9 Regulating tests of treatments: help or hindrance?

By now you will have realized that, all too often, careful evaluations of treatments do not happen and uncertainties about treatment effects persist unnecessarily. Perversely, as we commented in Chapter 5, some prevailing attitudes actively deter health professionals from working with patients to learn more about the effects of treatments. And, strange as it may seem, systems for regulating medical research in most countries contribute to this problem by forcing an artificial split between research and treatment. Research is assumed to be a highly risky activity requiring stringent oversight, whereas routine treatment

WHO SAYS MEDICAL RESEARCH IS BAD FOR YOUR HEALTH

'Most discussion about the ethics of medical research addresses the question of how research should be regulated. Indeed, medical research is in many ways much more strictly regulated than medical practice. From a perusal of the innumerable guidelines on medical research you could be forgiven for thinking that medical research, like smoking, must be bad for your health.'

Hope T. *Medical ethics: a very short introduction*. Oxford: Oxford University Press, 2004, p99.

is regarded as much less problematic – even though, as we have described, patients can be put at risk by being given unevaluated or poorly evaluated treatments outside a research context.

Why is research seen as so risky and requiring special regulation, but routine treatment (which affects many more patients) is not? There is no ignoring a history of abuse by researchers, including experiments in which patients were exploited and used as a means to an end. And things do go wrong in research from time to time, so there is an available fund of horror stories. There is always the worry, too, that once people become research participants, their individual interests may become less important to health professionals than the overall interests of research.

The situation is further complicated by the highly variable motives of researchers: while some researchers conduct studies primarily to benefit the public, others are clearly motivated by money, or by enhanced career prospects. And sometimes it may be difficult to judge what the researchers' motives are. Research may therefore appear to be a scary prospect for patients and members of the public. It is partly because of this that there is a high level of regulation of research in healthcare.

Independent committees generally known as Research Ethics Committees (RECs, eg, in Europe) or Institutional Review Boards (IRBs, eg, in the USA) have helped to protect people from abuses perpetrated in the name of research. They review each research project and advise whether it can proceed or not, and play an important part in providing oversight of research and reassuring the public that approved studies have been designed with their interests at heart.

These committees are often made up of unpaid volunteers, including lay people. They review many different kinds of study protocols (the researchers' plans for what they intend to do) and also all the information that will be given to those who might take part in the study. The committees can require researchers to make changes to their protocols or to the information for participants. Without approval of the committees, studies will not go ahead. The committees therefore help to ensure that research participants are not put at unnecessary risk, and reassure participants and the

public that researchers cannot simply do as they like.

Research is subject to many other forms of regulation. Laws specific to research exist in most countries. All countries in the European Union, for example, must comply with the Clinical Trials Directive, which lays out the requirements in relation to so-called 'clinical trials of medicinal products' – essentially this means drug trials. Several countries also operate regulatory systems that affect all or most types of research in healthcare. Many other laws can potentially affect research, even though they were not designed with research as their primary purpose. For example, data protection laws, intended to protect the confidentiality of people's personal data, apply, in many countries, to medical research. A range of different agencies is also usually involved in regulating research in most countries.

The conduct of research is also governed by professional codes of practice and by international statements. Doctors and nurses, for example, are bound by the codes of practice of their professional bodies, and can risk losing their registration or having other sanctions applied if they violate these codes. And international statements, such as the World Medical Association Declaration of Helsinki, are often highly influential in setting standards even when they have no legal force.

DO REGULATORY SYSTEMS FOR TESTING TREATMENTS GET IT RIGHT?

Although the level of regulation can be reassuring, current regulatory systems impose very onerous burdens on anyone wishing to study a poorly evaluated treatment rather than offer it to patients in normal clinical practice. In many countries, the sheer complexity of the system – involving laws, agencies, codes of practice, and so on – is overwhelming and time-consuming. Researchers may need to get multiple approvals from different places, and sometimes have to face resultant contradictory requirements.

Moreover, taken as a whole, the system can seriously discourage and delay the collection of information that would