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 Cross-Sectional Study of All Clinicians’ Conflict of Interest Disclosures to NHS Hospital Employers in England 2015-2016
AUTHORS	Feldman, Harriet; DeVito, Nicholas; Mendel, Jonathan; Carroll, David; Goldacre, Ben

VERSION 1 – REVIEW

REVIEWER	Aaron Mitchell University of North Carolina at Chapel Hill USA
REVIEW RETURNED	06-Nov-2017

GENERAL COMMENTS	This is an important research endeavor highlighting a lack of transparency regarding conflicts of interest between UK health care providers and the pharmaceutical industry. The authors’ findings make it clear that the current system of COI reporting in the UK is not sufficient to produce true transparency, either for use by individual health care consumers or for health services research. One of the central problems noted throughout is the voluntary nature of disclosure; trusts are not compelled to supply information on COIs, nor to do so in more than a cursory fashion. I have several suggestions to improve the clarity of the manuscript reporting this work. 1. The information in the paragraph “Summary Statistics on Disclosures” could be conveyed more clearly. Particularly confusing is the lack of a “total N” of the number of financial transaction entries contained in the spreadsheet for the 20 selected trusts. 428 seemed to be implied as the denominator, but then after reading the whole paragraph and doing some quick math, it became clear that this is not the case. My suggestion would be that the information in this paragraph could be presented much more clearly in a table format, including breakdowns (by both number and value of payments) into all the described categories, such as job description of the recipient, type of donor, etc. If there is a limitation on the number of tables/figures, my view is that a table showing these data would be more helpful than the current Figure #2, which does not add very much beyond what is shown in Table #1. 2. In line with the above comment, why is the Appendix corresponding to these data not cited in the text? Especially when there are so many different tables provided in the very appendices, it should be clear to the reader where look to find a given fact of figure.

	3. This same paragraph makes is clear that there at least 595 entries in the spreadsheet. But, why were only 428 used in calculating the mean declaration size? I was eventually able to answer this question myself by digging in to the appendix spreadsheets, but this should be more readily clear to the reader. This could probably be clarified through the creation of a table for this data, as recommended above. Otherwise, a statement such as, “of 616 total entries, 188 did not provide information on the dollar value of the transaction. Of the 428 entries that did, the mean declaration size was…” 4. The authors cite the Open Payments system (aka, Sunshine Act) in the US as providing a better infrastructure for ensuring transparency. It seems to me that the main components of Open Payments that distinguish it from the current UK system are: 1) reporting is mandatory, not voluntary, with potentially large fines for not complying; 2) the onus of COI reporting is on the donor (ie, pharmaceutical company) rather than the recipient (ie, health care provider), and 3) a common data model is provided to facilitate easy data manipulation and secondary analysis. Which do the authors feel is the most important? My sense from reading reading the manuscript is that #1 is probably most likely, but there is some discussion of the administrative burden on Trusts from providing this information; perhaps this warrants a discussion of #2 in the Conclusions section as well? 5. I am not clear on the authors’ recommendation for a voluntary COI registrar? Is this meant to be as a substitute for a national disclosure mandate, which they begin the paragraph by recommending (because such a national mandate does not appear politically realistic at this time?), or as an adjunct to such a system? If the former, it seems to be something of an awkward position to both make the main conclusion of the paper that the UK needs a system more like the US, while at the same time taking action that presumes this will not happen! 6. Furthermore, it seems that the voluntary system the authors propose may solve the problem of a lack of a common data model for COIs, but it would not solve the (larger?) problem that disclosing COIs is not required to begin with. If the authors are set on establishing such a system, then a stronger case should be made that providing a common reporting system – in the absence of mandatory reporting – would significantly improve the situation.

REVIEWER	Adam Dunn Macquarie University, Australia
REVIEW RETURNED	08-Nov-2017

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. The authors examined the nature of conflict of interest registers in NHS Trusts in the UK, and discovered that the registers were mostly incomplete and/or inaccessible. The results are interesting and highlight an important problem in COI disclosure. I have no major concerns about the methods but I do have suggestions for improving the presentation of the research (especially in fully describing the methods) and to ensure that the context in which the research was done is appropriately addressed with references.

Major comments:

1. Background: The literature review used to provide evidence in the background could be substantially improved. For example, there are quite a few systematic reviews covering interactions between doctors and other health professionals' interactions with the industry and their impact on decision-making (especially prescribing) other than Brax et al. Some of these, or their included references, may be useful (10.1371/journal.pmed.1001561; 10.7326/M15-2522; 10.1371/journal.pmed.1000352). [I noted later that Spurling et al. is probably cited in the correspondence.] Here and in the discussion section, the selection of references seems a little ad hoc and could have been done more thoroughly.

2. Methods: The section on Data and analysis doesn't describe the data or analysis. As a standard approach, imagine that the results section should only describe the consequences of performing the analyses and tests described fully in the methods; there should be no new outcome measures introduced in the results section.

