Medical Research and the Accident Rehabilitation Compensation Insurance Act

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"Medical misadventure" is defined by the Accident Rehabilitation and Compensation Insurance Act (1992) to cover adverse occurrences which are both rare and severe. It excludes cases in which there may be a greater risk of adverse consequences because of the "circumstances of the particular person"[1]. Section 5 (8) of the Act specifically excludes personal injury resulting from clinical trials or drug trials from the definition of medical misadventure. Hence no cover for treatment or rehabilitation of personal injury is provided under the Act to people who suffer injury as a result of taking part in medical research.

What is classified as research?
Definitions of clinical trials and drug trials are not given in the ARCI Act and there is no reference to a clinical trial as defined by Section 30 (1) of the Medicines Act (1981). Medical research trials may represent a spectrum from therapeutic research with new therapies for the treatment of disease in sick patients to non-therapeutic biomedical research involving healthy volunteers. Therapeutic trials include non-drug trials of surgical techniques, small drug trials using different treatment protocols organised by clinicians as part of their normal clinical practice, as well as pre-marketing studies by multinational pharmaceutical companies. Major pharmaceutical companies have provided indemnity cover for drug trials in line with the Association of the British Pharmaceutical Industry (ABPI) guidelines.

There are risks in any research procedure but scrupulous attention to detail and careful observation of both the subjects and controls, as laid down in research protocols, seek to minimise risks to the subjects. However misadventure, which is unanticipated and probably non-negligent, may occur. The subject will not be eligible for rehabilitation under the provisions of the ARCI Act and therefore may be required to seek treatment privately or at the least to pay user part-charges for treatment in a public hospital. Most area health board public liability insurance policies will pay only for negligent treatment and acts by board staff. It is debatable what cover there is for non-negligent misadventure.

Who benefits from research?
The community as a whole stands to benefit from the results of clinical trials. The patient who has a pathological condition requiring a form of treatment may welcome the introduction of a new treatment offering better chances of cure. Gaining informed consent before participation allows the individual to weigh up the benefits of a known treatment against the potential benefits of a different and possibly unproven treatment. The individual, who sees benefit from the newer treatment, may therefore be prepared to take the slight risk of misadventure arising during the treatment. These circumstances do not apply to the subjects of non-therapeutic research. They do not gain benefits from treatment. They may gain a sense of satisfaction from participating in a trial which contributes to the store of medical and scientific knowledge. If they suffer misadventure they may require treatment and rehabilitation. The Accident Compensation Act (1972) provided these services to the patient without direct charge. Treatment in public hospitals was free to all New Zealand residents.

Who should pay for treatment?
The present health reforms, which aim to ".....facilitate access to personal health services...."[2] have placed barriers to access by persons who are injured whilst taking part in clinical research trials. In February 1992 user part-charges were introduced for public hospital treatments. These were intended to make people more aware of the costs of treatment and so be better able to make treatment choices. Subjects in any research trial may be required to pay user part-charges if they attend public hospitals for the trial. However, if misadventure occurs, should the individual be expected to pay additional costs for treatment and possible rehabilitation? Local area health board commissioners may grant exemptions but there is no nationally agreed standard.

If the need for treatment is the result of an injury sustained during a research trial, it would seem reasonable for the potential beneficiaries of the research to pay for the treatment and rehabilitation of the injured person. In non-therapeutic research, the community is the potential beneficiary. The taxpayer, on behalf of the whole community, should pay the costs of misadventure arising as a result of clinical trials.

I would make two recommendations for serious consideration by national policy makers:

1 A "No Fault Compensation" scheme should be re-introduced for all cases for personal injury arising as a result of clinical research. Volunteers should be treated and rehabilitated as soon as possible after the occurrence of any injury.

2 There should be a national policy exempting from hospital user part-charges people taking part in clinical trials, which have been approved by an ethics committee. Treatment and rehabilitation of any injury arising as a result of participation in a research project should also be exempt from direct charges.

The adoption of these recommendations will recognise that research and the accompanying risks to volunteers are a fundamental part of a health and disability service which will "....secure the best health for the people of New Zealand".[3]

1 Accident Compensation and Rehabilitation Insurance Act (1992) Section 5 (2)

2 Health and Disability Services Bill (1992) Preamble

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Readers are invited to submit **articles** on matters of bioethical concern. We suggest a length of 600-1000 words.

We would also welcome **letters** responding to material published in the *Newsletter*.