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U.S. Policy on AIDS/TB: A Need for More Global Focus?

by Lynn W. Kitchen, M.D.

To a physician caring for wealthy HIV-infected patients in the developed world, the news from the Tenth International Conference on AIDS might seem optimistic. It is now clear, for instance, that infected women can reduce the risk to their babies by AZT therapy. Average life expectancy of patients diagnosed with AIDS in the developed world has increased from six months to more than three years during the last decade (Paul Abrahams, "Trials Raise Hope of Breakthrough Drug," *Financial Times* [London], August 12, 1994). An expanding arsenal of pharmaceuticals may enable physicians to control HIV infection for longer periods, although problems could arise due to adverse drug interactions and the ever-escalating costs of multiple-drug treatments.

But these advances will have little effect in the hardest-hit areas of the world—regions where women receive little prenatal care, most people cannot afford antiviral drugs, and doctors lack the diagnostic tools to use such drugs with maximum effectiveness. Moreover, the fight against the HIV pandemic probably will have to be waged for many years to come without the help of a magic-bullet cure or preventive vaccine. Although some 15 different vaccine candidates are being developed, there is much scientific skepticism regarding the effectiveness of current vaccine approaches. A large-scale HIV vaccine trial was canceled in the United States earlier this year, and the World Health Organization (WHO) plans to convene a conference in late 1994 to examine the ethical and practical problems of conducting HIV vaccine trials in developing countries.

This year's annual gathering of scientists and others involved in HIV research, prevention, and treatment was the first to be held in Asia (Yokohama, Japan)—in part to call attention to what health officials call the "explosive" spread of AIDS in such places as Thailand and India. According to WHO projections, Asia could have 10 million infected people by the year 2000 and will have surpassed Africa in the number of annual new infections.

The AIDS/TB Connection

Tuberculosis is an increasingly serious problem worldwide, in part because TB is the only known opportunistic infection in HIV patients that can be transmitted via casual contact to HIV-uninfected persons. Because one open (i.e., cavitary) case of pulmonary or lung tuberculosis can infect 15-20 other people, adequate diagnosis/treatment of tuberculosis is essential to prevent airborne spread. A person with TB/HIV infection is nearly 30 times more likely to develop clinically apparent tuberculosis in any given year than a



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person infected with just TB ("Tuberculosis, HIV on Collision Course in Asia," WHO Press Release, August 10, 1994). At the same time, tuberculosis and other chronic infectious diseases may increase the likelihood that a patient exposed to HIV will be infected by the virus.

WHO estimates that the annual number of new cases of tuberculosis will increase from 7.5 million in 1990 to 10.2 million in 2000, with almost 90 million new cases during the decade as a whole. Deaths attributable to tuberculosis are believed likely to rise from 2.5 million in 1990 to 3.5 million by 2000, with a total of 30 million deaths during the next decade.

With the pace of research accelerating and the public health and social imperatives presented by tuberculosis becoming more acute, the *Lancet* (a British medical journal) has scheduled a September 1995 conference in Washington, D.C. focusing on the elements needed to combat this disease. Specific additional laboratory and epidemiological evidence confirming an AIDS/TB connection will be sought and examined, and the role of tuberculosis vaccines discussed.

Another likely topic at the *Lancet* conference is whether the developed world can be persuaded to pay for global TB control using existing (relatively expensive) drugs, or whether some funds should be invested in the exploration of the antituberculous efficacy of less expensive drug regimens. (In the United States, a decline in tuberculosis rates has recently been reported after a sustained rise since 1984. This possibly temporary domestic trend toward more successful TB control may reduce the country's interest in funding a global program.) An October 1994 U.S. conference hosted by the National Jewish Center for Immunology and Respiratory Medicine in Colorado will focus on whether immune system modulating drugs are safe and effective treatments for persons coinfecting with both HIV and tuberculosis.

Women and Children

In the United States (where HIV was initially largely confined to male homosexuals, hemophiliacs, and intravenous drug abusers), women constitute a steadily growing but still relatively small proportion of reported AIDS cases. In many developing countries, on the other hand, heterosexual transmission has always been the most common mode of transmission for HIV, and there is often a 1:1 ratio of AIDS cases in men and women. According to a 1993 WHO prediction, by the year 2000 most of the more than 40 million HIV-infected persons in the world will be women and children. Deterring HIV vertical (mother-to-infant) transmission now appears feasible. The challenge is to provide affordable intervention to HIV-positive women in developing countries.

