

HOME II Harmonising Outcome Measures for Eczema

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What have we done as an international community?



The problem





Outcome measures – a real mess

Too many – at least 20 named scales

 Many not tested at all (Charman C et al *JID* 2003; 120:932–941)

Some are only partly tested (validity, repeatability, sensitivity change, consistency, interpretability)

Some that are tested do not pass the tests

Schmitt J, Langan S, Williams HC. What are the best outcome measurements for atopic eczema? A systematic review JACI 2007;120:1389-98.



Why core outcomes?

Easier to compare, contrast and synthesise results

Reduces risk of inappropriate outcomes

Reduces risk of selective reporting outcome bias

Review: Topical pimecrolimus for eczema Comparison: 01 Pimecrolimus 1.0% BID vs. vehicle BID Outcome: 01 Clear or almost clear eczema (IGA 0 or 1)

Study	Pimecrolimus 1% 8 n/N	810Vehicle BID n/N	Relative Risk (Random) 95% Cl	Weight ୯ଇ	Relative Risk (Random) 95% Cl
01 1 week CASM981C2322 2005	26/168	13/168	<mark></mark>	100.0	2.00 [1.06, 3.76]
Subtotal (95% Cl) Total events: 26 (Pimecro Test for heterogeneity: no Test for overall effect z=2	ot applicable	168 Vehicle BID)	-	100.0	2.00 [1.06, 3.76]
02 2 weeks CASM 981 C2322 2005	38/168	24/168	_ <mark></mark>	100.0	1.58 [1.00, 2.52]
Subtotal (95% Cl) Total events: 38 (Pimecro Test for heterogeneity: no Test for overall effect z=1	ot applicable	168 Vehicle BID)	-	100.0	1.58 [1.00, 2.52]
03 3 weeks Barba 2003	38/71	8/35		29.5	2.34 [1.23, 4.47]
Eichenfield (a) 2002	35/130	2/68		7 .5	9.15 [2.27, 36.91]
Eichenfield (b) 2002	37/137	8/68		25.5	2.30 [1.13, 4.65]
Ho 2003	54/123	11/63		35.6	2.51 [1.42, 4.46]
Luger 2001	5/45	0/43		→ 1.8	10.52 [0.60, 184.72]
Subtotal (95% Cl) Total events: 169 (Pimecr Test for heterogeneity ch Test for overall effect z=5	i-square=4.58 df=4	277 (Vehicle BID) 4 p=0.33 I ² =12.7%	•	100.0	2.72 [1.84, 4.03]
04 4 weeks CASM 981 C2322 2005	54/168	38/168	- <mark></mark> -	100.0	1.42 [1.00, 2.03]
Subtotal (95% Cl) Total events: 54 (Pimecro Test for heterogeneity: no Test for overall effect z=1	ot applicable	168 Vehicle BID)	-	100.0	1.42 [1.00, 2.03]
05 6 weeks Eichenfield (a) 2002	49/130	11/68	— —	26.5	2.33 [1.30, 4.18]
Eichenfield (b) 2002	44/137	14/68	—	32.6	1.56 [0.92, 2.64]
Ho 2003	67/123	15/63	_ 	40.9	2.29 [1.43, 3.66]
Subtotal (95% Cl) Total events: 160 (Pimecr Test for heterogeneity ch Test for overall effect z=4	i-square=1.43 df=1	199 (Vehicle BID) 2 p=0.49 I ² =0.0%	•	100.0	2.03 [1.50, 2.74]
		0.1 0. Favour	2 0.5 1 2 5 S Vehicle Favours Pimecrolim	10 us	

Ashcroft DM, Chen L-C, Garside R, Stein K, Williams HC. Topical pimecrolimus for eczema. *Cochrane Database of Systematic Reviews* 2007, Issue 4.

Selective reporting outcome bias

Viljanen et al randomised 230 infants with AD and cow's milk allergy to *Lacto rham* GG, or mix of four probiotics or inert cellulose and concluded

"Treatment with LGG may alleviate atopic dermatitis symptoms in IgE-sensitised infants but not in non-IgE sensitised infants"

Viljanen et al Allergy 2005;60:494-500

But if you read the paper...

 Viljanen – main analysis for primary outcome not significant.

Instead, they emphasised exploratory analysis in a subgroup 4 weeks after main assessment

It's a bit like....

Williams HC. Two "positive studies of probiotics for atopic dermatitis – or are they? Arch Dermatol 2006;142:1201-3

Throwing a dart



Then drawing the dartboard



Core outcome are just a minimum set



What is happening elsewhere?
OMERACT <u>http://www.omeract.org/</u>

Pain – IMMPACT: <u>www.immpact.com</u>

 COMET initiative: Core Outcome Measures in Effectiveness Trials
<u>http://www.liv.ac.uk/nwhtmr/comet/comet.htm</u>

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.

What are <u>core</u> outcomes?

- Minimum set for all clinical trials
- Typically an efficacy and harm measure
- Need to be relevant to patients
- Relevant to those making decisions about health care
- Maybe different for clinical trials and routine care
- Need to be valid, repeatable, sensitive to change, easy to use

OMERACT filter



Truth, Discrimination and Feasibility

The world of medicine is moving on – what about atopic dermatitis?



Why do it?



HOME I

Is there enough interest, enthusiasm and commitment to sort our core outcomes for atopic eczema/atopic dermatitis? - YES

Are you willing to set aside your preferences/prejudices/allegiances to work as a group? - YES

Aims of HOME II

 To develop a collaborative working community
To make decisions on which essential things need to measured in all eczema trials (and clinical record keeping)

- To make decisions about which tools should be used to measure those essential things
- To identify topics for further research

Philosophy of HOME

- Working together
- 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 have fun**



