

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	"Lines in the sand" - An Australian qualitative study of patient group practices to promote independence from pharmaceutical industry funders
AUTHORS	Parker, Lisa; Grundy, Quinn; Fabbri, Alice; Mintzes, Barbara; Bero, Lisa

VERSION 1 – REVIEW

REVIEWER	Piotr Ozieranski University of Bath
REVIEW RETURNED	26-Nov-2020

GENERAL COMMENTS	<p>Thank you for the opportunity to review a revised version of this important paper. I enjoyed reading it. The findings and discussion are excellent. My comments relate primarily to the Introduction and Methods.</p> <p>Article summary: strengths and limitations of this study As far as I understand the BMJ Open guidelines, this section should focus on methodological aspects of the study and not its findings.</p> <p>Introduction - I thought the opening sentences in the introduction could be better supported by relevant references from an extensive body of research.</p> <p>P. 6. What seems to be missing in the introduction is a sentence or two justifying why it is so important to look specifically at the funding of patient organisations alongside all the other actors that are referenced here.</p> <p>P. 10 line 47. Please explain what you mean by sings of pharmaceutical industry funding. I'm currently conducting similar research and it is clear that there are different signs that could be considered (e.g. funding mentioned "in general" and/or from specific companies). How deeply did you look at the websites? Depending on your approach what counts as a "sing" and where you find it you could be arriving at different results</p> <p>P 10, line 48 - what was the total number of organisations you arrived at?</p> <p>P 10. Line 55 (and below). It is unclear to me what you mean by purposive sampling here. Do you mean purposive sampling of patient organisations and/or participants within the patient organisations. It would be really useful for readers to have these two sampling processes, and relationships between them, clearly described.</p>
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	<p>P11 line 12 (and below). The group characteristics you list here are very useful and they all seem important and relevant. I would like to have seen these characteristics related systematically to the literature. Assuming that you are sampling your patient organisations purposively (or “theoretically”) it is important to tell the reader why these characteristics were important, even more so some of them, e.g. “pathological process” are not commonly used and some others “disease type” are not defined here (do you mean ICD-10 classification). Another important question is whether you studied these characteristics systematically and, if so, how they were distributed across the sampling frame. Again, this is another important step in purposive/ theoretical sampling - without this information it is impossible to tell in what ways your chosen organisations reflected the characteristics of the sampling frame (or combinations thereof). In particular, it would be important to know the share of groups receiving industry funding (including different quartiles) in your database and how this overall distribution was reflected in your interviewee characteristics. Finally, was your sampling frame the total number of patient organisations in your database (see my question above). Overall, consistent with what would normally be seen in similar qualitative studies, it would be very important for external validity and replicability reasons to have lot more insight into how you selected the patient organisations.</p> <p>P. 13 line 26 - what was the response rate at the group level and at the individual level? Because you approached several people from the same groups these are probably different.</p> <p>P.13 line 26 - please correct the typo.</p> <p>P13, line 30 - in the text you say you interviewed 17 people from groups receiving industry funding but</p> <p>P14 - table - similar to my comments above, it would be important to learn how your participants characteristics reflected your “target” / “theoretical” characteristics fro the participant sample. For example, did you end up interviewing more CEOs than originally expected? Again, having more detail on this part of the sampling process would normally be expected in similar qualitative studies.</p> <p>P 14 line 59 - I think it would be useful to have all key themes summarised somewhere at the beginning of the results to present the big picture before delving into the detail of each theme.</p> <p>Findings - throughout. Of the several patient group and participant characteristics mentioned in table 1 only the organisational role of participants is included systematically in the findings. Then on p.17 you refer to patient organisation / participant characteristics as they related to the views they expressed not having a clear relationship to one theme. Was it also the case for all other themes?</p>
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VERSION 1 – AUTHOR RESPONSE

Author responses to reviewer 1

Reviewer:

Comments to the Author

Thank you for the opportunity to review a revised version of this important paper. I enjoyed reading it. The findings and discussion are excellent. My comments relate primarily to the Introduction and Methods.

