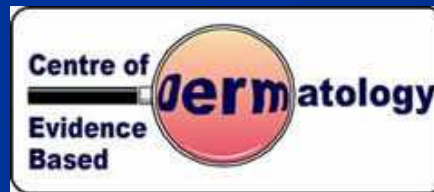




Why harmonise outcome measures?

Hywel Williams

Nottingham



Outcome measures for eczema/atopic dermatitis – a mess

- Too many – over 20 named scales
- Many not tested at all
- Some are only partly tested (validity, repeatability, sensitivity change, consistency, interpretability)
- Some that are tested do not pass the tests



What's all the
FSSS about?

SCORAD scores again

Take it
EASI

SASSAD rules OK

TIS a right
mess

Give me a POEM

Me too!

ADASI tonight?

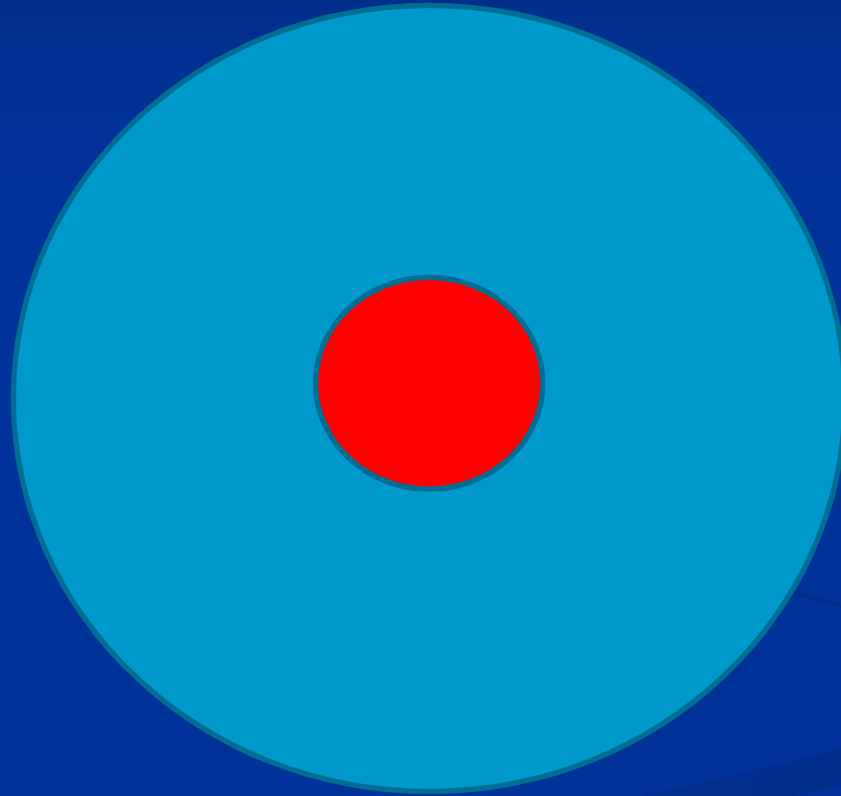
Meet my SIS

IGADA bad
headache

My name is
ADAM

Illustration by "Patriarchs and Propriets." Copyrighted 1898
THE TOWER OF BABEL.

What we need are *core* outcomes
that are used in all trials



What are core outcomes?

- Minimum set for all clinical trials
- Need to be relevant to patients
- Relevant to those making decisions about health care
- Maybe different for clinical trials and routine care
- Need to measure what they're supposed to measure, be repeatable, sensitive to change, and be easy to use

Why?

