Ethical issues posed by HIV testing and screening

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FROM the outset, the test developed to detect the antibody to the AIDS virus, which was first used on a broad scale in blood banking beginning in 1985, has been mired in controversy[1]. Would groups at increased risk for AIDS be encouraged to take the test? How forceful would such encouragement be? How would those who agreed to be tested be counselled about the test's significance for themselves and others? Would, and could, the results be kept confidential? Would voluntary testing be a prelude to compulsory screening? What would be the consequence of testing for the right to work? To go to school? To bear children? To remain free? Each of these questions would force a confrontation about the relationship between the right to privacy and the protection of the public health and about the roles of voluntarism and coercion in the social response to the threat of AIDS.

Controversy about the HIV test is not foreign to India. The November 1993 issue of the *Indian Journal of Medical Research* published three articles that touched on ethical and policy issues surrounding HIV testing. Mathan[2] argues that the HIV test should be freed of limits imposed by an 'exceptionalist'[3] perspective. 'HIV and AIDS are infectious and should be dealt with exactly as other infectious diseases are being handled. Diagnostic tests are best left to the discretion and judgment of the concerned clinicians[2]. Even this call for a standard of presumed consent, however, does not entail a call for wide-scale mandatory testing. 'Since the availability of HIV testing facilities is limited, the test in any case is not going to be done widely.'

In sharp contrast, Narain *et al.*[4] of the South East Asia Regional Office of the World Health Organization present a strong case for limiting the role of HIV testing in public health practice and for a standard of specific, informed consent because of its unique features: 'Compared to any other type of disease, the issues related to the diagnosis of HIV infection are far more complex.' This plea for 'exceptionalism' concludes by stating: 'Mandatory testing or testing without informed consent is not only counterproductive but also wasteful of scarce resources.'

Finally, Lal and Thakur[5], writing for the National AIDS Control Organization, present proposals then under consideration for its national HIV testing policy document. They too reject testing without 'explicit consent' except for surveillance purposes, where unlinked anonymous screening can assure that no individual is identified.

For an American, writing in a very different ethical, legal, social, economic and epidemiological context to provide simple ethical instruction on HIV testing would be presumptuous. Far more useful, I believe, would be to present a picture of how the ethics of screening have evolved in a variety of settings, thereby alerting readers of *Current Science* to issues that will require attention in the context of a growing AIDS epidemic in India.

In the United States and other economically advanced, democratic societies confronting the AIDS epidemic, a broad voluntarist consensus emerged from the early debates about HIV testing. This perspective drew upon American constitutional traditions and the liberal values that have informed those concerned with medical ethics, as well as upon pragmatic considerations. In part because of the United States' unique and early involvement with the AIDS epidemic and the compatibility of American constitutional values and international human rights standards, this perspective was to have a significant impact on the posture of the World Health Organization's Global Programme on AIDS.

Except for clearly circumscribed circumstances, testing was to be done under conditions of voluntary, informed consent, and the results were to be protected by stringent confidentiality safeguards. In the United States, to underscore the importance of protecting the privacy of tested individuals, the option of anonymity in testing centres was made broadly available.

Screening and behavioural change

Even before the screening of the blood supply had commenced in mid-1985, it was clear that the new antibody test would be enlisted in the effort to achieve the overriding public health goal of mass behavioural change. What was a matter of deep dispute and what has remained a matter of controversy was how much of a role testing would play. For public health officials who faced the daunting challenge of affecting the most intimate behaviours and for whom the legacy of other health promotion campaigns gave little reason for optimism, the test seemed to be a technology that could motivate the desired changes. Those who tested positive could be counselled about the urgent need for behavioural changes

to prevent the spread of HIV. Those who tested negative could be counselled about the importance of self-protection. Opponents of too great a reliance on testing – often representatives of the gay community and of civil liberties groups – were fearful of the social consequences of being identified as infected with HIV. Mass education and individual counselling, they argued, were the crucial options. From this perspective, testing, with all of its technical uncertainties, was too costly and too dangerous.

Over the years the bitter edge has all but vanished from the dispute. Public health officials have recognized that extraordinary changes have taken place in the behaviour of gay men, changes that could not be directly linked to the availability of testing. Such changes have, however, not been uniform. Mass education campaigns have not affected the sexual behaviours of some gay men and many intravenous drug users. What remains a matter of controversy is how aggressively to press for testing among those groups where the degree of behavioural change thus far attained gives cause for concern, or even alarm. Most recently, officials at the Centres for Disease Control have begun to acknowledge that the substantial resources committed to testing and counselling might not be the most effective approach for those at greatest risk.

Contributing to the always fragile consensus on testing for behavioural change has been a recognition on the part of public health officials of the need to win the confidence of those most at risk for HIV infection. To the fears that the confidentiality of test results would be breached, thus exposing those infected to stigma and discrimination, public health officials have responded by embracing the cause of confidentiality and legislation to protect the social and economic rights of individuals with HIV infection[6–9]. Without careful assurances of confidentiality and protection against irrational discrimination, encouraging those at risk to come forward for testing would be impossible.

Screening for clinical purposes

Early in the history of the epidemic, when medicine was all but impotent against the opportunistic diseases that afflicted those with HIV, the question with which some patients and many of their advocates confronted those who proposed antibody testing was: 'Of what benefit will a positive finding be for *me*?' Further, this was not a test like others, that clinicians generally used and that were typically covered by the broad, general consent implied in an agreement to be treated. Rather, critics argued, the antibody test was for social and psychological reasons, more like those invasive procedures for which special consent was required. Faced with such challenges and the undeniable reality of social stigma associated with HIV infection, physicians, their professional associations, and public health officials agreed that an exacting standard of consent to HIV testing was appropriate: specific informed consent was to be sought from patients or their surrogates. To many clinicians, however, such requirements represented an unacceptable intrusion into the therapeutic relationship, a hurdle designed to impede sound diagnostic work.

Now that medicine has made some remarkable advances in its capacity to control the life-threatening illnesses HIV-infected individuals face, given the increasing frequency with which physicians and researchers have begun to promote the prophylactic use of therapeutic agents and given the range of clinical trials for which infected people may be eligible, the picture for patients is very different from what it had been early in the epidemic. Under such circumstances one can answer the question, 'Of what benefit will a positive finding be for *me*?' quite differently than in 1985.

Under such circumstances, clinicians have begun to exert pressure to loosen the requirements for specific, informed consent before testing. In short, they have begun to maintain that the time has come to return AIDS to the medical mainstream[3].

Although one can appreciate clinicians' impatience as expressed by this perspective, resisting the pressure for routine testing without consent is important. In the first place, as much as the clinical picture has begun to change, no definitive therapeutic course is available for people infected with HIV but who are asymptomatic. At the same time, the possibility of stigma and discrimination remains an ever-present threat to the social well-being of the infected. Given these circumstances, arguments for specific, informed consent remain as pertinent as ever[10]. But even if the clinical picture improved dramatically, the moral grounds for insisting on informed consent before HIV testing would not change. It is an established principle of medical ethics that competent adults have the right to decide whether or not to undergo treatment and whether or not to terminate treatments already begun.

Certainly, the principle that limits the physician's paternalistic authority to order therapies in the interest of the patient extends to the authority to order tests that would serve as the basis for commencing treatment. But if respect for the autonomy of the patient requires that physicians exercise restraint, then their ethical responsibility to provide appropriate care now requires that they routinely offer HIV antibody testing to those patients whose social histories suggest an increased possibility of infection and for whom therapy is available and accessible.

Screening for safety

Because AIDS represented the first major infectious disease with which advanced industrial societies had had

to contend in almost a generation, and because the causative agent was not identified until three years after the first cases had been reported, it is not surprising that it provoked considerable social anxiety. Employers, landlords, schools and even some health care institutions evidenced a willingness to exclude those with the new disease. With the discovery of HIV and the development of a test that could detect the antibody to the virus, the potential for discriminatory activity increased despite the epidemiological evidence about how infection is spread.

In the United States, the Centers for Disease Control moved swiftly to contain the irrational impulse toward exclusion[11–13]. The message was clear: HIV could not be transmitted casually and thus no grounds existed for excluding infected individuals who were otherwise capable of performing their expected functions, from their schools or workplaces. In the context of the health care, setting universal blood and body fluid precautions would protect workers not only from HIV but also from the far more infectious hepatitis B. Screening could only provide illusory protection.

Although shameful efforts to exclude or isolate school children with AIDS or HIV infection and cases of discrimination by employers still occur, they are almost universally deplored as irrational, unscientific and retrograde.

