

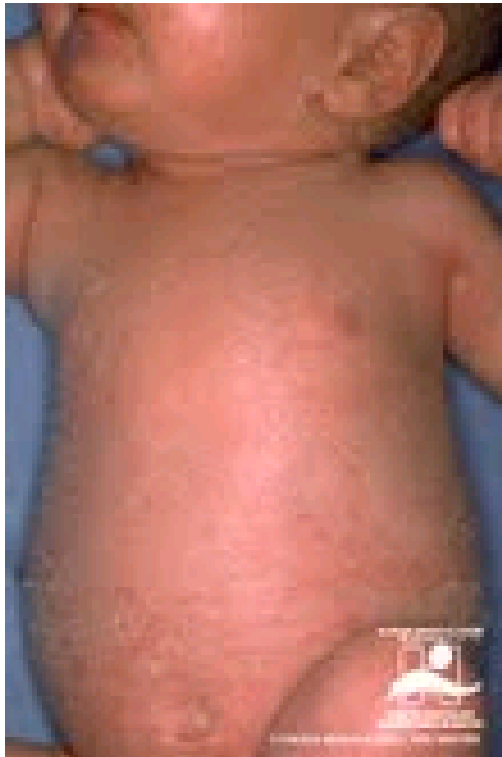
The Harmonizing Outcome Measures for Eczema (HOME) Roadmap

COMET meeting, Rome, 19/11/2014

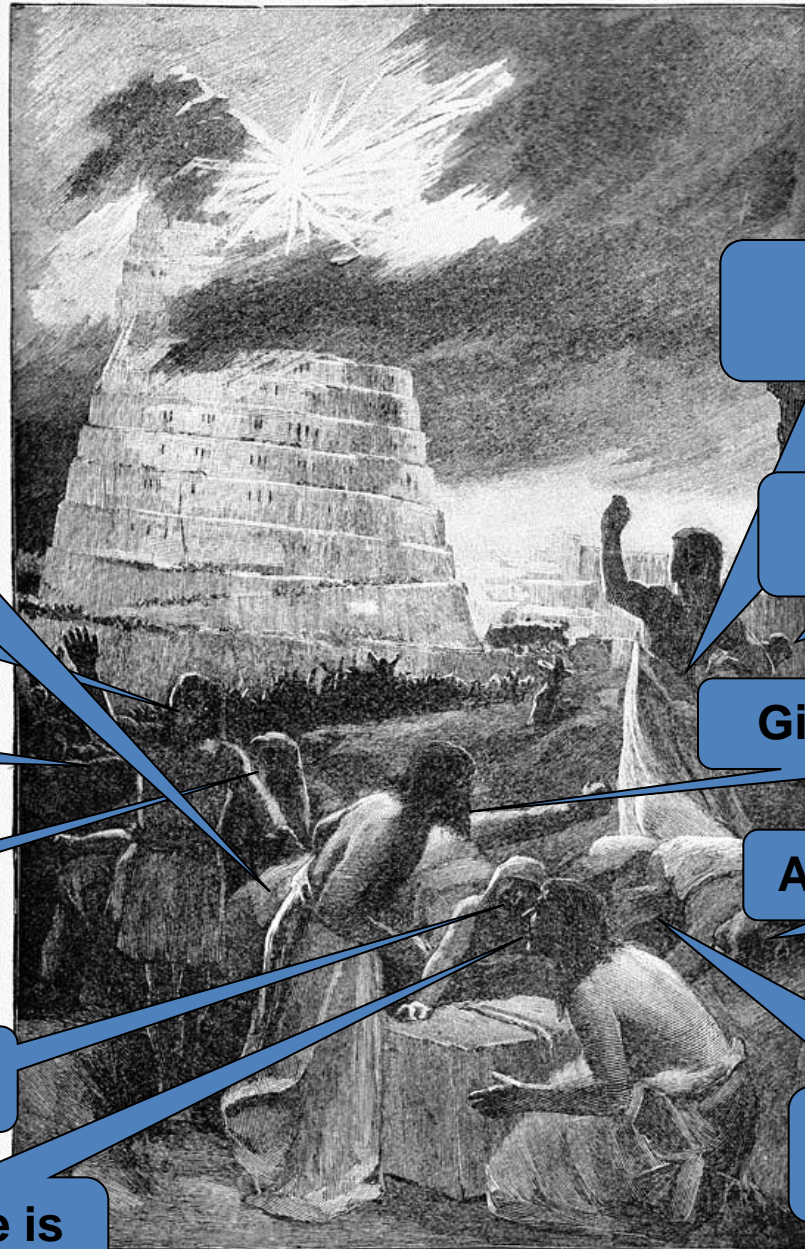
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The problem



Atopic
eczema/eczema/atopic
dermatitis
(Neurodermitis)



**What's all
the FSSS
about?**

**Take it
EASI**

**TIS a right
mess**

Me too!

