Research governance and ethics for adult social care research in England - issues and challenges

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Challenges for governance and ethics in adult social care research

Structure

- History & context
- Research governance in different settings
- Issues and challenges
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History & context

- Three main sources of review - NHS/NRES, URECs, CSSRs
- ADASS doesn’t ‘do’ ethics
- Separate histories different structures and functions
- RGF 2001/2005 the catalyst for growth of RG committees - all have status of ‘guidance’
- MCA (2005) - placed legal duties on researchers
- Academy of Medical Sciences (2011) - proposals to streamline clinical research - no mention of social care research
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History & Context

- Concerns (2001-04) about the imposition of an NHS RGF on social care research - social scientists in universities also concerned. Key reasons:
  - Time-consuming (bureaucratic delay)
  - Limited knowledge of Social Care research methodologies by NHS reviewers (knowledge often seen as out of date)
  - Responses seen as sometimes high-handed and unsupportive. (Failing to recognise constraints in which much social care research takes place)
  - Lack of consistency in outcome of reviews between different RECs.
  - Process encouraged a ‘mindset’ that the review process was an obstacle to overcome & didn’t challenge researchers to take an ethical approach to their work.

- Separate /longer timescales in local authorities to implement RGF.
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Research governance in different settings

NHS
- Has had LRECS prior to 1991 NHS circular that formalised ad hoc arrangements
- MRECs in 1997 to reduce bureaucratic burden on researchers: 200 LRECs, no standardised processes: multi-site studies = multiple reviews
- COREC in 2000 - to impose common procedures and standards
- IRAS 2008. Further efficiencies to review system
- Responsible for all research in NHS settings
- Well resourced
- Centralised approach - ‘command and control’
- Independent
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Research governance in different settings

Universities

- More URECs were set up since 2000 than before - to be RGF compliant.
- Responsible for research carried out by university staff and students.
- Coverage patchy - some (2003) did not cover student projects.
- Variety of different structures (committee, electronic, centralised, devolved. Some also have self-assessed triage arrangements by likely level of risk).
- All universities are likely to have RECs now as major funding agencies won’t fund and journals won’t publish non-reviewed proposals.
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Research governance in different settings

Local authorities

- Some strong on research. Others less so.
- In-house research often poorly resourced: not always a priority for managers
- Many CSSRs have no in-house research capacity
- Wide range of ‘research-like’ activity - ‘pure’ research, audit, service evaluation & consultation
- Often focused on managerial issues & narrowly defined performance (less on ‘best practice’) 
- Boddy & Warman (2003) - much more research activity than thought, mostly ‘grey’ literature, and mostly not independently reviewed
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Research governance in different settings

Resources

- ‘As a proportion of annual spend, investment in R&D runs at about 0.3% in social care compared with 5.4% in Health. The overall spend per workforce member stands at about £25 in social care compared with £3,400 in health. Using the more specific comparison with primary care, the annual R&D spend per social worker is about £60, compared with £1,466 per GP’.

Marsh & Fisher, 2005, p. ix

Chances of more investment by local authorities in R&D?
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Issues and challenges

Is there a need for regulation in adult social care research?

RGF was a response to a scandal in the NHS rather than social care and the NHS already had RECs then.
Motives may be fear of litigation rather than ethical practice?

Two narratives: imposition of unwelcome bureaucracy that’s undemocratic/stifles research or and opportunity to raise standards

- Can protect vulnerable people from ‘bad’ research
- Can help to raise standards
- Can co-ordinate activity locally and regionally (preventing unnecessary duplication, over-researching of local groups etc)
- Can help ‘plug’ research in so findings are accessible and are used.

‘At no point are we going to forcibly inject dependent patients with irreversibly toxic green stuff. Why are we treated as if we were going to?’

Dingwall (2006) p.52
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Issues and challenges

**What is research anyway?**

This is the current NRES guidance.

Are ethical issues *only* likely to be present if the study is described as ‘research?’

NRES feel most local authority studies are *not* research and so don’t need NRES review.
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Issues and challenges

The reach of research governance arrangements, and gaps in coverage

- Local authorities are responsible for in-house research reviews and for ensuring that any research they or service providers ‘host’ has had an appropriate review.
  - The number of local authorities with functioning RG arrangements is unknown.
  - Local authorities cannot ‘police’ all social care providers to make sure they comply. Personal budgets mean increasing numbers of providers will make this impossible.
  - Some regulatory agencies (e.g. NAO) don’t seek independent review of methods or ethics for their work.
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Issues and challenges

Where should researchers go to get their research reviewed?

