

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.

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)	Compliance with ethical standards in the reporting of donor sources and ethics review in peer-reviewed publications involving organ transplantation in China: A scoping review
AUTHORS	Rogers, Wendy; Robertson, Matthew P; Ballantyne, Angela; Blakely, Brette; Catsanos, Ruby; Clay-Williams, Robyn; Fiatarone Singh, Maria

VERSION 1 – REVIEW

REVIEWER	Michael E. Shapiro, MD, FACS Associate Professor of Surgery, Rutgers - New Jersey Medical School, Newark, New Jersey, USA I have co-authored papers in the past with the senior author of this paper.
REVIEW RETURNED	19-Jun-2018

GENERAL COMMENTS	<p>The authors have investigated the compliance of peer-reviewed journals with ethical standards regarding organ transplantation in China. Specifically, they describe the ethical concerns raised by the world ethics and transplant communities about the Chinese use of executed prisoners as organ donors, the vulnerability of such a population, and hence their inability to give consent to donation free from coercion. In response to these concerns, it has been agreed that journals would not publish transplant papers from China without assurances of (1) IRB approval, (2) donor consent, and (3) exclusion of any organs or tissues obtained from executed prisoners. This study has used a "scoping review" to ascertain whether these ethical rules have been followed, and found that, in the vast majority of cases they have not. This is an important finding, and is worthy of publication.</p> <p>The authors, in their methodology, excluded any papers concerning kidney transplants, because they felt they could not determine whether the organs came from living or deceased donors. This is the one weakness of this study, as kidney papers constituted 50% of the potential papers to be studied. Many kidney papers do state the donor source, and, in any case, if any deceased donor organs were used, the same requirements would apply.</p> <p>The pursuit of human rights requires the scientific community to speak out as long as injustice remains a part of scientific research. This paper continues that tradition.</p>
-------------------------	--

REVIEWER	<p>Huige Li Huige Li, MD, PhD, Professor of Pharmacology at the Johannes Gutenberg University Medical Center, Mainz, Germany</p> <p>HL is an advisory board member of Doctors Against Forced Organ Harvesting and a board member of China Organ Harvest Research Center</p>
REVIEW RETURNED	21-Jun-2018

GENERAL COMMENTS	<p>Rogers et al. have analyzed research papers published in peer-reviewed English language journals reporting on outcomes of research involving recipients of transplanted hearts, livers or lungs in mainland China from 2000 to 2017. Of the 445 included studies, 192 (43%) report on research that took place when the only organs available for transplant were from executed prisoners (before 2010), while another 148 (33%) spanned the start of the volunteer donor pilot (before and after 2010). 33 (7%) stated explicitly that transplanted organs were not procured from executed prisoners; and 6 (1%) reported that donors gave consent for transplantation. Of the papers claiming that no prisoners' organs were involved in the transplants, 18 of them involved 2,641 transplants that took place prior to 2010, when there was no volunteer donor program in China. This is the first paper of its kind. With valid methodology, the authors systematically analyzed the organ source reporting in scientific papers from China. The results demonstrate reliably and convincingly that at least 340 papers (76%) are based exclusively or partially on data from executed prisoners. Moreover, some published papers make almost certainly false claims about sourcing organs from non-prisoner sources.</p> <p>The findings are novel and of importance. The article shows that the transplant community has failed to implement ethical standards banning publication of research using material from executed prisoners. As a result, a large body of unethical research now exists. The raised questions, such as what to do about the large body of literature based on research using organs from prisoners, and how to deal with future publications of Chinese transplant papers, are highly relevant to the field.</p> <p>Minor point: The last paragraph in the Introduction section (lines 29-35, page 8) doesn't reflect the methods used in the paper. Based on the published papers, it is not feasible to determine whether a journal has excluded any researches using organs from executed prisoners. The journal may have excluded many papers, but some studies were overlooked. Improvement is needed.</p>
-------------------------	---

REVIEWER	<p>Kirk Allison University of Minnesota, Health Policy and Management (Graduate Faculty), College of Saint Scholastica (Adjunct Faculty), USA</p> <p>I publish/co-publish in this area (e.g. cited article in manuscript / reference indications).</p>
REVIEW RETURNED	27-Jun-2018

GENERAL COMMENTS	<p>Review BMJ Open Bmjopen-2018-024473 Research 30-May-2018</p> <p>For editor and authors:</p> <p>It is necessary that Supplemental File IV (the results table) be submitted and available to readers in Xcel format rather than .pdf as</p>
-------------------------	--

the entry columns currently exceed page width (A-M, but missing N-U). The cell contents are rich and considerable for some columns and will be tractable only in the original file where an interested reader can trace through cell specifics where of interest.

