    b. Perceived burden as well as actual
       NOTE: study ongoing about this in the Netherlands (see abstract by Jitske Dijkstra, Louise Gerbens, Phyllis Spuls)

11. **What is the best timing of assessments? (1 vote)**

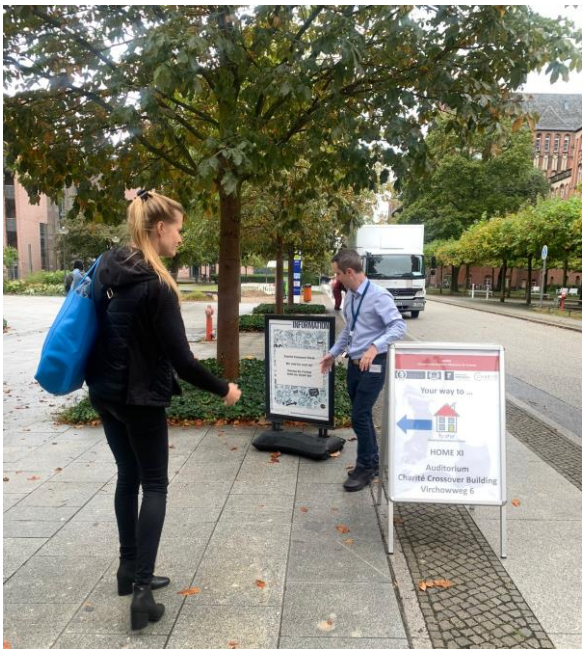
Other issues raised but not voted as highest priority to resolve:

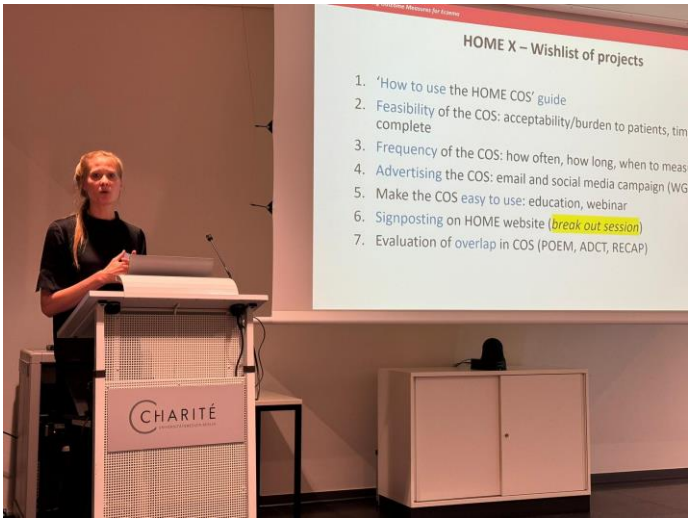
1. Are all timepoints needed for all questionnaires?

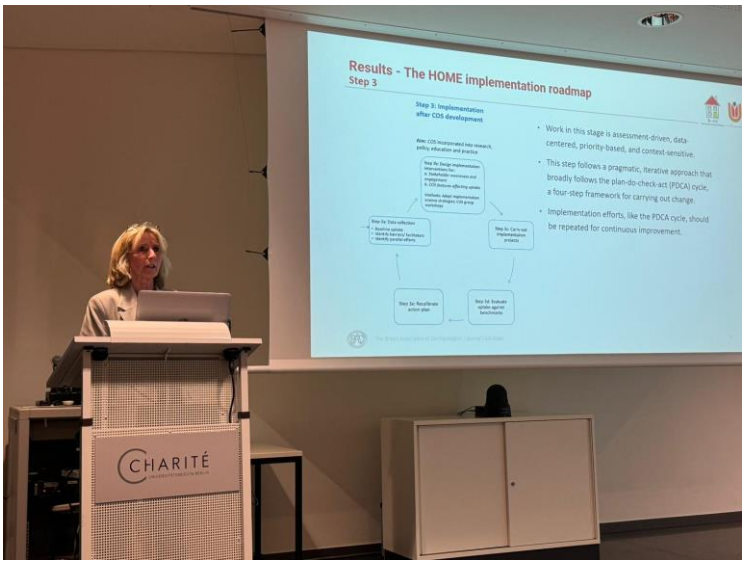
2. Signposting for participants of trials so understand topic and timeframe being asked about

