PEER REVIEW HISTORY

This paper was submitted to a another journal from BMJ but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

(This paper received three reviews from its previous journal but only two reviewers agreed to published their review.)

ARTICLE DETAILS

TITLE (PROVISIONAL)	What are the requirements for developing a successful national registry of auditory implants? A qualitative study
AUTHORS	Mandavia, Rishi; Knight, Alec; Carter, Alexander W; Toal, Connor; Mossialos, Elias; Littlejohns, Peter; Schilder, Anne GM

VERSION 1 – REVIEW

REVIEWER	Kara Kuntz-Melcavage Research Associate Johns Hopkins Carey Business School Johns Hopkins HealthCare LLC United States
REVIEW RETURNED	29-Jan-2018

GENERAL COMMENTS	This manuscript is well-written and it provides information that is crucial for development of a registry of auditory implants. The aims of the study are clearly articulated, the study process and findings are adequately described, and the conclusions are reasonable. I feel more knowledgeable after having read this paper, and I believe that is a good indication of why it should be accepted for publication.

REVIEWER	hinne rakhorst Medisch Spectrum Twente, dept of plastic reconstructive and hand surgery Enschede, the Netherlands
REVIEW RETURNED	28-Mar-2018

GENERAL COMMENTS	dear Authors. thank you for sharing the results of your survey and your submission. I agree with you that there is a need for clinical registries over simple track and trace registries. I feel that the manuscript needs dramatic shortening. The current version writes into too much detail on each individual question. To my mind it may even be more feasible to resubmit it as a short communication rather than a full article.

	I also miss the discussion of some basic things in developing a registry; 1 opt out vs opt in system 2 aiming for a maximum number of datapoints, in other words, description of the importance of less data points instead of more. 3 there are a number of clear lessons to be learned from breast implant, cardiological and more orthopedic device registries, where the Keogh report and various european union reports would back up your story line. I believe that when you write the manuscript in these separate sub headings a lot of text can be removed or moved into tables.

REVIEWER	Brian D Nicholas Upstate Medical University Department of Otolaryngology Syracuse, NY, USA
REVIEW RETURNED	07-May-2018

GENERAL COMMENTS	This is an interesting manuscript that builds on the prior work by the authoring group. Through a series of interviews and focus groups, the authors seek to validate the categories and themes for successful national registry development identified through a prior systematic review. There are a few minor suggestions that I feel would strengthen the manuscript: -The paper centers on the qualitative assessment of the opinions of stakeholders and implant recipients in what would be important in the development of a national registry for auditory implants. It seems that too much is spent on litigating the need for the national registry, itself, rather than on the qualitative data analysis that comprises the study. -The results section would be improved with an improved presentation of the data garnered from the interviews. As it is currently presented, the questions are presented followed by representative quotes or replies. Perhaps some quantitative assessment of the themes and how uniform (or not) the interviewees'/focus group participants' answers were. For instance, in the stakeholder group, were all themes documented and mapped, or were only those themes raised by a certain percentage of respondents mapped? -Question PS13 asks for the most important factor in making a registry successful. One answer is provided. Is this saying that all 40 stakeholders agreed on this point? -Would the proposed registry include patients with active middle ear implants (AMEIs)? -There are several answers in the focus group section that seem to have added some editorialization, which may impart bias. For instance, one answer states that patients felt that "existing research is overly influenced by industry with a potential publication bias and concerns about transparency." This seems like a very nuanced view of scientific research with regard to implant outcomes. Likewise, the patient belief that there should be representation on a "steering committee" appears to be a theme

	that the authors added based on patient desire to have a say in the development of the registry. -What are we to take away from question FG Q6? That some in the focus group felt surgeon names and hospital should be public while some felt it should remain anonymous? This seems to be the only question that has a binary answer and, perhaps not surprisingly, there are people who have differing views. Would it be possible to quantify the responses to this question? -The discussion seems too focused on how a national registry would compare to RCTs for research purposes. Again, I don't feel that this is the manuscript within which to defend the need for such a registry. -The study is strengthened by the authors' deep understanding of qualitative research. It is limited, as pointed out by the authoring team, by the selection of patients only from the greater London area. In addition, an improved presentation of the data would strengthen the manuscript.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Kara Kuntz-Melcavage

COMMENT This manuscript is well-written and it provides information that is crucial for development of a registry of auditory implants. The aims of the study are clearly articulated, the study process and findings are adequately described, and the conclusions are reasonable. I feel more knowledgeable after having read this paper, and I believe that is a good indication of why it should be accepted for publication.

