

its attendant risk of adverse reactions. Our findings do not support the use of routine urinalysis in unselected acute medical admissions.

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The trials and tribulations of implementing a multi-centre study of encephalitis in England

Over the last 10 years, increasing rules and regulations have severely hampered our ability to do clinical research in the UK. While no one would argue that ethical approval and research governance are needed, it is now recognised that they can create unnecessary hurdles which are often disproportionate to any risks involved. More recently, steps have been taken to try and streamline the processes. However, our experience in establishing a multi-centre study of encephalitis over the last couple of years suggests there is still a long way to go.

Viral encephalitis is a devastating neurological illness, with 700 cases estimated to occur annually in England.¹ Although notifiable by law only around 20 cases of encephalitis are reported annually, emphasising the gross underreporting. Its impact, however, extends far beyond the number of patients, because of the health economic costs to the NHS and society.² In England the cause of encephalitis remains unknown in more than 60% of cases.¹ The spread of West Nile virus across Europe, and perhaps into the UK,³ gave added impetus to try and establish the cause of encephalitis in more of our patients. The Health Protection Agency (HPA) therefore set up a study, funded by the Department of Health, to document the clinical and demographic features of patients with encephalitis in three regions of

England. We aimed to ensure that the appropriate samples are collected for all cases, and that they get a full diagnostic work-up to look for possible causes (www.hpa.org.uk/infections/topics_az/encephalitis/study.htm). Given that all cases of encephalitis should be reported to the HPA anyway, that most would like to have a diagnosis, and that no extra samples are taken for the study, it could be argued that the study involves little more than best clinical practice. Nevertheless, we went through the full ethics and research governance processes.

We had hoped to take advantage of recent developments designed to streamline the process. The introduction of multi-centre research ethics committee (MREC), a single ethical review irrespective of the number of UK sites involved, has been a great improvement.⁴ The design of a single standardised research and development (R&D) application form made available online as part of Central Office for Research Ethics Committees (COREC, Part D) and the Research Passport (RP), currently being piloted in the North West,⁵ are additional welcomed developments. Our experience over the past two years however, indicates that these changes have not yet been fully implemented. The online R&D form was accepted by none of the eight London trusts. Only one of 13 centres in the North West accepted the RP, which has still to be rolled out to the rest of the country. This lack of acceptance has

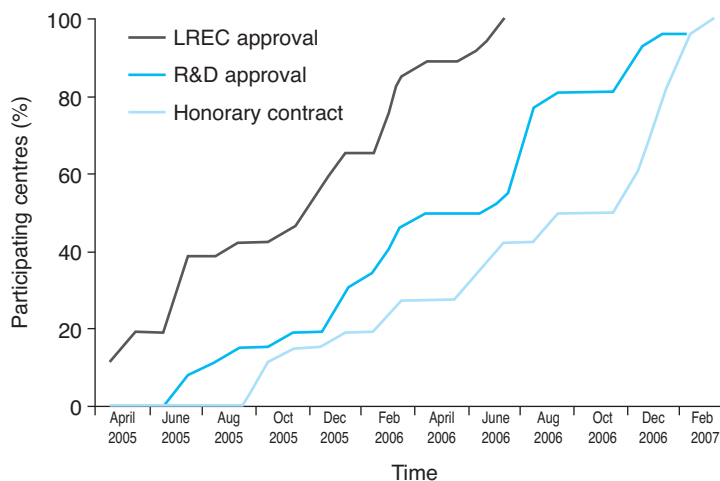


Fig 1. Time delay from multi-centre research ethics committee approval in obtaining local approvals and number of centres active in Health Protection Agency study (n=26). LREC = Local Research Ethics Committee; R&D = research and development.

resulted in copious amounts of duplicated paperwork, unacceptable delays (Fig 1) and variable turnaround times. Recently, the local research ethics committee (LREC) and R&D forms have become merged into a single form in COREC in a further attempt to help those trying to set up research. Our experience makes it clear, however, that unless there is some compulsion for all NHS trusts to accept the new procedures, then they will have failed in their objectives. We suggest that incorporation of new developments, designed to facilitate ethics and research governance procedures, becomes compulsory for NHS trusts that wish to receive research funding from government bodies.

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