Author's response to reviews

Title: The challenge of empirical research in medical ethics: how conceptual accounts on normative-empirical collaboration may improve research practice.

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Author's response to reviews: see over
Dear Editors,

Enclosed you will find the revised version of our paper “The challenge of empirical research in medical ethics: how conceptual accounts on normative-empirical collaboration may improve research practice” (former title: “Bridging the gap: Conceptual accounts and research practice in empirical medical ethics”).

We are indebted to all three reviewers for their insightful and helpful comments. You will find a point-by-point response to the reviewers’ concerns on the following pages. We have submitted two versions of the revised manuscript online: One with tracked changes and one without marking the changes.

Our manuscript has been reviewed by a native English speaker to improve the language quality.

Thank you for the opportunity to resubmit our article to “BMC Medical Ethics”.

Yours sincerely, (on behalf of the other authors)

Sabine Salloch
Response to the reviewers’ comments

Review 1

Reviewer: Michael Dunn

Major Compulsory Revisions

1. The value of descriptive ethics research. The authors – rightly, in my view – claim that empirical medical ethics research should set out to inform normative argument around practical ethical issues in medical practice. I agree that empirical ethics is distinct from descriptive ethics in that it sets out to address normative, rather than descriptive, research questions. However, to draw the conclusion that descriptive ethics lacks value because it fails to connect to the normative debate seems a little hasty. One could imagine a social scientist interested in the everyday moral dynamics of medical practice responding that without this deep, systematic analysis of the relevant experiences and attitudes of doctors and other health professionals in their work, it would be unclear what practical ethical issues were worthy of further ethical analysis by philosophers (or indeed empirical ethicists).

We agree with Dunn with regard to the value of descriptive ethics and we refer to this contribution of social science by a deep and systematic investigation of empirical contexts of ethical problems and ethical decision-making (see p. 6, paragraph 2 f.). However, the point we stress in our paper is that in empirical studies which want to contribute to medical ethics as a normative discipline, the normative background of the topic should be reflected.
on as part of the research project. Furthermore, the connection between the empirical research and the normative argument on this topic should be revealed. In the revised version of the paper, we provide two reasons for this claim: Firstly, the relevance which can be attributed to empirical data in ethics depends on the specific normative background which is chosen; Secondly, a lack of systematic background in conducting an empirical-ethical study can lead to unclear or cryptonormative conclusions (see p. 7, paragraph 1; p. 8, paragraph 2 ff.).

Moreover, given that medical ethics research is now well-established across cultural contexts, this exploratory descriptive analysis looks therefore to be an important first step on the road to identifying the normative questions that are directly relevant to practitioners and other stakeholders facing ethical challenges in health care. As the authors point out, such descriptive research is not empirical ethics research, but it is of no less value for that reason alone. I am happy for the authors to disagree with me on this, but I think the paper would be improved by at least giving consideration to this role for descriptive ethics research in medical ethics.

Again, we agree with the reviewer that exploration of the context is one important task of empirical research in medical ethics (which can, for instance, be found in Leget’s model). In the revised version of the manuscript, we now refer to the “exploratory” function of empirical research in ethics (see p. 7, paragraph 2 f.). However, this function of empirical research is also not fully independent from the respective ethical-theoretical background. Even if we use empirical research as a starting point, we need at least a vague conception of ethics in the background to be able to designate a problem as an “ethical problem”. Therefore, we would not regard empirical research in this exploratory function as purely descriptive research.
2. 'Bridging the gap'. At the heart of the authors’ arguments is the claim that empirical studies in medical ethics can be improved by drawing on conceptual accounts of the integration of empirical and normative research. I have a number of concerns in relation to this. I deal with the first concern here and the others in the following comments. First, it is rather unclear whether the authors want the reader to conclude that the value of an empirical ethics project stands and falls on whether it draws upon one or more conceptual accounts, or whether this judgment depends also on the convincingness of the conceptual account being drawn upon.

Thank you for pointing out this important aspect. Indeed, the convincingness of a conceptual account of empirical-normative collaboration is important with regard to its contribution for the doing of empirical-ethical research. In the revised version, we now provide a more elaborate account of why we think that Birnbacher’s and Leget’s approaches are suitable as a basis for empirical-ethical studies. We also discuss these approaches more critically (p. 10, paragraph 2 ff).

