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Reflections on applying for NHS ethical approval and governance in a climate of rapid change: prioritising process over principles

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Ethical review and governance of health services research in the UK have undergone significant changes in recent years. Tracing this incremental development helps to understand the rationale for introducing a more standardised process. Reflecting on our experience of approval for a national, multi-centred, qualitative study provides useful insights into both the advantages and disadvantages of this new approach. Advantages include promoting awareness of ethical issues and timely review of proposals. However, excessive bureaucracy and inconsistency in obtaining local governance approvals can lead to unacceptable delays. There is also a danger that the current focus on the process of applying for ethical approval may overshadow debate about the principles of ethical research practice. Over-reliance on a checklist approach may perpetuate an erroneous notion of ethical approval being a 'hurdle' to negotiate instead of an ongoing consideration. Unanticipated theoretical and methodological implications for future health services research are critically examined. Given the continued globalisation of health services research, this discussion may help inform debates and decisions about restructuring ethical review processes in other countries.

Introduction

Ethical review and monitoring of research (known as research governance) within the UK National Health Service (NHS) have undergone considerable changes in recent years. This article reflects on our experiences of applying for health service ethical approval for a national, multi-centred, qualitative study and subsequently obtaining local governance approvals from all 15 health board areas in Scotland. Although perhaps an extreme example, it provides an important illustration of the considerable, 'real world' implications of the new processes. Capturing this 'moment' in the rapid transition of the UK procedures provides useful insights into some of the welcome changes as well as those unintended, less desirable consequences. It may also prove useful for other institutions and decision makers in reviews of their own processes.

In order to understand the current system, this article traces the development of the ethical review and governance processes. The last few years have seen rapid change and uncertainty in these arrangements. Our experience suggests that, despite good intentions, lessons from the past may not always be learned. For example, Cartwright and Seale (1990) noted problems with inconsistent decision-making between committees, and subsequent delays in obtaining approval. Subsequent changes in the system were intended to address such issues, yet our experience suggests that this has not

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been the case. Following feedback and criticisms of the latest processes (Department of Health, 2005a), some of the problems identified have since been addressed. Many issues, however, remain unresolved.

Our experience highlights the need of critical examination of any proposed changes and their potential impact on future health services research. It also leads us to caution against casual acceptance of a prescriptive checklist of ethical rules and assumptions. Instead there is a need for greater debate about the impact of the new ethical review and governance system on the future design and conduct of health research.

Development of the ethical review and research governance process

The UK NHS ethical review and governance system has been criticised for a lack of co-ordination and consistency in decision-making (Cartwright & Seale, 1990; Tod et al., 2002). These criticisms, coupled with a number of major events, resulted in changes being introduced from 2003 onwards in order to develop more accountable, integrated and standardised processes for reviewing ethical issues in research studies.

The late 1990s saw a spate of high-profile scandals (Department of Health, 2000; Royal Liverpool Children's Inquiry Team, 2001) which led to demands for greater scrutiny and monitoring of clinical and research activity in the NHS. It was within this climate that the Research Governance Frameworks (RGFs) for England (Department of Health, 2001a) and then Scotland (Scottish Executive, 2001a) were introduced. These were 'aimed at continuous improvement of standards and the reduction of unacceptable variations in research practice across health and social care' (Department of Health, 2001a, p. 7). Maintaining public confidence and benefits in research activity were also key considerations, with an emphasis on the public's 'right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements' (p. 3).

These Frameworks have subsequently been updated in England (Department of Health, 2005a) and Scotland (Scottish Executive Health Department, 2006) to take account of the legislative requirements of the European Clinical Trials Directive in 2004, and wider debate about standards of good practice. They build on their original remit with the aim to 'improve research quality and safeguard the public by enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents and ensuring lessons are learned as well as forestalling poor performance and misconduct' (Scottish Executive Health Department, 2006, p. 1). These documents pull together standards of good practice across key domains: ethics, science, information, health and safety, and finance. Given that some of the standards are open to individual judgement and interpretation, the frameworks also call for a 'quality research culture' with strong leadership and expert management in an open and honest environment. The three features of the frameworks relating to ethical review and governance of research are considered in this article and are as follows.

Setting standards of ethics

The updated RGFs restate that the 'dignity, safety and well-being of participants must be the primary consideration in any research study' (Scottish Executive Health Department, 2006, p. *5*). Key standards of ethics included the need for independent ethical review of relevant research, informed consent, and appropriate use and protection of

patient data and confidentiality. Researchers were also required to adequately assess risk and minimise any potential for harm among participants, to respect diversity, avoid discrimination, and encourage participant involvement in the design, dissemination and implementation of research findings.

These standards drew heavily on a long history of well-established principles (U.S. Government Printing Office, 1949) and codes of professional conduct (World Medical Association, 1964), as well as various health policies and legislation covering medical and social research. The evolving nature of ethical codes of practice is illustrated in the five subsequent amendments to the original Declaration of Helsinki (1975, 1983, 1989, 1996 and 2002) (World Medical Association, 2002), with later versions reflecting growing concern about the storage and use of personal sensitive data.

The role of R&D departments within the NHS in issuing local governance approvals

The RGFs set out the responsibilities and accountabilities of researchers, participants, funders and ethics committees. In particular, it became mandatory that 'all organisations providing health care in the UK must be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation' (Scottish Executive Health Department, 2006, p. 26). Consequently, all research involving patients and health professionals must now have approval from the relevant Research & Development (R&D) department and/or Medical Director in each NHS location (in addition to ethical approval) *before* it can begin.

Roles and responsibilities of research ethics committees

The frameworks also called for a review of the roles and responsibilities of ethics committees and formalised the need to obtain independent ethical review for a wider range of research. This included *any* studies involving patients and users, their relatives or carers, or NHS professionals. It also governed access to data, organs or other bodily material of past/present NHS patients, and any research using NHS premises or facilities.

Although Local Research Ethics Committees (LRECs) were established in 1967, their roles and responsibilities were not properly formalised until 1991 (Department of Health, 1991). Complaints of inconsistency and time delays, particularly for multi-centre trials which required multiple LRECs' approval (each with its own unique paperwork and processes), alongside the impending European Clinical Trials Directive prompted the introduction of Multi-centre Research Ethics Committees (MRECs) in 1997 (Cave & Holm, 2002).

Criticisms of the ethics committees, however, continued. Tod et al. (2002) categorised LREC problems into four domains: variation in operating systems between LREC (Alberti, 2000; Lux, Edwards, & Osborne, 2000); potential disparity in opinions between committees even when reviewing the same research (Tully, Ninis, Booy, & Viner, 2000); and differences in the workload and resources (Blunt, Savulescu, & Watson, 1998). Also, a lack of methodological and theoretical expertise, particularly relating to qualitative research was identified (Dolan, 1999). The Central Office for Research Ethics Committees (COREC) was set up in 2000 to help simplify and standardise the process. It has rapidly developed into a one-stop shop to co-ordinate the MRECs.

As a result of the RGF review, new governance arrangements for Research Ethics Committees (RECs) (Department of Health, 2001b) were introduced. This 'set out general standards and principles for an accountable system of RECs, working collaboratively to common high standards of review and operating process throughout the NHS' (Department of Health, 2001b, p. 1). RECs were also given timelines for 'efficient, effective and timely' review of NHS research proposals.

Legislation changes

National and international legislative changes have also played a part in the development of the ethical review and governance process. For example, the UK Data Protection Act (HMSO, 1998), implemented to protect individuals from huge technological advances in the processing and storage of personal information, has had wide-ranging implications for research design and methodology. The European Clinical Trials directive (HMSO, 2004) also provided a common statutory framework for the conduct of clinical trials across Europe. This included a timeline of 60 days for an opinion on multi-centre studies—both for clinical and non-clinical research.

