PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Cardiac implant registries 2006-2016: a systematic review and summary of global experiences
AUTHORS	Zhang, Shixuan; Gaiser, Sebastian; Kolominsky-Rabas, Peter

VERSION 1 – REVIEW

REVIEWER	Xiaolin Xu The University of Queensland
REVIEW RETURNED	30-Aug-2017

GENERAL COMMENTS	I'm reviewing the statistical methods and analyses used, here are my comments: 1. P4 LINE 132, please indicate the details of the grey literature searching (websites? reports? etc.); 2. P4 LINE 137, please provide more details about the inclusion and exclusion criteria, so far I cant find the exclusion criteria; 3. P5 LINE 159, provide detailed research items and results for each database, for example, in tables as attachments; 4. P5 LINE 143, I suggested to list the name of the two independent researchers who did the data extraction.

REVIEWER	Bjørn Erik Mørk BI Norwegian Business School, Norway/Warwick Business School, England
REVIEW RETURNED	02-Oct-2017

GENERAL COMMENTS	The purpose of this paper is to provide an overview of Cardiac implant registries 2006-2016 on a global scale. To date this, to the best of my knowledge, a novel and important contribution which is highly relevant for practitioners and academics. Overall, the paper is well-written, and contains relevant information about state of the art to date. Meanwhile some aspects of the paper needs to be further improved. In the following I will briefly elaborate on my major concerns with the study: The introduction contains a section on strengths and limitations of the study. This section is underdeveloped so that it becomes clearer what the Authors actually consider to be strengths and weaknesses. In the current version this is unclear. There are also other limitations that could be included (such as biases, registries that have not be included and so forth) The rational of the study is clear. The authors could consider asking a specific research question to make it even clearer.

	The major concern I have with the paper is section 2 "Methods". This section is very under-developed, and lacks relevant information about how the study was conducted and critical reflection about limitations of this approach. Many registries have not been included due to Language (for instance in Scandinavia), but this is not discussed. Further, the authors need to discuss validity, reliability and generalisality of their study. To what extent would other researchers end up with the same results? In the text we read that an inductive approach was used, but we never get a proper explanation of what this actually means.Why did the authors not considering also performing interviews with informants that would enable them to better understand the different registries? by doing so they would also have been able to clarify whether their interpretations were correct. It would also have enabled them to include other important registries that were not in English. For instance, in the case of TAVI some of the Scandinavian countries have registries that would be important material, and given the role of Scandinavia for TAVI this would be relevant to include. In the results section we read that the authors started to 1529, and then ended up with going through 82 registries. This process of reducing the amount of data is not sufficiently discussed. The readers should be given much more details about the discussions the authors had in this process, and more reflections on how this exclusion of studies may have influenced the results should be spelled out in the text. In section 3.2 we read again that an inductive approach was used, but without any proper explanation. To what extent are the authors familiar with how inductive is used in social science? A final comment about aspects to improve is related to the choice of subtitle. In recent years there has been great interest in so-called "practice-based studies" in social science, strategy, marketing, innovation studies. Many scholars in this field would argue that you do not properly understand practice without doing observations. Hence, using the term "practice" when the study is "just" based on document analysis is somewhat problematic. It is well-known that there is a difference between what people write, what they say and what they actually do. This is therefore something that can be discussed in the methodology. Overall, I think that the paper is interesting, and has great potential. I therefore hope that the authors will further develop it towards a pubslishable paper.

REVIEWER	Mirko Di Martino Department of Epidemiology, Lazio Regional Health Service, Rome, Italy.
REVIEW RETURNED	30-Oct-2017

GENERAL COMMENTS	I was invited to review this manuscript with a particular emphasis on the statistical methods and analyses used. This study is a sistematic review "of global practices". No metanalytic estimates are presented. The study is well conducted. The "search methodology", "study selection" and "data extraction" sections are clear and consistent. The discussion about sample size calculation appears coherent with the kind of identified studies, i.e. registries. The potential "voluneer bias" is critically discussed.