After all, as the authors acknowledge, there are a number of such accounts, many of which are justified on the basis of accounts of ethics drawn from a range of different philosophical heritages. Thus, if I were to find myself in disagreement with the meta-ethical claims that underpin Birnbacher’s model, it seems that I would also likely to have problems both with the methodological strategies he proposes, and, consequently, the convincingness of the normative claims developed on the basis of empirical data collected from within this model. Do the authors want this question to lie in the background, and not to explicitly consider it? If so, a brief justification is, I think, required.
We now refer more explicitly to the background, limitations and meta-ethical commitments of the selected approaches (see p. 10, paragraph 3 ff.). We also refer to the aspect that suitability of the two models as guidance for research practice depends on the acceptance of these presuppositions (p. 10, paragraph 3 f.). While this issue certainly needs more analysis, we believe that this is beyond the scope of this paper.

3. Theoretical justification and methodological commitment. The nature of the linking of studies into the conceptual accounts that the authors put forward also raises some uncertainty. I am uncertain in the description of the Bendiane et al. study on pages 10-12, whether this linking is being proposed post hoc [“The study’s implications for the normative debate may be clarified by linking it to a conceptual approach to empirical ethics”, page 11], or as a way of formulating a pre-emptive and fundamental critique of the nature, purpose and design of this project. Retroactively attempting to align an empirical project with a theoretical account of the justification of combining empirical and normative analysis looks to be flawed because the varied theoretical justifications that lie at the heart of this ‘integration project’ seem to give rise – a priori – to a set of methodological commitments that cannot be used to shape a particular project, regardless of the closeness of fit.

Thank you for correctly pointing out the correlation between the theoretical backgrounds of specific conceptions of the normative-empirical relationship and the methodological commitments which follow from them. In our revised version, the two empirical studies (Craig 2007, Bendiane 2009) are now taken only as illustrations of the two deficits we identified in the current practice of empirical research (p. 6, paragraph 1; p. 8, paragraph 4 f.). They are no longer retroactively aligned with the theoretical conceptions of normative-empirical cooperation.
This also draws attention to another point of uncertainty: what exactly do the authors mean when they claim that there is a two-way relationship between the empirical work and the conceptual account? What is the validity in empirically ‘testing’ such an account, and would the evaluative standards here be internal to the justification of the account itself? Is this about ensuring the right kinds of methods fit within the methodological frameworks developed out of the conceptual accounts, or is it about the entire re-development of the methodological framework and conceptual account itself? An example or two and a bit more detail might help to elucidate matters here.

By “two-way relationship”, we refer to the idea that even central parts of a conception of normative-empirical collaboration which is practice-oriented should be open to revision if it turns out that they do not provide an appropriate model for conducting an empirical-ethical study (p. 15, paragraph 1).

With regard to the comment on a possible modification of the evaluative standards: We have selected two models of the empirical-normative collaboration which, in our view, have no fixed evaluative standards in the sense of a determined normative-ethical account which should underlie any project which operates on this account. We have elaborated on this point and have provided examples in the revised manuscript (p. 15, paragraph 1). We have also given examples of what could be meant by a modification of a theoretical account (p. 15, paragraph 1).
Review 2

Reviewer: Mette Ebbesen

This article is very interesting for researchers doing empirical ethics - it gives a profound overview and discussion of the literature and studies in the field. This is a valuable contribution.

Major compulsory revisions:
However, I do not find the authors own account on how to bridge the gap between the normative and the empirical clear. I miss a clear description on how to set up a concrete study that actually bridges the gap and a description on why exactly this study does this.

Thank you for pointing out the potential misleading of our title. We realise that the expressions “gap” and “bridge” are most often used in the current debate with reference to the gap between the normative and the empirical sphere. However, by using the term “gap”, we refer to the gap between conceptual accounts of empirical ethics and the “doing” of empirical research in medical ethics. We now see that this title provokes misunderstandings (see also our answer to reviewer 3, point 6), so we have changed it to clarify the focus of our work.

In line with the aforementioned comment, it was not our aim to present our own account on empirical-normative collaboration in this article. Instead, this article aims to point out deficits we perceive with regard to the current practice of empirical research in medical ethics. Furthermore, we make suggestions on how this practice may be improved by learning from already existing theoretical accounts of normative-empirical collaboration. We believe that our article with this focus can also be a contribution to the current discussion about the use of empirical research in a normative discipline. Even though we do not give our own account of empirical ethics, the last section of this paper provides a first sketch of some elements we deem to be relevant for a concept of empirical ethics (see p. 16, paragraph 2 ff.).
Review 3

Reviewer: Guy Widdershoven

Reviewer's report:
This paper examines the cooperation between empirical and normative disciplines in medical ethics. It discusses two models for cooperation. Based on these models, two examples of studies in empirical ethics are criticized and suggestions for improvement are developed. The paper ends with some recommendations for the practice of empirical ethics research.

