

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)	A Systematic Review Protocol for Reporting Deficiencies within Surgical Case Series
AUTHORS	Agha, Riaz; Fowler, Alexander; Lee, Seon-Young; Gundogan, Buket; Whitehurst, Katharine; Sagoo, Harkiran; Jeong, Kyung; Altman, Doug; Orgill, Dennis

VERSION 1 - REVIEW

REVIEWER	Joerg Albrecht Attending Dermatologist, Division of Dermatology, Department of Medicine J.H. Stroger Hospital of Cook County Assistant Professor, Department of Dermatology, Rush University Medical Center
REVIEW RETURNED	22-Apr-2015

GENERAL COMMENTS	<p>I am very excited to review this manuscript. I think it is excellent that the authors will publish their research protocol, which is very good, and thus open it for discussion. It allows other researchers to benefit from their very detailed methodology, beyond what can be found in the short paragraphs that usually make up the methodology section in the final paper.</p> <p>What they are proposing is an ambitious project that delineates the reporting deficiencies of case reports and series for surgical interventions. This is important.</p> <p>The manuscript is well written and I have no relevant criticism.</p> <p>What is not clear from the manuscript that was submitted is the core of the exercise, namely the data points they want to extract. Most likely, based on the introduction, these are going to be straightforward, like type of surgery, age, preexisting conditions, complications etc. What becomes clear in the introduction when radiotherapy and autologous fat transplant is mentioned, is that some of the deficient therapeutic information will only be noted by those who know a lot about the subject matter. What makes the work valuable beyond what is known about the deficiencies of case reporting in general, is the surgical expertise that this team brings to the table. I think it would be good to share the checklist for evaluations of papers. What this will be is totally up the authors and beyond this review. I would personally recommend to have an open comment section for observations of aspects that have not been thought about prior to the beginning of the evaluation, and possibly a section for quotations (some of them can be quite amusing). The authors should also think about how they would deal with unforeseen aspects that they want to capture, but had not been anticipated when the review began – this may be informal and does not need to be part of the protocol.</p> <p>The following comment concerns the project and not the paper since the current approach is fine. As far as the search strategy is</p>
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	<p>concerned, I wonder whether the project is not a bit ambitious. These projects are extremely tedious. In essence the goal of the project is to have an idea of the deficiencies of case reporting in surgery in the literature. I am not sure that the quantification of these deficiencies is terribly helpful beyond the point where their relevance is established. Much of this is thus going to be qualitative research where data collection should be to the point of saturation. An iterative process may therefore be helpful. The number of papers that are examined could be extended when the information gained is still fruitful – personally I would begin with 100 papers and go from there, maybe increasing the number in groups of 50 (since two groups work on them and this may facilitate the process). Given the increased interest in methodology of research I would expect that more recent reports are better and that higher impact – and British – journals have better reported cases, thus the authors may well decide to limit to high quality journals. To show that bad reports in poorly edited journals are deficient may not be worth their time – or a separate paper.</p>
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REVIEWER	<p>Michael Bigby Beth Israel Deaconess Medical Center and Harvard Medical School. Boston, MA, USA</p>
REVIEW RETURNED	<p>19-Jul-2015</p>

GENERAL COMMENTS	<p>The authors seem confused about what they propose to study.</p> <p>Page 5. It makes no sense to have types of participants be participants undergoing surgery. It makes no sense to have interventions be surgical interventions. Those features are not part of the search and the results of the proposed study are relevant to all case series.</p> <p>There should be no language restriction. Their search strategy only identified 31 non-English articles. The LILACS database should be searched.</p> <p>I hope their search strategy finds “Albrecht J, Werth VP, Bigby M. The role of case reports in evidence-based practice, with suggestions for improving their reporting. J Am Acad Dermatol. 2009 Mar;60(3):412-8. doi: 10.1016/j.jaad.2008.10.023. Review. PubMed PMID: 19231639.”</p> <p>Page 7. “The identified reporting quality issue was categorized...” implies that the study is already done. Is it?</p>
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REVIEWER	<p>Dr. Guillaume Martel Assistant Professor of Surgery, University of Ottawa Associate Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute Attending Surgeon, Liver and Pancreas Unit, The Ottawa Hospital, ON, Canada</p>
REVIEW RETURNED	<p>20-Jul-2015</p>

GENERAL COMMENTS	<p>Thank you for the opportunity to review this manuscript by Agha and colleagues. The authors present a systematic review protocol pertaining to reporting deficiencies in surgical case series. The</p>
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	<p>review protocol is appropriately registered with PROSPERO. I consider the research question and focus to be important, in general terms, as surgical case series continue to account for a large proportion of published surgical research. I have the following specific questions and concerns about the manuscript:</p> <ol style="list-style-type: none"> 1. The abstract does not reflect the remainder of the manuscript. It is too generic. 2. The authors should justify their review in the context of surgical case series specifically, as they have chosen to limit themselves to this field. This is an important aspect of their work and surgery is barely mentioned in the introduction. Perhaps the authors should consider discussing the role of case series in surgical research. 3. In the inclusion criteria, the authors should define what will be included under the “surgery” umbrella. Do you plan to include endoscopy or dental procedures for instance? 4. The proposed review should be further justified and discussed in the context of STROBE and SAMPL. While this protocol addresses a systematic review pertaining to reporting, it does appear to set the stage for the creation of a future reporting guideline. Is this useful, given the above two guidelines? 5. The authors identify only three broad quality headers within their data extraction/management plan. Data to be extracted should be expanded upon, including the listing of quality indicators to be examined.
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

I am very excited to review this manuscript. I think it is excellent that the authors will publish their research protocol, which is very good, and thus open it for discussion. It allows other researchers to benefit from their very detailed methodology, beyond what can be found in the short paragraphs that usually make up the methodology section in the final paper.

What they are proposing is an ambitious project that delineates the reporting deficiencies of case reports and series for surgical interventions. This is important.

The manuscript is well written and I have no relevant criticism.

>>> Thank you.

What is not clear from the manuscript that was submitted is the core of the exercise, namely the data points they want to extract.

>>>We have further clarified the data points we will extract. The reason these could not be clearly pre-defined is because this was an exercise aimed at identifying weaknesses identified by the current literature. As per the guidance provided by Moher et al (2010) for developing reporting guidelines, we plan to undertake the first step which is to critically appraise the relevant literature and identify potential items that may be included within a Delphi process. To ease this, we will outline the following features to numerate how often they occur (these are common problems that have been identified in previous articles we are aware of):

1. Failure to use standardised definitions
2. Missing or selective data
3. Transparency/complete reporting
4. Other areas highlighted

Most likely, based on the introduction, these are going to be straightforward, like type of surgery, age, preexisting conditions, complications etc. What becomes clear in the introduction when radiotherapy and autologous fat transplant is mentioned, is that some of the deficient therapeutic information will only be noted by those who know a lot about the subject matter. What makes the work valuable beyond what is known about the deficiencies of case reporting in general, is the surgical expertise that this team brings to the table. I think it would be good to share the checklist for evaluations of papers.

>>> Thank you, just to clarify, we are looking specifically for literature that report missing data within existing case series. We will not extract data points looking specifically at case series themselves (e.g. clinical details) as these are not relevant to the key question ("What are the currently identified lapses in case series reporting?").

What this will be is totally up to the authors and beyond this review. I would personally recommend to have an open comment section for observations of aspects that have not been thought about prior to the beginning of the evaluation, and possibly a section for quotations (some of them can be quite amusing). The authors should also think about how they would deal with unforeseen aspects that they want to capture, but had not been anticipated when the review began – this may be informal and does not need to be part of the protocol.

>>> Thank you for these suggestions. We plan to extract both quotes and 'Other' features, these are the features identified by the literature pertaining to the limitations of existing case series. While we have tried to create the aforementioned three broad areas of potential problems, obviously there are likely to be a very diverse group of reporting limitations. As such, we aim to extract all of them, and then group them under themes that may inform a future Delphi Process.

The following comment concerns the project and not the paper since the current approach is fine. As far as the search strategy is concerned, I wonder whether the project is not a bit ambitious. These projects are extremely tedious. In essence the goal of the project is to have an idea of the deficiencies of case reporting in surgery in the literature. I am not sure that the quantification of these deficiencies is terribly helpful beyond the point where their relevance is established. Much of this is thus going to be qualitative research where data collection should be to the point of saturation. An iterative process may therefore be helpful. The number of papers that are examined could be extended when the information gained is still fruitful – personally I would begin with 100 papers and go from there, maybe increasing the number in groups of 50 (since two groups work on them and this may facilitate the process). Given the increased interest in methodology of research I would expect that more recent reports are better and that higher impact – and British – journals have better reported cases, thus the authors may well decide to limit to high quality journals. To show that bad reports in poorly edited journals are deficient may not be worth their time – or a separate paper.

>>> Thank you for these suggestions. As you rightly suggest, this is more qualitative than quantitative. We want to ensure that this is conducted properly, in line with the recommendations put forward by Moher et al (2010). Ultimately this will provide suggestions and items that may be brought forward to the Delphi Process.

Reviewer: 2

The authors seem confused about what they propose to study.

Page 5. It makes no sense to have types of participants be participants undergoing surgery. It makes no sense to have interventions be surgical interventions. Those features are not part of the search and the results of the proposed study are relevant to all case series.

>>> We wish to focus on surgical case series, as they have specific and particular issues; such as the learning curve and experience of the surgeon performing the intervention. Similarly, we felt that a reporting guideline for case series across all of medicine and surgery would likely hold redundancy in many realms as they are fairly disparate groups. Given our experience looking at surgical reporting quality, and the fact a huge proportion of the surgical literature are case series, we have focussed on this. The aim of our study is clearly outlined in our “objective” – To conduct a systematic review exploring the reporting deficiencies within surgical case series that have been identified in the existing literature.

