Reviewer's report

Title: Patient safety in Dutch primary care: Study protocol

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Reviewer: Robert Fleetcroft

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Thank you for asking me to review this paper. The proposal covers a very important area of primary care which is in its infancy in terms of research. This proposal will need some major modifications to achieve its aims. The protocol in its current state not specific or clear enough on both what it is trying to achieve or how the research is to be carried out. I will make specific comments as to the text, but feel in general that the proposal needs to be a clearer description of what it is trying to achieve, and perhaps use a flow diagram or similar to demonstrate how it will be carried out. My general comments are, starting with the main text:

• (minor discretionary) P5 last sentence: this is a description of significant event reporting: it would be useful to use this term, rather than just describe it
• P6 first para: this states ‘insight in the frequency and seriousness of potential unsafe situations might improve patient safety’- the paper needs to discuss whether this is just an assertion of the authors, or whether there is any evidence that this is actually the case- and quote evidence where it exists
• (minor discretionary) P6 second para, although interesting only refers to secondary care, so not strictly relevant to this protocol
• P 7 para 1: there is important research not mentioned here here. For example,

• (minor discretionary) P8 last para, really is discussing aims, best to include in the next section. It also needs to follow a logical sequence: e.g. identify under performance (not gaps), examine underlying factors, tailor interventions, test interventions, then set targets for improvement.
• (minor essential) P9 para 1: objective (3) seems to be a repeat of parts of objectives 1 and 2, unnecessarily complicating the study
• (minor essential) Definitions of harm will need to be more tightly defined for this study to work- as the authors recognise, but the criteria in box 1 are I think is too vague for reproducibility between different observers, we will need more information to make this definition more precise, or evidence that these criteria actually will work.

• (minor discretionary) P10 para 1: ‘broadly accepted as valid’: I understand where this idea comes from, but this runs the risk of increasing variation- and disagreement- between observers. For example this definition might have been interpreted by one observer to include the absence of a primary prevention intervention in- for example- aspirin use as was recommended by some guidelines in the UK recently. However in this case this advice was not derived from Grade I/II/III levels of evidence but expert opinion, and later shown to be incorrect in the clinical trial setting. So this ‘error of omission’ in the eyes of guideline followers turns out to be a correct patient care pathway for the evidence based practitioner, and the guideline incorrect. I would suggest that the authors consider sticking to evidence for interventions which are supported by clinical trials of at least grade I/II/III levels of evidence.

• (minor discretionary) P14 para 1; selection criteria for interviewers is rather loosely defined, in terms of reputation and experience, and could be more specific.

• (major compulsory) P14 second para; it is not clear how many reviewers will review the patient record in the retrospective study- if I understand it correctly I think its only 1 reviewer for 50% of records, and 2 for the remaining 50% for quality assurance. However this is not clear, and a (for example) flow diagram of the study design (including time scales) would help the reader to understand the method clearly.

• (major compulsory) P15 para 1; if the review only discusses those cases they are unsure of meeting the criteria, then there is still a risk that incidents are included/ excluded inappropriately when one reviewer thought their decision was correct: therefore I think the authors need to consider 2 reviewers looking at all records.

• (minor discretionary) P15 para 3: is chart audit the same as patient record? If so please use one term consistently for clarity.

• (minor essential) P16: we will need more details about what the survey questionnaire includes, perhaps include a copy of it?

• (minor essential) P15 para4, power calculation; I am not familiar with this approach and think it needs a more knowledgeable opinion from a specialist in statistics; however if the assumption is correct of an incidence rate of 30 patient safety issues in the 1000 records reviewed, then it seems to be a very small sample to meet the study objectives 1+2, of determining the incidence/type/impact/causes of these incidents, as there will be many possible different types of incidents (though prescribing error is the most likely from previous research). Pirmohamed et al looked at over 18,000 case records of higher risk patients in their (those admitted from primary care to hospital)
• P17: a significant (but perhaps unavoidable) weakness of reviewing notes looking for evidence of harm is that if this has not been identified by the attending clinician, then its possible that the information included in the case notes might not lead the reviewer to come to the correct conclusion of harm, leading to under detection of cases.

• Clustering of practices skewing the results is discussed by the authors, but quite possibly will have the effect of decreasing the power of the study.

• (minor essential) P19 para 1: need to give more information on how level of harm is defined into the different groups mentioned

• (minor essential) P 19 para 3: please can the authors clearly state what analyses they will be performing: I assume this will include regression, but if so we need to know which dependant and independent variables, dummy variables to identify practice clusters etc. Are the retrospective reviews and prospective incident reporting study going to be linked? What precisely will happen/what data will be collected in the prospective study?

• (minor essential) P 20 ethics; an area where there may be greatest risk is when a reviewer detects probable harm to a patient that previously wasn’t identified, and what precisely will happen in this case (? Just discussion with internal ethics committee, will the patient be told, if so what is the potential risk, will this impede recruitment for the study?)

• (major compulsory) The abstract at the moment isn’t clear, but will need to be revised when the above points are addressed.

• The 2 attachments I couldn’t read, as they were in Dutch. It is possible that they may answer some of the points mentioned above

(major compulsory) So in summary, this subject area is important; this protocol needs to be written much more clearly, so the reader can easily understand the methods used, how the prospective and retrospective components inter relate (if indeed they are meant to), details of the proposed analyses and how the authors will deal with previously unrecognised but serious safety issues that this study might uncover. The literature review needs to be widened. The power calculations need to be examined by someone more experience in this area than me, to ensure this study will achieve its aims and objectives.

Thank you once again for asking me to peer review this interesting protocol

Kind regards

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Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests