Conflict of Interest Disclosures in Clinical Trials Need to be Clearer

August 26 2009

(PhysOrg.com) -- It's standard practice at leading academic medical centers: When enrolling patients in a clinical trial, researchers should disclose relevant financial relationships that might affect a patient's decision about participation, such as owning stock in the company that funds the study, or having a patent on the device being tested.

It's a process many believe builds trust and fulfills a patient's right to know about financial conflicts of interest.

"But patients often don't understand such disclosures and generally don't use the information when deciding what they are going to do," says Kevin Weinfurt, PhD, a medical psychologist at Duke University Medical Center and the lead author of a paper published in the August 27 issue of the New England Journal of Medicine.

"The public is increasingly demanding transparency, but if our disclosure system isn't accomplishing what we hope it will, then we may need to change it."

Weinfurt, along with Jeremy Sugarman, MD, professor of bioethics and medicine at the Berman Institute of Bioethics at Johns Hopkins and the senior author of the paper, drew upon a five-year research project examining disclosure policies and practices (the Conflict of Interest Notification Study, or "COINS") and developed the following guidelines for institutions attempting to fully comply with the spirit and intent of disclosure:

• Study participants should not be allowed to be the sole arbiters of acceptable risk when evaluating researchers' financial relationships with organizations that support their work. Institutional Review Boards, conflict of interest oversight committees, and other such authorities should play a much larger role.

• Disclosure statements during the consent process should be brief and simple, and should encourage patients' questions.

• Study coordinators need to be thoroughly familiar with researcher or institutional conflicts of interest so they can adequately answer patients' questions. COINS research showed that coordinators are often ill-prepared to do so, or are unaware of any financial conflicts of interest.

• Boards, committees, or entities charged with designing disclosure regulations should be clear about the goals they want to achieve and should be able to determine if their directives help reach those goals.

"Disclosure alone is not enough," says Sugarman. "It is not the remedy that many seek, although the process may have a positive effect on patients' satisfaction with and trust in the research process."

Weinfurt says patients considering whether to enter a clinical trial have every right to know about financial interests in research, such as doctors owning stock in the company that is paying for the research, or a physician who holds a patent interest in a device that is being studied.

But he also argues that patients need to do their homework, too. He says any patient considering enrolling in a clinical trial might want to be prepared to ask these four questions:

• If I enroll in this study, how will I be treated differently than you would otherwise treat me for this health problem?

• As a participant, what will I be asked to do?

• If there is more than one treatment group, how am I assigned to one or the other?

• Who will have access to the data from the trial?

The study was funded by a grant from the National Heart, Lung, and Blood Institute.

Provided by Duke University Health System