Changing bureaucratic requirements

Taken together, the cumulative changes in the review and governance process have contributed to a climate of rapid transition and uncertainty for NHS researchers and administrators alike. In 2003/2004 when our research proposal was developed and submitted, changes to the procedures were well underway. This ongoing evolution is illustrated in Table 1.

The original governance arrangements for RECs (July 2001) were supplemented with New Operating Procedures for RECs in March 2004 (Central Office for Research Ethics Committees (COREC), 2004a), updated in the second version in October 2004 (Central Office for Research Ethics Committees (COREC), 2004b) and third version in September 2005 (Central Office for Research Ethics Committees (COREC), 2005). Similarly, there have been five versions of the Standard REC application form in this period.

Our experience of NHS ethical review and research governance

Our project was a Scotland-wide, qualitative study aimed at capturing and critically examining complexities in the process of stakeholder involvement in diabetes service development. The term 'stakeholders' refers to those with a key 'stake' in diabetes services, including patients, carers and health professionals. The study was concerned with their involvement in service development and not the clinical care of any individuals. The potential ethical impact of the study on patients and carers was minimal as the study included no clinical intervention, no discussion of patient-sensitive topics, and no collection of individual patient data (clinical or otherwise). Indeed the only 'patients' included in the study were those who had already volunteered to sit on management committees and were speaking in their position as patient representatives. However, since the research was to take place on NHS property and recruitment was to take place through the NHS, the research frameworks within the UK NHS stipulated that both R&D approval and ethical approval were still required.

Table 1. Incremental changes to the Ethical Review & Research Governance Process 2000–2006.

Year	Month	Event
2000		Central Office for Research Ethics Committees established
2001	March	Research Governance Framework for England
	July	Governance Arrangements for RECs
	October	Research Governance Framework for Scotland
2003	January	MREC Central Allocation System launched
	February	Standard electronic REC application form piloted
2004	January	Revised version standard electronic REC application launched
	March	Standard REC online application becomes compulsory
	March	New Operating Procedures for RECs
	May	The Medicines for Human Use (Clinical Trials) Regulations 2004 UK legislation
	June	New COREC website launched
	October	Version 2 Standard Operating Procedures for RECs
2005	January	Version 4.0 online standard REC application form launched
	March	Standard R&D Application Form (March 2005)
	March	Part D of REC form (relating to R&D approval) withdrawn
	April	Second Edition of Research Governance Framework for England
	June	Report of ad hoc advisory group on the operation of RECs
	September	Version 5.0 online standard REC application form launched
	September	Version 3 of Standard Operating Procedures for RECs implemented
	September	New forms for notification of amendments, safety reports and progress reports launched
	October	Minor amendment to Second Edition of Research Governance Framework for England
	November	Draft plan for implementing the recommendations of the ad hoc advisory group on the operation of NHS RECs completed
2006	February	Second Edition of Research Governance Framework for Scotland
	March	Version 5.1 online standard REC application form launched
	April	End of consultation on draft plan for implementing the recommendations of the ad hoc advisory group on the operation of NHS RECs

The research was organised in two phases using multiple methods. Phase 1 involved describing and exploring the nature of stakeholder involvement in diabetes service development across Scotland. The Diabetes Managed Clinical Network in each health board region served as the ‘case’ from which to explore the process of involvement. Including all 15 regions in Scotland was an important aspect of the study, increasing its relevance to the NHS and ultimately its application (the study was funded by the Chief Scientist Office for Scotland).

Given the geographical distances involved, telephone interviewing and telephone focus groups were used alongside face-to-face interviews and a content analysis of strategy documents. Phase 2 drew on the findings to select two health board areas with specific characteristics to further explore the concept and process of stakeholder involvement. Observations at meetings were conducted in each of these areas.

Advantages and disadvantages of ethical review and governance system

The advantages and disadvantages at each of the three main stages of the process for obtaining ethical review and governance approval for this study are now considered in terms of both their individual and cumulative impact.

