Author's response to reviews

Title: Research across the disciplines: Quality criteria for empirical-ethical studies

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Author's response to reviews: see over
Dear editors, dear reviewers,

We hereby like to thank you for the opportunity to resubmit our paper to BMC Medical Ethics. We have carefully considered all critiques of the reviewers and have therefore substantially revised the new version.

We agree that the state of language was very bad and therefore was very difficult for the reviewer 1 to follow our argumentation. The paper underwent a critical shortening, a focus on conducting EE research and a very critical, substantial language editing by a native speaker. We believe the paper has very much improved by this and that we have fully addressed all concerns and questions raised by the reviewers.

We will answer in the following the critiques raised by the reviewers point by point (text that was substantially revised or added to address the critique is marked in yellow):

1. **Clarification of the paper’s focus:**

   Reviewer #2: “1. I do not think the paper is clear about whether it is trying to set out quality criteria for the assessment of research protocols (or funding proposals), the carrying out of EE research, or the writing up of EE research. It appears, at different times, to be doing all three. In a statement on page 2, the use of brackets around ‘the reporting of’ makes the intent even more ambiguous – as though the quality of EE studies is equivalent to the quality of the reporting, which suggests (wrongly) that the focus may be entirely on the reporting of EE studies. This needs to be clarified, and I would suggest that the authors pick one or the other, or make moving between them very clear.”

   We agree that it was necessary to be more precise for what focus of methodological debate our criteria were developed and that perhaps different contexts (e.g. evaluation of grants, reviewing, or writing) might imply slight differences. Therefore, we focus now on the most important usage for such quality criteria which is EE research. This focus is also flagged by the revised paper’s title, which is now: Research across the disciplines: A road map for quality criteria in empirical ethics research and is explained on pages 4-5, “This problem can be tackled by two strategies: either focusing only on one particular methodology, or trying to establish standards for ‘good’ EE research. The advantage of the latter is obvious: methodologies are highly dependent on theoretical assumptions, and there is no such thing as one true theory, neither in empirical research nor in ethics. It therefore seems most appropriate to focus on best practice instead of perfecting one particular methodology in EE.”

   And then we write later on in the section ‘aims’:

   “This article aims to provide a “road map” (see below) to assist researchers in conducting EE research, and also to initiate a more focused debate within bioethics about how to improve the quality of EE research. Our contribution should be understood primarily as a heuristic tool. This tool consists of a list of quality criteria to be considered by researchers when engaging in EE research.
Each formal quality criterion is guided by practical questions which illustrate its reflective and methodological purpose (see tables 1-8).

“It should be noted that the criteria we present are only designed for guiding EE research (and, partially and indirectly, for reporting on it). They can also inform the assessment of research protocols or proposals, but such usages will not be discussed further here.”

2. Clarification of our own methodology and approach to gain the criteria:

Reviewer #1: “It is unclear how the tables are generated. Your own methodology remains in the dark.”

Reviewer #2: “2. On page 5 it is implied that there is some kind of method to the analysis presented in the paper, involving systematic or critical review and synthesis, but it is not clear how this has been carried out. For example, it is not at all clear how the authors derived the ‘special criteria’ for EE from the generic criteria described directly above (on page 7). How were the generic quality criteria identified and selected?”

A more extensive description of the methodology is now included in the revised version.

See page 8f. It reads now:

“To survey specific “landmarks” of quality in EE research, and to draft a corresponding “road map”, our procedure consisted of the following main steps: (i) to study, present and critically discuss already-established quality criteria for each of the following three branches of relevant criteria, viz. a) empirical/social science research, b) philosophical/normative-ethical research, and c) EE research; (ii) to consider, present and critically discuss research ethics criteria for each of the three branches, in the light of our experience of EE research and knowledge of the EE debate; (iii) to develop a consensus among the authors; and (iv) to refine the different branches and reduce complexity for publication.

For step (i), we composed three subgroups (sociological empirical methodology, philosophy, EE research). Each group conducted a review of the methodological literature in the relevant area: empirical social science, philosophical/normative-ethical research and EE. We also included explicit recommendations for quality research drafted by scholarly societies (e.g. of psychology, sociology or philosophy). Each subgroup used textual analysis to identify and summarize the quality criteria proposed. Criteria were included in the preliminary compilation if they related to the validity or soundness of the research done, and were deemed relevant for issues of EE research. The subgroup of trained philosophers analysing criteria within philosophy often had to extract informal and implicitly given criteria (apart from criteria directly related to standards of argument, e.g. logic). After this procedure, the findings of each subgroup were discussed by the whole working group. Our next step was to systematize the criteria identified, by clustering them in main categories according to their field (empirical, philosophical, EE research), as well as in subcategories (e.g. different categories for qualitative and quantitative empirical research, or different categories for criteria related to logic/argumentation theory and philosophical approaches). The clustering was based on the literature search (inductive strategy), as well as on our theoretical experience (deductive strategy). The summarizing process was supported by mind mapping software to track modifications, deletions, additions or re-locations of criteria. Finally, we distilled three overarching standards of scientific research, which are articulated in formal, ethical and cognitive norms (see below) based especially in
the philosophy of science. The actual quality criteria were then seen as specific expressions of these overarching standards.

