

stamp of approval.

Primarily because of its high incidence rate—40% in pregnant women—Hlabisa, four hours northeast of Durban, has been chosen as a site for phase II and III trials of the VEE vaccine. The MRC gained access to Hlabisa villagers only after months of public-relations building with the chief of the tribal area, Inkosi Hlabisa, and his 25 'idunas', or cluster leaders, each of whom presides over 150 families. The Hlabisa chief eventually called together a community gathering of about 6,000 people to explain his reasons for supporting the MRC's research. "The head men cannot give consent for anybody's participation, but without their approval it would be difficult if not impossible to work in their communities," explains Salim Karim, MRC director of HIV Prevention and Vaccination.

For the past 20 months, health workers have been recruiting and training young community educators to take vaccine trial information to the 12 clusters that make up the Hlabisa tribal area. On weekends, cluster leaders host community meetings at which the educators demonstrate how blood is drawn and medical histories are obtained. Tribal songs and dances also are used to spread the HIV-prevention message.

The level of vaccine preparedness in Hlabisa has been "excellent," says Steve Self, senior biostatistician for the new international HIV Vaccine Trials Network, and professor of biostatistics at the University of Washington (*Nature Med.* 6, 488; 2000). "The kind of work going on there will have a huge impact on speeding up the process." So far, efforts to identify and educate potential trial volunteers seem to be paying off. Working out of a trailer and a two-room research clinic surrounded by a security fence, field site manager Janet Frolich says participation in the vaccine preparedness trial has been high. Although results are not yet published, more than 95% of those surveyed so far agreed to participate in the study, and about 70% have agreed to be tested.

Despite ongoing research, including the recent completion of a large randomized STD intervention study that provided condoms and drugs for symptomatic patients visiting local health clinics, HIV infection rates have continued to rise in Hlabisa. Last year, 'detuned' assay surveillance revealed a double-digit annual infection rate. Such



Community Educators discuss vaccination trials

a high incidence rate will reduce the necessary sample size to around 4,000, says Salim Abdool Karim, director of HIV Prevention and Vaccine research for the MRC.

Although the vaccine preparedness study has received no funding from SAAVI or IAVI—NIAID is the primary supporter—work in Hlabisa has progressed so well that Karim expects to have the site ready for an efficacy trail by the end of 2001. "I don't expect there will be a phase III vaccine available by then," he says, "but we should be ready to go with it."

Harold Connett, Atlanta

...while government causes confusion

In addition to the many problems that surround the trial of any vaccine against HIV/AIDS, those sponsoring the VEE trial face the additional obstacle that the South African population is receiving mixed messages from its leaders.

Speaking publicly last month, president Thabo Mbeki, who has angered many western scientists with his views that HIV does not cause AIDS, said that AIDS is acquired immune defense syndrome, and a syndrome can not be caused by a virus. He repeated his views—that HIV is a passenger virus and that the disease is caused by other factors—when addressing the parliamentary caucus of the African National Congress (ANC). He has now promised to remove himself from the debate to avoid further confusion.

He also told them that he and the government are the subject of propaganda by the American CIA and large pharmaceutical companies, partially because he has questioned the link between the virus and AIDS. But in spite of Mbeki's statements, the government is launching a R2 billion media campaign to clear up confusion over its stance on the issue. The campaign will be based on the premise that HIV is responsible

for the disease.

Although more than 60 phase I/II trials of 30 candidate human immunodeficiency virus (HIV) vaccines have been conducted worldwide, none has so far been dedicated to clade C, the predominant subtype in South Africa, which has the largest number of infected people in the world, 4.2 million. AlphaVax's VEE vaccine will be the first to do so (see main story).

In fact, only a fraction of the money spent on HIV vaccine development worldwide—\$10–25 million out of \$300–350 million—is invested in developing vaccines against subtypes of virus that affect most of the world's HIV patients, according to the latest report by the World Bank (<http://www.worldbank.org/poverty/wdrpoverty/report/-index.htm>). Moreover, the amount spent on HIV vaccine research is substantially less than the \$2 billion spent on R&D for drug treatments aimed at the three million people with HIV/AIDS in industrialized countries.

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This public relations exercise comes amid revelations that Members of Parliament benefit from a medical aid scheme, Parmed, that pays two thirds of the cost of anti-HIV therapy and provides AZT to pregnant MPs and those that have been raped. This is at odds with the government's policy for ordinary citizens which states that it is illegal to give AZT to rape victims, and with its charges that the drug is toxic. It has consistently refused to buy the drug at a 70% reduced price for use in mother-to-child transmission, and last month, Health Minister Manto Tshabalala-Msimang repeated her message to parliament that the government simply can not afford AIDS drugs for its people.

Meanwhile, a meeting of the country's insurance experts, which also took place last month, stressed the implications of the disease for the economy. Rob Dorrington, professor of actuarial studies at the University of Capetown, told attendees that 13% of the country's 42 million people would be infected by the end of this year, and that life expectancy will drop to 41 years by 2010, by which time 45% of adults will be infected.

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