Author's response to reviews

Title: Mix of methods is needed to identify adverse events in general practice: a prospective observational study

Authors:

Raymon Wetzels (M.Wensing@kwazo.umcn.nl)
René Wolters (R.Wolters@kwazo.umcn.nl)
Chris van Weel (C.vanWeel@hag.umcn.nl)
Michel Wensing (M.Wensing@kwazo.umcn.nl)

Version: 2 Date: 2 May 2008

Author's response to reviews:

dear editors and reviewers,

Please find a detailed description of our revisions below.
We hope that the paper can soon be published.

On behalf of the authors,
Raymond Wetzels
Michel Wensing

Response to reviewer D.J. Fernald:

Major essential revisions:

1. More explanation on types of events. The current paper reported on the different methods for identifying adverse events, their feasibility and yield. A different paper reports on the type of adverse events and their clinical implication. This paper is in press in J Eval Clin Pract; we have added the reference. We have not included examples of events, but we have expanded the methods and results section to make clearer what type of events were identified. We also added a table with subcategories of events per method (table 2).

2. Patient reported events were different. As we anticipated that patients might not want to speak badly about their GP, we asked them first whether something in general went wrong in their GP care. Subsequently we asked questions about specific items that might have happened and they may not have seen as potentially harmful for their health. The patient questionnaire has been added as a box in the paper.

3. Discuss study limitations. In the discussion section the limitations per method are discussed, and the overall limitations of this study are mentioned as well. We have slightly rephrased the first sentence of this paragraph to indicate this more clearly to the reader.
4. Categorize patient reported events. We have added a categorization of patients’ events. We have also an explanation in the results and discussion section.

Minor essential revisions:
1. Box 1 is an enumeration per method as we see it. As its content is already in the text we left the box out of the article.
2. The GPs checked a box in one of the subcategories of a simplified taxonomy; in addition we asked a description of the adverse events. In the results section we have added a table with the subcategories. See also above comments to point 1.
3. There was no overlap of events between methods, this is adjusted in the discussion section.

Discretionary revisions:
1. More explanation on subcategories is provided and an example of the patient questionnaire is included. We are willing to provide our instruments (in Dutch language) to those who are interested.
2. We have added the suggested references into the discussion.
3. We have expanded the discussion. Per method limitations are discussed and a paragraph is added that answers the questions of the reviewer.

Response to reviewer G. Neale:

Major essential revision:
1. Definition of adverse events. This reviewer suggests to differ between adverse events with and without health damage to the patient. We think both types of events are important and in primary care, so we focused on identifying as much events (either AE or PAE) as possible. This is consistent with the WHO World Alliance for Patient Safety definition, which we have included in the text (method section). We added a column to table 1 explaining how many events actually harmed patients.
2. Types of events. A more in depth analysis of the type of events will be published elsewhere (see point 1 of our response to the other reviewer).

Minor essential revision:
1. We refer to the suggested report in the discussion.
2. We have included the approval by the ethical committee.

We have corrected the errors in grammar and spelling as good as possib