Reviewer’s report

Title: Safety analysis over time: seven major changes to adverse event investigation

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Reviewer: Dawn Dowding

Reviewer’s report:

This paper provides an overview of a proposed revision of the approach to patient safety and adverse event investigations in health care settings. Whilst the premise of the paper is interesting - that adverse event investigations should focus more on analyzing fewer incidents in more depth across a longer time frame and health care organizations, I did feel that it could benefit from further revision as follows:

1. The introduction makes reference to safety-critical industries and their use of other methods for assessing safety - examples here to illustrate the point with evidence for their effectiveness would be helpful.

2. Page 1, lines 90-91 - could you provide evidence to demonstrate how understanding has been expanded.

3. The need for reassessment section - whilst I do not disagree with the points that are made in this section, I did feel that it was poorly argued, with a number of statements not backed up with evidence or thought regarding whether or if the types of safety incidents have changed because of the changing nature of the healthcare system. If this is the case, some discussion about what types of incidents should be investigated, exactly how they may be identified and prioritized, might be helpful. At present the discussion is very superficial, and there are a number of places where broad ranging statements are made without references/evidence to support them (e.g. lines 105-106; 108-111; 117-122)

4. In the section on the seven major changes to adverse event analysis - again overall there are a number of statements made without provision of evidence to substantiate them. I think this section could be strengthened by considering exactly what types of incident/adverse event would be the focus of a new approach - the argument is that at present professionals choose incidents that are most immediate/visible - but surely they are also chosen because there is general agreement that the incidents are also examples of poor/unsafe care. Do we need to revisit how we define what an patient safety/adverse event incident might be (if we are changing the approach to investigating them), and if so how would they be identified/prioritized for examination? Although I can accept that some patient safety/adverse event incidents may not be identified by professionals - and that patients could provide an important insight into these issues, some agreement of a definition of what we mean by an incident/safety event in this 'new' framework needs to be proposed. Similarly a definition or conceptualization of what is meant by 'significant harm' over time is needed.
5. The section that argues for conducting fewer analyses in more detail needs to be better substantiated with evidence to support the argument being made, and perhaps some thought could be given to the criteria by which incidents would be selected for extensive analysis to ensure that they do provide insights and understanding.

6. The section on understanding success/failure in detection and recovery would benefit from further clarification on the risk analysis methods that are mentioned (lines 277-279) - how do they differ from current approaches, how do they work. How are successful recovery events defined/identified, so that we can learn from them. Lines 296-298- where is the evidence for this?

7. Lines 312-313 - could you provide an example of how other industries do this?

8. Lines 339-341 - evidence that these strategies are not effective?

9. Lines 386-391 - these are broad ranging statements, and in the paper I don't think that ample evidence has been provided to support them.

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