

perfect studies to be conducted and published before we respond to the needs of patients with serious health problems. To create the evidence for evidence based practice we should develop "best bets" in a stepwise manner and use well conducted evaluations to initiate, guide, and sustain effective models of care while weeding out ineffective, harmful, or wasteful ones.

In Australia, where the building blocks of both community treatment and early intervention were constructed and the first wave of reforms was rolled out,<sup>12</sup> there has lately been a loss of momentum and a corresponding decay in services.<sup>13</sup> Many of the crisis resolution teams in big cities have lost funding, retreated into hospital emergency departments, or lost the key skills and sense of purpose required for this challenging role. Early intervention for psychosis is still supported by rhetoric but is struggling in practice.<sup>14</sup> One main reason for this is the failure to grasp that reform is a continuing task requiring sustainability as well as innovation.

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## Reforming research ethics committees

### *Latest proposals are a missed opportunity for a radical review*

For the first 25 years of their existence in the United Kingdom research ethics committees were left more or less in peace by the Department of Health. Since the publication of the "red book" in 1991,<sup>1</sup> however, they have undergone a continual process of radical change, from the introduction of multicentre research ethics committees in 1997, through research governance, to various legislative reforms of research practice including the clinical trials regulations of 2004.<sup>2-4</sup> Ethical review has been extended to more and more kinds and locations of research. At the same time, ethics committees have been subject to continuous criticism from researchers and public and private sector sponsors of research. Criticism from patients and the public has been less audible.

Some of the criticism of research ethics committees has focused on issues for which they can bear no responsibility, such as the interpretation of the Data Protection Act 1998 or the operation of trusts' research governance procedures. Ethics committees have been the lightning rod for the frustration researchers have felt about the bureaucratisation of research. Yet much of this frustration is reasonably directed at ethics committees. They can be slow, idiosyncratic, and poorly informed about research methods or guidelines on the ethics of research. And researchers can reasonably feel that many of the reforms since 1991, while intended to simplify ethics review of research, have actually made matters worse. This criticism appears to be common across Europe, with wide variations in approval times and required amendments being reported by many researchers.<sup>5-6</sup> Late last year Lord Warner, then a junior

health minister, commissioned an ad hoc advisory group to review the operation of NHS research ethics committees in the health and social care sector. The group's findings were published in June.<sup>7</sup>

The group's principal conclusions are that independent ethical review of research is important but that it needs to be efficient and timely and to concentrate on substantive ethical issues rather than scientific issues or minimal risk projects better overseen by other research governance mechanisms. Thus patient satisfaction surveys, assessment of the suitability of research sites, and research on NHS staff can all reasonably be dealt with outside research ethics committees. The processes of ethical review, such as the electronic form, can be simplified and improved. Decent administrative support needs to be provided for committees and for bodies such as the Central Office for Research Ethics Committees, which supports, manages, and trains ethics committees and their members. Most importantly, the report argues that committee process needs to be harmonised more closely both across Europe and within the United Kingdom and with a simplified research governance framework. The review also makes the important point that at least some "inconsistency" is actually the result of the inherent variability in moral judgment.<sup>8</sup>

All of these improvements should be welcomed by the research community: the test is whether they actually work as intended. More controversial are the conclusions that there are too many committees, some of which meet too infrequently to be useful, leading to preventable inconsistency, and that the way to deal

with this is to greatly reduce the number of committees, have them sit more often, and to pay members and chairs of committees.

The diagnosis is correct, the treatment dubious. No evidence is given to suggest that these changes will be effective in improving efficiency, reducing costs, increasing consistency, or retaining the loyalty of members and the respect of researchers. Professionalising committee membership will probably alter the kind of people serving, seeing many experienced members resigning because they cannot take on longer hours and greater workloads. Nor is it clear that a professional membership will lead to higher quality review. Indeed, it may well lead to a loss of members willing to serve out of a spirit of public or professional service.

Underlying this report's conclusions were two significant lacks: a lack of willingness to grasp the difficult question of the proper function of research ethics review, and a lack of willingness to engage with the fact that ethical review is a matter of deliberation rather than the application of formal rules. For instance, the report doesn't resolve the vexed question of what makes a project require review: the audit/research distinction is not addressed, the question of when a "student project" becomes a "research project" is skirted over, and the distinction between scientific and ethical review is made to bear too much weight. Although independent peer review of the science is crucial and requires different skills from ethical review, many suggestions made in ethical review may alter the science of the study sufficiently for the science to require revisiting. The idea that this can be devolved to "scientific officers" sounds like an excellent job creation scheme for the Central Office for Research Ethics Committees, but has little else to recommend it in practice. Thorny regulatory questions concerning non-medical or non-NHS research and their oversight have been glossed over.<sup>9 10</sup> Most of the blame for these defects lies with the panel's remit rather than the way the panel discharged it.

There is much good sense in this report and many worthwhile recommendations. Yet an opportunity to thoroughly review the oversight of research in the UK in the light of new legislation and regulatory

approaches has been missed due to the panel's narrow terms of reference and the short time frame for reporting. In the short term, at least, this report will probably continue the trend of disaffection with research ethics committees and of confused reform that requires fixing again within a short time. Cold comfort may be taken from the fact that this situation appears to be the norm across Europe.<sup>11</sup>

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## Which career first?

*The most secure age for childbearing remains 20-35*

**P**regnancies in women older than 35 are increasing markedly in Western countries.<sup>1</sup> Some commentators believe that this demographic shift poses a small or manageable problem as there are compensatory successful fertility treatments. However, it is harder for older women to become and stay pregnant, and outcomes for the mother and child are poorer.<sup>2-5</sup>

Age related fertility problems increase after 35 and dramatically after 40. Women have had more opportunity to acquire pelvic infections or develop endometriosis or premature menopause. Body mass index, which rises with age, independently affects fertility and treatment adversely. We do not understand reproductive senescence,<sup>w1</sup> but there are no immediate prospects of treatments to reverse it. Paradoxically, the

availability of in vitro fertilisation (IVF) may lull women into infertility while they wait for a suitable partner and concentrate on their careers and achieving security and a comfortable living standard. But this expensive, invasive treatment has high failure rates (more than 70% of women undergoing a cycle of IVF do not achieve a live birth—more than 90% when older than 40).<sup>6</sup> It brings extra risks of multiple pregnancy as two—and in women older than 40, three—embryos can be transferred. Delaying also affects partners<sup>w2</sup>; semen counts deteriorate gradually every year, and children of older men have an increased risk of schizophrenia and

 Additional references w1-w10 are on [bmj.com](http://bmj.com)

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