3. Mapping of outcomes to other validated scales e.g DLQI to utilities, SCORAD to EASI, RECAP to ADCT

4. How best to categorise skin tone and report findings by this?


Your way to ...
HOME XI
Auditorium
Charité Crossover Building
Virchowweg 6

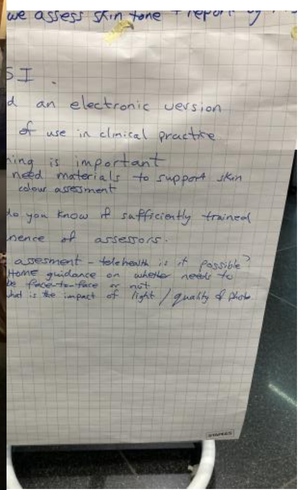

HOME X – Wishlist of projects
1. 'How to use the HOME COS' guide
2. Feasibility of the COS: acceptability/burden to patients, tim
complete
3. Frequency of the COS: how often, how long, when to meas
4. Advertising the COS: email and social media campaign (WG
5. Make the COS easy to use: education, webinar
6. Signposting on HOME website (break out session)
7. Evaluation of overlap in COS (POEM, ADCT, RECAP)
CHARITÉ

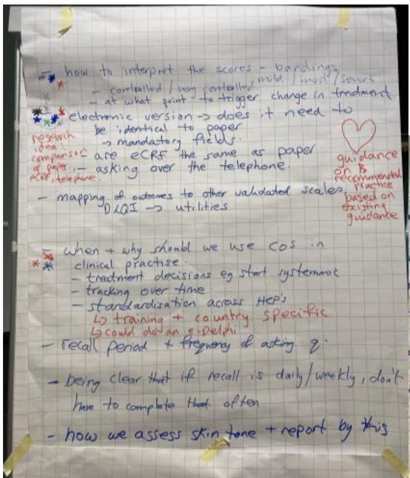

Results - The HOME implementation roadmap
Step 3
Step 3: Implementation
after COS development
Work in this stage is assessment-driven, data-centered, priority-based, and context-sensitive.
This step follows a pragmatic, iterative approach that broadly follows the plan-do-check-act (PDCA) cycle, a four-step framework for carrying out change.
Implementation efforts, like the PDCA cycle, should be repeated for continuous improvement.
CHARITÉ

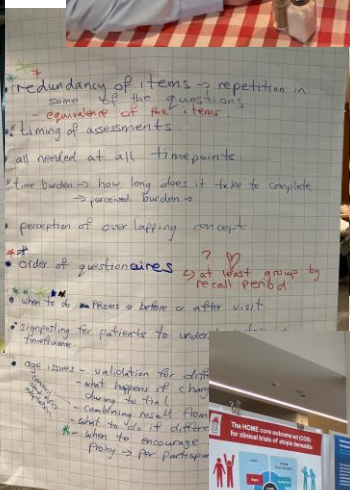

CHARITÉ


SKANE


CAMPARI
SPRITZ


we assess skin tone + report by
an electronic version
of use in clinical practice
is important
need materials to support skin colour assessment
do you know if sufficiently trained
of assessors
assessment - telehealth is it possible?
guidance on whether needs to be face-to-face or not
what is the impact of light / quality of photo


how to interpret the scores - bandings
electronic version → does it need to be identical to paper
→ mandatory fields
are eCRF the same as paper
- asking over the telephone
guidance
- mapping of outcomes to other validated scales
DLQI → utilities
- when + why should we use COS in clinical practise
- treatment decisions eg start systemic
- tracking over time
- standardization across HCPs
- training + country specific
- recall period + frequency of asking
- being clear that if recall is daily / weekly, don't have to complete that often
- how we assess skin tone + report by this


redundancy of items → repetition in some of the questions
- equivalence of the items
timing of assessments
all needed at all timepoints
time burden → how long does it take to complete
→ perceived burden
perception of overlapping concept
order of questionnaires
recall period


