

HIV in India — The Challenges Ahead

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On April 1, 2007, India will launch a new phase of its National AIDS Control Program (NACP). Its goals include reducing the number of new human immunodeficiency virus (HIV) infections —

currently, an estimated 98.5 to 99.5% of India's 1.1 billion people remain uninfected — improving treatment, and providing therapy to more people. The 5-year program, known as NACP-III, has a budget of about \$2.6 billion, two thirds of which is earmarked for prevention and one sixth for treatment (with the remainder primarily for management), and represents a substantial increase in the attention to and spending on HIV-AIDS. More than 80% of the funds will come from outside India — from the World Bank and other international organizations, governments, and philanthropies. Most of the funding has already been committed.

When I visited India earlier this year, it was evident that the HIV

epidemic was only one of the country's many pressing health problems.¹ India must decide whether to commit more of the resources that are fueling its rapid economic growth — and the growth of its private health care industry — to improvements in public health and basic health care.² In 2003, public expenditure on health represented only 1.2% of India's gross domestic product.³ There are 60 physicians per 100,000 population (as compared with 230 in Britain and 256 in the United States). With regard to HIV, challenges include increasing the number of patients receiving treatment, making additional antiretroviral medications available, improving the monitoring of therapy, training physicians and other health care workers,

caring for patients with tuberculosis coinfection (see pages 1198–1199), and reducing stigma and discrimination.

Although prevention will account for a smaller percentage of the total NACP resources than at present, it will remain the focus of India's AIDS control strategy. The components of the strategy are similar to those in other South Asian countries and include intensive prevention efforts directed at the high-risk groups of commercial sex workers, injection-drug users, and men who have sex with men, as well as “bridge populations” such as truckers and migrant workers.⁴ Avahan (Sanskrit for “a call to action”), the India AIDS initiative of the Bill and Melinda Gates Foundation, addresses gaps in India's national response and aims “to prove that prevention can be done at scale,” according to Ashok Alexander, the program's director. The components of India's strategy also include ex-

panded HIV counseling and testing and treatment for sexually transmitted diseases, broad communication of information on prevention, promotion of condom use, an increase in the proportion of blood donation that is voluntary (since payment for donation attracts high-risk donors), improved access to safe blood, and expansion of programs for preventing mother-to-child transmission.

Each year, about 28 million children are born in India. Skilled health care personnel attend less than half of all births; infant mortality is about 55 per 1000 live births. In 2004, only an estimated 4% of all pregnant women received HIV counseling and testing, and only about 2% of HIV-positive pregnant women received antiretroviral prophylaxis, usually consisting of a single peripartum dose of nevirapine. Moreover, HIV-positive pregnant women may benefit from antepartum combination antiretroviral treatment for their own health. Under NACP-III, more pregnant women should receive monitoring of their CD4 cell counts, antiretroviral treatment, regimens designed to prevent HIV transmission (including combinations of antiretroviral drugs), and other services.

In scaling up treatment, India's domestic pharmaceutical industry has a critical role. A paradox is that Indian companies have become major suppliers of low-cost generic antiretroviral medications to low- and middle-income countries in Africa and elsewhere at a time when there are still major unmet needs for HIV treatment in India. Cipla, a company based in Mumbai, manufactures the largest range of HIV drugs and has the largest market share. Cipla exports 18 times as much antiretroviral medication as it sells domestically, according to Amar Lulla, its

Tuberculosis and HIV in India

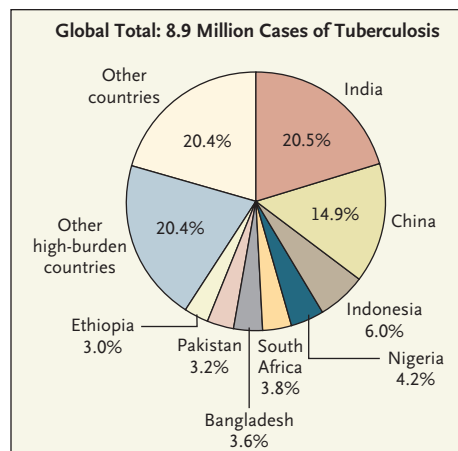
Tuberculosis is the most common HIV-related opportunistic infection in India, and caring for patients with both diseases is a major public health challenge. India has about 1.8 million new cases of tuberculosis annually, accounting for a fifth of new cases in the world — a greater number than in any other country (see pie chart).¹ Patients with latent *Mycobacterium tuberculosis* infection are at higher risk for progression if they are coinfecting with HIV. Patients with HIV infection have a similar bacteriologic response to tuberculosis treatment as those who are not infected but have higher risks of recurrence and death. The influence of tuberculosis coinfection on the progression of HIV disease is controversial.²

