Reviewer’s report

Title: Harmonization of Outcome Parameters and Evaluation (HOPE) for actinic keratosis: Protocol for the development of a core outcome set

Version: 0 Date: 05 Aug 2019

Reviewer: Mona Wanda Schmidt

Reviewer’s report:

The authors propose a study protocol to identify relevant outcomes for evaluating actinic keratosis based on the Delphi method. To create a homogenous reporting system is of great importance to improve comparability between treatment outcomes across studies. Therefore, the research question is of interest and the methodology proposed in this protocol is generally appropriate. However, the following points should be addressed/specified:

1) The Delphi method outcomes highly relies on the participating panel members. While I support the decision to include patient representatives as well as medical experts, I would criticize the recruitment decision (snow ball system) in the Delphi process. This might lead to a very uneven distribution for example 20% medical experts and 80% patient representatives, which would greatly influence the outcomes. I would recommend to decide on a distribution of the expert panel beforehand and include questions regarding their expertise/ability to judge the importance of outcomes on the first Delphi questionnaire to ensure the final panel members are qualified and the distribution is not too uneven.

2) It is unclear which items will be included in the second Delphi round. You first state "only endpoints that reach a consensus will move to the next round", Table 1 mentions that only "no consensus" items will be "retained for the next round" and you later state that "the second Delphi round will contain all outcomes from round 1" (all on page 8). Please specify which outcomes will move forward to the second Delphi round. My suggestion would be to exclude items where a consensus on the dispensability was reached in round 1 (rating of 1-3) and move items where a consensus was reached on their need (rating 7-8) to the consensus meeting, instead of reevaluating them in a second Delphi round. However, all items where no consensus was reached should be included in the second questionnaire. I would also recommend giving panel members the opportunity to comment on their judgement and provide these comments as anonymous feedback to the rest of the panel in round two, as sometimes these comments can help reaching a consensus as items can be viewed from a different perspective.

3) In your objective you mention your aim is to "identify and consent a catalogue of 5 endpoints". On page 9 (end of method section) you mention that you aim to achieve a maximum of 10 endpoints. It does not become clear how the list of outcomes will be cut down to 5/10. Please specify this. Why do you limit the number of relevant outcomes down to 5 instead of including all outcomes that are determined critically relevant by the
panel members in the consensus meeting? Please provide some sort of reference on your decision for this.

**Level of interest**
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**Statistical review**
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Please complete a declaration of competing interests, considering the following questions:

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