Bypassing bureaucracy to answer important questions quickly

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"Bureaucracy is a parasite that preys on free thought and suffocates free spirit"

Douglas Adams

So Long and Thanks for All the Fish (1984)

Introduction

Sometimes there is a need to answer important clinical questions quickly. Bureaucracy can erect an insurmountable barrier. The Research Governance Framework (RGF) for Health and Social Care was introduced in England in 2005 aiming to improve the efficiency and quality of research in the NHS, but has unwittingly introduced a new layer of bureaucracy which is preventing some important questions being answered.

We attempted to survey prescribing practices among UK psychiatrists in response to an urgent need for this information. There was huge variation between the responses of Research and Development (R&D) offices and our capacity to address the requirements of each office was overwhelmed. R&D approval can now be impossible to obtain. This implies the need for a radical rethink of the system. Scotland is now leading the way in the development of the first UK Multicentre R&D committee which aims to create a standardised and more simple system.

Word Count 1715

The question we tried to answer

In December 2003, the Committee on Safety of Medicines (CSM) issued guidelines suggesting that Fluoxetine was the only safe antidepressant for use in child and adolescent depression. We were aware that our clinical colleagues were struggling with having to implement an immediate and radical change in their practice and we wanted to find out how they (and, by inference, their patients) were coping with this. We knew that this was an important and urgent clinical question. We wanted to avoid bureaucratic and practical barriers and therefore, after obtaining a small grant from our local health board, we designed and piloted a simple questionnaire (taking no more than 10 minutes for clinicians to complete) and obtained MREC approval.

Our past experience had shown us that national survey research could be an efficient way for busy NHS clinicians to answer important questions that arose from clinical practice and which had the potential to influence future service development (1;2). Any research by NHS clinicians must be reviewed by the NHS R&D system before the research can be implemented and we realised that this was intended to be a supportive system designed to enable safe and cost-effective research in the NHS (3). We were therefore dismayed by the subsequent insurmountable bureaucratic barrier erected by NHS R&D nationally, which resulted in us having to abandon the study.

The question we succeeded in answering

Not to be defeated, we decided, instead, to ask the question "how did bureaucracy force us to abandon our study?".

In 2000, the English Department of Health released guidelines entitled the Research Governance Framework (RGF) for Health and Social Care (3) which were intended to

improve the quality of research, improve patients' rights, ensure financial control and accountability and prevent the investigation or publication of substandard or fraudulent work. The guidelines state that health care bodies must "be aware of research conducted in or through their organisation" and that, "no study should begin until a person with authority to do so has given written permission".

However, as our study was low risk, specific written approval by R&D offices other than our local one was not deemed necessary by the Multicentre Research Ethics Committee (MREC). MREC recommended that we should "arrange that all relevant care organisations to be notified that the research will be taking place". Being a national survey, our research was the remit of all R&D offices in the UK. Ordinarily, this requirement would have prevented a low-budget study such as ours proceeding, but our local R&D department was determined that their system should not impede research. They sent out a research pack, on our behalf, to each of the 604 UK R&D offices containing a covering letter, a copy of the local NHS R&D Management approval letter, a protocol for the study and a copy of the MREC approval letter. From our interpretation of the RGF, we were simply notifying everyone and planned to begin data collection shortly thereafter.

However, nearly one-third of all primary care trusts (PCTs) then requested further information. This led us to doubt whether non-responders (57% of the PCTs) had accepted the notion of simple notification and to wonder whether our notification had triggered an automatic and complex process of approval. To our dismay, we found ourselves in the midst of a slowly emerging and eventually insurmountable bureaucratic response from the R&D departments, with an alarmingly wide variation in interpretations of the RGF, as demonstrated in Figure 1. Some trusts requested documents in electronic format instead of

the supplied paper format. Others required unique local R&D forms, or forms which were additional to the standard national format. A number of documents requested were inappropriate for a survey of professionals including patient information sheets, introductory letters to GPs and requests for various parts of the ethics form which were either already included or not required. Some offices asked us to supply the names of the consultant psychiatrists that were to be involved in the research in their area, even though our covering letter stated that we did not have this level of detail in our database. One English R&D office required that all members of the Scottish research team apply for honorary clinical contracts in their Hospital Trust.

These requests suggest that a "one size fits all" approach had been taken by many R&D offices and that individual review of each study had either not been done or had been done by members of staff who were ill-equipped to evaluate levels of risk posed by different types of research.

Figure 1

The survival graph in Figure 2 shows that after 70 days, we only had formal approval from 15% of PCTs. From the shape of the curve, it is clear that our study would never have gained approval from all the relevant parties, at least within our research project's lifetime. Reluctantly, we realised that our urgent and important question had been condemned to a bureaucratic trashcan.

Figure 2 here

The silver lining

We (the research team and our local R&D department) felt that this must never happen again. We looked for precedents in which other systems had successfully removed unnecessary bureaucracy and found a useful model in Multicentre Research Ethics Committees. Variations in the functioning of ethics committees had erected barriers to research and a new system of multi-centre ethics approval was introduced in the UK during the last decade to address some of the problems highlighted by researchers when undertaking studies involving more than one site (4). The use of standardised means of assessment by the new multi-centre research ethics committees means that their approval is transferable throughout the entire United Kingdom (5).

Local R&D offices are now throwing up the same barriers that local research ethics committees once were and currently constitute the major barrier to multi-site research (5) (6). MREC had managed to achieve a national system, so, we asked ourselves, could R&D keep up? We attempted to drive forward a national response to the problem by describing our abandoned study to key UK policy figures however, despite significant efforts, it proved impossible to influence change in the system for the UK as a whole. Fortunately the Scottish R&D Consortium was more receptive, and, as a direct result of our findings, a Multi-Centre Research And Development Office is now being piloted in Scotland that will create a standardised system north of the border.

What are the arguments for MRAD?

Cost: We have found that to cover all the requests of R&D offices, 11 different documents (Fig 3) would be required. For each local UK R&D office to have a copy of all the information which they currently require, we estimate the costs (human resources and consumables) to be around £20 per application i.e. £12, 000 in total. At such a price, this kind of MREC-approved national survey research can no longer be the domain of the busy clinician using funds from small NHS endowments or slush funds. There are already some R&D systems in place that aim to improve the situation. The North Yorkshire NHS R&D Alliance, for example, has combined six trust R&D offices and is able to manage all research projects in North Yorkshire, cutting down on paperwork.

Standardisation: The makeup of the staff of R&D departments is variable in terms of skills and levels of experience. This may account for the range of replies which we received and the varying time taken for approval. Some offices have no scientifically trained risk assessment officers and may be unreasonably cautious with studies that they lack the skills to adequately assess.

How will the new committee work?

MRAD will be made up of R & D Managers and R & D Co-ordinators from offices throughout Scotland. Members will be experienced in the field of research and have a range of skills such as finance, statistics, ethics, risk assessment and clinical/pharmaceutical knowledge. The committee will meet twice per month and appropriate staff will serve on the committee on a rotational basis. R & D Offices that will be involved in the study will be on the review committee. A lead reviewer for each project

will be identified from the sites involved and it will be the lead reviewer only that will liaise with the applicant to resolve any issues relating to the project. MRAD will carry out the generic review leaving only local issues to be approved by the local offices. The researcher will benefit as all R & D issues & paperwork will be dealt with at the outset by one contact, clarified and then disseminated to all applicable sites. As each Health Board in Scotland is a legal entity in it's own right they must give final approval, however each board will shortly be asked to sign up to a Memorandum of Understanding in which they will agree to abide by the MRAD review and standardised paperwork.

The individual R&D offices will still be entitled to reject a favourable MRAD review but *only* if a local issue is recognised that had not been appreciated by the committee. It would be helpful if the MRAD system, as it develops, is overtly linked to the MREC system so that there is a "one-door entry" system for researchers and so that MRADs follow the same strict time frame of approval as MRECs. There is some evidence that the MREC system has improved the time taken to approval (4) and we would hope that the MRAD system would do the same.

The newly developing Scottish MRAD is attempting to incorporate all of these features. The pilot scheme is underway with plans to roll out to the whole of Scotland by the end of 2007.

Conclusion

For each member of our research and local R&D team, this was our first experience of being forced to abandon the investigation of an urgent and important clinical question because of bureaucracy. Luckily our sad tale appears to have resonated with our

colleagues in R&D offices across Scotland and has allowed us to pull together in an attempt to change the system to the benefit of researchers and, most importantly, patients. A UK-wide MRAD would considerably enhance the efficiency of clinical research. We can see no sensible reason why, if this can be achieved in Scotland, it cannot be achieved nationally.

Reference List

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Summary Box

- The Research Governance Framework has unwittingly introduced an insurmountable new layer of bureaucracy
- A nationwide survey of psychiatric prescribing practice was impossible under the RGF
- Our experience of this bureaucratic barrier stimulated us to undertake a study of the R&D system nationwide
- As a result of our study, a new Multicentre Research and Development (MRAD) approach has been introduced in Scotland along the lines of the Multicentre Research Ethics Committee system
- The Scottish MRAD innovation should be rolled out nationally

Article's provenance

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Contributions
HM, IMcC and AW conceived of the study and contributed core ideas. DY supervised statistical analysis and contributed core ideas. JEB analysed the data, drafted the paper and contributed core ideas. RR organised and contributed to data collection and core ideas. All authors approved the final draft of the paper.

Competing Interests – AW and RR have been asked to lead the development of the new Multicentre Research and Development office for Scotland. All other authors declare that the answer to the questions on your competing interest form [http://bmj.com/cgi/content/full/317/7154/291/DC1] are all No and therefore have nothing to declare

Guarantor: Helen Minnis

Ethical approval not required.