Supplementary File 3 [the listing of 445 included studies] re-alphabetizes at two points. If later singly alphabetized, then the Supplemental File 4 spreadsheet would also need to be to keep the order consistent.

%%%%%%%%%

For authors:

Page and line numbers will be given by P#.L# (1.23 is page 1 line 23) referring to the page number printed at the top (# of 122) as the supplemental materials are unpaginated.

The present contribution is a pathbreaking extensive scoping review of levels of compliance with The Transplantation Society ethical standards stated in 2006 in the reporting of organ sources and ethics in peer-reviewed publications involving organ transplantation in China. The results are as important as they are dispiriting concerning the failure to implement these standards across much of the scientific literature at issue, including in exceptional cases when journals have explicitly articulated these as editorial policy. The well-documented result is that a majority fail the criteria with the practical result of a large body of unethical research currently circulating. (This generates moral hazard in multiple directions.)

Recommendations are given concerning steps to responsibly address this context and future research concerning transplantation in China.

This contribution's bibliographic listings are a significant resource for research of other questions concerning transplantation in China and thus provide a general contribution at a higher level additionally to the import of its specific analysis. (It also raises the ethical issue of what uses of the same are licit when in violation of TTS standards.)

The manuscript was prepared by 7 authors, several of whom have previously published on aspects of the intersection of organ sourcing from executed prisoners for transplantation.

The paper is fundamentally a compliance study spanning years 2000 through April 2017 assaying publications using Chinese data specifically on heart, lung and liver transplantation in the English language space.

The Transplantation Society exclusion guidelines specifically proscribe publication or conference presentation which relies upon or exhibit:

- 1) biological material from executed prisoners;
- 2) lack IRB approval; or
- 3) lack consent of donors.

At the primary level the manuscript concerns researcher compliance; at the secondary level it concerns journal compliance with TTS standards.

The entire submission is 122 pages, none superfluous.

1-2 Author list, key words, word count
 3 Abstract
 4 Strengths & weaknesses of study
 5 Bullet point article summary
 6-27 Paper body
 28-29 Statements and Declarations (author contributions, competing interests, ethical review, registration, funding, data sharing)
 30 List of Supplementary Files
 31-38 References to main text
 39-41 Figures 1-3
 42-43 Supplementary File 1: Search strategies [full search strings]
 44 Supplementary File 2: Details extracted from included studies [A..U = 21 items]
 45-91 Supplementary File [3]: Full list of 445 studies, bibliographic details
 92-102 Supplementary File 4: Results Table [on paper with columns [A]-M [does it go to U in Xcel file?]
 103-108 Supplementary File 5: Bibliographic details of 63 studies containing some information regarding identity of and/or consent by donors. [make clear also included in 445 studies
 109-118 Supplementary File 6: Full list of journals where included papers were published
 119-121 PRISMA 2009 Checklist

Content issues and suggestions:

- In general whenever the term “donor” or “donation” is used, check to see whether it is determinative as voluntary (donare = give a gift) – where not, use “source” or “sourcing” (organ source / organ sourcing), for example 26.23-25: whether donors were living or deceased => whether sources were living or deceased
- Abstract: On page 5 (Article Summary) indicates: “412 of 445 (92.5%) Chinese transplant research papers in this study fail to report whether or not organs were sourced from prisoners.” This stark fact should be included in the abstract under Results. It is a key result.
- What do the authors propose for the afterlife of studies violating the TTS norms? (also make explicit) – One would think retraction until clarification is reached, and if not permanent retraction. This is hard medicine, but moral hazard is the alternative. (‘we deplore the means but will nonetheless reap the benefits’, etc. simply sets a standard of accommodation of more of the same in the future)
- Page 4 Strengths and weaknesses. Add item such as “Only English language sources were included. Chinese language publications in Chinese journals were not included.”