	Endpoints and results are exhaustively described. Overall, the methodological and statistical approach to data analysis is correct and satisfactory. I have only one minor request. Authors should better explain the meaning of the following sentence: "data also can be taken from device interrogation".

REVIEWER	Prof. Dr. med. Heinz Völler University of Potsdam Potsdam, Germany
REVIEW RETURNED	04-Dec-2017

GENERAL COMMENTS	The authors did a systematic search on cardiac implant registries (CIR) to investigate the structure and key elements of CIR in the last decade and to provide recommendations on best practice approaches. 82 registries in different cardiovascular diseases were identified in line with the PRISMA Guidelines. The authors summarized important aspects needed to be noticed in the process of designing a cardiac implant registry. But they did not fulfill their own promise to provide recommendation. For example, they noticed and explained volunteer bias but gave no recommendation how to overcome these limitations. Therefore the paper would be of added value if the authors will suggest solutions or proposals.

VERSION 1 – AUTHOR RESPONSE

Response letter of bmjopen-2017-019039
Cardiac implant registries 2006-2016: a systematic review of global practices

Dear editor:
We would like to express our sincere appreciation for your comments and your grateful work. The following is the illustration of changes we made in the manuscript.

Comments from the Associate Editor:

This paper is both a review and survey. I think the title needs to be reworked to say that they have summarised practice. We might suggest: “Cardiac implant registries 2006-2016: a systematic review and summary of global practices”
They need to address their English. For example in the Abstract, what is post-marked surveillance (do they mean post market) and “…existed CIR” – do they mean “…existing CIRs”
The Strengths and Limitations needs to be that, not an Article Summary.
They need to provide precise search dates (what month in 2016?)
The methods are rather thin. Can they provide a full electronic search strategy for at least one database. Can they state how they assessed which papers to include – how many researchers were involved, what did they do about discrepancies? How did they decide on and then extract the relevant information

This paper is both a review and survey. I think the title needs to be reworked to say that they have summarised practice. We might suggest: “Cardiac implant registries 2006-2016: a systematic review and summary of global practices”
Answer: Thank you for your valuable suggestion. There is another reviewer (Reviewer 2) who has concerns about “practice”. After consideration, we would like to take both suggestions to change the title, which makes more sense. We have also changed that accordingly in the manuscript.
“Cardiac implant registries 2006-2016: a systematic review and summary of global experiences”

They need to address their English. For example in the Abstract, what is post-marked surveillance (do they mean post market) and "…existed CIR" – do they mean "…existing CIRs"
Answer: Thank you for your comments. We have gone through the manuscript to check English again, in addition, we also asked a native speaker to go over to check the English again before submitting. We have also changed that with tracked version in the manuscript.
The Strengths and Limitations needs to be that, not an Article Summary.
Answer: Thank you for your comments. We have changed this section according to the authors' submission guideline as the followings in the manuscript.

- This study is the first review summarizing global practice experience of the structure and key elements of the cardiac implant registries.
- Strength of the study is the identification of 14 key elements for designing and planning a cardiac implant registry, based on the experiences from 82 different registries.
- General limitation of a systematic review is due to the language limits, not all of the registries have been included in the review, which might cause missing data.
- This study has focused on critically analysis of problems rising from planning a cardiac implant registry, and provided recommendations on how to solve problems as well.

