Reviewer’s report

Title: An update on the "empirical turn" in bioethics: Analysis of empirical research in nine bioethics journals

Version: 0 Date: 24 Oct 2017

Reviewer: Marcel Mertz

Reviewer’s report:

GENERAL/SUMMARY:

The authors aim at a follow-up study of an older study (Borry et al) regarding publication trends concerning empirical papers in nine selected bioethical journals. The method used is, in general, defensible, though some reporting aspects should be improved.

However, I think that two major problems arise with this study. Firstly, some assertions/conclusions are too bold given the actual findings or what the method used can justify from a methodological point of view. This can be corrected with not too much effort. Secondly, and more problematic, the scientific value of the study is, at least at the moment, not so obvious. The authors remain rather vague about what these findings can tell researchers in bioethics besides the fact that in the last years, the publication trend regarding empirical research in the selected nine journals was, at large, comparable to the older study - which might be an interesting fact if the paper would be more explicit about why exactly it should be interesting (what does it explain, what does it add to the debate in empirical bioethics etc.). The authors propose that their results "provide directions to still ongoing debates", but do not go much into detail regarding a) which debates/discussion points exactly, and b) which kind of directions (see more in detail in the major points below).

I see more potential for scientific value in the second analysis reported in the paper, regarding topics researched, methods used etc. in the empirical papers they included. In fact, I tend to think that the paper would be more worthwhile focussing on these results, and taking the publication trend questions more as a "side note".

However, the authors do not state this more detailed analysis even as a goal of their review in the abstract and background section (see also major points below). This is even more problematic as, strictly spoken, the details of what the empirical papers that were included have researched, what methods they have used etc. is completely unnecessary if the only (!) goal of the study was to analyse publication trends and compare these to the older study of Borry et al. (Of course, Borry et al also analysed methods and research topics, but these results are not compared with the current study, perhaps reasonably, as - as far as I can ascertain - the methods for analysing these characteristics were different then those used in Borry et al. Thus, even if Borry et al also analysed such characteristics, the study at hand has to provide a reason for why they also analyzed them, given that the goal was only to check if the publication trend was comparable).
Therefore, I generally propose that the authors state more explicit what the study should aim for and what the results can add to the debate.

ABSTRACT:

p. 2, lines 36-37: "This 'empirical turn' in bioethics has been criticized." - Though this statement is true, it is not clear what it adds to the description of the study: The study doesn't aim at discussing the arguments for or against the (alleged) "empirical turn" in bioethics. This sentence, thus, seems to play no role for the background section (at least in the abstract). It should either be deleted or put more in a context that makes its relevance clear for the study at hand. See also corresponding major points below.

p. 2, line 58: "[…] indicating a trend towards empirical research in bioethics". - This is a too bold statement given the limitations of the study, which the authors themselves are addressing in their manuscript (=> findings are not generalizable to the whole field of bioethics). See also corresponding major points below.

MANUSCRIPT - MAJOR POINTS:

p. 4, lines 67-68 (and following): As in the abstract, it does not become clear in the manuscript itself what exactly the status of the mentioned critique of the "empirical turn" for the study is, as the study does not "answer" to the critique in either way, nor comes back to it at the end (discussion/conclusions). It would have some relevance if the particular critique that there is no such a thing as an "empirical turn" in bioethics would be addressed; then, the evidence generated by the study would work as some kind of counter-argument. At the moment, indicating that the (alleged) "empirical turn" was criticized would work as a footnote after describing what the "empirical turn" actually means - which is also not very well described in the background section at the moment, more taken for granted that readers have pre-existing knowledge about what is meant with it (see e.g. Hurst 2010 for different understandings of the "empirical turn in bioethics").

Furthermore, some of the debates of the "last decade" the authors are referring to (lines 71-72) have not so much to do with the "empirical turn" itself (i.e. are not discussing the "turn", understood as "an increase in empirical research in bioethics" or the like, and its relevance for or impact to the field etc., e.g. if it is a "good thing" or a "bad thing"). They are more addressed to the questions of how to combine empirical research methods and normative methods etc. - and such questions were already addressed by some authors in the 1990s, though not necessarily focused on bioethics (see e.g. Weaver/Trevino 1994, Birnbacher 1999).

More important, these debates already acknowledge the existence of such an "empirical turn", and also acknowledge the need or the value of empirical research in bioethics (while critics of the "empirical turn" can question not only if there was such an "empirical turn" in any historical crucial way at all, but also if empirical research in bioethics is necessary, or a valuable path for the field that should be followed etc.).
Directly continuing with the explanation given by Borry et al (lines 72-73) for the existence of the "empirical turn" after stating that there is some (general?) debate concerning the "empirical turn" is somehow puzzling. As a reader, one would expect at least some examples of this debate before one reads the explanation why this "turn" happened (one example is stated in the sentence prior to the sentence beginning with "The last decade […]", but it is not clear why this example is not stated after introducing the fact that there are debates; also, on p. 5, lines 109f further such examples are mentioned, and it is not clear why they are positioned there in the text).

