

Research Governance in Social Science and Social Care Research

Jan Pahl

University of Kent

J.M.Pahl@kent.ac.uk

1 AIMS

- To summarise the main ethical issues in social science and social care research
- To outline what is meant by research governance, especially as set out in the Department of Health Research Governance Framework (RGF)
- To consider key differences between clinical and social science/social care research and to look at some definitions of research
- To report and discuss progress. The RGF is still in a process of consultation, especially in the field of social care, and the session will allow opportunities for feed back and discussion.

Note that:

- I am speaking for myself and not as a representative of the Department of Health (DoH). I am working as a consultant and as a part of a team which is responsible for implementing the RGF in the field of social care
- I shall be speaking as a someone who has been a social science researcher for most of my career and who has faced many ethical issues in that work.
- I bring to the job my experience of researching both in the NHS and in the social services, as well as in university settings.

2 ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH

There is broad agreement on the RGF core statement: ‘The dignity, rights, safety and well-being of participants must be the primary consideration in any research study’. The debates begin when we start to consider that that means in practice.

2.1 Giving informed consent to take part in research

Respect for the rights of individuals to decide whether to take part in research or not is fundamental. Researchers have an obligation to provide accurate information about the purpose and nature of a study when enlisting participants. People should not be deceived or misled when they are recruited, though in practice this is more difficult to achieve than might be expected. Two issues are:

- Many people who take part in studies cannot have a full understanding of what is being investigated. This can be a problem with people with learning difficulties. Consent may have to be obtained from parents or those in loco parentis; but the parents may say that the disabled person would not understand, or may be upset by the research, whereas in reality s/he would like to take part. See the scenario at the back of the programme about research involving young adults with LD.

- Explaining the purpose of the study can bias the results. So for example, if the study is about discrimination against Black people by the police, telling police officers that this is the main aim is likely to alter their behaviour.

2.2 Protecting the dignity, safety and well-being of research participants

This concerns the importance of respecting the dignity and rights of participants – not causing them distress, making them afraid or diminishing their dignity. The importance of not doing harm. We should not do something which might create unhappiness or expose people to unnecessary risks. This is particularly an issue in RCTs of new drugs or treatments, but can apply in other types of research; asking people about intimate aspects of their lives can be upsetting for them. But we may not know in advance what will upset people. eg from my own research of violence in marriage (not upsetting) vs. study of hospital meals (upsetting). Service users commented that some things which are by nature distressing are so important they should be researched. What is important is to have supports in place if people become distressed.

2.3 Protecting privacy and confidentiality

Privacy: respondents have the right to keep information from the researcher. They have the right not to take part at all and also the right not to answer particular questions or groups of questions. The researcher has to inform respondents of their right to privacy and respect whatever choice they may make in this respect. If interviews are to be tape recorded or videoed respondents have the right to refuse, even though this may be inconvenient for the researcher.

Confidentiality: researchers must not divulge what they have learnt to other people without the consent of the person to whom that information applies. Legislative backing was given to this rule by the Data Protection Act of 1998. However, there are some riders to that rule:

- Confidentiality is not the same as anonymity. It has to be possible to relate data to a particular individual, in order to understand the results of the research. So each participant should be identified in a way which cannot be understood by those outside the research team. Names linked to code numbers. Data stored in terms of code numbers. List of names and code numbers kept in locked filing cabinet.
- The rule of confidentiality is not absolute. There may be circumstances in which breaking confidence can be justified, or there may be legal reasons for disclosure of information. eg of health visitor research in which child abuse in the house next door is reported to her.
- Breaking the rule of confidentiality may damage the ability of future researchers to obtain the trust of participants in research. Thus there may be a longer term loss in terms of good which might have been done. There is an important principle in terms of the research community and the respect in which it is held.

2.4 Involving service users in research

RGF consultations have involved several discussions with service users. Reminder that they include adults with mental health problems, elderly people, people with

learning disabilities, children and young people. Many are in employment; some are already researchers themselves. So some are 'vulnerable', but many are not.

Note that it was service users who said that not upsetting people should not necessarily be a goal: some important subjects are likely to be upsetting. What is important is to have some support in place in case people are distressed.

Service users are often concerned about the use that will be made of the data they give. Will things be improved because of my contribution? It can be dis-empowering if information is used for a purpose which the subjects of the research would not have wanted eg research with disabled people, 'Nothing about us without us'.

