The CSG Outcomes Research Initiative (CSG-COUSIN)

Jochen Schmitt

Annual Cochrane Skin Group Meeting 2015
Dresden, 17th March
Scenario:

Trial shows no difference between new intervention and placebo.

„Clinical trials are only as credible as their endpoints.“ (OMERACT 1993)

- Outcome measures used are not adequate to detect the true effect of the intervention
Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

**Questions relevant to clinicians and patients?**
- Low priority questions addressed
- **Important outcomes not assessed**
- Clinicians and patients not involved in setting research agendas

**Appropriate design and methods?**
- Over 50% of studies designed without reference to systematic reviews of existing evidence
- Over 50% of studies fail to take adequate steps to reduce biases—e.g., unsealed treatment allocation

**Accessible full publication?**
- Over 50% of studies never published in full
- Biased under-reporting of studies with disappointing results

**Unbiased and usable report?**
- Over 30% of trial interventions not sufficiently described
- **Over 50% of planned study outcomes not reported**
- Most new research not interpreted in the context of systematic assessment of other relevant evidence

Research waste

*Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients.*
To measure WHAT matters
  The relevant OUTCOME DOMAINS

To measure with adequate INSTRUMENTS
  Validity, Reliability, Responsiveness, Sensitivity to change

To define a STANDARD for cross-trial comparison
  CORE SET to be used in all trials
Items used to measure the **intensity of eczema lesions** in different measurement instruments

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The outcome assessment barrier is an important EbM-threat

- **Choice of outcome domains** unclear
- **Outcome domains** highly heterogenous across trials
  - Trials cannot be compared
  - Meta-Analysis impossible
  - Guideline recommendations remain vague
- **Measurement instruments** heterogenous within same domain
- **Performance of measurement instruments** unclear or inadequate
  - Trials cannot be adequately interpreted
  - Trial evidence not suitable to guide clinical decision making

**Quality and harmonization of outcome assessment in trials needed to meet the goals of the Cochrane Collaboration**
The HOME Roadmap

**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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J Invest Dermatol 2014;135:24-30
COS development and implementation ....

- ... requires the involvement of different stakeholders
- ... is not a straight forward process, but a lot of work
- ... is currently en vogue
- ... the quality of a COS may differ
- ... COS quality and reporting standards are missing
- ... inappropriate COS will not resolve, but enforce the situation
Now dermatology tries to be the white horse in the game
The Cochrane Skin Group Core Outcomes Set Initiative

- Working group within the Cochrane Skin Group
- Proposed by Jochen Schmitt and Hywel Williams in 2014
- Official Kick-off today!
- Based at the Center for Evidence-based Healthcare Dresden
- Coordinated by Stefanie Deckert

- **Open for everyone** with an interest in outcomes research and evidence-based dermatology and with enthusiasm to develop and implement COS in dermatology
The Cochrane Skin Group Core Outcomes Set Initiative

- **Mission:** To develop and implement COS in dermatology in order to improve and standardize outcome measurement in clinical trials to make trial evidence more useful for clinical decision making.

- To develop standardized, evidence-based and consensus derived disease specific COS in dermatology for inclusion in all clinical trials.
- To apply and further develop the HOME roadmap
- To provide methodological input for COS developers and Cochrane reviewers
- To collect and disseminate dermatology core outcome sets
Choosing inappropriate outcomes in clinical trials may lead to “wasted resources or misleading information which either overestimates, underestimates, or completely misses the potential benefits of an intervention.” (Sinah et al. PLoS Med 2008)