Factors contributing to vertical transmission of HIV in the developing world include unavailability of (1) HIV testing/counseling (with the result that a woman may not know whether she is infected); (2) the abortion option (for cultural or religious reasons, or because of lack of trained

operators or sterile instruments); (3) affordable Zidovudine or alternatives (because developing inexpensive therapies is not a priority for most pharmaceutical companies); and (4) money or other means to purchase formula feedings, or refrigeration to prevent bacterial contamination of formula mixtures (so that breast feeding is sometimes the only option for nourishing infants).

As was emphasized at the Yokohama conference, supporting the empowerment of women through such means as improved access to education and employment is a logical step toward reducing the spread of HIV. In this connection, it is noteworthy that while there was little if any discussion of the possible demographic impact of HIV at the September 1994 International Conference on Population and Development in Cairo, a similar strategy of upgrading the status of women was seen as an important means of stabilizing population growth.

Coping With the Inevitable

On a global scale, it is now too late to prevent the HIV pandemic from taking many lives. In addition, the disease could well become a significant threat to economic development and political stability in some areas (see *Global HIV/AIDS: A Strategy for U.S. Leadership*, consensus report of the CSIS Working Group on Global HIV/AIDS, Washington, D.C., 1994). It would be simplistic, however, to ascribe all political conflicts in HIV-afflicted areas to the impact of AIDS. Rwanda, for example, has been hard hit by HIV, but the recent bloodletting there was unquestionably due to ethnic tensions and other factors that long predated the emergence of AIDS as a problem in the country.

A rational strategy for coping with the inevitable public-health disaster that many countries face might aim to (1) encourage leaders of all segments of society to accept the reality of the AIDS epidemic and to optimize

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efforts to prevent further HIV transmission; (2) minimize the chance of future epidemics arising in any socially marginalized group; (3) maximize stability of economies and governments; and (4) maximize cooperation regarding limited health care resources within countries and between countries.

Providing Treatment Along With Prevention

An important initial step toward creating a global policy might be to reexamine the traditional practice of separating prevention and treatment efforts for HIV and of assigning a lower priority to the latter. Two main arguments (neither of them completely valid) lie behind the emphasis on behavioral change as opposed to treatment, particularly in the developing world:

(1) As previously noted, neither curative treatment for established HIV infection nor prevention of HIV through a vaccine is likely in the near future. Some HIV-related opportunistic infections can be relieved by administering various drug treatments, but equitable distribution of such drugs is problematic given their expense, and drug toxicity and antimicrobial resistance may preclude use in some patients. Moreover, it is not clear that any pharmacological regimen can prolong survival in HIV-infected persons on a statistically significant basis. Therefore, devoting scarce resources to patients with a terminal disease may not be considered "cost-effective" by some international health economists. But these analysts could be overlooking the expenses that might arise if limitations on care of persons with HIV were to lead to sociopolitical instability.

In any case, refusing care does not seem to be a realistic option in developing countries any more than it would be in the developed world. Dr. Susan Foster of the London School of Hygiene and Tropical Medicine emphasized this point in a 1992 address at the Eighth International Conference on AIDS in Amsterdam:

You've been told that I'm an economist so you're probably waiting to hear me say that we can't afford to treat AIDS, to devote scarce health resources to palliative care of people with a short life expectancy. Well, I won't disappoint you. We cannot afford AIDS. But let me also make clear from the outset my working premise: that AIDS patients have as much right to care as anyone else with a chronic or terminal disease, and the fact is they *are* receiving care. I've been based at a district hospital in Zambia for the past year and a half and I can assure you that it doesn't make a particle of difference whether an international conference or the World Bank declares that treatment of HIV disease is not cost-effective. When a patient turns up in bad shape at the hospital, he will be looked after. . . . So we had better get used to the idea that care is going to be provided, and stop frightening ourselves by just counting the cost. Let's rather turn our attention to finding ways to improve and rationalize the care we provide. AIDS has been with us now—officially—for 10 years. But as far as treatment is concerned, we still think, deep down, that if we ignore AIDS hard enough it might just go away.

(2) There is a widely held notion that the availability of an effective treatment or vaccine—or anything *perceived* as an effective treatment or vaccine—would undermine attempts to change high-risk behavior (J. Cohen, "The HIV Vaccine Paradox," *Science* 264: 1072-1074, 1994).