Principles of the ‘route-map for researchers’

- reciprocity
- Avoidance of double handling
- Proportionality
- Independence
- Researcher led
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Issues and challenges

The problem with proportionality

Principle is of
• ‘light touch’ review for studies that are of low ethical risk.

Problems are
• How is this defined and by whom?
• How can a reviewer know if a research proposal is ‘low risk’ until he/she has read the whole application and all associated paperwork carefully?

Most researchers regarded the new streamlined ethics process as a great improvement…..
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Issues and challenges

The problem of reciprocity and ‘double-handling’.

Principle is that
• all research gets reviewed once

Problems are that
• Different sources of review don’t accept the currency of another reviewing body - there is ‘asymmetry’ in the relationship between reviewing bodies.
• This lack of trust may be justified in respect of the quality of some reviewing activity
How independent are different sources of review?

- **NRES.** Independently funded, & removed from local operational management in NHS. Too early to say what impact HRA (replacing NRES) will have on structural independence.

- **URECs.** Some potential conflicts of interest - pressure to publish, bring in research income but reviewing activity protects departmental/faculty reputations.

- **Local authorities.** Independence likely to vary. Support from a senior manager ‘champion’ probably vital. Risks that RG leads may be invited to favourably review some studies or avoid review without sanction.
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Issues and challenges

Researcher led?

- An unknown number of studies may evade scrutiny in local authorities - depending on whether research governance arrangements exist, local definitions of research, the robustness of reviewing arrangements and the support senior managers provide.
- Evasion from URECs probably less, due to other incentives and sanctions imposed by funders and publishers but quality of review may vary.
- Compliance more likely in NHS settings as RECs are more deeply embedded in NHS culture, but definitions of research are problematic.

"I've been here so long I don't remember what I did, but it had something to do with non-compliance."
### The scope of the review: what actually gets reviewed?

There seem to be different requirements both within and between different sources of review:

- Reviewers in some sectors may not receive or require all the paperwork. *(how can an assessment be made of a study, for example, if a proposal but no questionnaires are submitted for review?)*
- Lots of studies highly critical of the ethics review process, but almost nothing about the quality of submitted proposals.
- Is there a sufficient infrastructure/support to assist researchers in different occupational settings?

‘Applicants new to IRAS struggle with the idea of as much as with their actual use of it: the process is not yet, as is the case with most healthcare research, embedded in the organisational research culture of most of our applicants. Key sections in applications are not written in lay language, there are multiple typos, sections not completed, version numbers etc, not put on attached documentation; Information Sheets and Consent forms are inadequate, using language which is not written with the needs of the respondent in mind. Reviews of the basic science by e.g. university or organisational research committees are rarely included with applications’.

SCREC Annual Report (2011) p. 8
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Issues and challenges

**Speed of response & workload /capacity of reviewing systems**

- IRAS applications are still time-consuming to prepare and a response can take up to 60 days - a long time for project that has short term funding.
- Many funders - including SSCR - won’t cover the cost of securing ethics review.
- Student research places a considerable burden on UREC reviewers where departments insist students should do primary research.
- Withdrawal of HEFCE funding has not been helpful
- Little is known about capacity issues in local authorities - very few if any have created dedicated posts.
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## Issues and challenges

### Knowledge, skills, & experience

**a. Reviewers**
- In local authorities RG leads may not always have all the required knowledge and skills. May also be an issue in Universities.
- Less access to training in local authorities for reviewers.
- Skills and competencies amongst university and NRES reviewers are unknown but NRES do provide training.
- NRES do require service user involvement on their committees.

**b. Researchers**
- No career structure in local authorities.
- Is it better to learn to swim in a library or in the water? (everyone is inexperienced at some point).

‘...the majority of councils that provide services for adults do not have a workforce that is used to carrying out research.....This lack of familiarity with the conduct of research, combined with a tendency to proceduralise, generates an approach to research governance where all risks are managed through ever more detailed and precise procedural requirements. This is grounded in a belief that if the procedure is carried out then risk will be eliminated.’

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Concluding thoughts

Returning to the ‘route map’ principles

- Reciprocity limited by asymmetric relations and between different reviewing bodies
- Avoidance of double handling assumes basic levels of competence which if absent erodes trust
- Proportionality hard to achieve without self assessment of risk or a reviewer doing a full review
- Independence of RECs not always structurally guaranteed.
- People are probably better protected from bad research now than before RGF
- Price has been high for researcher time - systems still hard to navigate, still overlap & are still time consuming
- Reviewers also pointing to problems with the quality of applications
- Solutions likely to involve investment in training for researchers and reviewers
- Governance issues may reflect wider societal ambivalence towards risk and protection
Selected references


The Social Care Research Ethics Committee Annual Report (2011)