Author's response to reviews

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

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Author's response to reviews: see over
Ms. Armee Valencia

Subject: Manuscript Resubmission

Dear Ms. Valencia:

Thank you for the opportunity to respond to the review comments. I would like to resubmit our manuscript, "How Can We Improve the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals? A Qualitative Study of Physicians and Registered Nurses," by Julie Polisena, Anna Gagliardi, and Tammy Clifford for publication in Health Services Research. Enclosed please find our responses to the reviewer comments.

As indicated in a previous correspondence, the manuscript was completed through the contribution of the authors named in the manuscript. None of the authors declared any conflict of interests, and each has approved the version submitted. The content of this manuscript has not been published nor is being considered for publication elsewhere.

I have attached the manuscript abstract for your review.

Thank you and kind regards,

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Reviewer 1:

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.

Response: The following explanation was expanded to describe the process for thematic saturation, which determines the study sample size in qualitative research:

Thematic saturation, where the categories were explained adequately and new categories do not emerge, was assessed upon review of codes derived based on responses for each interview question. If no new themes emerged related to factors that influence incident recognition, reporting and resolution, as well as recommendations to improve medical device surveillance, the authors deemed that additional interviews with surgeons and RNs would not add new insights to the current responses [10]. As the interview questions were specific to medical device-related incidents in two teaching hospitals in the same jurisdiction, the authors deemed that thematic saturation was achieved after 16 interviews, where no new information was obtained and some redundancy was observed in the thematic categories in subsequent interviews.

- The protocol followed (including questions made) is not provided and it would be very valuable in our evaluation of the method.

Response: The authors included a copy of the interview questions in the supplemental file.

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.

Response: The following statements were added in the Background and Methods sections:

Background:
Polisena et al. conducted a systematic review on factors that influence device-related incident recognition, reporting and resolution of device-related incidents, as well as interventions or strategies to improve the recognition, reporting and resolution of device-related incidents. The authors expanded the scope to include other health technologies, such as drug therapies, diagnostic and screening tests, vaccines and surgical and non-
surgical procedures, to ensure the comprehensiveness of the literature found. Among the 30 studies selected, most focused on factors that influence incident reporting [7].

Methods

Approach

There is insufficient evidence in the published literature on the factors that influence physician’s and nurse’s roles in surveillance. A grounded qualitative approach was used to explore the perceptions, behaviours, practices, and experiences of surgeons and nurses related to the use of devices. This approach elicits views and insights for a rich understanding of phenomena[8,9]. Surgeons and registered nurses (RNs) were interviewed to explore factors that influence device incident recognition, reporting and resolution. The same interviews also solicited information about initiatives or strategies to improve the recognition, reporting and resolution of device-related incidents. The critical incident interviewing technique which asks respondents to provide detail about particularly relevant experiences also was employed [9]. Telephone interviews of approximately 30 minutes were audio-recorded and transcribed verbatim. The interviews were conducted between September and December 2013 in two Canadian teaching hospitals. A systematic review of the medical and grey literature on factors that influence common device incident and their recognition, reporting and resolution was supplemented by the results of our interview responses [7].

- 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.”

Response: The following definition of medical devices was added in the Background section:
The US Food and Drug Administration (FDA) defines a medical device as an instrument used to diagnose, treat or prevent a disease or abnormal physical condition without any chemical action in the body [1].

Response: The following statement was added in the Results section:

Although post-market surveillance systems for devices, such as the FDA MAUDE database, exist, one surgeon felt that there should be increased collaboration among hospital facilities to track the performance of medical devices.
Abstract:
- I recommend improving the definition of the uses of medical devices.

**Response:** The following definition of medical devices was added in the Background section:
The US Food and Drug Administration (FDA) defines a medical device as an instrument used to diagnose, treat or prevent a disease or abnormal physical condition without any chemical action in the body [1].

- 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.