The situation in health care has not been so clear-cut. The relatively few cases of transmission as a result of needle sticks[14], and the even smaller number of cases of transmission linked to blood splashes have provoked distress among health care workers, especially among surgeons, obstetricians, nurses and emergency room personnel. Those whose work regularly brings them into contact with their patients' blood feel vulnerable. On rare occasions they have asserted the right to refuse to care for those infected with HIV, thereby rejecting the fundamental principles of medical ethics[15, 16]. Far more frequently they have publicly challenged the adequacy of the recommendations for universal blood and body fluid precautions. They have demanded the right to know whether or not their patients are infected and the right to screen on a routine or mandatory basis for HIV infection. The level of vigilance demanded by the threat of a lethal infection cannot, they have argued, be maintained at all times. Protection requires knowledge of infection. The conflict between public health officials who have declared that universal precautions are adequate and clinicians who have asserted that they are not has not abated.

Haunting the entire debate about screening patients for safety reasons is the spectre of the refusal to treat. Those identified as infected will not simply be treated with greater vigilance. They will be given different care, lesser care, perhaps no care. In the absence of ironclad assurances to the contrary, those committed to protecting the infected will view all calls for mandatory screening of patients as a dangerous first step.

In the coming years, new controversies about screening will surely arise. In each conflict those who confront each other will predictably seek to appropriate the mantle of value-free decision making and will charge that those with whom they disagree have deserted the standards of science. On some occasions, the risk posed by the infected will be understood to be so small and the implications of screening and exclusion so burdensome that even the most cautious will find justifying compulsory testing and imposing restrictions hard. On other occasions the choices will not be clear-cut. Nevertheless, in each case more than 'science' will be involved. Decisions about screening policy will reflect the balance of moral commitments to privacy, reason and communal well-being.

Seroprevalence studies

With the identification of HIV as the aetiological agent of AIDS in 1984, investigators realized that an understanding of the dimensions of the epidemic would require more than a careful detailing of the incidence and prevalence of overt symptoms of the disease. To enable public health authorities to target and evaluate preventive interventions and plan for the health care services that would be required in the future as those infected progressed to symptomatic conditions, knowledge of the incidence and prevalence of HIV infection was critically needed.

Soon after antibody testing became possible, epidemiological specialists and public health officials concerned with the surveillance of the HIV epidemic realized that data based on volunteer studies involving only consenting individuals drawn from high-risk groups such as homosexual men, intravenous drug users, visitors to clinics for sexually transmitted diseases or from low-risk groups were insufficient for monitoring the incidence and prevalence of HIV infection because of selection and participation biases.

Anonymous, blinded or unlinked screening emerged as the method of choice for epidemiologists who sought to overcome the inadequacies of volunteer studies. Such screening would involve blood specimens collected for purposes other than HIV testing under conditions that permanently stripped such samples of personal identifiers. As an epidemiological tool, blinded studies had been used on other occasions to establish vaccination levels in populations and for reference purposes in hospital laboratories.

Because individuals participating in blinded screening could not be identified, researchers in the United States generally believed that the principles of privacy and informed consent were not being violated[17]. However, the very element of blinded studies that appeared to permit testing without negating these principles raised

problems for public health, and seemed to represent a breach of the ethical duty to inform individuals about clinical findings germane to their well-being. In the United Kingdom a leading medical ethicist based his profound objection to blinded studies on these grounds[18].

> We trade on deceit – a minor deceit but undoubtedly a deceit – if without either explicit or implicit permission we start using our patients for the benefit of others. The deceit is compounded if in so using our patients we discover important information that they may wish to know and we have deliberately both failed to find out whether or not they would wish to know it and so organized matters that we cannot pass it on even if they did wish to know.

Such objections were persuasive for a time in Great Britain, and in the Netherlands[19] and Denmark[20], where people have remained deeply suspicious of blinded studies. In the United States, however, such studies proceeded with virtually no dispute.

Those who propose to undertake such studies must now pay attention to the prospects of effective early intervention for those with HIV infection. The issue is no longer one of balancing the public health benefits of blinded studies against the potential benefits of studies that would not preclude the notification of infected people. Those with HIV infection have a clear and immediate interest in knowing that they are infected. The ethical standards that impose upon clinicians a duty to inform their patients may increasingly seem to be at odds with the ethical and professional duty of public health officials to develop the most accurate epidemiological foundations possible for guiding preventive interventions and organizing health care services. Under these circumstances, ensuring that the subjects of blinded seroprevalence studies have access to voluntary, confidential HIV antibody testing with appropriate clinical follow-up will be critically important.