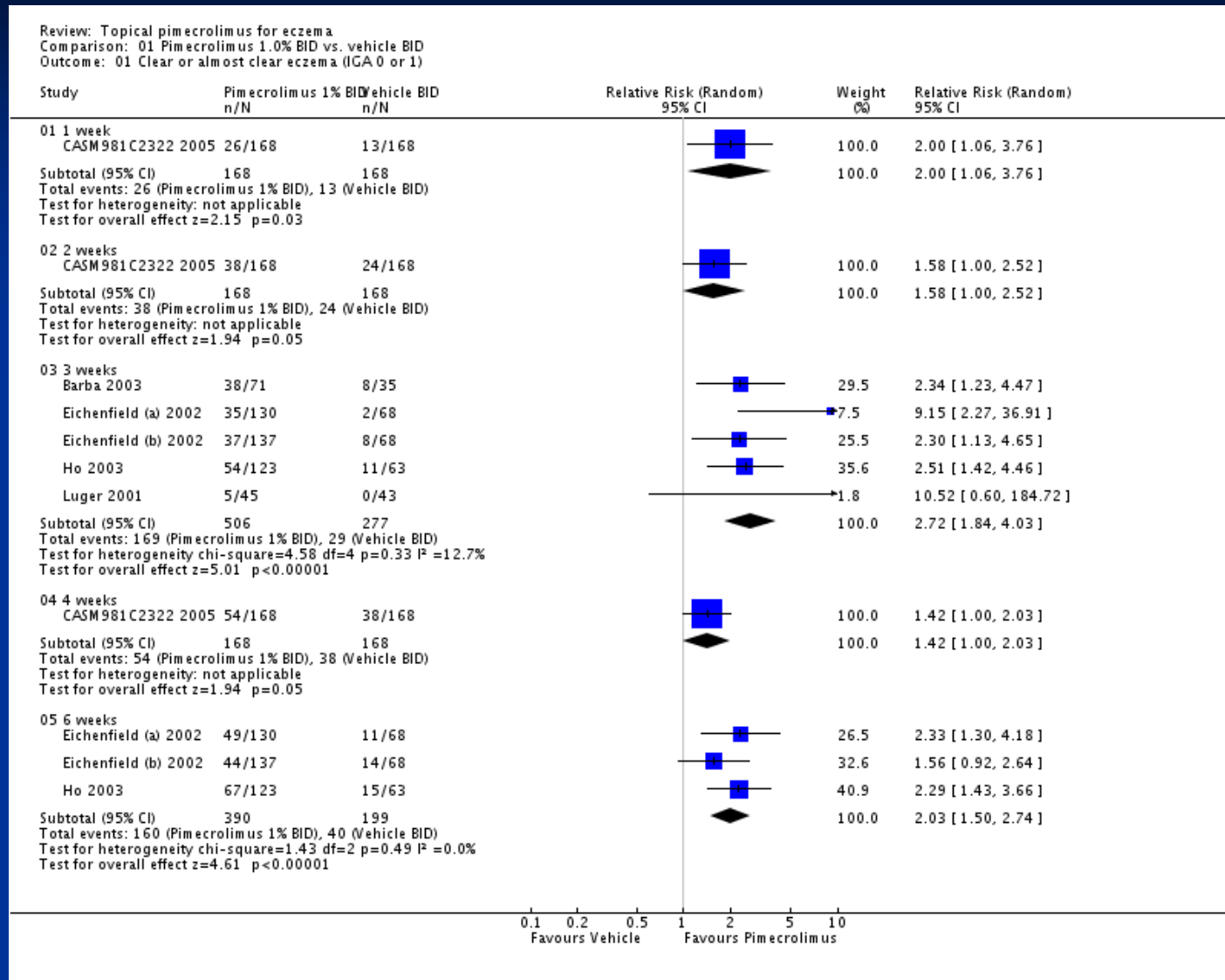
– so that we can compare

Standard Cochrane Skin Group abstract:

“We found 27 studies, but outcomes were heterogeneous precluding any formal meta-analysis”

And it goes on.....

If only we could do more of this...



..and compare something that is meaningful rather than just measurable

- Good outcomes that cover the key domains of a particular skin condition
- Instruments that pass the test of truth, discrimination and feasibility

What is happening elsewhere?

- OMERACT <http://www.omeract.org/>
- Pain – IMMPACT: www.immpact.com
- **COMET** initiative: Core Outcome Measures in Effectiveness Trials
<http://www.comet-initiative.org/>

Tugwell P BM et al. OMERACT: An initiative to improve outcome measurement in rheumatology. *Trials*. 2007;8(38).

Clarke M. Standardising Outcomes in Paediatric Clinical Trials. *PLoS Medicine / Public Library of Science*. 2008;5(4):e102.

The world of medicine is moving on
– what about skin diseases?



Some signs of hope in skin ..starting with HOME

- Agreed that core outcomes needed
- Started with clinical trials
- Domains identified
- Instrument for clinical signs determined
- Now about to tackle symptoms and QoL in Malmo
- Not easy....

AIM of HOME: To agree a set of core outcome measures for eczema for use in **all** clinical trials. Ultimately, the aim is to have just **one instrument** per domain for:

1. Signs
2. Symptoms
3. Quality of Life
4. Measure of long term control of flares

| | 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 meet the requirements of the OMERACT filter and be shortlisted for further consideration. | Carry out validation studies on shortlisted scales. | Finalise core outcome(s) 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. | Re-apply the OMERACT filter with the results of the completed validation studies. Consensus discussion and voting on core outcome to be recommended. |
| | | | <p style="text-align: center;">Truth</p> <p><i>"Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"</i></p> <p>Consensus discussion and voting on truth:</p> <ol style="list-style-type: none"> 1. Face validity 2. Content validity 3. Construct validity 4. Criterion validity | <p style="text-align: center;">Discrimination</p> <p><i>"Does the measure discriminate between situations that are of interest?"</i></p> <p>Consensus discussion and voting on discrimination:</p> <ol style="list-style-type: none"> 1. Reliability 2. Sensitivity to change | <p style="text-align: center;">Feasibility</p> <p><i>"Can the measure be applied easily in it's intended setting, given constraints of time, money, and interpretability?"</i></p> <p>Consensus discussion and voting on feasibility:</p> <ol style="list-style-type: none"> 1. Time taken 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(s) for the domain. | | |

And other skin diseases listed in COMET website...

