ARTICLE DETAILS

TITLE (PROVISIONAL) | How are declarations of interest working? A cross sectional study in declarations of interest in healthcare practice in Scotland and England in 2020/2021.

AUTHORS | McCartney, Margaret; Bergeron Hartman, Raphaella; Feldman, Harriet; MacDonald, Ronald; Sullivan, Frank; Heneghan, C; McCutcheon, Calum

VERSION 1 – REVIEW

REVIEWER | Joel Lexchin
York University, School of Health Policy & Management

REVIEW RETURNED | 19-Jun-2022

GENERAL COMMENTS | This study examines statements about conflict-of-interest in NHS trusts in England and Scotland and Clinical Commissioning Groups and private healthcare organizations in England to see if they conform to current recommendations.

1. There are a number of minor copyediting problems in the manuscript and it needs to be thoroughly reviewed.
2. There should be a Limitations section.
3. Has there been any comparable work in other countries? If so that work should be compared to what the authors found in the UK and Scotland.
4. The authors should offer recommendations about how the situation could be improved.
5. Page 4, line 5: The authors say that there have been a variety of Sunshine Acts enacted in North America but that is not quite accurate. There is a Sunshine Act in the United States, one was passed in the Canadian province of Ontario but the regulations to enforce the act were never finalized.
6. There is little to no evidence that disclosures in the US through the Open Payments database has led to behavioural change by physicians or that patients make use of the information in the database - see Journal of General Internal Medicine 2021;36:3194–3198.
7. Are there any sanctions in England for failure of hospitals and CCGs to collect and publish declarations of conflicts?
8. Not only is there not a Sunshine Act in Scotland but the government there has actively rejected such an act – see BMJ 2019;364:l1379.
9. Page 8, lines 25-26: The authors should provide a brief description of Disclosure UK.
10. There is no information contained in the cells in Table 3.
11. Page 12, lines 18-20: This is not a grammatically correct sentence.
GENERAL COMMENTS

While the paper addresses an important topic, I feel that several aspects of the paper could be improved.

Introduction
The authors could start by explaining how and why conflicts of interest arise in medical care and why it is a concern. The latter is addressed to some extent in lines 52 to 57 but this could be moved to the beginning, expanded and discussed specifically in relation to the UK organisations discussed in the paper. The authors could then discuss the different ways of addressing these conflicts of interest and explain why they are only focusing on declarations of interest. For example, with the decision to devolve responsibility to commission primary care to CCGs in 2015, concerns about conflict of interest arose from GPs being both providers and purchasers of primary care. However, this type of conflict is not sufficiently addressed by declarations of interest. In addition, CCGs implemented various governance arrangements to try to address the perceived conflict. So the conflict of interest was more akin to that seen in the corporate world rather than traditionally faced by doctors interacting with pharmaceutical companies, for example. Please see our paper Moran V, Allen P, McDermott I, et al. How are clinical commissioning groups managing conflicts of interest under primary care co-commissioning in England? A qualitative analysis. BMJ Open 2017;7:e018422. doi:10.1136/bmjopen-2017-018422.

There could also be an overview of relevant previous literature to underline what this study adds.

The authors should also explain why they include the private sector. Do they expect conflicts of interest to differ and declarations of interest to be more important compared to the public sector? Is there an overlap between the public and private provision with some doctors working in both sectors?

Methods
The sample size of 15 CCGs appears small. The authors should give some detail on these, for example in terms of geographical location, size. Are they quite heterogeneous?

Results
Again, it could be useful to give a summary description of the 67 Trusts. Also the private providers – are these mainly based in London or geographically dispersed?
Table 3 describing the NHS Scotland Board registers appears to be empty.

Discussion and Conclusion
Some of this text would seem to be more appropriate in the Results, for example, Box 1 and Box 2.

Can the authors compare their studies to any others in the health or medical fields or other fields where declarations of interest are used to address conflict of interest?
I cannot see any discussion of the study limitations although these are mentioned earlier in the paper. It would be good to reiterate
them here and how they could be addressed in future research.