INTRODUCTION (p.6-8)

- Page 7.40-8.3 (circa): One could include that the TTS policy of 2006 [References #7] continued to encourage the training of Chinese transplant surgeons hoping to influence their ethics, however this undeniably added capacity and demand to the system relying on prisoner organs.

METHODS (p.8-12)

- Page 10.12-25. Here it is stated that limiting the search to English sources and those found through the indicated searches would provide a conservative estimate. One should unpack conservative. It may be conservative as to the numerator, but not the denominator. IF one assumes the unfound sources have a lower rate of violation or same rate, it would be conservative. Were the unfound article violation rate lower than the found rate it, the found rate would be nonconservative. My expectation would be that ethical compliance might be higher in the English-speaking realm. In Chinese language periodicals (particularly those in Mainland China), one might expect ethical compliance not being as high (and not advertised). Were that the case, the here given estimate would again be conservative. I would unpack a little more why the expectation would be conservative.

- 10.35-40. Bullet list of exclusion factors for title & abstract screening [Non-English journals? Why and when? English-language journals published in China – simply not expecting any compliance? Unpack.]

RESULTS (p.12-23)

- Page 14. Main results summarized in Table 4. However, Table 4 is truncated on the .pdf (see note below). Elements N-U are unseeable. This must be fixed by making available the actual Xcel file.

- 15.33 perhaps note also that accepting prisoner ‘volunteering’ organs still violates TSS policy

- 16.41-42: the papers are listed in 3 separate sets of square brackets – are these grouped according to which element they are claiming? (unclear as to why) Very good analysis and helpful Table 5.

- 18.21-23 here I tend to disagree that severe injuries or accidents would be potential descriptors for executions for [94,95] when looking back at Table 6 on page 17. [94] states traffic accidents and severe injuries - injuries are not infrequently causes of death (roofs and ladders), so this would have to be extreme euphemism. For [95] I am however a little unclear of what ‘autopsies’ means with regard to “normal control hearts” or what the “control hearts” are in context [during my brief research at an ME office, an autopsy was long after any organ save skin or corneas would be in condition]. In general, though, very good content analysis on page 18.

DISCUSSION (p.23- 26)

- 23.22 that almost certainly include => that certainly or almost certainly include [you effectively point out several sets of studies for which, given the time period, it would be mathematically impossible to not include execute organs given low or no levels of other sources]

- 23.31-40 excellent point that IRB focus is on the recipients

- 23.50-25 [the crux of the discussion: what to do about this &

responsibilities]

- 24.31 Nazi medical experiments => Nazi and Japanese medical experiments

[for latter I would reference Till Bärnighausen's excellent chapter which addresses this context concerning use. His considerations of when ill-gotten data is of 'high quality' are particularly relevant.

Bärnighausen T (2006). Barbaric research- Japanese experiments in occupied China. Relevance, alternatives, ethics. In: Man, Medicine and the State. WU Eckart, ed. Stuttgart: Franz Steiner Verlag. 167-196.

(A copy of the chapter has been uploaded for your perusal – the entire volume is excellent, subtitled 'The human body as an object of government sponsored medical research in the 20th Century')]

- 24.49 about here I would insert a sentence concerning moral hazard, namely that not retracting or censoring creates incentives for future violations of research ethics, as well as the alluded to danger of complicity (unwitting or witting)

- 25.11-14 It is important to emphasize the need for a future comprehensive review both of Chinese language sources and of English-language publications in China (excluded by the present paper's criteria). The Chinese language material is mentioned in passing toward the end of the exposition.

- 25.28 could develop policy => could and should develop policy

- 26.11 likely to be conservative => likely to be conservative given reasonable assumptions [see prior comment on conservative]

- 26.23 the kidney sourcing ambiguity issue (living or cadaver) is itself a finding and should lead to a policy conclusion about source reporting in the future requiring that sources be tracked and declared

- 26.23-24: whether donors were living or deceased => whether sources were living or deceased

- 26.24 we were not able to report on the type of donation => we were not able to generally establish the type of sourcing

- 26.26 nice point on overlapping research cohorts [it would instead constitute multiple abuse of the same subjects]

- Issue to raise somewhere - Did TTS policy have any impact on Western pharmaceutical industry studies doing organ series trials that mathematically, in certain years, must involve executee organs?