The HOME core outcome set (COS) for clinical trials of atopic dermatitis

APPENDIX: Submitted abstracts

ORAL

Kerry Noonan

Eric Simpson1, David M. Pariser2, Jennifer Dine3, Michelle Brown3, Sheri Fehnel3, **Kerry Noonan4**, Zhixiao Wang5, Gaelle Bego-Le Bagousse61. Oregon Health and Science University, Portland, OR, USA; 2Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, USA; 3RTI Health Solutions, Research Triangle Park, NC, USA; 4Sanofi, Cambridge, MA, USA;5Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; 6Sanofi, Chilly-Mazarin, France

Atopic Dermatitis Control Tool: Adaptation and Content Validation for Children and Caregivers of Children With Atopic Dermatitis

Introduction & Objectives: The Atopic Dermatitis Control Tool (ADCT) is a validated instrument that assesses patient-perceived control of atopic dermatitis (AD) in adults. The objective of this study was to develop two modified ADCT versions: one for children with AD aged 8–11 years and one for caregivers of children with AD aged 6 months to 11 years.
Materials & Methods: Two iterative sets of qualitative interviews were conducted in children (8–11 years) with AD and caregivers of children (6 months to 11 years) with AD to refine the Child and Caregiver ADCT versions, respectively. A subset of interviews included paired child and caregiver participants. Inclusion criteria, based on caregiver report at screening, were clinician diagnosis of AD, prescription treatment use in the past 3 months, and itching/scratching or rash in the past month. Each interview began with concept elicitation to identify important symptoms, impacts, and perceptions of AD control, followed by cognitive debriefing to test and refine the modified ADCT items.
Results: Overall, 36 participants, including 19 children (mean age 9.2 years) and 17 caregivers (mean age 36.3 years) were interviewed; 12 interviews included paired child and caregiver participants. Most children and caregivers reported that AD symptoms, particularly itch, negatively impacted daily activities, such as playtime and school time, as well as sleep. The responses between children and caregivers on their respective versions were generally wellaligned, although questions related to the impact of AD on sleep, daily activities, and mood and emotions, in some cases generated a more frequent response from caregivers.
Conclusions: Both the Child and Caregiver ADCT versions were shown to have content and face validity. Quantitative validation of the Child and Caregiver AD

Isabel Bunola-Hadfield

Isabel Bunola-Hadfield (University of Nottingham), Ayley Loh (University of Nottingham), Kim Thomas (University of Nottingham)

HOME core outcome set implementation in systematic reviews. How are we doing?

We are currently resolving all disparities in data extraction therefore the results below are preliminary. Importance: Core outcome sets (COS) reduce selective reporting bias and increase homogeneity facilitating meta-analyses thereby reducing research waste. In the context of systematic reviews implementation facilitates updating reviews and contributes to the efficient use

of available research.
Objective: To assess the frequency of the HOME COS implementation over time in systematic reviews. The long-term outcome domain was not assessed due to its recent definition.
Review selection: Systematic reviews looking at eczema intervention containing randomised controlled trials published between 01/10/2010 – 01/02/2022 were included. No language restrictions were applied. Data was extracted in duplicate.
Main outcomes and measures: Implementation of the domains: signs; symptoms; and quality-of-life. Implementation of the instruments: Eczema Area and Severity Index (EASI); and Patient Oriented Eczema Measure (POEM). Secondary outcomes: Outcomes included frequency of meta-analyses of signs and/or symptoms; whether the HOME COS was mentioned; and whether there was any pattern between implementation and review quality.
Results: One hundred forty-four systematic reviews met the inclusion criteria. Implementation of the signs and symptoms domains were above 90% and did not show a time trend. The implementation of the quality-of-life domain decreased from 80% in 2012 to 55% in 2022. The implementation of both instruments increased from 10% in 2012 to 35% in 2022, EASI had consistently higher implementation than POEM. It was also noted that higher quality reviews reported both instruments more frequently than low quality reviews. The frequency of meta-analyses of signs and/or symptoms respectively increased since the 2012 publication of the COS. HOME was referred to in 29/144(20%) of reviews.
Conclusions and relevance: The COS is yet to be uniformly implemented in reviews, despite positive improvements and changes in reviewer's choices. A concerted effort is required to improve HOME COS reporting in systematic reviews. Further research is required to formulate an evidence-based plan to improve COS uptake.

