Microbicides and HIV prevention research in KwaZulu-Natal, South Africa: Addressing community issues

Neetha Morar, Samanta Lalla-Edward, Thabile Zimu & Gita Ramjee

The HIV Prevention Research Unit (HPRU) of the Medical Research Council (MRC) in Durban, South Africa, is conducting several HIV prevention studies in the urban and rural areas of KwaZulu-Natal, prompted by the high HIV incidence and prevalence rates within the province. The majority of these HPRU prevention studies are on testing new HIV prevention technologies such as microbicides. Current research in KwaZulu-Natal has focused on the gel formulation of microbicides. Clinical trials conducted within communities could play a significant role in raising awareness and providing information on HIV and AIDS among trial participants and other community members. Thus, as part of the research process, we have developed partnerships with the communities at the research trial sites, in the belief that these partnerships contribute to the implementation and sustainability of HIV prevention, treatment and care messages and also facilitate the acceptance of research by the community.

Community involvement and education are crucial to any trial. Cognisant of this, the HPRU has developed a community entry strategy and participation plan. The contents of education programmes focus far beyond the trials; whilst community education forms part of the entry and participation plans, the content is sometimes adapted to suit the educational needs of a particular community. Quarterly community meetings, outreach sessions (where the primary focus is on HIV awareness) and education sessions (focusing on HIV issues and HIV testing) are conducted throughout the research process. All communication, outreach and education in the community are provided in the local language, by trained and skilled team members. In order to address the cultural and language needs within the community, researchers developed a Lexicon that provides a translation to the terminology and outlines contextual interpretations.

Information provided at meetings includes updates on the research progress, HIV prevention, home-based care, and treatment access and availability.

Community members are also educated on the research protocol and procedures that participants undergo in the trials. Researchers provide a detailed explanation to the community and participants on the importance of adhering to study procedures, which include use of the investigational products, and reporting of behavioural and sexual practices. The meetings are attended by government officials, local health authorities, community-based organizations and traditional leaders.

Documenting Frequently Asked Questions

During these information sharing processes, research teams document questions raised by members of the community. Review and analysis of these questions has led to the following areas of concern:

- *Study design* – Communities could not grasp how the HIV prevention clinical trials would determine whether the product works or not if women were constantly urged to use condoms during every sex act. Further, researchers were questioned on how they could ensure that women remain sexually active for the duration of the trial. In addressing the first question, we explain the difference between effectiveness and efficacy and why ethically, condom use must be promoted in any HIV prevention research. In addressing the second question, we explain that researchers can never ensure that women are sexually active but have to rely on self-reported information (see the Box).
- *Informed consent* – A consenting participant is a participant who has solely made an informed decision to participate in the study after receiving and

Community meeting to encourage male involvement

Community members' FAQs on research and researchers' responses

Three frequently asked questions point to the fact that community members have limited understanding of study design and ethical issues therein:

1. *"How will the researchers determine if the gel or male condom is preventing HIV, if all women are asked to use condoms during sex in the study?"*
   In addressing this question, the difference between effectiveness (the extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do) and efficacy (the ability to produce a desired amount of the desired effect i.e. using the intervention 100% correctly 100% of the time) had to be explained. It is understood that not all people will use the intervention all the time and the results obtained from this percentage is usually enough to contribute to the results/outcomes of the trial. The research should have a large enough sample size to allow for this.
   With respect to condom usage – the message of condoms being the only proven HIV prevention method is constantly reinforced. Ethically, in any HIV prevention research, condom use must be promoted. Researchers explain that the HPRU will not allow the use of a new product whose efficacy and HIV prevention role is unknown without providing women with condoms.

2. *"One of the eligibility criteria is for women to be sexually active. What has been done to ensure that these women remain sexually active?"*
   Researchers have to explain to the community that they cannot ensure that women are sexually active but go by the information provided by the women with respect to condom use, product use, coital diaries and the presence of sexually transmitted diseases. Thus researchers rely on the self-reported information by women who are counselled to adhere to product use.

3. *"You have mentioned that some women come for testing even though they are aware of their status for the sake of getting the reimbursement; are you giving money to people?"*
   Regulatory authorities such as the South African Medicine Control Council and ethics committees stipulate that women be compensated for their time, travel and refreshments. Thus, researchers explain the need for the HPRU to comply.

understanding all the study information. However, patriarchy is still part of the African culture and researchers are often confronted with the issue of male consent: *"In an African culture, traditionally, a man has to be aware and thus decides what's good for his family and what is not. Is it not important for male partners to consent in having their female partners participate in a study before they are enrolled?"* Our researchers explain that whilst they acknowledge the role of men and their authority in their communities, given the nature of these clinical trials, it is only necessary for the women to complete the written informed consent documents for their trial participation.

