Reviewer's report

Title: Procedure vs process: ethical paradigms and the conduct of qualitative research

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Detailed Discussion

Background section – bureaucratic nature of research ethics oversight is undermining the research enterprise especially in regard to “sensitive topics and hard to reach groups” (Abstract).

Discussion section – Many researchers have offered criticisms of current research ethics oversight arrangements as hindering research. This paper focuses on a less explored topic namely the “different epistemologies characterising biomedical and qualitative investigation”. Argues that the “bioethical framework underlying current regulatory structures is fundamentally at odds with the practice of emergent, negotiated micro-ethics required in qualitative research” (Abstract). The world of qualitative research is less formulaic and subject to procedural resolution which relies on integrity of researchers in the field. Calls for an empirical ethics divorced from abstract “principalism” (sic).

Given this, I read the paper with the following in mind:

1. Is the background claim sufficiently supported with enough detail about how current research oversight is impairing access to sensitive topics etc.?
2. Are the “different epistemologies” adequately demonstrated?
3. Is a reasonably strong case made about the processes of current research ethics oversight running contrary the “micro-ethics” required for qualitative research?
4. Are terms like “micro-ethics” and “empirical ethics” adequately explained?

This is a well-documented paper with sufficient references especially on the discontent of researchers with research ethics oversight arrangements.

In the section on “bioethics” there is a brief but sufficient overview of the Belmont principles. In the discussion of “the contingent nature of ethical regulation” the author misses an important nuance in the history of ethics regulation, namely, that in many cases of the most egregious violations of participants’ rights and dignity the researchers were not only acting in ways that we now find repugnant, but they were also acting in ways that ran against the stated standards of the times (e.g., see the US Presidential Commission Report on the Human Radiation Experiments). In other words there seem to be some “contingent” ethical claims that have stood a test of time.

The section on “the case for proportionality” is pivotal in the paper. Basically the
The author argues that biomedical research has both “the potential” and the underlying interest structures (commercial and governmental interests) to do harm to participants; whereas, empirical research in the social sciences is an essentially benign and even beneficent enterprise that does not harm and often helps participants. However, very little evidence in terms of impacts on the lives of research participants in the two domains is provided for either of these propositions. In the qualitative research that my colleagues and I have conducted on the experiences of participants in health research, we found it is the situation of the participant (life-experiences, social context and the life) rather than the type of research methodology that makes the difference.

It also struck me that the author is painting the picture with a very broad brush – as if all biomedical research was one colour and all social science research was a contrasting colour. This is an overly simplified characterisation. Think about social science research in health behaviours and biomedical research in public health.

In “micro-ethics and qualitative research” the author argues that bioethics principles applied by RECs and their international counterparts lend themselves to a kind of empty and abstract proceduralism that is insensitive to the diverse contexts of qualitative research. Why would this not also apply to the diverse contexts of biomedical research? Why doesn’t biomedical research need “micro-ethics”? I should say that I do share the author’s concern about treating research participants as “passive” rather than “active”, but wonder why this doesn’t also apply to biomedical research.

It would really help the paper if the author provided a more fine-grained contrast of an area of qualitative research (say, from a health care area) with a particular area of biomedical research (e.g., randomised clinical trials) to illustrate the contrast.

On a more philosophical note, I think the characterisation of principle-based ethics as inherently formulaic an exaggeration. There is no inherent reason that the sort of principle-based ethics used in clinical or research settings could not be context sensitive. Indeed, my reading of Beauchamp and Childress and others is that this a context-sensitive ethics. That it may not be used in such a way may be more a product of particular bureaucratic histories and cultures.

In the section on personally identifiable data it would really help the author’s argument to provide some case studies. I think that one difficulty here is that the author is trying to advance too many substantive claims in a single paper. This is an important area of concern. It deserves elaboration on its own.

In the section on “autonomy and informed consent” the author offers a fairly standard critique of a rather attenuated and thin version of autonomy as a kind of autarchy. There are much richer and better versions of autonomy in the literatures (see for example Sue Sherwin’s work on relational autonomy). In any case, I don’t know why the arguments advanced here would only apply to qualitative research contexts and not also to biomedical settings.

The discussion of confidentiality is another area that deserves treatment on its own rather than as part of a rather long single paper. I would also suggest that
many of the underlying factors here have more to do with sort of surveillance state that has been created in the UK, US and elsewhere than with anything to do with the practice of medicine.

I would also say the same thing about the discussion of incapacity. It is a very large and important area deserving more detailed exploration. Again I did not see enough detail to draw the sharp line between qualitative and biomedical research that the author sees. The author moves into controversial areas at the end of this section on incapacity in the discussion of individual versus societal interests. First, it is not true that in biomedical research individual interests always trump individual interests (e.g., public health research). Second and more worrisome, is the implicit conclusion that we should simply trust qualitative researchers to balance individual and societal interests.

In the section on “ethical mindfulness and the deskilling of researchers” the author makes the good point that field work requires contextual judgement. I don’t see this as exclusively applying to qualitative researchers. In biomedical research contexts it also obtains though in some settings to a lesser degree. Here is another area where a more fine-grained analysis and comparison of contrasting research settings would go a long ways towards making the point.

I would say too that some of the points being made here while obviously heartfelt may more local than universal. The Research Ethics Boards that my colleagues and I have worked with do seem on the whole to be sensitive to the nuances of qualitative research. The regulatory structure (at least in Canada) pays a great deal of attention to qualitative research. This leads me to wonder if the issues more about local cultures than pervasive structures, but this is a large topic in itself.

In the “summary and conclusions” the author argues for an “opt-out” rather than an “opt-in” system for patient recruitment into research under NHS. This is a major topic in its own right which should be argued for in the body of the paper.

Recommendations

On the positive side, the author has an excellent grasp of the literature. The author also addresses a number of highly important issues in research ethics and human participant protection. As well a number of interesting propositions are advanced.

However, I did not feel the author adequately addressed the four questions that I set earlier as benchmarks. The contrast of biomedical and qualitative research is overly broad. Many of the good points made in the paper apply as much to biomedical as to qualitative research. The characterisation of principle-based approaches is simplistic and open to ready rejoinder. Too many important and controversial claims are advanced to be sufficiently supported in a single paper.

I also found the whole tone of the paper rather abstract for an author writing from a qualitative perspective.

I would suggest that the author focus on a particular area such as PID and confidentiality or autonomy and capacity and then develop the area with rich qualitative data.