ACADEMIC NICETY – OR SENSIBLE CHOICE?

'Twelve years ago I crossed the line between clinician and patient when, at the age of 33 years, I found out that I had breast cancer. At the time, I was doing a PhD about the problems of using randomised controlled trials (RCTs) to assess the effectiveness of treatments in my own discipline (orthodontics). During my research, I had become aware of the benefits of taking part in clinical trials and, ironically, the uncertainties about treating younger women with early breast cancer. So at the time of my diagnosis I asked my consultant if there were any RCTs that I could take part in. His response shocked me. He said that I "must not let academic niceties get in the way of the best treatment for me". But what was the best treatment? I certainly didn't know and also recognised that the profession was questioning what the optimum treatment was for early breast cancer in women younger than 50 years. So what was I to do?'

Harrison J. Testing times for clinical research. *Lancet* 2006;368:909-10.

WHAT REGULATORY SYSTEMS DO NOT DO

Although regulatory systems for research impose onerous requirements on researchers before studies start, there are many things they conspicuously fail to do, or do not do well. Many systems do not do enough to ensure that proposed studies are actually needed – for example, they do not require researchers to demonstrate that they have undertaken a thorough review of the existing evidence before embarking on new studies (see Chapter 8 for why systematic reviews are so important).

Moreover, most of the effort in regulating research is at the start-up stage, with the emphasis on controlling the entry of participants to studies. But there is surprisingly little effort devoted to monitoring studies once they are running, and to ensuring that researchers publish reports promptly at the end of their work (or even at all), stating how their findings have reduced uncertainty.

WHAT RESEARCH REGULATION SHOULD DO

'If ethicists and others want something to criticise in clinical trials, they should look at scientifically inadequate work, reinvention of wheels, and above all, unjustifiable exclusions and unjust and irrational uses of resources. The present debate is flawed by a failure to take note of what trials are for – to make sure that the treatments we use are safe, and do what they do better than the alternatives. There are no short cuts in ethics – no more than in trials.'

Ashcroft R. Giving medicine a fair trial. *BMJ* 2000;320:1686.

People who are invited to participate in research on the effects of treatments need to have confidence that the studies are worthwhile, and that their contributions will be useful. Regulatory systems need to do more to reassure them on both counts and dismantle needless barriers to good research directed towards research questions that matter to patients. There is a growing realization that testing treatments is everybody's business. As patients and the public take up the opportunities now being offered to become involved in planning and conducting research (see Chapter 11), they are likely to have an increasing voice in ensuring that regulatory obstacles are addressed.

KEY POINTS

- Regulation of research is unnecessarily complex
- Current systems of research regulation discourage fair tests of treatments that would make for better healthcare
- Despite the onerous regulatory requirements placed on researchers, regulatory systems do little to ensure that proposed studies are genuinely needed
- Research regulation does little to monitor and follow-up approved research