RESPONSE: Thank you for these positive comments

Reviewer: 2
Reviewer Name: Hinne Rakhorst

COMMENT: Thank you for sharing the results of your survey and your submission. I agree with you that there is a need for clinical registries over simple track and trace registries. I feel that the manuscript needs dramatic shortening. The current version writes into too much detail on each individual question. To my mind it may even be more feasible to resubmit it as a short communication rather than a full article.

RESPONSE: Thank you for your comments. We have considerably shortened the manuscript (by over 2000 words), principally by reducing the detail on each individual question.

COMMENT: I also miss the discussion of some basic things in developing a registry;
1 opt out vs opt in system
2 aiming for a maximum number of datapoints, in other words, description of the importance of less data points instead of more.
3 there are a number of clear lessons to be learned from breast implant, cardiological and more orthopedic device registries, where the Keogh report and various european union reports would back up your story line.

RESPONSE:

1) Apologies for this lack in clarity. This was raised in the stakeholder interviews. We have now emphasised in the results section that one of the key themes in the professional stakeholder interviews was the importance of making the registry compulsory for both clinician revalidation and commissioning. See pages 17 and 21. This theme is also presented in the new Table 3, which identifies all the themes from the stakeholder interviews and patients focus groups.

2) This was a theme that arose from the patient focus groups as well as the stakeholder interviews. We have now made it clearer in the results section that stakeholders advised that a minimal dataset should be employed that is quick to complete, with no free-text data entry (page 17). Further that patients thought that the registry dataset should reach a balance between comprehensibility and simplicity: comprehensive datasets would be too time consuming, whilst basic datasets would provide limited value (page 24).

3) We agree that this is important. We have now discussed in the introduction that the “Poly Implant Prostheses (PIP)” breast implant and the “metal-on-metal (MOM)” hip implant safety incidents highlight the need for registry data for surgical implants. Conversely that successful registries such as the National Hip Fracture Database (NHFD), the National Joint Registry (NJR) and the National Audit Cardiac Surgery (NACSA) registry highlight the benefits of registry data (see pages 4-5). In the discussion, we have now commented that several bodies including the IDEAL collaborative, the EU and the House of Commons Science and Technology committee have raised concerns over the evidence base for surgical implants and have called for registry data (page 30).

COMMENT: I believe that when you write the manuscript in these separate sub headings a lot of text can be removed or moved into tables.

RESPONSE: Thank you for this suggestion. We have now introduced Table 3, which has enabled us to considerably shorten the manuscript (by 2000 words) and present the themes obtained in a clearer format.

Reviewer: 3
Reviewer Name: Brian D Nicholas

This is an interesting manuscript that builds on the prior work by the authoring group. Through a series of interviews and focus groups, the authors seek to validate the categories and themes for successful national registry development identified through a prior systematic review.

There are a few minor suggestions that I feel would strengthen the manuscript:

COMMENT: The paper centers on the qualitative assessment of the opinions of stakeholders and implant recipients in what would be important in the development of a national registry for auditory implants. It seems that too much is spent on litigating the need for the national registry, itself, rather than on the qualitative data analysis that comprises the study.

RESPONSE: We agree that too much focus was given on the need for developing a registry, detracting from the qualitative analysis. We have edited the text throughout the document, reducing the text where we discussed the need for developing a national registry.

COMMENT: The results section would be improved with an improved presentation of the data garnered from the interviews. As it is currently presented, the questions are presented followed by representative quotes or replies. Perhaps some quantitative assessment of the themes and how uniform (or not) the interviewees'/focus group participants' answers were. For instance, in the stakeholder group, were all themes documented and mapped, or were only those themes raised by a certain percentage of respondents mapped?