They need to provide precise search dates (what month in 2016?)
Answer: Thank you for your comments. The search date is from 01 January 2006 until 31 December 2016. Because of comments from reviewers are more addressing methods part, we have rewritten method part. We have highlighted the search date in the new version: "The search was performed for articles published between 01 January 2006 and 31 December 2016 in English."
The methods are rather thin. Can they provide a full electronic search strategy for at least one database. Can they state how they assessed which papers to include – how many researchers were involved, what did they do about discrepancies? How did they decide on and then extract the relevant information.
Answer: Thank you for your comments. After consideration of your comments and other reviewers' comments on the methods part, we have reworked on this part, which is shown in the new version. We have also provided annex as supplementary information to show the search process.
"The full electronic search strategy for each database can be found in online supplementary additional file 1."
In addition, we described in more details on the process of identification and assessment of publications. The titles and abstracts of all retrieved articles were reviewed by two researchers (SZH & PKO) independently. As well the data extraction has been done by two researchers (SZH & PKO) independently. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. We assessed quality of observational studies based on Newcastle-Ottawa Scale (selection, comparability, and outcome) criteria and quality criteria described by Niederlaender et al., 2017. We extracted data based on 'Aggregative approaches to synthesis' described by Gough et al., 2013 and quality criteria described by Niederlaender et al., 2017. We have changed and highlighted in the manuscript.
"The titles and abstracts of all retrieved articles were reviewed by two researchers (SZH & PKO) independently after removing the duplicated studies. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. After identifying all the relevant articles, the researchers summarized them based on the same name of the registry. From those articles published by one single registry, the most recent or most significant article regarding the registry design has been chosen. The quality of observational studies included in our review was appraised by Newcastle-Ottawa Scale (selection, comparability, and outcome) criteria. According to the criteria described by Niederlaender et al., 2017, articles are included in the review if they precisely describe the design process of a cardiac implant registry. The publications were excluded if they were a single clinical study but with the registry name. Inclusion criteria and exclusion criteria for this review were listed in Table 1.
To identify the key elements of registry design, the researchers aggregated findings which are relevant to the design of a cardiac implant registry from each identified publication, based on

'Aggregative approaches to synthesis' described by Gough et al., 2013. The researchers took each element from identified articles which are relevant to the design of a cardiac implant registry. The quality of key elements was assessed based on the criteria described by Niederlaender et al., 2017. This step has been done by two researchers (SZH & PKO) independently. We assessed the possibility of publication bias both visually and formally to check if the publication contains description of each element for designing a cardiac implant registry."

Reviewer(s)' Comments to Author:

Reviewer: 1
Reviewer Name: Xiaolin Xu
Institution and Country: The University of Queensland
Please state any competing interests: None declared.

Please leave your comments for the authors below
I'm reviewing the statistical methods and analyses used, here are my comments:
1. P4 LINE 132, please indicate the details of the grey literature searching (websites? reports? etc.);
2. P4 LINE 137, please provide more details about the inclusion and exclusion criteria, so far I cant find the exclusion criteria;
3. P5 LINE 159, provide detailed research items and results for each database, for example, in tables as attachments;
4. P5 LINE 143, I suggested to list the name of the two independent researchers who did the data extraction.

Answer: Thank you very much for your very useful comments. After consideration, we have changed accordingly in the manuscript based on your comments. Here you can find our illustrations and amendments.

1. P4 LINE 132, please indicate the details of the grey literature searching (websites? reports? etc.);
Answer: Thank you for your very useful comments. "Grey literature searching" in this manuscript includes using national and international HTA web sites, clinical practice guideline producers, drug and device regulatory agencies to search CIR websites. To make it clear, we have already added this information in the method part.
"Finally, grey literature searching has been used to search the website of cardiac implant registry according to a practical tool for searching health-related grey literature published by Canada's Health Technology Assessment (HTA) Agency CADTH, and recommended by University of York. National and international HTA web sites, clinical practice guideline producers, drug and device regulatory agencies are main grey literature sources in this review."
2. P4 LINE 137, please provide more details about the inclusion and exclusion criteria, so far I cant find the exclusion criteria;
Answer: Thank you for your recommendation. We have added the description of defining inclusion criteria and exclusion criteria and one Table to support.
"According to the criteria described by Niederlaender et al., 2017, articles are included in the review if they precisely describe the design process of a cardiac implant registry. The publications were excluded if they were a single clinical study but with the registry name. Inclusion criteria and exclusion criteria for this review were listed in Table 1."
3. P5 LINE 159, provide detailed research items and results for each database, for example, in tables as attachments;
Answer: Thank you for your comments. After consideration of your comments, we have added supplementary information of detailed research items and results for each database.
"The search was limited to titles, abstracts in each addressed database. The full electronic search strategy for each database can be found in the Additional file 1."

