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The Ethical Involvement of Women in HIV Vaccine Trials in Africa: Discussion Paper Developed for the African AIDS Vaccine Programme

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The Ethical Involvement of Women in HIV Vaccine Trials in Africa: Discussion Paper Developed for the African AIDS Vaccine Programme

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ABSTRACT. HIV disproportionately affects women in developing countries, especially in Southern Africa. Women thus stand to benefit most from a successful HIV vaccine and must participate in trials to test appropriate, gender-specific products. Several HIV vaccine efforts are currently underway in Africa. Participation in HIV vaccine trials requires that participants not only understand the complex nature of trial

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procedures, but that they also have autonomous decisional capacity to enroll. Given that the risk factors inherent in women's greater vulnerability constitute an intricate mix of biological, economic and social variables, will women's very vulnerability to HIV be an obstacle to ethical participation in vaccine development? This paper addresses some of the challenges underlying the successful recruitment of women into vaccine research and makes research and policy recommendations for the ethical inclusion of women in HIV vaccine trials in Africa. doi:10.1300/J013v45n01_03

KEYWORDS. Women, HIV, vaccine trials, Africa, vulnerable, ethics

INTRODUCTION

The AIDS pandemic continues to expand at an alarming rate, with Africa bearing an overwhelming proportion of the unprecedented medical, social and economic consequences (Abdool Karim et al. 2005; UNAIDS 2005a). The importance of increasing HIV preventive and treatment interventions is critical. However, access to adequate treatment and care in Africa has been very poor. Even with newer initiatives aimed at universal access to such interventions, most Africans receive neither treatment nor adequate care (Dionisio et al. 2006). The best hope to end the AIDS pandemic remains the development and distribution of an effective HIV vaccine.

The African AIDS Vaccine Programme (AAVP) is a network of African HIV vaccine stakeholders, led by Africans across the continent, and driven by the vision of an African continent without AIDS. The AAVP supports and represents the diverse African communities involved in HIV vaccine research and development and is an important unified voice for African stakeholders. Since its launch in 2000, it has been an active contributor to the field of HIV vaccine development (AAVP 2006).

HIV disproportionately affects women in developing countries, especially in Southern Africa (UNAIDS 2004; UNAIDS 2005a; Ramjee 2000). Several HIV vaccine efforts are currently underway in Africa. If women are to benefit from a successful HIV vaccine, they must participate in sufficient numbers in these trials to enable the testing of appropriate, gender-specific products. In the past however, "vaccine science has rarely paused to consider gender differences, and has rarely had to"

(Bass 2001, p. 1). Successful vaccines for other infectious diseases, such as polio and tetanus, were developed without considering gender differences such as sex hormones or the male and female genital mucosa. Although HIV progresses similarly in men and women, the virus interacts differently with men's and women's bodies (Fowler et al. 1997; Segal 1993; UNAIDS 2000b). Persistent gender inequality in economic, social, educational and political life heightens women's risk, prevents them from accessing prevention and treatment, and contributes overall to their vulnerability and prevalence in the HIV epidemic (Gupta 2005). For these reasons, HIV vaccine trials are embedded in a broader scientific and social perspective determined by gender.

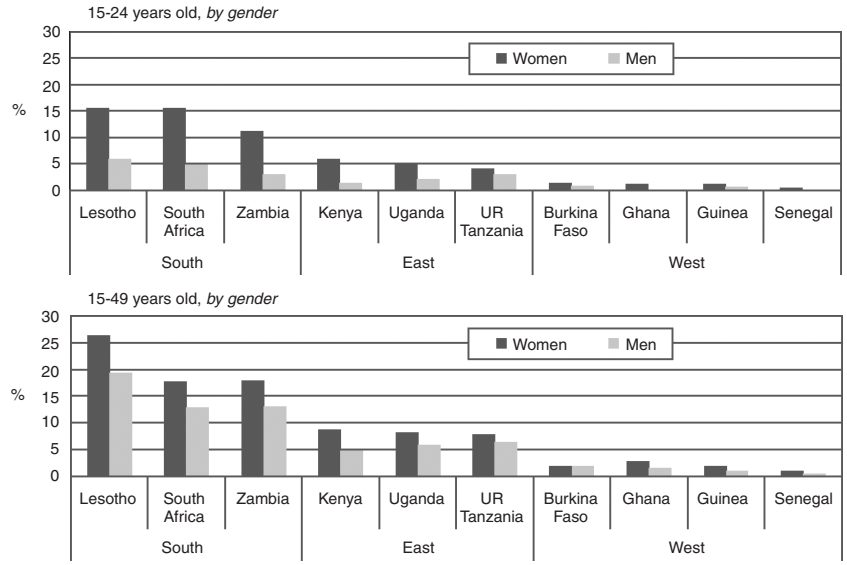
Women's active informed participation in clinical trials and prevention efforts in general is important, but this participation becomes vital when women are most affected by a given disease. Women's distinct vulnerability to HIV means that HIV vaccine trials must include women, not only because vaccines have to be tested in high-risk groups, but more importantly because HIV vaccine candidates need to be tested for their safety, suitability and efficacy in women. Moreover, special consideration must be given to ethical issues when including women in vaccine research because of their infective and social vulnerability.