Overall, the structure of the background section seems to be a bit "unorganized", and seems to presume too much knowledge about empirical bioethics and its history. I would therefore propose the following structure: a) explain what "empirical turn" means, that it is i.a. referring to an observed increase of empirical research in bioethical journals etc.; b) present the explanation for this (alleged) "turn"; c) indicate that, however, there are relevant debates about the "turn" itself, its impact or (possibly) the explanation given by Borry et al (and give some examples for this debate); d) develop your research question or hypothesis regarding the "empirical turn", make clear which debates are not addressed by it, and explain the relevance of your study; e) make e.g. a new sub-section called "Previous studies" or something like that where you describe the studies of Sugarman et al, Borry et al and DeBois et al in detail (as you do on p. 4-5 at the moment).

p. 6, lines 118-119: It is not clear why the "update" of the Borry et al study is "important to provide directions to still ongoing debates". Please provide some reasons for this statement, especially also regarding which debates or discussion points exactly the study should be important to give directions.

p. 6, lines 120-122: "We aim to evaluate if this 'empirical turn' is continuing […]" - As already pointed out in the remark regarding the abstract, this is too bold given the stark limitations of the Borry et al study and the study at hand. It is not possible with the methods used to say something about the whole field of bioethics - a problem that the original study already had. The aim of the study should be toned down a bit, e.g. should underline that the original study and the follow-up study can only give some hints to the alleged "empirical turn" regarding the whole field of bioethics (and not only regarding the nine journals examined), and should also change sentences in the conclusions section accordingly. At the moment, these statements here are not consistent with the (correct) statements that are made in the discussion/limitations section (p. 15f) where readers are warned from generalizing the findings etc.

p. 7, lines 155f (and also p. 10, line 221f): "This form was used to collect the following information: […]" - Though the information given here is of course unproblematic, it is not clear to the reader at this point WHY all this information was extracted, as the stated goal of the study was just to show if the trend of empirical research articles is comparable to the results of the older study of Borry et al. (see general comment above).
This analysis here goes way beyond just looking at the type of publication (i.e. empirical or not). Therefore, it should be addressed in the abstract and the background section that one (further) goal of the study was not just to explore and compare publications trends, but also to take a more detailed look at the researched topics, used methods, and so on (which of course makes sense!). Because this is not addressed at the beginning, the subheading "The nature of empirical research […]" on p. 10 is also surprising for the reader.

Overall, the review aims at analyzing and synthesizing two different, though related datasets (empirical/non-empirical papers; details of the empirical papers included), and that should be stated transparently for the reader.

p. 18, author's contribution: The author's contributions are too unclear and unspecific, so it is impossible to check if all authors fulfill ICMJE criteria of authorship (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html), which BMC Medical Ethics is endorsing (https://www.biomedcentral.com/getpublished/editorial-policies#authorship). Please state more in detail the contribution of each author in order to comply with current standards of publication ethics and research ethics.

MANUSCRIPT - MINOR POINTS:

p. 6, line 138: "To decide if an original work empirical or not […]" - Probably an "is" is missing here? (=> "To decide if an original work IS empirical or not [...]"

p. 6, lines 140-141: Please give more information about how "qualitative analysis" was operationalized as an inclusion criteria. An ethical analysis of statements of other persons or of data collected by other authors could also be labelled "qualitative analysis"; if it is meant "qualitative analysis as used in social science research (e.g. qualitative content analysis)" or something like that, make that clearer.

p. 6, line 141: "The inclusion criteria were kept the same […]" - If this refers to the "To decide if an original work [...]"-sentence, it would be better if it is stated before this sentence, and not following it. If it refers to other criteria, please mention these criteria.

p. 7, line 144: "[…] theoretical manuscripts without any empirical data […]" - How in detail was this analyzed? I would assume that "without any empirical data" (= no empirical data mentioned in the manuscript whatsoever) is not predominant in bioethics - at least when conceptualized as an interdisciplinary field and not as a branch of moral philosophy -, even for more theoretical manuscripts, as authors often will refer to empirical studies in their texts, or mentioning case studies. If "without any empirical data collected and/or analyzed" is meant, it would be clearer.
and probably also more "realistic" (though, as mentioned earlier, discussing empirical data from other authors could also be understood as some kind of qualitative analysis of empirical data).