In step (ii), known issues in research ethics were added to the mind map as further criteria. A consensus round took place for step (iii), where each criterion was again critically discussed, with a view to identifying possible redundancies.

The final step (iv) consisted of focusing on those criteria that were seen as specific and coherent only for EE research, and excluding those relating to broadly empirical research in the social sciences and philosophy.

We suggest that the “road map” presented below can be used as a checklist to guide EE research. For clarity, all criteria are also presented in tabular form (see tables 1-8). The tables contain each criterion, operationalized into questions. It is heuristically more effective to ask questions than to consider statements, and these questions are conceived as a pragmatic tool to guide scholars and help them reflect on their own research.

The questions that operationalize criteria should not be understood as simple “yes/no” queries – instead they should function as reflective and critical questions designed to assess certain quality-related aspects of EE research.”

3. Justification of the quality criteria and their discussion

Reviewer #1: “What do you mean by each of the items?”

Reviewer #2: “3. The authors are entitled to present their opinion on what should be used as quality criteria, and I personally agree with many of the criteria proposed. However, the paper lacks justification for any for these criteria, and there is very little in the way of critical discussion. The reader is expected to accept the criteria as self-evident and uncontroversial, but I don’t think all the criteria are uncontroversial.”

We provide now also brief explanations for each criteria and how they are justified., and added that we focus only on those criteria which are most important. We also clarified that the criteria should be understood as heuristic tool and some of some might self-evident, but the crucial point is to consider them as set for particular reflection.

In the section: Limitations, we have added again an overall discussion section (p. 19):

“We assume that it is theoretically acceptable to start from the analytical premise that there is genuine ethical research on one side and genuine empirical–descriptive research on the other, and that these have to be paired up with each other through interdisciplinary research practices. We reject, on the other hand, a stance that denies the need for, the possibility of, or the value of strong interdisciplinary collaboration between empirical and ethical research (e.g. being afraid of naturalistic fallacies) to gain a valid applied ethical conclusion.”

Our research is strongly influenced by experience and in-depth analysis of current EE research in the context of Western bioethics and medical ethics. It does not encompass other possible epistemic approaches such as revealing “concealed” normativity in empirical research, or more institutional aspects of a combination of ethical and empirical disciplines. Our “road map” is therefore restricted to this field.”
4. Clarification of interdisciplinary collaboration

Reviewer #2: “For example, the section across pages 11/12/13 about ‘car sharing’ implies that an interdisciplinary research team is necessary for EE research, but this is debated – in act in a recent publication of my own I challenged this notion and suggested there are benefits to this kind of work being undertaken by a single researcher. I mention this because is it a point I personally disagree with, but there is also a lack of argument to support the many claims I do agree with.”

We weakened the claim concerning the necessity of interdisciplinary research teams, included a remark that such research might also be done by a single researcher, but also argued why we think that most often, a research team is necessary in order to do quality research in this field.

We wrote now on page 7f:
“The above-mentioned integration of empirical research and normative-ethical argument makes interdisciplinary work inevitable. It implies collaboration between researchers trained in different fields and methodologies. While it is theoretically possible for interdisciplinary research to be carried out by a single researcher skilled in more than one academic field, most EE research will benefit from interdisciplinary research teams [e.g. 8]. This is because the skills needed for applying both sound empirical research methods and thorough normative analysis and argument are seldom possessed by a single researcher.

Working in teams also offers the opportunity to overcome methodological biases, penchants for particular research approaches and intellectual myopia in terms of background assumptions. For example, in qualitative research (e.g. interviews, observations), intersubjective exchange during the interpretation process is a necessary precondition for enhancing the validity of the results. It also seems unlikely, on the basis of the criteria we are about to present, that such interdisciplinary (team-) work can be done (fully) independently of other team members, based on a strict division of labour between empirical researchers and ethicists.”

Reviewer #2: “4. Connected to point 3 is that where the authors do make claims that are uncontroversial (particularly in the research ethics section) they are uncontroversial because they are pretty standard tenets of good research practice, which are not clearly unique to EE research. The authors claim on page 6 they will focus only on those criteria that are not already established or much discussed and/or which are particular to EE research. The authors have not done enough to show that the quality criteria they discuss fulfil these two criteria. In line with comment 3 above, some of this very uncontroversial material could be removed to focus in more depth on the issues that are unique to EE.”

