Reviewer’s report

Title: Healthcare professionals' and patients' perspectives on consent to clinical genetic testing: moving towards a more relational approach

Version: 0 Date: 27 Oct 2016

Reviewer: Simon Woods

Reviewer's report:

Thank you for submitting this interesting paper on the very topical theme of consent to genetic testing. Since it is such a topical subject there is the added challenge of rendering an original piece which makes a new contribution; much of what you address is not new. Since your paper combines both conceptual and empirical aspects it has the potential to do just this however in my opinion a little more work is needed to establish this. It is a clearly written piece but it would benefit from some relatively minor revisions and a few more substantive changes.

1. You are writing from the context of the UK and the NHS please ensure that you have allowed for an international readership e.g. National Health Service (NHS) etc.

2. Method and ethics approval: You declare that the research has ethics approval but I am confused by the discussion at p.9. Can you please clarify that the ethics approval and consents permitted author 1 to have access to these data for the purpose of this secondary analysis. It is not clear from the discussion here.

3. The paper's focus is consent in clinical genetic testing however I am not sure that you always sustain this focus throughout the paper as there seems to be some slippage into discussion of genetic investigations in the research context. I realise that some genetics tests require entry into a research study but I believe that your primary focus is on clinical testing. I think that the distinction is very relevant to the consent context and especially (though I may be mistaken) when discussing incidental and additional looked for findings which are less likely or at least differently managed in clinical as opposed to the research context. On the same point I am not sure why the discussion turns to matters related to dynamic consent, I may be mistaken or may be misunderstanding your point but as far as I am aware dynamic consent is a tool for the research context rather than the clinical context. You make the point but I don't understand why you refer to it if your focus is on the context of clinical testing? Dynamic consent could be seen as another version of the atomistic form of consent that you are critical of.

4. I have some concerns about your assertions regarding consent especially your characterisation of it as 'the foundation of contemporary medical ethics' - I think many
would take issue with this unqualified claim. Indeed your own paper is critical of consent at least on one understanding of the term. I don't recall any of your respondents commenting on consent in this way; some of the quotations rather imply that it is seen as a bureaucratic procedure, or a 'safety net'.

5. I realise that your analysis is an ethical analysis but I am surprised that you don't at least acknowledge that consent can be (perhaps fundamentally) regarded as a legal concept related to the right to self-determination and bodily integrity which are arguably not synonymous with respect for autonomy. It seems to me that the atomistic account of consent that you are critical of is linked to the legal framing of consent especially as the law allows, in principle, that a consent is valid and lawful even if the consenting individual forgets the detail of what they were informed about at a later date. I presume that this is not a position you would support? I am not clear if you have a view about what is an ethical consent such that it could substitute for the approach you are critical of.

6. As you are writing from the UK context I wonder why you make no reference to the recent legal challenges around specifically informed consent (see NM Vs Lanarkshire) as this seems so relevant to your discussion about the role of information, knowledge, understanding etc. as features of the consent process.

7. I am very sympathetic to your introduction of relational autonomy and the contextual factors influencing the ethics of consent but I do have a criticism which you ought to address; namely that the heading 'Relational Autonomy and consent' is rather slipped in than fully explained. On my reading it doesn't look like a product of your thematic analysis of these data. This is a point where your conceptual and your empirical are at odds. I would suggest that you limit your data analysis/ findings to what can be evidenced from the data and you ground the 'relational autonomy' in a stronger conceptual account starting in the introduction/ background and picked up again in the discussion. Something to address here is making the link between relational autonomy and consent.

8. A final point. You do not seem to mention the role of genetic counselling which usually accompanies consent for genetic testing and is often discussed as a positive 'ethical' feature of clinical genetics very relevant to the consent process.

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.

Not relevant to this manuscript

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 interest

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