Author's Commentary on "Does HIV Affect All? Researchers' Duty to Warn"

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One of the major issues in this case is separating what is legally required of the researcher from his/her ethical responsibility as a scientist working with human subjects. Sometimes the law offers incomplete answers to ethical questions that may arise in research involving vulnerable populations. (Fisher, 1997) The goal of science is to discover truth through controlled experiments, but the researcher also has an ethical duty to protect participants' welfare, In some instances these goals appear to conflict. (Fisher, 1993)

In HIV/AIDS research, many laws have been enacted as a response to litigation. Science and research, in trying to keep up with the rapid increase of this relatively new epidemic, have leapt ahead of the legal guidelines. Current federal regulations and professional ethics codes should be revised to accommodate new concerns in this field. In the meantime, scientists should take great care to implement and design ethical procedures that take a proactive stance regarding the impact of the research on individuals. They should adopt a relational ethical perspective, which involves dialogue between participants and researchers. This approach allows the investigator to reflect on participants' needs and concerns in the research context and serves as a guide to researchers in understanding their own boundaries, competencies and obligations. (Fisher, 1997)

It is important for research scientists to identify and evaluate the risks and benefits of research before they begin a study. An important factor in determining the benefit of research is whether the study has scientific merit. In order for research to be scientifically valid, it must produce reliable information. (Fisher, 1996) Many researchers promise confidentiality to ensure that participants feel comfortable enough to give accurate information. In many instances, confidentiality is integral to ensuring participant cooperation.

John made several mistakes in the design of his research. As a psychologist, he is

required to be knowledgeable about the population with whom he is working. He should have consulted with others who have conducted similar research and with HIV+ patients themselves. If he had used the experience of the investigators and the perspectives of prospective participants as a resource, John would have realized that it was highly likely that a participant would report having unprotected sex. John should have developed a protocol that would deal with all of the possible consequences of data revealed by the research.

Informed consent procedures are designed to protect participants by ensuring that their decision to participate is informed and voluntary. According to Federal Policy 46.116, informed consent forms must include:

- A statement that the study involves research, explanation of the purpose and duration of the research, and a description of the procedures.
- A description of any foreseeable risks or discomfort.
- A description of potential benefits to the participant or others.
- Disclosure of alternative procedures or treatments that may be advantageous to the subject.
- A description of the extent and limits of confidentiality
- For research involving more than minimal risk, information regarding compensation and availability and nature of treatment if injury occurs
- A statement describing the voluntary nature of the research, the right to refuse participation or withdraw participation at any time without penalty.

John's protocol complies with most of the informed consent requirements, but he fails to detail the extent and limits of confidentiality. His informed consent form should have stated that information indicating that a participant is having unprotected sex with a partner who is unaware of the participant's HIV status would lead to disclosure. This clause would have given participants the information needed to make an informed decision about participating in the study. John also could have added the option of helping participants disclose their HIV status to their partners.

In general, the scientific community needs to be more sensitive to misleading or inadequate informed consent protocols, especially when working with vulnerable

populations. Individuals in need of services or monetary compensation are at greater risk of coercion to participate in research. Participants must be given all the facts regarding a study in order to make an informed decision regarding participation.

Researchers are aware that if individuals are told that their actions will be disclosed if they report harming another person, some may either refuse to participate or withhold that information. The possibility of disclosure is likely to bias the sample and does not allow the researcher to gain an accurate understanding of the behavior in question.

Does the "good" accomplished by warning a third party about potential HIV risk outweigh the "good" that can be gained from a large subject pool whose members provide honest answers? Does the benefit of gaining a better understanding of a phenomenon outweigh the cost of potentially violating a participant's right to privacy in order to protect an individual outside the scope of the research?

Who is John responsible to -- himself, the participant, the participant's boyfriend, the HIV community, society at large, or the obligation to increase the body of scientific knowledge? Are these categories mutually exclusive? The answers depend on the scientific community's concerted efforts to address these ethical concerns. A balance between a consideration for the welfare of others and a scientist's obligation to ensure the validity of research findings is an important goal for investigators as we head into the twenty-first century.

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