THE NEED FOR A FOCUS ON GENDER IN HIV VACCINE TRIALS IN AFRICA

The need for a focus on gender in preparing for HIV vaccine trials is evident from Figure 1. HIV epidemic statistics show that in sub-Saharan Africa, 58% of adults infected are women, and 75% of young people infected are female. Women are more likely than men (gender ratio 1.3:1) to be HIV positive (Gupta 2005; World Health Organization 2004).

Biologically, in support of these striking statistics, the susceptibility of the vaginal tract makes women seven times more likely than men to become infected during any given sexual encounter (Abdool Karim 2004). Additionally, the presence of untreated Sexually Transmitted Diseases (STDs) increases the risk of HIV infection. Asymptomatic STDs are more prevalent in women (Wilkinson et al. 1999). Research has also demonstrated that gender affects the acquisition and transmissibility of HIV. A Zambian study of sero-discordant couples (in which one partner tested HIV positive while the other tested negative) suggested gender differences in viral load and transmissibility (d'Adesky 2001). Women with viral loads above 100,000 were nearly six times more likely to pass

FIGURE 1. HIV Prevalence by Gender, Selected Sub-Saharan African Countries, 2001-2005



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on the virus than women with less than 10,000 copies, while for men the difference was less than two times. The Kenyan HEPS (Highly Exposed Persistently Sero-negative) study found that, among a cohort of female sex workers, despite repeated exposure to HIV from multiple partners, a small minority of women demonstrated immunological resistance to acquiring HIV (Jeffreys 2001).

Given the gender-specific outcomes identified in these and other studies, it seems likely that an HIV vaccine might generate gender-specific effects. The experimental vaccine against HSV-2, and results from the VaxGen study, suggest that vaccines may not be gender blind (d'Adesky 2001; Taha et al. 2005).

WOMEN'S UNIQUE VULNERABILITY TO HIV

Moving beyond the science of biological vulnerability to HIV and gender-specific vaccine effects, it is clear that women must be well-represented in HIV vaccine trials. To achieve this, we need to see HIV

not only as a public health problem, but as a broader development issue. HIV is not just a problem of individual behaviour, but is influenced by the social, economic and cultural environment of inequality. Beyond biology and vaccine science, women's vulnerability to HIV can be identified in the social, economic and legal domains.

Women's social inequality and their vulnerability to HIV are interdependent. We argue here that many women in Africa, particularly but not exclusively those in the lowest socio-economic groups, should be regarded as vulnerable populations. Their social position is compatible with factors delineated in UNAIDS' guidance (Point 3) as those that may increase vulnerability of particular communities including the ability of individuals in the community to provide freely given informed consent in HIV vaccine trials (UNAIDS 2000a). Some acquired vulnerabilities are probably common in developing countries. These include (1) poverty, (2) landlessness, (3) post-colonial erosion of traditional protective factors, (4) male economic migrancy, and (5) the increased risk of women in the informal economic sector (Lee 2004). Gender and social class thus intersect to increase women's vulnerability to infection.

Violence against women, including rape, coercive sex or partner violence constitutes a serious social risk increasing the vulnerability of women to HIV. A South African study found that young women who had experienced coercive sex were three times more likely to be HIV positive (Jaspan et al. 2006). In South Africa, up to 28% of women are subjected to violence by a current or ex-partner (Shisana 2004). A Soweto study found that women with violent or controlling male partners were at higher risk for HIV infection than men or other women (Dunkle et al. 2004).

