Public perspectives on research governance

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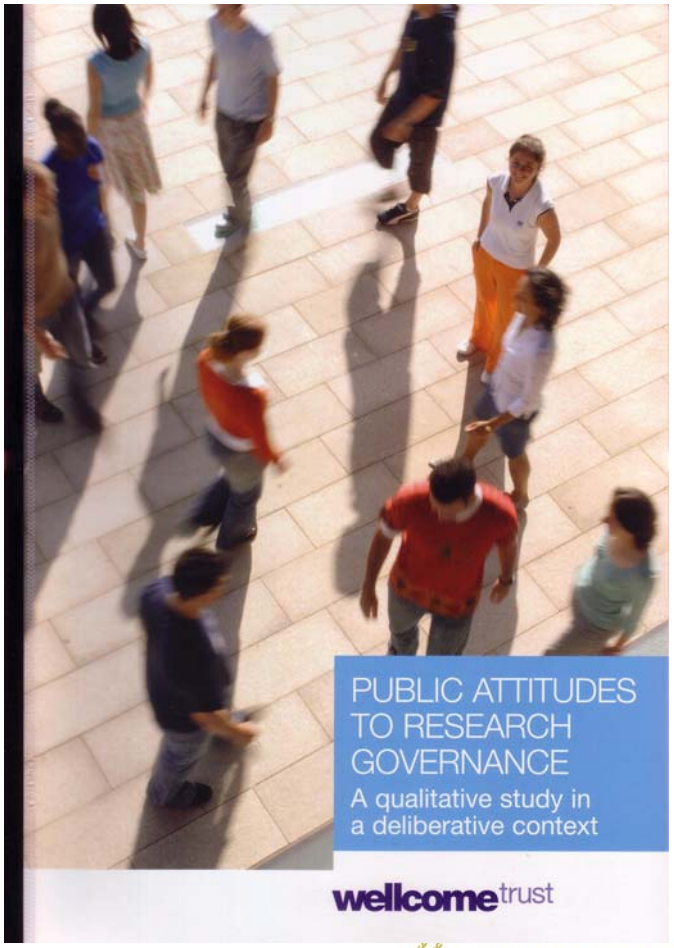
Wellcome Trust Project

- Armstrong, V., Barnett, J., Cooper, H., Monkman, M., Moran-Ellis, J. & Shepherd, R. (2007). *Public attitudes to research governance: A qualitative study in a deliberative context.* London: The Wellcome Trust.

- www.wellcome.ac.uk/doc_wtx038446.html



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Remit and scope

- Attitudes to governance of biomedical research
  - ‘the systems in place for ensuring that medical research on human beings is safe, conforms to ethical standards and is likely to contribute to scientific understanding’
- Use of health information rather than clinical trials
- Four facets of research governance
  - Personal data
  - Informed consent
  - Databases
  - Models of governance – legislation; professional self-regulation; external bodies

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Deliberative workshops

- 12 groups of 7-8 people (n=89 in total)
  - General Public (8 groups – including 4 mixed)
  - Patients with long term illness (2 groups)
  - Participants in biomedical research (2 groups)
- 5 hour session including:
  - Presentation of four short films
  - Written material about issues of governance, consent, etc.
- Groups reconvened 1 week later for 1.5 hours to reflect on the issues using scenarios

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Capacity of deliberative workshops

- Ability to get beyond initial responses
- Allowed information to be presented on a relatively novel topic in an accessible way
- To provide time to:
  - Make sense of new information
  - Discuss and explore issues in detail
  - Reflect on the views expressed by other participants
- To provide time to think or discuss with others outside the group
  - Reconvened session allows exploration of intervening reflection and discussion

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Deliberation and efficacy

- *One thing I'll be grateful to this group for apart from a pocket full of beer tokens is the fact that I will now be able to make an informed decision on what I wanted to do*
- *I think I'd feel more confident in the fact that I would be able to ask questions. I think that's an important thing whereas before I didn't*
- *I had to take my son to the hospital on Monday, cauterised, and the doctor gave me a form and said please sign this you know it's for anaesthetic. .. I queried it and said to him this isn't for anaesthesia, and he said no, but this paragraph on the flip-side of the page is. Nothing was explained to me, I only picked… I think I wouldn't have even thought about it because I've been here.*