In 2004, about 330,000 people in India died from tuberculosis.¹ Two of every five persons — more than 400 million — have latent tuberculosis infection.³ Tuberculosis can be expected to develop

in more than half of those who are also infected with HIV. At present, however, only about 5% of new tuberculosis cases in India occur in people with HIV coinfection. The situation differs from that in sub-Saharan Africa, where the incidence of tuberculosis in many countries is higher than in India and as many as 80% of patients with tuberculosis are coinfecting with HIV. In Africa, HIV has reversed gains in tuberculosis control that were achieved a quarter-century ago.^{1,2} Such a reversal is unlikely to occur in India.⁴

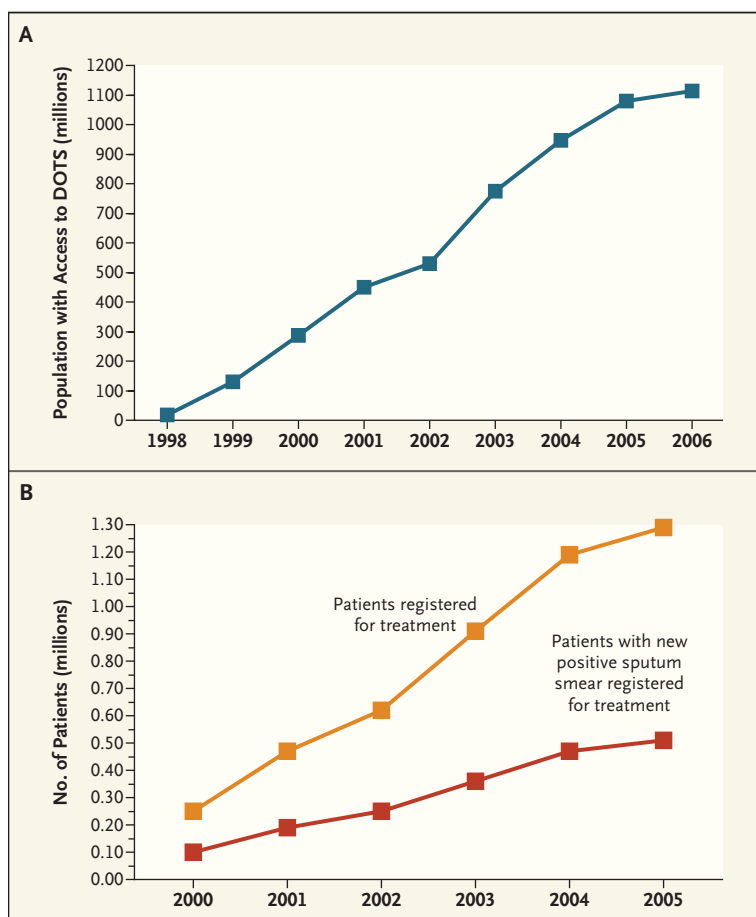
India began its Revised National Tuberculosis Control Program in 1993.⁵ Its mainstay is the strategy of directly observed treatment, short course (DOTS). Typically, during the initial 2 to 3 months of treatment, medication is administered three times a week under direct observation. During the subsequent 4 to 5 months, at least one of the three weekly administrations is directly supervised.³

After pilot testing, rapid expansion of DOTS began in the late 1990s, and in March 2006, India achieved nationwide coverage (see line graph). Each month, more than 100,000 Indian patients — about two fifths of them persons with a new positive sputum smear — begin treatment. The success rate of treatment — the percentage of new smear-positive patients who are cured (i.e., whose sputum smear is negative) plus the percentage who complete treatment without bacte-



Estimated Number of New Tuberculosis Cases, 2004.

Data are from the World Health Organization. The other high-burden countries, in descending order of number of cases, are the Philippines, Kenya, the Democratic Republic of Congo, Russia, Vietnam, Tanzania, Uganda, Brazil, Afghanistan, Thailand, Mozambique, Zimbabwe, Myanmar, and Cambodia.



Population with Access to DOTS, for Tuberculosis, and Patients Receiving DOTS.

