PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	What are the essential features of a successful surgical registry? A systematic review
AUTHORS	Mandavia, Rishi; Knight, Alec; Phillips, John; Mossialos, Elias; Littlejohns, Peter; Schilder, Anne

VERSION 1 – REVIEW

REVIEWER	Matthew Yung Department of Otolaryngology The Ipswich Hospital NHS Trust Heath Road, Ipswich, Suffolk United Kingdom IP4 5PD
REVIEW RETURNED	06-May-2017

GENERAL COMMENTS	This is a piece of qualitative research. This reviewer has developed a national otology database system and therefore may have an inherent bias on this paper. The authors rightly pointed out the lack of UK-registry on surgically-implanted hearing devices in the introduction, yet this systematic review examined all surgical registries rather than focused on those concerning surgical devices or appliances. They need to decide whether to have the systematic review on surgical registries in general or specifically on surgical implants. The findings and conclusion may well be quite different. Qualitative analysis is notoriously prone to bias. The authors should give an account for their possible personal experience which may have resulted in methodological bias. Did they have any attempt to engage with other researchers to reduce research bias, eg in the thematic analysis or categorisation? Saying that, the results and conclusion of the review are useful information and definitely worthy of publication. Can the authors clarify how they arrive at the themes or categorization in the 'Result' section? For example, did they base that on keywords or conclusion in each publication? The authors should provide a 'decision-trail' that can help other researchers to arrive at the same or comparable findings? Overall, this is a very useful paper worthy of publication. The only change I propose is to make the methodology more transparent so that other researchers can reproduce similar findings. This requires some minor revision to the paper.

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REVIEWER	Paramita Saha-Chaudhuri McGill University, Canada
REVIEW RETURNED	14-Jun-2017

GENERAL COMMENTS	Overall, this is a well-written manuscript. The use of statistical methods is minimal, if any. I have two minor comments: the authors used different publication types, all of which may not have equal reliability and quality. It would have been better if the authors focused on one/two types of publications. My second comment is related to the registry objectives. Frequently. the goals of surgical registries is to improve patient care and outcome, rather than research. Detailed discussion as to the issues stemming from using a non-research-focused database for scientific and clinical research and how one could design a database that serves the dual purposes, would be much appreciated.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

COMMENT: The authors rightly pointed out the lack of UK-registry on surgically-implanted hearing devices in the introduction, yet this systematic review examined all surgical registries rather than focused on those concerning surgical devices or appliances. They need to decide whether to have the systematic review on surgical registries in general or specifically on surgical implants. The findings and conclusion may well be quite different.

RESPONSE: Thank you for your comments and apologies for the lack in clarity. We have now clarified in the Introduction section that the aim of this systematic review was to identify the essential features of a successful surgical registry (see red font in Introduction). Therefore, we performed a systematic review on surgical registries in general. We felt that by only focusing on implant registries, we may fail to capture important information on surgical registry development.

COMMENT: Qualitative analysis is notoriously prone to bias. The authors should give an account for their possible personal experience which may have resulted in methodological bias. Did they have any attempt to engage with other researchers to reduce research bias, eg in the thematic analysis or categorisation? Saying that, the results and conclusion of the review are useful information and definitely worthy of publication.

RESPONSE: Thank you for this comment. We have now acknowledged in the Limitations section (see red font) that the development of the data extraction table and the data extraction may have been influenced by researcher bias. However, to mitigate this, both stages were cross-checked by a second researcher and discussed at two interim consensus meetings.

COMMENT: Can the authors clarify how they arrive at the themes or categorization in the 'Result' section? For example, did they base that on keywords or conclusion in each publication?

The authors should provide a 'decision-trail' that can help other researchers to arrive at the same or comparable findings? Overall, this is a very useful paper worthy of publication. The only change I propose is to make the methodology more transparent so that other researchers can reproduce

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similar findings. This requires some minor revision to the paper.

RESPONSE: Thank you for your comment. The headings or categorizations in the Results section were developed following immersion in the dataset and using thematic analysis to identify the key themes for data extraction. These themes were then cross-checked by a second author and discussed at consensus meetings to ensure reliability. We have now clarified this in the Methods and Results sections (see red font).

Reviewer: 2

Overall, this is a well-written manuscript. The use of statistical methods is minimal, if any.

COMMENT: I have two minor comments: the authors used different publication types, all of which may not have equal reliability and quality. It would have been better if the authors focused on one/two types of publications.

RESPONSE: Thank you for your comment. We have now acknowledged this as a limitation in the Limitations section (see red font).

COMMENT: My second comment is related to the registry objectives. Frequently, the goals of surgical registries are to improve patient care and outcome, rather than research. Detailed discussion as to the issues stemming from using a non-research-focused database for scientific and clinical research and how one could design a database that serves the dual purposes, would be much appreciated.

RESPONSE: We agree that this is an interesting area and have conducted further analysis in the 'The objective(s) of a surgical registry (1.H)' Results section to highlight the challenges of these dual objectives and how a registry can be developed to address both (see red font).

VERSION 2 – REVIEW

REVIEWER	Matthew Yung Department of Otolaryngology, The Ipswich Hospital NHS Trust, United Kingdom
REVIEW RETURNED	28-Jul-2017

GENERAL COMMENTS	The authors rightly pointed out the lack of UK-registry on surgically-implanted hearing devices in the introduction, yet this systematic review examined all surgical registries rather than focused on those concerning surgical devices or appliances. They need to decide whether to have the systematic review on surgical registries in general or specifically on surgical implants. The findings and conclusion may well be quite different. Qualitative analysis is notoriously prone to bias. The authors should give an account for their possible personal experience which may have resulted in methodological bias. Did they have any attempt to engage with other researchers to reduce research bias, eg in the thematic analysis or categorisation? Saying that, the results and conclusion of the review are useful information and definitely worthy of publication. Can the authors clarify how they arrive at the themes or categorization in the 'Result' section? For example, did they base that on keywords or conclusion in each publication? The authors should provide a 'decision-trail' that can help other researchers to

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	arrive at the same or comparable findings? Overall, this is a very useful paper worthy of publication. The only change I propose is to make the methodology more transparent so that other researchers can reproduce similar findings. This requires some minor revision to the paper.

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