Arabella Baker

Arabella Baker1,2, Eleanor J Mitchell2, Christopher Partlett2, Kim S Thomas1

1Centre of Evidence Based Dermatology, School of Medicine, University of Nottingham, Nottingham, UK
2Nottingham Clinical Trials Unit, School of Medicine, University of Nottingham, Nottingham, UK

The impact of weekly patient-reported symptom assessments on trial outcomes: results from an online randomised controlled trial in eczema

Background: Patient-reported outcome measures (PROMs) are commonly utilised in eczema clinical trials. Several trials have used PROMs weekly for symptom monitoring. However, the increased frequency of patient-reported symptom monitoring may prompt participants to enhance the self-management of eczema and increase standard topical treatment use that can lead to improvements in outcomes over time. This is concerning since weekly symptom assessments may constitute an unplanned intervention, which may mask small treatment effects and make it difficult to identify changes in the eczema resulting from the treatment under investigation.
Objectives: To evaluate the effect of weekly patient-reported symptom monitoring on trial outcomes and to inform the design of future eczema trials.
Methods: This was an online, parallel group, randomised controlled trial. People with eczema were recruited from social media. Electronic PROMs were used for data collection. Participants were randomised (1:1) to weekly POEM for 7 weeks (intervention) or no POEM completion during this period (control). Primary outcome was change in eczema severity based on POEM scores, assessed at baseline and week 8. Secondary outcomes included change in standard topical treatment use and data completeness at follow- up. Analyses were conducted according to randomised groups in those with complete data at week 8

Results: In four months, a total of 296 participants were randomised: 71% female, 77% white, mean age 26.7 years. Completion rate of follow-up was 82% (242/296, 82%; intervention group n = 118/147, 80% and control group n = 124/149, 83%). After adjusting for baseline disease severity and age, eczema severity improved in the intervention group: mean difference in POEM score -1.64 (95% CI -2.91 to -0.38; p = 0.01). No between group differences noted in the use of standard topical treatments and data completeness at follow-up.
Conclusions: Weekly patient-reported symptom monitoring led to a small perceived improvement in eczema severity.

Isabelle Thibau

Isabelle J.C. Thibau, MPH1, Bryan Mantell1, Wendy Smith Begolka, MBS1
1National Eczema Association, Novato, CA, USA

Implementation of HOME core outcomes in a mobile health app for eczema management and shared decision making.

Shared decision making (SDM) can improve patient outcomes and is well-suited for eczema where there is considerable clinical heterogeneity and treatment approaches. The National Eczema Association integrated instruments identified by the Harmonizing Outcome Measures for Eczema (HOME) group into EczemaWise – an app for patients and caregivers to log their symptoms, treatments, triggers, and prepare for SDM with their doctor. It is important that instruments used in a mobile health tool collects patient-reported outcomes identified by HOME so that real-world data collected outside the doctor's office is comparable to data collected at the doctor's office, ideally supporting patient-doctor SDM. Outcome tools from HOME in EczemaWise include PO-SCORAD as separate skin, itch, and sleep trackers; RECAP as questions in the annual survey, and the DLQI (adults), CDLQI (caregivers of children) and FDLQI (caregivers of other) as questions in the annual survey. We analyzed data from EczemaWise users registered between October 12, 2020-June 07, 2023 for tracker usage. Inclusion criteria (U.S. residents, opened EczemaWise ≥1 post-registration) were met by 40% (4,770/11,817). Users are adult patients (80%) and caregivers (20%), with most reporting an account for a female patient (75%), of White race (61%), non-Hispanic (85%), and mean age of 29.9 years (±17.7). We developed educational materials for patients and caregivers on the importance of logging their symptoms and specifically the usefulness of the PO-SCORAD for personal insights and in SDM. Of 36,232 app opens, 22,619 were tracking sessions by 4,360 users, averaging 5.2 (±18.3) tracking sessions/year. Average PO-SCORAD for users who completed skin+itch+sleep trackers was 34.63 (±18.77). Educational materials include emails, news articles, instagram posts, and in-app communications. We're additionally developing a health report feature for users to see changes in their severity, control, and quality of life scores based on tracking and survey activity which they can subsequently share with their doctor.

