Ethical Issues in the AIDS Epidemic

Robert Steinbrook, MD

During the first few years of the AIDS epidemic, only a relatively few physicians and health care workers faced ethical issues related to the disease. Now the circumstances have changed dramatically. Currently, there are more than 18,000 individuals living with AIDS in the United States and between one and two million are estimated to be infected with the human immunodeficiency virus (HIV) that causes the disease. As the number of AIDS cases continues to increase, more health care workers can expect to face ethical issues, sometimes on a daily basis.

Four ethical issues are of particular importance to health care professionals involved in AIDS patient care: (1) the obligation to care for AIDS patients, (2) patient confidentiality, (3) the responsibility to protect others from being infected with HIV, and (4) decisions about terminal care.

Obligation to Care for AIDS Patients

In accordance with traditional medical and nursing ethics, health care workers have an obligation to treat patients with all forms of illness, including those patients with a transmissible, fatal disease such as AIDS.

In the early days of the epidemic, before HIV was isolated and its mechanisms of transmission were clarified, the risks to health care workers of contracting AIDS from patients were unknown. In recent years epidemiologic studies have shown that the virus can be transmitted during unprotected sexual contact, through exposure to infected blood, and from an infected mother to her newborn. With rare exceptions, HIV is not occupationally transmitted, even in the health care setting. Those exceptions are the quite infrequent instances when there is extensive blood-to-blood exposure, as when nurses accidentally inject themselves with blood from an AIDS patient. Caregivers can protect themselves against HIV infections by following routine precautionary measures outlined in Public Health Service guidelines.

Nevertheless, many caregivers find working with patients with AIDS stressful. The patients may be young, well-educated, and previously healthy. They often require long hospitalizations, and their disease usually progresses despite optimal care. Some caregivers find it uncomfortable to work with patients who are gay men and intravenous drug users; many would rather avoid discussing life-sustaining treatments with AIDS patients in their care. Particular anxieties may occur when health care workers are unfamiliar with AIDS patients or when they feel overburdened by the demands of caring for a heavy caseload of patients.

Similar to other stressful psychological situations, information and frank discussion can substantially allay fears and misconceptions about the care of patients with HIV infection. Hospitals and outpatient clinics should organize periodic educational programs, and caregivers should seek emotional support from colleagues, friends, and family.

Many patients with HIV infection often suffer from considerable social stigma and isolation in addition to having a fatal illness. Many have legitimate fears of abandonment. For these reasons, it is all the more important for health care workers to provide compassionate and competent care.

Patient Confidentiality

As with all patients, caregivers should protect to the maximum extent possible the confidentiality of individuals infected with HIV. Although breaches of confidentiality appear to be infrequent, the consequences can be devastating. Violations may cause social isolation and discrimination against individuals in employment, housing, and insurance.

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However, it is impossible for the confidentiality of patients with AIDS or related disease to be absolute. For example, several state health authorities require reporting of confirmed seropositive tests for HIV antibody, and the Centers for Disease Control require that states report cases meeting its definition of AIDS. Blood banks maintain lists of ineligible donors — including those with HIV infection — although the reason for the exclusion is not listed. Patient information reported to public health authorities or maintained by blood banks should remain confidential. There is concern, however, that the very existence of such lists creates the potential for misuse.

Health care workers often must share information about HIV-infected individuals to provide them with proper medical care. Nevertheless, there is a good reason to avoid communicating information about a patient’s diagnosis or antibody test results to other individuals without explicit consent. In California, antibody testing must conform to a strict 1985 law enacted to permit screening of donated blood. It requires that written informed consent be obtained before anyone is tested for the HIV antibody. The law appears to make it illegal to record HIV test results in a patient’s medical record, although this provision has not been tested in court.

The California legislature is now considering “clean-up” legislation to make the 1985 state law more workable in the health care setting. One proposal would allow blood test results to be recorded in a separate part of the patient’s medical record, for example, in a sealed envelope. Test results would remain

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unavailable to employers, insurance companies, or government agencies without the patient’s specific authorization. The proposal would also permit surrogate consent for antibody testing in rare situations, such as for unconscious patients or for children who are being considered for placement in a foster home. In addition, it would safeguard the rights of individuals infected with HIV; such infections would be defined as a handicap, subject to state anti-discrimination laws.

Troubling AIDS-related confidentiality issues continue to occur. Some public health officials, for example, advocate wider use of HIV antibody testing to counsel patients and prevent disease transmission. The controversy is ongoing include routine HIV blood tests for patients admitted to hospitals or treated for pregnancy or sexually transmitted diseases and for couples applying for marriage licenses. These officials emphasize that many future AIDS patients may have acquired the virus from individuals who today have no idea that they are infected. Critics counter that civil rights implications of proposals for mandatory testing must be considered as well. They contend that infected individuals will respond by avoiding the health care system and delaying care until they are seriously ill.

Centers for Disease Control officials are currently testing anonymous blood samples from a random sample of hospital patients nationwide to obtain more accurate data on the magnitude of HIV infection. Such anonymous testing poses a different ethical question: Is it appropriate to test individuals who cannot be contacted and informed of positive results?

Responsibility to Protect Others from HIV Infection

There is a medical and ethical consensus that individuals infected with HIV have an obligation to protect others from acquiring it. Without a vaccine or curative drug against the virus, other means must be used to prevent disease transmission. These include not donating blood, semen, body tissues, or organs. In personal relations, precautions include not sharing equipment to inject intravenous drugs and following safer sex practices, such as the use of condoms. Some health care professionals feel that HIV-infected individuals should abstain entirely from sexual relations with those who are non-infected. Others suggest that this is an unrealistic expectation and one that may be unnecessary if precautions are followed conscientiously.

The role of health care workers in preventing HIV transmission by their patients is controversial. Caregivers may be torn between respecting the privacy rights of patients they know to be infected with the virus and their desire to protect others who may not be their patients from acquiring a fatal disease. Some feel that infected individuals have an obligation to know their antibody status. Others feel that caregivers should not take an advocacy position in counseling patients about HIV antibody testing.

Regardless of these conflicts, caregivers have a key role in educating patients about HIV infections, HIV antibody testing, and behaviors that put others at risk. Patients with AIDS-related illnesses and those who are seropositive can be asked to inform voluntarily their current and former sexual partners about their possible exposure to HIV. If interested, these partners should be encouraged to seek medical attention.

Some public health officials also advocate tracing the sexual contacts of infected individuals by asking them to name voluntarily their partners. Health departments routinely make this request of patients with such venereal diseases as syphilis and gonorrhea. Such tracing may be difficult, however; several sexual or needle-sharing partners may have been anonymous. In a pilot program in San Francisco that targets heterosexual AIDS cases, many patients either have refused to cooperate or had lost contact with past partners.

Decisions about Terminal Care

Despite recent advances in designing effective drugs to combat AIDS, there is no cure for it or for HIV-related diseases. Patients have a mean survival of less than one year after hospitalization for opportunistic infections. Thus, patients and physicians frequently must decide whether supportive care may be more appropriate than life-sustaining treatments, such as mechanical ventilation and cardiopulmonary resuscitation.

A medical, legal, and ethical consensus has developed among health care officials about limiting life-sustaining treatments when additional therapy is futile or when a mentally competent patient refuses such care. These decisions, which require both technical expertise and informed consent, should be made jointly by the physician and the patient.

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One approach to these decisions is to develop a legal system that protects the rights of patients. Some health care professionals feel that HIV-infected individuals should abstain entirely from sexual relations with those who are non-infected. Others suggest that this is an unrealistic expectation and one that may be unnecessary if precautions are followed conscientiously.

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AIDS Vaccine: Ethical Dilemmas

Bernard Lo, MD

A vaccine against the human immunodeficiency virus (HIV) offers hope for controlling the AIDS epidemic. While full-scale clinical trials to test the vaccine are several years away, it is not too soon to think about the ethical issues related to such trials.

Before widespread vaccination can be recommended to people at risk for HIV infection, the effectiveness of the vaccine must be demonstrated in clinical trials. The most rigorous design would be a randomized, controlled study in which half of the volunteers would receive a placebo. Comparing recipients of the vaccine with historical controls might be misleading, since changes in high risk behaviors during the preceding years would make comparisons between vaccine recipients and controls difficult. Some observers may object to withholding potentially useful measures to prevent AIDS, and yet a potential vaccine must be shown conclusively to be effective and safe.

Recruiting subjects for a clinical trial of a vaccine presents further dilemmas. Subjects should be reliable for follow-up, be at high risk for HIV infection, and be seronegative. It is likely that seronegative gay men will form the research cohort. Undoubtedly, many will want to participate in the trial because of the potential benefits of a vaccine. But any clinical research involves risks for the subjects. In this case, the risks include not only medical complications but also psychological and social ones. Some volunteers will test positive for HIV antibodies. Not only will they be ineligible for the study, but they will also need to cope with the psychological impact of positive test results. For those who do qualify and receive the potential vaccine, their immune systems may respond by producing antibodies to HIV (depending upon the type of vaccine developed). These seropositive individuals may face discrimination in obtaining and retaining employment, housing, and insurance. (Editor’s note: for further discussion of recruiting volunteers for a vaccine trial, see the related “Recent Report” in this issue).

