
Editorial

Compensating subjects of medical research

Tony Hope *Editorial Associate, Journal of Medical Ethics*

My aunt died in 1931 of diphtheria. She was five years old. The doctor who treated her died a few weeks later, also from diphtheria, caught, no doubt, from one of his patients. No one was to blame for his death, and I have little doubt that no compensation was paid to his family. Illness, and even death, was a risk he took in caring for others.

Guest argues, in this edition of the journal,¹ that those injured through being the subjects of medical research should receive compensation. This compensation should be paid even if no one has been negligent. Research subjects, in other words, would be covered by “no fault compensation”. He goes on to argue that local research ethics committees should use their power to withhold approval from medical research where no-fault compensation is not legally enforceable.

Guest provides powerful arguments in support of his view. He convincingly analyses the problems with negligence actions. However, I disagree with his conclusion. In my view it is for parliament and not for local research ethics committees to decide whether or not no-fault compensation should be provided for the subjects of medical research.

Guest distinguishes *research* from *innovative therapy*. The aim of innovative therapy is “entirely for the benefit of a particular individual patient”. Research, he writes, “begins where benefit to the patient becomes only secondary”.² This is not the same distinction as that often made between therapeutic research and non-therapeutic research.³ For example, a randomised controlled trial (RCT) comparing an established therapy with a new therapy is an example of therapeutic research. However, it does not fall within Guest’s definition of innovative therapy since the aim in entering a patient into the trial is not “entirely for the benefit of a particular individual patient”. On the contrary, a major aim is to find out the relative effectiveness of the two treatments in order to help people in the future. Thus Guest’s definition of research subjects, and therefore his identification of those who should be covered by no-fault compensation, goes far beyond Gillon’s suggestion that no-fault compensation should be provided for subjects of non-therapeutic research.⁴

I part company from Guest early in his arguments.

He writes: “the justification of the benefit to others . . . is an important justification for energetically pursuing medical research. But it essentially means that research subjects are being used for the benefit of others; a point not to be overshadowed by the fact that they consent”.² There seem to me to be several reasons why the subjects of medical research are not usually “being used for the benefit of others”. When we say that somebody is “being used” by someone else we normally are suggesting that the person being used is not fully aware of what is going on – that full consent has not been given. On Guest’s view most acts of altruism are examples of “being used”. When I donate blood, for example, I do not consider that I am being used. It is good to be able to help others in this way. Furthermore there is an element of justice. Were I to have an accident and require blood I would expect to be given it. It seems only fair, therefore, that I donate it. Taking part in medical research raises similar issues in justice.

Furthermore, although the subjects of research may be putting themselves at risk, they may also receive benefits. In the case of therapeutic research this is very frequently the case. A person who takes part, for example, in an RCT is likely to have as much to gain as to lose. In an RCT which compares a new therapy with conventional therapy, research subjects have a 50% chance of receiving the same therapy as they would receive outside the trial, and a 50% chance of receiving the new (unconventional) therapy. The new therapy poses risks but it may also prove to be of greater benefit. Even in the case of non-therapeutic research, subjects can benefit. A close relative of mine once took part in a non-therapeutic piece of research. As part of the research she had a blood test. An abnormality was discovered which led to correction of the underlying problem. The extra resources which often come with research frequently mean that the subjects receive attention and tests which can be to their benefit.

To return to the issue of no-fault compensation. Guest’s central argument is summarised as follows: “to employ sensible philosophical terminology, research subjects possess rights which cannot simply be balanced against the general welfare of society even where the subjects appear to consent. This can be

seen in the moral futility of denying compensation to a severely injured research subject by saying: 'you consented to taking the drug; you knew it was a new drug and that its effects were not fully known' ".²

There are many situations in our society where we do, in effect, say just this. To a general practitioner we essentially say: "You consented to taking the risk of catching infections from your patients. The likelihood and effects of many of these infections are not fully known. If you expect no-fault compensation you must take out the insurance yourself". If I were injured while climbing a mountain, and you saw my distress and came to help me you would take risks for altruistic reasons. If you were injured as a result there would be no automatic no-fault compensation – although the situation legally could be extremely complex. The degree of altruism and the risks taken in being a research subject are not unique or even unusual. In the UK there is no comprehensive no-fault compensation. Given this situation, why should medical research be singled out?

No-fault compensation is a complex issue with major economic implications. In the case of the subjects of medical research, who should pay for such compensation: the trust fund which is paying for the research; the university which employs the research worker; the research subject who volunteers to take part? And what would be the impact on medical research? The extra cost would presumably result in less research being carried out for the same overall sum of money. Is that desirable? These issues are for parliament to decide and not for local research ethics committees.

I think we should probably move away from compensation altogether. Consider three people. A loses his leg as a result of the clear negligence of his

employer. B loses his leg as a result of taking part in medical research – but not as a result of any negligence. C loses his leg as a result of a genetic abnormality (for example as a result of diabetes). Under the present system A gets compensation, but B and C don't. Under Guest's system A and B get compensation but C doesn't. And yet all three suffer exactly the same loss through no fault of their own. Both the current system and Guest's system are unfair to C. Instead of a system of compensation, I would favour a well-financed welfare system. A, B and C all deserve free treatment and support. The money used for compensation on the current scheme or on Guest's scheme should go into the "welfare pot" so that C gets his/her share. Of course, part of the current system is designed to act as a deterrent to negligent acts. But the issue of compensation should not be confused with deterrents. Deterrents should be the business of the criminal law and not a compensation.

Tony Hope, PhD, FRCPsych, is a Psychiatrist, Reader in Medicine and University Lecturer in Practice Skills, Oxford University. He is also Editorial Associate of the Journal of Medical Ethics.

References

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- 2 See reference 1: 181.
- 3 Kennedy I, Grubb A. *Medical law* [2nd ed]. London: Butterworth, 1994: 1029–32.
- 4 Gillon R. No-fault compensation for victims of non-therapeutic research – should government continue to be exempt? *Journal of Medical Ethics* 1992; **18**: 59–60.