

Ethical issues in HIV vaccine trials in South Africa

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IN THIS REVIEW WE DESCRIBE THE ETHICAL issues central to local and international debates about HIV vaccine trials. These issues include the physiological and psycho-social risks of trial participation, the preventative interventions to be provided to participants, access to treatment for participants who seroconvert, access to an effective vaccine after the trial, the role of placebo-controlled trials, and obtaining informed consent.

Background

About 30 HIV vaccine initiatives at various stages of development are in progress internationally, and a local vaccine may be ready for testing in clinical trials within the next two years. The trials will probably run over three or four years before conclusive results become available. Local work on vaccines against HIV is described in articles in this issue¹⁻³ (see refs 4-15 for studies conducted elsewhere). The main approaches to vaccine development are summarized in Table 1.

Initiated by international regulatory and advocacy groups, preparatory work began several years ago to identify, debate and start investigation of the ethical issues arising from vaccine development, and organizations like UNAIDS have focused on ethical considerations specific to HIV vaccine trials.

Behavioural issues in South African HIV vaccine trials

Behavioural issues are central to preparing vaccine sites and trial procedures. Thorough assessment is needed of the willingness and readiness of the role players and sectors to be involved directly or indirectly in such trials. The main sectors include communities from which participants are likely to be drawn, national and provincial health ministries, researchers, advocacy groups, funders, brokers and the media. Sexual and other risk behaviours of participants during the trials have to be reliably measured, so as to

control for the possible impact of such factors on trial outcomes.

Vaccine trials may be alien or unwelcome concepts in communities from which participants for trials are drawn. A counter-view posits that, since other forms of immunization and vaccination are already so widespread, HIV vaccine trials may be perceived as extensions of familiar health protective practices. Community attitudes to other forms of vaccination could be surveyed and monitored as part of the preparation for HIV vaccine trials.

Science and ethics

It is widely acknowledged that science and ethics are closely connected, and that poor science is, in principle, unethical. Ethics and review boards routinely consider the scientific integrity of research proposals as part of the process of giving approval. Requests for people to participate in studies with little likelihood of producing meaningful results because

the theoretical basis, design or analysis is fundamentally flawed, are likely to be considered unethical. Such studies waste resources and may foster false expectations that have no possibility of being met, so, from this perspective, good science is a necessary component of sound ethics.¹⁶

Comparatively little is written about the reciprocal way in which sound ethics are a necessary component of good science. The ethical principles of autonomy, beneficence and justice are inscribed in research practices such as informed consent and the protection of confidentiality. These inscriptions tend to be approached as 'add-ons' to scientific procedures rather than intrinsic to them; as additional requirements necessitated by increased sensitivity to human rights in scientific and other spheres of life.

Evidence exists, however, that procedures in scientific investigations associated with ethical practices — including attitudes and the behaviour of investigators — can significantly affect scientific validity, and that in several areas sound ethical practices improve the practice of science. For instance, volunteering and participation are shown to increase through processes that clearly outline and explain the purposes and procedures of the study.¹⁷ Second, more honest disclosures are promoted through assurances and procedures for protecting the confidentiality of participants' responses.¹⁸ Clinical studies depend entirely on vol-

Table 1. HIV vaccine concepts.

Recombinant subunit vaccine	Vaccine produced by genetic engineering, simulating a part of the outer surface envelope or other part of the virus
	First-generation subunit vaccines; gp160 and gp120 vaccines
	Second-generation subunit vaccines; multiple subunits
Peptide vaccine	Synthetic protein, simulating HIV proteins and used to produce immune response to HIV; V3 loop peptide vaccines
Particles/pseudovirion vaccine	A non-infectious particle resembling HIV and containing one or more HIV proteins; liposomes and other virus-like particles
Live vector vaccine	Live bacteria or viruses, harmless to humans, are used to transport a gene that makes a specific HIV protein. Current vectors include vaccinia virus, canarypox, adenovirus, Venezuelan equine encephalitis virus, poliovirus, <i>Salmonella</i> , <i>Bacille Calmette-Guérin</i> (BCG)
Naked DNA or nucleic acid vaccines	Direct inoculation of genetic material that produces HIV proteins, envelope or core DNA
Whole-killed or inactivated vaccine	Live HIV that has been inactivated by chemicals, irradiation, temperature or other means to render it non-infectious
Live-attenuated vaccine	Live HIV that has had its disease-producing potential reduced or removed through the deletion of viral genes responsible for viral replication or disease; nef/gp120/gp160-deleted HIV
Prime-boost vaccine	Live recombinant vaccine (poxvirus or alphavirus vectors) plus a boost with a recombinant gp120/gp160 vaccine in various combinations

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