**Response:** As previously indicated the following explanation was expanded to describe the process for thematic saturation, which determines the study sample size in qualitative research:

Thematic saturation, where the categories were explained adequately and new categories do not emerge, was assessed upon review of codes derived based on responses for each interview question. If no new themes emerged related to factors that influence incident recognition, reporting and resolution, as well as recommendations to improve medical device surveillance, the authors deemed that additional interviews with surgeons and RNs would not add new insights to the current responses [9]. As the interview questions were specific to medical device-related incidents in two teaching hospitals in the same jurisdiction, the authors deemed that thematic saturation was achieved after 16 interviews, where no new information was obtained and some redundancy was observed in the thematic categories in subsequent interviews.

Overall:
- Referencing should be verified. For instance, the point should be after the reference (for example [1]).

**Response:** The referencing has been modified to comply with the journal’s author guidelines.

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.
Response: Our scope was limited to the telephone interviews with physicians and registered nurses to discuss their experiences with the recognition, reporting and resolution of medical device-related incidents. The following statements were added in the Discussion section:

Moreover, the authors were unable to ascertain if the device incidents occurred due to the device malfunction, user error or insufficient knowledge on their proper use, as well as the severity of the device incident.

Future research can further investigate the device malfunctions cited by the interview respondents and compare them to reports of recalls to assess their prevalence and severity in clinical practice. In addition, a follow-up to review how device malfunctions were handled after they reported errors to the hospital and compare the results to their official policies and procedures merits an investigation.
Reviewer 2:

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

Response:

-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?)

**Response:** The following definition of medical devices was added in the Background section:
The US Food and Drug Administration (FDA) defines a medical device as an instrument used to diagnose, treat or prevent a disease or abnormal physical condition without any chemical action in the body [1].

The following comment in the Results section was added that lists the medical devices mentioned during the interviews:

**Medical Device-Related Incident Examples**
Types of medical devices commonly associated with incidents ranged from dialysis and extra corporeal life support machines and infusion pumps to implantable devices, such as catheters, stents, and inferior vena cava filters. Staplers also were mentioned by both clinicians and nurses as prone to incidents during a clinical procedure. One cardiologist responded that new medical devices were more prone to errors as a result of a learning curve associated with its use.

-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.

Response: The following statement was added in the Discussion section: Moreover, the authors were unable to ascertain if the device incidents occurred due to the device malfunction, user error or insufficient knowledge on their proper use, as well as the severity of the device incident.

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

**Response:** The title was modified to physicians and registered nurses.

Page 2: abstract: it is unclear what "multiple factors that influence their roles in medical device surveillance" refers to. Please clarify
Response: The sentence was modified to as follows: Results from the telephone interviews suggest that multiple factors that influence participation in medical device surveillance activities are consistent with results for medical errors as reported in previous studies.

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

Response: Done

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

Response: The following sentence in the Background section was modified: They are important health care innovations, enabling effective diagnosis and treatment using less invasive techniques in many instances, and improving health care delivery and patient outcomes.

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)

Response: The sentence was modified to as follows: They are important health care innovations, enabling effective diagnosis and treatment using less invasive techniques in many instances, and improving health care delivery and patient outcomes.

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

Response: The sentence was modified to as follows: Post-market surveillance (PMS) used to collect data on adverse events associated with the use of medical devices enables us to address the risks of device-related adverse events sooner via the earlier detection that is facilitated by structures surveillance systems.

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

Response: Done

line 11: what do the authors mean that PMS would "prospectively monitor" safety and effectiveness? There are many initiatives in place for PMS...

Response: The sentence was modified to as follows: This approach would prospectively monitor safety and effectiveness through its data collection without impeding access to innovative devices; more rapidly identify and communicate incident data to avoid further events; guide the development of training, organizational process improvement, or other patient safety interventions; direct decision-making about funding or replacement; and potentially inform device improvement by manufacturers.
line 12: the issue of access to innovative devices is a very complex topic

**Response:** Thank you for the comment.

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

**Response:** Done

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

**Response:** The sentence was modified to as follows: A systematic review identified 1,676 factors contributing to patient safety incidents in 83 eligible studies, and categorized factors into 20 domains including active failure in performance or behaviour, clinician, team, institution, system, culture, training, accountability and patient factors [5].

