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Research governance and ethics for adult social care research: procedures, practices and challenges

John Woolham

Methods Review 4

Improving the evidence base for adult social care practice

The School for Social Care Research

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About the author

John Woolham works as a Research Fellow at Coventry University. Prior to taking up this appointment he worked as a Senior Research Officer for Northamptonshire County Council. Whilst there, he set up and managed Research Governance arrangements for its Social Services Department. He was a member of the Department of Health Standing Advisory Group for Research Governance in Social Care between 2002–2007, and currently is Vice Chair of the Midlands Regional Research Governance Group (a consortium of Local Authorities), sits on Warwickshire County Council's Social Care Research Governance Board, and is also a member of the Health and Life Science Faculty Research Ethics Committee at Coventry University.

Research governance and ethics for adult social care research

ABSTRACT

The introduction of the Research Governance Framework for Health and Social Care by the Department of Health in 2001 extended the reach of research governance from the NHS, where reviewing arrangements were already well established, into universities and local authorities, who were requested in the guidance to introduce arrangements to ensure appropriate levels of ethical and methodological review.

This paper describes the different structures and processes used by the NHS, universities and local authorities to meet the expectations of the Department of Health, and offers a critical analysis of some of the consequences – both problems and opportunities – that have resulted.

KEYWORDS

Research governance, ethics, governance policies, research standards, research governance challenges

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NIHR School for Social Care Research Methods Review

Research governance and ethics for adult social care research

CONTENTS

Research governance and ethics for adult social care research

INTRODUCTION

This review describes the development of research governance arrangements in social care settings over the past decade and examines some of the consequences – both problems and opportunities – created for people who are interested in research: that is, people who undertake research, take part in it, and use it within adult social care settings. It is not a guide for people wanting to submit proposals to Research Ethics Committees (RECs), or a document written to support reviewing activity: others have already produced useful guidance on these kinds of topics (Iphofen 2009, Iphofen *et al*. 2010, Social Services Research Group 2010). Nor does it aim to present a detailed examination of ethical issues and approaches to resolving these issues in social care. Its aim is to describe as succinctly as possible the arrangements that exist for research governance and ethical review, and explore the issues that have emerged as these have been implemented in NHS, university and local authority sectors.

The review has four main parts:

■ The first offers a brief definition of key terms: ethics, governance and research, and their relevance to adult social care research.

■ The second looks at the context and history of research governance in social care. In this section the paper describes:

  • the antecedents to the publication of the Research Governance Framework;

  • the Framework document itself, and what this guidance set out to achieve;

  • the response to the guidance contained in the framework from the main 'stakeholder' organisations; and

  • the subsequent implementation of the Mental Capacity Act and the implications this has had for researchers.

■ The third considers what is known about the current extent of research governance arrangements, and differences in approach, in respect of:

  • different sources of research governance review and the criteria for researchers to decide where to go to seek a review. Here, the paper will describe the three main sources of review – the NHS (properly, NRES or the National Research Ethics Service that also includes the Social Care Research Ethics Committee – SCREC), University and local authority; and

  • the relationships between these three sources of review and pathways for researchers.

■ In the fourth and final part of this review, key issues emerging from these described arrangements for research governance are discussed.

GLOSSARY

Unfortunately, the use of abbreviations and acronyms is unavoidable in this review as they are commonly used by those working in this field. The full title or description will be given on first use of either. The glossary below is also available as an aide memoire.

RGF	Research Governance Framework for Health and Social Care
CSSR	Councils with Social Services Responsibilities
REC	Research Ethics Committee
REF	Research Excellence Framework
NRES	National Research Ethics Service
MCA	Mental Capacity Act
UREC	University Research Ethics Committee
COREC	Central Office of Research Ethics Committees
IRAS	Integrated Research Application Service
ADASS	Association of Directors of Social Services
GAFREC	Governance Arrangements for Research Ethics Committees
LREC	Local Research Ethics Committees
SCREC	Social Care Research Ethics Committees
NPSA	National Patient Safety Agency
HEFCE	Higher Education Funding Council for England
ESRC	Economic and Social Research Council.

DEFINITIONS

An essential starting point is to describe key terms that will be used in this review.

Ethics

Ethics is not, as the old canard goes, a county to the north of London, but a set of values which human beings use to regulate their behaviour. The *Oxford Shorter Dictionary* defines ethics as:

> The moral principles governing or influencing conduct. The branch of knowledge concerned with moral principles.

Most professional associations have developed standards, codes of practice, principles, or statements of values that inform the way in which these professions carry out their day-to-day roles. Social work and social care – and by extension, social work and social care researchers – are no exception in this respect. Researchers are skilled professionals whose job is to produce knowledge. Like other professional groups, their practice should be informed by a set of principles and values which are moral as well as technical.

Most of these codes of practice – for example, those published by Butler (2002), The British Association of Social Workers (2002), British Psychological Society (2011), Economic and Social Research Council (2010) and Social Services Research Group (1997) – are broadly similar, in that they are based on long-established principles of autonomy (respect for the individual), non-maleficence (not doing harm), beneficence (trying to do good) and justice (treating people fairly) (Beauchamp and Childress 2001). These principles have very deep historical and cultural roots that go back to Ancient Greek moral philosophy. Ethicists do not entirely agree that 'principlist' approaches are always the most appropriate way of understanding ethical issues (McCarthy 2003) but at the present time, if not paradigmatic, they are certainly the most commonly used.

Governance

The Department of Health's (DH) (2001a) Research Governance Framework (hereafter, RGF or 'framework'), which will be described more fully later, defines this as arrangements that involve

> … setting standards, defining mechanisms to deliver standards, monitoring and assessing arrangements, improving research quality and safeguarding the public by enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents ensuring that lessons are learned and preventing poor performance and misconduct (p.2).

Essentially, research governance arrangements are ways of taking principles, turning them into standards, and ensuring that these are applied by people who are involved in research. Obviously, this applies to researchers, but others too, as will be described later.

Research

A definition of research is important because it will determine the kinds of proposed studies that should be independently reviewed, and those that should not. The definition used in the RGF is

> … the attempt to derive generalisible new knowledge by addressing clearly defined questions with systematic and rigorous methods (Department of Health 2005a, p.3).

This is an intentionally broad definition, including most forms of disciplined enquiry. Although research governance embraces both clinical and non-clinical research, the focus of this review will be on non-clinical research.

Adult social care

Finally, a definition of adult social care is helpful because the research governance arrangements referred to in this review apply only in this field. The Department of Health (2004) describes this as

> …all research involving service users/carers, their data or staff for whom Directors of Social Services (or other departments within local Councils providing social care) have a duty of care. This is the case whether this care is provided directly by the local Council or contracted to other agencies in the statutory or independent sectors (p.3).

Why are research governance and ethical review arrangements needed in adult social care?

Superficially, it might be argued that ethics review and governance arrangements have simply been imposed on the social care research community in the UK. We need them because we are told – by the Department of Health – that we have to have them. The RGF was first published by the Department of Health in 2001(a): at the start of a decade in which public sector institutions – including local authority, NHS and university sectors – have had to digest, respond to, and implement a significant amount of new legislation from previous governments under the aegis of 'modernisation', and be held to account for this by means of new regulatory frameworks involving inspections, reviews, audits and performance indicators. In some ways, research governance can be seen to be simply 'more of the same'. As we shall see, the failure of the DH to properly consult with the social care research community when the RGF was published gave some support to this perspective. Some have argued forcefully against the extension of governance arrangements intended for health research to social care, describing them as unhelpful and inappropriate (Lewis 2002, Dingwall 2006) or a more sinister constraint on academic freedom (Haggarty 2004). Others have also pointed out that major 'drivers' of ethical scrutiny have also been research council requirements, insurance and funding issues as much as the desire to protect people from harm (Parker *et al*. 2011).

