guidelines for determining when treatment for men and women should be the same or differ, and that will help optimise treatment.

George H Perkins *assistant professor of radiation oncology*

Breast Radiation Oncology Service, Nelly B Connelly Breast Cancer Center Research Program, University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd, Houston TX, 77030 USA (gperkins@mdanderson.org)

Lavinia P Middleton *assistant professor of surgical pathology*

Breast Pathology Service (lpmiddleton@mdanderson.org)

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Clinical trials for tomorrow funded by the MRC

Future policy report raises several unanswered questions

The Medical Research Council has an honourable tradition of supporting high quality randomised controlled trials. It funded one of the most celebrated early trials—of streptomycin for pulmonary tuberculosis, published in the *BMJ* in 1948.[1] It has just published a commendably short 12 page report to determine its future policy and approach to randomised controlled trials[2]—so what does it say?

It is encouraging that the MRC intends to promote trials of so called complex interventions, where several components act both independently and interdependently.This is precisely where substantial methodological challenges are to be tackled—just what is the intervention, what outcomes are relevant, and how can the results be generalised to clinical practice? For example, the results of a trial of care in a stroke unit compared with care in a general medical ward must depend on the nature of the stroke unit and general medical ward being compared—their staffing, treatment policies, duration of admission, and so on. But although ring fenced funding for the development stage of such trials is welcome, the allocation of £250 000 ($405 000; €352 000) annually will hardly be enough to put trial proposals "on a more even footing with those involving drugs." After all, the pharmaceutical companies spend millions to get their products to the stage of large trials of efficacy.

The MRC has "begun discussions" with the Department of Health about the overwhelming difficulties researchers have in accessing funding from the NHS for the treatment to be tested and for the time of the practitioners involved. And not before time. The department is supposed to underpin these costs and must be told just how monumental this problem is, particularly when the intervention is not a drug. Equipment may be required, such as compression stockings for a trial of prevention of deep venous thrombosis or coils for a trial of coiling versus clipping to prevent rupture of intracranial aneurysms. Investigations may be needed, such as an extra computed tomography scan of the head in a trial of thrombolysis in acute stroke. Or an extra outpatient appointment for follow up for the trial, which also might well provide better care than is generally available in the NHS, where waiting time targets for new outpatients are emphasised rather than proper outpatient management of long term conditions. A trial might need people, for example, to provide physiotherapy or cognitive behaviour therapy. It is disheartening for the Department of Health to insist on evidence based treatments if it is not prepared to contribute properly to getting the evidence in the first place. Surely research in the NHS is not an optional extra.

The MRC wants trial collaborators to have more incentives, so more recognition for collaboration in a trial, both on the NHS side in the annual appraisals and on the university side in the research assessment exercise. Although the cynical view is "some hope," this is a worthwhile aim, so good luck to Sir Iain Chalmers, who will lead on this initiative. Another part of the same problem is that potential collaborators can so easily be swayed by the competition, in other words by the very considerable financial incentives for participating in industry trials. The MRC document is completely silent on this crucial issue—why join an MRC trial if an industry trial will provide a research nurse to help with routine NHS work and some new gear that the hospital trust won't buy? The MRC—and Department of Health—will need to provide very substantial incentives for trusts and practitioners if they are to compete with the might of the pharmaceutical industry.

The MRC acknowledges the increasing bureaucratic and regulatory sludge, which is such a disincentive to trialists and a major burden to trial

BMJ 2003;327:240–1

managers. Ethics related hurdles are higher and higher and entail endless form filling at frequent intervals, and even getting local ethics committees to understand their remit. Cajoling the management of the local trust to understand the funding system and then to support a trial without inordinate delay can be an exquisite form of torture for those trying to join a multicentre trial and causes huge delays in getting new centres to randomise patients. I fear that the proposal for a central MRC facility to deal with all this sludge could soon get bogged down for lack of resources and will not help non-MRC trials. Far better to deal with the cause of the problem rather than the consequences.