Data are from the Revised National Tuberculosis Control Program, India.

riologic confirmation of cure — is about 86%.¹ In about 2% of patients, treatment fails; in 7% treatment is interrupted for 2 consecutive months or more; and 4% die despite treatment.³ The estimated incidence of multidrug-resistant tuberculosis is 2.4% among patients with new cases and 15% among those who have previously received treatment. In 2006, the national budget for treatment was \$57 million and the total cost of tuberculosis control was \$100 million.¹

India's national tuberculosis-control program provides care, diagnosis, and treatment on a huge scale^{3,5} — offering an example that the National AIDS Control Program

may be able to learn from as it expands. Of course, HIV treatment is often more complex and expensive than tuberculosis treatment and must continue indefinitely. When patients with HIV infection are treated at the same facility as those with tuberculosis, effective infection-control measures are essential, given the high risk of nosocomial transmission of tuberculosis. When caring for coinfecting patients, physicians must consider many clinical issues, such as those related to the prevention of disease; the timing of treatment; the choice of medications; drug interactions, side effects, and resistance; and potential reinfection with other mycobacterium strains. Antiretroviral therapy

is essential for reducing the number of deaths from tuberculosis that are related to HIV infection.⁴

In India, tuberculosis care and HIV care are increasingly being coordinated, but the full benefits have yet to be realized. An example of successful coordination is the referral of people with suspected tuberculosis from voluntary counseling and testing centers for HIV to tuberculosis-control facilities. Between January and September 2006, a total of 15,000 people with suspected tuberculosis who were HIV-positive and 16,420 who were HIV-negative were referred to such facilities by centers in the six Indian states with the highest HIV prevalence (Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland, and Tamil Nadu); tuberculosis was diagnosed in 22.3% and 23.9% of patients in these groups, respectively. DOTS was begun in many of these patients. The control of both tuberculosis and HIV is likely to be most successful if programs collaborate whenever possible and are closely integrated with the rest of medical care.²

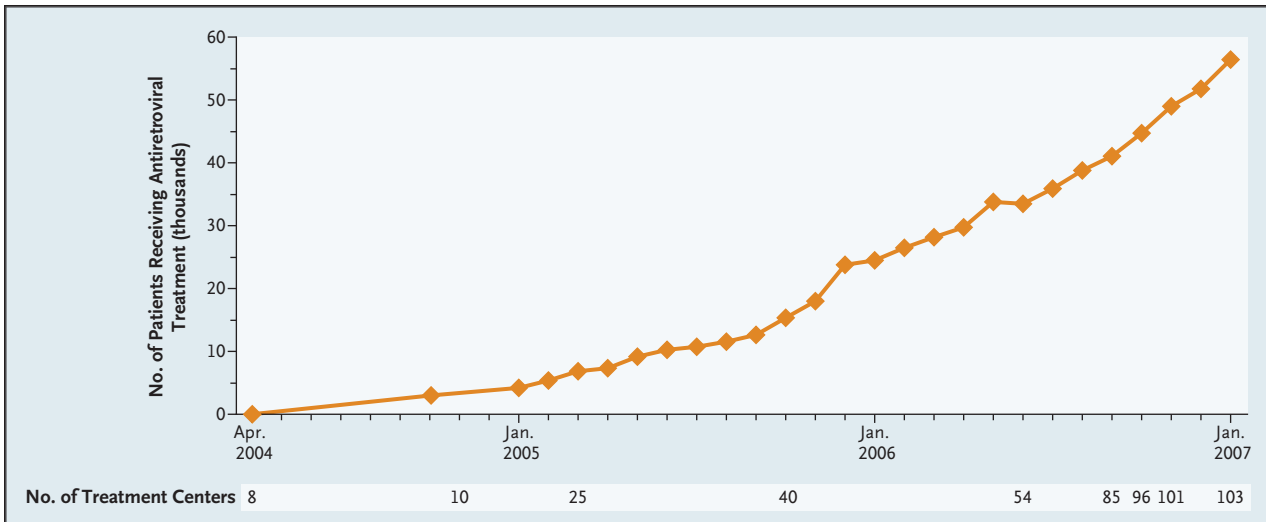
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HIV Treatment in Centers Supported by the National AIDS Control Organization, India, April 2004 through January 2007.

Data are from Dr. B.B. Rewari, National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India.

joint managing director. Retail drug prices are higher in India than in Africa, in part because of taxes. Eventually, enhanced patent protection for pharmaceuticals in India, which took effect in January 2005, may lead to higher prices. So far, however, no relevant patents have been issued.

Initially, “government activities were not [proceeding] at the speed at which the virus was spreading,” according to Suniti Solomon, director of Y.R.G. CARE, a nongovernmental treatment, research, and education facility in Chennai. In April 2004, India launched its public-sector antiretroviral treatment program at eight centers. As of January 31, 2007, about 56,500 patients were receiving treatment at 103 centers (see graph); about 62% were men, 32% women, and 6% children. Perhaps 10,000 to 20,000 additional patients were receiving treatment in the private and nongovernmental sectors. The goal is to have 250 public centers open within 5 years, providing free antiretroviral treatment to 300,000 adults and 40,000 children. However, there is no way to know whether this response will be sufficient.

