The Cochrane Skin - Core Outcome Set Initiative (CS-COUSIN)

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Background

• Extent of research waste due to outcome choice inconsistencies in dermatology?

→ Systematic review of 10 Cochrane Skin SRs and trials included in these SRs
The need for COS in dermatology

21 primary efficacy outcomes in 10 Cochrane reviews

For 5 of these efficacy outcomes (24%) not assessed in a single trial.

Another 6 review outcomes were assessed in less than 50% of trials.

Only 1/21 primary review outcome was reported in all corresponding trials.

For 11/21 primary review outcomes (52%) meta-analysis could not be performed because outcomes were not reported at all, imprecisely defined, or measured inappropriately in review trials.

Very low overlap between primary review outcomes and trial outcomes.

10 / 10 Cochrane review teams (100%) identified outcome assessment and reporting in trials as major barrier for evidence synthesis.

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The need for COS in dermatology

<table>
<thead>
<tr>
<th>Cochrane Reviews</th>
<th>Number of outcomes sought per Cochrane Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bamford atopic eczema</td>
<td>27</td>
</tr>
<tr>
<td>Bath-Hexall atopic eczema</td>
<td>11</td>
</tr>
<tr>
<td>Chen psoriasis</td>
<td>7</td>
</tr>
<tr>
<td>Chi lichen sclerosus (genital)</td>
<td>24</td>
</tr>
<tr>
<td>Eekhof ingrowing toenails</td>
<td>18</td>
</tr>
<tr>
<td>Saue metastatic malignant melanoma</td>
<td>36</td>
</tr>
<tr>
<td>Kastarinen seborrhoeic dermatitis</td>
<td>85</td>
</tr>
<tr>
<td>Martin pemphigus vulgaris &amp; foliaceous</td>
<td>10</td>
</tr>
</tbody>
</table>

**Legend**

The number above each pie chart is the number of trials assessed in each review. The y-axis represents the total number of review efficacy outcomes. The circles represent the maximal total number of trial outcomes relevant for the Cochrane review. The maximal total number of trial outcomes is the product of “the total number of review outcomes” times the “number of trials included in this review”.

(e.g. Chi: 4 review outcomes x 7 trials = 28 potential trial outcomes relevant for review)

The blue area in the inner circle of the pie chart represents the proportion of all actually reported trial outcomes from the maximal total number of trial outcomes relevant for the Cochrane review.

(e.g. Chi: 10 / 28 potential trial outcomes reported = 36%)

The blue area in the outer circle of the pie chart represents the proportion of all actually reported trial outcomes from the maximal total number of trial outcomes relevant for the Cochrane review WITH RESPECT TO THE OUTCOME CATEGORY CONCORDANCE (primary/secondary outcome).

(e.g. Chi: 0 / 28 potential trial outcomes reported = 0%)

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The HOME initiative

**STEP 1**
Define scope and applicability
- Population
- Intervention
- Setting
- 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

**STEP 4**
Disseminate, prepare guidance material, review, and possibly revise core set of outcome measurements

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The HOME roadmap; J Invest Dermatol 2014;135:24-30

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COS development and implementation ....

- … requires the involvement of all relevant stakeholders in the field
- … is not a straight forward process, but a lot of work
- … is currently en vogue
- … the quality of a COS may differ
- … inappropriate COS will not resolve, but enforce the situation
- … quality assurance in COS development is key
The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)

Established in 2016, structurally integrated in Cochrane Skin

Basic idea: To integrate clinical expertise, methodological expertise and stakeholder impact in dermatology

in order to develop and implement high quality COS in dermatology

in order to improve and standardize outcome measurement in clinical trials to make trial evidence more useful for clinical decision making

Necessary to help Cochrane to meet its goals
The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)

Methods Group
- Provides methodological advice
- Ensures uniformity of standards
- Undertakes methodological research
- Linked with COMET and COSMIN

Management Group
- Facilitates progress of Project Groups
- Assists administratively
- Delivers information & database management, holds library of key articles

Project Groups
- Develop topic-specific COS
- Researchers, clinicians, patients, other stakeholders

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The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)

CSG-COUSIN COS Domain Development Process

- **Step 1:** Preparation
  - A group wants to develop a COS
  - Complete the proposal form and submit it to CSG-COUSIN
  - Review by CSG-COUSIN within 4 weeks
  - Register at COMET

- **Step 2:** Protocol
  - Prepare a full protocol for domain development
  - Review by CSG-COUSIN within 6 weeks
  - Approve
  - Publish protocol (e.g. in journal)

- **Step 3:** Domains
  - Identify outcome domains
  - Develop the core set of outcome domains
  - Domains published at CSG-COUSIN homepage and in journal

- **Step 4:** Measurements
  - Application of quality assurance and peer review principles
  - Select domain(s)
  - Prepare a protocol (if not already done)
  - Review by CSG-COUSIN
  - Approve
  - Publish and register (if not already done)

Development of Core Outcome domains finished

Development of Outcome Measurement Instruments

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Project groups

Acne Core Outcomes Research Network (ACORN)

Acne is one of the most prevalent diseases worldwide, being one of three dermatoses in the global top ten (Hay R et al. J Invest Dermatol 2014; 134: 1527–34). Despite this, the quality of the evidence base for the comparative efficacy of acne treatments is poor. Numerous ... > Mehr...

