Reviewer's report

Title: Development of a validated Patient Reported Symptom Metric for Pediatric Eosinophilic Esophagitis: Qualitative Methods

Version: 1  Date: 21 July 2011

Reviewer: Emuella Flood

Reviewer's report:

This paper described the development of the PEESS version 2.0, a patient-reported symptom assessment tool for children with EoE. Given that the PEESS version 1.0 was developed without patient input, a key step in developing patient-reported outcomes, the authors performed concept elicitation interviews with patients and parents to identify any missing content and to draft the PEESS version 2.0 instrument. Cognitive interviews were then conducted to address issues with understanding and interpretation, and revisions were made based on these results.

General Comments:
The authors should note that this is not the first study to assess content validity of patient and parent-completed symptom assessment tools or EoE. See Flood et al., Patient and caregiver perspective on pediatric eosinophilic esophagitis and newly developed symptom questionnaires. Curr Med Res Opin. 2008 Dec;24(12):3369-81. Additionally, with respect to symptom assessment tools, there is a general move toward daily assessments through electronic diaries, at least in the trial setting. The one-month recall period is of particular concern. And finally, per FDA, parent proxy tools are generally not accepted. Parent observer tools are accepted, but the items can only be symptoms that would be clearly observed by the parent. Pain, for example, would not be included in a parent observer tool.

Discretionary revisions
1. Consider replacing “focus interviews” with “concept elicitation interviews”, which is now the commonly used term in PRO research

Major compulsory revisions
Abstract:
2. Objective should be clarified. As I understand it, your objective was to assess the content validity of the PEESS and revise it based on patient and parent input, thereby establishing its content validity.

3. Results section seems to include methods and conclusions and few results. Second-to-last sentence describes the methods. The last sentence is more of a conclusion. I would recommend that you report what the patients told you about symptoms and the specific changes you needed to make after cog debriefing.
Background:

4. First paragraph, last sentence. Not accurate per above.

5. “Proxy” should be replaced with parent “observer” throughout. As noted above, proxy measures are not acceptable by FDA. Only symptoms that the parent can observe should be included in the measure (ie, a parent cannot assess pain, or difficulty swallowing, etc. Only things like vomiting, trouble sleeping, etc., should be included.)

6. Clarify the objective as noted above. Are you developing a new PRO or assessing content validity of an existing PRO and updating it based on your findings?

Results:

7. Need a description of the sample – number per age group, males/females, etc.

8. More details on concept elicitation results would be useful. What symptoms were reported and how frequently? How were they described by children? Which ones were considered most severe or most troubling? What symptoms were missing from PEESS v1? Any differences by age group: 8-12 vs. 13-17?

9. Sample size could be considered low, particularly given the age range and variability of symptoms. Did you reach information saturation? Assessment of saturation should be added.

10. Recall period is of particular concern. One month is quite long, particularly for children, and in trials, symptoms are generally assessed in a daily diary format with a 24-hour recall period. Was recall explored during cognitive debriefing? If so, results should be included. Do you have a rationale for a one-month recall period?

11. There is mention of a VAS, but the graphic doesn’t seem to have a VAS. Do children provide their responses using a VAS?

12. If you do not want to include the measures themselves, a more detailed description of the final versions of each would be useful – X items covering the following symptoms, scored on a Likert? VAS? scale, etc.

Discussion:

13. Discussion is a bit lean. Would add reference to Flood et al and compare findings with respect to symptoms assessed in the respective measures. Also perhaps discuss differences by age, if any exist.

14. Need to add study limitations.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests.