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A 55 kg Paper Mountain: The impact of new research governance and ethics processes on mental health services research in England

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Abstract

Background: The guidelines about research ethics and research governance, implemented by the Department of Health, present new challenges to undertaking mental health service research within the National Health Service (NHS).

Aims: This paper describes how these new ethical and research governance procedures have adversely affected three multi-centre mental health service research studies, funded by the Department of Health.

Methods: The workload, time, and cost of meeting these requirements for each study is described.

Conclusion: The implementation of Government guidance has resulted in a level of bureaucracy that threatens the future of the type of research that underpins policy development and service planning. For the researcher, the work involved in meeting these new requirements can be greater than the work of data collection, and for the trust, greater than the cost of participation in the research itself. The Department of Health has made recommendations to streamline the research ethics process. However this will not address the tension between research ethics systems and localized research governance procedures.

Declaration of interest: None.

Keywords: *Research governance, ethical approval, mental health service research*

Introduction

Despite the common adoption of the Declaration of Helsinki, there is substantial variation between European countries in the requirements for approval by a research ethics committee. There is also evidence that the research ethics process in England is relatively arduous (Hearnshaw, 2004). Recent changes to this process in England, in response to the European Clinical Trials Directive, have made it yet more demanding (Alberti, 2000; Glasziou, 2004; Jamrozik, 2004; Wald, 2004). The problem has been compounded by the introduction of new procedures for obtaining agreement to conduct research that are separate from the research ethics system. The English Department of Health required this because of public concern about a highly publicized episode. For the purposes of research and teaching a medical hospital had retained children's organs without parental consent.

One of the conclusions from the subsequent inquiry was that there had been a failure of research governance (House of Commons, 2001).

This paper shows the impact of the English research ethics and governance processes, in place between 2003 and 2005, on three mental health research studies, conducted by a single research unit. It argues that they pose a significant threat to the future of this type of research. In the discussion we will examine how the recent recommendations could influence the processes described here.

The procedures

Research ethics approval

The whole ethics approval system in England is overseen by the Central Office for Research Ethics Committees whose current Standard Operating Procedures for Research Ethics Committees run to 208 pages (National Patient Safety Agency, 2005). Since 1998, research studies that involve more than five English health care providers must submit an application for approval by one of 12 Multi-centre Research Ethics Committees (MRECs). These were established to obviate the need to apply separately to the Local Research Ethics Committees (LRECs) of each provider organization. Once approval is granted by an MREC, the researchers must notify the LREC of each National Health Service (NHS) health care provider involved in the study. The system was recently modified to take account of the EU Clinical Trials Directive that outlines the statutory framework for the conduct of clinical trials of medicinal products in Europe. Although such trials only account for 15% of research ethics applications, the English Department of Health decided that the new guidance would apply to all types of research conducted in England, and not just to clinical trials (Department of Health, 2005a). The Department of Health stated that this was to avoid confusion that could arise from the use of different systems. Consequently, the same 19-page MREC application form applies to all studies submitted for research ethics approval. For studies that involve patient contact, or the collection of any data other than that derived from routine care, the MREC will deem that each LREC will also need to conduct a separate “site-specific assessment” (SSA) regarding the capacity of the service to engage in the research. This assessment requires the appointment of a local “principal investigator” at each site who is held responsible for the service’s participation in the research.

The local research governance process

The Department of Health’s research governance framework, first issued in 2001, specifies the responsibilities of health care providers in relation to local research (Department of Health, 2001). Its main aim is to encourage services to “manage any significant risk to patients, users and carers, staff and other individuals covered by a health care organisations’ duty of care” (Department of Health, 2001). The framework is subject to local interpretation. Most mental health care providers have responded by setting up a committee structure, separate from the LREC system, and overseen by one or more administrators.

The three studies

All three studies were funded by the English NHS Research and Development (R&D) Programme and were subject to independent academic review as part of the commissioning process.

Study 1 examined provision of specialist care for substance misuse problems available to patients in all 25 medium-secure psychiatric units in England. The one-year study involved telephone interviews, postal surveys and focus groups with staff in the units, and in-depth interviews and focus groups with a small number of staff from some of the units. No data were collected from or about individual patients.

Study 2 which involves 102 English health care providers (a mix of acute, primary care and mental health) examines the pathways through care of young people who are referred to, but not admitted by, Child and Adolescent Mental Health in-patient units. The study was commissioned because of concern that many of these young people are diverted to inappropriate services, including the criminal justice system and adult psychiatric wards. It was estimated that the study would collect information about 300 young people. Questionnaire data would be drawn from existing information sources about the young people and provided by the practitioners responsible for the patients' care. In addition, a researcher would interview a sub-sample of patients and their families. Consent for these interviews would be obtained from the young people and their parents or carers.

