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Community involvement in MDP 301 microbicide trial in Masaka: Successes and failures

THE MDP 301 microbicide trial used multiple approaches at the Masaka site to mobilise and sensitise the community, get feedback, share information, and communicate the final trial results. While this broad approach contributed to the success of the trial, a survey conducted early 2010 found no evidence that civil society advocacy groups were invited to contribute to the trial's design and implementation. By outlining the key successes and failures of the trial's community involvement initiatives, this brief highlights the need for HIV prevention research in general to follow good community participatory practice guidelines by nurturing local advocates from the civil society to partner with the investigators in the conduct of research.

The MDP 301 microbicide trial

The MDP 301 was a clinical trial of an experimental microbicide PRO 2000 (a vaginal gel) conducted in Masaka district, Uganda, and at five other sites in Tanzania, Zambia and South Africa. It enrolled a total of 9,385 women volunteers as participants. The Masaka site enrolled 840 HIV-negative women whose male partners were HIV-positive. The trial, which started in September 2005, announced its final results in December 2009, showing that the gel was not effective in preventing HIV infection in women.

Community involvement in HIV prevention research

Involving local leaders, civil society groups, the media and other influential individuals and groups in communities where HIV prevention clinical trials are conducted contributes to the success of the research, its relevance and the rapid dissemination of and actions based on the research findings.[1] National and international guidelines[2] encourage researchers to use multiple engagement strategies, such as a community advisory board (CAB), an information desk or a toll-free number, and community meetings.

Community involvement in the MDP 301 clinical trial

At least four of the approaches that the MDP 301 trial used to engage community stakeholders could be classified as structured: a community liaison officer, a 14-member CAB, and a network of parish-level participant peer leaders, and regular briefings for journalists. Others were unstructured: working with community leaders to mobilise people for sensitisation meetings; community meetings to disseminate research results; briefings to the district council; and sharing information at meetings organised by partner institutions.

Key successes of MDP 301's community involvement strategies

A flexible, participatory, broad approach

The MDP 301 research team kicked off with a CAB, where political leaders, the medical profession, HIV/AIDS care providers, community leaders and the media were represented. This gave different stakeholders chance to engage with the trial team, and helped the researchers tap into the faculties of the community through participatory interpretation and translation of key research concepts (e.g. randomisation, double blinding, etc) into the local language. Focus group

discussions with participants discussed culturally appropriate translations of sensitive terms (such as anal sex, etc) that were used in collecting important sexual information from trial volunteers.

Later, a network of "trial participant leaders" was established to help researchers get feedback from the grass-root level. In addition, the trial staff addressed the district council on three occasions, the media on a quarterly basis, and a meeting convened by another research institution.

Timely achievement of enrolment targets

The Masaka site recruited 840 HIV-negative women who had HIV-positive male partners. At the time, this was a hard-to-find population[3], and yet such women were not eligible if they were pregnant or within six weeks post-partum, suspected to have cervical problem that needed referral, or failed to pass other criteria.[4] The site raised the required number of volunteers on time by casting the net wide to cover the entire district, and by recruiting directly from the community rather than from health centres like most trials do.

High adherence and retention

Most of the former volunteers that were interviewed in Masaka admitted that they deliberately tried to keep their participation in the study unknown to neighbours, friends and relatives. Even though many of them did not succeed in keeping their participation discreet, the trial beat the odds of social stigma to record an impressive retention rate of 94% overall. Adherence to the gel was equally high, recorded at an average of 89%. These high retention and adherence rates were achieved in spite of the long period of follow-up (12-24 months).[5]

Networking with research centres

The trial team in Masaka worked closely with other MDP 301 research sites in Tanzania, Zambia and South Africa, as well as with other HIV prevention research institutions in Uganda – Makerere University-John Hopkins University Research Collaboration (MUJHU), Makerere Walter Reed Project (MUWRP), and the UVRI-IAVI HIV Vaccine Programme. UVRI/ Medical Research Council, which houses the Masaka site, strengthened their relations with the district administration, religious institutions in the district and the media. This enabled the investigators to use forums organised by some of these institutions to share information about the trial.

Research literacy

From the interviews with community representatives, the trial appeared to have improved public knowledge of what happens in clinical trials, which could have contributed to better appreciation and understanding of the trial, and willingness to participate and support similar research. The trial staff gave potential volunteers full information about the trial as a requirement to obtain informed consent; and undertook capacity building for CAB members and journalists. These efforts helped create a conducive research environment, not just for MDP 301, but for future trials as well.

