INDUCEMENTS TO PARTICIPATE IN HEALTH RESEARCH : AUTONOMOUS DECISION-MAKING?

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Dr Andrew Moore's provocative article, 'The Ethics of Payment for Research Participants', March 1996 issue, warrants a response from an ethics committee. This paper will examine some of the issues reviewed by Dr Moore and offer an alternative analysis.

Financial payment is but one incentive to participate in health research. There are a complex range of reasons why people are influenced to participate in research, from straight-out altruism to individual personal gain, including both non-financial and financial incentives.

Dr Moore asserts that it is ethically permissible for researchers to pay participants for their out-of-pocket expenses, participation inconvenience and risk taking. Dr Moore advocates financial inducement for research participants as being beneficial to all concerned. He says, "... financial inducement to take risks is already widespread in health research. Any promise to pay research participants out of pocket expenses is a financial inducement to participate and participation almost always causes extra risk".

This begs the question of whether as a society we should support, or indeed, encourage financial payments to participants in health research. There is underlying premise in Dr Moore's article that participants in the full range of health and disability research have the opportunity to give voluntary, free and informed consent. Not so. Listen to doctors and nurses grapple with the notion of informed consent for standard care and treatment of patients. Then add the additional complexity of consent for a research study. We would be naive to think that all the elements of the informed consent process are always present when a potential participant is recruited for research. The very nature of the power relationship between health professionals and patients relies heavily on the individual integrity of those concerned.

This is where ethics committees have a watchdog role to protect and safeguard the interests of participants in research. Ethics committees seek a safe environment for research to be undertaken. The principle of informed consent is largely centred in the principle of respect for autonomy. The essence of free and informed consent in a research context is to ensure that there is an environment free of coercion and pressure so that participation is voluntary and participants have the ability to say 'no'.

Motive : what are the incentives to participate in health research?

The public's motive to participate in health research is broad-ranging from individual benefit to be gained from access to new treatment, to a greater public good whereby individuals may not necessarily benefit themselves but altruism influences the desire to help others. Other motives may be less clear, such as 'because the doctor thinks its a good idea and I don't wish to offend them', or, ambivalence as to the inconvenience or hazards that might be associated with the project. Much research in New Zealand hinges on the 'good ol' kiwi goodwill'. Motivation to participate in research is to be encouraged.

Access to treatments and new drugs through participating in research is one area where a direct benefit to individuals can be identified and quantified. Patients may not otherwise have the opportunity or the money to afford a new drug that is only available through participation in a clinical trial. Indeed, Elks (1993) argues that there is a *right* to participate in research. Distributive justice through the fair allocation of resources takes an interesting twist in the research context when researchers endeavour to obtain resources and medicines for patients in their care through the research itself. In one American study (Cassileth et al, 1982), 52 percent of respondents saw participation in medical research as a way "to help me get the best medical care".

It is easy to understand how individuals faced with grim prognosis, such as AIDS, would opt for the hope of a new drug rather than 'doing nothing'. Autonomy may be compromised when patients have a fatal illness in circumstances where they cannot give free and informed consent. Minogue et al (1995) consider that the recruitment of such patients as subjects in human experimentation exploits their vulnerability in a morally objectionable way. They suggest two options : firstly, recruit only those patients who desire to contribute to medical knowledge, rather than gain access to experimental treatment. The second option is to provide prospective subjects the choice to participate in a standard double-blind study or receive the experimental treatment. If patients

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opt for the treatment rather than the closed experiment then they argue that the subjects have not been genuinely voluntary participants in research.

The worry is that research subjects have been participating only for otherwise non-available experimental medication, and not from a voluntary choice to participate in research. If in that case there is a slowing of research, that is unfortunate, but research progress at the price of autonomy violation is too steep a price. (Minogue et al, 1995, 52).

There is a variety of reasons why people volunteer for research. A distinction can be drawn between the factors that may influence a patient participating in therapeutic research who has an ongoing care and treatment relationship with the researcher, and participants who are truly healthy volunteers and do not have the same ties and potential for exploitation.

Payment to Participants

Financial incentives may prompt people to volunteer for research. Is it ethically acceptable to pay participants to take part in a research project? It is not uncommon for participants to be reimbursed for travel expenses, outpatient charges waived, and payment for time off work. Financial incentives are sometimes used when benefit to participants is remote or non-existent. An example is the early developmental phases of investigating a new drug or device. Applying the notion of reciprocity, it seems only fair that volunteers in this situation should get something back for their inconvenience and potential and real hazards that may result.

Moore (1996) reluctantly accepts that financial payment might introduce bias and researchers should 'watch this'. Research bias is important as the validity of the research may be affected, thus making the project ethically unacceptable. There is a tension because incentives may increase poor response rates, a particular concern in health survey research (Salmond, 1993). However, while financial incentives may maximise the response rates they may also affect the quality of the data through bias and exploitation of vulnerable groups, largely poorer people.

Dr Moore fails to consider the extent of the 'slippery slope' argument. A large proportion of clinical research (where physical risk is greater) is sponsored by drug companies. It is no secret that drug companies spend large amounts of money on not only research but marketing their products. If there were a green light for payment to participants in research, the sky is the limit. The net result would be that public good research where there are no financial ties and is arguably more independent, would not be able to attract participants who are otherwise lured by cash payments in drug company sponsored clinical trials.

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The difficulty lies in crossing the boundary between reimbursement, recovery of expenses, and, financial payment as the prime incentive. In the writer's view payment to research subjects for participation should be a reimbursement but it should not be considered a financial benefit. The ethics committee should review both the amount of payment and the proposed method of timing so that neither are coercive or present undue influence. This view is in line with the Food and Drug Administration (FDA, 1988) guidelines on this topic.

Financial payment to participants beyond reimbursement should be viewed with caution to avoid exploitation of vulnerable groups, especially where there is significant risk-taking. Despite these cautions there may be situations where financial incentives for recruitment are justified in situations when benefit to participants is remote or non-existent.

Conclusion

The issue of incentives to participate in research is a practical example where limits are placed on the principle of autonomy. Informed consent to research requires an environment free from coercion to allow voluntary participation. What motivates people to participate in research may vary according to a number of factors including the relationship of the participant to the researcher, patient or healthy volunteer status, benefits either real or perceived to the individuals concerned, or a sense of altruism.

Ethics committees do not place a blanket 'ban on participant pay' as Dr Moore suggests. There is a wide range of research submitted to ethics committees which adds to the complexity of establishing rules of thumb for financial incentives. Should the same principles apply to terminally ill patients participating in a clinical trial as apply to a community health survey? When does payment in kind, such as access to new drugs, become a financial incentive? Guidelines on the ethics of payment to research participants would assist ethics committees to tackle the full range of health research considered by them.

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