4. P5 LINE 143, I suggested to list the name of the two independent researchers who did the data extraction.
Answer: Thank you for your comments. We have reworked the whole methods part. Considering your comments of data extraction, we have changed this section as the followings:
"To identify the key elements of registry design, the researchers aggregated findings which are relevant to the design of a cardiac implant registry from each identified publication, based on 'Aggregative approaches to synthesis' described by Gough et al., 2013. The researchers took each element from identified articles which are relevant to the design of a cardiac implant registry. The quality of key elements was assessed based on the criteria described by Niederlaender et al., 2017. This step has been done by two researchers (SZH & PKO) independently. We assessed the possibility of publication bias both visually and formally to check if the publication contains description of each element for designing a cardiac implant registry."

Reviewer: 2
Reviewer Name: Bjørn Erik Mørk
Institution and Country: BI Norwegian Business School, Norway/Warwick Business School, England
Please state any competing interests: None declared

Please leave your comments for the authors below
The purpose of this paper is to provide an overview of Cardiac implant registries 2006-2016 on a global scale. To date this, to the best of my knowledge, a novel and important contribution which is highly relevant for practitioners and academics. Overall, the paper is well-written, and contains relevant information about state of the art to date. Meanwhile some aspects of the paper needs to be further improved. In the following I will briefly elaborate on my major concerns with the study:

The introduction contains a section on strengths and limitations of the study. This section is underdeveloped so that it becomes clearer what the Authors actually consider to be strengths and weaknesses. In the current version this is unclear. There are also other limitations that could be included (such as biases, registries that have not be included and so forth)
Answer: Thank you very much for your valuable comments. This part is a special requirement from BMJOpen. According to the authors' submission guideline stated by BMJOpen, "A section, placed after the abstract, consisting of the heading 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods. They should not include the results of the study." We have changed this section as the followings in the manuscript.

- This study is the first review summarizing global practice experience of the structure and key elements of the cardiac implant registries.
- Strength of the study is the identification of 14 key elements for designing and planning a cardiac implant registry, based on the experience from 82 different registries.
- General limitation of a systematic review is due to the language limits, not all of the registries have been included in the review, which might cause missing data.
- This study has focused on critically analysis of problems rising from planning a cardiac implant registry, and provided recommendations on how to solve problems as well.

The rational of the study is clear. The authors could consider asking a specific research question to make it even clearer.
Answer: Thank you for your confirmation and comments. After consideration, we have added the following texts at the end of rational section.
"What elements should be included to design a cardiac implant registry? For different type of cardiac implant registry, what should be noticed when performing each element? Questions like these to design a cardiac implant registry need to be answered."
The major concern I have with the paper is section 2 "Methods". This section is very under-developed, and lacks relevant information about how the study was conducted and critical reflection about

limitations of this approach. Many registries have not been included due to Language (for instance in Scandinavia), but this is not discussed.

Answer: Thank you very much for your valuable comments. Concerning language limitation, that is really a problem in this review, but we consider this as a problem for reviews in general. As we are only able to reach the international literature provided in English language as described in our inclusion criteria, therefore, we are assumed important publications written in Norwegian, Swedish and Danish do not meet our criteria. However, we do have included 3 registries from Scandinavia which met our inclusion criteria, such as Danish Pacemaker Register, Swedish Pacemaker and ICD Registry and single center CRT Registry from Sweden. The major purpose for this review is to summarize the structure and key elements to design a cardiac implant registry. So the more existing registries we can reach, the more completed information we can get. The registries we have not included in this review because of language limitation do not mean they do not exist. After consideration, we found that we should write more precisely in the methods part about the inclusion criteria and exclusion criteria, and in the discussion part, we should highlight our language limitation. We have changed the following text in the manuscript.

