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Editorial

Research governance in primary care trusts in England: making multi-centre studies even more difficult?

A research governance framework has been introduced in England to ensure that research is conducted in a manner which safeguards the health and well-being of participants (Department of Health, 2001; 2003). The guidance sets out the roles of the research sponsor, the funding organization, the host organization (e.g. primary care trusts – PCTs) and the investigators. Effective research governance is essential for the proper conduct of research, and setting out a framework by which this can be achieved is good practice. In primary care, Research Management and Governance Organisations (RM&GOs) have been set up as consortia of PCTs, to share in the governance of projects taking place in their area, although some PCTs have elected to stand-alone (Department of Health, 2002). RM&GOs are responsible for implementing systems for notification of all research activity in their locality, monitoring informed consent procedures, and ensuring compliance with Data Protection and Health and Safety law. Research projects based within primary care must all receive research governance as well as ethics approval from relevant PCTs before commencement. As researchers ourselves, we fully support the concept of research governance as a means of ensuring there is no exploitation of individuals taking part in research, and hope that it becomes an accepted practice which is fully understood by all concerned.

Currently, however, the processes for obtaining research governance approval are often poorly organized and time-consuming, and may threaten the feasibility of multi-centre research studies. A 'small industry' has been set up as a result of the RM&GO legislation, which must be costing millions nationally, and the dust has yet to settle. For researchers conducting studies in a single PCT where processes are well organized, there is little problem. However, when conducting studies across a large number of PCTs, such as national postal surveys, the multiplicity of individual RM&GO requirements means that numerous problems arise. There is a danger that such studies will become a thing of the past as researchers go for the easier, less bureaucratic options.

If RM&GOs are to be set up in other countries, there is much to learn from the experiences of English researchers (Caan, 2004; Dumville *et al.*, 2004; Elliott, 2004; Jones and Bamford, 2004). We will not reiterate the details here but rather we wish to provide advice for anyone in Europe or elsewhere so that they can avoid the pitfalls encountered by researchers in England.

Whilst research to date has been conducted within a time of major change during the setting up of research governance procedures, not all the difficulties experienced by researchers can be attributed to the teething problems of a new system. Fundamentally, it is essential that guidance exists for discriminating between different types of research, or even what constitutes research (as opposed to audit or practice which require no research governance approval), and determining an appropriate level of scrutiny for research governance purposes. Currently, researchers have to comply with the same requirements to gain approval in each RM&GO, regardless of the type of study. For example, in many instances very simple studies (e.g. postal questionnaires to staff asking about their jobs) will have no risk to individuals. However, to comply with procedures, RM&GOs have been known to demand a health check for a researcher sitting in a remote office sending out questionnaires by post to PCT staff. Much of the debate has centred (rightly) around research involving patients, but there has been little comment on the inclusion of NHS staff in the regulations, and the documentation is geared to patients,

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trial participants and locally based research. National postal surveys are very different to locally based studies in a single PCT. Some projects clearly need to be scrutinized in detail but others less so. Perhaps, in the absence of formal clarification, RM&GOs themselves might consider adopting a more pragmatic approach, as some do.

Documentation should be standardized across all organizations at the outset. There is no merit in having 30 or more forms, all different, but essentially collecting the same information. The resource implications associated with the staff time taken to devise these forms adds further to the costs of research governance as well, of course, as adding to the costs to the research team in completing each different application.

It would be of considerable assistance to researchers if the organizational changes required to achieve research governance approval had been in place before requiring researchers to comply with them. We would strongly recommend this to anyone developing an RM&GO system elsewhere. Even now, in England, whilst an up-to-date list of RM&GO contacts has recently been set up by the Primary Care Working Party of the NHS R&D Forum, and will greatly assist researchers, this still does not list any contact details for around 25% of PCTs, many of which may not be part of RM&GOs, and have to be approached individually (NHS R&D Forum). What is a researcher to do? Ignore the requirements or exclude these PCTs, compromising generalizability? It is also essential that lists of contacts that do exist are updated regularly and that ideally all PCTs (or similar primary care organizations) are all part of an RM&GO.

For RM&GOs in England or similar ones in other countries, it is essential that experienced researchers are part of the staff and that staffing is adequate for demand. Long delays in responding to researchers are unacceptable, and cover must be provided when staff are sick or on leave. Furthermore, someone in charge of an RM&GO who has research experience is absolutely vital. Our most sympathetic and helpful responses were from such individuals. Speed is of the essence in much research where there are contractual time limits for the staff being employed.

Researchers need to be alert, persistent and proactive in pursuing research governance. In the present climate in England we do not recommend conducting national postal surveys until all systems are fully operational. When setting up similar systems elsewhere we recommend becoming thoroughly acquainted with the English experience before proceeding.

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