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: Sanket Dhruva

Reviewer's report:

Drs. Polisena, Gagliardi, and Clifford explore reporting of device related adverse events in the hospital setting through interviews with healthcare providers. While this is a very important issue, there is a significant amount of clarification and revision which is needed to strengthen the manuscript.

Major issues:
- the authors discuss device-related incidents and the response to them, but how do we know if any of them were due to user error or insufficient knowledge of the device? This issue is not addressed
- the authors do not discuss what exactly that they mean by "device" as this is a broad term (are these implanted devices like hips and heart valves? are these devices that are used during surgery?)
- the issue of gravity of device-related adverse events is not issued and would have a huge impact on future use, adverse event reporting, and, most importantly, on patient outcomes.

Specific comments:
Title: change "clinicians" to "surgeons & registered nurses"

Page 2: abstract: it is unclear what "multiple factors that influence their roles in medical device surveillance" refers to. Please clarify

Page 5, line 3: add "diagnosis" after "effective" and before "treatment"

line 3: it is not always the case that devices use less invasive techniques

line 6: it is not only incidents among "high risk" devices that have garnered widespread attention (please see Zuckerman et al Archives of Internal Medicine June 13, 2011

line 10: "post-market surveillance" is too broad of a term

line 11: add "identifying & subsequently" before "reducing"

line 11: what do the authors mean that PMS would "prospectively monitor" safety and effectiveness? There are many initiatives in place for PMS...
line 12: the issue of access to innovative devices is a very complex topic

line 17: change "were" to "have been"

line 25: it seems that this reference is specific to devices

line 48: why did the authors decide not to interview device technicians? also why was the ratio of physicians to RNs 12:4?

line 59: "surgery" should be changed to "interventional procedures and surgery" as cardiologists and interventional radiologists are not surgeons. Calling them surgeons throughout the paper is inaccurate and a broader term like "physicians who perform interventional procedures or surgery" or something like that would be more correct

line 59: I do not see where in reference 8 that it says device incidents occur most often in surgery

lines 64-66: why were other surgeons or proceduralists excluded (e.g. gastroenterologists, ENT surgeons, OB)

lines 87: what type of devices? are these all implanted devices? Technically CT scanners and stethoscopes and glucose test strips are also devices. This issue needs to be clarified in the manuscript

line 115: Table 2 is unavailable for my review

line 118: what does clinician's experience mean? experience with the device? years in practice?

lines 119-120: what does it mean that "routine practice was not carried out as intended"?

line 129: regarding the "reporting system" - where is the report made to? to the hospital? to the device company? to a regulatory body?

line 135: what does "problem" mean? (a patient safety event, device malfunction, etc)

line 136: change "became" to "have become"

line 137: what does "learning culture" mean?

line 138: spell out "OR" as operating room

line 140: the authors do not mention that they interviewed hospital inventory suppliers

lines 141-142: important to address - is there a threshold of safety adverse effect for which the defective parts are returned to the company

line 144: this assumes that if the surgeon is unaware of the reporting process
that the RN is definitely aware of it. Is that accurate?

line 152: what type of procedural data was submitted? for what procedures?

line 153: although devices were registered, how was this data fed back?

line 171-3: what does it mean for hospitals to safeguard the availability of devices to avoid delays?

lines 204-207: how is interpretation of imaging related to device-related problems? Are the authors implying that device-related adverse events are often discovered on imaging?

lines 209-210: grammar needs to be corrected

line 218: need "if" after institution. Need to remove the plural on "incidents"

line 219: error reporting to whom?

line 220: what were RNs and surgeons concerned about their professional reputation? if they did report or if they did not report?

line 225: was it common that even manufacturer representatives had difficulties in troubleshooting device incidents?

line 226: by "open" do the authors mean that the staff did not want to discuss complications or just did not have time?

line 239: hospital staff should also receive training on updating devices and also on error reporting systems not just for the hospital but also more broadly

line 246: M&M is not always focused on devices

line 266: were patients themselves ever the first to recognize device-related adverse events?

lines 268-269: were patients always notified of incidents, even those that may have been corrected in the operating room?

line 270: how was "serious" determined? what are examples of serious adverse events

line 272: not reported to whom? to regulators or to families?

line 298: delete "and interview" because it was 16 total interviews

lines 304-305: the authors mention this framework but need to discuss it further

line 312: the staged notification refers to device recalls that are not necessarily in the hospital setting

line 317: the Maisel citation is good, but the authors should also find a more updated citation on device post-marketing surveillance
line 335: in this paragraph, consider discussing unique device identifiers (UDIs)

**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 declare that I have no competing interests