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Ethical approval for national studies in Ireland: an illustration of current challenges.

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Abstract

Background: Ethical approval of research projects is, appropriately, an essential prerequisite in health settings.

Aims: This paper outlines difficulties encountered with procedures for gaining ethical approval for two multi-centre surveys in Ireland.

Method: The experiences of two national surveys are compared.

Results: Delays in processing ethics applications led to substantial delay in both surveys. Research Ethics Committees assessed applications in an idiosyncratic manner.

Conclusion: In Ireland, there is currently no accepted mechanism for single location ethical approval for multi-centre studies. Instead, they require separate approval from all participating centres. The challenges of this system of application to multiple committees are outlined in this paper, and possible solutions presented.

Introduction

Evidence-based practice is informed by research. Health services research provides policy makers and service providers with information to plan for healthcare needs and for service evaluation. Health research involves finding the evidence for best practice and may be distinguished from audit, which addresses whether best practice is being followed. Ethical review of health services research is entirely appropriate and serves

the interest of the general public, funding agencies and the broad research community. The process of requiring ethical approval has expanded very rapidly from coverage of clinical trials only, to coverage of all human and animal research. At present, Research Ethics Committees (RECs) may distinguish between clinical trials and other human or animal research (such as health services research and audit). In practice however, most of the RECs preside over both clinical trials and other research submitted for approval, including audit. Audit, while not strictly research, is often undertaken as a research-type activity and will use staff time and resources. Institutions differ in the extent to which they require ethical evaluation of audit-type projects. In some institutions, there may be a wish to have documented such information-gathering work which is conducted on an irregular basis.

RECs have only recently been established in many centres and there appears to be significant variation in their modes of operation. For example, some RECs require the investigators to attend REC meetings. Of concern is the fact that conflicting decisions can be taken by different committees considering the same or similar research protocols. The time taken to obtain ethical approval for multi-centre studies is also a concern. This problem is not unique to Ireland[1]. The European Union (EU) is working to establish formal procedures and time limits for ethics submission and review[2]. This paper provides examples from our recent experience to illustrate areas of concern, to foster discussion of the challenges among researchers in Ireland and to consider some possible solutions.

Two studies recently undertaken by the Health Services Research Centre (HSRC) at the Royal College of Surgeons in Ireland (RCSI) involved data collection in national samples of hospitals. One study was a national evaluation of the management of acute coronary syndromes in all 39 hospitals providing cardiac services. The other was a staff survey of attitudes to organ donation. It was conducted in all relevant 37 public hospitals nationally. There is currently no single centre or group who can provide ethical approval that is acceptable across hospitals nationally. Both studies applied to and were given ethical approval by the RCSI REC. Researchers then contacted all potentially participating hospitals and asked about their ethics review procedures. They noted that the study had already received overall ethical approval from the RCSI REC. Details relating to processing the project at the various centres throughout Ireland are presented in table 1.

- Table 1 about here -

A number of idiosyncratic requests arose in the process of seeking ethical approval. In one hospital, the staff survey protocol was sent to both the REC and a patient-focused hospital liaison committee. While the REC provided approval, the patient-focused committee requested a number of changes to the (staff-only) interview schedule. In another hospital, REC approval was granted but the researcher was subsequently (informally) notified that approval was also needed from an internal research access committee who aimed to evaluate the level of staff input required to facilitate studies. This committee was not mentioned in correspondence by the

hospital's chief executive or REC. Its existence only became evident when plans to implement the study at ward level were initiated. Approval from a risk management group was required following REC approval at another centre. In another centre, one local sponsoring consultant physician was required to make a Designated Research Application before the researcher could seek REC approval. Two hospital executive committees and two senior consultants considered the question of acceptability of the study in two hospitals where RECs also operated. Finally, one consultant continued to insist that the local hospital REC provide evaluation (rather than the Health Board REC), despite confirmation from the relevant CEO's office that the hospital in question did not have a local REC.

Most centres had their own application form. While there were similarities across centres, the process of completing multiple application forms was a time-consuming one. In many cases, it was difficult to find out who to contact for details of the hospital's REC procedures and forms, when the next REC meeting was scheduled and whether the researcher needed to attend. Other sources of delay in processing applications including postponement of scheduled REC meetings.

One application took fully seven months to process, because of various administrative difficulties. Obviously, this is a significant strain on a project in terms of resources and logistics. An estimate of researcher time required to process ethics applications alone in a multi-centre project is surprising – our estimate is a two month full-time equivalent period but with the workload extending across approximately a 5 month timeframe: between time taken to complete different forms; contacting committees

for individual arrangements; travelling to committees to attend meetings; resubmissions; re-contact for other required procedures/committees, etc. Ultimately all ethics committee applications for the two projects were approved.

The time that may be required to obtain ethical approval is an important concern for researchers and research funders. Failure to predict and 'cost' for the time required for completion of the REC approval process can result in overruns and even abandonment of otherwise sound projects in relevant centres. The time required is likely to be either underestimated by researchers and/or considered excessive if requested in grant applications by reviewers.

That acquiring ethical approval should be so fraught with difficulties is not inevitable but rather suggests the system for REC approval itself requires review. Some observations from our experiences in conducting the studies presented above are illustrative of how the system for REC approval has failed to keep pace with the increasing demands made upon it.