The authors highlight the limitations of declarations of interest. Are there better ways to address conflicts of interest? This relates to my earlier suggestion for the Introduction that the authors explain the source of the conflicts of interest and why they are a concern in order to understand why declarations of interest are used and if there are potentially better ways to deal with the conflicts of interest.

Are there any implications of the finding that none of the private providers published gifts, hospitality or Conflicts of Interest registers?

What are the implications of the finding that most Trusts are not following NHS Guidance and that there is a lack of oversight and accountability – what would be the authors advice or recommendations to NHS England?

Are there any recommendations for future research, for example, in exploring whether and how registers could be useful to the public and professionals (leading on from the statement on 31/32 on page 15).

Minor comments

The authors should describe CCGs, NHS Trusts and NHS Scotland Boards as readers outside the UK may not be familiar with these.

In the title the authors refer to declarations of interest in medical practice. Medical practice may be too narrow - is it not the case that all staff (for example in CCGs or NHS England) need to declare interests? Similarly, in the abstract the authors refer to doctors’ declarations of interest but in the text they mention an example of a nurse consultant in the NHS England registers.

There could be more consistency across tables. For example, in Table 1 “Yes” and “No” are written out in full but are then abbreviated to N and Y in the following tables. In Table 2 “Unknown” is UK and is U in Table 4.

VERSIO N 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Joel Lexchin, York University
Comments to the Author:
This study examines statements about conflict-of-interest in NHS trusts in England and Scotland and Clinical Commissioning Groups and private healthcare organizations in England to see if they conform to current recommendations.

1. There are a number of minor copyediting problems in the manuscript and it needs to be thoroughly reviewed.

   - Many thanks. We have checked the manuscript and hope to have caught all of these. Apologies.

2. There should be a Limitations section.

   - Many thanks. The Limitations are described under the abstract in ‘Strengths and limitations’. However we agree that this should be expanded and we have done this in the Discussion section at greater length. These limitations include: the difficulty in having a denominator regarding sample
size in Clinical Commissioning Group registers, the impact of the pandemic on obtaining results via Freedom of Information from primary care organisations, and the pragmatic choice of private clinics to investigate.

3. Has there been any comparable work in other countries? If so that work should be compared to what the authors found in the UK and Scotland.

- Thank you. We have inserted a discussion of the most comparable work, mainly relating to the checking of declarations across conflict of interest disclosures in medical journals and public registers in the US. There has been no directly comparable work of registers held by employers that we are aware of in the UK or Europe.

4. The authors should offer recommendations about how the situation could be improved.

- Thank you, we have argued that the purpose of declarations needs to be agreed, in terms of whether they are purely for transparency, or transparency and management: either by fellow professionals, or professionals and patients. We recommend trials in different arenas, eg academic journals and hospitals, to improve utility and searching for unintended consequences. Registers may facilitate conflicts rather than reduce their negative impact. We have outlined these issues in the discussion section and recommended further work.

5. Page 4, line 5: The authors say that there have been a variety of Sunshine Acts enacted in North America but that is not quite accurate. There is a Sunshine Act in the United States, one was passed in the Canadian province of Ontario but the regulations to enforce the act were never finalized.

- Thankyou. We have changed ‘North America’ to ‘US’.

6. There is little to no evidence that disclosures in the US through the Open Payments database has led to behavioural change by physicians or that patients make use of the information in the database - see Journal of General Internal Medicine 2021;36:3194–3198.

- Thank you, we agree and are pleased to cite this helpful article which provides an overview of research subsequently examining the impact of the Open Payments database.

7. Are there any sanctions in England for failure of hospitals and CCGs to collect and publish declarations of conflicts?

- Many thanks. Sanctions appear to be restricted to individuals who are challenged about undeclared conflicts but there is scarce data about this and definitions may be opaque (see https://bmjopen.bmj.com/content/8/3/e019952). We agree that sanctions against organisations are more likely to lead to systemic change but we are not sure whether this would improve management of conflicts. We agree this is important and we have put a section under Discussion to elucidate this.

