

THE RESEARCH GOVERNANCE FRAMEWORK AND ITS IMPLICATIONS FOR PHARMACY PRACTICE RESEARCH

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The second edition of the Department of Health's research governance framework is expected to be published this autumn. Research governance is a system of quality assurance and safety checks that outlines the responsibilities of all parties conducting research on health and social care, including pharmacy practice research. This article outlines the key issues with which pharmacy practice researchers will have to familiarise themselves



In March 2001, the Research Governance Framework for Health and Social Care¹ was published by the Department of Health in the wake of a number of high-profile research scandals. Children's organs had been retained after post-mortem without informed parental consent. Parents described how their premature babies had been enrolled in research studies, again without their informed consent at that time. In October 2001 and February 2003, similar documents were published that pertained specifically to Scotland and Wales.^{2,3} They differ only in how they refer to the relevant legislation and organisations in those countries; fundamentally they are the same.

Now, two years later, the Department of Health is preparing to publish the 2nd edition of the framework for England, which clarifies the role required of the research sponsor and takes account of the new European Union (EU) legislation on clinical trials (Directive 2001/20/EC), which is being implemented in the United Kingdom under the Medicines for Human Use (Clinical Trials) Regulations 2003. It is expected that

Scotland and Wales will also update their frameworks in due course. Thus, it seems apposite to reflect on the implications that this framework has and will have on pharmacy practice research.

It is easy to understand the rationale behind the Department of Health's wish to improve the regulation of volunteer studies, clinical trials and other types of therapeutic research. The research subjects are clearly potentially at risk from adverse events and therefore the need for informed consent should be self-evident. However, most pharmacy practice research does not pose any obvious potential risk for participants. We

do not expect people to experience harm or sue because they take objection to the wording on a questionnaire or a question they are asked in an interview. Pharmacists and those undertaking practice or health services research may well ask why, then, should research governance be relevant to them.

The primary consideration of ethical research is not just about the safety and well-being of the research participants. It is also about their rights and their dignity. This is about the right of a potential participant to choose whether to take part in a study that they fully understand and it does not demean them in their own eyes or those of others — even if it is “just” a questionnaire survey.

Research governance sets standards for research, defines mechanisms to deliver them and describes how this should be monitored and assessed (Panel 1). It seeks to improve research quality and bring the general standard up to that of the best, while trying to prevent poor performance, adverse incidents, research misconduct and fraud. The framework pays particular attention to clarifying responsibilities and accountabilities of the people involved in research — the

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researchers themselves, the organisations that fund research and the organisations within which the research takes place.

This article does not seek to present all the detail of the research governance framework. What we have sought to do is to outline some of the key issues that we think pharmacy practice researchers need to familiarise themselves with if they are to conduct their research in accordance with the framework's requirements. This framework will apply to researchers practising at all levels and will also need to be considered by research supervisors (Panel 2). Considerable space is given to the subject of ethics and ethical approval, since this has the largest impact on the conduct of and publication of pharmacy practice research.

STANDARDS

The framework document outlines research standards in five key areas: ethics, science, information, finance, and health and safety. The standards themselves are set out in an annex to the main document and refer to already existing legislation or guidance. Examples include the Data Protection Act 1998, Medical Research Council (MRC) Guidelines for Good Clinical Practice in Clinical Trials 1998 and the Medicines for Human Use (Clinical Trials) Regulations 2003.

The standards for financial probity and health and safety are as expected for any work (research or otherwise) that is conducted in the public sector, and are therefore not discussed here. Those that are to do with research ethics, the quality of the research methods and methodology (the standards on "science"), and the dissemination of research findings (the standards on "information") are highly relevant to pharmacy practice research and are discussed in more detail below.

