

# Globalization, Ethics, and AIDS Vaccines

Salim S. Abdool Karim

**T**he global distribution of AIDS has highlighted the stark differences in social and economic realities across the world. Multicenter AIDS vaccine trials are most efficient where the rates of HIV infection are high; hence the importance of vaccine trial sites in less developed countries in Africa, Asia, and Latin America. Ethical concerns about exploitation arise because the conduct of such trials in less developed countries often depends on both funds and vaccines from developed countries.

One area of concern is that vaccines selected for clinical trials in less developed countries may include those already judged unacceptable or of low priority in developed countries. Conversely, vaccines that may be useful in less developed countries may not reach them because those vaccines are considered low priority for development and testing by developed countries. A lack of concordance between the vaccine candidate and the prevalent viral clades of the host country may be a serious concern in countries such as South Africa. In most host countries, institutional review boards (IRBs) and regulatory authorities for drug licensing usually review vaccine trial applications. However, if regulatory authorities and IRBs are not well developed and independent, political influence or economic interests can determine which vaccines proceed in human trials. An example of this type of political patronage that is reminiscent of the colonial era is the recent offer from a U.S.-based company to the president of South Africa of a free license to test its vaccine after the company failed to secure the support of local AIDS researchers to conduct the trials. International agencies such as UNAIDS, international research organizations, and local researchers need to intensify their efforts to support and strengthen local IRBs and regulatory authorities.

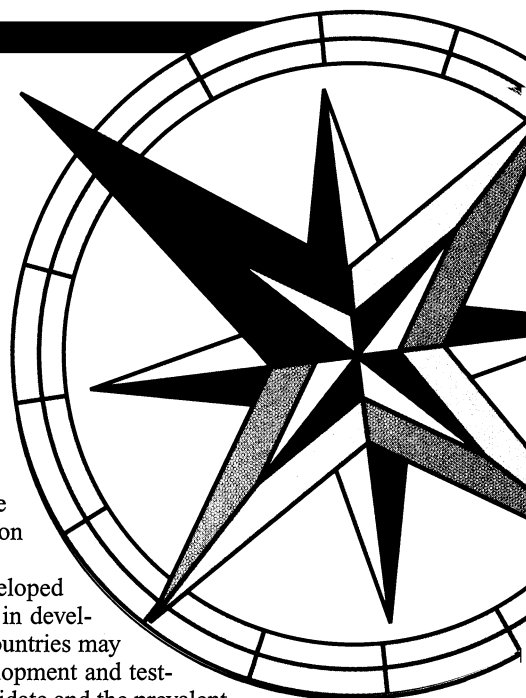
A second concern is the impact of local conditions on the implementation of ethical standards. As was determined in one South African study,\* a prime factor in the decision to participate in clinical trials can be the belief among those eligible that participation will result in better medical treatment, despite assurances by researchers to the contrary. Language creates additional constraints, such as when there are no local words for "placebo" and "randomization." One way of enhancing informed participation in AIDS vaccine trials is through researcher-community partnership. In rural Hlabisa, South Africa, HIV researchers undertook an extensive process of community consultation that culminated in the establishment of a Community Advisory Board. The board has taken the initiative to employ eight local people as community educators, to develop educational materials, consult with and inform the community about each new research project, and provide advice to researchers about local needs for the ethical conduct of research. To

achieve and sustain such a community-based approach at AIDS vaccine testing sites, funding agencies need to be made cognizant of such models and to set aside funds for this purpose.

Another concern is that countries and organizations that gain knowledge and advance their own interests by conducting research in less developed countries may not recognize any explicit obligation to support their hosts' research sustainability. Within less developed countries, however, most would consider it a fundamental ethical obligation to redress the global inequity in research. For less developed countries to move beyond serving merely as field sites to become full research partners, there must be a commitment to building local research capacity. The Fogarty Center's AIDS training programs in southern Africa provide models that deserve emulation for this purpose.

Finally, concerns about adequate post-trial access to a successful HIV vaccine at an affordable level must be addressed. Approaches are being developed by organizations such as the International AIDS Vaccine Initiative.† These efforts, which include commitments by pharmaceutical companies to a vaccine price of cost plus 10% for developing countries in return for financial investments in R&D, deserve support.

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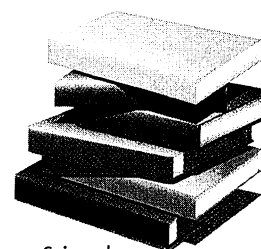
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Salim S. Abdool Karim is director of HIV Prevention and Vaccine Research at the Medical Research Council of South Africa and professor of Clinical Public Health at Columbia University, USA.

\*Q. Abdool Karim, S. S. Abdool Karim, H. Coovadia, M. Susser, *Am. J. Public Health* **88**, 637 (1998). †*International AIDS Vaccine Initiative Report* **4**, 3 (1999).