8. Not only is there not a Sunshine Act in Scotland but the government there has actively rejected such an act – see BMJ 2019;364:l1379.

- Thankyou, yes this was submitted via the Public Petition system (MM is resident in Scotland and the petition came from a colleague.) We are happy to insert this reference which reiterates our concerns about the system in Scotland.

9. Page 8, lines 25-26: The authors should provide a brief description of Disclosure UK.

- Thankyou, We agree this would be helpful and we have provided details.

- 10. There is no information contained in the cells in Table 3.
- We apologise, on our version (taken directly from the submission file) we can see information in all cells. For the avoidance of doubt we have reproduced it below. If there is further difficulty please let us know.

**TABLE 3 - NHS SCOTLAND BOARD REGISTERS**

| NHS Scotland Boards | Boards with a public published Board register of interests | Boards with a public published staff DOI register | Boards with all NHSE standard categories included in public DOI registers | Boards with all NHSE standard categories included in G+H registers | Boards with substantive retraction from any register | Registers more than 16m old |
|---------------------|----------------------------------------------------------|--------------------------------------------------|-------------------------------------------------|--------------------------------------------------|--------------------------------------------------|---------------------------|
| 14/14               | 6/14                                                     | 1/14                                            | 3/14                                            | 9/33                                             | 6/35                                             | 17%                      |
| Percentage: 100%    | 14%                                                     | 43%                                             | 7%                                              | 21%                                              | 27%                                              | 17%                      |

- 11. Page 12, lines 18-20: This is not a grammatically correct sentence.
- Apologies, we have altered this and shortened the sentences in this section for clarity.

Reviewer: 2
Dr. Valerie Moran, 1. Luxembourg Institute of Health and Luxembourg Institute of Socio-Economic Research, Luxembourg Institute of Health

Comments to the Author:
While the paper addresses an important topic, I feel that several aspects of the paper could be improved.

Introduction
The authors could start by explaining how and why conflicts of interest arise in medical care and why it is a concern. The latter is addressed to some extent in lines 52 to 57 but this could be moved to the beginning, expanded and discussed specifically in relation to the UK organisations discussed in the paper. The authors could then discuss the different ways of addressing these conflicts of interest and explain why they are only focusing on declarations of interest. For example, with the decision to devolve responsibility to commission primary care to CCGs in 2015, concerns about conflict of interest arose from GPs being both providers and purchasers of primary care. However, this type of conflict is not sufficiently addressed by declarations of interest. In addition, CCGs implemented various governance arrangements to try to address the perceived conflict. So the conflict of interest was more akin to that seen in the corporate world rather than traditionally faced by doctors interacting with pharmaceutical companies, for example. Please see our paper Moran V, Allen P, McDermott I, et al. How are clinical commissioning groups managing conflicts of interest under primary care co-commissioning in England? A qualitative analysis. BMJ Open 2017;7:e018422. doi:10.1136/bmjopen-2017-018422.
- Many thanks. We agree this is important to discuss and we are glad to do so at greater length. We have changed the Introduction as suggested, with an overview of why conflicts of interest are important and the different types and international and then UK situation. We have given greater prominence to the issues concerning CCGs and we are glad to cite this paper which helpfully explains the wider situation and concerns.

There could also be an overview of relevant previous literature to underline what this study adds.

- We agree, and this was also mentioned by reviewer 1. We have included this in the Discussion section and offered comparisons and contrasts with our work.

The authors should also explain why they include the private sector. Do they expect conflicts of interest to differ and declarations of interest to be more important compared to the public sector? Is there an overlap between the public and private provision with some doctors working in both sectors?

