Meeting the challenges of research governance

There is a tangible sense of hostility being expressed among UK clinical researchers at present, directed at NHS Trusts' implementation of the Department of Health's (DOH) Research Governance Framework (RGF) [1–4]. Researchers fear a decline in the UK's impressive research record due to the obstacles resulting from lengthy, complex, bureaucratic implementation procedures presented by research managers in NHS Trusts [5]. In addition, the UK health service has undergone radical organisational change, adding further complexities in the delivery of high quality research. Here we evaluate the impact of RGF particularly to multicentre clinical trials and contribute to the debate by sharing our personal experiences.

There is no doubt that patients must be assured that clinical research is undertaken to the highest standards, and an integral part of such an assurance includes improved standards of accountability. Urgent action has been required to address the crisis of public confidence in medical research, following the experiences of Bristol, and Alder Hey. The RGF, introduced in 2001 [6], sought to address perceived weaknesses in the way collaborative clinical research has historically been organised. It challenges researchers and their employers to make their responsibilities explicit and forces new standards and structures to improve safeguards for research participants.

From 2001, NHS trusts in secondary care settings, particularly in receipt of NHS R&D funds, proceeded to establish the necessary policies and procedures to comply with the RGF. This was driven by the NHS research governance implementation plan (2001) and Controls Assurance Standards, (recently replaced by the Health and Social Care Standards). A key component of Trusts' implementation of the RGF has been the development of a complex bureaucracy for approval of research projects. Full implementation of the RGF in Primary Care was delayed until 2003, when specific money was provided centrally to defined groups of Research Management and Governance Primary Care Trusts (R&K PCTs), to establish a national network to streamline their RGF arrangements. Often, primary care research studies cross a number of PCT boundaries, and the DOH's aim was to provide a unified approach, to reduce duplication and bureaucracy. Since 2003 there has been an explosion of activity as PCTs have embraced their new role. However, across both primary and secondary care, a wide range of organizational models and procedures are being adopted. Research studies have shown that there is confusion regarding the processes involved [7]. Our experience in setting up a multi-centre trial confirms this, and demonstrates the adverse impact that such confusion can cause to research.

Our study is funded by the Arthritis Research Campaign, and as such was internationally peer-reviewed. Before seeking approvals from the participating Trusts, multicentre ethical approval (MREC) was gained for the study. The trial is investigating the effectiveness of acupuncture in older adults with knee pain. It is being conducted across 41 physiotherapy centres in the West Midlands and Cheshire and involves 20 NHS Trusts (mainly PCTs), 104 physiotherapists and 7 university based researchers. Other clinical researchers have estimated the time to prepare ethical applications to be around 2 weeks with approximately 44.5 hours of activity [1]. We focus here on NHS Trust activities required to set up the trial. Following MREC approval, we collated data from correspondence relating to Trusts’ procedures for approving the trial, to enable us to describe the impact RGF arrangements had on the progress of the trial.

From past experience, we allocated 6 months to allow for setting up the trial, including gaining ethical approvals, preparing the study documentation and training study personnel. Because of new RGF procedures, we anticipated the need for the University to be more explicit in defining and allocating respective roles and responsibilities, and the quality assurance mechanisms in place for the research. We prepared a comprehensive written contract between each participating Trust and our University Research Centre, which defined the University as the 'Research Sponsor' for the trial. The agreement defined and allocated roles and responsibilities for the trial. It described the funding arrangements and approvals in place and confirmed that the University would take responsibility for the research design, provide resources to cover additional service costs, train participating physiotherapists and also audit and monitor the trial's progress. The 'Trusts' roles included ensuring the ongoing duty of care to patients and providing clinical indemnity arrangements.