Multi-centre research ethics committee (MREC) approval

Multi-centre Research Ethics Committees were introduced to address problems of inconsistent decision-making between various LRECs and lengthy time delays for multiple-site research. A key question would therefore be whether the new centralised system does provide a more co-ordinated and consistent process with a corresponding reduction in time delays.

Length of time

Our experience suggests that the new procedures and central co-ordination have helped. The MREC process lasted 10 weeks from original submission to final approval, including time to make minor amendments to the application form and supporting information.

Publication of submission dates for all the MREC meetings throughout the year, alongside the committees' statutory obligations of response within 60 days does afford researchers the opportunity to plan when and where to submit their application. This may be particularly important with health service research in Scotland as at present only 2 of the 13 MRECs are in Scotland. It is also worth noting that the 60-day time-line stops once the committee has sent out its recommendations. It is then set to zero again while they consider the research team's response. Since the committee is only allowed to ask for clarification on one occasion proposals cannot 'yo-yo' indefinitely between committee and research team.

Coping with flexibility

Another key question relevant to our proposal was the extent to which the new system could cope with flexible research designs such as our own—an iterative, two-phase, multiple methods study. Advice from the MREC was sought at an early stage as to whether it was best to submit the project in phases. We were advised to submit the complete proposal to help the committee understand the full nature of its design and intent. It was also suggested that any deviations could then be met with project amendments, which might be approved by the chair of the committee rather than requiring full committee scrutiny. This was indeed borne out on two separate occasions when minor project amendments were passed by the chair within a week. However, an ongoing dialogue for more dramatic project amendments may be less realistic when all the individual R&D departments and LRECs have to be notified—a point which will become clearer when the length of time taken to obtain local permissions are considered.

The amount of work that goes into preparing an MREC submission cannot be underestimated. It requires a robust protocol with sufficient coverage of the literature to set out the rationale and justify the design adopted. Although it is time-consuming, this is usually done when applying for funding *prior* to seeking ethical approval. Even

flexible, qualitative designs benefit from a thorough plan and protocol (Mason, 2002). The ethical review application affords an invaluable opportunity for reflection and anticipation of any potential problems.

The need to submit all research materials in advance, does, however, present considerable problems for a flexible research design, particularly when each part of the research process is supposed to inform the next (as in our case). There is an option to include draft materials and then return to the committee when these have been finalised. This option was taken up when Phase 2 information leaflets, consent forms and recruitment letters had to be altered slightly to reflect a previous minor project amendment. We were at first advised that this would require approval by the full committee, however, after considerable negotiation it was decided that these could, in fact, be passed by the Chairperson.

Reliance on templates

Informed consent is a fundamental aspect of good research practice in all of the ethical standards, professional codes and RGFs. Those conducting research in the NHS are required to demonstrate both their own competency and procedure for obtaining consent. Current MREC guidelines encourage the use of 'template' participant information sheets and consent forms. Although it is useful, there is a danger that this may foster a one-size-fits-all approach to what are highly contested issues. Indeed, concerns have been raised that reliance on prescriptive codes of ethical standards may in fact stifle debate of the underlying principles of important issues such as informed consent (Homan, 1991; Normand et al., 2003).

Level of bureaucracy

Attempts to standardise the process for applying for ethical review have not been without problems. Frustrations arising from technical glitches with the software have been well described (Greenhalgh, 2004). It can also be difficult keeping abreast of the changes. As mentioned earlier, by 2005 the original supporting guidelines had undergone three revisions and five separate versions of the standard REC application form issued since 2003. However, these changes and the filtering questions were intended to make the form more relevant to non-clinical research and avoid time wasted on non-applicable questions. Any new system needs time to bed down. This was the conclusion of the advisory group who accepted that the application form and process required improvement (Department of Health, 2005b). A draft plan has been developed and put forward for public consultation.

Our experience suggests that thorough preparation is essential before submitting an MREC application. Much has been made of the length of time it takes to obtain MREC approval, but there may be some confusion. In our case, it took 10 weeks from first submission of the application to obtaining final approval. However, taking account of the length of time required to prepare the submission does make for a much lengthier process which researchers and funders need to be aware of.