The paper shows good knowledge of the theoretical debate on and the current practice of empirical ethics. It rightly puts in question the lack of actual and fruitful cooperation between empirical and normative disciplines in much of what is presented as empirical ethics work. Yet, the solutions which are presented by the authors are not fully convincing. How are the models which are discussed related to one another, and what is their relationship with the four steps presented in the last part of the paper.

We would like to thank the reviewer for pointing out possibilities of strengthening the paper of which we have taken up a number in the revised version of this paper.

With regard to the relationship between the models of empirical-normative collaboration, it may be stated that Birnbacher's model begins with the question, “What is the relationship between ethics and morals?”, while Leget et al. have their focus on the question, “How can a social practice be judged by empirical data and normative ethics?” Therefore, one model has a more philosophical, and one a more social scientist account of doing “empirical ethics”. We believe that both models are good examples for conceptual accounts of how to integrate empirical data in normative deliberations. Furthermore, we have chosen these two models because they may be used by researchers who hold different normative theories and wish to integrate empirical methods as part of their research. In the revised version of the paper, we have elaborated on the different backgrounds and presuppositions of the two models (see p. 10, paragraph 2 ff.).

While the two models presented are more on the conceptual side, the four steps we indicate in the last part of our paper are closely related to research practice. However, they are not
meant as our own model of normative-empirical cooperation but as concrete suggestions for researchers planning empirical-ethical studies. In addition, these steps may serve as starting points for our own account of empirical ethics, which is, however, not the focus of this paper (see also our response to reviewer 2). We have clarified these points in the revised version of our paper (p. 16, paragraph 2 ff.).

Major revisions:
1. The theoretical part of the paper raises questions. What exactly does the model of Birnbacher entail? Why are the four parts necessary? Why is it a model of ethical reasoning, and how is it related to other models? What is the relationship between empirical information and normative conclusions in each of the parts? What relationship between empirical and normative aspects is for example characteristic for the implementation phase? A more thorough presentation of the work of Birnbacher is needed to clarify these issues.

We agree with the suggestion to elaborate on Birnbacher’s account and have provided a more detailed description combined with a critical analysis of this concept in the revised version of our manuscript (see p. 11, paragraph 3 ff.).

With regard to the questions above:
Birnbacher describes four tasks of ethics in relation to morals as an empirical phenomenon. The last two tasks he mentions (“construction” and “moral pragmatics”) are, following Birnbacher, especially dependent on interdisciplinary cooperation with empirical disciplines, such as sociology, psychology or pedagogics. Birnbacher describes the four parts of his model as “interrelated”; beyond that, his further comments on the model are sparse. Nevertheless, we see Birnbacher’s model as a valuable analytical tool which systematizes the different elements of an ethical judgement in applied ethics. The normative conclusion takes place at step three, “construction”, which Birnbacher describes as “formulation and justification of a specific normative approach and the development of specific solutions for particular moral problems” [our translation]. The other parts of his model are logically upstream respectively downstream to the normative conclusion itself.
Birnbacher mentions several functions of empirical knowledge in the implementation phase. To sum up, it can be said that empirical knowledge is necessary to make the normative position which had been developed become effective in society. To arrive at this, the ethicist has, for example, to think about institutional regulations, educational transfer and how to motivate people towards a behaviour which complies with the standards developed.

Similar questions can be raised about the approach of Leget et al. What does the metaphor of the ellipse mean?

Similar to the account of Birnbacher, we now provide a more detailed description and discussion of Leget et al.’s account (p. 13, paragraph 2 ff.).

Regarding the metaphor of an ellipse: Leget et al. stress that in their approach, normative and empirical perspectives are kept logically distinguished. Together with this independency, they aim for a close interdisciplinary cooperation, so that we have two distinct focuses which are, nevertheless, closely tied together. We have explained this ellipse-metaphor in the revised manuscript (p. 13, paragraph 2).

The paper would be much more interesting if the two proposals would be critically examined instead of just being sketched.

We have taken up this suggestion (which has also been expressed by reviewer 1) and now comment further on background, limitations and meta-ethical commitments of the selected approaches in the revised version of our manuscript (p. 10, paragraph 2 ff.).

2. The two examples of shortcomings of empirical ethics research also raise questions. Why were these two studies chosen? They do not seem to be very relevant in the field. Moreover, the criticism of the two studies is rather thin. Why would the first study be better if it would be presented as helpful to implementation?
Our criterion for the selection of the two studies was to provide illustrative examples of typical shortcomings which can be found when reading empirical studies in bioethics journals. Our reference to “implementation” in the discussion of the first study is also just one example to illustrate how the normative relevance of this study could have been clarified, and how the purely descriptive status could have been overcome. Other ways are possible as well, for example, a use of the empirical data to formulate context-specific ethical norms (this would have been the task of “construction” in Birnbacher’s model). We have clarified the reasons and purposes of our choice of examples in the revised version of the paper (p. 6, paragraph 1; p. 8, paragraph 3 ff.).

