Report of the Cochrane Skin-Core Outcome Set Initiative Meeting in Paris on 7 January 2019

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The meeting took place together with the Annual Cochrane Skin Meeting at the Musée des Moulages at the Hôpital Saint Louis in Paris (France). It was hosted by the French Society of Dermatology and EA 7379 EpiDermE, Université Paris Est Créteil.

After a welcome by Prof. Schmitt, who is the head of CS-COUSIN, gave a brief overview about what has been achieved within the last year. Currently 17 COS development projects covering various dermatological disease are ongoing. Results of methodological work was been published (Schmitt et al. 2019), a new homepage was launched and guidance material, updated checklists and templates have been developed and are available for free on the CS-COUSIN homepage (cs-cousin.org).

After this update two researchers from the Netherlands (Anne Fledderus and Welling Oei) presented 'Outcomes Measures for Congenital Melanocytic Nevi' (OCOMEN), representing a new COS development group.

This was followed by a session about involving patients in COS development. In her keynote, Heather Bagley (UK) introduced the COMET People and Patient Participation, Involvement and Engagement (PoPPIE) Working Group. She discussed key principles and the current state-of-the-art how to best involve and engage patients in COS development. She provided a number of examples how can patients be successfully involved but also discussed challenges. The video 'What are Core Outcome Sets?' produced by the Core Outcome Measures in Effectiveness Trials (COMET) initative was shown, that is most useful to explain laypersons what COS are and why they are needed. This video can be watched on YouTube (https://www.youtube.com/watch?v=AlLc2yN0pII). Because of the high quality a clear need was expressed, to translate this into languages other than English. Next, Dr. Jo Chalmers (UK) gave examples about the practice of involving patients in the HOME initiative and

this was followed by a general discussion about best practice how to involve patients in CS-COUSIN. Although patient involvement is considered essential, a number of challenges have been identified as well:

- For some diseases patient organizations are lacking thus making it difficult to approach patients.
- There was a debate, whether patients included in COS development should be 'representative' for all patients. Lacking diversity in patient representation was perceived to be a problem by some participants but the question was also discussed whether the concept generalizability actually applies in this context.
- Many COS development groups have no or only minor funding. However, travel, accommodation and meeting costs must be covered when patients are included. It is unclear how to achieve this. One option was discussed, that industry funds COS meetings.

The second part of the meeting was dedicated to classifying outcomes. Theoretical frameworks for outcome classifications have been proposed and are increasingly being used (Boers et al. 2014, Dodd et al. 2014). CS-COUSIN conducted a systematic review comparing outcomes used in published Cochrane reviews and the underlying clinical trials (Schmitt et al. 2019). Using the results of this work, Prof. Schmitt presented the numbers and types of identified outcomes and provided thoughts on a possible classification of skin related outcomes. This is particularly relevant, because it is highly likely that there are common domains within dermatology that could be applied by many COS groups (Kottner et al. 2018a). Therefore, existing 'long lists' from COS groups were reviewed and possible classifications discussed using the OMERACT 2.0 framework (Boers et al. 2014). This was done during group work with the overall aim to develop a dermatology specific taxonomy. While this was generally perceived to be useful, a number of questions emerged. For example:

- How to classify outcomes accurately? Should symptoms reported by patients classified under the domain area 'patient perception of health' or does it belong to 'life impact', to the core area 'pathophysiological manifestation', or to both?
- Should signs and symptoms be combined when they are similar? What degree of similarity is needed? How complex should general outcome domains be? Two examples illustrate the challenge:

(1) Cutaneous ‘inflammation’ is characterized by ‘redness/erythema’ and ‘oedema’. Are redness/erythema and oedema outcome domains on their own or do they just belong to the overall domain inflammation? Currently all three concepts are just listed in the long list on the same conceptual level.

(2) The concepts of ‘desquamation’, ‘scaling, and ‘dandruff’ have been identified in the review and can be found in long lists as well. Again it may be argued, that scaling and dandruff are subconcepts of desquamation. The question remains, what is the overall dermatology specific outcome domain?

• If a dermatology specific outcome taxonomy is to be created, what are the overall classes? A tree-like structure with main branches such as ‘inflammation’, ‘cancer’, or ‘congenital’ might be useful, but it is unclear how this fits to the proposed overall classifications?

Because these questions were discussed before already, there is a clear need to develop a dermatology specific conceptual framework first. A list of standard definitions of major and minor concepts such as cutaneous lesions (Nast et al. 2016) is needed as well and a clear understanding of the hierarchical relationships (Kottner 2018b). If such a list was available, the concepts and terms could then also be translated into lay language to be used in future COS projects. CS-COUSIN will address these challenges and questions to develop a dermatology specific outcome taxonomy that is compatible to the COMET framework (Dodd et al. 2018).

Overall, this meeting provided a useful networking event for all groups involved in core outcome set development and helped to support sharing of best practice across the initiative.

References

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