One could cite Schwarz A (2012). Responsibilities of international pharmaceutical companies in the abusive Chinese organ transplant system. State Organs. D. Matas & T. Trey, eds. Woodstock, Ontario: Seraphim Publishers. 119-135. [uploaded for perusing]

- Of possible interest on levels of complicity & history of TTS in issue:

Allison KC (2016). China's execution-transplantation system and international institutions: A too-sticky wicket? An Unprecedented Evil Persecution. T. Trey & C. Chu, eds. Clear Insight Publishing. (1st Chinese edition: Taipei: Broad Press, 2015) [uploaded for perusing]

- New article on death criteria in China that may be relevant:

Paul NW, Caplan A, Shapiro ME, Els C, Allison KC, Li H. Determination of death in execution by lethal injection in China. *Camb Q Healthc Ethics*. 2018 Jul;27(3):459-466. doi: 10.1017/S0963180117000846. <https://www.ncbi.nlm.nih.gov/pubmed/29845916>

[uploaded for perusing]

CONCLUSION (p.27)

- Concise and well-wrought

%%%%%%%%%

Contextual issues to briefly address:

- Discuss the search control for partial liver living donor sourcing earlier on [one finds the control in the search string list on p. 42, but make explicit earlier in the text]

- Similarly, explain why kidney transplantation (the original burgeoning market of transplant tourism) is not included. The reasoning is clear but should be introduced earlier. It also has policy implications for identification.

- Almost with apology: In Supplementary File 4 (p.45-91) – the 445 included studies: the bibliographical entries run alphabetically from entry 1 (A) through 329 (Z), however 330 begins again with C running then through 417 (Z) , then 418 (A) through 445 (G). Is there a reason for this (do they represent discrete searches)? If there is a reason, provide an indication in or for the list; if not consider resorting (also necessary for the results table if done).

%%%%%%%%%

Major supplemental file issue: Supplemental File 4: 92-102

Supplement File 4: Results Table is cut off on the right margin

- Not all columns appear in table, only A-M, but missing N-U – I cannot evaluate full table in this format, but full categories are found in Supplemental File 2 on p. 44. Readers will very much want to have access to the whole table.

- Miles of left margin. Adjust Left and Right margins to .5

- Use Word wrap for Line 1 (column titles), shift in content width (plenty of extra space in Yes/No columns) – I think you can make it to column U on the printed page (although the longer discursive entries will require the actual Xcel file to read)

- [Editors:] In any case, make actual Xcel file available to readers which may be the only way to scroll over and read the whole, including the text intensive columns. Under the supplemental file tab only the .pdf is available which cuts off N-U also in landscape.

%%%

Future research:

- The scope of the review was limited to English sources and excluded Chinese English periodicals. A future study (by this team or another) should also review Chinese language periodicals and other language sources (German, French, ...) where not in English. The Transplantation Society guidelines are an international standard which should be observed generally.

%%%

Minor edits:

- 3.21 Jan => January
- 5.8 this policy prohibition => this prohibition policy
- 5.24 transplants that occurred => transplants occurred
- 16.50 during pilot => during the pilot
- 16.54 statement ... stated => statement ... indicated [just sounds better]
- 17-18 single space Table 7 if allowable
- 20.19-21 start (No. of transplants) on own line
- 21-22 single space Table 8 if allowable
- 23.59 in China => in China at the time.
- 26.7 Limitations [italics] => Limitations [Bold]
- 29.32 This study is a scoping review therefore => This study is a scoping review and therefore
- 30.18 included in the study => included in the study and number of papers per journal
- 34.28 [can de-bold 'no pagination'] also for 36.39, 37.9
- 45.3 Supplementary File: => Supplementary File 3:
- 87.17 [artefact characters in Ref # 404 – take a look toward a parsimonious solution]
- 109.2 included in the study => included in the study and number of papers per journal [same as 30.18]

Bibliography files:

- Decapitalize references to main text (make consistent with others, pages 31-38): Ref #s 20, 35, 42, 44, 50, 56, 68, 77, 96, 97, 102, 111
- Decapitalize references in Supplementary File 3 (make consistent with others, pages 45-91): 7, 10, 27, 43, 60, 67, 89, 100, 116, 122, 138, 145, 149, 179, 193, 204, 221, 223, 227, 231, 249, 254, 287, 289, 296, 298, 301, 306, 308, 309, 314, 318, 328, 351, 361, 369, 373, 400, 414, 429
- Decapitalize references in Supplementary File 5 (make consistent with others, pages 103-108): 16, 23, 26, 28, 31, 35, 54
Also extra line between references 21. & 22.