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Validating the use of Recap of atopic eczema (RECAP) instrument to measure eczema control of adult patients in an Asian clinical setting.

RECAP is a self-reported seven-item questionnaire recommended by Harmonising Outcome Measures in Eczema initiative (2019) to measure eczema control. We aim to validate RECAP as a measure of eczema control in our clinical setting with Asian adult eczema patients. Patients with atopic dermatitis (AD) from July 2019 to January 2020 were recruited to complete RECAP, Patient-Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI). Clinical severity data with SCORAD (SCORing Atopic Dermatitis) and Eczema Area Severity Index (EASI) were collected. Construct validity in the form of correlation analysis and floor or ceiling effects of RECAP were assessed. Qualitative feedback was obtained with structured interview surveys. A total of 260 AD patients aged between 15 to 87 years-old were recruited. Majority of participants were Chinese (87.1%). RECAP scores were normally distributed with a mean score of 13.7(±6.9) and no floor or ceiling effect was noted. There were strong correlations of RECAP with POEM($r=0.84, p<0.001$), DLQI($r=0.81, p<0.001$) and SCORAD($r=0.60, p<0.001$). Discriminative validity was demonstrated by a significant linear trend of RECAP scores with increasing eczema severity by both POEM ($p <0.001$) and SCORAD ($p<0.001$). Patients with more severe eczema had higher mean RECAP scores. RECAP demonstrates good construct validity evidenced by strong correlations with symptoms and quality of life and moderate correlations with eczema signs. RECAP is useful to measure eczema control in our Asian clinical setting.

Kim Thomas

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How to use the HOME Core Outcomes set – a practical guide

The Harmonizing Outcome Measures for Eczema (HOME) initiative has agreed the core outcome set for use in eczema clinical trials, but additional guidance is needed to maximise uptake of the core set. This talk will provide guidance on how to use the HOME core set effectively and how to ensure that all data are reported transparently and appropriately. It will address common questions that people ask when trying to use the core instruments, signpost to key resources and highlight reporting requirements. By encouraging adoption of the core outcome set and facilitating consistent reporting of outcome data, we hope that results of eczema trials will be more readily combined in meta-analyses and patient care will be improved. Improving the reporting of trial data in a consistent way can significantly boost the power of sub-group analyses in systematic reviews and help make informed personalised-medicine decisions.

POSTER

Andrew Finlay

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Further validation of Family Reported Outcome Measure (FROM-16): a simple practical measure of major hidden disease burden

Atopic dermatitis and other diseases have an often hidden or ignored major impact on the lives of partners and family members. Measurement of this burden could identify those affected, inform clinical decisions, stimulate methodology to relieve the burden and allow incorporation into appraisal of novel therapies. The Family Reported Outcome Measure (FROM-16) (1) is a generic instrument, thereby allowing data comparison across different diseases. Developed using Rasch and factor analysis, it was validated across 26 medical specialties, including dermatology. It measures the impact on adult family members of having a relative of any age with a health condition. In an online UK study (2), 4,413 family members completed FROM-16 and a global question (GQ). Various score meaning band sets were devised and the FROM-16 band set with the best agreement with GQ based on weighted kappa selected: 0–1=no effect on quality of life of family member; 2–8=small effect; 9–16=moderate effect; 17–25=very large effect; 26–32=extremely large effect (weighted kappa=0.60). 4,228 family members completed FROM-16 and EQ-5D. Split-half cross-validation of FROM-16 data resulted in 10 multinomial logistic models: Monte Carlo simulation generated predicted EQ-5D-3L responses: calculated utility scores were compared with observed values. The highly predictive model allows calculation of EQ-5D health utility estimates from FROM-16 scores. Responsiveness and minimum important change (MIC) for FROM-16 were assessed prospectively in 83 patients and family members who completed EQ-5D and FROM-16 at baseline and three months after starting a new therapy. This study confirmed the longitudinal validity of FROM-16 and suggested a MIC value of 4 for FROM-16. FROM-16 has demonstrated major family impact of Covid-19(3) and of myalgic encephalitis(4). FROM-16 is available in >25 translations(5). The recent validation has transformed FROM-16's utility as a research tool and it could now be useful in routine practice across medicine.