Firstly, the administrative tasks associated with REC appear to be poorly supported. In our experience only one REC had dedicated secretarial/clerical support. Most operated with the REC chairperson (usually a senior hospital consultant) supported by a member of hospital staff (frequently a professional employed in the hospital laboratory setting), with clerical services supplied on an ad hoc basis by personnel from various work areas within the hospital. Tracking the progress of applications is difficult. In many cases, personnel from clinical and laboratory services within

hospitals appeared to have responsibility for progressing applications and supporting RECs. It is assumed that this is in addition to their routine tasks, which given the workload in most hospital departments today, allows little scope for added duties.

Secondly, application forms for ethical review are generally formulated in the 'clinical trial' model. Many RECs were set up specifically under the Clinical Trials Act (1987). This format is ill-suited to a wider programme of research activity. In our experience, completing the documentation and meeting the stated requirements based on the 'clinical trial model' presented a number of difficulties:

- Much of the information requested is inappropriate in the context of health services research.
- There is often a requirement that the principal investigator (PI) is a hospital consultant. This may be inappropriate in the context of service research and indeed has the potential to introduce bias where a project is effectively reliant on 'sponsorship' by a service which is being assessed or investigated. The requirement for a named PI from a hospital in one of our studies resulted in all correspondence relating to the project being routed through this local consultant (nominated and agreeing to act as PI to facilitate progress). This caused considerable confusion, delay to the project and inconvenience to the consultant.

Finally, RECs may take on a role, or be required to act in a manner, that goes beyond consideration of ethical concerns. One area which this is evident is comment on study methodology. It is of course the case that poor methodology makes for bad science.

Quite appropriately there are ethical concerns in approving a methodologically flawed study. In our experience however, some questions raised by RECs showed poor comprehension of methodological issues, or a willingness to propose alternative or 'preferred' methodological strategies. For instance, one REC in the group described initially required (and later retracted following correspondence) alterations to the methodology in a manner that would have compromised its scientific integrity. In conducting multi-centre studies with single institutional RECs, it is particularly important that the undertakings of the RECs should be restricted to the review of ethical considerations.

A number of recommendations can be proposed from the observations above. Firstly, the composition of an REC needs to be tailored to the topics/disciplines being assessed. Individuals with expertise/experience in the research methods to be used in the submitted research are needed. Since the RECs under consideration are hospital-based committees, there has typically been a preponderance of clinical medical personnel on such groups. Epidemiological and social science members are increasingly needed to assess the wider range of projects submitted to RECs. Secondly, consideration should be given to the development of national guidelines for the operation of RECs. A single national REC is an attractive option but likely to be unmanageable in terms of the time requirement for staff or the legal responsibilities they would face. However, this option may be required if the recent EU directive[2] is implemented fully. Directive 2001/20/EC may restrict the volume of research being conducted. It is also likely that several types of research (e.g. research on

incapacitated participants) will become increasingly difficult to conduct, as proxy consent of a legal representative will be required.[3]

A more manageable option may be a system of mutual acceptance of approval across centres for multi-centre studies (this would be facilitated if centres were committed to national guidelines). Another system would be for centres to focus on specific types of ethical application, e.g. animal research. Approval is now required from single RECs for projects as diverse as hospital-based clinical trials, community health studies and animal research. These options need to be discussed in open fora if progress is to be made. The most acceptable organisers of such discussions are likely to be the research funding agencies, and we understand some developments are already underway. This whole issue is all the more important given changing requirements for data protection from the EU and from the Data Protection (Amendment) Act 2003.

In essence, we are currently at a juncture where the currently considerable efforts of many individuals to provide ethical review of research projects needs some coordination and rationalisation if the system is to remain manageable for those providing, using and funding it.

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Table 1. Profile of the research ethics committee requirements to conduct national studies: two recent Irish projects

Study feature	**Study 1** Barriers to organ donation in Ireland: ICU staff survey	**Study 2** Hospital management of acute coronary syndromes in Ireland
Study format	Descriptive survey of staff attitudes	Patient chart data and patient self-report data
Data gathering instrument	Anonymous postal questionnaire distributed to relevant staff by Human Resources Departments of hospitals	Patient chart data and patient completion of self-report questionnaire. Patient 's name and permission for re-contact 12 months later were also requested
Funding body	Health Research Board	Department of Health & Children
Timeframe for data collection	2001-2003	2003
Number of hospitals included	37	39
Initial contact	Letter to hospital chief executive officer (CEO) introducing study and asking about requirements for local Research Ethics Committee approval (REC)	Letter to CEO. Subsequent telephone contact asking about REC considerations. Decision taken to submit protocol to each committee individually as lack of clarity and delays regarding same
Subsequent contact	Referral to appropriate REC	Correspondence to RECs
Outcome		
Hospital required application to individual hospital REC on their standard form	13 (two of these required re-submission)	13 (1 Committee covered 2 hospitals, another covered 8 hospitals)
Health board REC (N=8 health board authorities)	2 (2 boards which covered 3 relevant hospitals)	4 (4 boards which covered 15 relevant hospitals)
Informal approval/Approval by hospital CEO's office.	21	3
*Submissions to other committees or individuals required following local or regional REC approval**	6	2
Researcher attendance at REC required	4	3 (plus 2 additional sites where local consultant/PI was required to attend)

*details given in text of paper

**these are in addition to overall research approval by researcher institutions REC.

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