Is ethical approval required? In the not-so-distant past, it was the understanding of supervisors and many people working in research that it was only invasive research on patients that had to go before a National Health Service (NHS) ethics committee. However, the Central Office for Research Ethics Committees (COREC, see glossary) makes it quite clear that this is no longer the case. Research on NHS patients, ie, those subjects recruited by virtue of their past or present treatment by the NHS (including those treated under contract with the private sector) are still included in the list of types of research that require ethical approval. However, research that involves access to records of past and present NHS patients or the use of, or potential access to, NHS premises or facilities (including NHS staff), must also be reviewed independently by a local research ethics committee (LREC, see glossary) to ensure that it meets ethical standards. This means, for example, that a questionnaire survey of nursing staff or a study involving the extraction of prescribing data from the electronic patient record will need to be planned in such a way as to allow time for this ethical review. Not

Panel 1: Outline of Research Governance Framework for Health and Social Care

- Research governance sets standards
- Research governance defines mechanisms to deliver standards
- Research governance describes monitoring and assessment arrangements
- Research governance improves research quality and safeguards the public by:
 - Enhancing ethical and scientific quality
 - Promoting good practice
 - Reducing adverse incidents and ensuring lessons are learnt
 - Preventing poor performance and misconduct
- Research governance is for all those who:
 - Participate in research
 - Host research in their organisation
 - Fund research proposals or infrastructure
 - Manage research
 - Undertake research
- Research governance is for managers and staff, in all professional groups, no matter how senior or junior

Panel 2: Areas to which the framework must be applied within pharmacy practice

- Undergraduate (MPharm) projects
- Preregistration projects
- Postgraduate master's degree projects
- PhD programmes
- Service evaluations involving patients or NHS staff
- Empirical practice research

only will management approval to conduct such studies not be forthcoming, it will become increasingly difficult to publish research that has not had the requisite approval from an ethics committee.

This requirement for ethical review is regardless of whether the study is to be conducted in primary or secondary care or whether it is to be conducted by a team of experienced researchers or by an undergraduate student or preregistration trainee. There is no special treatment available for student projects — they are treated just the same as any kind of research. There is no longer "chairman's action" available for such projects. It is the responsibility of the supervisor of student projects to ensure that the necessary approval has been obtained.

However, research that is conducted in community pharmacies is currently a grey area. If the study is conducted with patients presenting an FP10 prescription, then the position is clear. They are being recruited into the study "by virtue of their past or present treatment by the NHS" and therefore the study must be submitted to an ethics committee. If they are coming into the pharmacy to buy perfume or cosmetics, then clearly they are not in this category. However, if they are purchasing over-the-counter medicines, where do they fit in? What if they were advised to purchase the medicines by their general practitioner? Observational studies in community pharmacies do not take place on NHS premises, or with NHS staff, but they may well

observe NHS patients. In such circumstances, the researchers should send a letter to the chairperson of the LREC where they would be submitting the study, explaining what was proposed and enclosing a protocol. An opinion will then be given as to whether the study requires or does not require a full LREC submission.

It is also worth noting that many universities have their own requirements for the ethical review of research involving human beings. The University of Manchester, for example, states that "it is of paramount importance that all research involving human subjects is considered and approved before it starts by a properly constituted ethics committee". The review that is conducted by an NHS ethics committee will be accepted as fulfilling this requirement. However, studies involving human beings that do not need such approval, such as "market research" type of interviews with members of the public, would still require full review and approval by the Senate Ethics Committee before they could commence.

What do I have to do? The research governance framework does not lay down the exact procedures for obtaining ethical approval, but in the past few years there have been a number of changes to how ethics committee applications are dealt with. The Governance Arrangements for Research Ethics Committees were published in July 2001 and they have sought to standardise the organisation and outcomes

Glossary

LRECs	Local research ethics committees are convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards. Each LREC covers a geographical area similar to that of the old health authorities.
MRECs	Multicentre research ethics committees are the committees convened to provide independent advice about research taking place within the boundaries of five or more research sites (see below).
COREC	The Central Office for Research Ethics Committees (www.corec.org.uk), on behalf of the Department of Health in England, has responsibilities that include co-ordinating the development of operational systems for LRECs and MRECs, maintaining an overview of the operation of the research ethics system in England, managing the MRECs in England, and implementing and maintaining consistent operating procedures and standards for RECs across the UK. (COREC works closely with colleagues with similar responsibilities in Scotland, Wales and Northern Ireland.)
ORECs	Regional offices of research ethics committees have been established and are managed by COREC to oversee the activity of LRECs.
Research site	The geographical area covered by one health authority, whether the research is based in institution(s) or in the community. This area will be covered by a number of LRECs, depending on the needs of the authority.

of the ethical approval process. Eventually, this should make the process more streamlined and consistent, even if it is currently in a state of flux.