Set timelines for responses and the ability for the chair to approve minor amendments provide some reassurance that the committees can process more flexible designs which develop as further findings emerge. Unfortunately, however, the story doesn't end there. In fact, we discovered that it was really only the beginning.

R&D local management approval/research governance issues

Phase 1 of our study involved collecting data from individuals in all 15 administrative regions (Health Boards areas) across Scotland. Each region had at least one R&D department. Some regions had two departments, one covering primary health care and one for secondary health care. The RGF makes clear that if data are to be collected within an NHS region, using NHS property or resources (e.g. rooms, telephones, staff time) in any way at all (no matter how small), then permission must be granted from that region's R&D department. In our case, despite the study having undergone rigorous peer review as part of the funding process and obtaining MREC approval (with no significant ethical issues noted), we were therefore still required to apply separately to all of the individual R&D departments across each of the 15 health boards in Scotland.

At the time of applying there were 26 different R&D departments from which to obtain permission, as some areas had more than one department. It would seem important that this process of obtaining local R&D approval does not merely duplicate the work of the MREC. A key question might therefore be what specific (and perhaps additional role) R&D departments have in relation to the scrutiny and monitoring of research proposals.

The fact that R&D departments were required to register all research within their organisation and apply to a central fund for any associated support costs, may go some way in explaining the bureaucracy involved. When our study was submitted in late 2003/early 2004, R&D managers were also responding to the new requirements of the RGF which for the first time held them individually accountable for if things went wrong. The introduction of focussed accountability meant that it was no longer practical or sustainable for researchers who were not employed by the NHS to conduct research on NHS property and/or among patients or NHS staff without some signed agreement in regard to behaviour, policies of confidentiality, or without any form of accountability to those senior NHS staff who would be legally held responsible. As a result researchers were required to sign honorary contracts with the NHS bodies within which the research was taking place. This new responsibility had to be managed alongside the changing guidelines for ethical review of NHS research as well as implementation of the European Clinical Trials Directive. Perhaps our experience is one of being in 'the wrong place at the wrong time'. Indeed, no centrally held list of R&D managers was available at the time of application. The list we did receive was in many cases out of date and it took some time and many wasted phone calls to establish contacts with the correct people.

Lack of integrated working

The lack of integration between R&D departments, particularly within the same Health Board Area presented further challenges. Although recent years have seen an increasing emphasis on joined-up working and a move towards unified health boards in Scotland, our experience suggests that this had not filtered down to all the R&D departments, who were to all intents and purposes operating as individual entities.

Each of these R&D departments had their own bureaucratic systems and personnel, many of whom were anxious or confused about interpreting certain aspects of the RGF or the new guidelines for ethical review, particularly given their new individual accountability. This contributed to inconsistent interpretations and disparity in the bureaucratic requirements for obtaining approval. The effect was lengthy delays in many areas. Figure 1 illustrates the cumulative variation in obtaining approvals at the