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Volunteers who are accepted into the study will be asked about private topics such as sexual practices and I.V. drug use. Confidentiality of research data must be thoroughly guaranteed or these subjects could face many risks, especially since some reported behaviors may be illegal or lead to discrimination.

Those who design the protocol must determine what amount of education about risk reduction to give each trial subject. To offer none at all might withhold life-saving information, and yet intensive education may result in uncertain trial results. If trial subjects reduce high-risk behaviors, few of them may be exposed to HIV; and researchers will not be able to determine the vaccine’s effectiveness.

Finally, dilemmas may occur as data from the trial accumulate. Preliminary analysis may show a trend suggesting that the vaccine is either effective or dangerous. What criteria should be applied in determining whether to stop the trial earlier than planned? On the one hand, there is a scientific question of how likely the seeming trend is simply due to chance. But on the other hand, there is also the question of values: how do we balance the public’s need to know about the effectiveness of the vaccine against the needs of volunteers who may be harmed or deprived of benefits if the trial continues?

For the trial to be conducted smoothly, it will be essential that volunteers and subjects trust the researchers. Public discussion of issues like informed consent and confidentiality and the involvement of advocates for the subjects in the design of the study will help promote a sense of partnership between researchers and subjects. Cooperation and trust not only protect those enrolled in the study but also increase the scientific rigor of the study. Subjects are more likely to cooperate with the protocol and provide follow-up data if they regard themselves as research partners.

Some of these dilemmas—such as establishing rigorous, protected confidentiality and determining interim phases for analysis of study data—will be easier to resolve if efforts are begun now to study the implications of vaccine development.

Other potential problems will be affected by the ongoing public discussions about when to make experimental drugs available to HIV-infected individuals and whether to protect this same population from discrimination. Although the time required for the scientific development of an AIDS vaccine frustrates our desire to see a quick end to this terrible HIV epidemic, serious consideration today of how to handle the related ethical dilemmas will allow the earliest possible use of a vaccine.

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BRIEFS

Recent Reports

Study Finds Willing Subjects for Possible Vaccine Trials. The ethical questions and sampling difficulties for a potential AIDS vaccine are formidable but not insurmountable, according to researchers at UC San Francisco. In a recent issue (February 1987) of The Western Journal of Medicine, Leon McKusick, PhD, Thomas J. Coates, PhD, and Marcus Conant, MD reported a survey of 676 gay men in San Francisco in which 43% (292) said they would be willing to volunteer for trials of an AIDS vaccine. Volunteers were significantly more likely to have been tested for HIV antibody and less likely to have eliminated high-risk, multiple-partner sexual activity than non-volunteers or those unsure about volunteering. Volunteers said they were particularly concerned about the safety and the confidentiality of such a trial. The researchers noted that although a small percentage of all the men surveyed still engaged in occasional high-risk sex, the level of such activity among San Francisco gay men may not be high enough to meet vaccine trial screening criteria. They suggested that other urban areas with lower HIV seroprevalence may be better suited to eventual vaccine trials.

Condom Use by Heterosexuals. A study last year by researchers at UC San Francisco employed laboratory tests to confirm that condoms provide an effective barrier against HIV. A retrospective study conducted in Zaire provides epidemiological data supporting the potential effectiveness of condoms in halting the spread of AIDS. American, Belgian, and Zairian researchers reported (New England Journal of Medicine, February 5, 1987) a survey of 377 female prostitutes in Kinshasa, Zaire. Of these women, 85 quantified their partners’ use of condoms. There was significantly less seropositivity among the women reporting condom use by half or more of their partners as compared to the higher HIV infection among women whose partners used condoms less frequently. The researchers noted that the two groups of women had similar numbers of annual and lifetime partners, and no differences were reported in the distribution of other risk factors for HIV. Although this study depended on participants’ recall, its data combined with the laboratory studies strongly indicate that proper use of condoms can help block the sexual transmission of HIV.
UCSF Study Reveals AIDS Antibody Increase Among SF Drug Users. During a twelve month period ending December 1986, the percentage of San Francisco I.V. drug users who were seropositive for the AIDS antibody jumped from 10% to 16%, according to a report published in the February issue of the American Journal of Public Health. UC San Francisco researchers monitored the seroconversion rate among 281 addicts. They found that of those who shared needles with two or more persons, 15% were seropositive. Of those addicts who did not share needles, only 3% were antibody positive. The researchers, led by Richard Chaisson, MD, found that the rate of increase in seropositivity has been especially high among the city's Black and Hispanic population of I.V. drug users. While 6% of white users had the antibody, 15% of Black and 14% of Hispanic users tested seropositive during the course of the study. The researchers did not discover a satisfactory explanation for the difference in incidence among the three ethnic groups. They did note that San Francisco's high incidence of AIDS has been confined until now to men who report having unprotected sex with other men; they fear that the city may follow the pattern of New York and other East Coast communities. Once HIV infection appeared among I.V. drug users there, it spread quickly to a majority of addicts. In New York the percentage increased from 11% in 1977 to 27% in 1979 to 58% in 1984.

