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## The Cochrane Skin Group Core Outcomes Set Initiative (CSG-COUSIN)

*“Our mission is to develop and implement core outcome sets in dermatology in order to improve and standardize outcome measurement in clinical trials and to make trial evidence more useful.”*

### **Who is working in CSG-COUSIN?**

The Cochrane Skin Group Outcomes Research Initiative (CSG-COUSIN) is a working group within the international Cochrane Skin Group. CSG-COUSIN was initiated by Prof. Jochen Schmitt and Prof. Hywel Williams in 2014 and supported by the editors of the Cochrane Skin Group. The collaborative initiative is co-ordinated by the Center for Evidence-Based Healthcare, University of Dresden, Germany.

CSG-COUSIN is a research group that is open for everyone with an interest in outcomes research and evidence-based dermatology and with enthusiasm to develop and implement Core Outcome Sets (COS) in dermatology.

### **Why do we need CSG-COUSIN?**

The Cochrane Collaboration plays a critical role in summarising and translating research knowledge into clinical practice by synthesizing and critically appraising clinical trials and by making research evidence accessible on a global level.

The choice of adequate outcome measures in clinical trials is essential to make trials meaningful and valid. The failure to assess the outcome domains most important to patients and the continued use of outcome measurement instruments with unclear validity and reliability are frequent and important barriers towards evidence-based medicine. ([Chalmers and Glasziou 2009](#))

The second barrier in evidence-based clinical decision making in dermatology is the use of many different outcome measures in clinical trials on a specific skin condition. Such a lack of standardization of outcome measures across trials for a specific skin condition makes it almost impossible to compare the studies or include them in a meta-analysis. Such a failure to synthesize all relevant evidence results in a failure to make evidence-based recommendations for clinical care.

The development of **core outcome sets (COS)** is a powerful strategy to overcome problems related to the use of different, frequently incomparable and unvalidated outcome measures in dermatology trials. A COS is a standardized consented minimum set of outcome measurement instruments to be

used in every trial in a medical field. A core outcome set does not mean that only the COS should be measured, but simply that the COS should be measured in all future trials of that particular skin disease. Outcomes that are additional to the COS can be measured as required by the specific study.

## ➤ Aims and structure

The over-arching goal of CSG-COUSIN is **to develop standardized, evidence-based and consensus derived disease specific core outcome sets in dermatology** for inclusion in all clinical trials. Through the development and implementation of core outcome sets, we aim to improve trials and to make trial information more useful for patients, health care professionals and policy makers.

### **How to develop core outcome sets in dermatology?**

The development of core outcome sets (COS) requires an integrated process of systematic reviews, consensus studies, validation studies, and structured consensus voting.

Typically, core outcome sets are developed in two steps:

Firstly, a **core set of outcome domains** has to be defined with the integration of key stakeholder groups including patients. Outcome domains refer to the WHAT to be measured, e.g. quality of life, disability, or survival.

In the second step, one adequate measurement instrument has to be identified for each core outcome domain. To be adequate a measurement instrument needs to be valid, reliable and feasible. Once one measurement instrument has been selected for each core outcome domain, the final **core set of outcome measurement instruments** is complete.

Methods for identifying and critically appraising measurement instruments in medicine have been summarized and standardized by the *Consensus based standards for the selection of health measurement instruments (COSMIN)* initiative ([http://www.cosmin.nl/cosmin\\_1\\_0.html](http://www.cosmin.nl/cosmin_1_0.html)).

Once a core set of outcome measurement instruments has been developed, it has to be implemented in the research community and its application needs to be monitored.

