To Tell or Not to Tell: The Ethical Dilemmas of HIV Test Notification in Epidemiologic Research

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Abstract: Epidemiologic studies involving HIV (human immunodeficiency virus) antibody testing create ethical dilemmas, particularly about notifying asymptomatic seropositive subjects. Four study designs address this problem: mandatory notification, optional notification, anonymous testing, and blind testing. No single design consistently optimizes the trade-off between valid and ethical research. Each strategy differs substantially from the others in its effect on response rates, bias, ability to perform longitudinal studies, numbers of subjects who learn their test results, and the number of subjects counseled about HIV risk reduction. Both local institutional review boards and potential subjects of study (and their sexual partners) should participate in decisions regarding the conduct of sensitive AIDS (acquired immunodeficiency syndrome) research. (*Am J Public Health* 1989; 79:1544–1548.)

Introduction

Testing for antibodies to the human immunodeficiency virus (HIV) is vital to the epidemiologic research which has taught us much of what we now know about the acquired immunodeficiency syndrome (AIDS).[1–3] Such research creates dilemmas because of conflicts among the ethical principles that guide research, particularly when research subjects decline to learn the results of their HIV tests. While honoring their refusals respects their autonomy and protects them from harm, it may also jeopardize the health of third parties who do not learn that they are at risk for infection.

Society benefits greatly from research involving HIV testing, although such testing may have harmful as well as beneficial effects on research subjects. A negative result may be reassuring and motivate subjects to practice less risky behaviors, and a positive result can lead to improved medical care and prevention of further transmission of HIV.[4,5] However, a positive result may also irreparably damage a subject's psychological, social, financial, and legal status[6–10]; if confidentiality is violated, patients may suffer serious discrimination.[6,11–13] To avoid these risks, some patients may not want to know if they are seropositive. Investigators cannot ignore the potential consequences to study subjects who are found to test positive for HIV during their research. Yet researchers may also have an obligation to protect sexual partners of identified seropositive subjects when such partners do not appreciate that they are at risk for HIV infection.[14,15] Infection of these third parties might be prevented if they and the subjects were notified. There is also the possibility that investigators may be held legally liable for not informing a seropositive subject if a partner or infant becomes infected.

Recognizing these dilemmas, the Office of Protection from Research Risks of the National Institutes of Health (NIH) issued the following guideline to local Institutional Review Boards (IRBs) in 1984: "Subjects are to be informed if tests confirm the presence of HTLV-III antibodies in their blood."[16] In 1988, the NIH reaffirmed this position, stating, "It is the policy of the Public Health Service (PHS) that when HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided with the opportunity to receive appropriate counseling . . . Individuals may not be given the option 'not to know.' "[17] While these regulations have had widespread impact on research protocols, they may not resolve the dilemmas presented by HIV testing in research. This article analyzes these dilemmas and the various research designs that have been proposed to resolve them.

Ethical Principles

Research on human subjects should be guided by well-established principles of biomedical ethics.[18,19] The principle of *beneficence* requires investigators to design protocols that will provide valid knowledge that will benefit society. Investigators must ensure that the benefits of the research are proportionate to the risks assumed by the subjects. The principle of *non-maleficence* imposes a duty on investigators to prevent harm. Researchers should educate subjects about HIV and its prevention. They may also have a duty to notify seropositive subjects and perhaps their sexual partners. The principle of *respect for persons* requires investigators to treat subjects as autonomous individuals, obtain their informed consent to participate in research, and maintain confidentiality of research data. Respecting autonomy implies that subjects may decline to obtain information about their HIV antibody status.

Implications of Various Study Designs

Currently, there are four approaches to HIV testing in epidemiologic research.

