UniversitätsCentrum Evidenzbasierte Gesundheitsversorgung

Universitätsklinikum Carl Gustav Carus
DIE DRESDNER.

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 adeqate to detect the true effect of the intervention

Lancet 2009; 374: 86–89
Published Online
June 15, 2009
DOI:10.1016/S0140-6736(09)60329-9

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

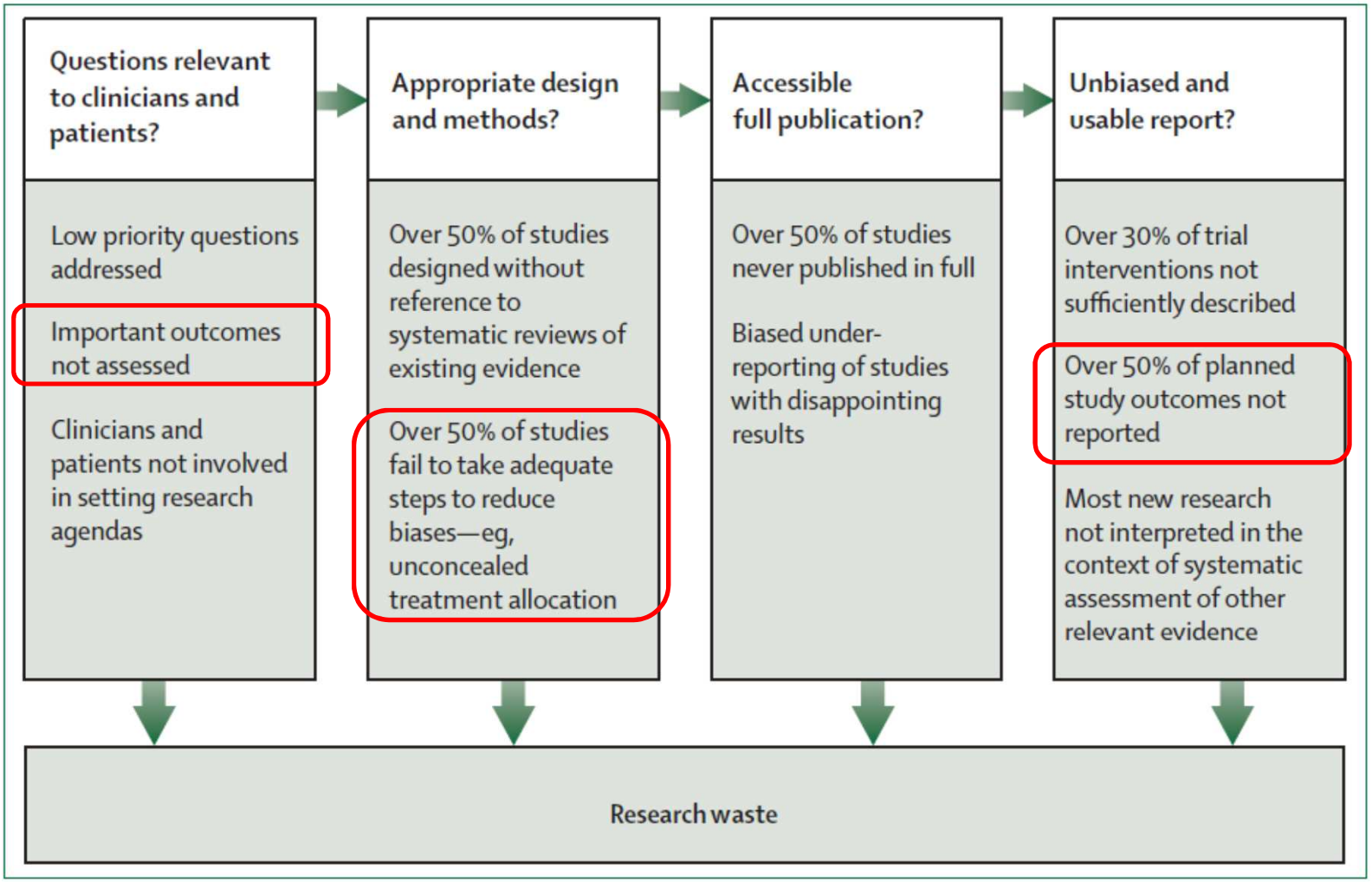


Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients

Outcome Assessment in Clinical Trials

- 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

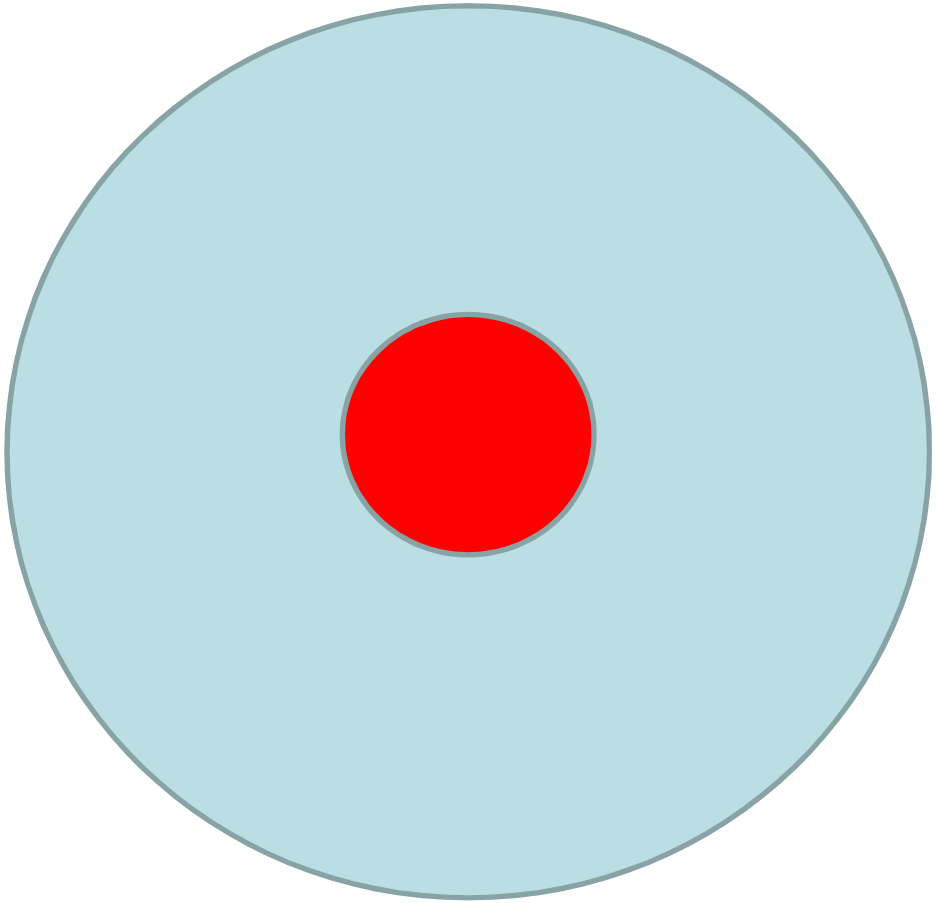
Items used to measure the **intensity of eczema lesions** in different measurement instruments

Scale	erythema	edema / papulation	oozing/ crusting	excoriation	licheni-fication	dryness	scaling	fissuring	vesicles	(de)pigmen-tation	flaking	bleeding	erosions
ADAM	•			•	•		•						
ADASI	•	•	•		•		•						
ADSI	•		•	•	•								
BCSS													
EASI	•	•		•	•								
FSSS	•	•	•	•	•	•							
IGADA	•	•	•	•	•		•						
Leicester	•			•	•	•		•					
NESS													
OSAAD	•		•	•	•								