Patients with HIV infection in India can receive care in the private sector that is indistinguishable from that provided in leading treatment centers around the world. All the relevant medications and laboratory tests are available. In fact, HIV medications, like other drugs, are sold over the counter. Some doctors and pharmacists, however, provide treatments that make no sense — Solomon says she knows of instances in which a patient was told to take ineffective regimens, such as one zidovudine tablet twice a day for 21 days. The provision of ineffective regimens and the development of drug resistance are major concerns.

The national program provides laboratory tests, such as CD4 cell counts, and medications at no charge to the patient. At present, five first-line antiretroviral medications are provided: the nucleoside analogues lamivudine, stavudine, and zidovudine and the nonnucleoside reverse-transcriptase inhibitors efavirenz and nevirapine. More expensive first-line medications (i.e., tenofovir and emtricitabine) are not provided, nor are second-line medications and more expensive laboratory tests, such as

measurement of plasma HIV RNA levels. The immediate priorities are to start patients on first-line regimens, to achieve high rates of compliance through supervised therapy and intensive counseling, to build infrastructure, and to ensure that people are not “dying for lack of access to drugs that are available and affordable,” according to Sujatha Rao, the director general of India’s National AIDS Control Organization.

It seems inevitable that the national program will have to cover additional first-line treatments, second-line treatments, and measurement of plasma HIV RNA levels and that its protocols will eventually reflect the updated recommendations of the World Health Organization.⁵ Yet the costs of such tests and second-line medications — which, at about \$2,000 a year, are about 10 times those of some first-line regimens — remain formidable. According to Rao, a policy of covering additional drugs is “a big responsibility. Once the government says it will provide you with these drugs, it is a commitment forever.”

The largest AIDS care center in India is the Government Hospital

of Thoracic Medicine, Tambaram Sanatorium, Chennai. Established in 1928 as a 12-bed private tuberculosis sanatorium, it now has extensive outpatient and laboratory facilities as well as 32 inpatient wards, with a total of 776 beds; 8 of the wards are devoted to patients with HIV. Between April 2004 and February 2007, more than 5000 patients began antiretroviral therapy at the hospital. "Every other government and private hospital would just throw the patient out as soon as they found they were HIV-positive," says Soumya Swaminathan, deputy director of the Tuberculosis Research Center in Chennai. "At Tambaram, anyone could walk in at any time. They would be taken care of."

In India, as in much of the

world, stigma and discrimination present major barriers to controlling AIDS. In 2005, the HIV-AIDS unit of the Mumbai-based Lawyers Collective, which provides free legal aid, drafted comprehensive antidiscrimination legislation. India's parliament has yet to consider the bill. There are other antidiscrimination efforts, such as a campaign to persuade the courts to overturn, or the parliament to rewrite, Section 377 of the Indian Penal Code, which makes homosexuality illegal and punishable by imprisonment.¹

Within the next several months, a more accurate estimate of the number of HIV-infected people in India should be released. Although the estimate is eagerly awaited, its effect, if any, on India's resolve is a matter of conjecture. Regard-

less of the number, the new phase of the AIDS control program is just beginning, and the challenges remain immense.

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Revising Medicare's Physician Fee Schedule — Much Activity, Little Change

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What garners attention when it comes to Medicare's payment rates for physicians is the annual drama over possible 11th-hour congressional intervention to prevent cuts under the sustainable growth rate formula. But behind the scenes, Medicare policymakers have been focusing on another aspect of the periodic adjustments: the updating of the relative values in the physician fee schedule and the accuracy of the data on which it relies. Since 1992, Medicare has paid physicians through a fee schedule according to a resource-based relative-value scale (RBRVS). This approach was intended to address distortions produced by basing payments on prevailing charges, which had resulted in relatively

low payment rates for evaluation and management services, as compared with procedures and technical services, as well as in large geographic variations not explainable by cost variation. The distortions were thought to discourage physicians from practicing in primary care specialties and in rural areas and to encourage a procedurally oriented style of care.

To develop its fee schedule, Medicare sets payments for services on the basis of relative costs, as determined by estimates of physician work (time and intensity), practice expenses, and malpractice insurance expenses, with geographic adjustments to reflect cost variation. A conversion factor is used to translate this structure

into dollar amounts for each service. Private insurers and Medicaid programs often base their payment rates on Medicare's relative values (using different conversion factors), so changes in Medicare's relative values can profoundly affect physicians' revenues.

Keeping the relative values current requires an effective process that reflects changes in medical practice and trends in physician productivity. But during the 15 years since this system was implemented, relative values have defied gravity — going up or staying the same but rarely coming down. For example, in 2006, the Centers for Medicare and Medicaid Services (CMS) raised physician-work values for 227 services