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

**Response:** The study was exploratory in design, and the intent was to gather information from physicians and registered nurses about their experiences with the recognition, reporting and resolution of medical device-related incidents in a hospital context as they frequent users of medical devices. Future studies can explore perspectives from other health care providers, including device technicians, administrators and manufacturers. The results from the current study would help to inform the development of future questionnaires. Also, a larger number of physicians were interviewed to represent an array of specialties that use medical devices on their patients. Registered nurses in the operating room and intensive care unit were targeted given their extensive use of medical device in health care delivery.

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

**Responses:** Done

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

**Response:** The sentence was removed.

lines 64-66: why were other surgeons or proceduralists excluded (e.g. gastroenterologists, ENT surgeons, OB)
Response: As this study was exploratory in design, future research can include additional physicians and surgeons to gain their perspectives. The following sentence was added in the Discussion section: Interviews with physicians with other specializations, hospital administration staff, the biomedical engineering department and manufacturers would provide additional information on factors that influence the recognition, reporting and resolution of device incidents.

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

Response: The following statement was added in the Results section:

Medical Device-Related Incident Examples
Types of medical devices commonly associated with incidents ranged from dialysis and extra corporeal life support machines and infusion pumps to implantable devices, such as catheters, stents, and inferior vena cava filters. Staplers also were mentioned by both clinicians and nurses as prone to incidents during a clinical procedure. One cardiologist responded that new medical devices were more prone to errors as a result of a learning curve associated with its use.

line 115: Table 2 is unavailable for my review

Response: Table 2 has been uploaded.

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

Response: The sentence was modified to as follows: Telephone responses revealed that the recognition of a medical device-related incident or malfunction is related to the clinician's past experience with the use and knowledge of device.

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

Response: The sentence was modified to as follows: Issues with medical devices also can be recognized if they did not operate according to the manufacturer instructions.

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

Response: The sentence was modified to as follows: Themes related to incident reporting include error reporting compliance, ethics, feedback on how reported information is used, information sharing, incentive for error reporting, institutional and professional cultures, and reporting system and process to the hospital, manufacturer and regulator.
line 135: what does "problem" mean? (a patient safety event, device malfunction, etc)

Response: Problem was changed to incident.

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

Response: Done

line 137: what does "learning culture" mean?

Response: They also observed that hospitals have become less punitive over time when an incident was reported and adopted more of a learning culture instead, where incidents were used as an education opportunity for the hospital staff.

line 138: spell out "OR" as operating room

Response: Done

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

Response: The sentence was modified to as follows: Based on the interview responses, physicians, nurse managers or hospital inventory suppliers reported device failures and malfunctions directly to the manufacturer and, in some instances, returned defective parts to the company.

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

Response: The following sentence was added in the Results section: The respondents, however, did not indicate the threshold of safety adverse effects for which the defective parts were returned to the manufacturer.

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?

Response: The following sentence was modified: In cases where a physician was unaware of the reporting process, he or she asked the RN to report the incident on his or her behalf.

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

Response: The sentence was modified to as follows: The same hospital also participated in a global vascular qualitative initiative that allowed vascular surgeons to submit data about per-operative patient and the procedure performed.
Although devices were registered, how was this data fed back?

**Response:** Another surgeon stated that a system is in place within his hospital, where malfunctioned devices were registered for tracking purposes, along with the actual malfunction and surgical team involved. The respondent did not elaborate on how the data was used by the hospital.

What does it mean for hospitals to safeguard the availability of devices to avoid delays?

**Response:** The sentence was modified to as follows: In addition, hospitals ensured a sufficient number of devices in stock to avoid delays in a clinical procedure, replace old equipment with a newer version and contact the manufacturer for in-servicing.