- Thankyou. We included the private sector as it has had, as far as we are aware, no interrogation over their practice on Declarations of Interest in the UK previously. In the UK there are doctors who work exclusively in the private sector but most have an NHS commitment. However this study was examining the practice of hospitals and clinics in organising registers, rather than individual clinicians. We should be clearer about this and so we have addressed it in the Objective and put this also as a limitation in the Discussion.

Methods
The sample size of 15 CCGs appears small. The authors should give some detail on these, for example in terms of geographical location, size. Are they quite heterogeneous?

- Thankyou. We agree the sample size was small although the Register size was large and, as there was an unclear denominator, and the CCGs themselves were in flux due to re-organisation, we have fully accepted this limitation and discussed it already. However we agree that a description of these randomly selected CCGs is useful and we have added additional information under Limitations.

Results
Again, it could be useful to give a summary description of the 67 Trusts. Also the private providers – are these mainly based in London or geographically dispersed?
Table 3 describing the NHS Scotland Board registers appears to be empty.

- We agree, these were randomly selected and we have inserted a description. There was clearly an issue with Table 3 as Reviewer One also could not view it. It has been reproduced above. The copy we have retrieved is the one submitted and we are not sure what the problem is and hope the Editors can help.

Discussion and Conclusion
Some of this text would seem to be more appropriate in the Results, for example, Box 1 and Box 2.

- Thank you, we have moved these sections to Results and kept the Discussion.

Can the authors compare their studies to any others in the health or medical fields or other fields where declarations of interest are used to address conflict of interest?
I cannot see any discussion of the study limitations although these are mentioned earlier in the paper. It would be good to reiterate them here and how they could be addressed in future research.

- Many thanks. We agree and have moved the Limitations to the Discussion section. We have also lengthened the information about similar studies and comparators as also mentioned by Reviewer 1.

The authors highlight the limitations of declarations of interest. Are there better ways to address conflicts of interest? This relates to my earlier suggestion for the Introduction that the authors explain the source of the conflicts of interest and why they are a concern in order to understand why
declarations of interest are used and if there are potentially better ways to deal with the conflicts of interest.

- We agree that the earlier Introduction section makes this easier to navigate the Discussion on limitations of declarations usefulness. We think there are major uncertainties about the best way to improve declarations and what the purpose of them currently is and what it should be. We have also taken on board Reviewer 1 comments in further examining this issue under Discussion and Conclusions.

Are there any implications of the finding that none of the private providers published gifts, hospitality or Conflicts of Interest registers?

- Thankyou. We are cautious of drawing firm conclusions but think it is safe to suggest that as there is no national guidance for declarations in the private sector, this should be reviewed. We have put this in the Discussion section.

What are the implications of the finding that most Trusts are not following NHS Guidance and that there is a lack of oversight and accountability – what would be the authors advice or recommendations to NHS England?

- Thankyou, We are cautious about making recommendations to the NHS as it could result in a lot of work (with opportunity cost) while not making a better system, given the uncertainties (which we have now expanded in the Introduction, Discussion and Conclusion.) We suggest that the purpose of DOIs is made clearer and research is organised to find how this should be done, as the concern is that the act of declaration is used as mitigation rather than management of conflicts. We have included this in the Discussion section.

Are there any recommendations for future research, for example, in exploring whether and how registers could be useful to the public and professionals (leading on from the statement on 31/32 on page 15).

- Thankyou, we agree that this is important. We are currently researching this area (see https://osf.io/e7gtq) and hope to publish soon. We have mentioned this.

Minor comments

The authors should describe CCGs, NHS Trusts and NHS Scotland Boards as readers outside the UK may not be familiar with these.

- Thankyou. We agree that this should be better described and we have done this in the Methods section.

In the title the authors refer to declarations of interest in medical practice. Medical practice may be too narrow - is it not the case that all staff (for example in CCGs or NHS England) need to declare interests? Similarly, in the abstract the authors refer to doctors’ declarations of interest but in the text they mention an example of a nurse consultant in the NHS England registers.

- Thankyou, by ‘medical’ we had meant healthcare practice broadly rather than simply medical staff. We have changed this to ‘healthcare practice’ in the title and replaced ‘doctors’ with ‘healthcare staff.