"The search was performed for articles published between 01 January 2006 and 31 December 2016 in English."

"The main limitation of this study is that the authors are only available to search in English, so other existing and well-developed cardiac implant registries have not been included in this review. Although the authors have done a global database search, grey search and hand search, however, it is difficult to assess whether all cardiac implant registries have been identified."

Further, the authors need to discuss validity, reliability and generalisality of their study. To what extent would other researchers end up with the same results?

Answer: Thank you for your comments. When we re-wrote our methods part, we have taken your comments into consideration.

For the generalizability of this study, to make sure all relevant literature to be found, we used methodologies like systematic search in four databases, citation snowballing and grey literature search.

"The search was performed for articles published between 01 January 2006 and 31 December 2016 in English. The following databases were searched: the PubMed (Medline), the ScienceDirect, the Scopus database and the EMBASE via DIMID. After performing the search, citation snowballing was used to make sure that all relevant literature was found. Finally, grey literature searching has been used to search the website of cardiac implant registry according to a practical tool for searching health-related grey literature published by Canada's Health Technology Assessment (HTA) Agency CADTH, and recommended by University of York. National and international HTA web sites, clinical practice guideline producers, drug and device regulatory agencies are main grey literature source in this review."

For the validity and reliability, we have recorded documentation of the search results for each database as supplementary information. Two researchers reviewed potential relevant articles by title and abstract independently. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. We have used Newcastle-Ottawa Scale criteria and quality criteria described by Niederlaender et al., 2017 to assess the quality of observational studies included in our review. We have identified inclusion criteria and exclusion criteria.

"The titles and abstracts of all retrieved articles were reviewed by two researchers (SZH & PKO) independently after removing the duplicated studies. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. After identifying all the relevant articles, the researchers summarized them based on the same name of the registry. From those articles published by one single registry, the most recent or most significant article regarding the registry design has been chosen. The quality of observational studies included in our review was appraised by Newcastle-Ottawa Scale (selection, comparability, and outcome) criteria. According to the criteria described by Niederlaender et al., 2017, articles are included in the review if

they precisely describe the design process of a cardiac implant registry. The publications were excluded if they were a single clinical study but with the registry name. Inclusion criteria and exclusion criteria for this review were listed in Table 1."

In the text we read that an inductive approach was used, but we never get a proper explanation of what this actually means.

Answer: Thank you for your comments. Our basic method here is to aggregate and summarize findings from identified articles, "inductive approach" is the term we have learned from Gough et al., 2013 (Learning from research: systematic reviews for informing policy decisions.). However, it seems not so clear to the readers, so we have changed the followings in the manuscript after taking your comments:

"To identify the key elements of registry design, the researchers aggregated findings which are relevant to the design of a cardiac implant registry from each identified publication, based on 'Aggregative approaches to synthesis' described by Gough et al., 2013. The researchers took each element from identified articles which are relevant to the design of a cardiac implant registry. The quality of key elements was assessed based on the criteria described by Niederlaender et al., 2017. This step has been done by two researchers (SZH & PKO) independently. We assessed the possibility of publication bias both visually and formally to check if the publication contains description of each element for designing a cardiac implant registry."

Why did the authors not considering also performing interviews with informants that would enable them to better understand the different registries? by doing so they would also have been able to clarify whether their interpretations were correct. It would also have enabled them to include other important registries that were not in English. For instance, in the case of TAVI some of the Scandinavian countries have registries that would be important material, and given the role of Scandinavia for TAVI this would be relevant to include.

