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?

Take it EASI

TIS a right mess

Me too!

Meet my SIS

My name is ADAM

SCORAD scores again

SASSAD rules OK

Give me a POEM

ADASI tonight?

IGADA bad headache
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...

<table>
<thead>
<tr>
<th>Study</th>
<th>Pimecrolimus 1% BID vs Vehicle BID</th>
<th>Relative Risk (Random)</th>
<th>Weight</th>
<th>Relative Risk (Random)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 1 week</td>
<td>CASN851C2322 2005 25/168 12/166</td>
<td>0.98 1.45</td>
<td>0.06 2.90</td>
<td>1.05 3.76</td>
</tr>
<tr>
<td>02 2 weeks</td>
<td>CASN851C2322 2005 38/168 24/168</td>
<td>0.96 1.58</td>
<td>0.06 1.59</td>
<td>1.00 2.52</td>
</tr>
<tr>
<td>03 3 weeks</td>
<td>Kaira 2002 28/71 8/35</td>
<td>28.5 2.24</td>
<td>0.00 2.90</td>
<td>1.00 3.76</td>
</tr>
<tr>
<td>Eisenfield (a) 2002 35/120 2/68</td>
<td>0.75 3.15</td>
<td>0.00 2.37</td>
<td>1.42 4.62</td>
<td></td>
</tr>
<tr>
<td>Eisenfield (b) 2002 37/127 8/68</td>
<td>25.5 2.20</td>
<td>0.00 1.18</td>
<td>1.42 4.62</td>
<td></td>
</tr>
<tr>
<td>Ho 2003 54/123 11/53</td>
<td>35.6 2.51</td>
<td>0.00 1.42</td>
<td>1.42 4.46</td>
<td></td>
</tr>
<tr>
<td>Lugner 2001 5/45</td>
<td>0.13</td>
<td>0.00</td>
<td>3.10</td>
<td>3.10</td>
</tr>
<tr>
<td>Subtotal</td>
<td>306</td>
<td>287</td>
<td>0.96 1.58</td>
<td>0.06 1.59</td>
</tr>
<tr>
<td>04 4 weeks</td>
<td>CASN851C2322 2005 54/168 36/166</td>
<td>0.98 1.45</td>
<td>0.06 2.90</td>
<td>1.05 3.76</td>
</tr>
<tr>
<td>05 5 weeks</td>
<td>CASN851C2322 2005 54/168 36/166</td>
<td>0.98 1.45</td>
<td>0.06 2.90</td>
<td>1.05 3.76</td>
</tr>
<tr>
<td>06 6 weeks</td>
<td>CASN851C2322 2005 54/168 36/166</td>
<td>0.98 1.45</td>
<td>0.06 2.90</td>
<td>1.05 3.76</td>
</tr>
</tbody>
</table>

..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?


- Pain – IMMPACT: [www.immpact.com](http://www.immpact.com)


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

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

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
<th>Stage 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Task</strong></td>
<td>Identify all instruments previously used to measure the domain.</td>
<td>Establish the extent and quality of testing of the identified instruments.</td>
<td>Determine which instruments are good enough quality meet the requirements of the OMERACT filter and be shortlisted for further consideration.</td>
<td>Carry out validation studies on shortlisted scales.</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
<td>Systematic review of outcome instruments used.</td>
<td>Systematic review of validation studies of the long-list of identified instruments. Highlight any gaps in validation.</td>
<td>Apply OMERACT filter; Truth, discrimination and feasibility:</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Output</strong></td>
<td>Long-list of all instruments previously used to measure the domain.</td>
<td>Summary of which instruments have been tested and the quality, extent and results of any testing.</td>
<td>Short-list of potential instruments that meet the requirements of the OMERACT filter.</td>
<td>Short-list of fully tested instruments.</td>
</tr>
</tbody>
</table>

**OMERACT Filter:**

- **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 situations that are of interest?

- **Feasibility**
  - 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
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 health Measurement 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
SCORAD scores again

Take it EASI

TIS a right mess

Me too!

Meet my SIS

My name is ADAM

FSSS about?

SASSAD rules OK

Give me a POEM

ADASI tonight?

IGADA bad headache
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.