Research governance and ethics for adult social care research

These are powerful arguments and may not be the most promising context to any attempt to suggest that research governance arrangements might also be useful. Nonetheless, a case can be made that governance and review arrangements are not just another thing for public bodies to respond to, but confer opportunities to improve the way social care research is carried out. For example:

■ Most importantly research governance can protect vulnerable people from 'bad' (unethical or poorly designed) research – the explicit purpose of the RGF;

■ If the guidance offered when a research proposal is reviewed is constructive, helpful, and reasonably authoritative it can help raise research standards;

■ It can offer opportunities to co-ordinate activities – particularly at local and regional levels: thereby preventing unnecessary duplication of studies, or the 'over-researching' of certain groups of people;

■ Research governance can help to ensure that research is brought to the attention of key stakeholders, thereby helping to ensure the accessibility of findings, and their wider use. (The Social Care Institute for Excellence website hosts the national register of social care research http://www.researchregister.org.uk/. This is intended to capture not just published academic literature but so-called 'grey' unpublished studies completed in social care settings: some local authority research governance leads upload information about studies that have been reviewed to this site in order that information about the study can be more widely shared.);

■ Some commentators have argued that it may even offer opportunities for practitioners with research interests – in primary, but also possibly social, care – to pursue these research interests in a more coherent way (Bryar 2002). Certainly, this would be a welcome development in local authority settings in particular, where researchers have few opportunities for career development as researchers.

Summary

Research governance refers to the ways in which research proposals are independently reviewed to ensure that they are both ethically and methodologically sound. This section has provided definitions of key terms and then discussed justifications for research governance arrangements.

CONTEXT AND HISTORY

Antecedents

Until comparatively recently, there were no regulatory frameworks other than professional codes of practice to guide researchers working in adult social services or social care. The catalyst for introducing arrangements came, not from the social care sector, but from within the NHS which already had a regulatory framework for research. This was the Alder Hey 'body parts' scandal in which a professor of pathology was found to have been removing body tissue and organs from deceased children without the knowledge or consent of parents. This shook the confidence of the public in the medical profession and their trust in NHS institutions.

Although the popular press at the time described the scandal as the work of a 'rogue' pathologist, the public inquiry that followed, and the ensuing Redfern Report (2001), identified systemic and organisational causes. Indeed, although there had been an expanding regulatory framework within the NHS, this event confirmed that it had been insufficiently rigorous to identify problems with the retention of human tissue and body parts. Amongst other things, Redfern recommended a new law on informed consent to prevent any repeat of what had happened at Alder Hey and elsewhere.

The Research Governance Framework

The Department of Health went further than the recommendations of the Redfern Report in publishing the Research Governance Framework for Health and Social Care in 2001, and an updated second edition in 2005.

The RGF had two main purposes: to codify standards within a series of 'domains'; and to define accountabilities. These are described briefly below but the interested reader is also invited to look at the original, which can be accessed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962.

Standards

Five domains are identified in the Framework within which standards are described. These are ethics, science, information, health and safety and finance. Of the five, it is in the ethical and scientific domains that the largest numbers of standards are described.

■ *Ethics*. This involves ensuring the dignity, well-being, rights and safety of all research participants. Key standards include:

that all proposed research involving patients, users of health or social services, care professionals or volunteers is independently reviewed to ensure it meets ethical standards;

that the informed consent of participants is sought;

that data collected are used appropriately and protected to ensure confidentiality;

that where possible or appropriate, participants are involved in all stages of the research process, including design, data collection and analysis;

that the research respects human diversity;

that risks to participants are identified, and minimised, and any that remain are fully explained to those taking part.

■ *Science*. This domain describes arrangements for ensuring scientific quality and ensuring completed studies are good enough to contribute something to knowledge. Key standards include:

that all proposed research is reviewed by experts in the relevant fields and able to offer independent advice on the quality of the proposed study;

the retention of data in a secure location for an appropriate period to support the audit and monitoring of research practice.

■ *Information*. This describes arrangements for ensuring the accessibility of information about research being conducted, and when completed. The RGF calls for:

investigators to open their work to critical review through accepted professional and scientific channels;

for findings of research to be made available to people who have taken part.

■ *Health and Safety*. This domain emphasises that safety of participants, including researchers, be given priority at all times, and for the observance of health and safety regulations.

■ *Finance*. Finally, this domain emphasises the need for financial probity, and for organisations employing researchers to be in a position to compensate anyone harmed as a result of negligence.

Accountabilities

The RGF also offered a clear definition of the responsibilities of all the main stakeholders who may be involved in some way in research activity.

■ *Participants*. The RGF suggests that anyone using health or social care services should give serious consideration about whether to respond to any invitation to take part in research on the basis that the research may be directly or indirectly beneficial. The Framework also advises participants to ensure they seek clarification about research in which they are invited to take part, should they not understand the explanation given.

- *Researchers* are described as having day-to-day responsibility for the conduct of the research, ensuring it follows agreed protocols (following ethical and methodological review) and the integrity and confidentiality of the data collected.

- *Principal investigators* are senior researchers responsible for the conduct of the research and accountable to their employer, and other stakeholders, for this. A series of specific responsibilities are detailed in the guidance to support the principal investigator in maintaining standards during the course of the study. It is the responsibility of the principal investigator to ensure that independent ethical and methodological reviews are sought.

- *Funders* are responsible within the RGF for ensuring value for money and that funding is used properly. If funding a study involving NHS or social care services in England, the RGF also requires them to act as the study's 'sponsor' (see below) or, if they are unable to do so, to collaborate with another organisation prepared to take on this responsibility.

- *Sponsors* are required is to make sure all resources are in place to ensure that the research can be brought to a successful conclusion, that arrangements exist for the monitoring and management of research, and, in a similar fashion to the principal investigator, the Framework defines detailed responsibilities of sponsors to ensure standards are maintained throughout the duration of the research.

- *Researcher employers* are responsible for developing and promoting a 'quality research culture' within their organisation in which researchers can develop professionally.

- *Care organisations* within the Framework are asked, amongst other things, to ensure they are aware of all research activity that may be going on, that participants have information about research that may have a direct impact upon them, that research has been approved by an appropriate research ethics committee, and to ensure that any research has an identified 'sponsor'.

- *Care professionals* are reminded that they retain responsibility for the care of patients or service users who may decide to take part in research, and that the proposed study has been approved by appropriate scrutinising authorities within their organisation.

Responses to the Research Governance Framework

The RGF was conceived in large measure as a response to the recommendations of the inquiry into the Alder Hey scandal and therefore developed by, and for, NHS organisations and staff. It seemed that the decision to extend the provisions of the Framework to social care organisations, as well as the NHS, happened at a comparatively late stage and without much prior consultation.

The initial response among many academics and researchers from the social care research community was not supportive. A range of concerns were expressed at a consultation

meeting in September 2001 between Department of Health representatives and members of the social care research community[1]:

- If NHS REC systems were to play a larger role in reviewing social care research proposals this was seen as time-consuming and creating bureaucratic delays: this would be less problematic for a large, well-funded, clinical trial, but a significant issue for social care research because so much of it is carried out with limited funding and with researchers expected to deliver findings over short timescales. Therefore, there was concern that the time needed to secure a favourable opinion from a REC would lead to a loss of research contracts;

- Social care researchers reported, anecdotally, a limited knowledge of research designs and methods commonly used in social care research amongst REC committee members (Ramcharan and Cutliffe 2001, Lewis 2002, Lewis *et al*. 2003), and a tendency on the part of some NHS REC committee members to regard these methods as inferior to the randomised control trial designs commonly used in clinical research;

- There were also reports of a lack of consistency in the outcome of reviews between different NHS RECs;

- The review process was also seen as an obstacle to be overcome and did not sufficiently encourage researchers to take an ethical approach throughout the conduct of their research (Watson and Manthorpe 2002).

However, it was also the case that at the time the Framework was launched, NHS Research Ethics Committees (RECs) were – for better or worse – the dominant source of independent ethical review. Many universities did not have proper systems of scrutiny in place and only one or two local authorities had any equivalent arrangements.

Concerns about the impact of imposing NHS-designed reviewing mechanisms on social care research led the Department of Health to set up a Standing Advisory Group for Research Governance in Social Care which met until 2007, and to publish a separate implementation plan for research governance arrangements in social care (Department of Health 2004).

The Mental Capacity Act (2005)

The Mental Capacity Act (MCA) can be seen as the final part of the Government's response to the recommendations made in the Redfern Report (2001). The Act, and subsequent Code of Practice (Department of Constitutional Affairs 2005), defines those circumstances in which adults with impaired mental capacity may be involved in research. Unlike the RGF, which has the status of 'guidance', the MCA places legal duties on researchers.

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1. The meeting was on 19 September 2001 and hosted by CIPFA in London. Although described as a consultation meeting, the Framework had by this time been published in its final form.

The Act applies only to 'intrusive research' – that is, research that would normally require consent from the participant. Researchers are asked to determine, in the first place, whether their findings would be compromised by not including people with impaired mental capacity. If the study *does* necessitate the inclusion of people in this group, then researchers are asked to justify this by describing possible benefits to those taking part, or indicating that the study will provide knowledge about the causes, treatments or care of people with similar conditions.

If the person cannot consent, the Code expects the researcher to identify someone close to the person – but not paid to care for them – who can act as a 'consultee'. The consultee is first asked if, had the person had capacity, they would have been likely to consent to take part in the proposed study. If the opinion of the consultee is that they would, then the researcher can seek the views of the consultee.

The Act also assumes different *degrees* of capacity: that people may be perfectly capable of making some decisions, or exercising some choices, but not others. Although capacity is to be generally assumed unless there is proof to the contrary, where the person's actual level of capacity is unknown, the Act states that a 'test' of capacity must be applied. This 'test' of a person's capacity to consent to take part in research – as with consent to treatment or other forms of intervention – involves assessing if the person can comprehend, retain, assess and respond to information about the study. This capacity to consent is time and time- and context-specific: it cannot be assumed that consent, once obtained, will apply if the study involves repeated contacts. Researchers working to best practice standards might therefore need to repeat the consent process to ensure that the consent is still valid.

Research involving adults with impaired mental capacity must be reviewed by a research ethics committee approved by the Secretary of State. In practice, this means an NRES (NHS) REC. The Social Care Research Ethics Committee (SCREC), established in 2008,[2] and a number of other NRES RECs that have been trained to understand the provisions of the Act, now have lead responsibility for the review of research proposals involving adults with impaired mental capacity.

Recent developments

At the time of writing (early 2011), two significant new reports have been published which deserve mention, although neither appear to have an immediate relevance to adult social care research.

Research Governance in Children's Services: the scope for new advice (2010)

Commissioned by the Department for Children, Schools and Families, though published by the Department for Education which replaced it following the 2010 general election, this

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2. Although the Social Care Research Ethics Committee was established in 2008, recruitment and training of committee members meant that it did not become operational until the following year.

report considers the extent to which existing research governance arrangements in local authority settings fully address ethical issues arising in the conduct of research involving children.

This is a problematic area as the Research Governance Framework was published when local authority children's services were part of a larger social services department. The transfer of children's services to local authority education departments occurred sometime later, following the Climbié Inquiry in 2003 and subsequent Children Act of 2004. By this time some local authorities had already established research governance arrangements that covered *both* adults and former children's services within a single social services department and some have continued to review research involving children since the structural changes following the Act. Gaps in coverage and questions about the applicability of the DH research governance framework led to the research on which this new advice was based. The authors offer a series of broad 'messages' intended to inform the development of guidance on research governance in children's services. Although these work within existing arrangements they also offer proposals for addressing areas where existing guidance is seen as inappropriate. The response of the Government to these messages is still awaited at the time of writing.

Proposals for a new pathway for the regulation and governance of health research (2011)

This report is the outcome of a review of the regulation and governance of health research involving human subjects commissioned by the Coalition Government. The review itself was informed by, and welcomed, commitments made in the Health White Paper of 2010 to simplify the bureaucracy affecting research. The report offers clear proposals to reduce the number of bureaucratic controls. These were warmly welcomed by the current Secretary of State for Health:

> National regulation and local governance of health research are too complex and scattered across too many different bodies. The Academy's report makes the case for simplification under a health research agency that will streamline and co-ordinate regulatory and governance processes. The Government welcomes the report and will consider carefully how to implement its recommendations (Rt, Hon. Andrew Lansley, Secretary of State for Health, quoted in http://www.nres.npsa.nhs.uk/news-and-publications/news/academy-of-medical-sciences-report/, accessed 21 January 2011).

However, this report is focused exclusively on health research: no mention is made of social care research. It remains to be seen what the Coalition Government plans for social care research, although there are clear indications that it wishes to simplify and streamline research governance arrangements.

Research governance and ethics for adult social care research

Summary

The RGF, and subsequently the MCA, can be seen as responses by the previous Government to the Redfern Report into the Alder Hey body parts scandal. Key parts of the RGF and MCA have been summarised in this section. Although originally intended to tighten up pre-existing arrangements for the review and regulation of research activity in the NHS, it was decided by the previous Government to extend the provisions of the RGF to cover social care research. The RGF was not enthusiastically greeted by the social care research community for a range of reasons, and, in response, the DH introduced a separate implementation plan for councils with social services responsibilities. More recently, attempts have been made to address a lack of fit between some elements of the RGF following the transfer of children's services from social services departments to the Department for Children Schools and Families (now replaced by the Department for Education). Proposals have also recently been made to the Department of Health for simplifying research bureaucracy within medical research. Although these have been warmly greeted by the current Secretary of State, the terms of reference for this review excluded social care research.

RESEARCH GOVERNANCE ARRANGEMENTS FOR ADULT SOCIAL CARE IN DIFFERENT SETTINGS

Since the publication of the RGF, research governance activity has been encouraged by the Department of Health, and grown, in three main organisational settings. These are the National Research Ethics Service (NRES) within the NHS (and including the Social Care Research Ethics Committee, or SCREC, which became operational in June 2009), the university sector and in Councils with Social Services Responsibilities (CSSRs). In this section of this review these will be described in turn.

The NRES/SCREC (NHS)

Development

The NHS has had Local Research Ethics Committees (LRECs) since 1991, when a Health Authority Circular letter (Department of Health 1991) formalised what had previously been ad hoc, uncoordinated local arrangements for reviewing research. This required District Health Authorities to establish one (or more) LRECs but offered no guidance to standardise the ways in which these committees were to operate.

The absence of standardised arrangements created difficulties particularly for researchers who wished to conduct multi-site research as they might find themselves having to follow an entirely different set of procedures in each location. The level of dissatisfaction with these arrangements was such that in 1997 an additional tier of Multi-Centre Research Ethics Committees (MRECS) were established to deal with multi-site applications. However, applications still needed local issues to be approved which led to reports of delays and inconsistencies (Alberti 2000). The creation of the Central Office for Research Ethics Committees (COREC) in 2000 was intended to deal with these issues by developing and introducing a consistent approach to reviews within NHS RECs throughout the UK. The creation of the RGF was followed in the same year by Governance Arrangements for Research Ethics Committees (GAFREC), guidance which effectively became the standard operating procedure for NHS RECs (Department of Health 2001b). This guidance was updated in September 2011 (Department of Health 2011). The revised governance arrangements aimed to bring together what had become disparate forms of guidance and legislation. Although much of this 'harmonised' guidance focused on clinical research, one significant change which arose was a relaxation of the requirement for research involving staff working in NHS settings (or certain kinds of research involving social care staff) to receive an NHS REC review (Department of Health 2011).

Since the publication of the Framework and original GAFREC guidance, a further review of NHS RECs by the Department of Health (2005b) led to a significant reduction in the number of RECs, the creation of the National Research Ethics Service (NRES; www.nres.org.uk) – which replaced COREC – and the introduction of an Integrated Research Application Service (IRAS) – essentially an on-line application process.

In 2008, the Social Care Research Ethics Committee (SCREC; www.screc.org.uk) was established. Although drawing on NRES resources, the SCREC is located within the Social Care Institute for Excellence and maintains a distinctive 'social care' rather than 'NHS' identity. Additionally, and within the constraints of resources available, it aims to act as a source of advice and guidance for social care researchers and local authority research governance leads. Its remit is to review all DH-funded social care research, social care research involving adults who lack mental capacity, social care research involving research sites in England and other UK countries, local authority research where the lead researcher considers that the research may have substantial ethical issues and wishes to seek guidance, and 'orphan' research – research carried out by researchers employed by organisations not covered within existing arrangements. As such, the Social Care REC complements, rather than replaces, the existing system of university and local authority REC arrangements. In March 2011 the remit of the Social Care REC was expanded to include proposals for social science research conducted in the NHS.

Operation

NRES has an operational definition of research which excludes many forms of data collection activity, including audits, service evaluations, 'surveillance' and 'usual practice' (both the latter largely restricted to public health settings) (see http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/). Although part of the NRES, the Social Care REC uses less tightly defined criteria:

> It should be noted that the Social Care REC operates to a wider interpretation of 'research' than may apply in the NHS. For example, most evaluations and certain types of audit would be accepted as suitable for review by the Social Care REC, whereas in the health sector such activity may not be presented in the same way and not considered as research (Social Care REC Annual Report 2011, p. 4).

NHS RECs – including the Social Care REC – meet in formal committees to discuss applications. Members comprise clinical and 'lay' (non-clinical) volunteers. NRES RECs are responsible for all research in NHS settings – both clinical and non-clinical – and also research involving adults who have impaired mental capacities. Despite recommendations to the contrary (Department of Health 2005b) their reviewing process considers methods as well as ethics (Angell *et al*. 2008). There is an electronic application process and applicants must, in addition, submit electronic copies of all relevant paperwork (for example, questionnaires, interview schedules, covering letters, consent forms, and information sheets). Once submitted, the researcher is notified of a date on which a designated committee will discuss their proposal. The process can take up to 60 days, depending on the outcome of the initial review and amendments required by the committee. The NRES system is well resourced, with a multi-million pound operational budget. Research ethics reviews in the NHS (and the NRES social care research ethics committee) have moved from a decentralised, localised and heterogeneous set of arrangements in the 1990s to a centralised, 'command and control' approach at the present time. Located within the National Patient Safety Agency (NPSA), NRES has a high

degree of independence from operational NHS and local authority social care organisations.

Universities

Development

Tinker and Coomber (2004) carried out a well-supported survey of UK universities in 2003 to assess the extent, role and remit and conduct of University Research Ethics Committees (URECs) and reviewing activity. At the time of the survey, 94% of universities claimed to have some form of ethical scrutiny and 83% had a research ethics committee. Many of these had been set up just before the survey: just under half had been set up after 2000 – presumably in response to the publication of the Research Governance Framework. The authors also found that there was some variation in coverage – with research carried out by staff and postgraduate students being more likely to be ethically reviewed than undergraduate research.

The volume of reviewing activity in the university sector might reasonably be expected to be large. However, the authors found a great deal of variation in the number of applications received for review, which led them to conclude that it was probable that many universities had operational systems for reviewing research proposals that were not scrutinising all the research that was being done.

In practice, as most higher education institutions are 'research-active', many will now have systems in place to support ethical review, as the UK's main governmental funding agencies – the Research Councils – will not fund research that has not had an independent ethical review, and increasingly, peer-review journals will not publish findings of research that has not been previously reviewed.

Operation

URECs are responsible for all research carried out by university staff and students. Although definitions of 'research' are likely to vary from university to university, Tinker and Coomber (2004) have suggested that many seemed to have adopted the NHS (COREC) definition at the time of their study. Membership of URECs included 'lay' representation in the majority of arrangements but not all of them. Half offered training to members, and four out of five had an administrator whose job included the facilitation of the reviewing processes.

Reviewing activity amongst universities may take place centrally (within a single, university-level, committee), at faculty or departmental levels (with more than one committee), and reviews may be conducted by committees which meet periodically, on an ad hoc basis, or, where applications are all reviewed electronically, rarely if ever. The independent review of methods (also required within the RGF guidance) is carried out either by the tutor or supervisor (for student research) or by head of department or equivalent (for research carried out by academic staff).

Universities receive no additional or ring-fenced funding for ethical review: costs are absorbed within Higher Education Funding Council for England (HEFCE) funding. Located in a range of settings in different universities, their level of independence from operational pressures was not assessed by Tinker and Coomber, although their study did adopt ten defined criteria by which the quality of the review process could be assessed, and found that 60% met eight or more of these criteria.

Local authority councils with social services responsibilities

Development

In contrast with NHS research activity, rather less was known about research carried out within local authority settings at the time the RGF was first published. A minority of local authorities – for example, Essex and West Sussex – had maintained a strong tradition of in-house research (Essex also had robust ethics review arrangements that actually pre-dated the RGF). Elsewhere, research 'culture' was less well-developed, and many CSSRs seem to have limited dedicated in-house research capacity, with others employing staff with a portfolio of responsibilities including research (Boddy and Warman 2003, Woolham 2007).

Boddy and Warman (2003) examined the nature and volume of research activity and research governance taking place over a retrospective 18-month period in eight CSSRs. They found a considerable volume of research taking place: 293 completed studies were found in seven of the local authorities: a number the authors suggested was likely to be an under-estimate. Although this volume of research was surprising, its quality was uncertain. 60% of the research identified in this study was carried out by staff in-house, 20% were student projects and less than 20% was externally funded. The studies were also almost all unpublished, and only 4% had been ethically reviewed.

Two studies by Pahl (2002, 2006) were also commissioned to find out how many local authorities were responding to the RGF guidance. By the time of the second study, Pahl found that 50% of CSSRs had RG systems in place, and a further 39% had plans to introduce systems by the end of 2006. Although this was progress when compared to the 2002 survey, it was also noted that a proportion of those who responded positively to the 2002 survey did not take part in the later study suggesting that in some local authorities arrangements may have failed to take root.

Operation

Local authorities are responsible for ensuring that in-house research is independently reviewed for ethics and methods and for checking that research they are requested to host from an external organisation like a university has received a favourable review from an appropriate source. At the time of writing, the exact number of functioning local authority research governance groups remains unknown. Woolham (2007) found that amongst CSSRs in the Midlands region, there was considerable variation in the time research governance 'leads' – officers or managers charged with introducing research governance arrangements in their local authority – devoted to this activity. This

unpublished study also found that there was considerable variance in the number of people who were involved in reviewing proposals. Although four-fifths of research governance leads who responded said they had prior experience of carrying out research, at the time of the survey only one authority had provided training to support them in their role.

Local definitions of 'research' are likely, with some CSSRs variously including or excluding service audit and evaluation, consultation activity, etc. Coverage will also vary: some CSSRs will review research involving both adults and children, others just adults. The level of independence of local authority research ethics/governance activity is unknown but will probably also vary.

Unlike NHS RECs, local authority research governance arrangements are not well resourced. The DH provided up to £500,000 to CSSRs to help them establish research governance arrangements in 2006. This worked out as £2,500 for single local authority CSSRs but an additional £1,000 was made available for corporate applicants, or applications for funding from more than one local authority. The funding was claimed retrospectively. Although many local authorities did not apply for funding, some CSSRs collaborated regionally, most notably in the Midlands and South East region. The purposes of these collaborations were to make the most efficient use of available funding, but also to pool resources and expertise and work on developing common protocols, standards and procedures. The Midlands Regional Research Governance Group, for example, now uses a single application pack and has developed a protocol for responding to multi-site local authority research applications. The Midlands and South East regional groups have also successfully collaborated in commissioning the publication of a handbook for reviewers (Iphofen *et al*. 2010).

The way in which CSSRs with research governance arrangements operate is also likely to vary, with some favouring an electronic review process, others a committee-based approach. The speed with which local authority research governance groups and committees respond to applications also varies.

Association of Directors of Adult Social Services

In addition to the three main sources of reviews described above, the Association of Directors of Adult Social Services (ADASS) also reviews multi-site research proposals where four or more local authorities are involved in hosting the study. However, these reviews do not look at ethics or methods *per se*, but focus on the likely costs and benefits to CSSRs in taking part, both for the individual CSSR and local government as a whole. ADASS will not usually recommend co-operation from CSSRs for studies that have not had favourable independent reviews of ethics and methods. ADASS continues to link the development of research governance in CSSRs with larger issues of funding and resources.

Research governance and ethics for adult social care research

Where should researchers go to get their research reviewed?

The current system is complex: there are three main sources of review, and each has responsibility for reviewing research in different areas of health and social care, and use different operational definitions of research. To summarise,

- *NRES/SCREC (NHS)*: If the study involves NHS patients, their carers or staff, or adults who have impaired mental capacity, and the study design meets the definition of research used by NRES, then the investigator should seek a review from NRES. Social care research funded by the DH or the School for Social Care Research should be reviewed by the SCREC. Those responsible for non-clinical multi-site studies are, at the present time, invited to seek a review from the SCREC.

- *Universities*: If the study is being carried out in non-NHS or social care settings, by academic staff or students, the investigator should seek a review from their university REC.

- *CSSRs*: CSSRs are responsible for reviewing all in-house research and for ensuring that any research they are invited to host has received a full review of methods and ethics from an appropriate source. (If it has not, they are encouraged either to offer to review of the proposed study or to request that the investigator seeks a review.)

- *ADASS*: The focus of ADASS reviews is on likely benefit to local authority participants. The decision of reviewers is made available not only to the researcher but to local authority members of ADASS, and its support may therefore be helpful in securing permission to conduct the study on the proposed host sites.

Relationships between organisations responsible for reviewing activity

Although research governance arrangements have a central aim of protecting research participants from poorly designed research, this has to be balanced against the need to allow researchers to do research. There has been concern expressed about the difficulties facing researchers since the introduction of the RGF because multiple reviews have been required to gain access to collect data. For example, a study of the hospital discharge of older patients carried out by a university research team might, as a result of the number of organisational 'permissions' required, have needed favourable reviews from the National Research Ethics Service (NRES) (as it involves research on NHS patients), the university (as the researcher would have to comply with the procedure of their employer), and the local authority (as the CSSR might have its own research governance arrangements). Throw in, for good measure, the requirements of local NHS trust research and development boards, and the need to seek an ADASS review (if the study involves more than four sites), and the researcher is burdened with a significant level of paperwork, made worse if there is no agreement between different sources of review (because accommodating the guidance offered by one source of review might mean that a further review may be required from other sources because of changes to aspects of the

design or methods etc). Small wonder, then, that researchers became extremely concerned about the implications of this for research activity (Hays and Murphy 2003, Jones and Bamford 2004, Brindle 2005, Salisbury *et al*. 2005, Cook *et al*. 2007, Keilman *et al*. 2007, Meenaghan *et al*. 2007, Munro 2008).

To try to reduce this bureaucratic burden, an ad hoc planning group of representatives from university, NHS, local authority CSSRs and funders was established to try to resolve these issues. The group published guidance, in the form of a paper describing principles, defining areas of responsibility and forms of reciprocity in arrangement in August 2009 (see Davies et al. 2009; http://www.screc.org.uk/files/routemap.pdf). Five principles were defined for organisations responsible for ethics review:

- *Reciprocity* – organisations offering different sources of ethics review and operating to the same standards should work on the basis of mutual respect;

- *Avoidance of double-handling* – studies approved by one REC should not be required to seek approval from other RECs;

- *Proportionality* – the level or intensity of the review should be appropriate to the level of risk involved;

- *Independence* – reviewing committees should be independent of organisations that are funding or carrying out the research;

- *Researcher-led* – responsibility for securing review should rest with the principal researcher.

The paper then considers the main sources of ethical review in England and Wales, defining their respective areas of responsibility in order that researchers and funders should know where to go to seek a review (see below). An overriding intention of the paper was to ensure that all research is independently reviewed for ethics, but only once.

Summary

This section has described the development, and operation of research reviewing arrangements in three settings: the NHS, the university sector and within local authorities. It has also considered the role of the ADASS research review process and the creation of the Social Care Research Ethics Committee within the NHS Research Ethics Service. With the exception of the NHS REC systems, which are centrally controlled, this review has described the heterogeneous nature of arrangements in universities and local authorities. The section ends by briefly summarising an attempt to delineate specific areas of responsibility for the three sources of review to minimise the bureaucratic burden on researchers.

ISSUES AND CHALLENGES

Thus far, it has been necessary for this review to provide fairly detailed descriptions of research governance arrangements for the independent review of the ethics and methods of research in adult social care. In this section this review moves from description to analysis, looking more directly at issues and challenges.

Although some of the issues and challenges facing organisations responsible for reviewing methods and ethics are unique or have unique characteristics within those organisations, most, although manifested in slightly different ways, are common to each.

Is there a need for regulation?

The opening sections of this review drew attention to those who questioned the need for governance and review arrangements. Haggerty (2004) warns against 'ethics creep' whereby regulatory agencies constrain scholarly activity and academic freedom. Although Haggerty's work reminds us of the need for vigilance, with the sole exception of research involving adults with impaired mental capacity, the impetus to develop and maintain research governance and review systems is based on *guidance* rather than legislation. Additionally, at the present time, there are no performance indicators or other systems through which the NHS, universities and councils with social services responsibilities can be held accountable for their governance and review systems. There are, however, pressures coming from researchers themselves that may lead in directions other researchers would find unwelcome. A common complaint of researchers is of inconsistency in decision-making by ethics committees (Angell *et al*. 2007, 2008). It was this inconsistency, as we have seen, that led to the creation of COREC within the NHS to offer clear guidance to local committees. This has led to some concern about the consequences of uniformity and whether it is appropriate to tell research ethics committees how to think (Sayers 2007). This is less of an issue in university and local authority research governance systems which are, for better or worse, much more decentralised in the way they operate, although more likely to produce inconsistency in decision making.

The present Coalition Government has made clear its intention to reduce the bureaucratic burden facing researchers in medical research, and to simplify existing governance arrangements within the NHS, and is likely to respond positively to the Review of the Academy of Medical Sciences (2011) which provided clear proposals to simplify current arrangements. NRES has itself welcomed the report and indicated that it intends to work with the DH to implement recommendations. Although no mention is made in this review of social care research, the Social Care Research Ethics Committee is funded by, and uses the standard operating procedures of, NRES, which suggests that, by default if not design, the recommendations made by the Academy of Medical Sciences will have implications of some kind for reviews carried out by the SCREC.

Definitions – what IS research?

An appropriate definition of research is important but often overlooked (Boddy *et al*. 2006). The 2005 review of the operation of NHS RECs recommended that

> The remit of NHS RECs should not include surveys or other non-research activity if they present no material ethical issues for human participants. COREC should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs (Department of Health 2005 p.15).

NRES requires only what it defines as 'research' to be independently reviewed for ethics and methods. This definition is narrow, and specifically excludes service evaluation, audit, surveillance and 'usual practice'. This can be seen as a form of triage – filtering out what would otherwise be an enormous number of studies that would need to be reviewed. However, it is problematic because it equates particular forms of method with higher or lower levels of risk to participants, which does not stand close examination. For example, a service evaluation – excluded from scrutiny by the NRES definition – may seek to collect information from patients or service users in questionnaire or interview that could include highly intrusive questions, with significant potential to cause distress to participants, but these kinds of issues would not be picked up, as independent scrutiny would not take place. The report has already drawn attention to evidence that the NRES definition of research appears to have been adopted by many universities, with the same problematic consequences. However, the Social Care REC, though part of NRES and using its standard operating procedures, has, as we have seen, a more flexible and inclusive definition of research. Whether the Social Care REC will be able to maintain this broader definition in the face of the Coalition Government's intention to simplify and streamline existing arrangements remains to be seen.

This review has already noted that the operational definition of 'research' used by CSSRs is likely to vary.

The 'reach' of research governance, and gaps in coverage

Another definitional issue, specifically for CSSRs, is coverage. The RGF implementation plan for social care research envisaged governance arrangements including research with service users and carers who might use services commissioned *but not provided* by the CSSR. Put simply, if a CSSR arranges care or support for a service user from a locally commissioned private or voluntary sector service, any research involving this service user should be independently reviewed. CSSRs are responsible for ensuring that research activity in local private or voluntary sector organisations that offer social care or support receives proper independent scrutiny of ethics and methods.

The problem with this is that the guidance *only* applies to people whose care or support is funded by the CSSR. A residential care home, for example, might have a mix of CSSR-funded residents and privately funded residents. Good practice would be for the same provisions to be applied *regardless* of the source of funding, but there is no requirement

for these provisions to be extended: it is up to the provider organisation. Very little information is currently available about the extent to which CSSRs have been able to ensure that research hosted in commissioned services – rather than services provided directly by the CSSR – is independently reviewed. The policy direction of successive governments over the past decades has been towards the creation of a mixed economy of care, and local care 'markets'. Public sector provision has declined whilst private and independent provision has have increased. It might therefore be reasonable to think that it will become increasingly difficult for CSSRs to ensure research governance arrangements are maintained in these sectors.

Some research – for example, non DH-funded social care research carried out by researchers not employed by local authorities or universities – has no immediate source of review. To prevent such research from falling through 'gaps' in coverage, guidance in the Route-map document referred to earlier advises the researcher to choose either a university or a local authority to secure a review.

These definitional problems over 'reach' are magnified by the introduction of personal budgets. Personal budgets are a new way of delivering services in which service users and carers are given a sum of money by the CSSR to spend on their care and support. Providing the money is spent on meeting defined needs, there is great flexibility as to how these needs can be met: the money does not have to be spent with existing care agencies, but can be spent in a multitude of different ways. Personal budgets were not a reality in 2001 when the RGF was originally published, or 2005 when it was revised. CSSR commissioning arrangements with local care provider organisations might include contractual clauses referring to research governance arrangements reminding them of their responsibilities within the RGF. The diverse nature and, potentially, the exceedingly large number of 'provider organisations' whose care and support may be purchased by personal budget holders means that these arrangements will no longer work.

Does the RGF apply to government departments and regulatory agencies?

The DH now complies with the RGF and insists that all research it funds is externally reviewed. In practice, it also applies the RGF to surveys such as the Personal Social Services User Experience Survey – at the time of writing, a mandatory annual survey carried out by all CSSRs under the direction of the DH. These arrangements were put in place following the publication of a report from ADASS that was critical of the ethical shortcomings of one such survey (Woolham *et al*. 2006). Some regulatory agencies, such as, for example, the National Audit Office do not, however, currently seek independent reviews of methods or ethics for their work.

Spicker (2007) suggests that a more fundamental problem with current methods of conducting ethical reviews is that the approach to consent and confidentiality/privacy offered in many codes of practice or guidance assumes that rights – for example, to privacy and confidentiality – apply universally, when in fact, they apply more properly in the private sphere only. Spicker argues that some research – for example, research

involving organisations, and individuals who represent these organisations – should be underpinned by different rules. The consequences of applying ethical codes designed to protect individual privacy in certain public settings are spelled out:

> It would mean, if taken literally, that criminologists did not have the right to observe or report on the process of criminal trials unless they have obtained the consent of judge, lawyers, accused, jury, court officials – even, where it is recorded in the research, the public in the gallery – and discussed how the research is to be used (p.106).

Proportionality

The need for the scrutiny of research to be proportional to the degree of risk is easy to agree with in principle, but extremely difficult to achieve in practice. Some see existing governance and review arrangements as appropriate only to clinical research. This is expressed rather pungently by Dingwall (2006):

> At no point are we going to forcibly inject dependent patients with irreversibly toxic green stuff. Why then are we treated as if we were going to? (p.52).

As a response to the recommendation of the 2005 review, quoted above, COREC's successor, NRES, established a London based pilot scheme which is currently being trialled, using a 'no material ethical conditions tool' (see http://www.nres.npsa.nhs.uk/applications/submitting-your-application/). The tool consists of six descriptions of types of research deemed suitable for proportionate review. The researcher is asked to declare if their study falls into one or more of these categories, in which case it may be considered suitable for review. Three of the research types are non-clinical and therefore relevant here:

• the use of data that is anonymous to the researcher;

• questionnaire research that does not include highly sensitive areas or where accidental exposure would not have serious consequences;

• research interviews or focus groups that do not include highly sensitive areas or where accidental disclosure would not have serious consequences.

The obvious difficulty with the latter two criteria is that they rely exclusively on researcher/reviewer definitions of 'sensitive area'.

Proportional review means that proposals deemed to offer low risk to participants should receive 'light touch' review, sometimes by a single individual charged with filtering proposals and deciding what needs a full review and what does not. Although a tool exists to enable reviewers to assess the level of risk to participants (Woolham 2010) the problem any reviewer has is that it is not possible to properly assess the level of risk of a given proposal without thoroughly reading and familiarising themselves with it first – a task that essentially amounts to a full review. Hunter (2007) develops this point further,

arguing that there are four inter-related reasons why a full review is needed to ensure full and appropriate identification of ethical issues: the need for a broader range of expertise to judge risk; to avoid situations in which prior individual experiences may lead individuals to ignore certain ethical issues; to avoid over-reliance on a particular theoretical perspective; and because of the inherent uncertainty implicit in all social research. McLaughlin and Shardlow (2009) also argue that a 'light touch' in practice is likely to mean that the suitability of a given research proposal will be judged on knowledge of the applicant rather than the proposal.

The impact of regulation on research involving people with impaired capacity

The Mental Capacity Act (MCA) places a legal duty on researchers to secure a favourable review for their proposed study from a REC deemed an 'appropriate body' by the Secretary of State. At the present time, only NHS RECs are registered as 'appropriate bodies'. Concerns have been expressed that the requirements of the MCA may deter researchers from conducting research with people who have impaired capacity as meeting the standards required to secure ethical approval may be too 'difficult' or too time-consuming. One recent, although small scale study by Parker et al. (2011) suggests that these may well be legitimate concerns, and the authors call for further research to monitor the impact of the MCA on research with and for people with impaired mental capacity.

Who does the research? Students and inexperienced researchers

Universities are likely to have different policies about whether to allow students to carry out non-desk based research involving 'live subjects' or primary research. Whilst on the one hand, some may allow this kind of research on the premise that it offers better learning opportunities for the student (important if the student is contemplating a career in research for example) there are also powerful counter arguments. Foremost amongst these is the need to protect vulnerable individuals from clumsy or intrusive questions, and the probability that the ensuing findings will not add very much to knowledge about the topic under investigation. Another is that students will need to seek an independent review of their study; if it does not meet required standards it will not be allowed to proceed. A third is that timescales for completion are comparatively short, leaving little time for amendments should these be required following review. As a result, many universities now actively discourage undergraduates from conducting 'live' research in the adult social care and health field.

Slightly different but analogous issues exist in CSSRs, where relatively inexperienced staff, whose role may encompass 'research' within a portfolio of other responsibilities are tasked by managers to carry out studies to support a decision or implement a plan of some kind.

Understanding of social care research methodologies

Although concerns are sometimes heard amongst social care researchers that NRES REC members appear to have a limited understanding of social care research methodologies,

Research governance and ethics for adult social care research

the objective truth of these concerns will always be hard to establish. Although the creation of the SCREC was arguably an attempt to address these concerns, NRES has not always been 'social care-minded'. For example, this review has already noted the imposition of the RGF without proper consultation when it was published in 2001. Additionally, in the review of NHS research governance that followed the publication of the RGF (Department of Health 2005b) the social care research community was not represented on the ad hoc advisory group responsible for the review's report, despite the report making recommendations relating to social care. Glasby and Beresford (2007) also make the important point that service users were not well represented on NHS RECs at the time of their study. However, since their paper was published, the IRAS application process used by NHS RECs includes specific questions on service user involvement and participation in the design and execution of research. Irrespective of the current composition of REC members, at least investigators are now obliged to consider the involvement of service users and carers.

Asymmetry in relationships between sources of review, and reciprocity

The bureaucratic burden imposed upon researchers by research governance arrangements can be reduced by ensuring that they are not expected to seek a review from more than one place. Reciprocity, respect and avoidance of 'double-handling' are key principles. One difficulty with this at the present time is the asymmetric relationship between the three main sources of independent review. For example, local authorities are invited to accept the currency of reviews carried out within university and NRES systems (although they obviously retain the ability to decide whether to host a study even if it has had a favourable review). NRES (NHS) RECs, however, will not accept reviews carried out by university or CSSR RECs if the study involves NHS patients or staff. Additionally, only NRES RECs (including the Social Care REC) are authorised to approve research involving adults who may lack, or have impaired, mental capacity, whether the research involves patients or not.

What actually gets reviewed?

Thorough reviews require scrutiny of *all* paperwork relating to the proposed study. This typically includes not just the research proposal itself but the questionnaire/interview schedule(s), information sheet(s), consent form(s) letters, etc. Considerable work will need to have been carried out by the applicant prior to submission. The NRES IRAS is extremely thorough in this regard, and the application process reminds the applicant of the importance of submitting all relevant documentation. There is some anecdotal evidence[3] that some research ethics reviews, particularly carried out within the university sector, may be completed on the basis of the reviewers having seen only some of the paperwork, for example proposals agreed without sight of questionnaires, consent forms, or covering

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3. Correspondence between the author and the Chair of the Midlands Region Research Governance Group 2009–2010.

letters etc. There is also some anecdotal evidence that the quality of methodological reviews in some university settings may leave something to be desired. Although there have been a number of studies published over the last few years that have been highly critical of existing review processes, there has not yet been any equivalent examination of the quality of research applications made to reviewing bodies, despite persuasive anecdotal evidence. The absence of evidence on which to draw suggests a need for research to assess the dimensions and significance of this issue. Reciprocity and the avoidance of double-handling require trust and confidence in systems operated within and between different sectors. Where there are problems with the quality of reviews, relationships of trust will be eroded. No information could be found about the quality of reviewing practices in CSSRs, although in some regions, CSSRs use the same application process, which includes questions about methods as well as ethics.

Speed of response

The introduction of the online Integrated Research Application Service in 2008 is likely to have improved the efficiency of NRES. However, the speed of response is still relatively slow, with the service taking up to 60 days between submission of a valid application and provision of an opinion on the proposed study. While it is important that committees have sufficient time to read submitted applications and to prepare a considered response, a 60-day time period may be problematic within adult social care research as much research in this field is expected to be completed within short timescales with limited resources. Delays create potential problems in ensuring continuity of employment for junior academics in non-tenured positions in universities. No research evidence could be found on the length of time needed to secure review in university or local authority systems but the decentralised nature of these systems mean that if there are standard times within which responses should be made, these are likely to vary.

An additional issue here is that many research funders will not cover the costs of securing ethical approval so any delays can make it difficult to cover researchers' salary costs.

Centralised vs. de-centralised systems

This review has already drawn attention to the heterogeneous nature of research ethics and methods review systems within the university sector. Single, university-wide ethics committees may offer advantages over faculty/school-level ethics committees in terms of control over procedure and policy (different standards may pertain in different faculty or school based committees) and offer a single co-ordination point for registration and recording purposes. However, without triage arrangements, these committees are likely to be very busy indeed. Faculty or school-based committees or arrangements might reasonably be expected to have proportionally more resources and less demand, but standards may vary. Hunter (2008) draws attention to parallels between the way in which URECs operate at the current time and NHS RECs a decade earlier, and which led to the creation of MRECs. Hunter advises that universities should not replicate the NHS approach,

but, instead adopt approaches to resolving the issue that reduce the bureaucratic burden on researchers.

Workload and capacity of reviewing systems

The number of students attending certain kinds of course in many universities place a considerable workload burden on reviewers, which may place further constraints on the conduct of primary research in adult social care and health settings. The withdrawal of HEFCE funding from arts and social sciences courses in English universities may increase these problems as universities have been expected to absorb the costs of URECs from this source of funding. NRES RECs, as we have seen, may manage workloads by operating restrictive definitions of research. Little is known at the present time about whether workload and capacity issues exist amongst local authority research governance groups/committees, and if so, how these are managed.

Knowledge, skills, experience and backgrounds of reviewers

Many CSSRs lack in-house research capacity, and there is evidence to suggest that research governance leads may not always have felt that they had the full range of skills or competencies to manage research governance arrangements in their CSSR. For reviewing activity to be of a consistently high standard a wide range of skill, knowledge and experience are needed, and their scarcity in CSSR settings may be another reason for the apparent fragility of research governance here. McLaughlin and Shardlow (2009) put this succinctly:

> …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 proceduralize, 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 (p. 16).

Additionally, although all NHS and most, if not all, university reviewers have access to training, it seems reasonable to suggest that much less is provided for local authority reviewers.

Quality of response

The volume of requests for ethical and methodological review within the university sector can reasonably be expected to be large, particularly amongst universities that do not discourage primary research at undergraduate level. This may affect the quality of the review carried out. Some academic staff are primarily teachers rather than researchers, and if inexperienced as researchers, this may also impact on the quality of the reviews they are asked to carry out. The quality of response amongst local authority reviewers might also be reasonably assumed to vary given the diversity of local arrangements, skills and experience of reviewers and level of access to training.

Compliance

The apparent fragility of reviewing and governance arrangements in many local authorities – evidenced by the seemingly high attrition rate between Pahl's two surveys (op. cit) – makes it likely that where arrangements do exist, significant amounts of research activity may be carried out without the study having had either ethical or methodological review. This may be for a variety of reasons, including ignorance (especially if research governance arrangements are not well publicised), tight timescales for the completion of work, because the study falls outside of whatever criteria the local authority may have adopted to define 'research', or deliberate evasion by the researcher. Although the Tinker and Coomber (2004) study concluded that at the time much research may have been evading scrutiny in the university sector, the requirements of funding agencies and publishers mean that it would be reasonable to assume that evasion will probably be less likely in universities at the present time. By comparison, it is less likely that research could be carried out in NHS premises without a favourable review having been obtained, as awareness of research governance arrangements is more widespread and systems are robust and effective.

How many CSSRs have functioning arrangements for reviewing ethics and methods of studies?

Pahl's two surveys of CSSRs found that the majority of CSSRs said they had arrangements in place or plans to implement research governance arrangements in 2006. Since then, no further assessments of progress have been made. Although many local authorities do have effective systems in place, further research would be needed to establish the extent of coverage, and the effectiveness of the arrangements that exist. Most recently, a survey of local authorities carried out by Boddy and Oliver (2010) seeking information about existing systems of research governance achieved a response rate of only 39%, suggesting that since Pahl's study there may have been a decline in the proportion of local authorities with functioning research governance arrangements.

Quality assurance

No quality assurance (QA) arrangements appear to exist for across university or CSSR research governance activities – although individual universities and CSSRs may have their own arrangements. The Social Care Research Ethics Committee may offer limited advice and guidance to local authorities. Within the NRES system, QA arrangements are described in GAFREC guidance, and supported by standard operating procedures with which NRES RECs must comply.

Levels of independence

Structurally, NRES arrangements probably offer the greatest level of independence from local vested interests or local attempts to influence or control, as it NRES independently funded and removed from local operational management within the National Patient Safety Agency (NPSA). At the time of writing, the Coalition Government have announced

plans to abolish NPSA. It is too soon to be able to say what implications this will have for NRES and its structural independence.

Conflicts of interest may – at least theoretically – exist in university faculties where, on the one hand, there is an expectation that staff will bring in research income and publish research to meet Research Excellence Framework (REF) criteria (briefly, a national, target-based system for auditing the performance of researchers working in the academic sector), and, on the other hand, the need to act independently to review research proposals necessary to protect reputation of the university.

In local authority settings, unless the research governance lead is a senior manager, the possibility of pressure being placed on reviewers to favourably review studies commissioned by senior managers or elected members cannot be excluded.

The Social Care Research Ethics Committee: progress and problems

The Social Care REC was established by the DH to address many of the criticisms that the social care research community had voiced about NHS RECs and to address gaps in coverage between different sources of review. Its first Annual Report (2011) contained reflections on its progress since it held its first meeting in June 2009. Amongst other things, the Annual Report draws attention to deficiencies in the quality of applications received, including a lack of knowledge by some applicants of the Mental Capacity Act, and a lack of understanding of the place of ethical review in the process of planning and conducting the research. The authors do not mince their words when describing the quality of some of the applications received:

> Applicants new to IRAS struggle with the idea of it as much as with their actual use of it: the process is not yet, unlike the case with most healthcare research, embedded in the organisational research culture of most of our applicants. Key sections in applications submitted 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 university or organisational research committees are rarely included with applications. (p.9).

This extract serves as a reminder that while a great deal has been written, principally by academics, about the time-consuming and bureaucratic nature of research governance procedures, less is heard from reviewers about the nature of the proposals they are expected to review.

Over a one-year period, the committee reviewed 35 applications, of which 13 (37%) concerned Mental Capacity Act issues: an average of 2.7 applications per meeting. Perhaps in recognition of this low number of applications, (and consequently high per-capita cost of reviews) NRES are at the time of writing amending the standard operating procedure of the SCREC to enable it to receive non-clinical NHS research, as previously indicated.

CONCLUSIONS

Research governance arrangements in adult social care have, despite initial concerns and misgivings from critics, developed in universities and local authorities since the introduction of the Framework in 2001, and evolved in NHS settings. In practice, implementation has been slow, patchy, and has not yet delivered the five key principles described in the Route-map for Researchers described earlier. For example, as this review has tried to show, in relation to the first four principles:

- *reciprocity* is limited by asymmetric relationships between NHS and university/CSSR research governance arrangements;

- the *avoidance of double-handling* assumes basic, uniform levels of competence of other sources of review which, if absent, erode trust;

- *proportionality* is hard to achieve in practice without effectively conducting a full review; and

- the *independence* of RECs is not, structurally at least, always guaranteed.

Despite these and other shortcomings, progress in this complex field has been made, although its future existence is not assured, especially in local authority settings where resources are less well developed and 'research culture' less well established.

Arguably, although vulnerable patients and services users are likely to be better protected now than a decade ago from unethical or poorly designed research, from the perspective of the research community, the price has been high. Existing arrangements remain difficult for researchers to navigate, sometimes overlap, and sometimes offer inconsistent opinions. They are also time-consuming, which is wasteful in researcher and reviewer time, and therefore an extremely inefficient use of scarce resources. This review has referred to a number of published studies – both those more ideologically opposed to review and governance, but also from empirical researchers who have documented the difficulties they have faced and the consequences for their research.

By contrast, those charged with the tasks of reviewing and governance point to examples of studies submitted without adequate paperwork, about proposed studies in highly sensitive areas prepared by inexperienced researchers and which fail to identify, let alone manage, the risks to participants, about attempts to evade scrutiny by re-defining *de facto* research studies as audit or consultation, about the over-researching of some groups of people (and the under-researching of others), and about the need to protect operational staff working in NHS and social care environments from taking part in research so poorly designed as to be worthless. By contrast to the research community, there appear to be no published empirical studies of the extent of these issues, and research that considers these issues from the perspective of reviewer rather than researcher could be very worthwhile.

Can these two different perspectives be reconciled? Few would disagree that the current system needs to be simplified and streamlined, but as this review has tried to show, principles, such as those outlined in the 'route-map' described earlier are often undermined or ignored. Additionally, a lack of understanding is sometimes apparent from researchers themselves that a favourable ethical opinion does not guarantee that a local NHS Trust or CSSR will agree to host a study. Simply advising those concerned to behave differently is unlikely to help: the robustness of ethics and governance systems requires independence and to the extent that they are independent, they may choose to ignore such guidance (Alberti 2000).

The issues and challenges raised in this paper are complex and, almost a decade after the first publication of the Research Governance Framework, though progress has been made, some issues seem as intractable as ever, perhaps because they reflect , or are responses to, wider, societal ambivalence towards risk and protection. Solutions are likely to require shifts in power and the sharing of resources, changes to organisational and professional culture, investment in training, and continuing dialogue.

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