

## *Virtual Mentor*

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### IN THE LITERATURE

#### **Should Clinician-Researchers Disclose Financial Incentives to Patients?**

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**Rao JN, Sant Cassia LJ. Ethics of undisclosed payments to doctors recruiting patients in clinical trials. *BMJ*. 2002;325:36-37.**

It is common practice for British doctors, like their US counterparts, to receive payments for enrolling their patients in clinical studies. In some instances doctors may follow their patients throughout the trial, while in others patients are recruited for studies in which the doctor is not personally involved. Regardless of the nature of recruiting, doctors in the UK, as is the case in the US, are under no obligation to disclose potential earnings for recruitment to their patients. While reimbursement of physicians is needed to ensure that important clinical research gets done, randomized clinical trials sponsored by pharmaceutical companies sometimes offer significant financial incentives to physicians. Jammi N. Rao and L. J. Sant Cassia question the ethics behind this current practice in their July 6, 2002 article, "Ethics of Undisclosed Payments to Doctors Recruiting Patients in Clinical Trials," in the *British Medical Journal*.<sup>1</sup>

Concerns about clinical equipoise, informed consent, and trust in the patient-physician relationship are brought to the forefront. A state of equipoise must be present during a clinical trial. The state exists when there is "genuine uncertainty within the expert medical community about the preferred treatment."<sup>2</sup> Many of the most lucrative clinical trials sponsored by pharmaceutical companies make no attempt to address areas of clinical uncertainty. Doctors who offer their services to these trials have very little control over the specifics of the study such as the research question, or the design and methods to be used. Rao and Cassia contend that oftentimes, it is "the size of the payment and not the buzz of research" that motivates doctors to join such trials.<sup>3</sup> One concern is that trials seeking to answer clinically important questions, which are designed by non-commercial sponsors, may not have the funding necessary to attract doctors.

Physicians are required to give their patients all the relevant information before a treatment decision is made. This allows patients to give their informed consent to a doctor's actions. Rao and Cassia assert that by not disclosing their potential gain from participating in clinical research, physicians are not allowing their patients to be truly informed before making their decisions. The authors cite an American survey,<sup>4</sup> for example, which found that 80 percent of patients feel they have a right to know that their doctor would be paid for enrolling them in a study and that over

half of those surveyed felt that payments to clinicians were unacceptable. These surveys suggest that patients are concerned about the financial interest their doctors may have in recruiting them for a clinical study.

Doctors must be trusted to put the interests of the patient above their own personal gain. Rao and Cassia stress that it is not enough to just disclose payment information to an ethics committee, a measure that the Royal College of Physicians does require. The authors are concerned that the current practice of financial disclosure requires patients to have "blind and unquestioning trust"<sup>5</sup> in their physicians.

Many of the studies sponsored by pharmaceutical companies are postmarketing research, or Phase IV studies, designed to familiarize physicians with new and recently licensed drugs. The commercial interests of such studies often outweigh their scientific interests. Rao and Cassia assert that postmarketing studies can sometimes be, "marketing thinly disguised as research," that probably would not be possible, "without a system of undisclosed payments."<sup>3</sup>

An interesting question raised in the article is why governing bodies do not require the disclosure of payments to patients at the present time. There is a widespread belief in the medical community that nothing prevents patients from asking their physicians about payments if they feel this is important to them. Yet, it is somewhat naïve to expect patients to inquire about something that they may not be aware is taking place.

The authors believe that most doctors and trial sponsors will not object to changes in regulations requiring doctors to disclose financial information to their patients.

### **Questions for Discussion**

1. Do you agree with Rao and Cassia that money is a greater enticement to doctors for participation in clinical trials than the opportunity to answer important clinical questions?
2. Are the ideals of clinical equipoise and informed consent threatened when doctors do not inform their patients of their potential financial earnings?
3. Do you agree with Rao and Cassia that physicians should be required to tell their patients about money they will receive for enrolling the patient in a clinical trial?

### **References**

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