- Vitiligo
- Acne
- Incontinence-dermatitis
- Vulval skin conditions
- Leishmaniasis
- HS
- Psoriasis (IDEOM – not sure)

Progress will vary...

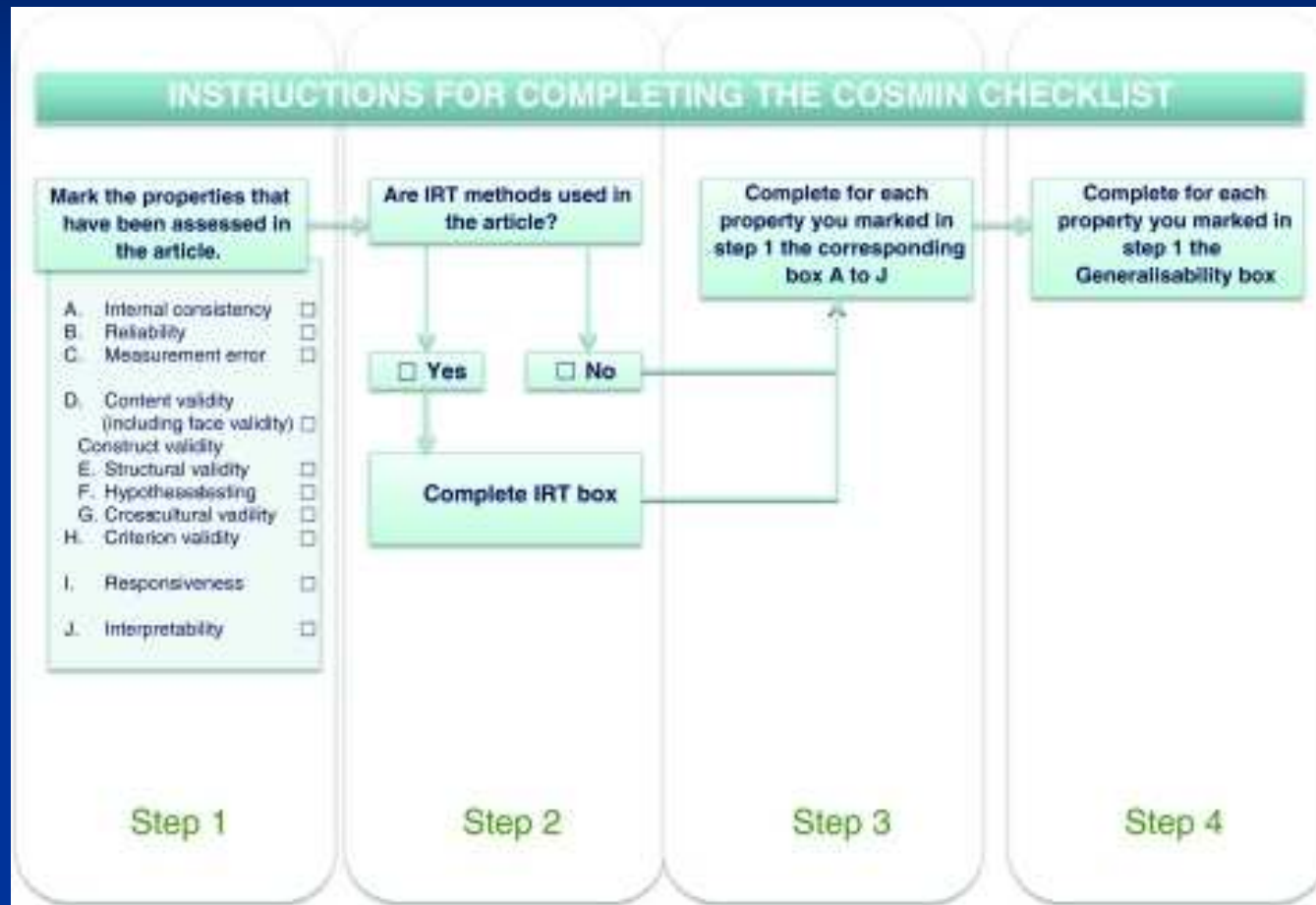


Adoption of the OMERACT filter



Truth, Discrimination and Feasibility

Use COSMIN to rate studies that rate outcomes



COnsensus-based Standards for the selection of healthMeasurement Instruments

<http://www.cosmin.nl/>

Philosophy of CSG-COUSIN

- Working hard together to help patients
- Respecting all stakeholder viewpoints
- Putting prejudices and allegiances aside in order to achieve the greater good for patient care
- Evidence-based and evidence-generating
- Pragmatic – to inform clinical decisions
- To have fun
- With very little money



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Cochrane reviews of the future..

- We found 27 acne studies for our intervention, 25 of which used our primary outcome of inflammatory lesion count
- We were able to directly and indirectly compare them as a result
- Treatment A is clearly very helpful, treatment B and C are only moderately so, and treatments D and E are pretty useless