Reviewer’s report

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

Version: 1 Date: 17 April 2008

Reviewer: Douglas H Fernald

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Overall, I like the setup of the study and the question it addresses: what can we learn from capturing adverse events using five different methods within the same practice settings? It’s a novel approach to thinking about understanding errors at a practice level, especially understanding from patients about safety issues. Yet, I want to know more: more details about the instruments used to gather reports, what are some of the limitations of this method, who else might report, and how does this fit with what’s already known about different sources of error or adverse event reporting. It seems like a good starting point for a more thorough and rigorous study to evaluate the differences between the different reporting sources.

Major Compulsory Revisions:

1. More explanation or examples of the types of events each of the four event categories described by the international taxonomy used to categorize the events. Most readers might not be familiar with the taxonomy. More detail would help readers get a feel for the types of events being reported from these 5 methods. The details could be provided in the Results section, if available.

2. Page 5: It’s difficult to tell from the description how the criteria the patients used to conceptualize an “adverse event” might have differed from those used by professionals. This might help explain why the reporting was so different from the other 4 methods. More detail here or in the Discussion would be helpful.

3. There is no discussion of limitations. This is important for understanding the limitations of the methods or data, to help put the results in perspective.

4. Table 1: Patient Registration: It’s not clear to me why the events patients reported can’t be categorized into the 4 categories used for the other reporting sources. It seems that at least some would fit under events in diagnosis or treatment, as an example.

Minor Essential Revisions:

1. “Box 1” was included in the additional materials along with Table 1. It’s not mentioned in the manuscript, so it’s not clear if this was intended to be included for review or not. I did not consider in this review. Please clarify if I missed something here.

2. Page 5: GP Reported Adverse Events: it would be helpful to give an example; it’s not clear if the physicians just checked off a box in one of the major
categories, or if they selected from among the several sub-categories in the taxonomy; or even if there was substantial narrative notation in the report.

3. Top of page 8: “There was hardly any overlap between the methods....”; but on page 6 in Results it reads, “no overlap between methods was detected.” This is an important point; can you clarify?

Discretionary Revisions:

1. It might be helpful to include the instruments (or detailed descriptions) used to capture the events. If they are easy to use, others might wish to build on this method to advance understanding of events in general practice.

2. The literature cited is relevant, but there is more out there on reporting in primary care/general practice and from patients that would help put this study in context with what is already known. Here are a couple that come to mind, but there are others: (Kuzel, AJ., et al. Patient Reports of Preventable Problems and Harms in Primary Health Care. Ann Fam Med 2004 2: 333-340; or VanVorst, RF et al. Rural Community Members' Perceptions of Harm from Medical Mistakes: A High Plains Research Network (HPRN) Study, J Am Board Fam Med 2007 20: 135-143)

3. I very much like the set-up, but wanted to hear more particularly about the methods. The results are interesting, but would the authors consider telling us more about what they learned from the application of the methods in two GP practices in the Discussion? For example, what’s missing from the reports, who else should report, what changes would they propose, what was the reaction of the participating GPs, or what would you do next in terms of research that builds on this method and what’s known in the literature? This seems particularly useful for helping practices identify the “blind spots” the authors keenly note.

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’