There could be more consistency across tables. For example, in Table 1 “Yes” and “No” are written out in full but are then abbreviated to N and Y in the following tables. In Table 2 “Unknown” is UK and is U in Table 4.

- Many thanks, we have changed all these to Yes and No in the tables (we had done this variably to save space in fuller tables but are happy to make this change.)
**VERSION 2 – REVIEW**

| REVIEWER                  | Joel Lexchin         |
|---------------------------|----------------------|
|                          | York University, School of Health Policy & Management |
| REVIEW RETURNED           | 29-Aug-2022          |
| GENERAL COMMENTS          | The authors have responded to my initial comments but there are still two issues to be resolved: |
|                           | 1. There continues to be copy editing problems and in addition at various points there are problems with word choice. For example, page 7, line 28 reads "who contributed in particular to what would contribute to a..." but should probably read "who contributed in particular to what would constitute a..." |
|                           | 2. References 3 and 22 are identical. |

| REVIEWER                  | Valerie Moran        |
|---------------------------|----------------------|
|                          | 1. Luxembourg Institute of Health and Luxembourg Institute of Socio-Economic Research |
| REVIEW RETURNED           | 09-Sep-2022          |
| GENERAL COMMENTS          | Thanks very much to the authors for taking on board my comments. I would only suggest that the Introduction requires some reorganization so that it is more coherent. |
|                           | The first sentence (page 4, line 10) is about the consequences of conflicts of interest and this would seem to fit better in the second paragraph where other consequences are discussed. Similarly, the second sentence (page 4, lines 10-11) addresses how to deal with conflicts of interest, which is discussed in the third and fourth paragraphs so perhaps the second sentence is more appropriate there. Probably there needs to be an alternative opening sentence before delving into the different types of interests. Apart from these two opening sentences, I think the paper then flows nicely by starting with the different types of interests, then discussing the consequences and how they are addressed. |
|                           | On page 5, line 8 the authors then start to discuss the NHS. I think this is where the authors should explain how the NHS is organised and describe the different bodies (NHSE, CCGs, Trusts, Scottish Health Boards) as I suggested previously. While I see that the authors added some text in response to my comment, this could be more coherent and comprehensive. For example, the authors could explain that in England there is a purchaser-provider split and CCGs were the main purchasers and Trusts are the main providers and NHSE is the regulator. CCGs were membership organisations comprised of GP practices (I understand CCGs ceased to exist as statutory organisations from July 2022) and this is why the conflict of interest arose when they started to commission primary care. The text on CCGs on Page 4, lines 34-39 could be moved here. The authors should also explain what NHS Trusts are as I do not see this in the revision and it is not clear for readers outside the UK (e.g. that they do not necessarily correspond to a single hospital or provider but may comprise several). The new text on Health Boards in Scotland on page 5, lines 31-32 and on page 7, lines 19-20 could be moved here also. Perhaps an additional point to make is that there is no purchaser-provider split in Scotland so it’s an integrated system under the responsibility of the Boards. |
I think I would also move lines 51-57 on Page 5 up to the beginning of the page (e.g. around line 5) so that text on disclosure websites is all together.

Table 3 is still empty although the authors say it was included in the document they uploaded.

The authors also mention a file that addresses the reviews point by point but I could not find this.

**VERSION 2 – AUTHOR RESPONSE**

Reviewer 1: Many thanks. We have been through the paper again looking for copy edits. We have redone the references in addition. We hope this is satisfactory.

Reviewer 2: Many thanks. We have restructured the organisation using almost all of these points. We have made the introduction concentrate on conflicts of interest, before describing the different structures of the UK’s different NHS, and their structure. The structures are complex due to frequent reorganisation and we have provided a summary with the details necessary for readers to understand the structure and differences. I understand that the file which addressed the points systematically was later made available to Dr Moran but we are happy to supply if not and are grateful for her comments.