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
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Reviewer: Lourdes A Medina

Reviewer’s report:

The paper presents an important and interesting problem in the daily use of medical devices. Therefore, it has the potential of becoming a great contribution to the literature. However, the execution of the paper along with the method used requires refining and improving in order to make this paper acceptable for publication. I congratulate the authors for their selection of this topic and encourage them to work on improving the paper for future publication.

Major Compulsory Revisions

Method:
- Sample size is too small with 12 surgeons and 4 nurses. Perhaps a second phase of a follow-up structured survey or focus group should be completed to assess the factors that were identified. As is the research seems incomplete.
- The protocol followed (including questions made) is not provided and it would be very valuable in our evaluation of the method.

Overall:
- The claim that this is the first study of this type (in the abstract, introduction and method-approach) is too strong and not credible without an in depth literature review. The discussion of existing literature is extremely brief to make such a statement. I think the authors should make an in depth study of the literature and improve their recognition of what their study is really adding to the literature.
- Very little reference to the regulatory bodies is made; in the USA the FDA does require post-market surveillance for most if not all class III devices. In addition, the FDA requires for malfunctions to be reported. I want to reinforce the regulations because a medical device malfunction is a global issue that should be reported and published in the public domain (to the world). Therefore, I question the following statement “One surgeon felt that there should be increased collaboration among hospital facilities to track the performance of medical devices.”

Minor Essential Revisions

Abstract:
- I recommend improving the definition of the uses of medical devices.
- The concept of thematic saturation should be better explained with reference to
the literature that defines it and justifies this as a recommended method. More
details of their application should be provided.
Overall:
- Referencing should be verified. For instance, the point should be after the
reference (for example [1].).

Discretionary Revisions
Results:
- Did the authors consider comparing their results to the reports of re-calls?
- Did the authors consider gathering data of specific device malfunctions?
Opinions sometimes are bias and there is always the issue of subjectivity.
Combining these opinions/experiences with data would make the research much
stronger.

**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.