SELECTED SUMMARY

Paying physicians for conducting clinical trials: motivation or inducement?

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James Raftery, Christine Kerr, Sheila Hawker, Johan Powell. Paying clinicians to join clinical trials: a review of guidelines and interview study of trialists. *Trials*. 2009 Mar; 10: 15.

Clinical trials contribute to the growth of medical science and the dissemination of medical knowledge. They straddle a wide range of subjects and issues and have been instrumental in helping physicians achieve much of the success that they have achieved in their fight with diseases and disorders. In the conventional consciousness today, they have come to be considered an integral part of drug development – for the introduction of new drugs, for the use of drugs in novel indications and for the study of outcomes of treatment.

The utility of clinical trials is, however, not limited to drug development. Clinical trials are important tools for assessing the health of the community, bringing about healthcare innovations, guiding health economics and providing the evidence for the development of clinical practice guidelines. In critical areas, they have also provided the basis for development of triage protocols and treatment algorithms. This aspect often escapes notice; all attention is grabbed by clinical trials that are conducted as part of the drug development process.

Well-conceived randomised controlled trials powered by good recruitment, subject retention and completion numbers are today the backbone of clinical research; their results form the highest level of evidence. However, several studies fold up due to inadequate recruitment (1, 2). The loss to the body of medical knowledge as a consequence is considerable, as is the discouragement to investigators that ensues.

There are many elements that go into improving recruitment into a clinical trial: a good patient database, a clinical research team that communicates well with the subjects in the database, good professional relationships resulting in referrals, a study team that is responsive to the needs of trial participants, the location of the site in an institution of good standing, etc. However, it is also commonly believed that rewarding the participant for participation in clinical trials directly through incentives and extending similar incentives to investigators (or trialists as the authors in the article under review call them) will result in better recruitment. This belief is most often held in the matter of industry-sponsored trials of a new molecule. Subtle pressure is also applied by making payments per participant recruited in an environment of competitive recruitment; the payout is highest for the recruiter who recruits the highest number in the limited time for recruitment. Such a time limit is not based on any scientific reasoning. It is set by the sponsor based on the economic and financial compulsions faced. Such practices have resulted in serious ethical concerns. Many organisations have developed guidelines to limit the ethical deviations that creep in (3,4). Even these have failed to satisfy many of the parties involved (5).

Regulatory measures to tighten practices and reduce abuses have been put in place in many countries, but concerns persist even in developed nations (5). Such concerns about recruiting practices in a "competitive, commercial research environment" have been well articulated and presented in the *Canadian Medical Association Journal* (6). Payments for clinical trials in countries like India would naturally be a cause for even greater worry. It is no coincidence that sponsors are moving out to countries and environments where regulatory supervision is lax or non-existent. Combined with low literacy, poor penetration of education, poor observance of civic rights, lack of access to the system of justice, and indifference to human rights, the exploitative potential inherent in a system of reward for recruitment is obvious.

The authors of the article under review undertook their study with the stated aim of collating and analysing "views of clinical trialists on the role of payments and other factors that motivated clinicians to join clinical trials". They conducted this survey in the controlled environment of the National Health Service in the United Kingdom using semi-structured interviews. They concede that all payments in the UK have become "highly regulated and increasingly transparent" and conclude that "payment of clinicians beyond expenses is perceived to be a less important motivating factor than researching important salient questions" in that country. They did not find that payments improved recruitment into trials.

The scope for payments in excess of "reasonable compensation for time and expenses" is great in unregulated environments, and that is our worry. Such payments can be, and are, used by industry sponsors to arm-twist investigators to dilute important ethical commitments and violate the rights of participants in order to fulfil their recruitment targets. Institutional review boards and ethics committees are by default the major regulators of clinical trials in our country, but they do not have access to details of payments made to investigators. In many instances, payments are made directly to investigators

who are free to spend the money in any manner they wish to. While these "financial practices" should not directly concern us, this reviewer is certainly concerned about the consequences – unbridled violation of trial participants' rights in the open pursuit of reward and pelf held out by sponsors.

It is certainly in the larger interests of society that every clinical trial achieves its recruitment targets and results in the emergence of sound evidence which will benefit trial participants and society at large. The performance of trials in areas of public importance will enthuse greater participation and retention. If the results obtained then translate to better health, there would be a great incentive for people to participate in future trials. In the absence of such benefits to trial participants, offering financial incentives will only serve to make the public even more cynical and suspicious of such trials and trialists. This would negate any interest that people may have in participation. We would be trading a small and dubious short-time gain for the loss of concrete benefits to society.

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Financial disclosure and conflict of interest: *The author has been an investigator for Pfizer, Sanofi-Aventis, Allergan, Amgen, CIPLA Pharmaceuticals and Dr Reddy's Laboratories.*