Article summary: strengths and limitations of this study As far as I understand the BMJ Open guidelines, this section should focus on methodological aspects of the study and not its findings.

Author response:

We have altered the strengths and limitations section in accordance with BMJ Open guidelines. It now reads as follows:

“Strengths and limitations of this study

- This interview study draws on comprehensive data from patient groups with diverse industry funding experiences, disease focus and jurisdiction
- This is the first empirical study to focus on how patient groups manage risks to independence
- The study was limited to the Australian setting
- We spoke to staff and board members from patient groups but did not speak to individual patient advocates
- Participants may have spoken selectively about their group's interactions with the pharmaceutical industry in a way that supported the concept of an independent patient group sector”

Page 4, lines 91-100

Reviewer:

Introduction - I thought the opening sentences in the introduction could be better supported by relevant references from an extensive body of research.

Author response:

We have included some relevant references here. (Baggott et al 2014; Baggott et al 2008; Mandeville et al 2019; Rothman et al 2011).

Reviewer:

P. 6. What seems to be missing in the introduction is a sentence or two justifying why it is so important to look specifically at the funding of patient organisations alongside all the other actors that are referenced here.

Author response:

I have added a sentence on the importance of patient group independence:

“This is important because a compromised patient group voice might end up furthering industry interests rather than those of their membership, for example by selectively providing advice and lobbying for services and products that are also in sponsors' interests, and remaining silent on issues such as medication safety or high prices.” Page 5, line 113-7

Reviewer:

P. 10 line 47. Please explain what you mean by sings of pharmaceutical industry funding. I'm

currently conducting similar research and it is clear that there are different signs that could be considered (e.g. funding mentioned “in general” and/or from specific companies). How deeply did you look at the websites? Depending on your approach what counts as a “sing” and where you find it you could be arriving at different results

Author response:

We used patient group websites as a supplementary source of data about patient group receipt of pharmaceutical industry money in order to assist with our purposive recruitment. The predominant source of information was the transparency database compiled from pharmaceutical industry reports of spending on patient groups, as described in the manuscript. However we did also want to find groups that had no industry money, and as described used several strategies for that. For those groups that did not appear in the database, we double-checked for industry affiliations using a search of the patient group webpage. This was a limited search, looking for evidence of financial association with the industry, such as pharmaceutical logos on the main website, presence of pharmaceutical companies on sponsorship pages, and receipt of money on financial statements. If we recruited successfully from a group that did not appear to have any financial association with industry we also asked directly about their group’s financial interactions with the pharmaceutical industry.

We have included the following text:

“When considering recruitment from those groups that did not appear on the database we checked for evidence of pharmaceutical industry funding on groups’ websites (e.g. pharmaceutical logos, sponsorship lists, annual financial reports).” Page 9-10, line 224-7

Reviewer:

P 10, line 48 - what was the total number of organisations you arrived at?

Author response:

There is no definitive list of patient groups in Australia to work from which is why we used the system that we describe. As we mention at the outset of this paragraph, we constructed a ‘non-exhaustive’ list of patient groups. However we have provided some additional information as requested, editing the text to provide more detail (and correct a numerical error). The text now reads:

“Third, we accessed the 53 patient groups listed as members on the website of the peak national patient group organisation, Consumers Health Forum (<https://chf.org.au/our-members>) on 15 November 2017 and searched for organisations not identified through our other methods. This provided an additional 21 groups (running total 259).”

Page 9, line 218-22

Reviewer:

P 10. Line 55 (and below). It is unclear to me what you mean by purposive sampling here. Do you mean purposive sampling of patient organisations and/or participants within the patient organisations. It would be really useful for readers to have these two sampling processes, and relationships between them, clearly described.