%%%

Thank you for addressing this important topic, requiring such painstaking detail, to illuminate the state of the ethical situation related to Chinese transplantation publishing, with impetus toward an adequate response.

VERSION 1 – AUTHOR RESPONSE

<p>Reviewer 1: Michael E. Shapiro</p>	<p>The authors, in their methodology, excluded any papers concerning kidney transplants, because they felt they could not determine whether the organs came from living or deceased donors. This is the one weakness of this study, as kidney papers constituted 50% of the potential papers to be studied. Many kidney papers do state the donor source, and, in any case, if any deceased donor organs were used, the same requirements would apply</p>	<p>We have added further discussion of this point under Table 2: “Papers reporting on recipients of kidney transplants were excluded at the full text review after a trial of 200 full text analyses. In this sample, 40% of kidney papers failed to report whether organ sources were living or deceased. As a key question in our research concerned procurement of organs from executed prisoners, we did not want to include a potentially large number of papers in which it was unclear whether or not organs were procured from living donors.” We hope that our methods will be used by other scholars who may wish to investigate compliance with ethical standards in the reporting of kidney transplant papers and for that purpose, we are willing to share the bibliographic details of the kidney papers identified in our research.</p>
<p>Reviewer 2: Huige Li</p>	<p>The last paragraph in the Introduction section (lines 29-35, page 8) doesn’t reflect the methods used in the paper. Based on the published papers, it is not feasible to determine whether a journal has excluded any researches using organs from executed prisoners. The journal may have excluded many papers, but some studies were overlooked. Improvement is needed.</p>	<p>We thank the reviewer for alerting us to this point and agree that our study has not identified exclusions, but rather only published papers. We have edited the relevant section: “In this study, we investigated the extent to which journals have complied with these ethical standards by: 1) publishing only research using organs from volunteer donors”</p>
<p>Reviewer 3: Kirk Allison</p>	<p>It is necessary that Supplemental File IV (the results table) be submitted and available to readers in Xcel format</p>	<p>We have submitted this file as an Excel document</p>
	<p>Supplementary File 3 [the listing of 445 included studies] re-alphabetizes at two points. If later singly alphabetized, then the Supplementary File 4 spreadsheet would also need to be to keep the order consistent.</p>	<p>We have reordered the references to be a single list alphabetically ordered.</p>
	<p>Supplementary File 5: Bibliographic details of 63 studies containing some information regarding identity of and/or consent by donors. [make clear also included in 445 studies]</p>	<p>We have added a note to Supplementary file 5 to clarify this: “Note: these 63 studies are a subset of the 445 papers reported in the study and their details are also are included in Supplementary file 3.”</p>

	In general whenever the term “donor” or “donation” is used, check to see whether it is determinative as voluntary (donare = give a gift) – where not, use “source” or “sourcing” (organ source / organ sourcing), for example 26.23-25: whether donors were living or deceased => whether sources were living or deceased	We have made the suggested change throughout the paper.
	On page 5 (Article Summary) indicates: “412 of 445 (92.5%) Chinese transplant research papers in this study fail to report whether or not organs were sourced from prisoners.” This stark fact should be included in the abstract under Results. It is a key result.	The article summary has been removed as it is not a BMJ Open requirement, but we have edited the abstract to more strongly highlight the number of papers failing to meet this ethical standard.
	What do the authors propose for the afterlife of studies violating the TTS norms? (also make explicit) – One would think retraction until clarification is reached, and if not permanent retraction. This is hard medicine, but moral hazard is the alternative. (‘we deplore the means but will nonetheless reap the benefits’, etc. simply sets a standard of accommodation of more of the same in the future)	We have edited the abstract to reflect our stronger conclusion calling for retraction pending investigation of papers in breach of the ethical guidelines.
	Strengths and weaknesses. Add item such as “Only English language sources were included. Chinese language publications in Chinese journals were not included.”	We have edited the ‘Strengths and weaknesses’ to include this point: “Publications in Chinese journals were excluded, regardless of the language of publication”
	Page 7.40-8.3 (circa): One could include that the TTS policy of 2006 [References #7] continued to encourage the training of Chinese transplant surgeons hoping to influence their ethics, however this undeniably added capacity and demand to the system relying on prisoner organs	We agree with the reviewer on this point but have not included it in the Introduction, where our focus is solely on publication standards. We respectfully suggest that this is a broader point that would be relevant in any commentaries on our paper.
	Page 10.12-25. Here it is stated that limiting the search to English sources and those found through	We have addressed this point by making the following change: “We recognised that our search strategy might potentially miss some papers

