Author’s response to reviews

Title: Multiple constraints compromise decision-making about implantable medical devices for individual patients: qualitative interviews with physicians

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Author’s response to reviews:

Hello:

Many thanks for inviting us to submit a revised manuscript for further consideration by your journal, and many thanks to the editors and peer reviewer for their insightful and helpful comments. Our responses to each comment are outlined in the response letter, which notes specific page numbers, and in the manuscript using track changes. We would be pleased to provide further information or clarification of any details if needed.

Best regards,

Anna Gagliardi, PhD
EDITOR

Please describe the contributions of each individual author in the Authors' contributions section and ensure that every author has been named.

Response:

The manuscript now includes specific author contributions (p 19)

REVIEWER

Research question: The research question is still not well defined. The abstract states: "This study explored factors that influence decision-making for higher-risk implantable devices." The introduction states "The purpose of this study was to explore factors that influence individual physician decision-making about choice of higher-risk implantable medical devices to treat a given patient from among options available to them, and identify factors that may constrain choice and potentially compromise clinical outcomes, which should be targeted in the future through policies or behavioral interventions?" Are the authors talking about decisions on whether to receive a device or not or are they talking about choices among available devices once the decision has been made to pursue therapy? These are two very different decisions - the authors need to be consistent.

Response:

The reviewer is quite correct that the study purpose could be more clearly and more consistently stated, and that the focus was on factors that influence choice among available devices. We edited both statements as follows:
Abstract (p 2)

This study explored factors that influence choice of implantable devices from among available options.

Manuscript, Background (p 6)

“…to explore factors that influence individual physician decision-making about choice of implantable medical device from among options available to treat a given patient…”

Cardiac vs. orthopedic devices: For me, this is the single major challenge in this manuscript. The choice to include both cardiac and orthopedic devices creates some confusion. I think the authors were looking to include two sets of devices to provide some understanding of what themes existed across devices. For example, the authors find a theme that there is so little evidence for devices ("Participants described a lack of high-quality data from the medical literature on the safety and effectiveness of devices to inform decision-making.") However, two devices specifically mentioned in the manuscript (implantable defibrillators and left ventricular assist devices) actually have a robust evidence based with multiple RCTs. The exemplar included in the manuscript is only from orthopedics. Were there differences between orthopedics and cardiology - I strongly suspect there were. I note the quotes in the appendix from the cardiologists but I'm still struggling with this theme applied to ALL devices - it lacks face validity and makes me question the results. Could the authors either defend this theme with more data or explore if there were nuances by devices? Also, the authors should consider including a list of specific devices that the interviewees mentioned in the interviews to give the reader this contextual understanding.

Response:

We appreciate this comment and, for each key point, will specify how we addressed the concern in the manuscript.
Background

Reviewer: Two devices mentioned (implantable defibrillators and left ventricular assist devices) actually have robust evidence

Response: References 5 and 6 (and others that we could add) support the following revised statement: “Studies analyzing the quality of research for frequently emerging new versions of medical devices found they are marketed without the rigorous scientific evidence expected for drug approval…” (p 4)

Results

Reviewer: The authors find a theme that there is so little evidence for devices (which contrasts with the reviewer’s assertion that there is robust evidence)

Response: The theme of lack of high quality evidence that was articulated by participants supports the research cited in the Background (reference 5 and 6). Even if this was not the case, we would need to report that the participants believe there is no/little evidence because that is what they told us, and those views, valid or not, may be influencing decision-making (p 9)

Results and Additional File 1

Reviewer: The exemplar included in the manuscript is only from orthopedics. Were there differences between orthopedics and cardiology - I strongly suspect there were. I note the quotes in the appendix from the cardiologists but I'm still struggling with this theme applied to ALL devices - it lacks face validity and makes me question the results.

Response: The single exemplar in the manuscript is indeed a quote for orthopedic devices, however, Additional File 1 includes two additional quotes for orthopedic devices and two quotes for cardiovascular devices, which shows that many respondents believe there to be no/little evidence for the safety and effectiveness of implantable devices. (p 9, Add File 1)
Results and Discussion, Limitations

Reviewer: Could the authors either defend this theme with more data or explore if there were nuances by devices? Also, the authors should consider including a list of specific devices that the interviewees mentioned in the interviews to give the reader this contextual understanding.

Response: Given that this was qualitative research that explored factors that may influence decision-making rather than a questionnaire survey that collected specific factors related to specific devices, we did not consistently collect data on the specific device being addressed by participants in each idea they articulated. Overall, we agree that there may be some variation in the actual evidence for the safety and effectiveness of different devices, however, being explicit about that was not really in the scope of the current study. Still, we included this as a potential limitation of our study in the Discussion, Limitations paragraph (p 15) as follows: “Participants described factors that influenced choice of device in general; they may have responded differently if asked about particular types of orthopedic or cardiovascular devices.”

"higher risk" - In the title and several times in the manuscript, the authors refer to "Higher-risk…devices" - how was "higher-risk” defined. Some things like a pacemaker or even a defibrillator are debatable if they are "high risk" - Do the authors mean "invasive"? Certainly an LVAD is high risk. Again, more nuance on the devices will be helpful. Trying to simplify and call all devices "high risk" and all themes applied to all devices is part of the challenge interpreting this paper.

Response:

Given differences in how “high risk” may be defined by different regulatory agencies (i.e. Health Canada, which has four risk categories from high to low/no risk versus FDA) it may be more straightforward to remove “high risk” and simply refer to “implantable devices” since we focused on two examples that were invasive, as the reviewer suggests. Hence, we removed “higher risk” in the following:
• Title, p 1
• Abstract, Background, p 2
• Background, p 4 and 6
• Conclusions, p 17