The potential impact of the European Union's clinical trials directive for new medicines (which could spread to other interventions) threatens even more red tape and overwhelming expense. The impact assessment led by the MRC carried out as part of the consultation process, together with those from other major providers of funds and charities, has highlighted areas that will bring clinical trials to a halt. Unless the Medicines and Healthcare Products Regulatory Agency avoids overinterpretation of the directive and transposes the directive into UK legislation that is flexible, publicly funded trials will wither and disappear.

It is encouraging that the MRC will try to speed up the grant application process, but I did not notice any targets. It is also encouraging that the MRC will more formally recognise that many trials take years to complete and so require long term funding, subject to satisfactory progress—for example, the final view on whether coils are better than clips to prevent rupture of an intracranial aneurysm or whether operating on asymptomatic carotid stenosis is really worth while, requires at least 20 years of tenacious follow up. The MRC has for the past six years supported an initiative that recognised the work of trial managers on trials funded by the council. It is good news that this initiative will continue and that the MRC has pledged better to support the career development and aspirations of trial managers. It is also good that the council will encourage involvement of consumers and try to understand their perspectives better, and that they want to open up wide public discussions about just what randomised controlled trials are and what they can achieve (another task for Sir Iain). It would certainly help all of us if the public, health service managers, politicians, and the media—and some healthcare professionals did too—understood randomised controlled trials better.

Charles Warlow *professor of medical neurology*

Department of Clinical Neurosciences, Western General Hospital, Edinburgh EH4 2XU
(cpw@skull.dcn.ed.ac.uk)

Competing interests: CW has been successful—and unsuccessful—in attracting funding from the MRC for randomised controlled trials. He was a member of one of the subgroups that reported to the main review panel of the MRC.

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Paying for bmj.com

From 2005, some users will have to pay for some content

Almost 10 years after it began, the *BMJ*'s experiment of allowing free access to everything on its website will come to an end. The BMJ Publishing Group board has decided that, from January 2005, visitors to bmj.com should pay for access. The resulting revenue should not only defray the website's current costs but also allow us to fund further developments.

Exactly which content will be behind access controls, for how long, and for whom has yet to be decided. We can, however, assure BMA members (including student members) and users from the World Bank's list of 120 low and lower middle income countries[1] that access will remain free to them. We had hoped to extend this dispensation to medical students everywhere, but the difficulty of verifying the credentials of an estimated 14 000 medical student visitors each week makes this unlikely. Access to studentbmj.com will remain free.

The model we are currently finalising for bmj.com is likely to make all content free for a week or two after publication. Most of it will then be behind access controls for a year or more. Content that we intend keeping free throughout this period includes abstracts of articles, rapid responses, and the Editor's Choice column. All of *BMJ Careers* (Career Focus, recruitment and of course advertisements, and career services) will remain free.

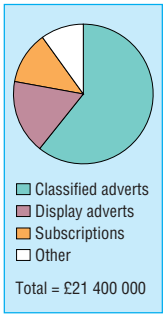

Fig 1 *BMJ*'s revenue, 2002

Our intention is to continue making the full text versions of our original research articles freely available on bmj.com and PubMed Central from the day of publication. The abridged versions of these articles ("paper short") are likely to be behind access controls.

The board's decision to introduce access controls was precipitated by anxiety over falling library subscriptions to the paper journal. In common with many scientific journals, numbers of subscribers have been falling steadily over the past decade, but the *BMJ*'s rate of decline has increased recently. Our current total is 9% lower than the same time last year, whereas the publishing group's 26 specialist journals, 25 of which have access controls, have experienced falls of only 4%. Access controls have given these journals the possibility of selling electronic subscriptions—an opportunity lost to bmj.com because of its free status.

The fall in *BMJ* subscription revenue is likely to accelerate as increasing numbers of libraries abandon paper subscriptions in favour of electronic ones. A recent survey of large American academic libraries suggests that between 50% and 80% of journal subscriptions will be solely electronic within five years (Morna Conway, personal communication). So long as access to the electronic *BMJ* remains free, we will have

BMJ 2003;327:241–2