RESPONSE: We apologise for this lack in clarity. We have now introduced Table 3, which clearly presents all the themes identified from both the interviews and focus groups. We have also clarified that all themes identified from the interview and focus groups questions are documented in the results section (pages 10 and 21). Further that under each theme, we have summarised the extracted data that gave rise to each theme. We are unable to provide a quantitative assessment of the themes. This is because a theme arises following analyses of all extracted data from the interview and focus group responses and; a theme represents a pattern within the extracted data for that specific interview/focus group question.

COMMENT: Question PS13 asks for the most important factor in making a registry successful. One answer is provided. Is this saying that all 40 stakeholders agreed on this point?

RESPONSE: When our data judges qualitatively analysed the responses to this question both data judges and the data auditor agreed that one overall theme arose from the extracted data – namely "Data completeness". We have clarified in our methodology how data judges developed and reached agreement on the themes from the extracted data (pages 9-10).

COMMENT: Would the proposed registry include patients with active middle ear implants (AMEIs)?

RESPONSE: We have now specified that auditory implants include cochlear implants (CIs), Bone Conducting Hearing Devices (BCHDs) and Middle Ear Implants. Further that the proposed registry could collect data on all these implants (see page 4)

COMMENT -There are several answers in the focus group section that seem to have added some editorialization, which may impart bias. For instance, one answer states that patients felt that "existing research is overly influenced by industry with a potential publication bias and concerns about transparency." This seems like a very nuanced view of scientific research with regard to implant outcomes. Likewise, the patient belief that there should be representation on a "steering committee" appears to be a theme that the authors added based on patient desire to have a say in the development of the registry.

RESPONSE: Thank you for this comment. We have re-analysed the extracted data from our focus groups and edited our narrative summary in the focus group results section ensuring that our summary was a credible representation of the extracted data.

COMMENT: What are we to take away from question FG Q6? That some in the focus group felt surgeon names and hospital should be public while some felt it should remain anonymous? This seems to be the only question that has a binary answer and, perhaps not surprisingly, there are people who have differing views. Would it be possible to quantify the responses to this question?

RESPONSE: We agree that we have not presented the extracted data clearly here and have now edited this section. When our data judges qualitatively analysed the responses to this question, 2 themes arose: 1) Inaccurate reflection of practices, 2) Increase patient choice. We have also provided a clearer summary of the extracted data giving rise to these themes. We would prefer not to quantify the responses to this question since we feel that this would detract from the qualitative nature of the study.

COMMENT: The discussion seems too focused on how a national registry would compare to RCTs for research purposes. Again, I don't feel that this is the manuscript within which to defend the need for such a registry.

RESPONSE: We have edited the discussion so that there is no longer focus on how a national registry would compare to a RCT. We have also considerably reduced the text throughout the document where we discussed the need for developing a national registry.

COMMENT: The study is strengthened by the authors' deep understanding of qualitative research. It is limited, as pointed out by the authoring team, by the selection of patients only from the greater London area. In addition, an improved presentation of the data would strengthen the manuscript.

RESPONSE: We have now introduced Table 3 and have considerably edited the results section, resulting in clearer presentation of our findings.

VERSION 2 – REVIEW

REVIEWER	hinne rakhorst The Department of plastic, reconstructive and hand surgery MST enschede, The Netherlands
REVIEW RETURNED	04-Jul-2018

GENERAL COMMENTS	thank you for your revised manuscript. I feel it benefited from the revisions that you made.

REVIEWER	Brian D. Nicholas Upstate Medical University Department of Otolaryngology Syracuse, NY, USA
REVIEW RETURNED	03-Jul-2018

GENERAL COMMENTS	I congratulate the authors on incorporating changes to strengthen the manuscript. The amended discussion is far more concise and focused and the extensive qualitative data are presented in a more reader-friendly way. The authors are correct to point out the geographical bias in their focus group sampling and how the derived data may not reflect themes from other regions of country. Finally, a small point: Table 3 may be best split in to two tables, one for the stakeholders' themed responses, and the other for the focus group responses.