How is interpretation of imaging related to device-related problems? Are the authors implying that device-related adverse events are often discovered on imaging?

**Response:** The statement was based on radiologist’s experiences and was not meant to be generalized to the whole study sample.

Grammar needs to be corrected

**Response:** Done

Need "if" after institution. Need to remove the plural on "incidents"

**Response:** Done

Error reporting to whom?

**Response:** The statement was modified to as follows: Others also felt that error reporting to the hospital was complicated and time-consuming.

What were RNs and surgeons concerned about their professional reputation? If they did report or if they did not report?

**Response:** The statement was modified to as follows: Both RNs and physicians were concerned about their professional reputation if they reported the error.

Was it common that even manufacturer representatives had difficulties in troubleshooting device incidents?

**Response:** The following sentence was added: It is unclear if manufacturers frequently had difficulties 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?

**Response:** The following sentence was modified: Hospital staff **did not always want** to discuss each other’s complications with the use of medical devices, but some felt that they had a professional obligation to report a device incident or malfunction to the hospital.

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

**Response:** The sentence was modified to as follows: Hospitals must ensure that their staff receives adequate training on the use of new medical devices and existing error reporting systems and how to report device incidents and malfunctions to ensure consistency in clinical practice.

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

**Response:** Thank you for your comment.

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

**Response:** Based on the interviewee’s responses, it was not apparent if patients were ever the first to recognize device-related adverse events since the participants focused on their experiences.

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

**Response:** The following sentence was added: Based on the physician’s response, it was a challenge to discern if the error reporting to various parties was consistent.

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

**Response:** The sentence was modified to as follows: Conversely, **errors not deemed to be serious by the physician or nurse** or near misses were not always reported to the hospital.

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

**Response:** The sentence was modified to as follows: Conversely, errors not deemed to be serious by the physician or nurse or near misses were not always reported to the hospital.
line 298: delete "and interview" because it was 16 total interviews

Response: Done

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

Response: A figure that outlines the framework has been uploaded, and a brief explanation is included under the Implications heading. In addition, a reference to the article was added.

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

Response: The sentence was modified to as follows: Although previous studies developed a framework on incident **reporting to improve patient safety in a hospital context** [4,16,17], this is the first study to collect data on factors that influence the recognition, reporting and resolution of medical device incidents and improvement strategies.

line 317: the Maisel citation is good, but the authors should also find a more updated citation on device post-marketing surveillance

Response: The following citation was added: Sorenson and Drummond. Improvement in the Medical Device Regulation: The United States and Europe in Perspective. *The Milbank Quarterly*, Vol. 92, No. 1, 2014 (pp. 114-150).

line 335: in this paragraph, consider discussing unique device identifiers (UDIs)

Response: The following statement was modified: Since the use of medical devices in clinical practice continues to expand, rigorous monitoring for medical device performance, **the introduction of unique device identifiers on devices to improve their traceability in the United States and Europe**, greater awareness of device malfunctions and demand for increased reliability of medical devices are warranted [20,21].
Reviewer 3:

1. What are the hospitals like and what are their written policies (if any) in regards to medical devices?

Response: A brief description of the hospitals was added in the Methods section. Their policies, however, were out of scope for this study. The revised statement is as follows: Physicians and RNs at two tertiary care hospitals with over 1,500 hospital beds combined, one in Ottawa and another in Toronto, Canada were identified by research team members to collect information about their experiences with medical device-related incidents.

2. It would be helpful to know how each step of the methodology compares with similar qualitative studies done previously, especially ones that are highly regarded in their field. See attached comments for questions regarding the stopping point for the interviews.

Response: The results of qualitative research are not intended to be generalizable to the study population. In the current study, the objectives were to describe the perspectives of physicians and registered nurses in how they recognize a device incident, if and how they report and actions taken to prevent similar errors from reoccurring. In addition, the interviews also solicited ideas and strategies to improve medical device surveillance in a hospital setting. Please see the authors’ responses to the specific comments on the study methodology.

