

the 'one-size-fits-all' approach to research ethics review may be unnecessarily burdensome.<sup>1</sup> In the UK, for example, procedures for 'proportionate review' are now being evaluated to see whether a simplified and swifter review process can be safely used for research studies that do not raise any material ethical issues.

## INFORMATION AND CONSENT

Requirements relating to provision of information and consent for studies are one of the ways in which the regulatory system acts to discourage rather than encourage research to address uncertainties about treatments. It is important – and ethical – to consider the interests of *everyone* currently receiving treatment, not just the few who participate in controlled trials.<sup>2</sup> The standard for informed consent to treatment should therefore be the same whether people are being offered treatment within or outside the context of formal treatment assessments. To come to a decision that accords with their values and preferences, patients should have as much information as they want, and at a time that they want it.

When treatment is being offered or prescribed in day-to-day practice, it is accepted that people may have different individual preferences and requirements, which may change over time. It is also recognized that people may vary not only in the amount or type of information they want, but also in their ability to understand all the information in the time available, and

### RETHINKING INFORMED CONSENT

'[Some] have come to suspect that informed consent is not fundamental to good biomedical practice, and . . . attempts to make it so are neither necessary nor achievable. We hope that the juggernaut of informed consent requirements that has been constructed across the last fifty years will be reformed and reduced within a far shorter period.'

Manson NC, O'Neill O. *Rethinking informed consent in bioethics*. Cambridge: Cambridge University Press, 2007, p200.

and fear. Health professionals are encouraged to help patients make choices about treatment in ways that are responsive and sensitive to what each individual wants at a particular time.

In research, however, provision of information to potential participants is overseen by regulatory agencies which often insist on the fullest possible disclosure of all potentially relevant information at the time that people are being invited to take part in studies. This may needlessly upset, frustrate, or frighten those who prefer to 'leave it to the doctor', or may raise needless concerns.<sup>3</sup>

The clinical trial of caffeine in premature babies that we mentioned in Chapter 5 (p57-58) provides a vivid illustration of how harm can be done by insisting that the fullest possible information be given to people who are candidates for research studies. The caffeine study recruited over 2,000 premature infants worldwide, but it took a year longer than expected because recruitment to the trial was slow. Recruitment was particularly

### **A COMMONSENSE APPROACH TO INFORMED CONSENT IN GOOD MEDICAL PRACTICE**

'What is missing in the debate surrounding informed consent is the true nature of patient understanding, what information patients want to know, and how to deal with patients who wish to know only the minimum. There is little work in the area of assessing the understanding of the information given to patients. Clinicians often find it difficult to be certain how much patients or their relatives have correctly understood the information given to them. Understanding is affected by who is giving them the information, how it is explained, and the time or environment required to assimilate information. A paternalistic approach is unacceptable in medical practice; a common sense approach – explaining things clearly, tailoring what is said to what the patient seems to want, and checking understanding – is required for good medical practice.'

Gill R. How to seek consent and gain understanding. *BMJ* 2010;341:c4000.

slow in the UK, where several centres pulled out of the trial owing to regulatory delays in the approval process. On top of that, the research ethics committee insisted on parents being told that caffeine could cause fits in babies – when this complication had only been seen after a ten-fold overdose. So parents were being confronted by apparently frightening information that they probably did not need, and probably would not have been given if caffeine were to be used as part of routine treatment.

There is little evidence that widely promoted forms of research regulation do more good than harm.<sup>4</sup> Indeed, what evidence there is, is very disturbing. For example, in studies assessing the effects of treatments that have to be given without delay, requiring that the ‘ritual’ of written informed consent be observed can result in avoidable deaths as well as underestimates of the effects of treatments.<sup>5</sup>

Obtaining consent is a public health intervention which can do more harm than good. Like other well-intentioned interventions, its effects should be evaluated rigorously. The lethal consequences we have described might have been identified decades ago had the research ethics community accepted a responsibility to provide robust evidence showing that its ‘prescriptions’ are likely to do more good than harm.

A flexible approach to providing information for potential research participants, recognizing that trust between clinician and patient is the bedrock of any satisfactory consultation, is better than a rigid, standardized approach. But because of the way that regulatory systems intervene in research, clinicians are not currently free to choose how to explain research studies to patients. Moreover, they often find it difficult to talk about the uncertainties inherent in research. For example, as we mentioned in Chapter 5, clinicians recruiting patients to clinical trials often feel uncomfortable saying ‘I don’t know which treatment is best’ and patients often do not want to hear it. Both doctors and patients therefore need a better appreciation of uncertainties and a better understanding of why research is needed (see Chapter 11).

### **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.