Study 3 which began in April 2004 compares costs, outcomes and satisfaction with care for young people admitted to general adolescent and specialist eating disorder mental health in-patient units (both NHS and independent sector services). It also examines the same factors for young people admitted to adult psychiatric and paediatric wards. Sixty-six health care providers are participating. The data collection process, a combination of questionnaires completed by staff and interviews with a sub-sample of young people, is similar to *Study 2*.

The process of obtaining research ethics approval

All three studies were approved by different MRECs. The MREC considering *Study 1* decided that LRECs would not have to be notified because the research involves no patient contact. *Study 2* was approved with the requirement that all LRECs be informed. This involved submission to the LRECs of a letter and an information sheet outlining the study. The MREC considering *Study 3* decided that a SSA was required for each participating service. This involves identifying a local investigator who takes on local responsibility for the research. This proved to be a time-consuming and difficult process for both the central research team and local services. For 70 out of the 90 adult psychiatric and paediatric wards that would occasionally admit a young person relevant to the study, the time and effort required to undertake the SSA was so great that they decided to withdraw. Some, however, did agree that they would reconsider involvement if the study only involved collecting data on a young person if and when a case relevant to the study was admitted during the recruitment phase.

The process of obtaining local research governance approval

Although securing research ethics approval was a considerable task, getting agreement from research governance committees proved more difficult. For some services, several telephone calls were required just to obtain the contact details for the committee or manager responsible for research governance. During this period many services were unable to specify precisely what the local procedure was, and others changed the procedure during the application process. There was little standardization between services. For example, despite the provision by the Central Office for Research Ethics Committees (COREC) of a standard application form for research governance approval, the central research team was required to

complete 19 different forms for Study 1 and 58 different forms for Study 2. The committees requested a range of attachments to accompany the application. Although the requirement varied from committee to committee, most included a core set of the MREC application form and approval letter, copies of correspondence with the LREC, specimen information sheets and letters to potential participants and a sponsor letter from the funding body. Some research governance committees required the LREC letter of approval before the R&D application process could be completed or, in a few instances, prior to initiating this process.

For all three studies, some services required members of the central research team to apply for honorary contracts of employment. This was despite the fact that the central researchers would have little or no involvement in on-site data collection, and would not even visit some of the services involved. Obtaining an honorary contract was a lengthy process that involved: the submission of a CV; the provision of two references; the completion of an occupational health form; and presentation of proof of clearance from the Criminal Records Bureau (CRB). Five trusts would not accept the current CRB check previously obtained by the researchers who were subsequently asked to visit the human resources department with the required documentation.

Similar to examples reported in other journals (Elwyn et al., 2005; Galbraith et al., 2006), some services made further idiosyncratic demands. These included: refusal to provide an application form until a subject had been identified for the study. This created a ‘‘Catch 22’’ because we could not identify study subjects without research governance approval; subjecting a study proposal to academic review despite the fact that it had been extensively peer-reviewed during the grant application stage; in one case even requesting that the researchers visit the trust in order to have Hepatitis B injections.

The cost

Table I summarizes the work involved in obtaining approval to conduct these three studies and the quantity of paper that had to be submitted to the many committees involved. Although Study 3 involved only 66 research governance committees, 126 applications for site-specific assessments had to be made. This was because more than one local investigator was required by services where more than one ward was participating in the study. A single copy of all of the paperwork submitted for these three studies would weigh 55 kg.

The work of obtaining these approvals occupied a full-time research worker for 4 months for Study 1 and 12 months for Study 2 and 3. This has delayed these projects (studies 2 and 3) by 12 months. For those trusts that required the central researchers to have honorary

Table I. The administrative burden of applying for research governance approval for the three studies.

	Study 1	Study 2	Study 3
Number of services participating in the study	25	102	74
Number of LRECs to which an application was submitted ¹	0	0	As below
Number of research governance committees to which an application was submitted ¹	25	62	66
Number of pages submitted to LRECs	N/A	512	1260
Number of pages submitted to research governance committees	2450	5929	6039
Total number of pages submitted to obtain approval to conduct the study ²	2539	6530	7388
Number of trusts requiring an honorary contract	5	25	31
Average number of phone calls and letters per trust	15	9	6

¹Some LRECs and research governance committees serve more than one service. ²Includes MREC applications.

contracts, the process of obtaining CRB checks and occupational health clearance added up to two months to these times.

For Study 3, the average time to complete the SSA process, i.e., engaging with a service, identifying a local principal investigator, explaining the process and responsibilities involved, and completing the necessary documents. The average time to complete the SSA process took four months; the research team did however experience processes that required up to 12 months for completion.