Women in general have lower socio-economic status in African society. Despite recent evidence of increasing condom use by young African women (Cleland and Ali 2006), the uneven power dynamics in relationships perpetuate and increase women's risk for HIV infection by limiting their power to negotiate condom use or other protections (Leclerc 2001; Ssekubugu et al. 2006; Van der Vliet 1999; World Health Organization 2004). Furthermore, some preventive efforts fail to provide women with information necessary to protect their sexual and reproductive health. For example, in attempting to prevent unwanted pregnancy, some women resort to anal intercourse, unaware that this in fact increases their risk of HIV infection (World Health Organization 2004).

Socio-cultural factors also affect partner choice and sexual behaviour in ways that increase the vulnerability of women to HIV infection. Some African men prefer dry sex and young female sex partners, leading to

increased vaginal lesions and increased risk of infection (Bass and Jeffreys 2001; Gupta 2001; Shisana 2004; Ssekubugu et al. 2006). Women's additional role as caregivers to HIV orphans and ill family members further burdens them and adds to their social and economic vulnerability (SAPA 2005; World Health Organization 2004). Women's economic dependence on men also increases pressure to engage in transactional sex, posing further risks to their reproductive and general health (Mills et al. 2006; Gupta 2001).

Gender-insensitive laws increase women's vulnerability to HIV by perpetuating male-female sexual power inequalities. The South African AIDS Law Project found that in Botswana, tribal courts prosecute adultery as a female crime. This suggests that men can have multiple partners, again increasing HIV risk for women (Zungu-Dirwayi et al. 2004). In Lesotho and Swaziland, women married without a prenuptial agreement are considered legal minors and cannot sign contracts without the permission of their husbands (Barnett and Whiteside 2002). Legalised gender discrimination provides fertile ground for the spread of HIV (Shisana 2004).

Thus, in addition to their greater biological vulnerability, social, economic and legal disadvantages imposed on women in many developing societies greatly increase their vulnerability to HIV. These cumulative vulnerabilities have implications for the conduct of HIV vaccine trials in many African settings.

ETHICS OF HIV VACCINE TRIALS

Because women are hardest hit by this epidemic, it is clear that they stand to benefit most from an effective HIV vaccine. Indications of gender differences in vaccine effects make it imperative that women participate in vaccine development to ensure that potential benefits apply to them. Women's exclusion from HIV vaccine trials would be unacceptable for scientific, social and ethical reasons. But will women's very vulnerability compromise their ability to participate ethically in HIV vaccine development?

To date, Phase I HIV vaccine trials in Africa have had low female participation (Mills et al. 2006; Kapoor 2004). In the Kenyan trial, only two of the 18 Phase I volunteers were women. Senior trial staff suggested: (1) Many women do not have the capacity to make the decisions themselves. They said "I might be interested but I need to discuss this with my partner or with some experts"; and (2) another issue important for women was that of fertility. When women realize that they will not

be able to have a child in the next year and a half, this makes many of them think twice (Bass and Jeffreys 2001). In the IAVI Ugandan Phase I trial, 8 of the 50 volunteers were women (Poole Konde et al. 2005). The NIH Ugandan Phase I trial reported that one of the challenges encountered during recruitment was low enrollment of women, despite high numbers that came for screening (Mawa et al. 2005). However, South Africa's Phase I trial at Chris Hani-Baragwanath Hospital shows promise. Around 50 percent of the volunteers enrolled were women. These higher numbers are probably due to the urban setting, good literacy and the number of women-headed households in this population (Gray 2006).

To get the gender-specific data that are needed, vaccine efficacy trials will need to enroll enough men *and* women to have sufficient statistical power in the trials to detect gender differences. Much more data are needed on rates of enrollment and retention of women in HIV vaccine trials throughout Africa. However, the low female participation evidenced in most Phase I HIV vaccine trials to date in Africa illustrates the difficulty in recruiting sufficient numbers of women. Phase I trials are quite different from larger efficacy trials (n = thousands) in that they focus on safety (and some immunogenicity) and require only a small number of participants (n = 40 to 120). However, they also represent the HIV vaccine trial entry-point in obtaining community buy-in and support for the long process of further trial phases ahead. Securing the support and involvement of women early on can therefore be critical in determining long-term success in balanced recruitment (Tucker 2006). The small numbers of women compared with men in initial trials might indicate the need for gender-specific approaches to enrollment and retention methods that address the negative aspects of the broader sociocultural environment of inequality in potential host communities.

To ensure the successful and ethical implementation of HIV vaccine efficacy trials, "gender issues will need to be considered in terms of: (1) the ability of women to give adequately informed and voluntary consent to participation and (2) the ability of women to meet the ongoing and multiple requirements of trial participation (clinic visits, risk reduction behavior compliance and monitoring, blood draws, etc.)" (Wassenaar et al. 2005, p. 127). These two concerns may differentially affect women in stable partnerships, women with multiple partners and women engaged in commercial sex work. They will also differ according to the particular social, economic and legal aspects of a given setting.

