New study on effects of disclosing financial interests on participation in medical research

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Knowing how an investigator is paid for running a research study surprisingly plays a small role in patients' willingness to take part in clinical trials. However, according to a new Johns Hopkins University study more participants are troubled when they are told that the investigator could profit or lose money depending on the results.

In an effort to learn more about the effects of disclosing an investigator's financial interests on potential study participants, researchers from the Johns Hopkins Berman Institute of Bioethics, Duke University Medical Center, and Wake Forest University surveyed 470 patients from an outpatient cardiology clinic. Each of these patients, who were diagnosed with coronary artery disease, agreed to go through a consent process over the phone for a hypothetical clinical trial.

The study, published in the October issue of the *American Heart Journal,* found that simply revealing an investigator's financial interest in a study does little to affect the patient's decisions to enroll in a hypothetical clinical trial. What the study did find was that patients were more concerned about certain types of financial interests, especially when the investigator owned stock in the company financing the study.

"Disclosure of investigators' financial interests in research does not substantially affect a person's willingness to participate," says Jeremy Sugarman, M.D., senior author of the study and Harvey M. Meyerhoff Professor of Bioethics and Medicine at the Johns Hopkins Berman Institute of Bioethics, however, "ethically it's important that the patient's 'right to know' is respected before they consent to enroll in research."

"What seems to be important in the decision-making process was the patients' pre-existing level of trust in medical research in general," says Dr. Kevin Weinfurt, a medical psychologist at Duke and the lead author of the study.

The team of researchers first assessed the patients' overall level of trust in medical research. Investigators then randomly assigned them to one of three disclosure groups: Members of one group were told the clinic involved in the study would receive per capita payments per enrollee that would be used to cover the costs of the trial, including the doctor's salary. Participants in a second group were told that the investigator held stock in the company sponsoring the research. There were no disclosure statements made to members of the third group.

When asked how likely they would be to join a clinical trial, members of all three groups expressed a moderate degree of willingness to do so. Still, there were some important differences between the groups.

Patients who heard about stock ownership were less willing than those in the other two groups to indicate that they would participate in the study. In addition, they spontaneously offered three times the number of negative comments about the relationship than participants in the other groups, using words like, "disingenuous," "unacceptable," and "unethical." In addition, ten members of the group that were told about stock ownership in the company sponsoring the trial, spontaneously said they would not take part in the trial compared with only one such comment from the other two groups.

In general, members of the per capita group felt that a financial arrangement that helped cover costs of the trial was acceptable, saying, "OK, that sounds more appropriate. So there's no payment to him, but through the university. OK, I'm good."

But some members in the group that was told about stock ownership found positive things to say about that arrangement, too. One person volunteered that "It looks like he'd have this real incentive for this thing to go real well, and I guess that's all to the good."

"The findings of this study make it clear that policy makers need to continue to address the issue of conflicts of interest in research conducted by investigators who stand to profit from the results of clinical trials," says Sugarman. When it comes to financial disclosure between investigators and research participants Sugarman says, "Policy makers may want to consider more restrictive policies for equity relationships than for other financial interests in research."

It's important to note that participants in the study were disproportionately middle-to higher income white men, and the researchers say lower income participants from other racial groups might feel differently about financial relationships between researchers and sponsoring companies.

Source: Johns Hopkins Berman Institute of Bioethics

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