	<p>the indicated searches would provide a conservative estimate. One should unpack conservative. It may be conservative as to the numerator, but not the denominator. IF one assumes the unfound sources have a lower rate of violation or same rate, it would be conservative. Were the unfound article violation rate lower than the found rate it, the found rate would be nonconservative. My expectation would be that ethical compliance might be higher in the English-speaking realm. In Chinese language periodicals (particularly those in Mainland China), one might expect ethical compliance not being as high (and not advertised). Were that the case, the here given estimate would again be conservative. I would unpack a little more why the expectation would be conservative.</p>	<p>published in difficult to find journals as well as those published in languages other than English, with a potential reduction in sensitivity. However, we do not think that papers omitted as a result of this strategy undermine the reliability of the findings. Rather, these omissions may make our estimate of the magnitude of any ethical breaches of publication standards conservative, based on the assumption that ethical compliance is likely to be higher in international journals published in English compared to journals published in China whether in Chinese or English language.”</p>
	<p>10.35-40. Bullet list of exclusion factors for title & abstract screening [Non-English journals? Why and when? English-language journals published in China – simply not expecting any compliance? Unpack.]</p>	<p>This point is in part addressed by the previous edit identifying our assumption that ethical compliance is likely to be lower in journals published in China, and in addition, we have added the following text in Table 2: ““Chinese Journal” – Exclude any papers published in (English language) journals published in China, on the assumption of low compliance with ethical standards”</p>
	<p>Page 14. Main results summarized in Table 4. However, Table 4 is truncated on the .pdf (see note below). Elements N-U are unseeable. This must be fixed by making available the actual Xcel file.</p>	<p>We have made the Excel file available. We have also edited Supplementary file 2 to explain the reduced number of columns in the published results table compared with the original data extraction elements: “For the Results Table in Supplementary File 4, we have omitted the administrative data e.g. EndNote reference numbers, initials of authors doing extractions and checks), the data relating to exclusions (as we are not reporting on these), and the institution where the transplants took place (because this was inconsistently reported by data extractors and was not relevant to the research questions).”</p>
	<p>15.33 perhaps note also that accepting prisoner ‘volunteering’</p>	<p>We have edited to include this observation: “Under Chinese policy, prisoners are permitted to make allegedly voluntary donations, which is in</p>

	organs still violates TSS policy	violation of TTS policy”
	16.41-42: the papers are listed in 3 separate sets of square brackets – are these grouped according to which element they are claiming? (unclear as to why) Very good analysis and helpful Table 5.	This error in the referencing has been corrected.
	18.21-23 here I tend to disagree that severe injuries or accidents would be potential descriptors for executions for [94,95] when looking back at Table 6 on page 17. [94] states traffic accidents and severe injuries - injuries are not infrequently causes of death (roads and ladders), so this would have to be extreme euphemism. For [95] I am however a little unclear of what ‘autopsies’ means with regard to “normal control hearts” or what the “control hearts” are in context [In general, though, very good content analysis on page 18.	While we agree with the reviewer that describing severe injuries or accidents as potential descriptions for executions would be an ‘extreme euphemism’, we do not think that this is totally improbable. We have amended the text to reflect this: “Two papers refer to donors dying from severe injuries or in accidents. While these are potentially legitimate causes of death for organ donors, it is possible that these could be extreme euphemisms for deaths caused by execution.” Regarding the query about autopsies and control hearts, the paper in question used control hearts obtained at autopsy for tissue for mitochondrial studies.
	23.22 that almost certainly include => that certainly or almost certainly include [you effectively point out several sets of studies for which, given the time period, it would be mathematically impossible to not include execute organs given low or no levels of other sources]	We have edited to reflect this point: “The body of literature contains a large number of papers that certainly, or almost certainly include data from executed prisoners.”
	Nazi medical experiments => Nazi and Japanese medical experiments [for latter I would reference Till Bärnighausen’s excellent chapter which addresses this context concerning use.	WE have edited to include the Japanese experiments and thank the reviewer for alerting us to the Bärnighausen reference, which we have included.
	24.49 about here I would insert a sentence concerning moral hazard, namely that not retracting or censuring creates incentives for future violations of research ethics, as well as the alluded to danger of complicity (unwitting or witting)	We have made the following edit in response to this point: “In addition, due to lack of vigilance by the journals on reporting organ sources, readers also risk witting or unwitting complicity. Finally, the continued presence of these papers in the literature creates moral hazard as it demonstrates that breaches of ethical standards in research will be ignored or tolerated, therefore creating incentives for future research ethics