Women's autonomous and informed participation in HIV vaccine research is essential to prevention efforts. Because the everyday experi-

ence of consent may be seriously compromised, challenges may occur in securing truly ethical participation, both in: (1) securing informed and autonomous consent to enrollment; and (2) facilitating successful retention by anticipating potential challenges within that particular context to women's ability to meet efficacy trial requirements. The danger of low enrollment and retention rates is that women may not reap the benefits of a much-needed vaccine that has been tested for differential effects by gender.

The informed consent process rests on the assumption of autonomous decisional capacity and requires (1) information, (2) comprehension, (3) voluntariness, (4) capacity, and (5) explicit formal consent. The adequacy of standard (Western) informed consent procedures is called into question when we consider the potential for impairment of voluntariness based on the unsatisfactory psychosocial and economic conditions of many women in southern Africa. While empirical data are sparse on African women's experience of voluntariness and consent, some data suggest that in particular settings, Africans do not perceive health research "volunteers" to be true volunteers (Barsdorf and Wassenaar 2005). Similarly, for many women in southern Africa, understanding and voluntariness may be compromised, particularly for those at-risk women most likely to be candidates for HIV vaccine efficacy trials (Molyneux et al. 2005).

Risk-reduction in HIV vaccine efficacy trials requires ongoing counseling of participants by trained research staff that is sensitive to the needs of this high-risk and vulnerable group. Women affected by some of the socio-cultural factors discussed in this paper would face not only the physical or medical risks of being involved in an HIV vaccine efficacy trial, but also the social risks of stigma and discrimination outside of the trial. The social position of women may increase their vulnerability to social harm. In some settings women are less empowered and may thus be more likely to experience violence and abandonment as a consequence of perceived HIV positive status (Dunkle et al. 2004). Successfully retaining women in an efficacy trial over time presents ongoing challenges related to trial validity. Retention rates might be negatively affected as women may find it difficult to meet trial requirements. They may be burdened with childcare, care taking of other ill persons, and/or a lack of means (physical or financial) for transportation. For women with children, participation may be limited by having to attend only trial sites that offer childcare (Mills et al. 2006). Gender sensitive approaches are therefore key to designing recruitment, consent, risk-reduction and retention procedures essential for HIV vaccine efficacy trials.

HIV vaccine trials will need to take into account the broader social position and particular socially embedded vulnerabilities of female volunteers and offer support to potential trial participants, both during and after the trial. A bridge is needed between (1) the standard Western conceptions of voluntariness; (2) the standard practices of recruitment, consent, risk-reduction and retention; and (3) the grounded position of African women, to facilitate ethical and emancipatory health research practice. This bridge must be built on the voices of women and therefore requires informed and sensitive formative social science research prior to trial implementation (Wassenaar et al. 2005).

Broadly speaking, challenges will need to be addressed at multiple levels using multiple media, including research, advocacy, networking, capacity building, policy formulation, and law reform if indicated. At a more limited level, as a beginning point, we have ten recommendations that could be put into practice within the context of HIV vaccine trial development and implementation to address the challenges of participation of women in these efficacy trials (see Table 1). These recommendations have been grouped in the areas of proposed research, policy considerations and resource development.

The importance of considering gender issues in HIV entered the global agenda at the end of the first decade of HIV/AIDS in WHO's 1994 "Women and AIDS: Agenda for Action." However, by 2004 it was clear from UNAIDS, UNIFEM and UNFPA's "Women and HIV/AIDS: Confronting a Crisis" that despite some language changes, the two, ten-year-apart documents, were advocating for education of women in reproductive health and sexual communication, economic empowerment of women, protecting and promoting women's rights, and campaigning against gender-based violence.

The limited implementation of gender-sensitive policies at the national and local level perhaps explains why the 1994 and 2004 "Women and AIDS" plans bore so much resemblance to one another and the growing HIV epidemic in women. "Even though women and AIDS have moved from the periphery to the centre of the AIDS movement, moving this message from the centre of Geneva to the 'periphery' of more than 150 national country programs and policies that recognize women's and girls' differing social, political and economic opportunities remains a challenge. The challenge is bringing public health policy and practice to our local cities, states, provinces and countries" (Hartwig 2004; 75).