For all three studies, the time and effort required to obtain ethics and research governance approval will be greater than that of data collection and data analysis. The delays to Studies 2 and 3 have meant that the English Department of Health has had to provide additional funding for both projects (£67,699 for Study 2 and £97,469 for Study 3). Although we are not able to estimate the time it has taken NHS staff to process our applications, it is likely that this too will far exceed the time that these staff will spend in data collection during the course of their participation in these three studies.

Discussion

Research conducted in England over the past 50 years has made a significant contribution to understanding the relationship between mental health service structures and processes, and quality of care and patient outcome. One of the factors that have enabled this is the presence of a National Health Service with its single, top-level management structure and common policy direction. This has encouraged collaboration between services in large-scale health services research. Our experience with these three studies suggests that the future of such research is being put at risk by the cumbersome research ethics and governance processes introduced in response to the European Union Clinical Trials Directive and high profile scandals. These guidelines have been applied indiscriminately to types of research, such as the studies described here that pose little risk of causing harm to patients (Doll, 2001).

English Department of Health guidance about research governance states that “the NHS is expected to manage risk, minimise bureaucracy, and facilitate research” (Department of Health, 2004). Our experience suggests that, in relation to large national health services research, the NHS has achieved the opposite of the last two aims, and only looks likely to achieve the first by making it virtually impossible to conduct such studies at all. A recent review suggests applications to local research ethics committees are down by around 40% (Bently & Enderby, 2005). In our opinion, the cost of implementing the Department of Health guidance requirements far outweighs any potential benefit. The cost is both quantitative in terms of finance, resources, and time, and qualitative in terms of the future of this type of health services research upon which policy development and service planning depend. We question the ethics both of this use of NHS funds and of a system that creates almost insurmountable obstacles to research conducted about the disadvantaged groups of people who are the subject of our three studies.

It is evident that our experiences are far from unique. This phenomenon transcends research fields within the UK (Boshier et al., 2005; Elwyn et al., 2005; Galbraith et al., 2006), and exists in Canada (Burgess & Brunger, 2000; McDonald, 2001), Australia (Roberts et al., 2004; Walsh et al., 2005) and America (Brody et al., 2005).

As researchers, we have no argument with the principles of research governance; nor do we blame staff in the R&D departments of English mental health services or members of the LRECs. In fact we are grateful for their help, support and forbearance in our quest for approval. Our impression is that many of these staff share our frustration at the extensive

bureaucracy that has been imposed and are unsettled by the lack of clarity about what is expected.

We thought that we might have been unfortunate in our timing when making the applications for Studies 1 and 2, in that we sought approval for our studies during a period when research governance committees were establishing themselves. However, the fact that the task of obtaining approval for the most recent study, Study 3, was the most arduous suggests little evidence of a reduction in the bureaucratic process.

In response to the clamour from the research community, the Government established an Ad-Hoc Advisory Group to examine the research ethics process in England. This recommended that a distinction be made between different types of research and data collection, and that the ethics approval process be modified to take account of these differences (Department of Health 2005a; National Patient Safety Agency, 2006). The sentiment behind these recommendations is welcome, as is the Advisory Group's calls for the adoption of "common national systems" and improved links between ethics reviews and local research governance procedures that could make "multiple use of information supplied once" (Department of Health 2005a). The bureaucratic processes experienced by national health service research studies, as described in this paper, would only be addressed if the information supplied once for ethical review and research governance approval could be transferable across all the RECs and NHS trusts nationwide, as supported by other members of the research community (Boshier et al., 2005). This would also constitute part of a drive towards a more knowledge-based approach and with it an emphasis on joined-up thinking and policy (Newman, 2001).

Only time will tell whether action arising from these recommendations will result in a reduction in the paper mountain facing researchers. There are two reasons for caution. First, and contrary to the intention, previous moves to centralize the ethics review process have led to greater bureaucratization. It remains to be seen whether the further centralization, recommended by the Advisory Group through the reduction in the number of ethics committees, can solve the problem. Second, neither COREC nor the National Patient Safety Agency, which now manages COREC, have any jurisdiction to oversee local research governance procedures. These were the major obstacles to our studies. The tension between centralized ethics review process and local research governance procedures remains.

The stakes are high. If action is not taken to streamline and simplify both the research ethics and governance processes, the UK will not achieve the government's stated aim of becoming "the best place in the world for health research and innovation" (Department of Health, 2005b), and will not be viewed as an attractive partner for international research collaborations. This will apply particularly to the type of large-scale health service research referred to here.

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