The Science in Ethics: What counts as Good Research?

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Issues in Research Ethics

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Mixing Science and Ethics

- RECs pass judgements on ‘science’

Results: ‘‘Scientific issues’’ were raised in 104 (74%) of the 141 letters in our sample. The present data suggest that RECs frequently considered scientific issues and that judgments of these often informed their decisions About approval of applications. Current processes of peer review seemed insufficient to reassure RECs about the scientific quality of applications they were asked to review.

‘An analysis of decision letters by research ethics committees: the ethics/scientific quality boundary examined’
(E.L.Angell et.al. *Qual Saf Health Care* 2008;17:131–136.)

Mixing Science and Ethics

- Issues raised (104 letters mention science): Sampling (65%), choice of method (50%), research question (27%), measuring instrument (28%), data analysis, bias, feasibility, equipoise and others
- Problem – RECs don't have the appropriate expertise: a broad range of expertise with significant lay membership (1/3)

Good Research

The Ambiguities of Good:

At least two senses of ‘good’

(1) Ethical sense

(2) Functional sense

- Defined in terms of a ‘characteristic activity’
- A good X is an X that does what X’s are supposed to do, well

The Ethical Sense of 'Good'

1. 'External': In order to be ethical, research might need to be constrained in various ways
   - Side constraints – avoidance of harm, individual benefits, valid consent, confidentiality (etc.)
3. 'Internal': In order to be ethical, the research itself needs to be a good thing to do, worthwhile
   - Justification of the research: why should medical research be undertaken?

Justifying Medical Research

- This is an ethical issue
- Aims and justification of medical science
  - most medical research aims at improvements in the well-being of patients in some way
- Provides knowledge which will then (perhaps eventually) be used for the benefit of patients in some way
- The knowledge generated by the research process is instrumentally valuable

The Functional Sense of ‘Good’

- Good research does what research is supposed to do, well
- Research involves a cognitive output achieved with a systematic methodology or strategy
  - Cognitive output: Knowledge, understanding, etc
  - Method: RCT, ethnography, interview
- Not perfect definition - it will do for now and is fully inclusive

The Functional Sense of ‘Good’

Good research:

- Research with clear aims, a clear, succinct research question and a methodology that can and is best suited to address the question

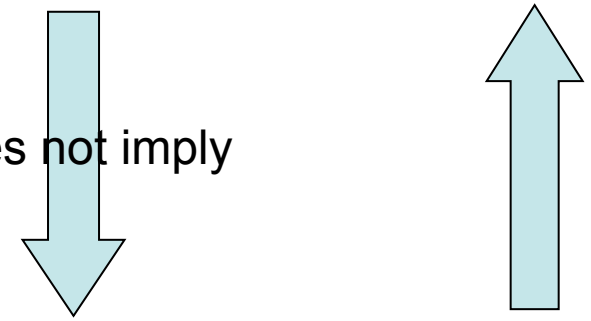
The Functional Sense of ‘Good’

We might also ask here:

- What is the function of (medical) research? What is it *for*?
- This shows the connection between ‘function’ and ‘justification’
  - The ‘knowledge’ generated by medical research is *for application* in the medical context
  - Fulfilling its function here will help with its being justified

Good Research

- ‘Good’ understood as ‘functional’
  - ‘Methodologically sound’ research



Does imply subject to other ethical constraints

- ‘Good’ understood as ‘ethical’
  - ‘Ethical’ research

Practicalities

A. Planning Research: demonstrating applicability and benefit

- Many ways of demonstrating potential value
- Main point: Justification is connected to instrumental value – knowledge as instrumental extrinsically valuable, valuable for something, i.e. welfare
- Ethically this matters because of 'internal' trade-offs: potential welfare benefits vs. potential costs (resources as well)

Practicalities

B. The role of science in REC review

- Not sure there is a neat answer given the connections
- Three tentative suggestions …

1. Encourage researchers to see the importance of the scientific justification for the ethics

Practicalities

2. Tighten and standardise the Peer Review procedure
   - Simply having more thorough peer review will not help: dialogue is needed
   - Tailor it peer review to the ethics review process (i.e. reviewer reports ‘to’ RECs)
   - Bring R&D and RECs ‘closer’ – cross membership?

Practicalities

3. Encourage RECs to understand the limits of their expertise

   - Questions rather than judgements about 'science'
     - [This touches on broader issues about authority and the role of RECs in research]
   - Making RECs more expert will not help – this duplicates the peer review process

Concluding Remarks

- The science cannot be separated from ethical assessment
- This shouldn't be taken as a threat to research
- It does lead to practical problems that are to a certain extent part and parcel of the enterprise