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Psychometric Evaluation of Three Patient-Reported Outcome Questionnaires Assessing the Symptoms and Impacts of Atopic Dermatitis in Adults and Adolescents

The Atopic Dermatitis Symptom Scale (ADerm-SS) and the Atopic Dermatitis Impact Scale (ADerm-IS) were developed to measure the symptoms and impacts of AD, respectively. The ADerm-SS is an 11-item questionnaire (0-10 numerical rating scale [NRS] for each item) with a 7-item total symptom score developed (ADerm-SS TSS-7; range 0-70). The ADerm-IS uses 10 items (0-10 NRS) to score three domains: Sleep (range 0-30), Daily Activities (range 0-40), and Emotional State (range 0-30). The Worst Pruritus NRS (WP-NRS) measures itch severity at its worst (single-item; range 0-10). This study evaluated the psychometric properties of the ADerm-SS TSS-7, ADerm-IS, and Worst Pruritus NRS scores.
Clinical trial data of adolescent and adult patients with moderate-to-severe AD were used. A priori factor structures were evaluated by confirmatory factor analyses (CFAs). Test-retest reliability, internal consistency reliability, and convergent validity were assessed by intraclass correlation coefficient (ICC), Cronbach's Alpha (Cr-α), and correlation coefficient (r), respectively. Responder definitions were evaluated using anchor-based analyses.
Adolescents (age 12-17; n=113) and adults (age 18-75; n=769) were included. Scores showed no floor or ceiling effects. The CFAs supported the three ADerm-IS domains and unidimensionality for the ADerm-SS TSS-7. Scores demonstrated internal consistency reliability (Cr-α > 0.89) and adequate test-retest reliability in adults (ICC > 0.60). ADerm-SS TSS-7 and WP-NRS were strongly correlated with the Patient Oriented Eczema Measure (r=0.70-0.80); ADerm-IS domains were strongly correlated with the Dermatology Life Quality Index (r=0.63-0.78). Estimates of minimally important within-person change were: 19-29 points for ADerm-SS TSS-7; 8-13 points for ADerm-IS Sleep; 10-16 points for ADerm-IS Daily Activities; 8-12 points for ADerm-IS Emotional State; and 3-4 points for WP-NRS.
Results demonstrate the reliability, convergent validity, and meaning of change for the ADerm-SS TSS-7, ADerm-IS, and Worst Pruritus NRS scores within adults and adolescents with moderate-to-severe AD.

Jennifer Austin

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Patient-centred development and validation of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure

Existing dermatology-specific patient-reported outcome measures (PROMs) do not fully capture the substantial physical, psychological, and social impact on patients' lives and are not recommended for use according to the COSMIN criteria. We have developed the new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients through a mixed methods study consisting of five phases: 1) COSMIN systematic review. 2) Qualitative interviews developing the conceptual framework of impact and generating items. 3) Delphi study eliciting consensus from patients on items to prioritise for inclusion in PRIDD. 4) Cognitive interviews evaluating content validity, acceptability, and feasibility. 5) Psychometric testing. Adults (≥ 18 years) living with a dermatological condition worldwide were recruited through GlobalSkin's membership network of over 200 patient organisations worldwide. 2,221 people representing 90 conditions from 61 countries participated. 1) None of the 36 PROMs evaluated in the systematic review were recommended for use. 2) The conceptual framework depicted impact as a multifaceted construct involving physical, life responsibilities, psychological, social and financial impacts. 3) The Delphi study reduced the item pool of 263 to 27. 4) Cognitive interviews produced a 26-item PRIDD with evidence of content validity, feasibility, and acceptability. 5) Psychometric testing produced the final 16-item PRIDD with four domains: physical, life responsibilities, psychological and social. PRIDD fitted the Rasch model and met the COSMIN criteria for content validity, structural validity, internal consistency, construct validity, and test-retest reliability. PRIDD is a valid and reliable tool to help clinicians provide better care and stakeholders to understand the global burden of dermatological disease. It is the first theory-led dermatology-specific PROM developed in partnership with patients and patient organisations worldwide and meets the COSMIN criteria. The next steps include further testing of measurement error and responsiveness, cross-cultural translation, linguistic validation, and collecting global data on the life impact of dermatological conditions.