- The first is *"mandatory notification":* all subjects agree to be informed of their test results and permit the investigators to retain this information. This design has been employed in research involving blood donors or military recruits (these populations are required to learn their results when tested).
- The second approach is *"optional notification":* subjects permit their blood to be tested for HIV but may decide not to be informed of their test results. Optional notification was used, for example, in studies of intravenous drug users[20] and homosexually active men,[21] and parts of the Multi-center AIDS Cohort Study.[22]
- The third method is *"anonymous testing,"* in which subjects are informed of their test results but the investigators do not know which subjects have tested

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positive. This approach was recently employed in a study of intravenous drug users in treatment.[23]

- The final approach is *"blind testing":* identifiers are removed from blood samples so that test results cannot be linked to subjects. This study design was used to study the prevalence of HIV infection in emergency room patients,[24] clients of sexually transmitted disease clinics,[25] and newborn infants.[26]

We now consider these design options in detail.

Mandatory Notification

As noted above, NIH requires all federally funded AIDS researchers to employ mandatory notification in studies where test results and subjects are linked. Others have also advocated this position.[27]

Mandatory notification is a comfortable ethical choice since only subjects who are willing to learn their test results are enrolled. There is no conflict between the investigator's duty to respect the autonomy of the subject and the duty to protect third parties. Mandatory notification is also an attractive study design because subjects may be followed longitudinally and the incidence and correlates of seroconversion studied.

Despite these advantages, mandatory notification leads to serious problems with both study design and ethics. It may result in low participation rates and selection bias. Many individuals may decline to participate in research if they are required to learn their HIV test status. Hence, participation rates may be low when notification is mandatory. More seriously, patients at higher risk for HIV infection may be less likely to participate in studies requiring notification. This bias could lead to inaccurate assessments of the prevalence of HIV infection in the population, the strength of risk factors for seroconversion, and the impact of public health interventions on the spread of HIV. Indeed, *no research* may be preferable to *unsound research*. Inaccurate estimates may be dangerous as well as misleading, providing false assurances (if mistakenly low) or fueling unwarranted fear (if mistakenly high). It has been cogently argued that bad research is itself unethical, violating the principle of beneficence: subjects may be exposed to risks even though their participation will not advance scientific knowledge.[28]

The magnitude of the refusal problem is difficult to estimate. We know of no study in which optional notification of HIV test results was initially offered, and then changed to mandatory notification. We currently do not know what proportion of the population would permit their blood to be tested for HIV antibodies, how many of these would refuse to learn their test results, and whether these probabilities are a function of an individual's serostatus or risk group. The National Center for Health Statistics surveyed public attitudes toward AIDS and found that only 70 percent of adults would agree to be tested in a seroprevalence study.[29] Clearly, such a low participation rate would undermine the validity of any epidemiologic study. In this survey (in which HIV testing was not actually performed), 97 percent of those who would agree to be tested stated that they would want to know their test results.[29]

However, individuals at greatest risk for HIV infection may also be the most likely to refuse testing. In one study, 1,383 patients of a sexually transmitted disease clinic were offered HIV testing. Of the 1,146 patients who agreed to be tested, 0.7 percent had positive tests. Blood samples of the 237 patients who refused testing were analyzed in a blinded fashion; 3.8 percent of these samples were positive for HIV antibodies. That is, patients who refused to be tested were 5.4 times more likely to be harboring HIV than those who were willing to learn their serostatus.[30] Similarly, in the Pittsburgh arm of the Multicenter AIDS Cohort Study, only 54 percent of the original 2,047 high-risk participants returned to be informed of their antibody status.[31] Such data suggest that studies relying solely on subjects who agree to learn their serostatus may seriously underestimate the true prevalence of HIV infection.

Mandatory notification may also violate the policy of permitting subjects to withdraw from a study at any time.[32] Should a subject have second thoughts and choose not to receive his test result after a blood sample had been drawn and tested, he would have no choice under mandatory notification. That is, a subject's consent to participate in a study becomes irrevocable after a blood sample is taken *even if he changes his mind about continuing participation.* Such a possibility should not be dismissed lightly; several suicides have been reported among individuals who have tested positive in the clinical setting.[33–35]

Finally, the poor participation rates potentially induced by mandatory notification may cause fewer subjects to be educated about HIV and its spread to sexual partners. Since counseling study subjects about HIV is a clear obligation of researchers, the number of individuals who learn about preventing transmission of HIV may actually *decrease* as a result of mandatory notification.

In summary, compelling all study subjects to learn their test results may not minimize the risks to partners of seropositive subjects. Knowledge about individuals who prefer not to learn their serostatus is vital epidemiologic information. Mandatory notification would only eliminate such individuals from research studies without enhancing their knowledge about AIDS or reducing the risk to their partners or children.

Optional Notification

The second alternative, optional notification, has other advantages and difficulties. Like mandatory notification, longitudinal studies of seroconversion may be performed, permitting analysis of the factors associated with those individuals who seroconvert. A distinct advantage over mandatory notification is that participation rates will probably be higher, since subjects who do not want to be informed of their HIV test result could still participate.

As previously noted, however, there are potential conflicts when some seropositive individuals are known to the researchers, yet neither the subjects nor their partners are aware of these test results. One approach is to counsel all subjects who decline to learn their HIV test results as if they were seropositive. Some subjects, however, may also refuse such counseling. In this situation, is there any justification for the use of optional notification? We believe there is; optional notification not only can be ethically justified but also has several advantages over the alternatives.

As noted above, *the number of subjects who learn their antibody status with optional notification will be the same or greater than with mandatory notification.* Persons who prefer not to know their serostatus would, if properly informed, refuse to participate if notification were mandatory. Because of the higher enrollment rates with optional notification, the number of persons who are educated about HIV infection would increase. This, in turn, would benefit more partners of seropositive subjects.

A further benefit of optional notification is that individuals who may not want to know their HIV test results may still participate in epidemiologic investigations, and subjects who change their minds about learning their serostatus may be easily accommodated. For example, subjects who initially decline to learn their results may wish to do so over time as their concerns about confidentiality and discrimination are allayed or as effective treatments or prophylaxis are developed. And because optional notification would result in studies of higher quality and validity, it would enhance each individual's contribution to research activities.

Most importantly, it should be remembered that the benefits of research accrue to all members of society, including those subjects who would refuse mandatory notification and their partners. When people choose not to participate in a study because of mandatory notification, both they and their partners would lose the direct benefits of participation as well as the indirect benefits of sound epidemiologic research about conditions for which they and their partners are at risk.

Legal issues surrounding optional notification have not been resolved and should be examined separately from the ethical issues. While physicians may have a legal duty to warn third parties who may be harmed by patients,[14] there are also legal mechanisms for the protection of subjects' confidentiality. Certificates of confidentiality which provide legal immunity from subpoena can be obtained from federal funding agencies[36,37] and new language in the Public Health Services Act may provide powerful protection of sensitive research data.[38,39] Further legal safeguards may be required in order to guarantee subjects' confidentiality and the legal protection of investigators. The possibility of civil liability must also be addressed, as well as the variation in legal mandates and safeguards in different locations.[40]

Anonymous Testing

Anonymous testing has not found widespread use in epidemiologic research. It provides no more research information than blind testing, i.e., only aggregate proportions of positive and negative tests, but results in greater refusal rates since subjects must agree to learn their results; in the drug-users study noted above, only 8.5 percent of the potential subjects participated.[23] As a study design, anonymous testing has no advantage over blind testing for cross-sectional studies. In addition, it is inferior to mandatory or optional notification for prospective studies since prior test results, biologic measurements, and behaviors cannot be linked to the individuals who seroconvert. Such knowledge is essential for designing effective interventions to control the spread of HIV.

The ethical advantage of anonymous testing over blind testing is that more subjects will learn their test results and perhaps reduce their high-risk behaviors. This is certainly a desirable goal, but as with mandatory notification, data generated from studies that enroll only subjects willing to learn their test results may be seriously biased. Furthermore, the demographic information often collected may be enough to identify a subject even if the name has been removed; testing in this situation cannot be considered truly "anonymous."[41] While anonymous testing may find greater use in the future as part of hybrid designs (discussed below), as a single design strategy, it has many problems.

Blind Testing

Blind (or unlinked) testing has found increasing use in HIV seroepidemiologic research. Two types of blind testing have been employed. One involves obtaining consent from individuals prior to taking blood for HIV testing. Alternatively, blood "left over" from other procedures is tested without the patient's knowledge or consent.

The primary study design advantage of blind testing is better participation rates and less bias. Indeed, in testing without a subject's consent, there are virtually no "refusals" and the only limit is the availability of "waste blood." But since test results cannot be linked to subjects, longitudinal incidence studies cannot be performed on an individual basis. Since blood is unlabeled, bias may be introduced by repeatedly testing the same individuals. Finally, generalizing from population-based studies that use "left-over" blood specimens may be difficult. Subjects must have entered the medical system for other reasons and seroprevalence in this group may not reflect the prevalence in the general population.

Ethically, the advantage of blind testing is that no subjects will be known to the investigators as HIV carriers who do not know themselves. On deeper examination, however, the ethical issues are not so clear-cut. Even though, theoretically, no individual study subject could be identified as seropositive, some subjects may object if they knew their blood was being tested for the presence of antibodies to HIV.[42,43] Also, if there is no patient contact, there is also no opportunity to educate subjects about reducing high-risk behaviors.

A further concern is that anonymity often may not be guaranteed. For example, in one study, patient identifiers were removed from the blood samples and replaced with numbered labels after demographic information was collected.[44] It is possible that the investigator involved in the relabeling of blood samples could, intentionally or unintentionally, link a particular test result to a blood sample by simply remembering the name and number that were associated with the same tube of blood. It should be emphasized that in studies using blood collected for other purposes, the subject has no opportunity to prevent his or her blood from being used. And, as with anonymous testing, when demographic information is collected with the blood samples, the anonymity of subjects may also be compromised.

Most importantly, when blood samples are "scrambled," persons testing positive will not be identified because distinguishing information was removed by the investigators. Having made it impossible to identify seropositive specimens, it is not clear that the investigators are absolved of any moral duty to warn third parties of potential harm.

Discussion

The current requirement of the PHS restricting the use of optional notification may not fully address the complexity of the ethical dilemmas. For example, the US Department of Health and Human Services intends to study the nationwide prevalence of HIV infection using blind testing.[45,46] This study would uncover numerous infected individuals who could never be identified, notified, or counseled.

How, then, should investigators and research-policy officials respond? One approach is to permit the local institutional review board (IRB) to set policy on this question. As we have seen, none of the four major study designs is clearly superior. The choice of the study design which yields the greatest research value while minimizing risks to study subjects and third parties is likely to vary among different studies and locales. Since IRBs currently are responsible for

applying ethical guidelines to individual studies, they may be best suited for making the decisions about notifying seropositive subjects.

A second approach to this problem would involve convening a national "consensus conference" to establish uniform guidelines for HIV testing in research. The notion of a centrally mandated policy may be appealing in that it would ensure consistency among research protocols. Such consistency, however, may actually be less desirable than decentralized decision making (the current norm for most research ethics decisions) in that the specific aspects of each individual study design that affect ethical judgments could not be considered.

A third, and more creative, approach to ethical decision making in research has been suggested by Winer, Veatch, and their colleagues.[47] Since research benefits and risks must ultimately be borne by the subjects and their partners, these groups should participate in formulating research guidelines. Providing these people with a voice in the decision-making process through appropriate survey techniques may improve assessment of the benefits and burdens of epidemiologic studies of AIDS. There are obvious difficulties with such an approach, but turning to potentially affected persons to help resolve the dilemma may correct the potential bias occurring when researchers make decisions without input from those directly affected. We may find, for example, that sexual partners of HIV-positive subjects support optional notification. They might forego knowledge of their own risk (information that they would not learn anyway under mandatory notification or with blind testing) in return for the benefits that sound research would provide. Indeed, denying them such valuable knowledge may be the most unethical posture of all.