Meet my SIS

**My name is
ADAM**

**SCORAD scores
again**

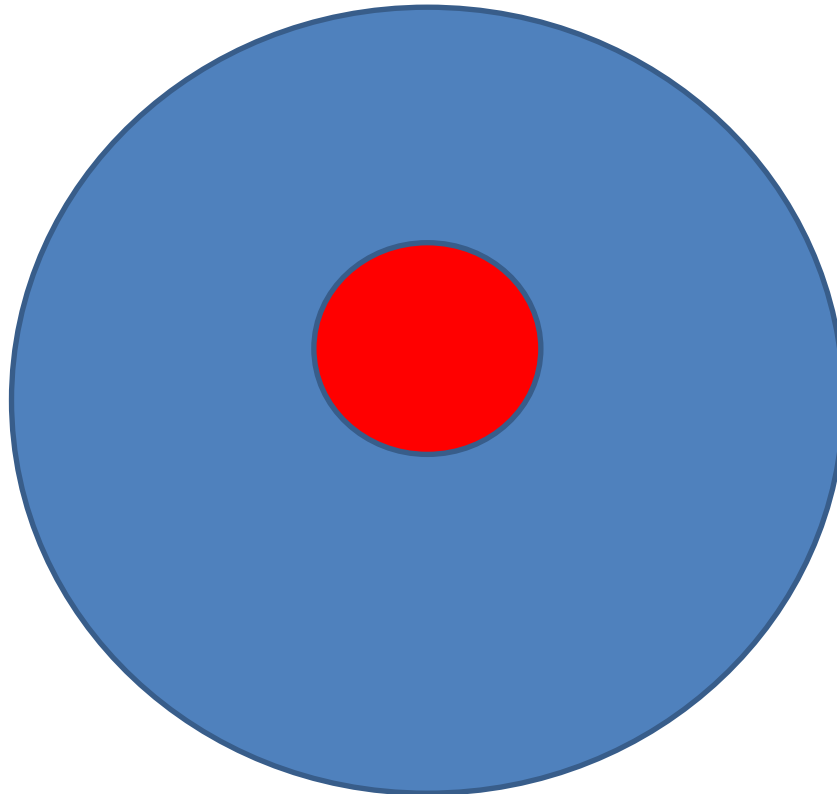
**SASSAD rules
OK**

Give me a POEM

ADASI tonight?

**IGADA bad
headache**

What we need: *core* outcomes set (COS)



The HOME initiative

HOME = Harmonizing Outcome Measures for Eczema

Founded in 2010 (Schmitt and Williams 2010)

Aim: to develop and implement a COS for (atopic) eczema

Global & multiprofessional

Evidence-driven and evidence-generating

The HOME roadmap

Methods to develop and implement COS not standardized (Williamson 2012)

➔ Need for a methodological framework

The Harmonizing Outcome Measures for Eczema (HOME) Roadmap: A Methodological Framework to Develop Core Sets of Outcome Measurements in Dermatology

Jochen Schmitt¹, Christian Apfelbacher², Phyllis I. Spuls³, Kim S. Thomas⁴, Eric L. Simpson⁵, Masutaka Furue⁶, Joanne Chalmers⁴ and Hywel C. Williams⁴

Step 1: Define scope and applicability
 Population (condition)
 Intervention
 Setting (e.g., trial, registry, clinical practice)
 Geographical/regional scope*
 Stakeholders

Step 2: Develop core set of outcome domains
 Consensus study involving representatives of relevant stakeholders

Step 3: Develop core set of outcome measurements
 Identification and recommendation of adequate measurement instrument(s) for each core outcome domain by a 5-stage process