3. Results: I was hoping and expecting to see what was found when auditing the actual information contained within the registers rather than just its presence. On Page 9 the authors explain how data from 20 trusts were transcribed but I wanted to know more about this process of transcribing (and it should be detailed in the methods - e.g. how many people did it? Which 20? Why 20? etc.). Other examples where these types of data have been released in other countries have shown that even where information exists, much of it can be hard to use due to differences in format, inconsistencies, and the nature of the way in which the data are released (e.g. in pdfs that are not machine-readable).

4. Discussion: I agree that it would be a good idea to have a publicly-accessible register for researchers to disclose COIs in a structured searchable format. It might be worth checking the recommendations I have made in RIPR (10.1186/s41073-016-0006-7) and Nature (10.1038/533009a) describing exactly this, and the processes that might make it work. The first proposal of this type I know of was from 2012 in JAMA (10.1001/jama.2012.51172).

5. Discussion: I was surprised that the discussion did not cover the known weaknesses of the version of the Open Payments in the United States, including the quality of the data, its incompleteness, etc. and the number of studies that have examined biases and issues. It is important to recognise and be clear that this it is unlikely that this alone "would provide a simple and effective solution". Ignoring the implementation and advocating in this manner makes the manuscript appear somewhat unbalanced and readers might go back to question the design of the study under the assumption that the authors had a specific result in mind before they started, especially when the methods are not fully described.

Minor comments:

1. Background: For international audiences, it might be worth spelling out what a Trust covers, and if they employ healthcare professionals other than doctors. This isn't clear in the background, which sometimes discusses doctors alone and sometimes generalises to all healthcare professionals.

	2. Results: The data sharing statement could be moved to the methods section. 3. Results: Table 1 is probably not necessary given that it would take up less room as a paragraph in the main text.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Aaron Mitchell
Institution and Country: University of North Carolina at Chapel Hill, USA
Competing Interests: None declared

This is an important research endeavor highlighting a lack of transparency regarding conflicts of interest between UK health care providers and the pharmaceutical industry. The authors' findings make it clear that the current system of COI reporting in the UK is not sufficient to produce true transparency, either for use by individual health care consumers or for health services research. One of the central problems noted throughout is the voluntary nature of disclosure; trusts are not compelled to supply information on COIs, nor to do so in more than a cursory fashion. I have several suggestions to improve the clarity of the manuscript reporting this work.

1. The information in the paragraph "Summary Statistics on Disclosures" could be conveyed more clearly. Particularly confusing is the lack of a "total N" of the number of financial transaction entries contained in the spreadsheet for the 20 selected trusts. 428 seemed to be implied as the denominator, but then after reading the whole paragraph and doing some quick math, it became clear that this is not the case. My suggestion would be that the information in this paragraph could be presented much more clearly in a table format, including breakdowns (by both number and value of payments) into all the described categories, such as job description of the recipient, type of donor, etc. If there is a limitation on the number of tables/figures, my view is that a table showing these data would be more helpful than the current Figure #2, which does not add very much beyond what is shown in Table #1.

Response: We have attempted to improve the clarity of this paragraph by moving some of the data into a new figure (figure 3) and making clear the total number of disclosures and the number with a cash amount given.

2. In line with the above comment, why is the Appendix corresponding to these data not cited in the text? Especially when there are so many different tables provided in the very appendices, it should be clear to the reader where look to find a given fact of figure.

Response: Thank you for bringing this to our attention; we have now cited the appendix in the text.

3. This same paragraph makes is clear that there at least 595 entries in the spreadsheet. But, why were only 428 used in calculating the mean declaration size? I was eventually able to answer this question myself by digging in to the appendix spreadsheets, but this should be more readily clear to the reader. This could probably be clarified through the creation of a table for this data, as recommended above. Otherwise, a statement such as, "of 616 total entries, 188 did not provide information on the dollar value of the transaction. Of the 428 entries that did, the mean declaration size was…"

Response: We have attempted to clarify this paragraph and have made a figure to encapsulate some of these data (figure 3).

4. The authors cite the Open Payments system (aka, Sunshine Act) in the US as providing a better infrastructure for ensuring transparency. It seems to me that the main components of Open Payments that distinguish it from the current UK system are: 1) reporting is mandatory, not voluntary, with potentially large fines for not complying; 2) the onus of COI reporting is on the donor (ie, pharmaceutical company) rather than the recipient (ie, health care provider), and 3) a common data model is provided to facilitate easy data manipulation and secondary analysis. Which do the authors feel is the most important? My sense from reading reading the manuscript is that #1 is probably most likely, but there is some discussion of the administrative burden on Trusts from providing this information; perhaps this warrants a discussion of #2 in the Conclusions section as well?

Response: Many thanks, we have expanded on this aspect in the discussion.

5. I am not clear on the authors' recommendation for a voluntary COI registrar? Is this meant to be as a substitute for a national disclosure mandate, which they begin the paragraph by recommending (because such a national mandate does not appear politically realistic at this time?), or as an adjunct to such a system? If the former, it seems to be something of an awkward position to both make the main conclusion of the paper that the UK needs a system more like the US, while at the same time taking action that presumes this will not happen!