3. Was any effort made to find out if the suggestions made are in place at other hospitals or being considered at these facilities?

Response: Several respondents indicated if the strategies that they had suggested to reduce the risk of medical device-related incidents from reoccurring were being implemented. Otherwise, the majority were based on their opinions and ideas.

4. The narrative nature of the results makes it difficult to see patterns that would lead to next steps. Another Table might be useful to delineate those patterns and compare the facilities.

Response: Table 2 presents the code and themes that were derived from the interviews to help identify potential patterns.

Specific comments follow:
Title is appropriate and the questions are quite well defined. It is well written.

Methodology:
Note general comments above..
Line 71-78: It is unclear if the researchers had more respondents lined up, but stopped
interviewing after saturation, or if saturation simply occurred with the number of interviewees they expected or because of time constraints. How many interviews had no new themes before it was determine that saturation had occurred?

**Response:** The authors had intended to six interview physicians in various specialties and two registered nurses in operating rooms and intensive care units from each teaching hospitals. Since responses were repeated before all 16 interviews were completed, the authors decided not conduct additional interviews beyond the original sample size.

**Results:**
Line 111: There does not seem to be a Table 1 with this information in the paper.

**Response:** Table 1 has been uploaded

Lines 126-262: Was any work done to confirm if the respondents were correct on how device malfunctions were handled after the report left their hands? How does the real-life experiences compare to the hospital’s official procedures? For example, referring to lines 249-251, do nurses?

**Response:** The study objectives were to explore factors that influence device-related incident recognition, reporting and resolution and describe barriers and existing and/or recommended initiatives to improve the recognition, reporting and resolution of device-related incidents based on telephone interview responses by physicians and registered nurses. The following statement was added in the Discussion section: Future research can further investigate the device malfunctions cited by the interview respondents and compare them to reports of recalls to assess their prevalence and severity in clinical practice. In addition, a follow-up to review how device malfunctions were handled after they reported errors to the hospital and compare the results to their official policies and procedures merits an investigation.

Lines 268-271: Did all respondents agree that this is what occurs every time? This is inconsistent with recent media reports about underreporting of problems with da Vinci robotic surgery, with morcellation devices, and with transvaginal mesh, for example. Those are 3 examples where media reports suggest that surgeons are aware of medical problems associated with devices, and those problems were not reported to the company or the FDA.

**Response:** The following statement was added: Based on the physician’s response, it was a challenge to discern if the error reporting to various parties was consistent.

Line 277: what does “fixed” mean in this case? Replaced a defective device? Redesigned the device? Suggested a different way to use the device so it would work better? Type of fixing has implications for how long it takes to “fix” and how many patients might be harmed in the meanwhile.
Response: The following statement was modified: The telephone interviews also revealed that physicians discontinued using a specific device if it malfunctioned and the problem was not resolved and the risk, therefore, of a similar incident reoccurring continued to exist.

Line 278: Were these risk mitigation strategies personal to the surgeon, or developed with the department?

Response: The sentence was modified to as follows: Should an alternative therapy not be available, then risk mitigation strategies developed by the hospital department were planned for future clinical procedures.

Lines 317-321: This is confusing. What are the authors saying?

Response: The sentence was modified to as follows: Although previous studies developed a framework on incident reporting to improve patient safety in a hospital context [4,16,17], this is the first study to collect data on factors that influence the recognition, reporting and resolution of medical device incidents and improvement strategies.

Lines 309-321: Perhaps this belongs in the introduction, to compare the new study with previous studies?

Response: This section aims to summarize the study findings and suggests conclusions based on the results of the interviews.

Lines 329-330: The authors make an excellent point regarding responder bias. It is unclear if the authors mean the specific RNs and surgeons interested in medical devices were the ones who responded or if they meant surgeons and RNs in general are more interested in medical devices. This is confusing because I am under the impression that only surgeons and RNs were recruited. How many people did the authors ask to interview who refused? If participants agreed to be interviewed because of relationships with the authors, did that also influence their responses?