	Stage 1 →	Stage 2 →	Stage 3 →			Stage 4 →	Stage 5
Task	Identify all instruments previously used to measure the domain.	Establish the extent and quality of testing of the identified instruments.	Determine which instruments are good enough quality and meet the requirements of the OMERACT filter and be shortlisted for further consideration.			Carry out validation studies on shortlisted scales.	Finalize of core outcome instrument for domain.
Methodology	Systematic review of outcome instruments used.	Systematic review of validation studies of the long-list of identified instruments. Highlight any gaps in validation.	Apply OMERACT filter; truth, discrimination, and feasibility:			Consensus discussion and voting to determine what validation studies will be conducted on short-listed instruments. Gaps in testing were highlighted in stage 2 (systematic review). Appropriate methods used to fill the gaps in validation.	Reapply the OMERACT filter with the results of the completed validation studies. Consensus discussion and voting on core outcome to be recommended.
			Truth "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"	Discrimination "Does the measure discriminate between situation that are of interest?"	Feasibility "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"		
			Consensus discussion and voting on truth: 1. Face validity 2. Content validity 3. Construct validity 4. Criterion validity	Consensus discussion and voting on discrimination: 1. Reliability 2. Sensitivity to change	Consensus discussion and voting on feasibility: 1. Time take 2. Cost 3. Interpretability		
Output	Long list of all instruments previously used to measure the domain.	Summary of which instruments have been tested and the quality, extent, and results of any testing.	Short-list of potential instruments that meet the requirements of the OMERACT filter.			Short list of fully tested instruments.	Recommended core outcome instrument for the domain.

Step 4: Disseminate, prepare guidance material, review, and possibly revise core set of outcome measurements

Schmitt 2014 JID

Step 1: Define scope

- Condition: (atopic) eczema
- Setting: clinical trials & recordkeeping
- Geographical scope: global
- Stakeholders: patients, healthcare professionals, researchers, regulatory agencies, pharmaceutical companies

Involving stakeholders globally needs proactive approach!

Step 2: Define core set of outcome domains

Use of consensus methodology, e.g. Delphi

Consensus process should be based on *a priori* protocol

Protocol should include consensus rules

HOME agreed that consensus is reached when less than 30% of voters disagree

HOME Delphi questionnaire

Indication of the importance of outcome domains for eczema on a 9-point Likert scale (rounds 1 and 2)

Scores 1-3: domain is not important

Scores 4-6: equivocal

Scores 7-9: domain is important

Final round: Explicit question on whether or not to include outcome domain into the core set

2 different contexts / settings

Clinical trials

Record keeping in daily practice

Outcome domain Universität Regensburg	Proportion recommending including outcome domain into the CORE SET of outcomes for eczema that should be routinely assessed in every CLINICAL TRIAL on eczema?				Consensus to include domain into core set		
	Consumers (n=6)	Experts (n=29)	Agency (n=1)	Editors (n=7)	YES	Un-clear	NO
Clinical signs (physician)	100%	100%	100%	100%	•		
Clinical signs (patient)	17%	21%	0%	0%			•
Investigator global assessment	33%	59%	0%	57%			•
Patient global assessment of	17%	34%	0%	29%			•
Symptoms	83%	76%	0%	57%	•		
Quality of life (specific)	33%	72%	100%	86%		•	
Quality of life (general)	17%	3%	0%	0%			•
Short term control of flares	33%	7%	0%	0%			•
Long term control of flares	67%	62%	100%	43%	•		
Cost	17%	3%	0%	0%			•
Overall extent of disease	17%	21%	0%	14%			•
Involvement of high expr. areas	17%	7%	0%	14%			•
Treatment utilization	17%	31%	0%	14%			•

Preliminary core set of outcome domains

Clinical trials

- Measurement of eczema symptoms
- Physician-assessed clinical signs using a score
- Measurement for long term control of flares

Recordkeeping in daily practice

- Measurement of eczema symptoms

HOME II meeting (Amsterdam 2011)

- 43 people came from around the world (included 4 consumers)
- Presentations, discussions and key pad voting
- Consensus rules – if less than 30% disagree

Results from HOME II

Refined core set of domains to include:

- ✓ Symptoms
- ✓ Clinical signs using a score
- ✓ Long term control of flares
- ✓ Quality of life

