

challenges recruiting women into trials

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IN KENYA, developing an effective AIDS vaccine is a high priority for women, because they bear the greatest burden of the disease. Yet our site at the University of Nairobi, which has been involved in four *Phase I* and *I/II* trials since 2000, is finding it difficult to recruit women: Of 106 volunteers so far, about 15% are female. Our experience with these (and other potential) volunteers, plus consultations with women's health and community groups and outside experts, have given us first-hand information on the barriers to women's participation.

Many of the obstacles are deeply rooted in the lower status of women and their lack of economic power. Traditionally, a man is the wage earner, household head and decision-maker. Since he is her sole provider, a woman may knowingly continue living with a man whose behavior puts her at increased risk of infection, for the sake of her children and for the bread he puts on the table. Yet it is often the woman who is blamed for bringing HIV into the family.

These dynamics also mean that women will usually not participate in a vaccine trial if her spouse or boyfriend is opposed. Our society is strict in expecting a woman to be “loyal” to her husband, boyfriend, brothers and parents, even when these men contribute little to her well-being.

At the Kenyan AIDS Vaccine Initiative (KAVI), we continue to work towards including women in trials for several reasons. We recognize the importance of ensuring that vaccines will be effective in women, and of understanding factors that could affect how well they work (e.g., contraceptive use; presence of other sexually transmitted diseases). Women are also important allies in helping their communities prepare for the day when an effective AIDS vaccine is available, since they almost always bear sole responsibility for getting their babies *immunized* against common childhood diseases. And their perspectives are sorely needed—on *Community Advisory Boards (CABs)* and *protocol* teams—to increase the involvement of other women.

In talking with potential volunteers, we hear several worries. The enormous stigma attached to AIDS makes women afraid to get tested. If a woman tests positive at screening or during the trial, her husband or boyfriend may accuse her of promiscuity, which can lead to extreme consequences: Her

husband may divorce her, which would mean losing her children and her property rights. She could become homeless, and face even worse mistreatment, violence or rejection by her family and community. Even if she is allowed to leave with her children, their future is likely to be dim, since they would be left to languish in poverty and misery. It's no wonder that many women prefer the status quo, bad as it may be.

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We also find that women tend to be cautious, since the traditional expectation is that men should be at the forefront in taking risks. Another disincentive for some women is the requirement to use contraception during the trial, and avoid pregnancy. Our Phase I studies have sought recruits among college students, and this issue arises with women who often expect to marry upon graduation and have children as soon as possible.

Among women who do enroll (or who enroll without their partner's initial knowledge and then reveal their participation later), a few find—often to their surprise—that their partners are supportive. But more often the man refuses to agree to her participation. Occasionally he agrees initially, and then withdraws support later on. Sometimes women say that this negative reaction is based on fear that participation will confer protection against HIV, freeing the woman to have sex with other men.

Over time we're learning to deal with some of these issues, and are slowly increasing the pool of willing female volunteers for future trials. Our strategies include seeking out couples in our community outreach work, reinforcing to women that their participation will be completely confidential, and other measures described in the article on women, AIDS and vaccines (see chapter 24).