		violations.”
	25.11-14 It is important to emphasize the need for a future comprehensive review both of Chinese language sources and of English-language publications in China (excluded by the present paper’s criteria). The Chinese language material is mentioned in passing toward the end of the exposition.	We have added a new brief paragraph to make this point: “Third, there is a pressing need for further reviews of the literature excluded in this study. In particular, we need review of Chinese language sources and English language publications in China where a further large body of unethical research may be published as well as review of papers published in languages other than English and Chinese. A future review of kidney transplant papers is also required.”
	25.28 [actually ling 48, not 28] could develop policy => could and should develop policy	We have included the moral ‘should’ here as suggested by the reviewer: “A summit involving representatives from the International Committee of Medical Journal Editors, Committee on Publication Ethics, The Transplantation Society and members of other relevant national and international transplant societies, together with China human rights experts, ethicists and any other relevant stakeholders could and should develop policy on handling relevant published and future research.”
	26.11 likely to be conservative => likely to be conservative given reasonable assumptions [see prior comment on conservative]	We have amended the sentence: “These give confidence that the results are reliable and likely to be conservative (given reasonable assumptions as described in the Methods) rather than to overestimate the findings”
	26.23 the kidney sourcing ambiguity issue (living or cadaver) is itself a finding and should lead to a policy conclusion about source reporting in the future requiring that sources be tracked and declared	We have addressed this point in the previous paragraph where we discuss the potential value of a transplant publication checklist: “One outcome of this process could be the development of a checklist tool for all transplant papers, listing required information about organ sources. Given our lack of capacity in this research to report on papers involving kidney transplants due to missing information about the status of organ sources, one requirement of a checklist should be an unambiguous statement regarding whether the organ sources were living or deceased.”
	26.23-24: whether donors were living or deceased => whether	Here and elsewhere we have changed ‘donors’ to ‘sources’.

	sources were living or deceased	
	26.24 we were not able to report on the type of donation => we were not able to generally establish the type of sourcing	Here and elsewhere we have changed 'donation to 'sourcing'.
	Issue to raise somewhere - Did TTS policy have any impact on Western pharmaceutical industry studies doing organ series trials that mathematically, in certain years, must involve executed organs?	We have included this in a comment on a potential limitation of the study which does not capture unpublished pharmaceutical research: 'Fourth, we have reported on published literature, but during the period when only organs from executed prisoners were available, the pharmaceutical industry ran clinical trials on immunosuppressant drugs for transplantation in China (including after 2007 when TTS policy was promulgated). Unpublished industry trials have not been included in our study.
	Discuss the search control for partial liver living donor sourcing earlier on [one finds the control in the search string list on p. 42, but make explicit earlier in the text]	The exclusion of living donors is in the description of the search strategy in the methods section and it identified in Table 2.
	Similarly, explain why kidney transplantation (the original burgeoning market of transplant tourism) is not included. The reasoning is clear but should be introduced earlier. It also has policy implications for identification.	This has been addressed in our response to reviewer 1, with additional text now included under Table 2
	Almost with apology: In Supplementary File 4 (p.45-91) – the 445 included studies: the bibliographical entries run alphabetically from entry 1 (A) through 329 (Z), however 330 begins again with C running then through 417 (Z), then 418 (A) through 445 (G).	This has been corrected.
	Supplement File 4: Results Table is cut off on the right margin	This has been addressed through submission of the Excel file.
	Future research: The scope of the review was limited to English sources and excluded Chinese English periodicals. A future study (by this team or another) should also review Chinese language periodicals and other language sources (German,	We have made this point in our response to a previous comment about the need for further research.