Conclusions

India is beginning to experience a striking and disastrous increase in HIV infection. This epidemiological threat is taking place in a vast and populous nation with limited resources compared to those available to the industrialized democracies. The fundamental ethical challenges presented by the AIDS epidemic in India will basically be no different from those in the United States: to inhibit the spread of HIV infection, to provide medical care to the level permitted by the resources available, and to treat those individuals infected with HIV or diagnosed with AIDS with dignity and respect.

It is within the context of these ethical challenges that India must confront the question of how best to employ the HIV test. Like any other technology it can be used to the advantage of those who are vulnerable or it can be abused, thereby further burdening those most in need of protection, care and respect. How India chooses to employ the HIV test will represent an important measure of its commitment to both the public health needs imposed by the AIDS epidemic and to the human rights that may be compromised in the face of the challenge of a growing epidemic.

1. Bayer, R., *Private Acts, Social Consequences: AIDS and the Politics of Public Health*, Rutgers University Press, New Brunswick, NJ, 1991.
2. Mathan, V. I., The management of HIV infection in India, *Indian J. Med. Res.*, 1993, **97**, 225–226.
3. Bayer, R., Public Health Policy and the AIDS Epidemic: An End to HIV Exceptionalism? *N. Engl. J. Med.*, 1991, **324**, 1500–1504.
4. Narain, J. P., Pattanayak, S. and Shah. N. K., HIV testing policies: An overview, *Indian J. Med. Res.*, 1993, **97**, 219–222.
5. Lal, Shiv, and Thakur, B. B., Proposed national HIV testing policy, *Indian J. Med. Res.*, 1993, **97**, 223–224.
6. Centres for Disease Control, Recommended additional guidelines for HIV antibody counselling and testing in the prevention of HIV infection and AIDS, Atlanta, Georgia, 1987.
7. Surgeon General, Report on Acquired Immune Deficiency Syndrome, Washington DC, 1986.
8. Institute of Medicine and the National Academy of Sciences, *Confronting AIDS*, National Academy Press, Washington DC, 1986.
9. Presidential Commission, Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, Washington DC, 1988.
10. Levine, C., and Bayer, R., The ethics of screening for early intervention in HIV disease, *Am. J. Publ. Health*, 1989, **79**, 1661–1667.
11. Centres for Disease Control, Education and foster care for children infected with human T-lymphotropic virus Type III/lymphadenopathy-associated virus, *Morb. Mortal. Weekly Rep.*, 1985, **34**, 517–521.
12. Centres for Disease Control, Recommendations for preventing transmission of infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus, *Morb. Mortal. Weekly Rep.*, 1985, November 15, 681–686, 691–695.
13. Centres for Disease Control, Recommendations for preventing transmission of infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus during invasive procedures, *Morb. Mortal. Weekly Rep.*, 1986, April 11, 221–223.
14. Centres for Disease Control, Update: Acquired immunodeficiency syndrome and human immunodeficiency virus infection among health-care workers, *Morb. Mortal. Weekly Rep.*, 1988, **37**, 229–239.
15. *New York Times*, 9 November 1987.
16. Zuger, A and Miles, S. H., Physicians, AIDS and the occupational risk: Historic traditions and ethical obligations, *J. Am. Med. Assoc.*, 1987, **258**, 1924–1928
17. Bayer, R., Lumey, L. H. and Wan, L., The American, British and Dutch responses to unlinked anonymous HIV seroprevalence studies: An international comparison, *AIDS (UK)*, reprinted in *Law, Medicine & Health Care*, 1991, **19**, 3–4.
18. Gillon, R., Testing for HIV without permission, *Br. Med. J.*, 1987, **294**, 281–283.
19. van Wijngaarden, J. L., The Netherlands: AIDS in a consensual society, in *AIDS in the Industrialized Democracies: Passions, Politics, and Policies*, (eds Kirp, D. L. and Bayer, R), Rutgers University Press, New Brunswick, NJ, 1992.
20. Albaek, E., Denmark: AIDS and the Political Pink Triangle, in *AIDS in the Industrialized Democracies: Passions, Politics and Policies* (eds Kirp, D. L. and Bayer, R), Rutgers University Press, New Brunswick, NJ, 1992.