The other face of research governance

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After inadvertently making an unauthorised protocol deviation, two researchers were left with a weakened study and feeling disillusioned

Editorial by Warlow

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Research governance is designed to ensure that "health and social care research is conducted to high scientific and ethical standards."[1] Currently the same process is applied to all breaches, regardless of their severity or likely implications. Although we do not deny the importance and relevance of research governance, our experience leads us to question how it is applied.

What we did

Our project, funded through a small grant from the trust, explored the effect of several variables on outcome in a day therapy service for eating disorders. Our outcome measures comprised several questionnaires administered at three monthly intervals to clients with eating disorders. As a result of advice from our project steering group (a necessary requirement for such projects), we agreed to introduce a simple qualitative measure to balance the fact that our original protocol used only quantitative measures. We used an interview based on a standard questionnaire (the Morgan and Russell scale[2]) but adapted to form a semistructured interview covering quality of life areas such as social contacts, relationships, family, and employment.

The reason for the study becoming subject to the research governance process was that we incorporated this improvement into the protocol without informing the assistant research and development director or local research ethics committee and without adding it to the patient information and consent forms. We were unaware of the requirement to do this and were not told that it was necessary. However, we have been told that in future researchers will be formally notified of this requirement.

What happened

The transgression emerged during a routine telephone conversation with the assistant research and development director. Immediately, we were asked to stop all our research activities while our protocol deviation was subjected to the research governance procedures. This involved three months of formal meetings with the assistant research and development director, resubmission of the protocol and associated patient information and consent forms, and amendments to the application to the ethics committee (15 copies required). We also had to write letters to the ethics committee and the assistant research and development director explaining where we had gone wrong and the amendments made. Furthermore, all other projects in the unit were subjected to a lengthy audit process. To restart the project we had to formally request permission from the assistant director.

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After effects

This process had a major effect on the study. The research was frozen for two months, during which time patients left the service and could not be followed up and other patients joined the service and could not be incorporated into our project. Moreover, ongoing monitoring of patients in the project (weekly measures of self rated motivation) could not be obtained. This has left us with incomplete datasets and an overall loss of patient numbers, which is critical for statistical analysis. These deficiencies affected the validity of our overall results and waste the efforts of both patients and researchers.

The two month freeze also had financial implications. The research assistant's time was not used for the project during that time. This meant a net loss of one sixth of her overall time allocated to the project amounting to a cost of just under £1000. Costs were also incurred for our time to conduct all the research governance procedures and the time of the ethics committee.

The process put us under a lot of stress, and we felt that something shameful and wrong had occurred. It was suggested, for example, at one point that our error had to be treated in the same way as giving the wrong drug to a cancer patient. Clearly, this was not realistic.

Completing the reparative activities as requested was time consuming and competed with other pressing clinical demands. Moreover, we felt that the reparation was excessive in relation to the problem identified. The process felt arbitrary and punitive; it bore no obvious relation to the simple, creative idea that had instigated it. We both felt demoralised and angry about the process and less inclined to undertake research in the future.

Reflections and recommendations

In our case, the research governance process seems an over-reaction to a small, technical infringement of the procedures. Its effect was to destroy the very thing it was designed to protect—the quality of the research.

Summary points

- The process of research governance does not take into account the type of transgression
- This can result in a heavy handed approach for minor problems
- The process carries with it ethical implications—for example, loss of researchers' time, impairments in the quality of data collected
- Research governance needs to be governed more closely

We believe that the research governance process itself carries with it ethical implications. Is it ethical to waste the time of patients and staff and taxpayers' money? Is it ethical to destroy the results of a sound research project? Just as we would not expect a surgeon to be stopped halfway through a successful operation on a patient, so we consider good research should be allowed to be completed and not interfered with unnecessarily.

The research governance process needs to be governed more closely, so that it is only correctly applied where research requires it, and the process modified accordingly to the "deviation" identified. As Glasziou and Chalmers write regarding ethics review, we need to challenge the "one size fits all" approach.[3]

Contributors and sources: AMJ has research interests in service evaluation and eating disorders. She has several publications on eating disorders. BB was co-researcher in the study and responsible for administration, collation of data, and clinical interviews. AMJ is guarantor.

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1 Medical Research Council. *Policy and procedure for inquiring into allegations of scientific misconduct*. London: MRC, 1997.
2 Morgan HGP, Hayward AE. Clinical assessment of anorexia nervosa: the Morgan-Russell outcome assessment schedule. *Br J Psychiatry* 1998;152:367-71.
3 Glasziou P, Chalmers I. Ethics review roulette: what can we learn? *BMJ* 2004;328:121-2.

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Commentary: View from the research and development office

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English NHS trusts are obliged to implement research governance for all NHS health and social care research.[1] The NHS trust that I work for, which funded the research highlighted by Jones and Bamford,[2] sees research as integral to providing high quality health and social care services, and research governance is paramount to our research strategy.

Research involving NHS patients or service users should be reviewed by the NHS research ethics committee and be of appropriate scientific quality. If a research protocol changes, then it needs to be reassessed for the new methods and research ethics. Research not meeting these ethical and quality standards can represent a potential risk to patients, researchers, and wider NHS research, as shown by the Alder Hey and other inquiries.[3–5] Trusts therefore need to implement training for researchers, together with governance and guidelines on good practice. Researchers and clinicians engaged in research also have a professional responsibility to take steps to increase their knowledge of NHS research governance.

In the case highlighted here, communication about the reasons behind the actions of the research and development office was clearly not adequate, and we regret that the researchers felt unduly stressed. The office is continually developing research governance communication and is keen to discuss how best to handle difficult research management decisions with researchers.

Why the study stopped

The research in question was a small pilot project funded from the trust's research and development budget through an open call for research applications. When the change to the approved study methods came to my office's attention, the research protocol had not yet been adapted to reflect the additional qualitative component and the patient information and consent sheets had not been updated to describe the qualitative research. Most importantly, some people had already participated in the qualitative research without being initially presented with accurate information about the qualitative nature of the research. It could therefore be argued they had not given full informed consent, potentially representing a serious breach to participants' rights.

After discussion with the research ethics committee, we decided that the alterations to the protocol, patient information, and consent needed to be reviewed by the committee after the revised protocol had been peer reviewed. This was to ensure that the decision to convert and extend a validated quantitative measure to a qualitative interview had sufficient rigour.

We therefore advised the researchers to halt the research temporarily. Continuation of the research would have involved further data collection from participants who had not fully consented. The pilot research project was non-interventional, and no treatments were withheld. Our analogy with a cancer patient's prescription was to highlight that if a complaint had been made by participants or other staff then a formal investigation would have been required.

Overcoming the problem

As lack of training had contributed to this research being conducted without appropriate ethics committee and methodological review, we held discussions with the researchers and clinical team to increase familiarity with ethical and best practice guidelines. We worked with the researchers to revise the protocol to