There should be no language restriction. Their search strategy only identified 31 non-English articles. The LILACS database should be searched.

>>> As we are looking at reporting, we decided to not include non-English titles, we realise this is a limitation and would expand on this in our discussion of the main work. We felt that lilacs would likely hold no further articles than our comprehensive strategy. We have done a search of lilacs now, and find no articles related to case series reporting quality.

I hope their search strategy finds “Albrecht J, Werth VP, Bigby M. The role of case reports in evidence-based practice, with suggestions for improving their reporting. *J Am Acad Dermatol*. 2009 Mar;60(3):412-8. doi: 10.1016/j.jaad.2008.10.023. Review. PubMed PMID: 19231639.”

>>> Thank you, we did identify this article prior to writing the protocol. As we are looking specifically at case series, not case reports, we would not include this in analysis portion.

Page 7. “The identified reporting quality issue was categorized...” implies that the study is already done. Is it?

>>>The study is underway, we have completed our initial searches and article selection. We initially submitted a number of months ago and rather than wait for a number of months, planned to begin the process, and will adapt our methods in light of the helpful peer reviewer comments here.

Reviewer: 3

Thank you for the opportunity to review this manuscript by Agha and colleagues. The authors present a systematic review protocol pertaining to reporting deficiencies in surgical case series. The review protocol is appropriately registered with PROSPERO.

I consider the research question and focus to be important, in general terms, as surgical case series continue to account for a large proportion of published surgical research. I have the following specific questions and concerns about the manuscript:

1. The abstract does not reflect the remainder of the manuscript. It is too generic.

>>> Thank you, we have adapted this to be more specific and descriptive of our study.

2. The authors should justify their review in the context of surgical case series specifically, as they have chosen to limit themselves to this field. This is an important aspect of their work and surgery is barely mentioned in the introduction. Perhaps the authors should consider discussing the role of case series in surgical research.

>>>> Thank you, we will add specific examples in the introduction of the full paper. There are a number of important examples of case series within surgery, for example early Cesarean section

experience and laparoscopy.

3. In the inclusion criteria, the authors should define what will be included under the “surgery” umbrella. Do you plan to include endoscopy or dental procedures for instance?

>>> The Oxford Dictionary defines surgery as ‘The treatment of injuries or disorders of the body by incision or manipulation, especially with instruments’. We have used this definition, and in our exclusion criteria, have kept it deliberately broad. If any papers arise that are contentious with regards to the nature of their intervention, these will be adjudicated on by a senior author and reasons for exclusion/inclusion clearly documented.

4. The proposed review should be further justified and discussed in the context of STROBE and SAMPL. While this protocol addresses a systematic review pertaining to reporting, it does appear to set the stage for the creation of a future reporting guideline. Is this useful, given the above two guidelines?

>>> Certainly, the plan is to take this work forward and create a reporting guideline specific to case series in surgery. As described by Moher et al (2010), this is the protocol to conduct the first stage of guideline development. We discussed this in the context of CONSORT and STROBE in the introduction.

5. The authors identify only three broad quality headers within their data extraction/management plan. Data to be extracted should be expanded upon, including the listing of quality indicators to be examined.

>>> The aim of the study is not to purely assess the quality of all case series. The aim is to identify what reporting deficiencies have been identified within the current literature. This information will be combined with expert opinion and a formal Delphi exercise (including experts from a range of fields), which will inform the final development of the reporting guideline.

Correction

Agha R, Fowler AJ, Lee S-Y, *et al.* A systematic review protocol for reporting deficiencies within surgical case series. *BMJ Open* 2015;5:e008007. There are several corrections to this paper, shown in underlined, bold typeface below.

- ▶ The lead author name is Riaz A Agha.
- ▶ Abstract/Introduction/First sentence: ‘..common study type in the surgical literature’.
- ▶ Introduction/First page/Second column: ‘for example, emergency medicine’
- ▶ Page 2/Methodology: The following reference should be included at the end of the sentence ‘This systematic review will be conducted according to the recommendations outlined in the Cochrane Handbook for reviews and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement’: Moher D, Liberati A, Tetzlaff J, *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *J Clin Epidemiol* 2009;62:1006–12.
- ▶ Page 2/Identification and selection of articles section: ‘...into a Microsoft Excel Database...’
- ▶ Page 3/First paragraph: ‘Articles selected after title and abstract screening will be downloaded and a further assessment made of their eligibility’.
- ▶ Page 3/First column/Penultimate sentence: ‘... the lead author (RA) will have the final say’.
- ▶ Page 3/Second column/First sentence: ‘... into a Microsoft Excel 2011 database (Microsoft)’.
- ▶ Page 3/Sensitivity analysis section: ‘...separately from those articles which may mention the...’
- ▶ Page 2/First column: ‘Patients need to be carefully selected, appropriately worked-up, the technique has to be meticulously worked out and implemented in an appropriate setting, with an appropriate postoperative regimen’.

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