HOME working groups

Signs Group	Symptoms	Long term control	Quality of Life
Jochen Schmitt (Lead)	Phyllis Spuls (Lead)	Kim Thomas (Lead)	Christian
Valeria Aoki	Tim Burton	Richard Allsopp	Apfelbacher(Lead)
Marjolein de Bruin-Weller	Joanne Chalmers	Valeria Aoki	Shehla Admani
Stefanie Deckert	Carolyn Charman	Sebastien Barbarot	Julie Block
Thomas Diepgen	Baraka Chaula	Carl Bruijnzeel-Koomen	Sarah Chamlin
Regina Foelster-Holst	Ulf Darsow	Kevin Cooper	Mary-Margaret Chren
Laura von Kobyletzki	Regina Foelster-Holst	Thomas Diepgen	Magdalene Dohil
Jon Hanifin	Masutaka Furue	Carsten Flohr	Uwe Gieler
Dedee Murrell	Jon Hanifin	Jon Hanifin	Daniel Heint
Mandy Schram	Ellis Hon	Yoko Kataoka	Rosemary Humphreys
Eric Simpson	Norito Katoh	Sinead Langan	Henrique Akira Ishii
Phyllis Spuls	Helen Nankervis	Areti Makrygeorgeou	Willem Kouwenhoven
Ake Svensson	Cecilia Prinsen	David Margolis	Sue Lewis-Jones
Kim Thomas	Matthew Ridd	Dedee Murrell	Stephanie Merhand
Carl Frederik Wahgren	Hidehisa Saeki	Luigi Naldi	Kaspar Mossman
Tobias Weberschock	Kim Thomas	Amy Paller	Yukihiro Ohya
	Elke Weisshaar	Matthew Ridd	Cecilia Prinsen
		Marie-Louise Schuttelaar	Harmieke van
		Kyle Tang	Os-Medendorp
		Annika Volke	
		Stephan Weidinger	
		Andreas Wollenberg	

Structure of the HOME initiative

Executive Committee

Scientific Advisory Board

Project Coordinator (based at the
Centre of Evidence Based Medicine
in Nottingham, UK)

Research working groups

Step 3: Define core set of outcome measurement instruments

- Aim: identify, validate, or develop an appropriate measurement instrument for each core outcome domain
- Ideally, one best instrument should be identified for each core outcome domain
- Five stages

Stages 1 & 2

Aim	Identify all measurement instruments previously used to assess the domain of interest
Method	Systematic review
Output	Long list of outcome measurement instruments

Aim	To investigate the extent and quality of testing and the measurement properties of existing measurement instruments
Method	Systematic review
Output	Summary of extent, quality and results of any testing of the existing measurement instruments

Stage 3

Aim	Determine which instruments are of good enough quality to be shortlisted for further consideration
Method	Consensus discussion and voting in relation to truth, discrimination and feasibility (OMERACT filter, Boers 1998)
Output	Short list of potential instruments that meet the requirements of the OMERACT filter

Stage 4

Aim	To fully validate shortlisted measurement instruments (to fill the gaps in validation)
Method	Consensus discussion and voting to determine what validation studies need to be conducted Appropriate methods for validation studies
Output	Short list of fully tested instruments

Stage 5

Aim	To determine the core outcome instrument for the domain of interest
Method	<p>Re-application of the OMERACT filter with the results of the completed validation studies</p> <p>Consensus discussion and voting to determine on core outcome instrument to be recommended</p>
Output	Recommended core outcome measurement instrument

HOME III meeting, San Diego 2013



HOME III meeting

Roadmap completed for the domain „clinical signs“

Systematic review indicated that only the Eczema Area Severity Index (EASI) and the objective Scoring Atopic Dermatitis Index (SCORAD) could be shortlisted (Schmitt 2013 JACI)

International consensus process during the HOME III meeting: consensus that the EASI is the preferred instrument (Chalmers 2014 BJD)

HOME III meeting 2013



Consensus statement

The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials

Jochen Schmitt, MD,^a Phyllis I. Spuls, MD, PhD,^b Kim S. Thomas, PhD,^c Eric Simpson, MD,^d Masutaka Furue, MD,^e Stefanie Deckert, MPH,^a Magdalene Dohil, MD,^f Christian Apfelbacher, PhD,^g Jasvinder A. Singh, MD,^h Joanne Chalmers, PhD,^c and Hywel C. Williams, DSc,^c on behalf of the HOME initiative collaborators* *Dresden and Regensburg, Germany, Amsterdam, The Netherlands, Nottingham, United Kingdom, Portland, Ore, Fukuoka, Japan, San Diego, Calif, and Birmingham, Ala*

Schmitt 2014 JACI

Step 4: Dissemination & Implementation

- Publication in leading journals
- Dissemination to journal editors
- Presentations at relevant meetings
- Dissemination to industry and regulatory authorities
- Development of guidance material is recommended

Important: implementation strategy!

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Summary

The HOME roadmap provides a methodological framework & guidance for COS development

Roadmap completed for the domain „clinical signs“

Working groups have started to work on the core domains „symptoms“, „quality of life“ and „long term control of flares“

Useful for other COS initiatives in dermatology (COS developments for vitiligo and melanoma are underway) and beyond

further information:

www.homeforeczema.org

Thank you very much for
your attention!