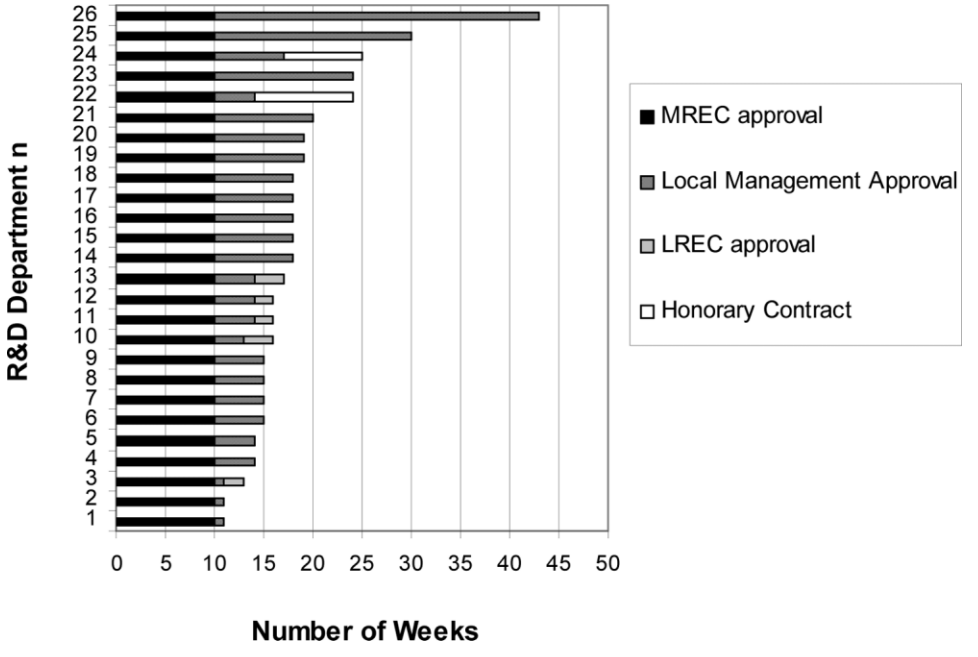

Figure 1. Cumulative variation in time to obtain approvals.

three key stages in the process across all the 26 R&D departments, as well as additional time required to obtain an honorary contract in two areas.

As mentioned earlier, the process of obtaining full MREC approval (black) lasted 10 weeks. This is a necessary requirement before local management approval can be received. The length of time to obtain local management approval (stripes) ranged from 1 to 33 additional weeks from the time of application. It is worth noting that R&D department 12 and 26 are the primary care and acute R&D departments *within the same health board*—yet there was 27 weeks difference in issuing approval due to the requirement that the principal researcher hold an honorary contract with their area. Additional time to obtain LREC approval (white) and honorary contracts in some areas (grey) are also included.

Variations in the interpretation of the RGF are worth emphasising as they contributed to delays. Out of the 26 R&D departments, 6 required the principal investigator or his/her supervisors to have an honorary contract with their health board, because they felt that patient representatives recruited were classified as patients (although the research was not concerned with any aspect of their individual clinical care). It is not clear why the other 21 areas did not take this view. Issuing an honorary contract in some of these areas became quite a protracted process, primarily as the structures were not yet in place. Fieldwork was not able to commence until these contracts were received.

Another inconsistency involved one area *requesting* and another area *insisting* on inserting a local Principal investigator—a GP in the former and a consultant in the latter region—despite these individuals having no prior involvement in the study. The rationale in the first area was that it would make a difference to the level of support costs which they could claim and greater local accountability in the second area. These

requests caused our research team some concern around issues of accountability and intellectual property rights. The research team had already been approved by the MREC as having the necessary skills and experience to conduct the research. With the support of our funding body and a great deal of negotiation these requests were successfully resisted.

Unpredictable decision-making was another feature of our experience with one area maintaining that the principal researcher undergoes a medical examination to confirm her suitability to conduct the research and to protect patient representatives. Interestingly, the other 25 departments did not consider this necessary. We therefore refused this request and the area agreed to issue approval on the basis that Phase 1 of the study involved only telephone contact with participants without setting foot on their premises—the implication being that a medical examination would be required for face-to-face contact.

The level of bureaucracy involved in obtaining local management approval should not be underestimated, as illustrated in Table 2. Many of the areas also requested multiple paper copies in addition to electronic copies of all the documentation. Several also required health-board specific forms to be completed, despite the fact that the same information was contained within existing documentation.

The need to provide regular feedback to each R&D department raises additional questions about proportionate bureaucracy. Some areas require six-monthly progress reports, others annual reports. The level of detail required also varies. Approval was issued by each R&D department at different dates due to the varying amount of time each one took to issue approval. This meant that the researcher could be compiling 26 different reports at different time points throughout the year, with obvious knock-on resource issues.