Core Outcome Measures in Chronic Spontaneous Urticaria

Chronic spontaneous urticaria (CSU) is a frequent, distressing, embarrassing and often disabling skin condition which can last for years. Its estimated point prevalence is 0.5-1% of the total population [1]

Developing a Core Outcome Set for Chronic Wounds

Based on "The German national consensus on wound documentation and outcomes: Rationale, working program and current status" an international consensus and data base should be developed.

Harmonising Outcome Measures for Eczema (HOME)

The Harmonising Outcome Measures for Eczema (HOME) project is an international group working together to agree a core outcome set (COS) for atopic eczema clinical trials.

Core Outcome Set for the Appearance of Facial Aging

"While aging is not a disease, it is treated as a condition in the context of efforts to treat aging by interventions like cosmetics, cosmeceuticals, minimally invasive cosmetic procedures, laser and energy procedures, and invasive cosmetic surgery, among others. There is hence ...

> Mehr...

HECOS: Development of a Hand Eczema Core Outcome Set

Hand eczema (HE) is a common skin disease in the general population. Certain occupations are at increased risk to develop chronic, severe forms which may result in negative consequences in terms of long-term quality of life impairment, psychological co-morbidity and cost...

> Mehr...

Development of a Core Outcome Set in Hidradenitis Suppurativa (HS)

One of the key rate limiting steps in the design and funding of robust clinical trials to improve the care of people with hidradenitis suppurativa (HS) is heterogeneity of outcome measures used to determine treatment success or failure. This issue has been highlighted in the ...

> Mehr...

CONSIDER – Core Outcome Set in IAD Research project: development of a core set of outcomes and measurement instruments for Incontinence-Associated Dermatitis (IAD) research

This project aims to develop a core set of outcomes and a core set of measurements to be assessed in clinical incontinence associated dermatitis (IAD) research.

> Mehr...

Developing a Core Outcome Set for Melanoma trials

In melanoma research there is no uniformity in outcome reporting. Further, it is unknown which outcomes, for example 'survival' and 'health-related quality of life', are most important to patients and healthcare providers. This causes inconsistencies in outcome reporting, ...
Project groups

Development of a Core Outcome Set in Nail Psoriasis
Prof. Dr. Phyllis Spuls (a senior lecturer and consultant dermatologist with psoriasis and eczema expertise in Amsterdam, The Netherlands) and Dr. Marcel Pasch (a senior lecturer and consultant dermatologist with nail disease expertise, Nijmegen, The Netherlands), both authors ...

Core Outcome Set for Rosacea
"The purpose of this COS is to better detect difference in degree/type of presentation and track response to medical and procedural therapies." ... Mehr...

The Outcomes for Pressure Ulcer Trials (OUTPUTs) project
"The Outcomes for Pressure Ulcer Trials (OUTPUTs) project. Development of a core outcome set for trials evaluating the clinical efficacy or effectiveness of pressure ulcer prevention interventions" ... Mehr...

Development of a Core Outcome Set for Vascular Malformations (OVAMA project)
The OVAMA project aims to develop a core outcome set (COS) for adult and pediatric patients with congenital vascular malformations ...

Developing a Core Outcome Set for future clinical trials for the management of Vitiligo
Vitiligo is the most common depigmentation disorder, which affects around 1% of the population worldwide. Currently, no cure or firm clinical recommendations exist for the treatment of this disorder. One of the main issues identified by the Cochrane systematic review [1] was the ...

Core outcome set for clinical trials in Basal Cell Carcinoma
Basal cell carcinoma is the most common skin cancer worldwide. Treatment options include both surgical and topical modalities. Although risk of metastasis is low, basal cell carcinoma can be invasive and infiltrate important underlying structures such as bone or cartilage. While ...

European Laser TrEAtment Dermatology registry (LEAD)
During the past decades, advancements and modifications in laser technology has further widened its scope and greatly expanded the cutaneous laser surgeon’s armamentarium to the point that is now considered the treatment of choice for numerous cutaneous disorders. Different ...

COMET VII Meeting 2018, Amsterdam
Priorities for the future

• To finish high quality COS in dermatology.

• To implement these COS in trials and reviews.

• To implement the standards and methods developed by COMET and COSMIN into our field and thus to validate these standards.

• To serve as a model for other clinical disciplines to bridge clinical and methodological expertise in COS development and implementation.

• To receive structural support / funding from Cochrane.
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