Author’s response to reviews

Title: Informed Consent and Registry-based Research - The Case of the Danish Circumcision Registry

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Author’s response to reviews:

Your manuscript "Informed Consent and Registry-based Research on Religious Circumcision" (METH-D-16-00013R1) has been assessed by our reviewers and our editorial board. Based on these reports and this advice our handling editor would like to request a further minor revision. We ask that you pay particular attention to the comments provided by Section Editor Jonathan Ives in his report as 'reviewer 3'.

Reviewer #1:

We appreciate the opportunity to reevaluate this excellent and provocative manuscript. The authors have clearly dissociated the question of research ethics from that of circumcision, Furthermore, their revisions have capably dealt with the points we raised in our comments. We have just two remaining concerns, neither of which is major.

1. On page 4, the authors allude to "formal aspects relating to the lines of responsibility." By "formal," do they mean "administrative" or something in addition. A small amount of revision should clarify this brief passage.

We have clarified this on p. 4.

2. Regarding our comments on informed consent as a cure for the problems they describe, we certainly do not expect them to change their established and legitimate views on this subject. Nor
is it reasonable to ask them to recapitulate opposing arguments and provide detailed refutations. (If only reviewers treated our own manuscripts with these courtesies!) However, they should acknowledge contrary views in a few lines, with citation. This would facilitate efforts of readers who wish to familiarize themselves more thoroughly with the field.

We have added a few lines and a previously suggested reference from this reviewer on p. 12.

Reviewer #2:
No further comments

Reviewer #3: (Jonathan Ives, PhD)
This is a well written and interesting paper exploring the ethics of informed consent in registry based research, asking the question of whether secondary use of data ought to require informed consent. The authors use a case study to explore the issues, specifically a Danish proposal to use registry data to conduct research on ritual male circumcision. Using this example, the authors problematise the assumption that informed consent is not necessary for the secondary use of registry data, and instead propose that for some kinds of research at least informed consent ought to be required. Overall, I think the paper is very effective and makes a relatively subtle, but important, point that has generally been neglected. The arguments are well made, engaging and interesting.

Having seen the response the authors make to previous reviewers, it is clear that there are some concerns about the subject matter and the way the arguments are made. I do not share these concerns and I feel the paper is of high quality. The authors have taken pains to clarify their position, and the Danish context in which this particular debate had its genesis, and I feel that it is very clear. However, it is the case that the use of a case study that centres on such a controversial topic carries risk of misunderstanding and misinterpretation of the paper, with the reader focussing on the case material rather than the general point being taken from the case. With that in mind I have a few suggestions about the way some of the issues might be framed (mostly signposting) that the authors might find helpful.
1. The title may be a little misleading, and suggests the main focus is on religious circumcision, whereas my reading of the paper is that religious circumcision is merely a case study that is (effectively) used to highlight problems with consent not being required. I would suggest a change of title that reflects that focus.

We have changed the title to emphasize that it is a case-study into the Danish Circumcision Registry.

2. It may be worth making more, early on, of the fact that your starting point for this paper is that circumcision is legal and therefore permissible, whether you agree with it or not. This could perhaps be reinforced when you discuss the problem of overreaching social pressure, where you are relying (I think) on the assumption that it is prima facie wrong for the state to engage in activity that can stigmatise a practice that is legal and permitted. This argument is, of course problematic and will have critics, but it is certainly a permissible stipulation in the context of this argument. The problem, of course, with the circumcision case study is that practice that can easily be argued to be harming others, and so not a good (or uncontroversial) case with which to illustrate an argument about the legitimacy of self-expression. This then invites the reader to focus on that, rather than on the more abstract point you are actually making. You do deal with this at the end of the section (p7, lines 11-22), but the careless reader may not get that far - so some signposting may be useful.

We have on p. 2 added that our starting point is that circumcision is legal.

3. Before the discussion, and immediately after the description of the circumcision registry, it may be useful to have a linking and summarising passage that reinforces the way that the registry will be used as case study to challenge the assumption that anonymised data can be used without consent. You will show using this study, that there can be harms arising even with the use of anonymised data, and in showing these harms can arise in this particular case you show that these harms could arise in other such research, making it important to look at any such research a case by case basis.

We have p. 5 – before the discussion – added a summarising passage.
4. At the end of the discrimination argument, you raise for the first time the point about the harm (of discrimination) being sufficient to allow a person to choose not to take part in a research study. I think the paper would benefit from this being made as a general point earlier on, and from being repeated at the end of each section with reference to that particular harm. This reinforces the central argument that these putative harms are sufficient to justify giving a person a choice about whether or not to participate in the research that putatively leads to the those harms.

We have p. 7 added a sentence on the harm of social pressure. We already mention harm in relation to stigmatization and medicalization.

5. The point about a conflict of interests in the polarisation of research section is a fair one, I think, but perhaps it could be framed in terms of putative participants having a right to decide who uses their data. If they felt that a person was using their data to push forward an agenda that they disagreed with, then this would be sufficient reason to withhold consent. But, this is not an option when registry data are used. It could be made as a more general point, and the more general point, I think, could be made more prominent.

We have rewritten an extensive part of that section.

6. It may be useful to have a linking passage at the end of sections on harm that end with a general point that acknowledges whilst you have shown that the assumption of not needing consent is flawed, this does not mean it will never be justified. The point is that the assumption does hold and that additional argument is needed. It might be the case that the wrongs/harms of ritual circumcision are such that a registry that does not require consent is justified. What this paper shows is that that additional argument is needed, and it is not enough to assume that because data is anonymous no-one can be harmed. You have shown that indirect harms may follow - but that it not the same as asserting that risking those harms can never be justified. This might then lead nicely into the implications section. It may even be worth foregrounding this general argument, so that it is signposted right at the start before the discussions of harm begin.

We have in the added section on p. 5 signposted this point.
7. The implications discussion is, to my mind, excellent and brings everything together very nicely dealing with objections swiftly and effectively. The risk is that a reader not versed in philosophical ethics may jump to the wrong conclusion too soon and assume you are doing something you are not - hence my suggestions above to increase signposting so that you avoid providing ammunition to the careless reader.