Reviewer’s report

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

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Reviewer: Daniel Matlock

Reviewer's report:

Interestingly, I had the opportunity to review this paper previously when it was submitted to Medical Decision Making. I like this paper and it appears that the authors have made some edits based on the prior reviews. This is an interesting paper describing a qualitative study of physicians (cardiologists and orthopedic surgeons) use of technologies. The authors use a nice organizational approach for the results looking at device factors, patient factors, physician factors, organizational and health system factors. Their major finding is that this decision making is highly complex and is a function of multiple factors. Overall, the paper is interesting.

1) 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 patients 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.

2) 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.

3) "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.

Those are my remaining concerns. I think this is a nice paper.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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Not relevant to this manuscript

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