We clarified this point by reducing the number of criteria only on those that are relevant for the particular EE focus. We decided that we still need a short explanation of why such criteria generally seemed relevant for a broader audience. However, the major issues now mentioned are particular relevant for EE. The passage reads now on page 18f:

“With regard to so-called informed consent, different standards may obtain in different disciplines such as medicine [42,43], psychology [44] or social sciences [45,46,47]. It is therefore the task of the interdisciplinary research team to openly and ethically consider the possibilities and to choose the
most appropriate format – which may exceed the legal standard. Regardless of consent by the participants, the definitive ethical responsibility remains with the researcher – especially as the EE researcher may be faced with a confidence bonus granted by the research participants just because she/he is an ethicist (an “ethical misconception” analogous to the “therapeutic misconception” in some clinical research). It is the researcher’s duty to deal with this bonus very carefully.

EE research can be misinterpreted by politicians and special interest groups, and researchers need to reflect on the following questions: have we ensured that the results cannot easily be misunderstood or misused? Might the EE study have unanticipated negative consequences that could be detected in advance and therefore avoided? Although it seems clear that we cannot anticipate every kind of negative consequences, the EE researcher may have a particular responsibility to carefully reflect on the outcomes of her/his own research beyond the short time frame of the study, since EE might have a strong influence on public policies, e.g. in health care or biopolitics.

5. Language/terminology/structure issues:

We explain the usage of the road map metaphor now on page 8:

“Road map” analogy
We propose to use the analogy of a “road map” in order to structure the different criteria in our paper, applying the metaphor of moving through a (not yet familiar) landscape for the conduct of EE research. According to this metaphor, the following criteria can be understood as ‘landmarks’, indicating what paths to take, how fast to go, and where to expect a rocky road or a dead end.”

Reviewer 2: “I think there is a translation problem with the term ‘leading question’. To me this means a question that, when asked, leads the person being questioned towards answering in a particular way. I think the authors mean ‘primary research question’ when they say ‘leading question’.”

Thank you for this remark. We changed the wording accordingly.

Reviewer 2: “6. On page 9 the claims made about the kinds of empirical methods that are associated with certain theoretical approaches are generalisations, and ought to be acknowledged as being non-exhaustive.”

That remark is now included. It reads now on page 13;
“Both methods need to be compatible with the combined theoretical framework of the research (see table 2), but should also reflect how the results of each part can inform the other part. For example – and this is far from being an exhaustive list –, discursive ethical approaches have strong links with argumentative, discursive methods of surveying opinion, while liberal-utilitarian ethical approaches tend to accept opinion polls and quantitative surveys.”

Reviewer #1: “Table 1 is identical with Table 3 - why??”
Table 1 was just intended as an example for the way the tables which were already mentioned in the text will look like. As this apparently confused the reader, we decided to eliminate table 1.

Reviewer #1: “How can "criteria" be translated into questions, as given in the complicated tables?”

We clarified the rationale for translating the criteria into questions. But in general, we like to add that translating quality criteria in guiding question is a common methodology. In fact, many “checklist” approaches in clinical ethics or research ethics evaluation are doing this as a matter of routine. As an example from another field, the criteria for logical validity in logic can easily be put into the question “Is the conclusion necessarily following from the premises?”, and answering “yes” would mean that the criteria is fulfilled (= the argument is valid).

The added part in methodology of our own analysis should clarify this, too (see above).

Reviewer #1: “The subtitles need to be checked (for instance on p. 4 there is “Discussion / Approach / Empirical ethics-research/Subject area of the paper”. This does not make sense.”

We agree that the structure had to be revised. But as the author guidelines of BMC Medical Ethics requires that the three main headings in “Debates” articles have to be “Background”, “Discussion” and “Summary”, we can only revise subheadings.

So, we added the following subheadings in “Background”: “Empirical Ethics”, “Research problem”, “Aims & Premises”, and “Approach”. Second order subheadings under “Approach” are now: “Definition of empirical ethics research”, “Road map analogy”, and “Mapping landmarks of quality and drafting a road map”.

Under “Discussion”, we have now included the first order subheading “The road map” and “Limitations and Conclusions”; second order subheadings for “The road map” are now “An aerial view: spotting hills and valleys”, “Three peaks that dominate the scenery: “good science” criteria”, “Existing philosophical and empirical road networks”, “Looking for an interdisciplinary highway”, “a) “Setting up the road signs”: designing a primary research question and selecting a theoretical framework and corresponding methods”, “b) “Driving only when necessary”: demonstrating relevance”, “c) “Enabling car sharing”: guaranteeing interdisciplinary research practice”, and “d) “Driving responsibly”: observing research ethics & scientific ethos”.

We would be very happy if the editors accept our major revisions. The discussion of quality criteria in EE is a very timely, even if controversial endeavor. We believe that our contribution will help to elicit new lines of discussions and bring forward such a discussion.

Sincerely

On behalf of all authors,
Silke Schicktanz