Arabella Baker

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Assessing language variation and age suitability of RECAP: an international content validity study

Background: Eczema is a common, inflammatory, itchy skin condition characterised by periods of increased disease activity and relative remission, affecting both children and adults. Patient-reported eczema control is an important outcome when evaluating treatments. The Recap of atopic eczema (RECAP) is a patient-reported outcome measure (PROM) assessing eczema control and it is part of the core outcome set for eczema. This instrument was developed and validated in the UK. There is a self-reported and a proxy-reported version in English, Dutch and German. However, it is unclear whether the self-reported version shows adequate content validity when completed by young people in these languages.

Objectives: To assess the content validity (comprehensibility, relevance and comprehensiveness) of the English, German and Dutch versions of the self-reported RECAP in young people with eczema and to identify the most appropriate age cut-off for self-completion.

Methods: We conducted 23 semi-structured cognitive interviews with young people from 8 to 16 years, using the "think-aloud" method. In Germany and the Netherlands, participants were recruited in dermatology clinics and in the UK through social media. Interviews were audio recorded, transcribed verbatim and analysed in the three languages, using a problem-focused coding manual. Transcripts were coded by two independent reviewers in each country. Themes were translated into English and compared across the three countries.

Results: Significant age-related comprehensibility issues with the last three items of the questionnaire occurred with young people aged 8 to 11 years, causing difficulties in completing RECAP without assistance. However, older children had only minor problems and were able to complete the questionnaire by themselves. The self-reported version of RECAP has sufficient content validity for self-completion in young people aged 12 years and above.

Conclusions: The self-reported version of RECAP is appropriate for use from the age of 12 years and above. The proxy-version is suitable for children younger than 12 years.

Laura von Kobyletzki

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Planning and initial testing of a nationwide e-health platform for atopic dermatitis patients and the use of patient related outcome measures. Patient education is central for reaching treatment goals. There are huge differences across Sweden in the organization and availability of patient education. We plan to create a prototype of a digital patient education platform for AD, and to assess the effect of a reduction in the severity of the disease compared with standard care. An E-health platform was assessed as useful for patient education. The following five themes with several items were

important to patients and their caregivers. i. Help to prepare health care contact including treatment plan, where and how to seek care and information about what treatment options are available. ii. Information about self-care. iii. Information about AD, symptoms, and trigger factors. iv. Tools to follow the severity of AD. V. Information related to social impact of AD. The content of the platform will be based on the needs of the patients and caregivers to patients that were identified. The platform will be built in accordance with scientific evidence together with researchers, physicians, and patient representatives.

Further results will be described: The use of patient related outcome measures (PROMS) in an AD e-health platform will be presented. In detail, PROMS will be used as a tool to identify triggers, to assess treatment effect and to follow the course of AD. The efficacy of the platform will be assessed using validated outcome measures for AD including self-assessed severity of AD and quality of life (QoL) and compared to persons with AD using standard care. Patient satisfaction, and feasibility will also be assessed.

~~These were the poster ones~~

~~Planning and initial testing of a nationwide e-health platform for atopic dermatitis patients and the use of patient related outcome measures~~	~~Laura von Kobyletzki~~
~~Assessing language variation and age suitability of RECAP: an international content validity study~~	~~Arabella Baker~~
~~Patient-centred development and validation of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure~~	~~Jennifer Austin~~
~~Psychometric Evaluation of Three Patient-Reported Outcome Questionnaires Assessing the Symptoms and Impacts of Atopic Dermatitis in Adults and Adolescents~~	~~TBA (Calimlim/Abernathy?)~~
~~Further validation of Family Reported Outcome Measure (FROM-16): a simple practical measure of major hidden disease burden~~	~~Andrew Finlay~~