Case 3b: Intentional Nondisclosure of Information in a Study of Cocaine Use Among Minority Inner-City Clinic

Patients

Controversy arose over a study of the prevalence of cocaine use among low-income, predominantly African American patients seen at an inner-city hospital clinic. An important goal of the study, which was approved by an institutional review board, was to determine the validity of self-reported cocaine use in this population.

The researchers asked clinic patients to participate in a study of sexually transmitted diseases (STOs) in return for an incentive of ten dollars. Informed consent was obtained from the participants for the study of STOs, but not for the undisclosed study of the prevalence of cocaine use and the validity of self-reported information about cocaine use. The participants were told that their urine would be tested for STOs, but were unaware that it also would be tested for cocaine metabolites.

The response rate among eligible patients was 82 percent. The participants averaged about 30 years of age. About 92 percent were African Americans and 89 percent were uninsured. Among male participants, 39 percent (162 of 415) tested positive for a major cocaine metabolite in their urine. Among those with positive urine tests, however, 72 percent denied any illicit drug use in the recent past.

Questions for Discussion

1. What was the ethical challenge faced by these investigators in their attempt to obtain accurate information about cocaine use and the reliability of patient self-reports? If they had been fully informed about the objectives of the study, how would many of the potential participants probably have responded?
2. How does the fact that this study dealt with illicit drug use bear on the ethical analysis of this case?
3. Under what circumstances, if any, is intentional nondisclosure of information permissible in research studies?
4. What information should normally be disclosed to potential participants in research studies when their informed consent is obtained?

References
