

# Programme Brief



## Women in AIDS Vaccine Clinical Research: Applying a Gender Lens in India

### Women and girls need an AIDS vaccine

A preventive AIDS vaccine is a promising new technology that women and men will be able to use to prevent or reduce the risk of HIV infection or progression to disease. Given women's vulnerability to HIV infection and limited power to protect themselves, women need methods that they can initiate and control. Microbicides, also under development, and other female initiated methods can increase women's level of control and ability to protect themselves. An AIDS vaccine, although rarely viewed through the lens of women's vulnerability, is a method that women may be able to access or use with or without their partners' knowledge or cooperation. Adolescent girls, who are particularly vulnerable to infection, could potentially be vaccinated as pre-adolescents before the onset of sexual activity or other potentially high-risk behaviours. The development of an AIDS vaccine therefore has the potential to be an important part of the response to women's and girls' vulnerability to HIV/AIDS.

In order to ensure that an AIDS vaccine will be safe, effective, acceptable and accessible to women, it is critically important to examine and address gender issues in clinical trials and vaccine preparedness efforts. Equitable numbers of women should ideally be enrolled in trials in order to determine whether a vaccine has the same efficacy and/or side effects in men and women. A vaccine must be tested in sufficient numbers of men and women to ensure licensure. In addition, principles of health equity require that both women and men have access to the benefits of participation – education, counseling and care. However, enrolling sufficient numbers of women may be a challenge in some settings given gender norms that restrict women's mobility and freedom to make independent decisions. Women and men also may have concerns about the effects of an experimental vaccine on fertility and reproduction. Additionally, social pressures to bear children may prohibit women's partici-

pation given trial exclusion criteria around lactation and requirements that trial volunteers avoid pregnancy up to four months after the scheduled vaccinations.

### IAVI in India: Starting with a gender lens

When the International AIDS Vaccine Initiative (IAVI) started its programme in India in 2002 and began preparations for future Phase I trials of an AIDS vaccine, there was little understanding of the issues related to women's participation in AIDS clinical research. IAVI recognised the need to explore barriers and means to facilitate participation of both men and women in clinical trials. Women's health advocates are an important constituency that could help identify the issues and means to address them. IAVI approached the women's health advocates in the belief that they would be able to offer insight about the constraints that women face, and contribute knowledge about engaging women in scientific research and conducting research in a gender-sensitive manner. Their insights into the long and complicated history of contraceptive trials in India would assist IAVI in understanding the pitfalls to avoid and directions to take. IAVI recognised the critical importance of engaging these constituencies in order to inform its work and move its programmes forward. Gaining their trust and support was an important challenge.

*By applying a gender lens when conducting clinical research, IAVI has set a trend that is being taken note of by other research studies in India. It has been like a national wake-up call.*

Dr. Prakasamma, Director, Institute of Nursing Studies, Hyderabad

### Engaging women's health advocates

From the initial stages of its preparatory work, IAVI undertook efforts to engage individuals and organisations working on issues of gender, women's

health, ethics and rights. During the initial outreach efforts, there was reluctance by some members of the women's health community in India to engage with IAVI on the issue of involving women in AIDS clinical trials. While reasons behind this reluctance varied, it is likely that an underlying factor – implied although not clearly stated – was that unlike microbicides and the female condom, which are perceived as women's methods that stem largely from the women's movement, vaccines stem from the biomedical sector and are linked to child immunisation programmes. Vaccines, therefore, are not perceived as a women's method of protection. Another reason, never openly articulated but an undercurrent in the early stages, was the overall conflict of interest between HIV/AIDS and other health programmes. The latter saw the former as taking away from the focus and funding for critical programmes for women's health.<sup>1</sup>

A more openly stated reason behind this reluctance is related to the history of abuse of contraceptive technologies in India, making women's advocates wary and suspicious about the motivations behind efforts to involve women in clinical trials. They feared putting their weight behind any clinical trial involving women due to lack of trust in medical research, and fear that Indians – especially women – were going to be used as guinea pigs. Some were reluctant to engage with an international organisation due to a history of local NGOs and advocates being involved merely in tokenistic ways, and skepticism about IAVI's willingness to listen

### IAVI's Global Gender Efforts

The gender work initiated in India has served as a foundation for IAVI's gender efforts globally. Some current/recent activities include:

- Adaptation of the gender training curriculum for clinical trial staff in India for use in East Africa
- Efforts to engage women's health stakeholders globally, and in other countries where IAVI works
- Development of gender advisory boards in Kenya and Uganda
- Development of advocacy collaborations with groups working on other female-initiated/controlled HIV prevention methods
- Conduct social research in Kenya on gender-related barriers to women's and men's participation in vaccine research and social impact of participation
- Efforts to engage the MSM and transgender communities in India, examine stigma and other gender issues related to voluntary counseling and testing and barriers to participation in vaccine research

and actually incorporate their advice. In India, there has long been concern about international organisations imposing their own agenda. Finally, the fact that IAVI already had a memorandum of understanding to work with the government, while a huge plus in some ways, was perceived negatively by some NGOs, who viewed government programmes with skepticism, and lacking in accountability and transparency.

### From skepticism to support and engagement

Facing these challenges, IAVI approached the women's health community in a spirit of transparency, collaboration and openness, willing to listen and learn, as well as to inform. Consultations were held in an open, participatory manner, making room for the women's health advocates to steer the process and agenda. Perceptions began to shift when advocates saw IAVI making efforts not only to engage them openly, but also to be transparent by engaging a range of stakeholders and constituencies, including the media, policymakers, state-level community groups and NGOs, and forming a range of advisory mechanisms. IAVI gained credibility with women's advocates since it has staff with reproductive health and gender background dedicated to exploring gender issues and ensuring gender-sensitive approaches to its work. These perceptions were further solidified as IAVI began implementing the recommendations stemming from consultations with the women's health community.

Starting with a one-on-one outreach, IAVI conducted a round of consultative meetings. In November 2002, a participatory group consultation was held to discuss gender issues related to bringing women into AIDS clinical trials.<sup>2</sup> This initial meeting was well-attended, and generated considerable interest and questions about the nature and process of AIDS clinical trials planned in the country. Why do we need to include women in clinical trials? How many visits will it entail? Will childcare be available? How will women deal with the issue of pregnancy? IAVI provided the answers, and emphasised the idea that an AIDS vaccine held potential for women by offering women the freedom to use this prevention tool with or without the knowledge of their partners. In order to give women that choice in the future, it is important that the AIDS vaccine be tested for efficacy in both women and men to determine any differential impact it may have.

Once the process of clinical trials was better understood, and it was accepted that a preventive AIDS vaccine held potential in reducing women's vulnerability to HIV, the focus of the discussion shifted to issues that could help IAVI plan for the trials, including the im-

portance of protecting the rights of potential volunteers and conducting trials in gender-sensitive ways. The group explored likely barriers to women's participation and suggested means to facilitate enrollment through a gender-sensitive approach. Of paramount importance to this group were issues related to informed consent, confidentiality, stigma and discrimination that could arise from disclosing participation, and prevention of social harm of any kind to all volunteers, particularly women. The group consultation not only offered IAVI a broader perspective to apply to its programme, but also resulted in some concrete recommendations:

**Informed consent:** The group recommended that a gender-analysis framework be applied when developing the informed consent form that trial volunteers are required to sign to indicate that they agree to participate, and that their decision is free and informed. Staff taking consent must be conscious of the fact that women can often be vulnerable to coercion by family members, and should take extra care to ensure women's autonomous decisions.

**Trial environment:** They also recommended that the physical environment at the trial site must be women-friendly, allowing for convenient location and timing, childcare and privacy for all trial-related procedures.

**Counseling:** Counseling must be done in a gender-sensitive manner, based on an understanding of issues as they impact women and men in different ways.

**Training:** All trial staff must be sensitised to gender issues and trained to incorporate a gender perspective in their individual roles, and the institution must be held accountable for ensuring that gender sensitive norms and practices are applied when the trial team interfaces with trial volunteers.

**Gender Advisory Board:** A unanimous recommendation was that IAVI should set up a gender advisory board to guide and oversee the process of incorporating gender issues in the planned trials.

### Implementing the recommendations

Following the gender consultation, IAVI set up a Gender Advisory Board of independent experts, which has met regularly to follow through on its mandate. One of its immediate tasks was to guide IAVI in developing and reviewing a gender training curriculum and methodology that could be applied to train the trial teams. Another was providing gender inputs to the informed consent forms. Two members of the Board were invited to an ad hoc group convened to review and finalise

the informed consent form for the trial. In their capacity as gender experts, they ensured that the informed consent form incorporated a gender perspective with appropriate wording.

