Research and Development in Social Care: Governance and Good Practice

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Abstract
This article examines some of the challenges posed by the Department of Health's proposals for a research governance framework for social care, focusing particularly on the ethical dimensions. These challenges include the definition of research; what constitutes ethical research design and how this differs from ethical practice; the process of ethical scrutiny; and the role of the Research Ethics Committees (RECs). The need to raise ethical standards across the whole of social research, not just social care, is discussed together with the rights of individuals to decide for themselves whether to participate in research. Some suggestions are put forward for ways of carrying out ethical scrutiny, and for developing ethical practice, without the creation of RECs for social care.

Introduction

The Department of Health published its *Research Governance Framework for Health and Social Care* in March 2001 (Department of Health, 2001a). The document raises some important issues about the standards that will apply to publicly funded research in health and social care; the responsibilities of the various parties involved in research; and the way research is managed. It has come at a time when a number of professional bodies, such as the Social Research Association and the British Sociological Association have been revising their ethical codes of practice for research (SRA, 2002 and BSA, 2002). It is therefore a fruitful time to be looking at ethical aspects of doing social research – and whether the Department of Health's proposals are appropriate to social as opposed to health care research.

In order to be able to discuss the details of the Department of Health's *Framework* it is perhaps useful to summarise what it proposes. This is not a very easy task, but the Annex attempts to list the key features relating to Ethics, and to the responsibilities of the research 'sponsor'.

Challenges posed by the Framework document for social research

What do we mean by research?
The work that is called 'research' covers a very broad range of techniques and activities ranging from secondary analysis of large scale datasets, with no interaction between the researcher and an individual, through experiments and Randomised Controlled Trials (RCTs), postal questionnaires to small scale qualitative studies. But in addition, there are a number of things that public bodies do that use most of the techniques of data collection familiar to researchers, which may not get defined as research. For example, local authorities are carrying out a variety of different kinds of surveys and are collecting data as part of the Best Value reviews. It is not clear if these constitute 'research' under the DoH's definition. If they do, then do they automatically come within the remit of the *Research Governance Framework* when the subjects of the Best Value review are patients or users of health or social care services?

The ethical issues raised by different kinds of research can vary hugely. It is questionable whether they all require the same degree of ethical scrutiny. Secondary analysis of existing anonymised data sets poses very few ethical dilemmas whereas, in the social care field, interviewing children who have been abused raises a whole host of issues about access, informed consent and the protection of the rights of the individual from harm. There are also big differences between some forms of medical research and most social care research. Some medical interventions are concerned with life threatening conditions and the techniques used may be very invasive, for example, taking tissue samples. The threats to individuals posed by social care research take a different form and relate more to possible psychological rather than physical harm. Is it appropriate to treat all research in the same way when it comes to scrutiny?

The role of Research Ethics Committees
The central feature of the Department of Health's *Framework* is the Research Ethics Committee (REC). At the present time these only exist in the medical context. One of the current debates is whether parallel Committees should be set up for social care research. A broader question about the RECs is whether they are the best mechanism for

safeguarding the interests of participants in research and in the development of good ethical standards.

Committees and systems can certainly assess scientific and financial standards, can have transparent decision-making processes, and create clear allocations of responsibility as required by the Framework. The procedures outlined in the Framework expect a proposal to be approved by an ethics committee. The point in the process at which the REC is involved is therefore before the work has started which means that the main focus of the REC is on assessing whether the research *design* for a project is 'ethical'.

Discussion with almost any social researcher doing empirical work reveals that although there are ethical dimensions to research design, the really difficult ethical issues arise in the course of the day-to-day research work. For example, how can you be sure that someone with a learning difficulty and little or no speech has given their informed consent? Or how do you balance, in practice, the commitment to protect confidentiality to an individual with the need to protect the individual from other harm and therefore pass on information about cases of child abuse? Sometimes these difficulties are covered by the law, but often there is no right answer - it is a matter of judgement. RECs are unlikely to be the right bodies to enter into discussion with researchers on these issues, as they are decision-making rather than advisory bodies.

What is 'ethical' research design and who assesses it?

It is implicit in the discussion so far that what constitutes ethical research design is a very important issue. It has received far too little attention in the past so the current developments are welcome. But it seems that there can be different views on what constitutes an ethical design between different disciplines, or what constitute legitimate methods to use, particularly between medicine and social science.

Discussions with social researchers who have been through the NHS Research Ethics Committee process, because they have wanted access to patients' records, reveal occasions when there has been a major difference of view between the researchers and the REC on issues concerning research design and methods. For example, the use of qualitative methods has been misunderstood, including trying to impose a quantitative framework onto a qualitative study; or accepted survey practice, such as allowing people to contract out of a survey rather than requiring them to formally contract in, has been rejected (1). It is probably impossible to have a definitive statement about what constitutes ethical research design so it would be wrong to assume that there is one 'right' approach. As a social scientist, I naturally expect that professional researchers, making considered decisions, will reach a better view of what constitutes ethical research design than people whose professional expertise lies elsewhere.

The possible lack of consensus on what constitutes ethical research means that it is quite difficult to decide what knowledge, qualifications and experience are needed to make these decisions. In this context the training and expertise of the people carrying out ethical scrutiny – at present the RECs – become very important. The document giving the details of the arrangements for NHS Research Ethics Committees (Department of Health, 2001b) says that the appointment of members is by an open process, compatible with the Nolan standards (p.11, para. 5.3). There is a maximum of 18 members which 'should allow for a sufficiently broad range of experience and expertise, so that the scientific, clinical and methodological aspects of a research proposal can be reconciled with the welfare of research participants, and with broader ethical implications' (p.13, para. 6.1). The need for initial and continuing education and training in relation to research ethics, research methodology and research governance, is accepted (p.10, para. 4.10).

The expert members of the committee, who constitute up to two-thirds of the group, have to have relevant methodological and ethical expertise in: clinical research, non-clinical research or qualitative or other research methods; clinical practice; statistics relevant to research; or pharmacy (p.13, para. 6.4). This membership is therefore heavily weighted towards people with medical knowledge.

In addition to different disciplines having different interpretations of what is ethical design, it may also be the case that different arrangements should apply to different kinds of research. For example, if the study is concerned with an intervention in relation to a life-threatening condition there need to be stronger ethical safeguards in place, than when a service user is given a short questionnaire to ask their views on some minor change in a service. In the latter case, it may be sufficient to leave responsibility for carrying out the work ethically to the researcher, with a very low level of external scrutiny (if any). In the case of the former, it would be an important part of the protection of the individual patients that the ethical standards of the research were very high and seen to involve external scrutiny.

The limited scope of an ethical scrutiny process in social care

The Department of Health's *Governance Framework* relates to research which 'requires the collaboration of the NHS or social care services in England' (Department of Health, 2001a: 3.7.2). But there are big differences in the research environment between the NHS and social care. At the present time there is very little social research that *requires* collaboration with social care providers. Often it would be good to have this collaboration, but if it is not forthcoming there are usually ways round it – even if they are more expensive and tedious to organise.

In the medical field, ethics committees control access to patients' records and patients' addresses, and the work that is done by health service employees. This does not mean that they can control all research on health issues but access to patients and staff is often crucial to being able to carry out medically-based research. In the social care field, similar kinds of structures would have less control over what is done. Most social care research is not experimental and samples are often drawn from a population that can be located without reference to social care agencies. In these circumstances an application to the REC, or social care equivalent, would be avoided. Whether a piece of work went ahead would depend on whether the funds were made available. (It is important to note that if systems are set up that make access to social care service users very complex, this will be a disincentive to researchers to do research on those issues).

It is clear that not all research that is addressing social care issues will go through Department of Health initiated ethical scrutiny. But if it is thought that creating structures for doing this would be beneficial, then simply focusing on social care is too limited. Research on people in prisons, on the police and policing, on benefit receipt, on the experiences of refugees and people seeking asylum, and on many other social policy issues raise exactly the same kinds of concerns as research on social care. If we are serious about raising ethical standards it has to be across the whole of social research.

The rights of individuals to decide to participate in research

In the current concern about research standards there is beginning to be an assumption that individuals have to be protected and are incapable of deciding for themselves whether they want to participate in a project or not. One of the strands in the Department of Health *Framework* is the need to keep risk to a minimum. One way of doing this is through paternalism – protecting and controlling access to people seen to be at risk.

Frank Furedi has discussed the growth in ethics committees, particularly in the US, and the threats to academic freedom that this poses (Furedi, 2002). While agreeing that researchers have a responsibility to ensure that people are treated with dignity and respect he says that 'ethics committees treat vulnerability as the defining characteristic of the human condition. As a result there is a growing tendency to regard research as risky and as a potentially dangerous activity.' The author points out that ethics review bodies are concerned with issues such as risk, litigation and reputation. 'In practice, they are not so much an ethics committee, as bureaucratic gatekeepers who use ethics as a managerial ideology.'

As a researcher committed to the notion that individuals have rights – and who subscribes to the social model of disability – I reject the idea that vulnerability is the defining characteristic of the human condition. If appropriate ethical procedures have been put in place so that individuals are

genuinely giving their informed consent, I believe it should be the individual who decides whether to participate or not, rather than the service provider or the members of ethics committees.

Being a research sponsor and the allocation of responsibilities

A great deal is made in the Department of Health Framework document about responsibility and accountability, and it being essential that 'clear agreements describing allocation of responsibilities and rights are reached, documented and enacted' (Department of Health, 2001a: 3.2.1). The responsibilities of the Research Sponsor, who will often be the Research Funder, are spelt out in detail. All the important criteria for good research are listed including:

- The research proposal is worthwhile, of high scientific quality and represents good value for money.
- The principal investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successful.
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources being proposed are those required to allow appropriate data analysis and data protection.
- Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards.
- Organisations and individuals involved in the research all agree the division of responsibilities between them.
- Arrangements are proposed for disseminating the findings.
- All scientific judgements made by the sponsor in relation to responsibilities set out here are based on independent and expert advice (DoH, 2001a: 3.8.6).

(There are additional ones that mainly apply to medical research such as the registration of trials and provision for compensation in the event of non-negligent harm).

These conditions are not difficult for established funding bodies, like the Joseph Rowntree Foundation (JRF), to meet as they are the basis of the decisions that they take. But they may be more difficult for occasional or small funders of research who may well not have the infrastructure for scientific scrutiny. Will such bodies be willing to take on the role of sponsor? There is also a question of whether the Department of Health can enforce, in practice, the requirements that are being placed upon sponsors. There will be a list of recognised sponsors and researchers funded by organisations not on the list will presumably not be able to get access to the NHS staff or patients. It is not clear how strong a sanction this will be or what would happen if a funder fulfilled all the requirements except one.

There are problems too in relation to the responsibilities of other parties to the agreements. Universities and other organisations employing researchers are expected to be responsible for 'developing and promoting a quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research' (DoH, 2001a: 3.9.1). If one discovers half way through a research project that the employer is not fulfilling this role, what can be done about it, by the Department of Health, or the research sponsor? Because the funds for social care research are modest, and much of the work is carried out by staff on short term contracts, the infrastructure for social research is much less well developed than in the medical arena. This is another difference between health and social care which may affect the context in which ethical scrutiny is carried out.

The responsibilities of research sponsors for ethical matters

It is the research sponsor's responsibility to ensure that: 'The research proposal has been approved by an appropriate research ethics committee' (DoH, 2001a: 3.8.6). Before the work begins, therefore, the *research design* must be scrutinised and agreed to be ethical.

Once a study has begun, responsibility for the conduct of the work shifts slightly. The NHS REC requires researchers to keep it informed about the progress of a study and review its advice on ethical acceptability in the light of this information (DoH, 2001a: 3.12.8). But it is the research sponsor and

other stakeholder organisations that need to be alerted if significant developments occur as the study progresses (DoH, 2001a: 3.8.6). This suggests that it is the research sponsor who is expected to take responsibility for ensuring that the day to day decisions about *ethical practice* are taken appropriately (Often the resolution of these dilemmas do not require any change to the project design at all).

If this interpretation of the *Framework* is correct it raises two questions:

- What mechanisms are in place to help research sponsors and researchers to make the difficult judgements about what constitutes *ethical practice* that arise in the day to day work? And
- Why is the ethical scrutiny of research design separated off into a special Committee?

What kind of system is needed?

The current system of NHS Research Ethics Committees does not provide a number of the components that would make for a robust system of ethical scrutiny across all of social research because they are restricted to the NHS and social care. It is also not clear whether RECs are equipped to assess properly the design of social science as opposed to medical research, given that there is often a lack of consensus across different disciplines as to what constitutes ethical research design. Also, although 'RECs are responsible for acting primarily in the interest of potential research participants and concerned communities' (DoH, 2001b: 2.3) there is also pressure on RECs to protect the interests of the NHS and of the Secretary of State in any research that is funded.

The current structure does not facilitate discussion and debate that would help researchers make a judgement about what to do. One of the biggest difficulties is that ensuring that researchers carry out their research in an ethical way is not currently anyone's responsibility. Given that at the present time there is a formal system to scrutinise research design within the NHS, but only informal systems to assist with the development of ethical practice, it is worth considering these two aspects separately. In terms of ethical design there are a number of options including:

1. Move away from a committee-based system altogether and substitute an alternative process of review;
2. Continue with the NHS REC structure, create an additional Social Care Research Committee structure, and additional structures for other specific areas of social policy;
3. Create a cross-subject system based on a new institutional framework – perhaps giving this responsibility to employers of researchers;
4. Giving this as an additional responsibility to research sponsors.

It is unlikely that the demands of accountability and transparency could be met from an informal process of review, and it is difficult to envisage a formal process without some kind of committee structure. Option 1 does not appear to be a starter therefore. There are considerable problems with Option 2 as well because there would be a huge proliferation of different committees, no doubt operating to different criteria.

This leaves Options 3 and 4. There are pros and cons with both. Both employers of researchers and research sponsors could be said to have a vested interest in the outcome of ethical scrutiny. An employer who wants money to keep a researcher in business might be willing to make more compromises than someone funding a piece of work. But equally, some funders who have a close interest in the topic of the research may also be under pressure to bend the rules in order to get a piece of work done. Both employers and funders might be tempted to be more concerned about protecting their backs against external criticism than protecting the rights of the individuals being researched. They might both focus on the issues of risk, litigation and reputation rather than the benefits to be gained from carrying out a good piece of research on a risky topic. At a meeting of the Academy of Learned Societies for the Social Sciences in February 2002, some examples were given of University Ethics Committees taking decisions on the basis of the threat to the University's reputation of a project on a controversial topic. If employers, many of them Universities, were to take responsibility through their own Ethics Committees there would also be a huge proliferation of different Committees, with no means of developing standards procedures across them.

There are considerably fewer organisations that fund social science research to any significant degree. A possible option to pursue, at least in the short term, could therefore be for the NHS RECs to continue in being to assess ethical research design for NHS projects, and for the main funders of social care and other social policy research to take responsibility, either individually or collectively, for the detailed scrutiny of the ethical dimensions of the social research that they fund. At the present time, the Joseph Rowntree Foundation includes an assessment of ethical aspects of a proposal almost implicitly in the process of deciding whether or not to support a piece of work. It would be relatively easy to stress that this will be a more important feature of our assessment in future, and put some system in place to ensure that this is carried out by appropriately qualified and experienced people.

If the main funders of social research including the relevant Government Departments (Department of Health, Home Office, Department of Transport, Local Government and the Regions, Department of Work and Pensions, Department of Education and Skills, plus the Scottish, Welsh and Northern Irish bodies), the Economic and Social Research Council (ESRC), Nuffield Foundation, JRF, and voluntary organisations that fund research like Barnardo's, came together with representatives from relevant service providers such as the Association of Directors of Social Services (ADSS), a common framework for carrying out ethical scrutiny of proposals could no doubt be worked out.

But *ethical practice* probably requires a very different approach. The ethical guidelines produced by social science bodies are generally 'informative and descriptive rather than authoritarian or rigidly prescriptive' (SRA, 2002: 2). As such, therefore, they do not provide definitive answers to ethical dilemmas. This reinforces the view that judgements have to be made in relation to each piece of work. To help people make ethically sound judgements requires space within which the alternatives can be debated and a consensus view reached. This is unlikely to be achieved within a formal committee of people at arm's length from the piece of work.

The Advisory Groups that the Joseph Rowntree Foundation supports for most of the research projects it funds have the capacity to provide a setting for the discussion of such issues in helpful ways (Pahl, 2002). What is lacking from such a system is that it is not widespread across all funders, and it is not reinforced by any panel of experts to whom to turn when uncertainties remain. The need for a body to take responsibility for the development and promotion of ethical practice by providing advice and guidance seems to exist.

If such a body was set up it could have a number of tasks in addition to providing a panel of experts to whom researchers (and employers and research funders) could turn when an ethical issue arose about which there were uncertainties as to how to proceed. These could include:

- Some informed discussion and debate about whether there are any absolutist positions on ethical practice – and getting agreement on what these are, preferably across medical and social research.
- The development and dissemination of protocols and forms for: obtaining informed consent; safeguarding confidentiality; complying with data protection requirements etc (SRA, 2002, Section 6).
- The development of stronger statements of good practice, with some examples, that relate to the issues faced by social care researchers.
- The development of appropriate training materials and training courses, building on this material.

The development of robust examples of good social science practice could also be useful to the NHS RECs, when they are faced with research on the delivery of health care, as opposed to drug trials and standard RCT designs.

The obvious body to take on the task of providing expert advice to social science researchers, and developing a consensus about good practice, is the Academy of the Learned Societies for the Social Sciences. Most of the major social science associations are members of the Academy. To channel a focus on ethical practice through the Academy would be good for the professional

development of the social sciences generally and for higher standards in social research across the board.

Note

1. Examples of fundamental differences of perspective were given by participants at two events: Social Services Research Group, *Research and Development in Social Care: Governance and Good Practice*, 25 January 2002 and Academy of Learned Societies for the Social Sciences, *Ethics and research guidelines*, 6 February 2002.

An announcement about the research governance arrangements for social care is expected by the end of 2002. It is not known whether there will be a further consultation phase. But comments and views can be sent to Jan Pahl at the University of Kent or jmp5@ukc.ac.uk

References

BSA guidelines on: www.britsoc.org.uk/about/ethic.htm

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Pahl, J. (2002) 'Research Governance in Social Care', presentation at SSRG workshop, *Research and Development in Social Care: Governance and Good Practice*, Birmingham, 25 January.

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Annex: Summary of the key features of the Department of Health Framework for Research Governance

Research governance is aimed at continuous improvement of standards and the reduction of unacceptable variations in research practice across health and social care (2.1.1)

Health and social care research is not the province of a single discipline, profession or organisation and no single document adequately captures the full range of legislation, standards and guidelines that need to be applied across this wide ranging body of work. They are presented here in five domains:

- Ethics
- Science
- Information
- Health, safety and employment
- Finance and intellectual property. (2.1.3)

Details in relation to *Ethics* are:

2.2.1 The dignity, rights, safety and well-being of participants must be the primary consideration of any research study.

2.2.2 The Department of Health requires all research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.

2.2.3 – 2.2.9 cover informed consent; particular care needed where research involves tissue or organs of the deceased; the use and protection of patient data; the involvement of participants or their representatives in the design, conduct, analysis and reporting of research; respect for the diversity of human culture; risk to be kept at a minimum (and compensation for non-negligent harm); and research involving animals.

Responsibilities
The Framework document spells out the responsibilities of the various participants in the research process – participants, researchers, principal investigators, research funders, research 'sponsors', organisations employing researchers, organisations providing care, care professionals, and research ethics committees. (3.1.1 -3.12.8)

Research ethics committees
These are particularly relevant to ethical questions. Those establishing research ethics committees are expected, among other things, to ensure that the committees have clearly defined remits and terms of reference and to have clearly defined arrangements for appointing and replacing members. The 'primary responsibility of research ethics committees is to ensure that the research respects the dignity, rights, safety and well-being of individual research participants. They should also work efficiently to facilitate the good conduct of high quality research that offers benefits to participants, services and society at large.' (3.12.2).

Research within the NHS, whether it concerns individuals, their organs, tissues or data, or social care involving work in NHS settings must have the prior approval of an NHS research ethics committee (REC). The Department of Health is discussing with the Association of Directors of Social Services (ADSS) on how arrangements can best be developed to provide a more comprehensive system for the ethical review of social care research. (3.12.3 – 3.12.5)

'The decision on whether or not research in an NHS organisation should ultimately proceed rests with that organisation. No research should proceed without prior REC approval. However, even though REC approval may have been obtained, an NHS organisation may need to consider other factors before permitting the research to proceed. Similarly, Directors of Social Services are responsible for approving social care research within their local authorities.' (3.12.6)

Responsibilities of research funders and research sponsors
The role of research sponsor seems to be a very important one in the Framework document. Organisations wishing to fund research that requires the collaboration of the NHS or social care services must be able to discharge the responsibilities of research sponsor, or find some other organisation that is prepared to do so. (3.7.2).

'The research sponsor plays a critical role in assuring the quality of research.' (3.8.1). The research sponsor is responsible for assessment of the quality of the research proposed; the quality of the research environment within which the research will be undertaken; the experience and expertise of the researchers; that agreements are in place to specify responsibilities for the management and monitoring of research; and that arrangements are in place to review significant developments as the research proceeds and to approve modifications to the design (3.8.2-3.8.5). Among a long list of other responsibilities the research sponsor has to ensure that:

'The research proposal has been approved by an appropriate research ethics committee' (3.8.6).