Supporting ethical practice in primary care research: strategies for action

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SUMMARY

Researchers in primary care share the general ethical obligations of all researchers. However, these obligations may raise different issues in the unique context of primary care. Current professional ethical guidance for primary care research is complex and fragmentary. The newly introduced research governance framework does not specifically address primary care research, and recent changes in legal requirements have significant implications for research.

In this paper, ethical issues arising from research in primary care are considered, current standards and resources are described, and strategies for supporting ethical practice are discussed. Four ethical issues are discussed: consent and competence; confidentiality; power relations; and procedural issues. In the final part of the paper, broad strategies to support ethical practice in primary care research are recommended. These include education and resources, greater clarity of relevant standards, financial support, a greater role for primary care networks, and greater public debate.

Keywords: *research ethics; legal standards; research governance framework.*

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Introduction

ALL researchers share general ethical obligations towards participants in research of the type outlined in the Declaration of Helsinki.[1] The research governance framework recently launched by the Department of Health is aimed at codifying these obligations and ensuring high scientific and ethical standards for all research.[2] This initiative highlights the need for researchers to be aware of their responsibilities and to have appropriate support in fulfilling them. The framework is written in general terms, which are broadly applicable to all types of health related research. However, there are several features of primary care that contribute to a unique environment for research that have not received due attention. There are differences between doctor–patient relationships in primary care and those in secondary care. In primary care, relationships are often long-term, so that the consequences of research projects may influence care long after the project has finished. General practitioners (GPs) with a commitment to holistic, patient-centred care may find it difficult to balance the needs of individual patients with the needs of present and future communities for research information. Research confidentiality may be hard to maintain within multi-disciplinary teams or in the context of treating several members of a family.

In spite of the ethical relevance of these features, there is little information about ethical issues facing researchers in primary care.[3-5] The research governance framework, and other changes currently occurring in legal and regulatory standards for research, contribute to an atmosphere of increasing complexity.[6-8] New governance regulations, which may lead to greater clarity about the role of local research ethics committees (LRECs), were introduced in mid-2001.[9] These are welcome, as there is currently some confusion about their roles.[10]

In this climate of change, there has been some attention focused upon supports for primary care, in the form of research networks[11] and proposals for ethics support for clinical practice.[12] To date, there has been no specific discussion about support for ethical practice in primary care research, which is poorly supported anecdotally. This paper offers an analysis of ethical issues in primary care research and suggests seven broad strategies to develop and support ethical research.

Ethical issues in primary care research

Four ethical issues are described in this section (Box 1), together with possible strategies for addressing the identified problems. This discussion is based on the experiences of primary care researchers who participated in two work-

Consent and competence
Confidentiality
Power relations between researchers and participants
Procedural issues and research development

Box 1. Ethical issues in primary care research.

shops, and on the authors' own experiences.[13]

Consent and competence

The process of seeking and obtaining consent from patients or members of the community to participate in primary care research presents a number of problems. Recruitment usually occurs in two stages: obtaining a list of potential participants, and then contacting these people to participate in specific projects. The first stage may breach confidentiality, which is discussed below, unless contact is made by the practitioner. Recruitment by practitioners protects confidentiality, but may compromise the integrity of the decision to participate because of undue persuasion or coercion. Patients may be wary of refusing participation in research if this comes from their treating practitioner, as they may fear compromising their long-term care relationships. In general practice, this relationship underpins access to all future health care, therefore the harms from compromising the relationship are proportionately greater than those in secondary care.

The second stage of consent involves informing participants about the nature of the research, including possible harms and benefits, and about the process of research. It is not clear who is the most appropriate person to seek this consent. Researchers have a vested interest in obtaining consent for their studies, but they are also the ones with the greatest knowledge about the study, and are best placed to answer any questions. Practitioners may know less about details of the research, but have the advantage of knowing the patient, and may be better able to address a patient's specific concerns.

Fully informed consent for research requires balancing the scope and depth of information against the sheer length of materials. How much should participants be told about the ways in which data will be used, or the interests driving the research? A significant proportion of pharmaceutical trials in general practice are little more than post-marketing surveillance studies, in which GPs are remunerated for recruitment.[14] Patients may rightly view this kind of research differently from a trial funded by a public body with no direct financial beneficiaries, which aims to increase medical knowledge, or a qualitative project undertaken as part of a higher degree.

Obtaining consent from patients whose first language is not English, or whose cultural background differs markedly from that of Western medicine, raises special issues. Translations of information materials and consent forms are not always available, and using relatives or local translators leads to loss of control over the accuracy of the information and may involve undue persuasion, or breach confidentiality.[15]

Research with vulnerable groups requires special attention to ensure that members are not exploited or coerced into research. For example, it may be difficult to recruit homeless people for a trial, or obtain consent for research participation from people with depression, as a result of their illness. If research is to proceed in such cases, the level of persuasion may exceed that usually approved by ethics committees. On the other hand, it is important that research does proceed with vulnerable groups despite the challenges, otherwise they are excluded from any potential benefits.

Possible strategies to address consent and competence issues include the following: use of third parties (who are well-informed but disinterested, and bound by confidentiality agreements) to obtain consent, which would be costly; introduction of mandatory cooling-off periods before consent to participate is accepted (this already occurs in some areas, but is not part of the research governance framework); greater emphasis on the obligation of individual researchers to check participants' understanding of the project and its implications throughout data collection;[16] more training for researchers in the process of obtaining consent, including ethical and legal issues; provision of more information for potential participants about implications of research and ways in which data will be used (for example, publication of speech extracts in qualitative research); and raising public awareness about research in primary care through general publicity in surgeries and through GPs notifying patients about projects that may be relevant to them.

Confidentiality

The ethical duty to maintain confidentiality is supported by a complex legal framework. Information held by practitioners about their patients is confidential, and disclosing any personal information details to third parties for research potentially breaches all of the regulations listed in Box 2.

The Data Protection Act 1998 specifically prohibits direct access to GPs' lists. Researchers can no longer access patient lists held by GPs unless patients have given prior consent for their information to be used in this way. Meeting this requirement creates more work for GPs and their staff. In addition, the Data Protection Act requires that the researcher collecting the data informs the research participant about who will have access to their data and how the data will be used in the future. Providing accurate answers to these questions may be difficult; research staff often have a rapid turnover, and not all of the final uses of the research data may be fully anticipated at the time of collection. These requirements may seem onerous and complicated, especially when using stored data or case notes.

Appeals to the common good may sometimes justify breaches of confidentiality. However, there is little concrete guidance for researchers on this issue. At the very least, ethics committee approval provides external validation for research that breaches confidentiality, but this does not protect practitioners from professional disciplinary procedures in the case of complaints.

Communicating research findings within teams may breach confidentiality. This can be a problem if participants divulge unexpected or significant findings to the researcher, who then has to decide whether or not to breach confidentiality by reporting these findings to the practitioner who is responsible for the participant.

With regard to some aspects of primary care, it is the family rather than an individual that is the unit of care; for exam-

ple, district nurses visit homes where other family members are often involved in caring for the patient. This pattern of care may create problems with maintaining confidentiality in research, as other members of the family may be used to discussing all aspects of care. Research with children raises similar issues. The question of who should be present when children are interviewed has no single answer, as there are several factors to consider, including the age of the child, the subject matter of the interview, the preferences of both child and parents, and the setting.

Finally, publishing anonymised data may breach confidentiality if it contains potential identifiers (Box 3).[17] Some of these are obvious, but publishing qualitative research raises new questions about anonymity.[16]

Possible strategies to address confidentiality issues include the following: practitioners to identify patients who are willing in principle to be contacted for research purposes, prior to any specific projects, but this may be difficult in practice; practitioners to obtain consent from patients willing to be contacted by research teams for specific projects; recruitment to be performed by practitioners — however, this is expensive and time consuming; greater use of practice or NHS leaflets explaining confidentiality in research; participants to view examples of data results prior to publication (but note practical difficulties of tracing participants, owing to the slow process of research and publication); educational initiatives to help researchers to understand levels of anonymity and legal standards;[2,17] and research/practice team to clarify strategies for responding to significant findings prior to commencing research, especially disclosure of potentially significant information.[18]

The researcher and power relations

Issues to do with the practitioner–patient relationship are relevant to all aspects of primary care research. The research population in primary care is both more and less vulnerable than hospital-based populations. In primary care, people are not captive in a hospital bed or specialist clinic, and often are not acutely ill. However, the long-term nature of primary care relationships can create vulnerabilities, as patients may feel less able to refuse participation in research when asked by their GP, as opposed to being asked by comparative strangers who will not be involved in their long-term care.

The multiple roles held by many primary care researchers can be confusing; participants may mistake academic qualifications for medical ones, or medical practitioners doing research for active clinicians. These mistakes may lead to inappropriate disclosures or to unrealistic expectations.