It is noteworthy that this argument has not been applied to another major cause of death in the developed world—coronary artery disease, a noncommunicable condition that tends to affect the affluent. Various treatments (some costly) for coronary artery disease are available, and probably improve the quality, and sometimes the length, of life. But the availability of these treatment options does not seem to have deterred the widespread adoption of such preventive measures as low-fat diets and exercise programs, particularly in the United States. The prevalence of coronary artery disease, as assessed by reported diagnosed cases and deaths attributed to this cause, is decreasing in this country, although the exact cause for this declining incidence cannot be pinpointed (R. Beaglehole, "International Trends in Coronary Artery Disease: Mortality, Morbidity, and Risk Factors," *Epidemiologic Reviews* 12: 1-15, 1990).

The coronary artery disease example suggests that prevention programs can be effective even when treatments are available (at least if the population at risk has reasonably good access to education). Therefore, assertions that HIV treatment inhibits HIV prevention may sometimes reflect a veiled inclination to limit the health care access of marginalized or impoverished groups. This is congruent with the commonly held notion that the AIDS epidemic will have little impact on the lives of most Americans or the way society functions.

The Pharmaceutical Catch-22

A key obstacle to a "community-oriented" approach (i.e., one that encompasses treatment as well as behavioral change) is the fact that medications inexpensive enough to be used in both the developed and developing world rarely get funded for evaluation. Only a few HIV-infected persons in developing countries are able to afford standard antiretroviral therapy (such as Zidovudine or AZT), and management of patients with Zidovudine-induced adverse effects can also be costly (see, for example, Lenderking *et al.*, "Evaluation of the Quality of Life Associated with Zidovudine Treatment in Asymptomatic Human Immunodeficiency Virus Infection," *New England Journal of Medicine* 330: 738-743, 1994).

Most clinical trials are sponsored by pharmaceutical companies, whose leaders view the pursuit of novel, patentable approaches as the most profitable corporate strategy. For example, a study published in the July 11, 1991 issue of the *New England Journal of Medicine* concluded that the prophylactic use of intravenous immune globulin (an expensive approach requiring skilled nursing care and equipment) significantly increased the time free from serious bacterial infections in symptomatic HIV-infected children. The immune globulin for this

study was donated by Cutter Biological, Miles Laboratories. Because many of the documented infections were caused by *Streptococcus pneumoniae*, low-cost penicillin or other oral antibiotics might have been equally effective, but evaluation of this practical approach was not funded.

As another example, preliminary studies of diethylcarbamazine (DEC), a drug commonly used in tropical areas to control filariasis (a worm infection), indicate additional anti-infective effects; if so, DEC could be a useful and inexpensive treatment for HIV-infected persons. So far, though, DEC has received more attention from WHO than from officials at the (U.S.) National Institutes of Health (NIH).

What Happened to Clinton's Global Focus?

As I wrote in a 1993 contribution to *CSIS Africa Notes*, "We need leaders who understand the importance of health-care issues in a world where, for example, the scarcity of sterile needles in a given country can have consequences that do not stop at that country's borders. In this connection, it was encouraging to hear President Clinton acknowledge in his inaugural address that 'There is no longer a clear division between what is foreign and what is domestic. The world economy, the world environment, the world AIDS crisis, the world arms race—they affect us all.'"

It is now two years into Clinton's presidency, but the global view of HIV/AIDS he put forth in 1993 does not yet prevail. At the Yokohama conference, Dr. William E. Paul, a non-physician immunologist who became overall director of the recently empowered Office of AIDS Research at NIH in February 1994, outlined a national AIDS policy reoriented to encourage more broad-based basic research. NIH's drug development would also be redirected, he said, to put "special emphasis" on therapies based on new molecular targets that will require greater understanding of the virus.

Does Dr. Paul simply share an apparent reluctance on the part of U.S. government health officials about addressing the international dimensions of health issues? Or could part of the driving force behind the increased focus on molecular biology in AIDS research be a perceived competitive imperative to strengthen "national security" by encouraging U.S. predominance in biomedical technology? In any case, the low priority

given to the global implications of AIDS is painful to observe as HIV continues to spread.

Conceivably Dr. Paul realizes that his policy—although likely to be popular with the NIH, Congress, and U.S. voters, and congruent with his own scientific interests—might not lead to an AIDS cure, since he also warned research administrators to remember that breakthroughs could come from insights that cannot be planned: "Command science is no more likely to succeed than command economics." Perhaps this afterthought should be given more credence than his primary AIDS strategy.

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