On average, Trust approvals took 21 weeks (5 months) to obtain, despite regular telephone contact and personal follow-up. The main reason for these delays was variation in organization and practice (contrary to DOH recommendations), as each Trust developed individualized approval systems. This fragmentation and variation echoes the experience of other researchers [5]. Some Trusts had newly appointed R&D officers but clinical managers were often unaware of their existence, whilst others were still without R&D personnel. Trust staff were often unsure who had the remit to sign the agreement with the research centre, and some clinical centres even consulted legal advisors, adding considerable delay and expense. Many Trusts had set up their own internal Trust R&D scientific peer review committees to vet research studies before allowing them to proceed, which meant unnecessary duplication for the trial, as it had already been through a comprehensive, independent peer review process. The committees appeared to be indiscriminately applying the same review procedures to all studies regardless of information provided by the research sponsor. Although the committees provide effective quality assurance for self-funded research projects, they were the cause of significant delay for us, as multiple reviews were undertaken across numerous Trust boundaries. A mechanism to fast track those projects with a research sponsor is needed to avoid duplication of effort and avoid unnecessary delay.

The RGF requires that research staff who have direct patient contact as part of a clinical study, must hold an honorary contract with each participating NHS Trust. This means that Trusts need to arrange honorary contracts for external researchers. This involves performing risk assessment exercises, occupational health screens and criminal record bureau (CRB) checks. In our trial 7 university clinical research staff required honorary contracts with 20 participating NHS Trusts. We dedicated time specifically to assist this administrative process and, on average, it took us 8 contacts and over 3 months to organise each set of honorary

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contracts. We were forced to duplicate the process across all 20 NHS Trusts as there were no shared systems in place, despite the DOH guidance stating that Trusts can accept each other’s honorary contracts. One Trust even insisted that all 7 of the University research centre staff attend their ‘Trust Induction Course’ over one week.

Like other clinical trial units, we encountered frustrating barriers in setting up our clinical trial, which are attributable to the implementation of RGF. In total, even with 7 University based researchers dedicated to gaining the necessary Trust R&D approvals, it took 12 months to put all of these systems in place, resulting in a delay of 6 months in commencing the trial. In reflecting on our experiences, and in the knowledge that our experiences are common to others, we have the following recommendations.

(i) Echoing others [5], clear partnerships are needed between primary and secondary care organizations and partner organizations such as University research centres and academic departments, so that arrangements for research management and governance are defined and distributed.

(ii) There is a need for stronger operational guidance to simplify the processes involved in the RGF. For example, NHS Trusts could apply the RG regulation more consistently through better practical support, such as that available from the NHS R&D Forum [8]. A simple framework of information sharing for research approvals and honorary contracts should be adopted nationally. The standardization of forms for research approvals from Trusts would reduce duplication and administrative delays [8].

(iii) If duplication of scientific peer review, auditing and monitoring procedures is to be avoided, then Trusts need to adopt a nationally applied system on which to base their risk assessment of multicentre projects that already have a designated research sponsor. They also need to improve shared systems across Trust boundaries to provide efficiency, particularly for issuing research honorary contracts.

(iv) Current requirements make it increasingly difficult for practising clinicians to conduct clinical research. In order to conduct multicentre trials successfully, robust infrastructure support and experienced research staff are needed, who can dedicate time to fulfil the RGF requirements. However, the source of funding for this is less easy to identify. Implementing the RGF is costly and may require dedicated funding within grant applications.

The RGF is here to stay and we hope it will improve the standards of research. We have shown that it can be implemented in a large-scale multicentre trial; our trial has recruited two-thirds of the patients we need to date, and is progressing well. However, the complexity of the process which has developed around the RGF and the additional administrative challenges are real concerns, as they serve to increase bureaucracy, duplication, delays and cost. Perhaps we were unfortunate to be setting up our trial in a transitional period (in 2003), but we feel urgent changes are needed to operational systems, if clinical research is to provide the robust evidence required to underpin clinical practice and quality improvements.

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8. The NHS R&D Forum is to be commended on their work in developing practical advice and support for Trusts in their implementation of research governance. See http://www.rdforum.nhs.uk/toolkit.htm.