Research on practitioners' own patient populations raises questions about voluntariness and researcher bias. Practitioners who have known patients/research participants for some time may have biases that affect both the selection of participants and the interpretation of data. Researchers ought to be conscious of how this can influence outcomes.

Finally, research with practitioners may lead to heightened patient expectations about future contacts or current care, especially when the research has involved longer consultations than usual or greater disclosure of personal information.

Possible strategies to address power relations include the following: greater researcher awareness of potential vulnerability and exploitation of practitioner–patient relationships; researchers to be honest about their identity, and to emphasise the non-clinical role of research; greater sharing of expertise, non-clinical researchers could provide contact details or other resources for participants, and clinician researchers could offer advice if appropriate; researchers to be aware of the pitfalls in research on their own patient populations; and participants to receive careful explanations about the process of research and future care.

Data Protection Act 1998
Human Rights Act 1998
Common Law
Professional standards (General Medical Council, Nursing and Midwifery Council, Medical Research Council)
Caldicott recommendations

Box 2. Standards for confidentiality.

Rare disease/treatment or visible illness/disability
Partial postcode or address
Place of treatment or name of health care provider
Rare occupation or place of work
Combinations of ethnicity, date of birth, place of birth, date of death
Speech mannerisms, accounts of experiences, named carers

Box 3. Potential identifiers.

Procedural issues and research development

There is confusion over apparent discrepancies in activities requiring LREC approval. Audit and evaluation may raise ethical issues, such as consent and confidentiality, but they do not currently require LREC approval, as they are not classified as research.[19] Paradoxically, evaluating a change in service delivery may require ethics approval, although implementing the change does not. Until recently, LREC approval was limited to research involving NHS patients, records, and facilities, but research involving professionals, support staff, or care providers also raises ethical issues.[18] Under the new governance arrangements for NHS ethics committees (due to be phased in by April 2002), research with NHS staff (including primary care staff) will also require ethics committee approval.[9]

Some LRECs lack expertise about the nature and methods of primary care research, particularly qualitative research. This can lead to problems in assessing ethical issues, such as potential harm from interviews.[20]

Significant ethical issues may be raised by financial inducements offered to general practices to participate in pharmaceutical research. This funding may offer substantial benefits to practices, but should not facilitate poor quality research, nor displace high quality publicly funded research.

Sharing research results with participants, which is now specified as an obligation of researchers under the research governance framework, is another area of difficulty. Owing to lengthy delays in the research process and writing up, running out of time on contracts, and publication requirements for previously unpublicised material, many researchers feel that it is not possible to honour this duty.

Finally, there is little information about the distribution of

the research burden among patient groups in primary care. Some general practices participate in multiple projects funded by pharmaceutical companies, leading to a high rate of participation among patients of those practices. The effects of this increased participation are not known.

Possible strategies to address procedural issues include the following: debate about the ethical requirements of research, evaluation, and audit, with the adoption of uniform ethical standards, irrespective of the specific activity; vetting of research proposals prior to formal submission, either by nominated members of LRECs, or by primary care research networks, to identify potential ethical problems or projects that do not require formal review; increased qualitative research expertise on LRECs and greater provision of training/support for committee members, as recommended in the new governance regulations for ethics committees;[9] dedicated funding for feedback and dissemination of research results; support for, and development of, research databases of current projects in general practice by local research networks, and co-ordination of this information with LRECs to avoid overburdening some patient populations (this already happens in some areas, but is not a requirement of the research governance framework); and increased consumer involvement in research, including public debate about the nature and benefits of primary care research.

Discussion

The authors believe that primary care researchers are aware of ethical issues and are concerned about them, and that they would welcome support in achieving high ethical standards in research. In the final part of this paper, the preceding specific strategies are synthesised into recommendations that address these issues.

Education

Further education is crucial for all of those involved in primary care research, and should include initiatives for the following groups: multi-centre research ethics committee (MREC) and LREC members — about the nature of primary care and of primary care research methods, the ethical implications of primary care, and the practical implications of meeting some of the current requirements; researchers — about understanding and meeting ethical obligations and overcoming obstacles to best practice; and practitioners whose patients are involved in research — about their responsibilities before, during, and after research projects.