Author response:

We purposively sampled both for patient group characteristics and also for participant role. Our aim was to hear about a wide variety of experiences within the patient group sector on this topic. In order to do that we reasoned that it would be important to speak with people affiliated with groups that differed from each other on a variety of characteristics but also to speak with people who occupied different sorts of positions within groups. In order to do that, we deliberately sought to recruit from organisations that varied according to the characteristics we describe, and also to seek out individuals with different roles. We have edited the manuscript to explain this more clearly:

“We began by targeting a few patient groups across a range of characteristics including disease/pathological process and funding status. Our first recruitment email went out to just four groups. As data collection proceeded, we focused on recruiting from patient groups with characteristics that we had not previously managed to recruit from and for participants with different roles. Our recruitment emails were sent directly to the CEOs and/or Board Presidents if those contact details were publicly available, or if not, to the generic email address of our target patient groups.” Page 11, line 252-60

Reviewer:

P11 line 12 (and below). The group characteristics you list here are very useful and they all seem important and relevant. I would like to have seen these characteristics related systematically to the literature. Assuming that you are sampling your patient organisations purposively (or “theoretically”) it is important to tell the reader why these characteristics were important, even more so some of them, e.g. “pathological process” are not commonly used and some others “disease type” are not defined here (do you mean ICD-10 classification). Another important question is whether you studied these characteristics systematically and, if so, how they were distributed across the sampling frame. Again, this is another important step in purposive/ theoretical sampling - without this information it is impossible to tell in what ways your chosen organisations reflected the characteristics of the sampling frame (or combinations thereof).

Author response:

We have provided more information about how and why we sought to recruit with variation in patient group characteristics of disease and pathological process. We have modified the text and included more detail in a supplementary file:

“We also aimed to recruit from patient groups focusing on different types of disease and body system and different pathological processes (see Supplementary File 1). This was because we knew from clinical experience that new medications tended to coalesce around particular illnesses and/or pathophysiological processes. As such, we reasoned that some types of groups might be more likely than others to receive overtures from pharmaceutical companies with new drugs to market. We wanted to hear from groups representing current marketing opportunities for industry and also those that weren't. We drew up a rough list of body systems and pathological processes (see Supplementary File 1) and tried to ensure that our final participant group included a reasonable spread across both lists.” Page 10, line 240-9

Supplementary file 1

Body systems

Respiratory

Neurological

Cardiovascular

Renal

Gastrointestinal

Sensorineural

Dermatological

Musculoskeletal

Women's health

Mental health

Haematological

Endocrine

Pathological processes

Immunological
Infection
Genetic
Cancer
Degenerative
Inflammatory
Endocrine
Vascular
Trauma
Toxic
Metabolic

Reviewer:

In particular, it would be important to know the share of groups receiving industry funding (including different quartiles) in your database and how this overall distribution was reflected in your interviewee characteristics. Finally, was your sampling frame the total number of patient organisations in your database (see my question above). Overall, consistent with what would normally be seen in similar qualitative studies, it would be very important for external validity and replicability reasons to have lot more insight into how you selected the patient organisations.

Author response:

The database was compiled from pharmaceutical company disclosures of spending on named patient groups so all the groups on that list had received industry funding at some stage over 2013-2016. The database listed 230 identified Australian patient groups. We divided the list into quartiles by number of groups, so each quartile had 57-58 groups. We recruited from groups that were clearly in the top quartile, i.e. receiving more pharmaceutical money than most other patient groups, and also from groups across the lower quartiles. As per the manuscript, our sample frame also included groups that did not receive pharmaceutical industry money (7 national and regional health services group, 21 additional groups in the Consumers Health Forum member list and sundry others that were suggested by previous participants or identified through targeted Google searches for groups linked to others in our list that did not obviously appear to have industry links from a limited webpage search). We recruited widely from these groups as well.

Our aim was to speak with participants from groups receiving a large amount of pharmaceutical industry money compared to other groups, and also groups that were receiving similar to or less than others or none at all. As per well-recognised qualitative methods (Palys T. Purposive Sampling. In: Given L, editor. The Sage Encyclopedia of Qualitative Research Methods. 2. Los Angeles: Sage; 2008. p. 697-8.) we were looking to speak with people likely to have different experiences in order to capture the broad range of relevant information. The spread of participant's patient group sponsorship as well as other characteristics is provided in Table 1.