Our experience of contradictory decision-making suggests that such requests should be met with ongoing dialogue to ensure the appropriateness and relevance to the particular project. A key issue was the blurring of boundaries between the R&D department and the RECs. No significant ethical issues in our study were noted by the MREC and it did not involve any clinical intervention. In fact, no problems with the ethics, design and conduct of the study were raised by any of the R&D departments. However, it took 33 additional weeks to obtain approval from all 26 R&D departments. The lack of standardised approach between R&D departments and their need to reduce duplication of paperwork is stated as the ‘most pressing’ of all the recommendations of the recent advisory group on RECs (Department of Health, 2005b, p. 15).

Local research ethics committee (LREC) approval

In addition to obtaining R&D local management approval, the terms of our MREC approval required only that relevant LRECs be *informed* about the study. Given the

Table 2. Summary of bureaucracy in obtaining R&D local management approval.

	Sent/Made	Received
Emails	164	121
Telephone Calls	69	17
Letters	17	32

national remit of the study all 19 LRECs in Scotland were contacted. Variation in their responses was again seen with 7 LRECs noting the study within one week, whereas 12 committees required the proposal to go to a full committee. This took from one to seven weeks and required considerable time and resources to make all the calls, faxes and send all the necessary documentation. This is an important time delay as fieldwork can only commence when all the requirements of MREC approval are met.

Discussion

Our experience of the new ethical review and governance processes suggests that there may be unintentional and unanticipated problems within the new governance procedures that have the potential to undermine more complex, multi-site research studies. Ethical considerations in health research are not new (e.g. Nuremberg, 1949), nor are they fixed (e.g. five amendments to Declaration of Helsinki since 1964), nor are they unaltered by events in the wider world (such as the rapid development of technology and the need for a Data Protection Act). The important issue is that open dialogue should be encouraged to ensure the highest standard of conduct, to improve the quality of research and protect the interests of participants and the public.

The risk with overly standardised systems is that the process can overshadow debate about the principles. Clive Seale makes a related point when referring to the British Sociological Association statement on ethics that it does not 'provide a set of recipes for resolving ethical choices or dilemmas, but recognises that often it will be necessary to make such choices on the basis of principles and values and the (often conflicting) interests of those involved …' (Seale, 2004, pp. 448–449) The ongoing focus on the *process* of ethical review and research governance means that much-needed debates about the methodological and theoretical implications of the new systems are often neglected. The following subsections critically examine some instances.

Inhibiting flexible design

Cumulative bureaucracy, delays and inconsistencies, combined with the need to submit research materials in advance, may inhibit flexible design. This is an important aspect of qualitative work, in particular, which is perfectly placed to capitalise on the unexpected outcomes rather than relying on prediction. With an increase in mixed methods research, organisational evaluation and embedding of qualitative methods in randomised controlled trials, these issues are likely to increase in frequency and importance. Ultimately, future research could be theoretically impoverished with academic insights jeopardised (Barbour, 2000).

Discouraging multi-centre research

Multi-centre research can provide important comparative insights. Our research was a relatively non-contentious, observational study, with no significant ethical or design issues raised. Despite this, the whole process of obtaining all the necessary approvals took a total of 43 weeks from first submission. This does not include time spent preparing the proposal. It begs the question of what would happen if there were more complex ethical issues to consider. Length of time, additional complexity and cost may ultimately discourage future multi-centre, national and international studies—particularly

more complex intervention work. This is not a new issue (Cartwright & Seale, 1990; Hearnshaw, 2004; Tod et al., 2002). Unfortunately, the new systems that we experienced had not taken sufficient heed of such lessons.

Maintaining medical dominance

In some regions, we were asked to install a local senior doctor (consultant or general practitioner) as principal investigator for the research in that region. The reason for this was unclear. The inclusion of local staff may be justified and beneficial in order to develop research capacity and capability among NHS staff. However, there appeared to be an assumption that such involvement would be at a senior rather than junior level and that it would take the form of medical rather than nursing, allied health professional, administrative or managerial involvement. The rationale along with the potential benefits and dangers of such policies need to be clearly outlined if research projects are not to be compromised and the medical profession accused of attempting to assert medical dominance on research that may stem from paradigms outwith its traditional remit.