Capacity building for community systems

The MDP 301 trial investigators, support staff, field mobilisers and other trial staff gained valuable experience at their different levels. These skills were transferred to the mainstream health system where the trial staff worked with nurses and doctors at government health facilities during mobile clinics. Public education campaigns improved community access to information on HIV/AIDS and primary health care.[6] The trial provided an opportunity for many people to know their HIV status and that of their partners. It increased awareness about sero-discordance and was the first real effort to promote condom use in stable marriages. In addition, the trial supplied the referral facilities with major treatment drugs especially for treatment of sexually-transmitted infections (STIs).

Gaps in community involvement in the MDP 301 trial

No model yet for nurturing local advocates

Good community participatory practice guidelines encourage HIV prevention trials to nurture local advocates from the civil society sector to partner with the investigators in the conduct of research. Overall however, this survey did not find evidence

that the civil society was invited to contribute to the design of the trial, and its contribution to the trial conduct appeared to have been minimal. The MDP 301 trial therefore, did not provide a model for nurturing local advocates for HIV prevention research.

Civil society groups felt excluded

At the time of the trial, civil society groups in HIV-related advocacy work were organised under Masaka District Network of AIDS Service Organisations (MADNASO). Although two MADNASO member organisations were represented on the trial's CAB, the membership of the network – advocacy groups – felt excluded from the principal community engagement mechanism because the duo were more of care providers than advocacy organisations. A key concern is that the umbrella organisation did not participate in the selection of civil society representatives to the CAB.

Concerns about the independence of the CAB, media

Autonomy of the community advisory process is an important principle of community engagement as it is needed for critical input into the research process.[7] The main challenge to the autonomy of the CAB stems from the fact that it is selected, trained and facilitated by the researchers. The presence of the media on the CAB also raises ethical issues in terms of potential conflict of interest. And while CAB members are in principle volunteers, but in Masaka and at other research sites in Uganda, they believe that mobilisation of potential participants is part of their role. However, the concern is that any financial support they may access from the trial to undertake this time-consuming, demanding but important responsibility has the potential to blur the dividing line between voluntary advisory service and gainful work, or to unsettled the balance of allegiance of CAB members between the community and the researchers.

Information and knowledge gaps

To some community stakeholders, the logic of asking volunteers "to use the gel during all episodes of sexual intercourse during the study, and, because it is not known if the gels prevent HIV transmission, it is required that condoms are used with gel" was not apparent.[8] This suggested poor knowledge of one of the most important ethical benchmarks of HIV prevention research.

Much as the trial staff disseminated the trial results as widely as possible, knowledge of the results was neither widespread at the district nor at the national level. At least one of the former trial participants said she had never received or known the trial results, more than three months after the official release. There were a few more respondents within the communities, particularly the community leaders, who were not even aware that the trial had ended. The debate of the results in the community was limited.

Stakeholders ill-prepared for a flat result

From the interviews, it appears that in spite of the effort that the trial team invested in preparing the various stakeholders for the results, some of the community stakeholders, particularly those directly involved with the trial – the participants and members of CAB – seemed not well prepared for a flat result. Knowledge of the challenges of research was found to be low, and people seemed to hope for or expect immediate results. People needed to have been told and to understand that flat results are part of the long research processes, and that even a negative result adds to the existing knowledge. Some volunteers and members of the CAB had strong hope that PRO 2000 would work, and in the end, they faced varying challenges in coming to terms with the final result.

Conclusion

The MDP 301 registered many successes in community engagement at the Masaka site: the trial worked with a broad range of stakeholders; took advantage of opportunities presented by stakeholder forums to provide information; responded to issues that arose from the community; and established a network of community-level contact persons through whom information was channelled to and from the host community. Future trials should adopt these strategies, and in addition be more creative in working with advocacy groups, use more participatory approaches in selecting the CAB, build the capacity of the media to understand trial processes and interpret research results accurately, and deepen and broaden their results preparation activities.

(Endnotes)

1 International Council of AIDS Service Organisations (ICASO), 2006: "Community involvement in HIV vaccine research: Making it work". Available at www.icaso.org

2 "Good participatory practice: Guidelines for biomedical HIV prevention trials", published by UNAIDS and AVAC in 2007; and "Uganda Guidelines for AIDS Vaccine Research: A Guide for Vaccine Research, Development and Evaluation", published by Uganda AIDS Commission in 2001.

3 Interview with MDP 301 trial coordinator

4 McCormack, S. et al, 2010. PRO2000 vaginal gel for prevention of HIV-1 infection (Microbicides Development Programme 301): a phase 3,randomised, double-blind, parallel-group trial. *Lancet*; 376: 1329-37

5 MDP 301 study protocol, and MDP press release issued 14 December 2009

6 Interview with member of the trial staff

7 UNAIDS and AVAC, 2007. *Good participatory practice: Guidelines for biomedical HIV prevention trials*. Geneva. pp.15

8 MDP 301 study protocol, version 2.1, May 2008, pp.25

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