- *Male involvement* – Some women did not initially inform their partners of their participation, but eventually disclosed. Women are always encouraged to disclose their trial participation and product usage to their partners. However, we have had a few women unwilling to join because of partner reluctance. The issue of patriarchy highlights the importance and the need for male involvement. We have learned that men would like to be involved in the process and on many occasions it has been enquired whether study participants' partners could be a part of the education and study process. Males are educated about HIV and AIDS in the communities and about the study at male involvement meetings. However, the extent and the actual initiatives are dependent on the needs and requests received from the community in question. Male involvement initiatives include hosting recreational sporting activities between researchers and the males as well as having male-only information and education sessions. Further, all women who have informed their partners about the study are encouraged to bring them to the research sites for couple counselling.
- *Treatment and care* – One of the eligibility criteria for participating in an HIV prevention trial is that the women must be HIV negative. However, it is often the case that during screening, women test HIV positive, and sometimes they seroconvert during the course of the trial. *"If they test you and you are found to be HIV positive, what happens to you?"* is another frequently asked question. In response, we explain why HIV-positive women cannot be part of the trial and what services are available to them (explained in detail below).

Addressing community needs

One of the transitions undergone by the HPRU after the first community meetings is in the area of treatment and care. The HPRU has two PEPFAR (the President's Emergency Plan for AIDS Relief) wellness clinics at two trial sites, to which HIV-positive women are referred. The clinic offers voluntary counselling and testing (VCT), ongoing counselling (STIs, sexual health, lifestyle, couple, nutrition, anti-retroviral initiation), regular CD4 count and viral load checks, regular clinical assessment and treatment for opportunistic infections. Since the clinics are not accredited to dispense antiretrovirals, the HPRU has several Memoranda of Understanding (MOUs) with clinics and VCT centres to which the HIV-positive women requiring antiretroviral therapy are referred. All women requiring treatment receive it according to the national treatment guidelines. Women requiring treatment out of the scope of the HPRU (e.g. TB investigation and treatment) are also referred to hospitals and clinics that are party to the MOUs.

Community participation is the cornerstone of all effective public health action and should start at inception of the research

Lessons learned

- Clinical trials conducted within communities could play a significant role in raising awareness and providing information on HIV and AIDS among trial participants and other community members.
- Partnerships with the communities at trial sites may contribute to the implementation and sustainability of HIV prevention, treatment and care messages and also facilitate the acceptance of research by the community.
- Community participation should start at inception of the research planning process.
- Regular communication and feedback with the community ensures that researchers understand cultural, social and ethnic factors that impact on communities.
- By documenting, reviewing and analysing questions raised by members of the community, researchers can adapt the content of information sessions to the community's information needs.

planning process. Regular communication and feedback with the community ensures that researchers understand cultural, social and ethnic factors that impact on communities and is necessary to address these concerns. In our case, the HPRU developed additional outreach and education programmes to address the communities' information needs on trial designs, local regulatory and ethical processes and support for HIV-positive women. ■

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Resources

on HIV prevention technologies

Community involvement In HIV vaccine Trials: Making it work
ICASO, 2006 (40 p.)

In countries where HIV vaccine trials are planned or already underway, non-governmental organizations and communities have an important role to play in all stages of the design, planning and implementation of the trials. This involvement is key to ensuring the ethical and scientific quality of the research, its relevance to the affected communities and the rapid dissemination of and actions based on research results. ICASO and IAVI undertook an in-depth assessment of the role that communities play in efforts to develop and test an HIV vaccine, especially in low- and middle-income countries. This report presents the main findings of the project, and serves as a stepping-stone for the creation of an action plan for greater involvement of communities in the vaccine research and development process.

http://www.icaso.org/publications/Comm_Involv_VaccineResearch2006.pdf

AIDS Vaccine Handbook: Global Perspectives
AIDS Vaccine Advocacy Coalition, Patricia Kahn (ed.), 2005 (2nd edition, 404 p.)

This revised edition provides an overview of the key scientific, policy, social, ethical and economic challenges, and of the diverse experiences gained around the world on AIDS vaccine research and advocacy over the past two decades. The essays are written by people involved in this work as community educators and advocates, trial staff and volunteers, scientists and researchers, and policy-makers and journalists. The handbook serves as a resource and reference guide and is aimed to stimulate action.

http://www.avac.org/handbook.htm (print copy: handbook@avac.org)