2.5 Protecting the welfare of research staff

Much social science research is done by interviewers who may find themselves in quite dangerous situations, for example, going around housing estates at night – taking a mobile and telling people where they are going may be important. Other interviewers may be distressed by what they hear and need counselling to support them.

2.6 The publication and dissemination of research findings

This is a central responsibility of researchers, not just contractually to the funding body, to their employer and the people who will use the research – but also to those who took part. Researchers have a responsibility to disseminate appropriately and to feed back to those who took part in the research.

More generally there is an implicit promise that research be conducted according to recognised principles of good practice, which includes:

- Not using data collection instruments which may bias the results
- Not falsifying or massaging the raw data to get the desired results

2.7 The power imbalance between researchers and research participants

The researcher is likely to have more power than the subjects of the research and that power must not be exploited. Research can disempower or empower people. Involving service users in the planning and carrying out of the research is one way to give them more power: they know what should be researched.

The British Psychological Society Ethical Principles say:

Investigators should realise that they are often in a position of authority or influence over participants who may be their students, employees or clients. This relationship must not be allowed to pressurise the participants to take part in or remain in the investigation.

3 DOMAINS WITHIN THE RGF

The aims of the RGF are to be secured by implementing key standards in five domains:

- **Ethics:** ensuring the dignity, rights, safety and well being of research participants: the main focus in this presentation.
- **Science:** ensuring that the design and methods of research are subject to independent review by relevant experts – peer review.
- **Information:** ensuring full and free public access to information on the research and its findings – often a concern among participants who take part in research.
- **Health and safety:** ensuring at all times the safety of research participants, researchers and other staff. Note that research staff are covered by the RGF as well as participants.
- **Finance:** ensuring financial probity and compliance with the law in the conduct of research.

4 THE RESEARCH GOVERNANCE FRAMEWORK

- The *Research Governance Framework for Health and Social Care*. The RGF was published by DoH in 2001. It came in response to a number of widely publicised scandals relating to research in the health service eg Alder Hey baby parts and Bristol Hospital scandal. There was strong ministerial support for setting up a system to ensure that such things cannot happen again.
- Research governance also reflects **recent legislation**, in particular the European Directive 2001/20/EC of the European Parliament and Council on the conduct of clinical trials on medical products, the Data Protection Act, and Health and Safety legislation.
- **Ethical review** a key part of research governance. Builds on well-established systems in the NHS, with Local Research Ethics Committees (LRECS) and Multi-site Research Ethics Committees (MRECS).
- Note that it is the RGF for **health and social care**, but the situation in the social care field is rather different from that in the NHS. The Baseline Assessment Exercise (BAE) surveyed CSSRs and showed that only two currently had their own ethics committees, though 14 per cent had a system for ethical review, usually based in a partnership with a university.
- **Separate development of research governance in social care:** same commitment to core principles, but different mechanisms by which principles are to be implemented.
- **University involvement** is also important and reflects concern in universities and research institutes about possible litigation – universities are currently engaged in setting up ethical review systems, if they do not already have them. The ESRC has recently carried out a review of university arrangements for ethical review and is developing a Research Ethics Framework for Social Sciences Research.
- Baseline Assessment Exercise was carried out in 2002 and 2005, mapping the situation in Councils with Social Services Responsibilities (CSSRs), but the situation is fast changing.

Note that as many people work in social care as in the NHS but many work in the private and voluntary sector or within education depts. There are many differences between research in the NHS and the research which takes place within the

organisations which provide social care and social services. These differences relate to definitions of the word ‘research’ and to differences in the scale, volume and funding of the research, the context in which research takes place, the mix of stakeholders involved, and the multiplicity of academic disciplines.

5 DEFINITIONS IN HEALTH AND SOCIAL CARE RESEARCH

The definition of research used in the RGF is:

‘The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods’, based on an accessible written plan (Department of Health, 2001)

This is a relatively tight definition of research and implies that much research-like activity will be excluded from the controls involved in the RGF. ‘Disciplined enquiries’ and small scale studies in the NHS have never been covered by RECs. One reason for the troubles which many research proposals face when they go to NHS RECs is that they are not the studies which RECs typically see – for example, student projects when members of the REC expect to approve RCTs.

In implementing the RGF in the field of social care, this was the definition which was proposed, but the consultation process revealed widespread concern about the mass of smaller studies which take place in the social care field.