It seems clear that before proceeding with HIV vaccine trials, it is crucial to conduct or commission intensive, site-specific formative re-

TABLE 1. Recommendations for HIV Vaccine Efficacy Trial Development and Implementation to Address the Challenges of Participation of Women

Proposed Research

1. Vaccine trial investigators should commission study of the preparedness of local communities for hosting HIV vaccine trials. The specific circumstances of rural women, their readiness to volunteer autonomously for a trial and the benefits that can accrue to local women through HIV vaccine trials must be examined.
2. The African AIDS Vaccine Programme (AAVP) Ethics Law and Human Rights Working Group (ELH) should study the legal frameworks of targeted countries to identify laws that discriminate against women's health. Such studies are currently being undertaken by the Ethics, Law and Human Rights Working Group of the WHO/UNAIDS African AIDS Vaccine Program.
3. AAVP/UNAIDS should commission a study to identify the enrollment practices and outcomes by gender for HIV vaccine trials in developing countries, generally, and in southern Africa, specifically. A systematic study should be conducted of the sites with the best enrollment strategies to identify key factors associated with optimal recruitment and retention outcomes by gender. With specific regard to retention, potential gender specific patterns of trial-related injury also need to be identified, monitored and provided for. Collectively, these "best practices" could form the basis of a resource guide.

Policy Considerations

4. Trial investigators and sponsors should promote and fund the inclusion of social science research into the planning phase of HIV vaccine trials to identify local gender issues before the trial is implemented. This strategy will assist in designing gender sensitive and locally appropriate recruitment, retention, and post trial access to treatment plans (UNAIDS 2005b). RECs could also require that such studies precede vaccine trials.
5. All stakeholders in HIV vaccine trials (e.g., investigators, funders, relevant civil society groups) should engage in gender advocacy to promote an environment in which trials can be run ethically.
6. Sponsors/investigators should make a commitment to initiating, or developing in collaboration with other funders, a sustainable approach to providing benefits that can accrue to local women through HIV vaccine trials. The International Centre for Research on Women (ICRW) recommends more than the ABC approach. Promoting "Abstinence, Being faithful, and using Condoms is necessary but not sufficient for women and girls." The ICRW advocates for five additional strategies known as the "ABC Plus" approach (Gupta 2005):
   - 6.1 Improve girls' and women's access to information and education on HIV/AIDS and reproductive health.
   - 6.2 Advocate for law reform that increases women's ownership and control of economic assets.
   - 6.3 Facilitate women's access to prevention options that they can control and use, such as the female condom and microbicides.
   - 6.4 Increase women's access to prevention, care, treatment and reproductive health services by contributing to the modification of existing HIV/AIDS and reproductive services to address women's constraints.
   - 6.5 Advocate for/facilitate the launch of campaigns to end violence against women.

7. Sponsors and RECs should encourage closer cooperation and resource sharing between HIV vaccine and microbicide initiatives to promote best recruitment, consent, risk-reduction and retention practices in women.

Resource Development

8. AAVP ELH should, on the basis of some of the above suggestions and data, develop a "resource pack" of materials outlining key elements of "best practices" in recruitment, consent, risk-reduction, injury monitoring and retention practices to build capacity at other African HIV vaccine trial sites. This should include examination of Community Advisory Boards, where they exist, and how gender representation is assured.
9. AAVP should build a global network and database of perhaps twenty key persons committed to improving the enrollment of women in developing country settings. They could act as resource persons to trials globally and assist in an advisory capacity with the meaningful and ethical inclusion of women in HIV vaccine trials. For example, the International AIDS Vaccines Initiative has a dedicated gender officer (Mills 2006).
10. UNAIDS could use data from the above efforts to develop a global policy document specifying minimum and optimal steps for the ethical enrollment of women into HIV prevention studies. The inequities requiring such a document should not be taken for granted, and should be seen in the broader context of UN policies to reduce global poverty and discrimination, particularly for women in the developing world.

search into gender issues. This social science data would illuminate gender-specific nuances that may adversely affect recruitment and consent processes, as well as risk reduction and retention practices for women, and would inform potential remedies. Such research could be seen as integral to trial site development and as a component of preparatory social science and behavioural studies that precede vaccine trials. Ideally, such steps might initiate further social emancipations (Alvarado et al. 1999) to supplement, in small local ways, the global development agenda (Labonte et al. 2005) and offset the pernicious links between gender, low social class and infectious disease mortality. This process would ensure that HIV vaccine trials can be conducted ethically, and ultimately would bring increasing health and social benefits to this disproportionately affected population.

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