Answer: Thank you for your very useful suggestions and comments. That is really a great idea to get more information. The reason we have not done this is due to the following reasons: the first is the formation of this review, we planned to identify key elements of a cardiac implant registry through publications; the second reason is that our author group has many years' experience on device registries and patient registries, during the process of formulating this manuscript, they provided so much experiences and ideas; there is also the third reason, we have considered to use this review as a basic concept paper, then to make an online-survey, then we can get more information to reflect what we have learned from the review. To the next step, we plan to make an online-survey.

In the results section we read that the authors started to 1529, and then ended up with going through 82 registries. This process of reducing the amount of data is not sufficiently discussed. The readers should be given much more details about the discussions the authors had in this process, and more reflections on how this exclusion of studies may have influenced the results should be spelled out in the text.

Answer: Thank you for your valuable comments. We have re-formulated our study selection part due to your recommendations:

"The titles and abstracts of all retrieved articles were reviewed by two researchers (SZH & PKO) independently after removing the duplicated studies. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. After identifying all the relevant articles, the researchers summarized them based on the same name of the registry. From those articles published by one single registry, the most recent or most significant article regarding the registry design has been chosen. The quality of observational studies included in our review was appraised by Newcastle-Ottawa Scale (selection, comparability, and outcome) criteria. According to the criteria described by Niederlaender et al., 2017, articles are included in the review if they precisely describe the design process of a cardiac implant registry. The publications were excluded if they were a single clinical study but with the registry name. Inclusion criteria and exclusion criteria for this review were listed in Table 1."

Thank you for your comments on this part. We have added the whole searching result in the new version. In addition, we also changed Figure 1 PRISMA diagram. We added supplementary

information of detailed research items and results for each database in the online supplementary additional file 1 as well.
"This review identified 1529 studies that were potentially relevant. Of all these studies, 406 originated from the PubMed (Medline) database, 344 from the Scopus database, and 251 from the ScienceDirect, as well as 528 from the EMBASE. After removing duplicates, 624 abstracts have been reviewed by two researchers independently. 438 articles have been put into full text review afterwards. 416 articles were actually relevant and then included in the review. Among of them, 217 were related to an ICD registry, 13 were a CRT registry, 29 were about a pacemaker registry, 76 were from a coronary stent registry, and 81 were from a TAVI registry. To summarize the cardiac implant registries from the identified articles, 82 registries were achieved, which shows in Figure 1. Detailed information of full electronic search strategy for each database can be found in online supplementary additional file 1."
In section 3.2 we read again that an inductive approach was used, but without any proper explanation. To what extent are the authors familiar with how inductive is used in social science?
Answer: Thank you for your comments. As we described above, we have already changed this part in the manuscript. We have also changed the wording in the result part,
"A systematic 'Aggregative approaches to synthesis' described by Gough et al., 2013 was used to collect key elements arising from identified cardiac implant registries."
A final comment about aspects to improve is related to the choice of subtitle. In recent years there has been great interest in so-called "practice-based studies" in social science, strategy, marketing, innovation studies. Many scholars in this field would argue that you do not properly understand practice without doing observations. Hence, using the term "practice" when the study is "just" based on document analysis is somewhat problematic. It is well-known that there is a difference between what people write, what they say and what they actually do. This is therefore something that can be discussed in the methodology.
Answer: Thank you for your comments. We used "practice" because we assumed the result we got from publications can be seen as the practice from their registry. We absolutely agree, there is a big difference between what people write, what they say and what they actually do. We would like to take your suggestion, and we have changed to "Cardiac implant registries 2006-2016: a systematic review and summary of global experiences".
Overall, I think that the paper is interesting, and has great potential. I therefore hope that the authors will further develop it towards a pubslishable paper.
Answer: We'd appreciate for your very useful comments and suggestions. We are also very impressed for your extensive careful detailed comments. We will take them into consideration, and try our best to make this manuscript towards a publishable paper.

