Reviewer's report

Title: Assessing hospitals' clinical risk management: Development of a monitoring instrument

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Reviewer: Willem Herbert van Harten

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The paper has gained much in transparency, and this makes reviewing easier, but it also reveals certain flaws in the setup of the paper that still need improvement (and were not obvious in the first version, so some of my comments are new due to that fact).

The purpose is stated as "to develop an instrument that allows for a continuous monitoring of the current state and planned developments in hospitals".

A minor revision is needed in the last sentence of the introduction where it is stated that the instrument "will" provide valuable data, but that is of course to be seen....

A major issue deals with the cultural aspect of the developed instrument either in the introduction or the method and certainly in the discussion, some text should be dedicated to the cultural context and organisational vision regarding CRM. In some cultures much value is given towards bureaucratic systems and verifications, whereas from management literature it can also be deduced that embedding these activities in hierarchical management (as opposed to employing support staff for this purpose) with a very small support structure is possibly more effective. There is also evidence, especially from US health services literature (Shortell et al) that not so much the exact system but the systematic adherence within the organisation is decisive in quality and safety management, and this may have some repercussions for the normative aspects embedded in the questionnaire. The questions, for example under 2A and 2B reflect a managerial paradigm that is not yet proven to be actually related to patient safety; the reader may want to know how the decision process on these items actually went.

A major issue is that the authors should more specifically describe how they selected the most relevant literature (what is a "critical" review?) and what were the criteria to choose the Australian etc standard (for instance most applicable to hospital environment, fitting to a certain management approach etc).

Another major compulsory revision is the description of the steps in improving the instrument. Either this can be very short or -preferably- more detailed on the exact development and changes. Now the steps are described but the content and influence of the responders (how many had what type of valuable comments and were these all valued in the same way?) I think the paper should thus focus
more on the objective as provided in the introd.

The part on development stages remains weak. Also the way it was piloted becomes not clear and the exact translation in the questionare (table?) is odd; I would skip the whole TTM unless a much more thorough introduction on this issue and the monitoring over time (continuous?)which is also not methodologically elaborated, is provided. This is also missing point in the discussion.

Major compulsive. In the method we note different steps with 6 CRM practitioners, an expert panel, nn CRM practitioners, an expert panel, applied in Swiss hospitals with 25 CRM practitioners, approval by the expert panel and a final passage on a measurement in a nationwide survey of which it is not clear what the role was regarding the papers’ objective. I would suggest describing this in a methodologically more structured way: how were the respondents selected, what was the decision method, etc etc. Only on page 18 a remark is made on the review of monitoring instruments with experts without specifying the procedure. The description of the second application does not overtly contribute information relating to the papaers objective.

Lastly the two issues raised on page 19 seem to conflict; it is suggested to include the questionnaire in a Swiss certification and later on a passage is provided on the most critical issue, being whether the resulting data really reflect clinical safety, casting doubt on formal applications. This should be more coherently presented..

Especially a thorough reflection on the validity (one remark found) and the actual relation with patient safety in actual practice (one passage) are not very well elaborated upon.

When looking at the questionnaire mainly aspects relevant for the policy agency is found; so this could b easily seen as a bureaucratic burden (no reflection is found on this issue);for the hospital itself probably only in case of meaningful benchmarking data a certain usefulness can be presumed, but this aspect (also the way of presenting) is not reflected upon.

No mention is made of the way of reporting in such a way that the information leads to improvements within the hospital or policy actions when used on national scale.

(p16)I would suggest leaving out the passage on setting the survey out in all Swiss hospitals as it does not seem to add information on the objective of the study.

In all the paper is improved, but not to a degree where publication is justified. More focus on the methodological aspects in de various steps of de development and less secondary information is advised. It would be advisable to leave out the TTM part and teh parts on nation wide surveys as long as these do not visibly contribute to the objective as stated in the introduction. A major revision is still advised.
An additional remark, as major issues are still to be tackled, it is not very useful to perform a strict textual review. However I would advise the editor to demand a thorough text review so that the revised paper will only get a go or no-go.

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

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I do not have any competing interests.
But am active in the board of the Dutch hospital association responsible for a national safety management project; am member of the board of a mutual insurance on hospital claims and member of the accreditation board of the OECI.