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Use of personal information

- People are sensitive about the type of information, e.g. sexual health, mental health
- This is influenced by who will have access to the data
- Aggregate anonymised data were not considered to be personal data
- With identifiable data people wanted to know the purpose and relevance of the information for the study
- People preferred irreversible (rather than reversible) anonymity but had a problem if information relevant to their own health could not then be tied back to them

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Communication

- Despite low levels of awareness people are keen to have more information
  - But would not have simply read material on this topic
  - Not a simple process of more information = greater acceptance
  - Needs to be related to everyday experience – will use previous experiences to test the veracity of information
- Greater levels of transparency of the research process
  - Why particular data are required
  - What is the aim of the research

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Governance and oversight

- Low awareness of governance mechanisms
- But generally positive about self regulation bodies (e.g. BMA, GMC, RECs)
- Bodies that regulate research seen as remote
- Governance bodies need to be more visibly grounded in everyday procedures:
  - Consent
  - Anonymity
  - Confidentiality

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Confidentiality and anonymity

- Tended not to differentiate between confidentiality and anonymity
- Used examples of breaches from everyday life
  - Banks, identity theft, ‘borrowing’ passwords at work
- Individuals processing data not secure
- Vulnerability to hacking
  - Scepticism on whether individual health data would attract attention

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Trust in the system

- GP seen as trusted mediator between participants and the researchers
  - People valued a personal approach
- But participants aware of difficulties in implementing due to other pressures
- Less trust in other parts of the NHS
  - Including outsourcing
  - Greater problem for more local
- Drug companies seen as professional but negative about insurance companies

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The centrality of consent

- Consent domain in biomedical research
  - Personal data (e.g. medical records) or tissue
- Strong consensus about the meaning of consent
  - Formal and explicit indication of understanding and agreement
- Media stories around misuse of data/tissue
  - Framed as resulting from dangers of lack of explicit consent
- Strong consensus that seeking consent is desirable
  - The right/desire to be asked was the dominant framing independent of willingness to participate

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Caveats around consent

- Recognised that needing to provide consent may work against the greater good
- Considerable variation across individuals in their preferences
  - People recognised the limitations of a ‘one size fits all’ consent seeking system
- Practical constraints to thoughtful provision of consent
  - Routine nature of consent giving – ‘nation of signers’
  - Use of heuristics – e.g. imagining worst case scenario

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Variations of consent

- Type of research
  - More minimal procedures around (e.g.) data used epidemiological studies
  - Uncertainties around purpose linked with greater reluctance to participate
  - Differences between tissue and data
- Implied consent
  - Not welcomed as a model of the consent process
  - Equivalent of no consent

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Practicalities of consent

- Ideal for consent to be sought and given in the context of an ongoing relationship
  - Recognised that this is often impracticable
- Reflections on NHS consent form and consent for *this* research
  - Clarity - of information and options - on the consent form is paramount
  - Heuristics here – who is asking and what is it for?
- Opt in/out boxes
  - Opt in - seen as being on the safe side
  - Opt out – ideal long term

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The ‘reach’ of consent

- Wide awareness of the potential need and value of using personal data/tissue for different research aims
- Intractable practical difficulties of obtaining re-consent led to notions of ‘levels of consent’ being developed
  - Blanket consent across uses/users/times
  - Specifying re-consent options
  - No further consent

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General conclusions

- Participants were very supportive of biomedical research and of taking part in research, based on altruism and social responsibility
- Low awareness of the issues, even for those who had taken part in biomedical research
- Consent is the key to public trust and confidence
- Bodies and procedures that regulate research seen as remote

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Overall implications

- Researchers need to actively engage with participants' desire for more transparency
  - Why data are required
  - How data are stored
  - Who will have access
- GPs are the ideal broker for research participation
- Implied consent is seen as no consent
- Explicit consent could include a range of possible future uses
- Participants require reassurance on the security of databases
- Governance bodies seen as remote and need to be grounded in more concrete aspects of research participation, e.g. consent, anonymity
- 'One stop shop' with access/links to information on participation in research

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Further information

- Email: r.shepherd@surrey.ac.uk
- Project report: www.wellcome.ac.uk/doc_wtx038446.html
- Personal website: www.psy.surrey.ac.uk/people/staff/RShepherd.htm

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