AIDS patients demand drugs as government hesitates

Despite requests in April by the WHO for governments to consider the "progressive introduction" of new antiretroviral drugs to combat AIDS, and their prediction that India — with over three million cases of HIV infection — will surpass Africa in 2005 (*Nature Med.* 2, 951, 1996), AZT (azidothiamidine) remains the only drug currently approved for the treatment of AIDS in India. The Indian government is still lingering over the decision whether or not to officially permit the sale of new agents in the country.

Not surprisingly, this inactivity is under attack from many sources: AIDS activists, sections of the medical profession and even the National AIDS Control Organization (NACO), which functions under the health ministry, are campaigning for the introduction of the new protease and reverse transcriptase inhibitors.

"It is criminal to use only AZT because there is evidence that monotherapy leads to resistance of HIV," says NACO consultant Durgadas Sengupta. "We have advised the government to introduce the cocktail drugs without delay, but nobody is listening to us." Written pleas from the director of health services for the government of Maharashtra — a state with more than half the country's AIDS cases — urging the central government to change its policy and make the drugs freely available, have also gone unanswered.

The official reason for delay appears to be a government requirement for new clinical trials on Indian subjects. Any drug introduced into the country must be approved by the Drugs Controller General of India (DCGI), who in turn is advised by the Indian Council of Medical Research (ICMR), the research wing of the health ministry. Six months ago, the ICMR recommended that it was "essential" to first clinically evaluate the combination drugs in Indian subjects, 95% of whom are infected with HIV-1 subtype C, before approval can be granted. "Most of the clinical trials abroad were carried out in patients with subtype-B infection," says Gowdagiri Satyavati, director general of ICMR.

However, Michael Saag, director of the AIDS outpatient clinic at the University of Alabama, says that he knows of "no evidence that indicates that the new antiviral drugs are subtype-specific within the HIV-1 group" and suggests that a simple two-week study of viral load in as few as ten Indian patients would answer the question.

Suniti Solomon, director of the Chennai-based non-governmental organization YRG Care, agrees. "We don't need any more trials" says Solomon. "I have four patients on combination therapy who have improved remarkably." Solomon's patients bought their drugs on the black market, where desperate individuals who can afford it pay up to $1,500 per month for the contraband medicines.

In fact, no clinical trials have been initiated and the health ministry is apparently in no hurry for them to begin, causing speculation that the real reason behind the government's delay is the potentially huge cost to the State that would accompany approval of the drugs.

The subsidy for AZT is around $700 per person per year. "Similar subsidies for the combination therapy would make the government bankrupt" say sources within the health ministry. Ishwar Gilada, secretary-general of the Mumbai-based Indian Health Organization, estimates that around 100,000 HIV infected Indians would be in a position to afford the combination therapy by year 2000. He says that subsidy for so many patients would leave no money for other health programs.

Although the new drugs are not marketed in the country, patients can import them directly without customs duty. But the import procedures are cumbersome, with officials taking two months to issue an import license for a quantity of drug that will last only three months. "If they are life saving drugs, why do we have to wait that long?" asks an angry AIDS patient from Mumbai, who is planning to take the health ministry to court on this issue.

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Advisory panel: Marijuana data are inconclusive

An NIH advisory panel convened in February to debate the use of marijuana as a therapeutic agent, has concluded that "more and better" studies are needed before a scientific decision on the issue can be reached. In a report released in mid-August, the panel also requested that future studies evaluate the effects of the drug on the immune system, because "frequent and prolonged marijuana use might lead to clinically significant impairments of immune system function." This point is highly relevant, since marijuana is known to be used by many AIDS patients, a group that is already immunocompromised.

The panel evaluated marijuana in the context of analgesia, treating movement disorders, chemotherapy-induced nausea and vomiting, glaucoma and as an appetite stimulant in AIDS and cancer cachexia patients. They acknowledged that the availability of existing products for each of these disorders, supported by extensive clinical trials, makes the endorsement of marijuana difficult.

Critics such as the Marijuana Policy Project, a Washington D.C.-based organization that lobby's for federal reform of marijuana law, claim that both the NIH and the Clinton administration have tried to delay release of the findings.

However, the NIH says that by making the report immediately available, they have not even taken the time to formulate a reaction to its contents.

KAREN BIRMINGHAM

NIH expands clinical research

In addition to laying the foundations for a new 250-bed hospital, this month sees the expansion of clinical research efforts at the NIH with the start of a new program designed to "train the nation's future physicians and dentists in the conduct of clinical research."

Nine third-year medical and dental students, selected from 75 applicants, will be enrolled in the Clinical Research Training Program to work alongside top clinical investigators for a 1–2-year period. They will study the causes and potential treatments of intractable disease under the guidance of designated clinical research tutors from the various institutes, and complete the NIH Core Course in Clinical Research. Students will receive a $21,000 stipend and tuition fees; healthcare and moving costs will be paid by the NIH. K.B.