Research funding

The length of time required to prepare, submit and, obtain all the necessary approvals—particularly those from the local R&D departments—has important implications for the way in which research is funded. There are also issues of wasted resources where funded studies suffer unnecessary delays and duplicated efforts all around. The principal of proportionality in terms of the nature of the study and potential ethical issues appeared to be conspicuously absent. Subsequent delays could potentially account for a major part of a research budget; however, most funders do not currently take this into account.

Improving the quality of research

One of the main drivers of recent changes has been the intention to improve the quality of research within the NHS. Our experience suggests that the new ethical review process, with its standardised application and central co-ordination, has helped to simplify the process for independent scrutiny of research proposals. The system of R&D local management approval may also improve local accountability and monitoring of research as well as emphasising the need for dissemination.

However, there are questions around the duplication of roles between MREC, LREC and R&D. This blurring of boundaries between the various organisations, combined with the volume of information received by committees (Norman, 2004) must impact on the amount of time available for detailed scrutiny of proposals. It also increases the likelihood of delays in obtaining approvals. Delays at the outset of a funded project have knock-on effects with later stages having to be 'crammed' into shorter time frames. This has the potential to undermine the quality of the study and its findings.

Our experience also raises concerns around the insertion of local principal investigators who have no prior involvement with the study, and questions what they may add as well as raising issues of accountability. The full implications of the R&D local management approval agreements have possibly yet to be realised, with some Health Board areas insisting that they have prior sight and approval of any

published work involving their area, raising issues of intellectual property and academic freedom.

Protecting research participants

Another aspect of the new systems of ethical review and governance was the desire to increase the protection of research participants and the public. Increased awareness and consideration of ethical issues, alongside improvements in the quality of research must be important in this regard. However, there are also some concerns of over-zealous use of the RGFs and data protection legislation by 'gate-keepers' to impede access to participants, particularly patients. It was our experience that health professional gatekeepers often wanted to act as go-betweens for patient representatives which raises issues about individuals' autonomy to take part in research as well as their anonymity. There may be a potential conflict between gatekeepers desire to protect access to patients and the current patient and public involvement agenda within the NHS (Scottish Executive, 2001b).

Conclusions

The current NHS ethical review and governance processes are the products of a long incremental history. They are often the butt of researchers' frustrations, with numerous horror stories in circulation. Our experience suggests that it is important to critically examine both the advantages and disadvantages at each of the key stages in the process and not 'throw the baby out with the bathwater'.

The new centralised system of multi-centre ethical review, despite being in a period of rapid transition, was in fact relatively easy to negotiate. Statutory timelines proved important in avoiding any undue delays in the initial stages. Problems with bureaucracy, delays and inconsistent decisions were more likely to occur at the subsequent stage of applying for R&D local management approval. There were often idiosyncratic approaches in each area for dealing with the request and no particular guidance about potential timescales. Duplication of MREC and LREC resources on a study which had no significant ethical or local issues created further challenges. It is important that these issues are addressed in future developments.

Standardising the process of ethical review of research has undoubtedly had many benefits. However, there are dangers associated with a prescriptive, approach to 'ethics', which neglects the need to acknowledge, and grapple with the inevitable grey areas of working with human participants in a complex, changing environment. Adopting a checklist or template approach may encourage the perception of ethical approval being a 'hurdle' to get past instead of being continually revisited.

There is a need for greater debate about the methodological and theoretical implications of any new processes. Associated bureaucracy and delays may discourage complex multi-centre work, inhibit flexible design and the valuable comparative and theoretical insights that these can offer. Implications for research coverage, comparability and building the knowledge base in health services research must therefore be considered.

Health services research has become a global endeavour in recent decades. Many other countries are attempting to develop and/or restructure their ethical review and research monitoring processes. There has also been an increasing trend to standardise procedures to ensure the progress of multi-national studies through the necessary

stages of review. Insights from the UK experience may be useful in helping to inform debates and decisions about the nature of these developments.

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