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Figure1

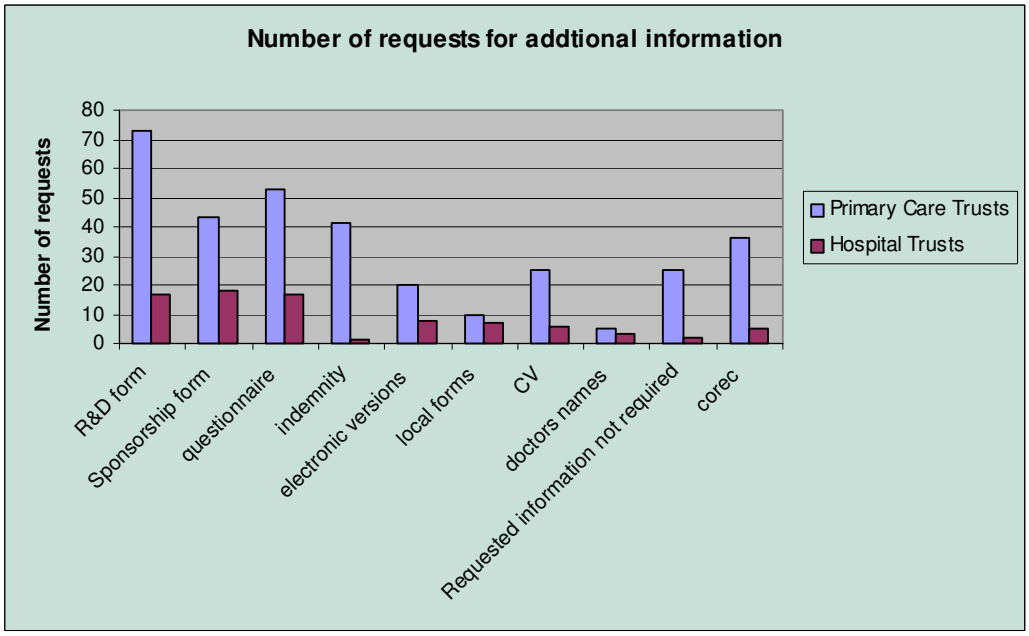
Number of requests for addtional information
Number of requests
80
70
60
50
40
30
20
10
0
R&D form
Sponsorship form
questionnaire
indemnity
electronic versions
local forms
CV
doctors names
Requested information not required
corec
Primary Care Trusts
Hospital Trusts

Figure2

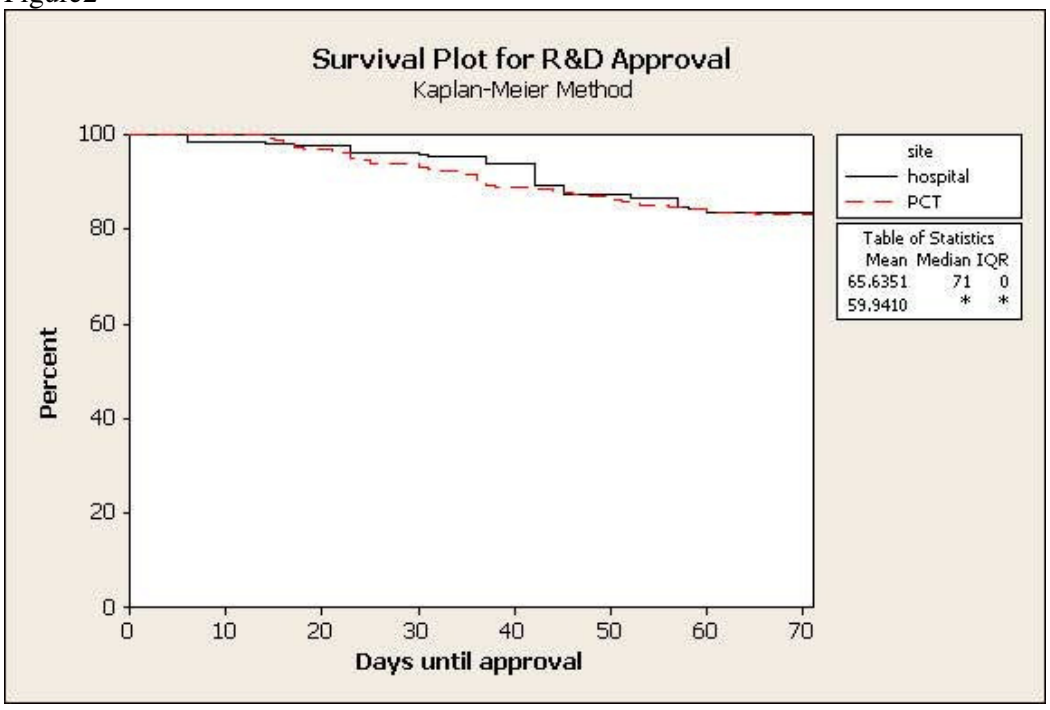
Survival Plot for R&D Approval
Kaplan-Meier Method
Percent
100
80
60
40
20
0
0
10
20
30
40
50
60
70
Days until approval
site
hospital
PCT
Table of Statistics
Mean Median IQR
65.6351 71 0
59.9410 * *

Figure 3 – documents currently required for local R&D office approval

- covering letter
- copy of MREC application and approval letter
- national R&D form
- sponsorship confirmation
- indemnity form
- copy of survey instruments
- CV of all researchers
- all of the above in electronic format and hard copy
- local R&D forms
- data protection forms
- evidence of peer review