As plans for starting Phase I trials of AIDS vaccines in India were underway, IAVI facilitated a gender sensitisation training for trial teams at both vaccine trial centres it was sponsoring. In August 2005, training was conducted with the National AIDS Research Centre (NARI) in Pune, and in July 2005, with the Tuberculosis Research Centre (TRC) in Chennai. Workshops were three days in length and involved the entire team, from the director of the institute and the principal investigator to clinical and laboratory staff and community coordinators. A range of gender issues were covered, including, for example, the limited autonomy in decision-making that women often face; the potential consequences for women of breaches of confidentiality, including stigma, blame, loss of economic support or even violence; and what the trial team could do individually and effectively to address these barriers and improve recruitment and retention.

*IAVI has put in place systems to address gender issues in vaccine trials which didn't exist before - for example, setting up the gender advisory board, revising the informed consent form and facilitating a gender training workshop. This process sets a new standard for conducting ethical and gender-sensitive trials in India. That in itself is a tremendous achievement.*

Anjali Gopalan, Director,  
Naz Foundation, New Delhi

### The trials

Thus far, both Phase I trials in India (Pune and Chennai) have enrolled fifty per cent women and men. Whether these equal enrolment figures can be attributed to a higher awareness of gender issues and a more gender-sensitive approach, or a combination of other factors, can only be determined once an assessment is conducted of the gender training.

While the trials conducted to date have been relatively small Phase I trials (with approximately 30 volunteers), the experience is helping the field to plan for feasibility studies that will be conducted in preparation for large-scale efficacy trials. Such studies will be conducted in populations at higher risk of infection, and are likely to include female sex workers, men who have sex with men and transgender populations. Highlighting the

gender-sensitive approaches that were developed for Phase I trials will assist in the preparation for future larger studies and trials, where complex gender issues inherent in working with these vulnerable, at-risk populations will be key to successful recruitment and retention.

*IAVI has gained respect and credibility in India by establishing ethical norms in conducting clinical trials. The next challenge IAVI faces is to convince programme implementers and civil society groups that the AIDS vaccine is an empowering tool not only for women, but also for large numbers of men who have sex with men, and who face vulnerabilities because they do not conform to the prevailing norms of hegemonic masculinity.*

Madhu Bala Nath, Regional Director,  
IPPF South Asia Region

### Beyond clinical trials

Working with women's health advocates proved to be extremely beneficial to IAVI in preparing for the first Phase I trial of an AIDS vaccine in India:

- Their hands-on experience with women's sexual and reproductive health provided IAVI with a roadmap to design its studies;
- They reinforced the importance of keeping ethics and human rights at the centre of IAVI's research efforts;

### References

<sup>1</sup> Radhika Ramasubban, "HIV/AIDS in India: Gulf between Rhetoric and Reality," in *Implementing a Reproductive Health Agenda in India: The Beginning*, ed S Pachauri, Population Council, Delhi, 1999.

<sup>2</sup> See "Addressing Gender Concerns in AIDS Vaccine Trials in India. Report based on consultations held in New Delhi, 2002-2003," S. Kapoor, IAVI, New Delhi, 2004.

- They validated the importance of including equitable numbers of men and women in trials; and
- They emphasised the importance of true informed consent, based on a full understanding of benefits and risks of participating in such a study.

Beyond the value of these constituencies in helping IAVI and its partners prepare for clinical trials in India, women's health advocates also have the potential to be powerful allies in advocating for AIDS vaccines as a key part of the response to women's vulnerability. While often absent from the discourse on women's HIV prevention needs, AIDS vaccines are one method among a range of potential new and existing prevention technologies that could meet women's HIV prevention needs and offer them real choices.

It will be important to build upon the partnerships with women's health advocates established to date, and to draw in spokespersons, social scientists, the medical community and human rights advocates who can become champions, help to establish AIDS vaccines as part of a range of future options for women and girls, and demand continued investment in AIDS vaccine research. Accelerated vaccine *and* microbiocide research must be among the top global health – and women's health – priorities.

*To empower women we must ... support the development of an AIDS vaccine that is safe, effective, and accessible to women and girls.*

Geeta Rao Gupta, President,  
International Centre for Research on Women



*IAVI's Programme Brief series reports on programme models and case studies in advocacy, education and AIDS vaccine preparedness in the developing world.*

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