	<p>French, ...) where not in English. The Transplantation Society guidelines are an international standard which should be observed generally.</p>	
	<p>Minor edits:</p> <p>3.21 Jan => January</p> <p>5.8 this policy prohibition => this prohibition policy</p> <p>5.24 transplants that occurred => transplants occurred</p> <p>16.50 during pilot => during the pilot</p> <p>16.54 statement ... stated => statement ... indicated [just sounds better]</p> <p>17-18 single space Table 7 if allowable</p> <p>20.19-21 start (No. of transplants) on own line</p> <p>21-22 single space Table 8 if allowable</p> <p>23.59 in China => in China at the time.</p> <p>26.7 Limitations [italics] => Limitations [Bold]</p> <p>29.32 This study is a scoping review therefore => This study is a scoping review and therefore</p> <p>30.18 included in the study => included in the study and number of papers per journal</p> <p>34.28 [can de-bold 'no pagination'] also for 36.39, 37.9</p> <p>45.3 Supplementary File: => Supplementary File 3:</p> <p>87.17 [artefact characters in Ref # 404 – take a look toward a</p>	<p>Corrected.</p> <p>Article summary is no longer included.</p> <p>Article summary is no longer included</p> <p>Corrected.</p> <p>Corrected.</p> <p>Done.</p> <p>Done.</p> <p>Done.</p> <p>Corrected.</p> <p>Done.</p> <p>Corrected.</p> <p>Corrected.</p> <p>Corrected.</p> <p>Corrected.</p> <p>Corrected.</p>

	<p>once again.)</p> <p>The page and line numbers are indicated in the following as page.line# referring to the .pdf file page numbers 1-167.</p> <p>4.8 and 132.18 of poor quality => often imprecise [or: often underspecified as to source]</p> <p>10.42 Exclude any papers reporting data from kidney transplant recipients => Exclude any papers reporting data from kidney transplant recipients due to ambiguity of source (living or deceased)</p> <p>13.52 donation => source</p> <p>16.12-14 [consider]: donors => sources</p> <p>19.2 [check context: donor or source]</p> <p>23.37 publishe dunethical => published unethical</p> <p>30.16 [donors or sources or both?]: by donors => by sources Fix font in references (page#reference number): 32#16, 33#33, 35#66, 160#16, 161#33, 163#66</p> <p>31#7 [date of accessing?]</p> <p>32#21 [delete extra colon]</p> <p>38#101 [add period]</p> <p>Pages 97-107 [saved in .pdf in landscape orientation: change to portrait so table is (easily) readable]</p> <p>Thank you authors for the prior revisions and dedicated labors on this paper.</p>
--	---

VERSION 2 – AUTHOR RESPONSE

We thank the reviewer (Kirk Allison) for his careful review of our paper.

We have addressed all of the points he raises and these are marked in the submitted version, and documented below:

4.8 and 132.18 of poor quality => often imprecise [or: often underspecified as to source]

10.42 Exclude any papers reporting data from kidney transplant recipients => Exclude any papers reporting data from kidney transplant recipients due to ambiguity of source (living or deceased)
We have changed the wording as suggested.

13.52 donation => source
We have changed the wording as suggested.

16.12-14 [consider]: donors => sources
We have changed the wording as suggested.

19.2 [check context: donor or source]
We have checked the context and changed the wording as suggested.

23.37 publishe dunethical => published unethicial
WE have corrected this typographical error.

30.16 [donors or sources or both?]: by donors => by sources
We have changed the wording as suggested.

Fix font in references (page#reference number): 32#16, 33#33, 35#66, 160#16, 161#33, 163#66
These Chinese language titles of articles have all been checked and are now displaying correctly.

31#7 [date of accessing?]
This has been inserted.

32#21 [delete extra colon]
The extra colon has been deleted.

38#101 [add period]
A period has been added to the end of the reference.

Pages 97-107 [saved in .pdf in landscape orientation: change to portrait so table is (easily) readable]
We have reformatted this file so that the tables are easily readable.