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Reducing **U**ncertainties for
People with **S**kin **D**isease

International consensus on core outcomes for vitiligo

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Background

- Vitiligo: the most common depigmentation disorder
- 50 years of research and 90 interventions tested
- Lack of consensus as to the outcome measures
- No cure and no firm clinical recommendations

WHITTON M, *et al.* Interventions for vitiligo. Cochrane Database of Systematic Reviews 2010, Issue 1



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Outcomes in vitiligo research

- Systematic review on outcome measures
- Survey amongst clinicians and patients on most desirable outcomes (UK)



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Systematic review on outcomes measures in vitiligo trials

- 25 different outcomes reported in 54 trials
- Repigmentation assessed by patients: only 4% of trials
- 17% of trials asked for patient opinion on treatment efficacy
- 96% reported repigmentation BUT...

ELEFTHERIADOU *et al.* Which outcomes should we measure in vitiligo? Results of a systematic review and a survey amongst patients and clinicians on outcomes in vitiligo *BJD* 2012; 164 (4): 804-814



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Repigmentation

- Grades 0-3; 0-4; 0-5
- Point
- VAS
- % qu
- % te
- Mean
- mm/cm
- Etc....etc.....etc

- 48 different scales used
- No set percentage quartiles



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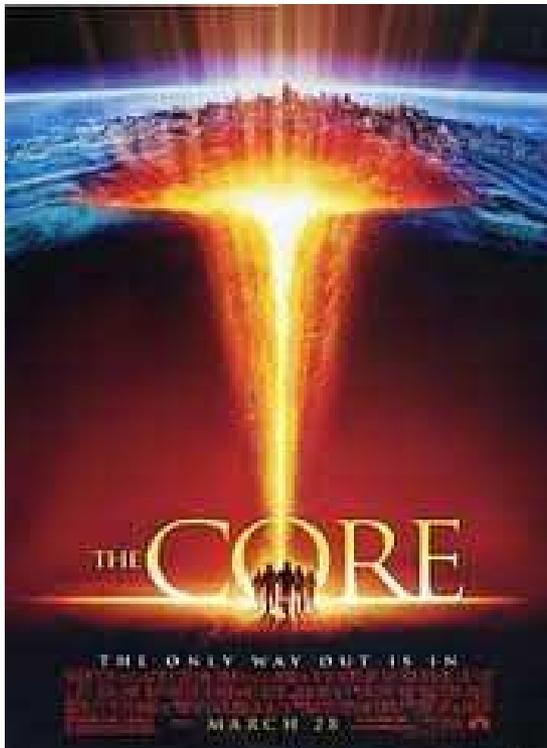
Survey amongst clinicians & patients

- **Cosmetically acceptable** repigmentation rather than %
- Quality of life
- Maintenance of gained repigmentation



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Aim: core outcomes set for future vitiligo trials



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Why outcomes are important?

- 85% of research money is wasted:
 - Important outcomes not measured
 - 50% of planned outcomes not reported
 - Published research fails to set the study in the context with all previous similar research

CHALMERS *et al.* Avoidable waste in the production and reporting of research evidence. *Lancet* 2009; 374:86-89



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What is happening elsewhere?

- HOME (Harmonising Outcomes Measures for Eczema) <http://www.homeforeczema.org/>
- OMERACT (Outcome measures in Rheumatology) 20 years old!
<http://omeract.org/>



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Methods



International consensus on outcomes for vitiligo

- e-Delphi process
- 3 rounds (electronic questionnaires)
- patients, clinicians & researchers (min12 representatives from each group)
- establishment of domains (outcomes)



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Results

- Centre of Evidence Based Dermatology
- Steering group: Dr V. Eleftheriadou, Profs. K. Ezzedine, M. Picardo, K.Thomas and A. Taieb
- 101 participants:
 - International Federation of Pigment Cell Societies (IFPCS) (European, American, Asian, and Japanese)
- 24 countries:
 - Algeria, Australia, Austria, Bahrain, Belgium, Brazil, Canada, Colombia, Egypt, France, Germany, Greece, India, Italy, Mexico, Morocco, Netherlands, Saudi Arabia, Spain, Taiwan, Tunis, United Arab Emirates, United Kingdom, and United States of America.



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IPCC 2014, Singapore

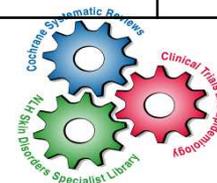


IPCC 2011 Bordeaux, France



Results: international e-Delphi consensus

Stakeholder group	Responders in:		
	Round 1	Round 2	Round 3
Dermatologists	51	44 (85%)	42 (95%)
Patients/carers	32	26 (81%)	21 (81%)
Other (journal editors, regulatory authorities)	18	18 (100%)	18 (100%)
Total number of participants	101	87 (86%)	81(80%)



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Round 1:

Proposed outcomes for vitiligo based on the recommendations of the systematic review*:

1. Repigmentation
2. Cosmetically acceptable repigmentation
3. Global assessment of the disease
4. Quality of life
5. Main concerns
6. Costs
7. Side effects
8. Self-esteem
9. Psychological impact

Consensus pre-defined:
At least 75% of participants in two stakeholders groups

* ELEFTHERIADOU V *et al.* Which outcomes should we measure in vitiligo? Results of a systematic review and a survey amongst patients and clinicians on outcomes in vitiligo trials. *BJD* 2012. 167: 804-14.



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Round 2 results:

1. Repigmentation
2. Cosmetically acceptable repigmentation
3. Quality of life
4. Maintenance of gained repigmentation
5. Cessation of spread
6. Side effects and harms
7. Tolerability/burden of vitiligo

Excluded items (did not reached consensus):

- Global assessment of the disease
- Self-esteem
- Psychological impact of vitiligo
- Economic impact of treatment



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Round 3 results:

- **Essential** (relevant to all interventions for vitiligo/ reported in ALL clinical trials):
 - Repigmentation
 - Side effects and harms of treatment
 - Maintenance of gained repigmentation
- **Recommended** (reported IF relevant to the intervention and trial design):
 - Cosmetic acceptability of the results
 - Quality of life
 - Cessation of spreading of vitiligo
 - Tolerability/burden of treatment

ELEFThERiADOU V *et al.* Developing core outcome set for vitiligo clinical trials : International e-Delphi consensus. *PCMR*. Jan 2015 (Epub ahead of print)



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Conclusions (1):

- Establishment of domains completed
- High number of participants and response rate in all 3 rounds: valid results
- No geographical constraints, high degree of experience and skills
- Self esteem and psychological impact of vitiligo (important to patients) didn't make it to core outcomes set



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Conclusions (2):

- No validated scales for vitiligo outcomes*
- Guidance by COSMIN recommended (Consensus-based Standards for the selection of health Measurement Instruments)**
- Next step: identification of a unified scale to measure % repigmentation and its characteristics (for target lesions)

*VRIJMAN C *et al.* Measurement properties of outcome measures for Vitiligo: a systematic review. *Arch. Dermatol* 2012. 148, 1302–1309.

**MOKKIN L.B. *et al.* The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual. Life Res* 2010. 19, 539–549.



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Thank you

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