Reviewer's report

Title: A Systematic Review of Empirical Bioethics Methodologies

Version: 1 Date: 15 September 2014

Reviewer: Daniel Strech

Reviewer's report:

Summary

Opportunities, limitations and other conceptual challenges of empirical approaches in bioethics were intensively discussed in the last 5-10 years. Against this background, the objective of this paper, namely to review and structure the proposed methodologies for empirical bioethics is important for the scientific community. The fact that the review finally included 33 papers undermines the importance and timeliness of such a review. The search strategy as well as the conceptual framework for synthesizing and presenting the gathered information is appropriate. The findings themselves and the several conceptual distinctions in the framing and discussion of these findings help to structure the future debate on appropriate methodologies in empirical bioethics. The findings as reported in the Results section and in table 3 as well as their conceptual analysis in the Discussion section are also of high value for researchers (newcomers as well as established ones) that aim to design future research projects in empirical bioethics. The paper warrants publication. The following comments might be considered by the authors and the editor in a revision of the current version.

Comments

Are full/further data available? Table 2 highlights the elements of the extraction sheet. The authors mention that several included papers did not address some of these elements. The existing tables that present findings do not tell the reader what the individual papers specifically said to important elements such as “aim of the research”, “details of data collection method”, “data analysis method given”, “details of method for developing normative outcomes”. Table 3 gives some narrative comments for each paper on these issues under the heading “Summary of process described”. More important, the Discussion section discusses, again in a narrative style, what differences across the papers were. However, because this paper can be very helpful to researchers that plan to design and perform future empirical bioethics it would be helpful to see further (maybe full) data according to the extraction sheet. This could be presented as supplemental information. I assume that an Excel spreadsheet or a similar document exist that reports the original wording of each included paper for each element of the extraction scheme. Such a document would also highlight if a certain element was not addressed in any way in the paper. If available, an additional world file that reports such basic data according to the extraction scheme in table 2 will not
only illustrate the current status quo of the “methodological awareness” in empirical bioethics publications and its language. It will also demonstrate the frequency of papers that did not mention some or all of the important elements from the extraction sheet. These additional findings, in turn, could be discussed briefly with some comments on the quality of reporting in empirical bioethics and how to improve the current status quo.

Competing interests: I recommend that the authors comment on the fact that some (3 or 4 or 5?) of the papers included in the review were authored by themselves. The search method is transparent and reproducible and the discussion of all papers is neutral enough but a potential “competing interest” exists nevertheless. If the authors mention this in the “competing interest” section the reader can judge by herself whether she thinks that the competing interest played a role in the conduct of this review. Personally, I did not have the impression, that the competing interests influenced the conduct and presentation of the review.

I had difficulties with understanding the explanation for how to “interpret coherence with reference to argumentative standards in ‘real-world’ practical reasoning” (Page 10). An example might be helpful that illustrates how to meet “universal standards of justification for convincing arguments of all kinds”.

Revise “find three possible three answers” (page 11)

I found the sentence starting with “Any normative conclusions belong to that ‘thinker’ …” somewhat misleading. The “thinker”-approach is not that relativistic as this and the following sentence might suggest. It is about “coherent thinkers”. For example, it is only accepted that a different BUT LIKewise COHERENT thinker could reach a different conclusion.

In the following passage introducing the “theory”-approach at least one example might help to understand how “the theory dominates the analysis”. The authors might consider commenting briefly on what sort/type of moral questions in bioethics can be addressed by such a pure theory approach. Examples that came to my mind were the very foundational moral questions such as the status of the human embryo etc. The more applied and context-sensitive the ethical questions are the more difficult or meaningless becomes the pure theory approach. My latter statement might be wrong but some remarks on the practicability of the theory approach in applied ethics might be worthwhile in this passage.

In the first passage under the heading “Should we aim for particularity or …” the authors mention some difficulties for methods that “seek a dialogical consensus between a specific group of people”. I wonder whether the authors might briefly comment on the relevance of these difficulties for the whole field of public engagement approaches. Just for example: See the recent report from the Nuffield Council on “Emerging Biotechnologies”. Is the “public discourse ethics” as recommended by the Nuffield Council a sort of “action research” as outlined in the paper? Or does public engagement result in generalizable findings that
should inform policy makers, funders and biotech researchers? Are results from public engagement efforts such as citizen councils or town hall meetings relevant for people outside the small group of people who engaged in the town hall meetings? I do not ask the authors to comment on the mentioned questions specifically (because it is outside the scope of this paper). But a short link to the increasing calls for public engagement in medical research and health policy might be worthwhile.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I know one author personally from two meetings and we were gave a workshop together. But we did not cooperate in research or published any paper together. I am convinced that these potentially competing interests did not influence my review.