So a more recent definition of ‘social care research’ is:

All research that involves access to service users or staff by researchers who are NOT employees of the local council or its contracted agencies (Stage 1 of the Social Care Implementation Plan)

At the second stage of implementation it is proposed that the remit is broader:

All forms of disciplined enquiry that set out to address clearly defined questions by the systematic collection of data using explicit research methods and techniques.

6 DIFFERENCES BETWEEN CLINICAL RESEARCH AND SOCIAL SCIENCE / SOCIAL CARE RESEARCH

Social care research differs from much NHS research in terms of:

- **Academic disciplines**
Health services research and social care research draw on a wide range of social science disciplines, including economics, geography, psychology, social policy, social work and sociology.
- **Research methods**

Methods are likely to include both quantitative and qualitative surveys, focus groups, participant observation, anthropological and ethnographic methods, case studies and so on.

- **Sources of funding**

The funding base is relatively fragile, with relatively few sources of funds and none to compare with the drug companies. Few social care professionals manage to combine their practice with research and there is not a strong tradition of practitioner research as in the NHS.

- **Scale of studies**

Many very small in-house studies. The 2002 BAE showed that 80 of all research in CSSRs are in-house studies carried out by practitioners, students or in-house researchers, with little or no extra funding.

- **Involvement of service users**

An important difference between health and social care is in the **involvement of service users and their representatives** in research, as well as in debates about ethics review. Several meetings have taken place with service users. The views they put forward included:

- Ensuring that participants know they have the right to refuse;
- Making the purpose and methods of research clear to participants;
- Recognising that there may be conflicts of interest between service users and their relatives;
- Paying research participants;
- Providing for a complaints procedure;
- Ensuring that participants are properly thanked for their contribution.

7 PROGRESS WITH THE RGF IN SOCIAL CARE

Progress in social care research

- **Progress Report** is on the DoH website. It documents extensive consultations which showed that while there was strong support for ethics review in social care, there was considerable concern that this review should be tailored to the particular characteristics of social care research.
- **The Baseline Assessment Exercise in CSSRs.** Carried out to find out more about the current situation in social care a Baseline Assessment Form and circulated to all CSSRs. The results showed that while only two councils currently had their own Research Ethics Committee (REC), around 14 per cent had a system in place for the ethics review of research, often based in a partnership with a university; another 27 per cent had plans for developing a system of ethics review. Repeat in 2005.
- **Implementation Plan** Sets deadlines for actions in social care. Check DoH web site
- **Options for ethical approval in social care.** These are very much still under discussion. The recent consultation exercise presented four options:

Model 1 A national system of social care RECs, similar in operation to NHS RECs, but organisationally distinct

Model 2 A specialist social care committee system, operating within the existing COREC/OREC structure

Model 3 A national system of social care ethics review, operating within a tiered decision-making process and using panel review

Model 4 A pluralist system of ethics review based on local diversity

Note that the response to the consultation was good. There was a clear difference between responses from the social care and voluntary sectors and from the health sector. **Most of the major national organisations in social care responded** at length, in addition to national voluntary organisations and social services organisations at local authority level. By contrast, few of the responses from the health service came from nationally-based organisations, and the majority were from individuals in locally or regionally-based organisations, many being quite brief.

Almost all social care responses argued for a system of ethics review which would combine the best features of **Models 3 and 4 above**. 'Model 3/4' was a three tier system: it would consist of a national ethical committee to approve national and multi-site research, regional consortia to approve high-risk and inter-authority research, and research governance systems within CSSRs to approve the majority of the work which takes place within local authorities. It was pointed out that many of the structures which would be necessary are already in place.

8 CONCLUSIONS

Research governance is concerned with protecting some of the most vulnerable people against being upset or exploited by researchers; it is also about protecting those who actually do research, who must be some of the most marginal members of university staff.

So far the consultation process in the field of social care has suggested that there is considerable support for the RGF, allied with a variety of anxieties about the definition of research in this context, the process of implementation, the delays which may be created in research timetables and the resource implications.

However, it is also important that good research goes on taking place and is not unduly delayed or messed up by bureaucratic procedures. Research is about developing a more reflective approach to the society in which we live and to the services which the welfare state provides. The key for the future will be to devise systems which will combine a reasonable level of protection for those who take part in research with continuing support for good research in the important areas of health and social care.

In conclusion, it is important:

- not to create bureaucratic barriers to good research
- to recognise the fragility of research and research careers in social care
- to make ethics review responsive to the variety of research methods used in the social sciences
- to respect people's right to choose whether or not to take part in research
- to create a climate in which research can continue to play a part in the development of better social services