To structure and guide the COS development process, our group has developed a roadmap with our colleagues from the international and multi-professional *Harmonizing Outcome Measures for Eczema (HOME)* initiative ([www.homeforeczema.org](http://www.homeforeczema.org)). (Schmitt et al. [2010](#); [2012](#); [2013](#))

The **HOME roadmap** provides guidance how to define, select and recommend most important core outcome domains and how to identify the best measurement instruments for these core outcome domains. ([Schmitt et al. 2014](#))

**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						
<b>Task</b>	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 meet the requirements of the OMERACT filter and be shortlisted for further consideration.	Carry out validation studies on shortlisted scales.	Finalise core outcome instrument for domain.						
<b>Methodology</b>	Systematic review of outcome instruments used.	Systematic review of validation studies of the long-list of identified instruments. Highlight any gaps in validation.	<b>Apply OMERACT filter; Truth, discrimination and feasibility:</b>  <table border="1"> <tr> <td><b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"</td> <td><b>Discrimination</b> "Does the measure discriminate between situations that are of interest?"</td> <td><b>Feasibility</b> "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"</td> </tr> <tr> <td>Consensus discussion and voting on truth: 1. Face validity 2. Content validity 3. Construct validity 4. Criterion validity</td> <td>Consensus discussion and voting on discrimination: 1. Reliability 2. Sensitivity to change</td> <td>Consensus discussion and voting on feasibility: 1. Time taken 2. Cost 3. Interpretability</td> </tr> </table>	<b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"	<b>Discrimination</b> "Does the measure discriminate between situations that are of interest?"	<b>Feasibility</b> "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 taken 2. Cost 3. Interpretability	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.	Re-apply the OMERACT filter with the results of the completed validation studies. Consensus discussion and voting on core outcome to be recommended.
<b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"	<b>Discrimination</b> "Does the measure discriminate between situations that are of interest?"	<b>Feasibility</b> "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"									
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<b>Output</b>	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**

### ***How can I get involved in CSG-COUSIN?***

Everyone with an interest in outcomes research and evidence-based dermatology and with enthusiasm to develop and/or implement Core Outcome Sets (COS) in dermatology is welcome to participate in CSG-COUSIN.

We appreciate the involvement of clinicians, other healthcare professionals, researchers, representatives of regulatory authorities, and particularly patients from all parts of the world to make this initiative meaningful and to reach our overarching goal to develop, implement, and monitor a broad range of disease specific core outcome sets in dermatology.

Please get in touch if you are currently developing a core outcome set for a dermatological disease, or if you are planning to do so, or if you think a core outcome set needs to be developed for a specific dermatological condition.

#### **↗ Ongoing projects:**

The Harmonising Outcome Measures for **Eczema** (HOME) [initiative](#)

For further details please contact **Joanne Chalmers** ([HOME@nottingham.ac.uk](mailto:HOME@nottingham.ac.uk))

Systematic review on primary and secondary outcome measurements in **melanoma** research in randomized controlled and open-label extension trials (Prospero registration number: CRD42014010366)

For further details please contact **Jochen Schmitt** ([jochen.schmitt@uniklinikum-dresden.de](mailto:jochen.schmitt@uniklinikum-dresden.de))

Developing a core outcome set for **vitiligo** clinical trials

For further details please contact **Khaled Ezzedine** ([khaled.ezzedine@chu-bordeaux.fr](mailto:khaled.ezzedine@chu-bordeaux.fr))

Prioritizing areas for future COS development in **skin surgery**

For further details please contact **Alam Murad** ([m-alam@northwestern.edu](mailto:m-alam@northwestern.edu))

#### **↗ Events:**

The kick-off meeting of CSG-COUSIN will take place at the Annual Cochrane Skin Group Meeting on 17./18. March 2015 in Dresden, Germany

[↗ Program](#)

### ➤ Contact:

CSG-COUSIN is co-ordinated by the Center for Evidence-Based Healthcare, University of Dresden, Germany. If you are interested in getting involved, or just finding out more about CSG-COUSIN, please contact

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### ➤ Links:

Harmonizing Outcome Measures for Eczema (HOME) (<http://www.homeforeczema.org/>)

European Wound Management Association Patient Outcome Group (EWMA)

(<http://ewma.org/english/ewma-projects-and-studies/patient-outcome-group.html>)

The COMET Initiative (Core Outcome Measures in Effectiveness Trials) (<http://www.comet-initiative.org/>)

Core Outcomes in Women's Health (CROWN) <http://www.crown-initiative.org/>

Outcome Measures in Rheumatology (OMERACT) (<http://www.omeract.org/>)

Consensus based standards for the selection of health measurement instruments (COSMIN)

([http://www.cosmin.nl/cosmin\\_1\\_0.html](http://www.cosmin.nl/cosmin_1_0.html))