In the same issue of the journal, Peter Drotman, MD, MPH of the CDC cited the promising “needle exchange program” in Amsterdam as one option for halting the spread of HIV infection. Drotman reported that the number of I.V. drug users in Amsterdam has not increased since the program began. He also noted that 70% of children with AIDS under the age of 13 in the United States contracted the disease from mothers who are I.V. drug users.

Survey of Physician Attitudes About AIDS. Significant numbers of physicians in private practice disagree with AIDS experts on the risk of exposure to HIV, the safety of the nation’s blood supply, and public health measures for halting the spread of the disease. MD Magazine recently surveyed its readers about AIDS and published the results (January 1987). More than 4,000 readers responded from all regions of the country and from urban as well as suburban and rural areas. Of 1,500 responses tabulated, 28% of physicians favored some form of quarantine, 45% said they did not believe hospital blood supplies are safe, and sizable numbers advocated mandatory HIV antibody testing for specific groups: military personnel (43%), dentists (40%), doctors (37%), hospital employees (37%), food handlers (34%), and life insurance applicants (31%). The physician’s fears about the nation’s blood supply and the possibility of casual contagion and their advocacy of quarantine and mandatory testing conflict with recent official statements of the Surgeon General, the National Institutes of Health, the CDC, and the American Medical Association.

In addition, 25% suggested providing drug users with sterilized hypodermic needles, 78% said they would not disguise the cause of death on a death certificate if asked to do so by a patient or a family member, and 79% favored special high school classes on AIDS prevention.

AZT Update. Researchers studying the antiviral drug AZT have accumulated more data about the effect of the drug on people with AIDS and AIDS related conditions. AZT has been found effective against Epstein-Barr virus and HTLV-1 (a human leukemia retrovirus) but not against cytomegalovirus (CMV). The drug also helps fight the parasite giardia. AZT appears to work synergistically with the drug acyclovir to block not only HIV duplication but also herpes viral infection. Physicians have reported dramatic improvement in some patients with neurolgic complications from HIV infection who have taken AZT. Researchers working with AZT manufacturer Burroughs Wellcome have reported that many AIDS patients have experienced improvement in cognitive and motor ability. Even with these beneficial effects, AZT remains a drug that is quite toxic to bone marrow. More than 45% of the subjects in the recently-interrupted clinical trials of AZT had bone marrow suppression, and 31% of them required transfusions, according to Caroline Kennedy, MD, an AIDS researcher at UC San Diego, who provided an updated report during a January antiviral conference sponsored by ICN Pharmaceuticals, Inc. She listed the known side effects of AZT as nausea, leukopenia (lower than normal white blood cell counts in the circulating blood), neutropenia (decreased granulocyte white blood cells), insomnia, anemia, and muscle pains. Other possible side effects include fever, headache, anorexia, abdominal pain, diarrhea, skin rash, and thrombocytopenia (a decrease in blood platelets, essential for blood clotting). The initial reports of the clinical trial of AZT revealed a 16 to 1 mortality rate for those on the placebo compared to those receiving the drug. Ongoing monitoring of the subjects in the trial (with all now receiving AZT) show a drop in the mortality statistics to a rate of 5 to 1. Researchers consider the data to still be a significant difference. The drug is expected to be licensed by the Food and Drug Administration this spring; physicians will be warned at that time of the potential serious side effects of AZT on their patients.

FOCUS A GUIDE TO AIDS RESEARCH

SUBSCRIPTIONS/CORRESPONDENCE

The amount of research information now appearing in the medical and lay press staggered most AIDS health care and service providers. The goal of FOCUS is to place the data and medical reports in a context that is meaningful and useful to its readers.