In the near future, there will be a standard electronic application for all ethics committee applications, both to multicentre ethics committees (MRECs, see glossary) and LRECs. Currently, this four-part form is being tested on applications to MRECs only but, after October 2003, it should be available for applications to all committees. The first two parts of the form are currently sent to the MREC that will do the initial ethical review; the other two parts (which will partially self populate from the first two parts) are intended for locality and management approval (see below) in all areas where the research will be conducted.

Studies to be conducted at one or two research sites (see glossary) need only be submitted to one LREC in each site; those being conducted at five or more research sites must be submitted to an MREC. Currently (until at least October 2003), researchers who are conducting studies crossing between two and four research sites may choose to submit their study either to an MREC or to one LREC in each site. Under the new arrangements, if one LREC in a research site has given a favourable opinion on an application, then the other LRECs in that site need only give locality approval for the study to be conducted in their area. Similarly, if the research has been approved by an MREC, only locality approval needs to be obtained from each relevant LREC.

The short locality approval form, together with the original application and LREC or MREC approval letter, has to be submitted to the other LRECs within which

the research will take place. Opinion is then given on the suitability of the researcher and the facilities for conducting the research and comment made about whether there are any unusual issues about the research subject group in that area. For example, in a study of emergency hormonal contraception, which had MREC approval, an LREC requested that the information sheet be translated into their local minority languages, because they believed that informed consent could not be obtained locally if this did not occur. One advantage of this system is that it is now possible for one LREC to transfer full applications (not those for locality approval) to another committee if their next meeting is full, to enable researchers to have an ethical opinion as quickly as possible.

One of the key areas of ethical research is that freely given, informed consent is required from the participants. Because of the importance of this basic right, the participant information sheet is usually closely scrutinised by ethics committee members. In particular, it should be written in plain, concise English, should invite participation and should be factually true and not withhold information. If there is a risk of the whole truth influencing the outcome of the study or reducing patients' confidence in their GPs, for example, this needs to be justified in the application form and the information sheet must at least not be misleading. If people are being asked for interviews, or to complete questionnaires, they should be told what to expect and given a realistic idea of the time commitment and the general content of the questions. All information sheets should make it clear that participation is entirely voluntary and that people can withdraw their consent at

any time. If the research participants are potentially in a dependent relationship with the researcher (such as subordinates in a department or students on a course) then the recruitment procedures will be examined very closely.

The Department of Health has an initiative to encourage patients to become actively involved, not just as research subjects, but working with researchers to decide what and how research should take place, and how results are interpreted and used in practice. Clearly, not every patient can or would wish to do this, but pharmacists often know "expert patients" who could become involved in such a process. The research conducted may then be more relevant to patient needs than that which reflects researchers' interests alone.⁴

How are standards in research quality to be maintained? Standards of good quality research are laid out in the document. One point that is considered essential is that due account is taken of existing literature (especially systematic reviews, which are now becoming more common in pharmacy practice research), because research that unnecessarily duplicates other work is, of itself, considered unethical. However, with so much pharmacy practice research unpublished, this can be rather hard to do. The Guild of Healthcare Pharmacists has an invaluable resource of currently published literature on its website. This literature review sometimes appears to be left to the end of the preparation of a protocol, even to the writing of the final report, which does nothing to further the unnecessary duplication of research.

Arrangements for peer review should be in place, commensurate with the scale of the research. Projects that are submitted for open competitions (such as the Galen and Linstead or Research Council awards) have peer review as part of the assessment and funding process. For small-scale pharmacy practice research, it would be adequate for a local practitioner with appropriate training and experience or university supervisor to provide this review. However, this does presume a core level of expertise, particularly in those who supervise preregistration projects, which we must foster and nurture.

Additionally, "raw" research data (eg, the original questionnaires and data files) should be retained, to allow both further analysis (perhaps in comparison to a later period) and quality monitoring and inspection. The time for retention is undefined, but it is usual for this to be several years or at least until the work has been published.

Why should research be disseminated?

Research is conducted for the benefit of patients, users, health care professionals and the public in general. Pharmacy practice researchers, therefore, need to note the recommendations surrounding the appropriate dissemination of research findings. This should mean publication in scientific or professional journals or presentation at a conference to a relevant audience. It must also mean the preparation of comprehensible

Panel 3: Key elements of a quality research culture

- Respect for participants' dignity, rights, safety and well being
- Valuing the diversity within society
- Personal and scientific integrity
- Leadership
- Honesty
- Accountability
- Openness
- Clear and supportive management

reports to inform the research participants of the findings and their implications.