Resources

There is a need to produce clear and authoritative information about ethical standards required in primary care research and how to meet them. Web-based resources would be useful and practical, as these are quick to find and access, easy to keep up to date, environmentally friendly, and require little storage space, and approval for posting within the NHS Intranet would ensure wide availability. Resources should be targeted to specific audiences, such as MREC and LREC members, researchers, and practitioners. Appropriate dissemination methods might include workshops approved for continuing professional development, and modules in research degrees, as well as succinct executive summaries. Organisations that may be suitable to take on the task of resource development include the Royal College of General Practitioners, the NHS — through the research and development programme — or academic units based in primary care. Current resources for guidance on research are listed in Box 4.

Clarification of standards relevant in primary care research

There is an urgent need to clarify and simplify the multiple standards relevant to research in primary care (Box 5). Currently, these are complex and difficult to navigate.[6] This will require debate among all interested parties, including robust consumer input, as well as professional input and academic and legal contributions. Research to identify the practical barriers faced by researchers in applying ethical guidelines will be invaluable in this process.

Funding for research

There is a need for funders of research to recognise that implementing higher ethical standards in primary care research will be costly and may require dedicated funding within grants. Developing new recruitment methods that conform with the Data Protection Act and other legal standards, and ensuring dissemination of results to research participants (as stipulated by the research governance framework), are two areas in which higher costs may be anticipated.

Developing the role of primary care research networks

Primary care research networks are now an established part of the primary care research infrastructure.[11] These networks are ideally suited to playing a role in supporting ethical research for practitioners and researchers. Support might include the provision of expert peer review and troubleshooting for research proposals prior to MREC or LREC submission; dissemination of resource materials; organisation of ethics education for researchers; maintenance of local research registers; and communication with primary care trusts. Many networks are already working in these areas.

Debate

Debate of these issues is needed at all levels. Primary care research has much to offer, but the requirements of research in turn raise ethical issues which should be debated by the public, who fund, participate in, and benefit from the research. In particular, there is a need for debate about managing the tension between protecting individuals from potentially harmful research, and the benefits to the community obtained through research.

Conclusion

Providing the conditions for achieving the highest possible ethical standards in research will benefit the public and all participants in research. The research governance frame-

Adults with Incapacity (Scotland) Act 2000: http://www.scotland-legislation.hmso.gov.uk/legislation/scotland/s-acts.htm

British Sociological Association statement of ethical practice: http://www.britsoc.org.uk/about/ethic.htm

Caldicott recommendations on *The protection and use of patient information*: http://www.doh.gov.uk/confiden/calcon1.htm

Central Office for Research Ethics Committees: http://www.corec.org.uk/index.htm

Council for International Organisations of Medical Sciences international ethical guidelines for biomedical research involving human subjects (CIOMS): http://www.cioms.ch/frame_guidelines_january_2002.htm

Data Protection Act 1998: www.dataprotection.gov.uk

Department of Health research governance documents: http://www.doh.gov.uk/research/rd1/researchgovernance/researchgovindex.htm

European Parliament Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on good clinical practice in the conduct of clinical trials on medicinal products for human use: *Official Journal of the European Communities*, L121/34, 1.5.2001

General Medical Council guidance on confidentiality: http://www.gmc-uk.org/

Human Rights Act 1998: http://www.hmso.gov.uk/acts/acts1998/19980042.htm

Medical Research Council Ethics Series, *Personal information in medical research*: www.mrc.ac.uk

National Health Service in Scotland draft research governance framework: http://www.show.scot.nhs.uk/cso/

Nursing and Midwifery Council (formerly United Kingdom Central Council) http://www.nmc-uk.org

The Royal College of Nursing (RCN): http://www.rcn.org.uk/index.html

World Medical Association Declaration of Helsinki: http://www.wma.net/e/policy/17-c_e.html

Box 4. Available resources for guidance on research.

International ethical codes for research

World Medical Association Declaration of Helsinki
Council for International Organisations of Medical Sciences international ethical guidelines for biomedical research involving human subjects

Professional

General Medical Council
Medical Research Council
British Medical Association
British Sociological Association
Guidance from individual Royal Colleges

Legal

Data Protection Acts
Human Rights Act
Common Law
Adults with Mental Incapacity (Scotland) Act

Other

Caldicott recommendations
Department of Health Research Governance framework
Defence unions' advice
MREC/LREC review

Box 5. Multiple standards for research in primary care.

work sets out an ambitious agenda for attaining these high standards. However, the framework offers little guidance on supporting ethical practice in primary care research. We believe that the issues discussed in this paper warrant further and systematic documentation and that the strategies offer practical ways of pursuing high standards — support for these strategies is urgently required.

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