Are people with Intellectual and Developmental Disabilities who lack capacity to consent at risk of being excluded from research? Ethical implications of the UK Mental Capacity Act 2005

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BACKGROUND

- Mental Capacity Act 2005 (MCA) came into force in 2007 – Covers ‘intrusive’ research involving participants who lack capacity, i.e. any study that would normally require the consent of a participant in order to be lawful
- The Act requires these projects to be reviewed and approved by an National Health Service (NHS) research ethics committee (REC) before it can begin
- It has thus brought a large section of social care research into a formalised regulatory process which has been designed to deal with interventional clinical research (Dingwall 2006; Haggerty 2004; Parker et al. 2011)
- There has also been criticism that NHS RECs are predisposed towards clinical projects following quantitative methodologies and do not have sufficient knowledge or expertise of qualitative research methods, or the specific issues they raise, to be able to provide a fair assessment of social care research (Angell et al. 2007; Haggerty 2004)
- Establishment of the National Social Care Ethics Committee (SCREC) in 2009 has addressed some of these concerns
  - However, to gain a favourable opinion for a research project involving participants who do not have capacity to consent, researchers must demonstrate in-depth knowledge of the Act and be able to convincingly evidence how their project complies with the relevant sections
  - This additional regulatory burden may be affecting researchers’ decisions on whether to involve people with Intellectual and Developmental Disabilities (IDD) in their projects, and may lead to the exclusion of this population from research from which they could benefit.

AIMS

- Small pilot study to investigate the impact of the MCA on research involving people with IDD who lack capacity to consent to research participation
  - Specifically: does the Act mediate researchers’ decisions to include these kinds of people in their studies?
  - Do the NHS REC, and SCREC take different approaches to review and approval?
- What measures could universities take to improve researchers’ confidence and expertise with navigating the approvals process for research involving participants with IDD who lack capacity to consent?

METHODS

Two stage project:

- Retrospective review and content analysis of NRES decision-letters for applications involving people with IDD who lack capacity to consent
- Semi-structured interviews with people researching participants with IDD who lack capacity to consent, exploring their experiences and opinions on whether the MCA affects the involvement in research of people who do not have capacity to consent to their participation

Research ethics approval for the study was gained from the University of Kent Research Ethics Committee.

RESULTS

- REC decision-letters for 12 studies that were reviewed for compliance with the MCA were identified for the 3-year period between 2011 and 2014
- 7 studies reviewed by SCREC; 5 by an NHS REC
- All 12 studies needed amendments or additional information before a final favourable opinion was granted
- Content analysis identified the most common themes raised by RECs. The top 3 were:
  - Methodological questions
  - Issues with documentation
  - Consent
- Interviews identified researcher frustration with ‘challenging’, ‘confrontational’, ‘tortuous’ ‘disproportionate’ process
  - ‘I think that the starting point that they have is that you should not include anybody that lacks capacity in research’
  - Inconsistencies identified in review style and assessment of MCA criteria between SCREC and NHS RECs
  - ‘If I had my way I would rather go through an NHS REC’
  - Evidence that complexity and adversarial nature of process affects recruitment decisions
    - ‘I know for a fact it stops people doing research with this group’; ‘We decided … there’s absolutely no way it can go through the MCA, so we have excluded people without capacity to consent’

CONCLUSIONS

- Researchers report that the REC review process for involving people with IDD who lack capacity to consent is confrontational and difficult when its aim should be to facilitate ethical research
- Perception that rigour of review is disproportionate to the level of risks posed by projects
- Analysis of decision letters shows the main issue raised is about methodology; there is contention over whether RECs should question methodology of peer reviewed studies
- Evidence that time and financial costs of navigating the MCA review process are leading to decisions to exclude people with IDD who lack capacity to consent from participation in research, especially for student researchers
- There are calls for mentoring networks to be created within universities to share techniques for navigating the process and for universities and funders to urge the authorities to re-evaluate the approvals process for non-interventional, low-risk, qualitative studies involving people with IDD who lack capacity to consent.

REFERENCES


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