Editorial

No-fault compensation for victims of non-therapeutic research – should government continue to be exempt?

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There is an odd anomaly in British medical research that deserves wider professional and public discussion than it has yet received. If a volunteer for non-therapeutic research suffers as a direct result of such participation, then provided the research is initiated and/or carried out on behalf of the pharmaceutical industry the volunteer has a right under the Association of the British Pharmaceutical Industry (ABPI) guidelines to be compensated speedily and without any need to prove fault – only evidence of causation is required (1). If on the other hand the research is non-pharmaceutical, or not carried out on behalf of or in co-operation with the pharmaceutical industry, then the volunteer has no such right – it is a matter either of proof of negligence or of 'ex-gratia payment' at the discretion of the government, via the National Health Service (NHS) and the Department of Health (DH), or the Department of Education and Science (DES), or the Medical Research Council (MRC), as appropriate.

In 1986 the Royal College of Physicians (RCP) drew attention to this anomaly in its report on research on healthy volunteers and recommends that '[t]he sponsor, whether this be a commercial organisation, university, NHS or other institution, should agree to pay compensation for injury, accident, ill health or death caused by participation in a research study without regard to proof of negligence and without delay. Provision for arbitration of disagreement should be included' (2).

In 1990 the RCP, in its revised guidelines to research ethics committees, noted that matters were still 'clearly unsatisfactory'. Observing with approval that the MRC had formally accepted the recommendation of the Medicines Commission respecting healthy volunteers that: 'there should be assurance in advance that there would be adequate compensation without the need for the volunteer to show negligence' the RCP advised that 'Ethics Committees should expect a similar commitment from other public sector bodies' (3).

The British government, far from accepting this advice, has made it quite clear that no such commitment can be made by the NHS. In its 1991 guidelines to Research Ethics Committees, the Department of Health states unequivocally: 'NHS

bodies are not empowered to offer advance indemnity to participants in research projects. A person suffering injury as a result of having taken part in research would be able to pursue a claim for negligence through litigation. Each case would of course have to be considered on its merits'. Thus the government guidelines reject the RCP, MRC and Medicines Commission advice so far as it applies to the government, though they point out that private sector companies sponsoring research – mostly pharmaceutical companies – 'are usually able to ensure that effective provision is made to compensate any research subject whose health may be affected' (4). Whatever the arrangements for compensation are, the DH guidelines make it quite clear that research subjects, whether patients or volunteers, must be told about them in advance: 'Volunteers must therefore be told in advance of all known risks and be made aware that there could also be unforeseen risks and of the possible difficulties in obtaining compensation'.

The outcome is that not only does an effective double standard continue, but also that healthy volunteers must be told that the NHS is unable to commit itself to standards for compensation that the medical profession itself believes should apply.

What might be the justification of such a policy? Well it certainly respects the autonomy of research subjects. And in requiring explanation of the risks of harm, known and unknown, the policy is doubtless helping to protect potential research subjects from undertaking anything they might perceive to be too harmful to themselves – though since the 'rules' of non-therapeutic research are that risks higher than minimal are unacceptable, the actual harm prevented by such a policy (as distinct from its contribution to respect for volunteers' autonomy or self-determination) is likely to be minimal too. Nonetheless it seems quite likely that more people will be put off from volunteering by the new policy, if for no other reason because they are likely to be irritated by the apparent ingratitude of those who are asking for their help with medical research intended to benefit not them but others. For under the government guidelines potential volunteers are in effect to be told: 'While the risks of volunteering to help others are very small, nonetheless if you draw the short straw, tough luck – you'll get no

compensation unless you can prove negligence in a court of law, or unless we choose to make a charitable donation to you'. No matter how nicely this message is dressed up, if it is transmitted clearly, as required by the DH guidelines, reduced participation by volunteers and thus an impediment to medical research is surely inevitable.

Is the problem one of resources? So far as non-therapeutic medical research is concerned the answer must surely be no – for the additional cost of providing even a commercially obtained institutional insurance cover against harm caused by participation in non-therapeutic research is likely to be insignificant in comparison with the government's total research budget. The more likely worry at the Department of Health is that if the principle is conceded for non-therapeutic research, it will be difficult to draw the line. The notorious difficulty of distinguishing between therapeutic and non-therapeutic components of medical research in clinical projects where elements of both are involved will lead, it may be argued, to claims for no fault compensation for *any* harm caused by participation in medical research, including therapeutic research. Thus patients entered for a trial of standard versus new therapy who suffer a standard drug side-effect will claim compensation and the costs of the scheme will become prohibitive. Nor need the slide stop there, for if patients accidentally suffering as a result of a treatment given during research are to be given no-fault compensation then so too should patients who sustain accidental but non-negligent harm as a result of ordinary, non-research, treatment. Soon the flood-gates are open to exceedingly expensive no-fault compensation for any non-negligent harm, including every undesired side-effect caused by any medical treatment; so better not to start down that road, concludes this line of argument.

In a world with unlimited resources it would of course be nice to compensate everyone who was harmed in any way, from any cause. In the real world of severe limitation of resources a clear moral distinction has to be drawn between being accidentally harmed in the pursuit of one's own interests and being accidentally harmed in the altruistic pursuit of benefit for others. Most medical treatment is pursued from self-interest and entails some risk and patients know this (or should know it). If there were a change in norms such that either only minimal-risk treatment could be offered as therapy, or alternatively that compensation had to be produced when any risk of treatment was actually instantiated, then the possibilities of providing medical treatment would be radically diminished and the costs of compensation radically increased, to the general detriment of medical care.

Similar reasoning applies to therapeutic research. For example, in a context of 'clinical equipoise' about which of two standard treatment regimes would most benefit a patient with, say, leukaemia it is in the patient's medical interest that the answer to that question is obtained and participation in a clinical trial

to try to find out (a clear example of therapeutic research) can justifiably be undertaken without provision for compensation if the patient should suffer from a drug side-effect. (Compensation for medical negligence is of course a separate issue.)

Suppose, however, that the patient also agreed to participate in a dermatology project in which clinically benign moles were being biopsied in people of different ages in order to gain better knowledge of the natural history of moles; and suppose too that the patient, having agreed to participate in this non-therapeutic research (not intended or expected to benefit the subject) then became extremely ill as a result of, for instance, an idiosyncratic and totally unpredictable reaction to the local anaesthetic. Here the case for no-fault compensation of the subject is surely very strong; a person has altruistically agreed to participate in a research project in order to benefit others, is non-negligently harmed as a direct result of such participation and the doctor and organisation responsible for the research desire to try to compensate for the harm inflicted.

There is little doubt that 'fuzzy border' problems would arise if compensation were introduced for non-negligent harm caused by non-therapeutic research interventions in clinical contexts. But the distinguishing principle seems clear and important and in the case of non-patient volunteers straightforwardly applicable without disproportionate expense. So far as research on patients is concerned, efforts to clarify which types of case should and should not qualify for no-fault compensation are made in a further RCP publication (5) where once again arbitration is suggested for cases of disagreement, and pursued in the ABPI guidelines on clinical trial compensation (6).

There is a clear contradiction between the advice on this issue of the Royal College of Physicians, the Medical Research Council and the Medicines Commission on the one hand, and the guidelines to research ethics committees provided by the government via its Department of Health, on the other. Further professional and public discussion is needed to decide which advice better supports the interests not only of subjects of non-therapeutic research, but also of medical research more generally and its potential beneficiaries, the general public.

References

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