Reviewer:

P. 13 line 26 - what was the response rate at the group level and at the individual level? Because you approached several people from the same groups these are probably different.

Author response:

We have provided this information in the manuscript:

"We had more recruiting success from individualised emails than from generic emails: 7/10 (70%) emails to targeted staff members and 4/7 (57%) targeted Board members resulted in interviews compared with 15/38 (39%) generic patient group emails." Page 13, line 314-7

Reviewer:

P.13 line 26 - please correct the typo.

Author response:

This has been corrected

Reviewer:

P13, line 30 - in the text you say you interviewed 17 people from groups receiving industry funding but

Author response:

This comment was incomplete, so I am not able to respond

Reviewer:

P14 - table - similar to my comments above, it would be important to learn how your participants characteristics reflected your "target" / "theoretical" characteristics from the participant sample. For example, did you end up interviewing more CEOs than originally expected? Again, having more detail on this part of the sampling process would normally be expected in similar qualitative studies.

Author response:

As mentioned above, we used well-recognised qualitative methods to capture the broad range of experiences. We used purposive sampling to make sure that we included a reasonable spread of participant / patient group characteristics that might be likely to affect participant experiences, (Palys T. Purposive Sampling. In: Given L, editor. The Sage Encyclopedia of Qualitative Research Methods. 2. Los Angeles: Sage; 2008. p. 697-8) and continued sampling until we reached saturation of information (Saumure K, Given L. Data saturation. In: Given L, editor. The SAGE encyclopedia of qualitative research methods. Thousand Oaks, CA: SAGE Publications; 2008. p. 196).

Reviewer:

P 14 line 59 - I think it would be useful to have all key themes summarised somewhere at the beginning of the results to present the big picture before delving into the detail of each theme.

Author response:

We have included a short summary of the major themes and concepts at the beginning of the Results section as suggested:

"Participants talked about receiving pressure from the pharmaceutical industry to act in particular ways. They described strategies to maintain their independence, including paying attention to issues of: sponsor exclusivity, brand marketing, agenda setting, advocacy partnerships and content of patient group communications and events. We identified variation between patient groups in where they drew the line between acceptable and unacceptable practices relating to these topics. We also identified variation in patient group practices and policies around transparency of pharmaceutical industry sponsorship. We discuss all of these matters in more detail below." Page 15, line 342-97

Reviewer:

Findings - throughout. Of the several patient group and participant characteristics mentioned in table 1 only the organisational role of participants is included systematically in the findings. Then on p.17 you refer to patient organisation / participant characteristics as they related to the views they expressed not having a clear relationship to one theme. Was it also the case for all other themes?

Author response:

We limited the amount of participant information provided with each quotation in order to protect participant confidentiality. We did notice some association between patient organisation characteristics and participant views and discuss this in the text. For example, the section title 'Risks and benefits of accepting industry funding' explains the different views of participants affiliated with groups that did not accept pharmaceutical industry money vs those that did. We did not notice any association between patient organisation / participant characteristics and transparency and have included a comment about that in the text.

"We did not discern any particular patterns among the patient group characteristics (funding status, disease/pathological process, geographic jurisdiction) and whether the organisation had transparency policies or practices in place." Page 23, line 527-9

VERSION 2 – REVIEW

REVIEWER	Piotr Ozieranski University of Bath
REVIEW RETURNED	12-Jan-2021
GENERAL COMMENTS	<p>Thank you for addressing my comments so clearly and comprehensively. I'm very happy with the responses you provided. I don't have any further comments or suggestions.</p> <p>This is a splendid paper and an important intervention. It was a pleasure to read it and I hope it will be published soon.</p> <p>Please accept my congratulations on your impressive research.</p>