

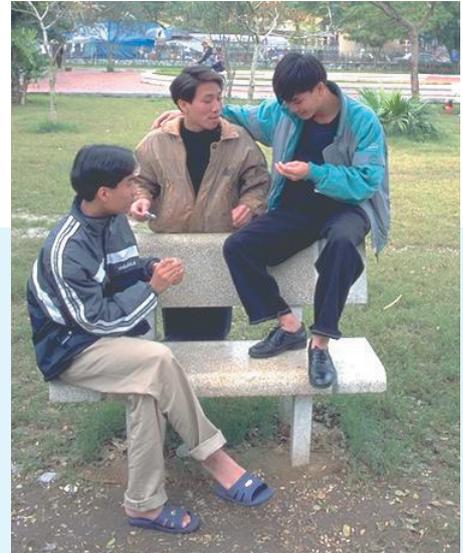


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## Creating Effective Partnerships for HIV Prevention Trials

The HIV epidemic has changed the way that HIV-focused clinical research is conducted. Trial participants and communities have demanded that they be included in defining research priorities, determining how trials will be conducted, and monitoring trial implementation. Many researchers have worked to respond to these demands through efforts such as including people living with HIV and community representatives on review committees and establishing community advisory boards to work on specific protocols and trials.



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Against this backdrop, communities and researchers are working to define new approaches to collaboration that will facilitate critically important research while being responsive and accountable to community needs and priorities. Prompted by the 2004 debate about trials of Tenofovir for pre-exposure prophylaxis, UNAIDS initiated a year-long process to promote effective partnerships between researchers and civil society in HIV prevention trials. This process, which was supported financially by the Bill and Melinda Gates Foundation, engaged a wide range of stakeholders, including researchers, activists, ethicists, government officials, international agencies, civil society, trial participants, sponsors and funders. Three regional consultations held in Durban, South Africa; Abuja, Nigeria; and Pattaya, Thailand culminated in an international consultation in Geneva in June 2005.

Planned by a steering committee of diverse membership, the international consultation brought together some 60 participants. Participants considered and debated a number of cross-cutting issues including community engagement in study design and implementation, communication among stakeholders, vulnerable populations, and building human and physical capacity through research. Small group discussions developed recommendations on models for building and sustaining

research partnerships, 'standard of prevention' in HIV trials, approaches to assuring provision of antiretroviral therapy to trial participants in need and the role of national policies.

### **New models for building and sustaining partnerships for prevention research**

The challenge of defining "community" arose repeatedly at the international consultation. As more groups and people define themselves as part of the interested "community" both the concept of community and terminology need to be broadened to "civil society" or "stakeholders". The role government is willing to play varies by setting, and challenges can arise with changes in government. However, national governments need to play a strong role in providing oversight, monitoring and follow-up.

Modes for community consultation are evolving. In many settings, community advisory boards have contributed significantly to developing sustained relationships and communication between researchers and community members. However, community advisory boards can become strong interest groups and may have members that are not representative or accountable to their communities.

In reality, the number of HIV prevention researchers and the amount of money available to undertake this research are limited; funded protocols come with tight deadlines. All parties must agree to clearly defined roles and responsibilities, aiming to find a balance between appropriate consultations with stakeholders, and conducting research in a timely fashion.

### Recommendations

- Funding agencies should provide resources to develop and document innovative approaches to partnership and community engagement, in addition to established mechanisms such as Community Advisory Boards.
- UNAIDS/WHO should sponsor the development of guidelines for “Good Community Practice”<sup>\*</sup> to inform best practice approaches to partnership in the context of HIV prevention trials, as well as provide standards for monitoring and evaluation.
- National governments and UNAIDS/WHO should explore establishing national or other boards to review, approve and monitor research partnership approaches similar to those for regulatory or ethical review.
- Partnership agreements should include clear delineation of roles for all stakeholders and should specify responsibilities—and rights—of sponsors, governments, community, advocacy organizations and media, and researchers.

## Developing and Delivering a “Standard of Prevention” for HIV Prevention Trials

Prevention trials are based on the premise that despite provision of risk reduction interventions, some participants will continue to engage in risk behaviours that lead to them acquiring HIV infection and seroconverting. Legitimate concerns have been raised for at least 15 years that reliance on research staff to provide comprehensive risk reduction counselling and services while conducting a trial that

uses HIV infection to measure effectiveness introduces a “researchers’ dilemma” or conflict of interest. Advocates and researchers in a number of settings have proposed that an outside organization provide a trial’s risk reduction services and counselling. While this approach separates risk reduction counselling from research (and may reduce any real or perceived conflict of interest) delegating to an outside organization may in fact compromise rather than strengthen researchers’ abilities to meet ethical obligations to trial participants.

In some trial settings and populations, defining an appropriate intervention for trial volunteers has been extremely charged. For example, a prevention trial conducted among injecting drug users to assess the effect of an intervention on injecting-related HIV transmission which does not provide ‘standard of prevention’ risk reduction tools such as sterilized injection equipment raises serious concerns. Where national or local policy constraints impinge on good public health practice, conditions for ethical conduct of HIV prevention research may not be met.

### Recommendations

- Researchers should engage appropriate stakeholders in design, implementation and oversight of risk reduction interventions, tailored to the specific needs and risks of trial participants in a given community.
- National and international research oversight groups should evaluate the pros and cons of independent organizations implementing risk reduction interventions in prevention trials; if warranted and feasible, such efforts should be undertaken and rigorously evaluated.
- Sponsors, researchers and activists should continue efforts to resolve ongoing conflicts about provision of appropriate risk reduction interventions for injecting drug user trial participants, including sterile injecting equipment and drug substitution treatment such as methadone, and work to develop a common “standard of prevention”.