Finally, hybrid designs may permit some optimization of response rates and test notification. For example, we have recently proposed a prospective study of HIV infection in alcoholics which encourages mandatory notification for subjects. Those subjects who refuse to permit their results to be held confidentially by the investigators would be offered anonymous testing. Those subjects who refuse to learn their results at all would then be encouraged to undergo blind testing. This design encourages as many subjects as possible to learn their test results while keeping refusal rates to a minimum by offering anonymous and blind testing. The inability to offer optional notification, however, reduces the power of the study to identify factors individually associated with seroconversion.

Partner notification presents related difficulties. Currently, it would seem reasonable to apply local guidelines for partner tracing to only those individuals who agree to learn their test results; such procedures should be clearly delineated in the informed consent. Notification of partners of seropositive persons has not been generally required, even though some states encourage partner tracing and give physicians or public health officials the option of notifying partners.[40] It would be unfair to impose on seropositive research subjects the obligation to notify sexual partners when no such obligation is imposed on others who test positive for HIV infection. Imposing such a requirement only on persons who volunteer to advance scientific knowledge would seem particularly misguided.

As the PHS emphasizes, all HIV research carries a stringent obligation on the part of the investigators to provide adequate counseling and referral.[17] To merely test subjects for the presence of HIV without attempting to educate them about the virus would clearly violate the principle of beneficence. Procedures to maintain confidentiality must also be as strict as possible.

In summary, the ethical complexities of HIV seroepidemiologic research must be balanced against the vital importance of the knowledge it provides. Unwise choices about notification policies may compromise validity as well as ethics. All study design options result in some undermining of research ethics. No single design will consistently achieve the optimal trade-off between the ability to perform meaningful research and the mandate to perform it ethically. Investigators, IRBs, policy-makers, and persons at risk for HIV infection must collaborate in addressing these dilemmas.

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Two New AIDS Documents Announced

AIDS Service Issues Outlined in Conference Report

Current and emerging issues in AIDS service delivery and AIDS service research were highlighted in the report of a HRSA-sponsored conference. The volume incorporates papers and presentations delivered by service providers, recipients, and researchers at a conference hosted by the University of South Carolina School of Public Health August 1988 in Charleston. The papers focus on nine topics, including: case management and treatment, service delivery, long-term care, psychosocial support, challenges for health care workers, education for health professionals, mobilizing community resources, information sharing and the health system's response as seen by persons with AIDS.

A limited number of single copies of the 176-page report, *Managing AIDS Services and Resources: Selected Reading from a National Conference,* are available from: Sonja Snowden, University of South Carolina School of Public Health, Building 76, Columbia, SC 29208, Tel. (803) 777-4855.

Pediatric AIDS Activities Listed in Workbook

Public and private prevention and health care efforts aimed at combating pediatric HIV infection are described in a workbook prepared by HRSA's Office of Maternal and Child Health. The book tracks efforts to implement the 82 recommendations of the 1987 Surgeon General's Workshop on Children with HIV Infection and Their Families. It is organized around the 10 work group topics selected for the 1987 conference ranging from the natural history of the infection to family issues. It also incorporates monographs on legal and ethical issues and cross-references pediatric AIDS recommendations of other bodies including the Presidential Commission on the HIV Epidemic.

The workbook was distributed to participants in the Fifth National Pediatric AIDS Conference Sept. 6–8, 1989 and the Surgeon General's Follow-Up Workshop Sept. 8–9, 1989 in Los Angeles, CA. Copies of the 142-page *Workbook for the Fifth National* Pediatric AIDS Conference and the Follow-up to the 1987 Surgeon General's *Workshop on Children with HIV Infection and Their Families* are available from Dr. John J. Hutchings, Office of Maternal and Child Health, Room 9-34, 5600 Fishers Lane, Rockville, MD 20857, Tel. (301) 443-2350.