Response: We do not propose a voluntary system: we propose mandatory disclosure, which we believe can and should be delivered under current contractual and regulatory relationships between doctors, the NHS, and the GMC. This is now clarified and expanded in the discussion.

6. Furthermore, it seems that the voluntary system the authors propose may solve the problem of a lack of a common data model for COIs, but it would not solve the (larger?) problem that disclosing COIs is not required to begin with. If the authors are set on establishing such a system, then a stronger case should be made that providing a common reporting system – in the absence of mandatory reporting – would significantly improve the situation.

As above.

Reviewer: 2
Reviewer Name: Adam Dunn
Institution and Country: Macquarie University, Australia
Competing Interests: None declared.

Comment: Thank you for the opportunity to review this manuscript. The authors examined the nature of conflict of interest registers in NHS Trusts in the UK, and discovered that the registers were mostly incomplete and/or inaccessible. The results are interesting and highlight an important problem in COI disclosure.

Response: I have no major concerns about the methods but I do have suggestions for improving the presentation of the research (especially in fully describing the methods) and to ensure that the context in which the research was done is appropriately addressed with references.

Major comments:

1. Background: The literature review used to provide evidence in the background could be substantially improved. For example, there are quite a few systematic reviews covering interactions between doctors and other health professionals' interactions with the industry and their impact on decision-making (especially prescribing) other than Brax et al. Some of these, or their included references, may be useful (10.1371/journal.pmed.1001561; 10.7326/M15-2522; 10.1371/journal.pmed.1000352). [I noted later that Spurling et al. is probably cited in the correspondence.] Here and in the discussion section, the selection of references seems a little ad hoc and could have been done more thoroughly.

Response: vThank you for directing our attention to this relevant literature - we have made use of it in our introduction and discussion.

2. Methods: The section on Data and analysis doesn't describe the data or analysis. As a standard approach, imagine that the results section should only describe the consequences of performing the analyses and tests described fully in the methods; there should be no new outcome measures introduced in the results section.

Response: We have clarified the heading for this section. We have moved the description of the ‘transparency score to the Methods section.

3. Results: I was hoping and expecting to see what was found when auditing the actual information contained within the registers rather than just its presence. On Page 9 the authors explain how data from 20 trusts were transcribed but I wanted to know more about this process of transcribing (and it should be detailed in the methods - e.g. how many people did it? Which 20? Why 20? etc.). Other examples where these types of data have been released in other countries have shown that even where information exists, much of it can be hard to use due to differences in format, inconsistencies, and the nature of the way in which the data are released (e.g. in pdfs that are not machine-readable).

Response: Because of the large number of responses received (187) we felt it best to present these data quantitatively rather than analyse them qualitatively. All responses are presented in Appendix 2, and Appendix 3 highlights some exemplars. We have improved our description of the methods for transcribing these data.

4. Discussion: I agree that it would be a good idea to have a publicly-accessible register for researchers to disclose COIs in a structured searchable format. It might be worth checking the recommendations I have made in RIPR (10.1186/s41073-016-0006-7) and Nature (10.1038/533009a) describing exactly this, and the processes that might make it work. The first proposal of this type I know of was from 2012 in JAMA (10.1001/jama.2012.51172).

Response: Read and cited, very useful, many thanks.

5. Discussion: I was surprised that the discussion did not cover the known weaknesses of the version of the Open Payments in the United States, including the quality of the data, its incompleteness, etc. and the number of studies that have examined biases and issues. It is important to recognise and be clear that this it is unlikely that this alone "would provide a simple and effective solution". Ignoring the implementation and advocating in this manner makes the manuscript appear somewhat unbalanced and readers might go back to question the design of the study under the assumption that the authors had a specific result in mind before they started, especially when the methods are not fully described.

Response: We have expanded our discussion on shortcomings at OP, many thanks.

Minor comments:

1. Background: For international audiences, it might be worth spelling out what a Trust covers, and if they employ healthcare professionals other than doctors. This isn't clear in the background, which sometimes discusses doctors alone and sometimes generalises to all healthcare professionals.

Response: We have clarified in the text where we are referring to all healthcare professionals and where we refer to doctors alone. We have briefly clarified the nature of NHS trusts for international readers.

2. Results: The data sharing statement could be moved to the methods section.

Response: Thank you for this suggestion; we would prefer to leave this section here as it presents the responses received and the analysis and final figures, which we feel are more appropriately described as results.

3. Results: Table 1 is probably not necessary given that it would take up less room as a paragraph in the main text.

Response: Thank you for this suggestion. We have retained the table for clarity, however if space is an issue we can revisit this at an editorial stage.

VERSION 2 – REVIEW

REVIEWER	Adam Dunn Macquarie University, Australia
REVIEW RETURNED	28-Dec-2017

GENERAL COMMENTS	Thank you for the opportunity to look at the revised version of the manuscript. The authors have addressed each of the suggestions and comments I have made in the previous round and I can see no new issues that might need to be addressed.