<sup>\*</sup> Guidelines for “Good Community Practice” could be modelled on “Good Clinical Practice”, “Good Manufacturing Practice” or “Good Laboratory Practice” and would outline processes, procedures, and minimum requirements for community engagement in research.

## Approaches to developing and delivering antiretroviral therapy for trial volunteers

Although some health ethicists continue to debate whether researchers are obligated to provide antiretroviral therapy to trial volunteers who become HIV-infected during prevention trials, there is growing consensus that firm arrangements for the provision of such treatment should be explicitly defined in trial protocols.

There are significant challenges to developing mechanisms for provision of antiretroviral therapy to trial participants. Trial participants who become infected during an HIV prevention trial may not need treatment for years, possibly decades. Research infrastructure and funding mechanisms may have changed dramatically; current private and public health and financing systems may no longer be in existence. Treatment protocols, drug access and pricing and clinical monitoring will almost certainly have changed significantly. One clear need is to develop, document and publish reliable technical approaches to providing and financing antiretroviral therapy for trial participants.

### Recommendations

- Sponsors and researchers should specify in protocols what commitments have been made to provide services, care and treatment for volunteers who become HIV-infected during the trial (and other health outcomes as appropriate) and indicate how the services will be provided, by whom and for how long.
- National and international research oversight groups should develop realistic standards for care and treatment of study participants, recognizing that requiring trials to provide for multiple needs of participants and setting unrealistic expectations and standards could jeopardize trial conduct and prevention research more broadly.
- National AIDS plans should provide clear guidance on care and support to be provided for HIV prevention trial participants who become HIV-infected, and specify the responsibilities of government, research sponsors and other stakeholders.
- Researchers should formalize referral networks, ensure that local services to which trial participants are to be referred have the capacity to provide needed services, and provide resources and capacity development to strengthen these services.
- All stakeholders should continue debate at international and local levels to determine their respective obligations to trial volunteers who discover they are HIV-infected at screening and should agree on how services can be provided.
- Researchers and sponsors should link with initiatives to pilot and expand access to treatment services to attract resources for communities participating in research so that services for trial volunteers and other community members can be expanded.
- UNAIDS should convene a technical expert group to identify specific approaches to providing care and treatment for intercurrent infections including insurance plans, payments to trial participants, contracts with government or private providers, escrow accounts or other approaches.
- All stakeholders should recognize that this is a critically important, volatile and highly uncertain area that requires all partners to commit themselves to experimentation and careful documentation of approaches, successes and failures.



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## Role of national policies

National and international policies can play an important role in facilitating clinical research and research partnerships by establishing clear terms for all actors.

With support from the African AIDS Vaccine Programme, ten African national governments have developed and adopted national AIDS vaccine plans that define rules and terms for research conduct and post trial access. Stakeholders participated in defining these policies, so they reflect multiple perspectives and needs.

In India a comprehensive set of national and state policies governs the response to HIV. An ongoing preparedness effort among stakeholders involved in HIV vaccine research has informed government policies related to clinical research, including those on intercurrent infections and mechanisms for resolving conflicts within trials. For example, trial volunteers who become HIV-infected while enrolled in trials will be provided with treatment by the trial for five years, after which they will be enrolled in the national treatment programme. Researchers and government representatives have developed an Arbitration Board to adjudicate any conflicts that cannot be resolved within existing trial structures.

## Recommendations

- National governments should develop HIV prevention research plans as part of national AIDS plans, drawing on experience with HIV vaccine plans.
- National plans should include clear requirements for stakeholder partnership and for care and support for trial volunteers and participants.
- United Nations and other agencies should continue and expand efforts to strengthen national capacity using existing review processes, including regulatory and ethical review.

## Conclusion

As the field of HIV prevention research moves forward, it will be critical to continually evaluate and question these new approaches to ensure that they reflect the priorities of multiple stakeholders and communities—not just the most powerful or most vocal. Documenting and disseminating information on the diverse partnership approaches, and key elements contributing to their strengths and weaknesses, are key to building the best practice base on effective researcher-civil society partnerships in HIV prevention research. With an estimated five million adults and children newly infected in 2005<sup>1</sup>, ultimately these efforts must enable and facilitate research into urgently needed new HIV prevention technologies and approaches.

Two background papers were commissioned to inform discussions at the regional and international consultations<sup>2,3</sup>. The first by Weijer and LeBlanc explores ethical considerations and arguments concerning several key issues in HIV prevention research. Stating that there is still no consensus on whether researchers are ethically obligated to guarantee access to antiretroviral therapy to participants who become HIV-infected during prevention trials, the authors underline this as a critical political consideration in trial design and implementation. The second by Collins outlines gaps and inconsistencies in existing ethical guidance on a range of HIV prevention trial-related topics and highlights relevant approaches to collaborative partnerships with communities.

<sup>1</sup> UNAIDS (2005). AIDS Epidemic Update December 2005. Geneva.

<sup>2</sup> Weijer C and LeBlanc G (2005). Revisiting the ethics of HIV prevention research in developing countries. Background paper prepared for UNAIDS, June 2005. Geneva.

<sup>3</sup> Collins C (2005). Gaps and Inconsistencies in Ethical Guidance for HIV Prevention Research. Background paper prepared for UNAIDS, June 2005. Geneva.