Many small-scale student research projects are conducted because they are convenient — resources and expertise exist and recruitment of research participants does not pose any problems. Once completed, the research report then languishes on a shelf, never to be read again. People choose to take part in research for a variety of reasons, including that they believe it will be for the “greater good”.⁵ It can no longer be acceptable to ask people to devote their time and energy to providing us with data, which is not then disseminated to enable that “greater good” to be achieved.

RESPONSIBILITIES AND ACCOUNTABILITIES

The framework document details the responsibilities of all participants in the research process from the researchers themselves to their managers, the research sponsors and the funding agencies. The framework required all research to have had a sponsor by March 2003. The research sponsor has the responsibility for ensuring its compliance with the standards outlined above. For research that is funded internally by a university, hospital department or community pharmacy organisation, the sponsor would be the employer. However, the research funders are also expected to take on this role, in addition to commissioning the research. In the main, the funding bodies were concerned about the lack of clarity about what they were expected to do and the largest of the medical charities, the Wellcome Trust, has initially refused to do it. The result has been that the Department of Health has delayed the deadline for the identification of a sponsor until March 2004, pending clarification of the role of the sponsor in the 2nd edition of the framework.

Clearly, researchers must conduct their studies to the highest scientific and ethical standards possible. To ensure this, there is specific mention made about the need for all those involved in research to be appropriately qualified, by education, training and experience. This is specifically stated as the responsibility of employers of staff, in both the private and public sector. Directors of pharmacy, for example, will be responsible for implementing this on behalf of the hospital trust. The Department of Health intends to promote the inclusion of research governance in pharmacy undergraduate courses and continuing education, among other similar courses. The current requirements for the four-year undergraduate MPharm courses dictate that all students undertake a research project of three to six months' duration. The current framework, therefore, places an obligation on schools of pharmacy to ensure that not only is ethical approval sought when necessary, but also that students are given appropriate research training and grounding in the principles of research governance.

DELIVERY SYSTEMS, MONITORING AND INSPECTION

Organisations undertaking, sponsoring, funding or hosting pharmacy practice research must ensure that the standards and good practice set out in this framework are followed. In addition, systems should be able to detect failures to adhere to the requirements, via routine and random monitoring and audit. The research and development departments of primary and secondary care trusts now have systems in place to ensure that they know about all research conducted on their premises. Some scan the minutes of the ethics committee meetings to ensure that they have been informed about all relevant research.

Currently, most trusts have separate forms for researchers to use to inform the

necessary people about their project, in order to get management and financial approval. When the new electronic form becomes available, this will be much more streamlined, using a separate section of the overall larger form.

Adherence to this framework of research governance must be demonstrable. Pharmacists will be no different from other health care researchers in having to work within the current and new systems of monitoring and inspection. The Department of Health intends sanctions to be put in place, to deal with unacceptable research standards. In particular, monitoring will check that systems are in place to detect and investigate possible research fraud, such as fabrication of data.

Some of the standards set out in the existing guidelines or legislation are clear-cut. However, others require judgement and interpretation. For these, the framework suggests the development of a quality research culture (Panel 3) within organisations where research takes place (such as hospital or primary care trusts). A quality research culture is considered essential for proper research governance; promotion of its principles and values must be prioritised.

CONCLUSION

The most important implication of the research governance framework is that almost all the pharmacy practice research that we do will now need ethics committee approval, probably followed by management and financial approval from the relevant trusts. This will mean that researchers will have to include at least three months in their plans, to ensure adequate time for this. Obvious advantages will be that it will result in better-planned research and prevent the conduct of poorly designed or ethically questionable research. However, for preregistration or undergraduate projects, this planning means that it will be the supervisors who will have to prepare the protocol and ethics application, probably with minimal, if any, input from the students who will be doing the research. This will have a profound impact on the research training that conducting the study will provide. Further, the procedures for obtaining approval to conduct even a small research project may be perceived to be so arduous as to deter some researchers. The longer-term impact on pharmacy practice research, a respected discipline that has grown from the seed of small research studies conducted by enthusiastic practitioners, remains to be seen.

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