Response: The sentence was modified to as follows: There was a potential for responder bias, where physicians and RNs, who were more interested in medical device-related incidents compared with their colleagues, agreed to be interviewed, influencing the responses.
Looking at the supplementary material, it appears the two hospitals examined have very different experiences. It might be useful to do some analysis of this so to avoid some of the seemingly contradictory statements at these two hospitals have a theoretical right to refuse to use defective equipment? If so, is the problem a cultural expectation to not rock the boat, or do they simply not know they have the ability?

**Response:** Supplemental Table 1 represents example quotes based on the interview response. The information presented is not intended to compare the two hospitals. Based on the complete interview responses, there were no contradictory statements identified between these institutions.

Lines 260-262: Related to above, are there any such initiatives? Was any effort made to find out if such a registry is in place at other hospitals or being considered at these facilities? Have they been suggested?

**Response:** A formal investigation on whether any of the initiatives were being implemented was out of scope for this study. The study findings presented were based on interview responses.

Lines 265-268: Clarify. Are the authors saying technology is supposed to be finding errors but the interviews suggest that errors are found by the health professionals without help from technology in the results.

Response: The sentence was modified to as follows for clarification purposes: **Even though the literature identified the performance of a health technology** as a factor that influenced the recognition of incidents, numerous respondents attributed the recognition of incidents to devices not operating as intended and to the hospital staff’s knowledge and professional experience on both medical device performance and clinical manifestations of patients.
Reviewer 4:
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.

Response: The term “snowball sampling” was removed to avoid any confusion.

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.

Response: The following statement was added in the Results section:

**Medical Device-Related Incident Examples**
Types of medical devices commonly associated with incidents ranged from dialysis and extra corporeal life support machines and infusion pumps to implantable devices, such as catheters, stents, and inferior vena cava filters. Staplers also were mentioned by both clinicians and nurses as prone to incidents during a clinical procedure. One cardiologist responded that new medical devices were more prone to errors as a result of a learning curve associated with its use.

The following statement was added in the Discussion section: Moreover, the authors were unable to ascertain if the devices incidents occurred due to the device malfunction, user error or insufficient knowledge on their proper use, as well as the severity of the device incident.

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.

Response: Under the Implications section, the authors present a conceptual framework for a medical device surveillance system in a Canadian hospital context and uploaded a figure that depicts the framework. A reference to the published article was added:

Implications
The results of our telephone interviews were used to propose a conceptual framework on medical device surveillance in hospitals (Figure 1). In addition to education and training, an open communication and feedback strategy, and an adverse medical device database/registry, the proposed framework would integrate medical devices with information systems to identify, track, and manage their location. This framework would capture and evaluate the appropriate resolutions to help lower the risk of incidents and adverse events associated with medical device use in hospitalized patients [15].

-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.”

Response: Done

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.

Response: Done

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.

Response: The sentence was modified to as follows: Post-market surveillance (PMS) used to collect data on adverse events associated with the use of medical devices enables us to address the risks of device-related adverse events sooner via the earlier detection that is facilitated by structured surveillance systems.

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.
Response: The sentence was modified to as follows: This approach would prospectively monitor safety and effectiveness through its data collection without impeding access to innovative devices; more rapidly identify and communicate incident data to avoid further events; guide the development of training, organizational process improvement, or other patient safety interventions; direct decision-making about funding or replacement; and potentially inform the total product lifecycle by manufacturers.

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

Response: Done

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.

Response: The term, “system”, was added.

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.”

Response: Done

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.

Response: The interview guide was uploaded as a supplemental file

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

Response: Done

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

Response: Done

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

Response: Done

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

Response: Done
17. Line 217, change “intimated” to “intimidated”.

Response: Done

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

Response: Done

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

Response: Done

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.

Response: Thank you for your comment. As per your suggestion, the codes were removed from the supplementary table.

21. Near the end of page 4 of the Supplemental 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.