p. 7, lines 146-147: Comparability with the study of Borry et al would still have been possible when literature reviews would have been included, but then analyzed separately (= one analysis without literature reviews for comparison with Borry et al, one additional analysis with the reviews included). It is fully understandable that there are practical limitations (time, effort, complexity), but the stated reason - comparability - is not convincing for not including literature reviews when acknowledging that they are, by strict definition, empirical. To repeat a possible shortcoming of the older Borry et al study should not be justified by compatibility reasons as long (!) it is still possible to analyze a sub-sample of a whole, more inclusive sample in a comparable way. (In addition, I would, of course, argue on the basis of our own research about (systematic) literature reviews in bioethics that the increase in published reviews is a further possible hint to something like an "empirical turn" in bioethics).

p. 7-8, lines 168-171: "Any manuscript deemed ineligible […]. This resulted in the removal of […]." - Why is this information stated under the subheading "Data entry, management, and analysis"? It seems to be part of the selection process ("Data source and selection process"), although not on the abstract/title level, but on the full-text level. I would therefore propose to include this information in the respective heading, as it has nothing to do with data entry or analysis.

p. 9-10, lines 207-208: "Empirical and non-empirical manuscripts […]" - Not sure if I understood this sentence, or at least the relevance of it. Is it necessary?

p. 11, lines 234-235: Why is ethnographic method a separate category? Could it not be subsumed under qualitative or quantitative methods as well? If not, please state the reasons why this should be regarded as a separate category.

p. 11, lines 235-236: "In most cases, each study identified which type of method was employed." - In how many cases exactly? And what was done with studies that did not report their methods clear enough?

p. 11, line 237: Similar to the question related to ethnographic method: Why are evaluation studies a separate category? Will they not use either qualitative or quantitative or both methods?

p. 14, line 300: "[…] it also underlines that more […]" - Maybe replace "underline" with "makes plausible" or something similar that is not so strong as "underline" (see limitations of the study as discussed above).
One should also consider the fact that journals write in their descriptions, aims & scopes and/or author guidelines which kind of papers they accept, or tend to accept. If a journal makes clear to an author that it will have the general tendency to rather reject empirical papers, it seems natural that authors will have to look elsewhere to publish their empirical papers, or will not even think of publishing in these journals in the first place. ("Theoretical Medicine and Bioethics", for example, does not even mention in its description empirical papers, but talks much about theoretical/philosophical papers, scholarly papers and methods - e.g. "All philosophical methods and orientations receive equal consideration" - , etc. Though they might occasionally accept empirical papers, already the description - and the title! - of the journal makes clear that empirical papers are not the typical kind of paper they are interested in as a journal …).

"This pattern in study sampling highlights the value placed in their knowledge and experiences." - Why? A researcher might be interested in knowing what physicians and nurses think, but that does not mean she/he values their knowledge or experiences; she/he just wants to understand what, for example, motivates them, or why they make decisions the way they do (which the researcher possibly would criticize from a normative-ethical point of view, so would not say that she/he values their knowledge or experience - on the contrary, perhaps!). It is correct that there are specific conceptions of empirical bioethics where knowledge and "internal morality" etc. of physicians and nurses are regarded as central (e.g. the approach of Musschenga, and also the approaches of Widdershoven and Molewiijk in part), but this cannot be generalized to all empirical bioethics and their methodologies/conceptions.

"[…] as there are 41 English language journals in bioethics […]" - And even more other journals when also looking at German, French and other non-English languages. This is an additional limitation to generalization aspects which the study does not acknowledge at the moment; bioethical research cannot be reduced to English publications only! Furthermore, journal articles are not the only publication type in bioethics. Books and book chapters can also play a role, but are often completely ignored in the studies regarding the "empirical turn" (but, then again, most empirical ethics research will probably be published via journal articles - however, not looking at books and book chapters should still be addressed in the limitations).

Why is this discussion of limitations not subsumed under the following subheading "Limitations and future research"?

"[…] healthcare and medical journals whose core audience are not ethicists […]" - This seems to be a very important point, as it might be that a lot of important empirical research which can be subsumed under "bioethics" is published there, with non-ethicists as intended readers rightly from the start. However, it can be difficult to decide then if something is a) empirical bioethical research just published in a non-bioethical journal, or b) empirical (e.g. social science) research published in a non-bioethical journal that we, as bioethicists, would say is "empirical bioethical research" because of its topic or aim. What would constitute "empirical
bioethical research", then? The affiliation of the first or last author, which would have to be a "bioethics institution", or a similar institution? - I don't expect the paper to answer these questions, of course, but would suggest stronger highlighting this point and related problems, as any more generalizable answer to the questions if there is an "empirical turn" and how its characteristics are would probably have to address these kinds of publications somehow.

Figure 1: "Excluded full-text articles, with reasons": Please state the number of excluded texts (for comprehensiveness) and the reasons for it (preferably indicate for each reason how many texts were excluded).

SUGGESTIONS:

It might be better to split up "Limitations" and "Future Research" into separate sub-sections, in order to make clearer what are possible ideas for overcoming certain limitations, and what are other/further research interests in the context of empirical research in bioethics.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable
Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal.