JEFFREY P. KAHN, PhD, MPH
Maas Family Chair in Bioethics and Director, Center for Bioethics,
University of Minnesota, Minneapolis, MN

Beyond disclosure: The necessity of trust in biomedical research

ABSTRACT

Biomedical research is experiencing a crisis in public trust. Although the vast majority of clinical studies are conducted in an ethical fashion, public perceptions are fueled by well-publicized examples of unethical practices. Mistrust is further encouraged by the duality of the role of the clinical researcher, who is charged with both caring for patients and answering a research question. Disclosure is not adequate to fully address conflicts of interest in biomedical research; instead, efforts to protect patients' interests and enhance trust should combine disclosure with an attempt to reduce conflicts in the first place as much as possible.

Historical and recent breaches of ethics in the conduct of biomedical research have been well publicized, leading to a crisis in public trust. Moreover, the blurring of clinician researchers' dual roles as caretakers and scientists inevitably leads to confusion and distrust. This article discusses the historical context of breaches of trust, the inherent conflicts of interest in clinical research, issues surrounding disclosure, and the need to move toward better protection of research subjects' interests.

A CRISIS OF PUBLIC TRUST

Trust is an important issue surrounding biomedical conflicts of interest. As a bioethicist, I see just how central trust is to medical research from how frequently the media ask me some variation of the basic question, "Are all clinical trials rigged?"

As a faculty member in a medical school, I want to answer such loaded questions with, "No, of course not." Yet the fact that I am asked questions in such a provocative way provides a sense of public perception.

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Distrust is certainly compounded when the public reads reports that highlight real or potential research conflicts.

Overcoming a spotty history

Unfortunately, the biomedical research enterprise has a long history of trying to rebuild public trust, mostly to remedy breaches of trust. The Nuremberg war crimes trials following World War II, in which it was revealed that prisoners were misused for a variety of experiments, provide an early example. In the United States, the Tuskegee Syphilis Study, in which the US Public Health Service from 1932 to 1972 conducted deceptive research on African American men with syphilis in Alabama, is another important example. In more contemporary times, other cases can be cited.

As a result of these breaches of trust, the research community has had to work continually to convince the public that such cases are just a tiny portion of scientific research and that policies and practices are now in place to prevent serious breaches from recurring.

Track records can be read different ways

Earlier in today's conference, the notion that "trust comes from our track record" has been used in a positive sense: that biomedical research has accomplished great things. Yet this phrase can also connote the exact opposite sense: that the track record of biomedical research includes examples of misconduct. Although the good certainly outweighs the bad by a vast margin, the magnitude is uncertain. It does not take many bad cases to alter public perception and cause people to think that our track record is one of conflict of interest and the problematic use of human subjects.

CONFLICT IS INHERENT TO THE DUAL ROLES OF THE CLINICAL RESEARCHER

Notorious examples of ethical breaches are not the only factors that damage public trust. In addition, conflicts in biomedical research are inevitable when the researchers are also part of a team that provides clinical

care. If the same person is charged with both caring for a patient and answering an important biomedical research question, a problem of role responsibility arises. Blurring the roles of researcher and caregiver creates obvious conflicts on the part of the researcher and confusion on the part of research subjects.

Role responsibilities become even more complicated when financial stakes, equity interests, or consultancy arrangements are involved.

DISCLOSURE ENHANCES TRUST BUT DOES NOT PROTECT

Many people believe that one solution to conflicts of interest is to disclose everything—every potential conflict, financial or otherwise.

We already use disclosure extensively in the conduct of biomedical research in the United States and throughout most other developed countries. However, most people who are engaged in clinical research or other biomedical research involving human subjects can attest that disclosure does not always work to address the problems we are trying to solve.

Emerging research on subjects' views of disclosure

Recent studies have begun to evaluate issues surrounding disclosure. Weinfurt et al[1] examined what potential participants in biomedical research would want to know about financial conflicts of interest and how such information would affect their decisions. They found that people like to be informed of such conflicts, and that the importance of the disclosure to their decision to participate in the study depends on the level of risk that the research would entail. The authors concluded that disclosing financial interests enhances trust.

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Disclosure does not equal protection

Yet disclosing risk is not the same as protecting people from risk. Experience with informed-consent procedures has shown that the process is inadequate and does not always work well to protect patients.

Patients are already confused when their doctors invite them to participate in research. They wonder, "Am I their patient … or something else? What is the doctor's interest in relation to my interest?" We must recognize that adding even more information to the informed-consent process—ie, disclosure of financial interests—will only make the process more complicated and confusing.

Combine disclosure with serious conflict elimination

Rather than relying predominantly on disclosure, I believe it is more important for the research community to focus on the root of the problem and try to reduce conflicting relationships in the first place. Disclosure and reducing conflict are both important solutions, and not every conflict-associated relationship can be avoided, but I would argue that conflicts should first be eliminated to the extent possible.

PROTECTING PATIENTS IS THE ULTIMATE GOAL

Moving forward, we need to think about conflicts of interest and financial interests in research at three different levels:

- The individual researcher
- The institution
- The process (rules, regulations, and an oversight process).

We must not forget that our ultimate goal is to protect people—both by shielding subjects from risks that could arise from conflicting interests on the part of researchers and by ensuring that all patients have access to the benefits of continued research.

REFERENCES

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Address: *Jeffrey P. Kahn, PhD, MPH, Maas Family Chair in Bioethics and Director, Center for Bioethics, University of Minnesota, N504 Boyn HS, 410 Church Street SE, Minneapolis, MN 55455; kahnx009@umn.edu.*