Reviewer: 3
Reviewer Name: Mirko Di Martino
Institution and Country
Department of Epidemiology, Lazio Regional Health Service, Rome, Italy.
Please state any competing interests: None declared.

Please leave your comments for the authors below
I was invited to review this manuscript with a particular emphasis on the statistical methods and analyses used.

This study is a sistematic review "of global practices". No metanalytic estimates are presented. The study is well conducted.
The "search methodology", "study selection" and "data extraction" sections are clear and consistent.
The discussion about sample size calculation appears coherent with the kind of identified studies, i.e. registries. The potential "voluneer bias" is critically discussed. Endpoints and results are exhaustively described. Overall, the methodological and statistical approach to data analysis is correct and

satisfactory. I have only one minor request. Authors should better explain the meaning of the following sentence: "data also can be taken from device interrogation".
Answer: Thank you for your confirmation and comments. About the sentence “data also can be taken from device interrogation”, we meant that the transmitters are able to interrogate to most of the CIED devices, and then download data from the device, which can support the data collection and data entry. To make it clear in the manuscript, we changed this sentence to followings in the manuscript. “For the CIED device, transmitters are able to interrogate to most of the devices, and then download data from the device, which also can support data collection and data entry.”

Reviewer: 4
Reviewer Name: Prof. Dr. med. Heinz Völler
Institution and Country: University of Potsdam, Potsdam, Germany
Please state any competing interests: None declared

Please leave your comments for the authors below
The authors did a systematic search on cardiac implant registries (CIR) to investigate the structure and key elements of CIR in the last decade and to provide recommendations on best practice approaches. 82 registries in different cardiovascular diseases were identified in line with the PRISMA Guidelines. The authors summarized important aspects needed to be noticed in the process of designing a cardiac implant registry. But they did not fulfill their own promise to provide recommendation. For example, they noticed and explained volunteer bias but gave no recommendation how to overcome these limitations. Therefore the paper would be of added value if the authors will suggest solutions or proposals.

Answer: Thank you for your very valuable comments. That is really helpful. We have added some recommendations to improve added value of this manuscript.

To avoid volunteer bias, we suggested that registries can learn from compulsory registries, which required participation from all implanting individuals and centers mandatorily. We have added: “To avoid volunteer bias, registries can learn from compulsory registries. Of all identified registries, 5 registries are compulsory registries, which were not subject to volunteer bias and were able to study all patients. For example, the Ontario Database was mandated by the administrator of health care services in Ontario, and participation from all ICD implanting centers was required. In addition, the Swiss TAVI registry has stated that consecutive patient enrolment was mandatory.”
To improve tracking of potentially impacted patients, we have added: “This example of a patient tracking strategy and usage is close to the authors’ recommendation. Political authorities began to set up a device identification system to track the patients affected. The FDA issued the complete Global Unique Device Identification Database (GUDID) on 26 June 2014. The European Commission released a recommendation for a common framework for a UDI system of medical devices in the European Union on 05 April 2013 after the first announcement in the United States.”
To improve public accessibility of a registry, we have added: “In an ideal setting, the communication between patients and physicians should be based on registry data. Therefore a personalized treatment can be delivered.

Publication is a way to show the study outcome from the registry, however, the public can only find limit information about registry design. Registries in principle are a new scientific entity as stated by Labek et al., 2016; there is a need from the research side for standardization for creation of a cardiac implant registry. If each registry describes their registry design and shares their experience with other researchers, it will improve the development of the registry study. One example of this would be sharing the requirements of randomized clinical trials (RCTs): “all RCTs are needed to provide a protocol describing the rational, methods, proposed analysis plan and organizational details.””

VERSION 2 – REVIEW

REVIEWER	Xiaolin Xu The University of Queensland
REVIEW RETURNED	11-Jan-2018

GENERAL COMMENTS	I was asked for a review on statistical methods and analyses used. The authors have addressed all of my points.