The last sentence of the second study is criticized; why is this one sentence of the study so important? In fact, the criticism does not seem valid. The sentence merely states that more knowledge of palliative care would improve end-of-life care; this does not entail a negative stance towards legalising euthanasia (since legalisation of euthanasia is not at odds with high quality palliative care). Even if the criticism would have been correct, it would not entail the need for involving representatives of normative disciplines in the research, but only more refined use of logic and argumentation (which is not the prerequisite of normative disciplines, but can and also should be part of empirical disciplines).

We quoted this sentence as it represents the study’s normative conclusion, and we have tried to clarify this in the revised version of our manuscript (p. 9, paragraph 1 f.). We fully agree with you that a legalisation of euthanasia does not, as such, speak against the provision of high-quality palliative care. Nevertheless, in our view, in this study (as in other empirical studies published in medical ethical journals), it is not clear how the authors reach their normative conclusion on the basis of their empirical data. If the statement in favour of a better knowledge in palliative care is to be linked to the study’s empirical findings, then this statement can be interpreted as being crytonormative. The data developed in this study indicate that a better knowledge in palliative care would lead to a decrease in the acceptance of euthanasia and PAS.
Even if the criticism would have been correct, it would not entail
the need for involving representatives of normative disciplines in the research,
but only more refined use of logic and argumentation (which is not the
prerequisite of normative disciplines, but can and also should be part of empirical
disciplines).

_We fully agree with this statement. However, next to logic and argumentation, it can be expected from representatives of the normative disciplines that they are usually more sensitive towards the question: From what can a normative statement be derived? Maybe this sensitivity to refrain from not well-justified normative statements could have been a help for the study. In addition to this, the representatives of the normative disciplines could also have stressed the need to clarify how the empirical findings of the study are linked to a normative-ethical discussion about euthanasia and PAS._

3. The four steps in the last part of the paper are certainly relevant. Yet, their
relationship to the rest of the paper is not evident.

_We have tried to strengthen the relationship between our four points in the final part and the preceding analysis in the revised version of our manuscript (p. 16, paragraph 2 ff.). While we are not aiming to develop our own account of empirical-normative collaboration in this article, the four points in that last part should serve as first indications for researchers who are planning an empirical-ethical study._

4. Instead of a final section ‘summary’ (which is more of an abstract), a section
with conclusions is needed.

_We fully agree with this comment. The quite unusual final section is due to the guidelines of BMC Medical Ethics for a “debate” article. It says that the summary section of these articles “should present in brief the arguments outlined throughout the article.”_ ([http://www.biomedcentral.com/bmcmed/authors/instructions/debate#summary](http://www.biomedcentral.com/bmcmed/authors/instructions/debate#summary))
However, we tried to integrate the substance of the conclusion in the preceding section of the article.

Suggestions/discretionary revisions:

5. The paper might be improved by starting with examples of problems in empirical ethics work (focusing on the lack of integration of empirical and normative analysis). Then proposals for improvement could be presented (such as Birnbacher and Leget et al, but maybe also other examples), with a critical examination of how they would work and how they would be of help in preventing the problems found in the examples analyzed before. Finally the authors could discuss what is missing in these proposals/models, and what they want to add. This would provide a clearer structure and a more convincing line of argumentation.

Thank you for this helpful suggestion regarding the structure of the text which we have used for the current version of our article (see p. 5 ff.). We have also discussed what is missing, e.g. in Birnbacher’s model (p. 12, paragraph 2 f.), and have elaborated more on our four points in the final section (p. 16, paragraph 2 ff.).

6. A remark on the title and the use of headings. The title of the paper is not really illuminating. The phrase ‘Bridging the gap’ has been used too often in this context. The subtitle is not specific enough; it does not clarify what the paper is about.

Thank you for pointing out the possible misunderstanding regarding our (former) title which had also been identified by reviewer 2. As opposed to the often-used metaphor of a gap between the normative and the empirical side, our title should have referred to the gap between conceptual approaches and research practice, therefore, a theory-practice-gap. In
light of the misunderstandings pointed out in the reviews, we have decided to change our title.

The heading of the sections is not very helpful. Why is section 2 called discussion? The subsections 1-3 could be separate sections (preferably in another order, as mentioned above).

We agree with the suggestion. However, according the journal’s guidelines, debate articles should include the sections “Background”, “Discussion” and “Summary”. Furthermore, as the guidelines indicate, the discussion section “may be broken into subsections with appropriate subheadings”.