Reviewer’s report

Title: Towards a standardised approach for evaluating guidelines on Palliative Sedation: Study Protocol

Version: 2 Date: 23 January 2014

Reviewer: Birgit Jaspers

Reviewer’s report:

Mayor compulsory revisions

General remarks:
This is a well-written paper on a very important issue and I am very much looking forward to the results of this interesting and well-designed study of which this manuscript reports the study protocol. Some issues, however, may need consideration:

1. There is a definition of guidance documents, but not of guidelines. Many documents may be titled guideline, but according to which criteria do the authors refer to texts as guidelines? I would like to pose the same question for documents referred to as framework. Considering an unambiguous interpretation of your work by the recipients of your article, I believe a presentation of your definitions for categorization would be useful.

2. In the manuscript, only in the discussion the term EOL care is used (nowhere written out in full and not defined); it is also used in the checklist. I would like to suggest changing EOL care to palliative care, because there is an ongoing discussion about what is understood by end of life, let alone end-of-life care. Also, the WHO definition (2002) of palliative care includes early integration, therefore the use of this term may be counterproductive.

3. The use of the term EOL sedation or EOL sedation practice or EOL practice should also be avoided for consistency of the study including use of terms and openness of the study approach to exploring its mayor subject.

4. Figure 1 (flowchart) is pretty but doesn’t add much to the manuscript.

Detailed remarks: Manuscript

5. Page 4, Background, line 7-9
For instance, European studies showed the frequency of deep and continuous sedation of patients until death varies between 2.5% of all deaths in 2001 – 2002 (Denmark) and 16.5% of all deaths in 2007 – 2008 (UK) [4, 6].

Comment:
Misleading wording, sounds as if there were a range from 2.5 to 16.5, even though the studies were conducted in different years and it is not clear if the definition of what is meant by the term deep and continuous sedation is identical – better change to
European studies showed the frequency of deep and continuous sedation of patients until death varies, for instance 2.5% of all deaths in 2001 – 2002 (Denmark) and 16.5% of all deaths in 2007 – 2008 (UK) [4, 6]… and add information on the comparability regarding definition/procedure.

6. Page 4, Background

There appears to be a growing trend in this practice in Europe [4, 23-27], and in the various care settings where people die [25, 26]. Amidst relatively large country variations in prevalence, the actual practice of palliative sedation has been widely reported [27].

Comment:
Considering the rather general remarks more literature from a greater variety of countries and settings should be cited.

7. EOL care – see above, in general remarks on discussion

8. Page 9-10, Methods

To ensure the intentional inclusion of literature published in English, as well as Dutch, Flemish, French, German, Italian and Spanish, we will apply the terms “palliative sedation”, “terminal sedation”, “dying”, “end of life”, “guidelines”, and “framework”, and the following translated terms in varying combinations:

palliatieve sedatie, richtlijn; sédation en médecine palliative, la sédation pour détresse en phase terminale ou en fin de vie, recommandations; guia de sedacion paliativa; raccomandazioni, sedazione terminale, sedazione palliative; therapeutische palliative sedierung, einsatz sedierender, leitlinie.

Comment:
This list is not consistent. Some of the translated terms are not additional but translations of the above mentioned list, and the choice of additional terms varies in the presented languages.

Detailed remarks additional file checklist:

9. Since the explanatory document to go with the checklist was not submitted, I would like to mention that it should contain definitions of the terms guideline, guidance document, framework etc. as mentioned for the revision of the manuscript (if not already incorporated)

10. Part 2: TERMS, DEFINITIONS AND TYPES

(14) and (18) change EOL sedation practice to palliative sedation practice or sedation practice for the reasons mentioned in comment 3. I have not found any items on depth of palliative sedation (or overlooked these) – if they are not in, shouldn’t they be incorporated?

Since continuous sedation is incorporated in the answer option of (14) and (18), intermittent/transient… etc. should also be listed in both

11. B: COMPARABILITY
I don’t understand 2.3.b. Does no. 4 in Appendix I of the EAPC document (on which 2.3.b. is probably based) really refer to continuous sedation? I hadn’t thought so. Please check.

12. 2.5 Temporary sedation should not stand alone - for consistency of the paper there should be written intermittent/transient/respite/temporary

13. 3.2. What is meant by relevant investigations?

14. 4.3.d Here or elsewhere: wouldn’t it make sense to add asking/looking for the planning of the duration and depth of palliative sedation?

15. 7.9. Why dignified? Is there a definition?

16. 8.1. Those involved is a very unclear term

17. 8.2.b. Isn’t that true for any treatment situation? Why do you include an item that reflects a medical error in any treatment situation?

18. 9.1. Is there a definition of supportive care to which is referred? Also, provide seems a bit ambitious (unless only multidisciplinary teams are addressed), maybe add facilitate or facilitate access to…

19. 9.2., 9.3. and 10.2. If I understood this right, the information given in the items before was based on checking the documents for content; do 9.2., 9.3. and 10.2. ask for opinions of the respondent which are not to be found in the document. How does this go with the described methodology? Also, the items in 9.3 regarding family information needs may suggest that these should be met in which case it should be clarified that there are legal regulations for information of family (patient’s permission etc.)

20. 12. What is meant by non-EAPC (member states? Not based on EAPC framework? Clarification of end-of-life decision needed, see comments to the manuscript.

Minor essential revision
Page 2, Abstract, paragraph 2
AGREE instrument = AGREE II instrument

Discretionary Revisions
Page 4, end of paragraph 1
In Google Scholar is also to be found, for example, Neitzke, G., Oehmichen, F., Schliep, H. J., & Wördehoff, D. (2010). Sedierung am Lebensende. Ethik in der Medizin, 22(2), 139-147.

There is also a new version of the Dutch Guideline dating from 2009 (Royal Dutch Medical Association 2009) – shouldn’t this one be included instead of the older version?

Page 6, Method,
Title should be changed to Methods

Page 12, Discussion line 5
Lit 42: correct Schilmann to Schildmann

Section Weaknesses, page 12 f

In this section, the authors only talk about guidelines: In order to be consistent, please change all relevant parts of the text to guidelines and guidance documents.

Some spelling mistakes in the checklist (4/4.3.b)

**Level of interest:** An article of importance in its field

**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.