Reviewer’s report

Title: How Can We Improve the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals? A Qualitative Study of Frontline Clinicians

Version: 2  Date: 15 October 2014

Reviewer: Theodore Lystig

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Major Compulsory Revisions
1. None noted.

-Minor Essential Revisions
2. The sampling scheme used is described as using both purposive and snowball components (starting in the abstract). Starting on line 71 we learn that the sampling “proceeded until no further unique themes occurred.” Given that such sampling stopped after 16 interviews, which is the same number as the number of individuals originally identified for the purposive sampling, it seems likely that the snowball portion of the sampling scheme was not actually implemented. Clarification is needed here.

3. There are times when it seems that by medical devices, the authors are referring primarily to medical equipment (large items used repeatedly by hospital staff) in exclusion of medical devices that might be implanted in patients. As the range of medical devices is so broad, it would be helpful to have some discussion of the extent to which the authors felt that their findings applied to all types of devices and the extent to which some findings might be more applicable to certain subclasses of devices. For example, are there different issues encountered for a single use implantable device such as a drug eluting stent relative to the issues that are pertinent to an MRI scanner? Some discussion of this issue (surveillance needs differing by type of device) would be very helpful.

4. The authors have neglected to capitalize on an opportunity to provide some form of suggested prioritization for first steps in the design and development of a hospital medical device surveillance system that would help to improve patient safety and health care delivery. The reader is presented with a catalog of issues of concern to the interviewees, but little qualitative assessment has been provided as to the relative merits of these various concerns. Some discussion of suggested prioritization of the items covered would be encouraged.

-Discretionary Revisions
5. The third sentence in the Background portion of the Abstract is awkward. Suggest rephrasing to “…multiple factors that influence participation in medical device surveillance activities.”

6. In line 5, suggest amending to “devices can be harmful particularly when
misused.” This would more accurately link to the subsequent cited statistic concerning adverse events associated with medical device user-error incidents.

7. In lines 10-11, post market surveillance does not directly reduce the risk of device related adverse events by itself. Instead it enables us to act on such risks sooner, via the earlier detection that is facilitated by structured surveillance programs.

8. On line 15, the phrase “inform device improvement by manufacturers” refers to the general idea of feeding into the total product lifecycle (TPLC). The concept of TPLC might resonate better with the audience for this paper; it appears to good effect later on line 338.

9. In line 17, it might be better to say something along the lines of “We found three studies”, instead of just “Three studies”.

10. In line 32, the sentence starts with “The most effective medical device surveillance that…” It might be helpful to add an additional noun here, such as approach, method, or system. Otherwise it seems unnecessarily vague.

11. For the sentence starting on line 35 and ending on line 39, consider indicating something along the lines of “with a particular focus on potential roles of physicians and nurses.”

12. On line 86 we learn that an interview guide was developed in the course of this study. Consider providing this guide as supplementary electronic material.

13. Suggest splitting the sentence on lines 114-116 into two sentences, where the second sentence would start with “Exemplar quotes”.

14. On line 137, “According one surgeon” should be “According to one surgeon”.

15. For line 152, would “perioperative” be better than “per-operative”?

16. Line 198, change “lack of follow-up the hospital” to “lack of follow-up from the hospital”.

17. Line 217, change “intimated” to “intimidated”.

18. Line 218, change “institution they reported” to “institution if they reported”.

19. Line 273, change “reluctant or adverse” to “reluctant or averse”.

20. In Supplementary Table 1, some form of code (e.g., ACA1) is used for each exemplar quote. These codes are not defined, and do not seem necessary for the table. They appear to indicate the source of a given quote, yet there are two instances where the same two code pair is used (BVS1 & BIR1). Despite this discrepancy, it seems as if these codes could help serve to reveal the hidden identity of the interviewee to the reader, which would not be appropriate. In any event, it might be better simply to omit these codes.

21. Near the end of page 4 of the Supplementary Table 1, the exemplar quotes given for “Feedback on how reported information is used” and for “Hospital staff knowledge and experience” are identical. Presumably there should be distinct quotes used for these two different themes.

**Level of interest:** An article of limited interest
Quality of written English: Acceptable

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

Declaration of competing interests:

I am currently employed by Medtronic, a medical device manufacturer, and hold stock and options in the company.