POEM			•			•		•			•	•	
RL Score													
SA-EASI	•	•		•		•							
SASSAD	•		•	•	•	•		•					
SCORAD	•	•	•	•	•	•							
SIS	•					•							
SSS	•	•	•	•	•		•		•	•			
TBSA	•	•	•	•		•	•	•	•				
TISS	•	•		•									
WAZ-S	•	•	•				•		•	•			•

The outcome assessment barrier is an important EbM-threat

- Choice of **outcome domains** unclear
- **Outcome domains** highly heterogenious acoss trials
  - → Trials cannot be compared
  - → Meta-Analysis impossible
  - → Guideline recommendations remain vague
- **Measurement instruments** heterogenious 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



OMERACT

COMET INITIATIVE

http://www.liv.ac.uk/nwhtmr/comet/comet.htm

COSMIN

home

http://www.homeforeczema.org/

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

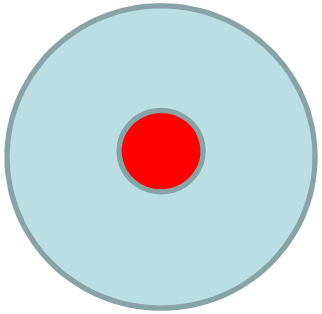
Disseminate, prepare guidance material, review, and possibly revise core set of outcome measurements

	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 it's 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.

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)*