engaging in risky sexual behaviour. Similar strategies will be developed for all HVTN sites.

HVTN’s decision to provide antiretrovirals might set a precedent for HIV-1 vaccine trials in developing countries. However, the decision may not be relevant for other HIV-1 prevention research, which might not require the capacity needed to support antiretroviral delivery, or involve follow-up of disease progression.

One research organisation cannot reverse global inequities in HIV-1 care, but researchers from wealthy countries who work with resource-poor countries have an obligation to try to narrow the equity gap. HIV-1 vaccine researchers can work with communities to develop, implement, and assess high-quality treatment models for participants in research programmes, and encourage the development of sustainable community access to good quality HIV-1 care.

HVTN is supported by NIAID of NIH. Ethics discussions were also supported by the NIH Fogarty International Center.
*Daniel W Fitzgerald, Joan William Pape, Judith N Wasserheit, George W Counts, Lawrence Corey
The HIV Vaccine Trials Network (HVTN), Seattle, WA 98109, USA
(e-mail: dfitzgerald@gheskio.org)

HIV-1 care in resource-poor settings: a view from Haiti

When asked, “Have you no morals?” Alfred Doolittle, in George Bernard Shaw’s Pygmalion, answered: “Can’t afford them, governor. Neither could you if you was as poor as me.” The modern concept of human rights underpins a moral society and holds governments responsible for fulfilling these rights. From informed consent to the right to privacy, civil and political rights have dominated the human rights focus of the HIV-1 epidemic. Yet, the economic and social rights of people with HIV-1 infection, in particular the rights to health care and to share in scientific advances, are glaringly disparate between rich and poor countries. This disparity has become the focus of debate in transnational HIV-1 vaccine research.

Haiti, whose yearly health budget is US$15 million, less than $2 per person per year, is one of the sites for the HIV Vaccine Trials Network (see page 993). Health care and HIV-1 treatment will be guaranteed to trial participants. Yet, Haiti’s public-health infrastructure cannot provide even basic medical care for the rest of the population. How can governments as poor as Haiti’s fulfil the right to health care without external help?

The Global Fund to Fight AIDS, Tuberculosis and Malaria is the first international fund with which antiretrovirals can be purchased. With help from the Haitian Ministry of Public Health, money from the fund has been used to provide HIV-1 prevention and treatment throughout Haiti: in Port au Prince at GHESKIO centres, and in central Haiti by Partners In Health’s HIV Equity Initiative (HEI).

Providing a comprehensive HIV-1 treatment programme has necessitated revitalising the public-health infrastructure, and improving the delivery of essentials such as vaccination, sanitation, and clean water. For example, the Clinique San Michel in Boucan Carre serves a rural population of 40 000. Because of the financial crisis in Haiti, the clinic was in disrepair, poorly stocked, and inadequately staffed (figure 1). During the past 10 years, fewer than ten patients per day were seen and no testing or treatment for HIV-1 or tuberculosis offered. Early in 2003, HEI stocked the clinic with essential medicines, hired and trained health workers to do active case finding, and increased wages to prevent the drain of staff from this rural area to Port au Prince. After 6 months, the clinic sees more than 150 patients for general medical care daily (figure 2), does more than 100 HIV-1 tests per month, and treats about 100 patients for tuberculosis. Thus, improving basic health care has been a building block in expanding HIV-1 prevention and treatment.

Certainly, the search for a vaccine is of urgent importance. Yet the achievements of the first two decades of HIV-1 research, in particular HAART, have not been shared with resource-poor countries. Not only are poor governments unable to provide HAART, but also the public-health community has opposed provision because of cost and perceived competition with resources for HIV-1 prevention.

In 1998, in rural Haiti, we began providing HAART to a few patients with advanced AIDS. This effort was met with scepticism because of cost and the perceived lack of evidence that such therapy would be feasible, sustainable, or effective in resource-poor settings. Access to HAART has now been scaled up, and should cover all central Haiti and Port au Prince in

Figure 1: Clinique San Michel, January, 2003
Figure 2: Clinique San Michel, July, 2003
Figure 3: Before initiation of HAART

Figure 4: After 1 year of HAART

Governments are the guarantors of human rights, but it is only with international assistance that the government of Haiti has been able to begin to address the right to health. The Global Fund is the first step towards a worldwide responsibility to fulfil this right. However, the fund lacks support from donors and will not meet its financial needs for the third round of proposals.

At a national health research ethics meeting in South Africa in February, 2003, it was proposed that participants who became HIV-1 infected during HIV-1 vaccine trials should have access to high quality HIV-1 treatment, and moreover, that this should be financed by trial sponsors. Ethics arguments for sponsor financing have been described (CS, unpublished data); the challenge now is logistical. Establishing a national mechanism to manage treatment and care for more than 10 years after a trial ends is a complex task, especially in resource-poor settings. We propose a way to do this in South Africa.

Our solution is for the government to establish a trust fund, nationally operated by a managed health-care service provider. Volunteers who become infected during trials could access a national network of doctors for HIV-1-related treatment and care. Issuing volunteers with an identity card specifying a telephone helpline number that they could call, irrespective of their location in South Africa, would enable them to move around the country without prejudicing access to medical care.

Treatment and care would be financed by sponsor agencies, but this would be the limit of their long-term responsibilities. Sponsors would commit a fixed amount of money per infected volunteer per year to cover these costs for at least 10 years. This mechanism would not constitute a broad medical aid—ie, infected volunteers would receive regular HIV-1-related care, such as viral load monitoring and CD4 cell counts, and vaccinations and access to antiretrovirals as stipulated by South African HIV Clinicians Society treatment guidelines. However, should volunteers develop the complications of later stages of AIDS, such as tuberculosis or meningitis, they would be referred for treatment in the public sector.

All laboratory and clinical data obtained by the managed health-care provider from infected volunteers would be collated on a central national database and, with the informed consent of volunteers, could be accessed by the investigator team and sponsors to track the progress of trial participants. So far, one potential managed health-care provider has volunteered to provide this service, as part of their corporate responsibility programme, and certain international agencies have agreed in principle to the mechanism.

Our proposal would allow trial sponsors in South Africa to operate within a higher than routinely available standard of care framework, using a defined national mechanism. It would ensure that volunteers in all trials receive similar treatment, that service provision is the responsibility of national providers of health care rather than of researchers, and would enable a positive public-private partnership.

This approach is possible in South Africa because of national private-sector managed health-care capacity, but may not suit low-income countries without such infrastructure. The mechanism does not redress inequities in HIV-1 treatment between public and private sectors, and until there is universal access to antiretroviral treatment programmes, might even introduce inequalities between volunteers in HIV-1 vaccine trials and those in other HIV-1 preventive trials and other community members. Therefore, researchers should attempt to build health-care service delivery capacity at trial-linked community centres, and ensure that the whole community benefits.1

We thank Prof S Benatar for his advice.

* T Tucker, C Slack

*South African AIDS Vaccine Initiative, PO Box 19070, Tygerberg 7505, South Africa (TT); HIV/AIDS Vaccines Ethics Group, University of Natal, Pietermaritzburg, South Africa (CS)
(e-mail: saavi@mrc.ac.za)