

## **Sexual and reproductive health and the Millennium Development Goals in the Australian Aid program – the way forward**

### **Introduction**

The connection between the Millennium Development Goals of empowering women and combating HIV has been frequently noted. HIV flourishes in environments where there is social and political inequity, and while gay and homosexually active men remain a priority in the Asia/Pacific region, the feminization of the epidemic globally means that new partnerships need to be formed and different communities mobilized

The need for female-controlled methods of HIV prevention has again been well documented, and advocacy for microbicides has taken on new urgency. But topical microbicides are only one of three HIV prevention technologies currently in development that do not require partner negotiation.

Research into biomedical HIV prevention is complex, because research participants need to be well-educated about the process, need to understand that the nature of placebos and that the investigational product may not work. Further, because populations at high risk of HIV are required to prove efficacy, access to treatment and care are critical, both for those who acquire HIV while on a clinical trial and those who discover their status by volunteering, believing themselves to be HIV negative. The availability of an effective product post-trial for the communities who have participated is also an important ethical consideration.

Community participation is recognized by UNAIDS, the International AIDS Society and the HIV community advocacy bodies as being vitally important for planning and implementation of HIV prevention research. People, whether literate or not, are capable of understanding very complex information when carefully communicated, particularly when the health and wellbeing of themselves, their families and their communities are at stake. But investment needs to be made to build community capacity, to strengthen links between research institutions and civil society, and to forge alliances between the HIV sector and the women's sexual and reproductive health sectors.

In this submission the Australian Federation of AIDS Organisations will agree that there is an urgent need to establish a multi-disciplinary coalition of women's sexual health and HIV advocates from Australia and the Asia-Pacific region to provide strategic input and advice to researchers, and facilitate information exchange, education and meaningful participation of communities in HIV prevention research projects.

### **Background**

New technologies that aim to prevent HIV by biomedical means are being developed in Australia and tested both within Australia and in the Australia/Pacific region. These technologies, which include microbicides, pre-exposure prophylaxis (PrEP) and vaccines are unlikely to be as effective as condoms and lubricant for the prevention of HIV, but nevertheless may be strategically important as tools for women and men who have difficulty using, or negotiating the use of, condoms.

### **The need for more tools for women's reproductive and sexual health**

While condoms and lubricant provide effective protection against HIV, sexually transmissible infections and pregnancy, women have limited ability to negotiate their use. With regard to HIV, women are vulnerable to HIV infection through the behaviour of their sexual partners as well as through their own.

The repertoire of contraceptives also needs expansion, particularly with regard to products that do not require partner negotiation and have minimal side effects. Many women rely upon

hormonal contraception (either oral or long-lasting injectables) for convenience despite having to live with side effects. Hormonal products may also exacerbate other health risks, for instance in smokers or women with strong family histories of breast cancer.

In the development of products that may have multiple uses, such as HIV/STI prevention and contraception, it is critical that all aspects of such are products are investigated.

### **Investigational biomedical prevention technologies for HIV**

**Microbicides:** topical agents intended to be active against HIV and a range of STIs, some of which are also contraceptive. First-generation microbicides intended for use as HIV prophylaxis may prove ineffective in that regard, but may have application as contraceptives.

**PrEP:** Antiretroviral drugs taken prior to HIV exposure to prevent infection. The effectiveness of this kind of strategy in humans is unknown, but if trials show it to be effective it is likely to have some level of toxicity associated with it, despite it being generally considered a fairly safe drug. This toxicity may have particular gender implications, as in practice in women rather than men may be expected to adopt it.

**Vaccines:** long-lasting products that stimulate the human immune system to respond to HIV infection. The current generation of products being tested are considered more likely to ameliorate HIV disease progression rather than prevent HIV acquisition.

### **Recent developments in microbicides**

Starpharma, an Australian biotechnology company based in Melbourne, is developing a microbicide called VivaGel which may have activity against HIV, HSV and possibly some other sexually transmissible infections. In addition, it may act as a contraceptive.

A consortium consisting of Starpharma, the MacFarlane Burnet Institute, the National Centre in HIV Epidemiology and Clinical Research and the Thai Red Cross has formed to conduct clinical trials of the product, funded through the USA's National Institutes of Health. Three trials are planned for the near future:

- testing the product for penile irritation in HIV-negative sexually inactive men,
- testing the product for safety in HIV positive women in Thailand
- testing the product for safety/dosage in HIV negative sexually active women.

### **Recent developments in PrEP**

**The technical:** Currently one drug, tenofovir, has been the focus of human PrEP studies, but following animal evidence that a combination of two drugs may be significantly more effective, one humans study has been amended to allow the combination of tenofovir and emtricitabine to be evaluated.

**The ethical and political:** PrEP studies have been fraught with controversy. The Australian-run study that aimed to evaluate the intervention in Cambodia sex workers was halted due to community, and later government, concerns. Subsequently Family Health International managed trials proved problematic: the Nigerian PrEP site was closed to inability to meet protocol requirements, and the Cameroon site was suspended due to concerns raised by the national government, community members and activists. Lack of genuine community participation, understanding and negotiation regarding the conduct of the research were the root causes of these studies being interrupted.

Several other trials are going ahead with some results expected by the end of 2007.

### **Preventing HIV acquisition: proven behavioural and biomedical approaches**

HIV infection is effectively prevented by consistently using condoms and lubricant or avoidance of sex, and by the provision of clean injecting equipment for people who inject drugs. In addition HIV infection can be prevented through biomedical means: Mother-to-child prevention, which consists of a regimen of antiretroviral drugs, pre-labour elective Caesarean delivery and post-exposure treatment of infants; and post-exposure prophylaxis (PEP) in occupational and non-occupational settings, where the exposed individual commences antiretroviral therapy within 72 hours of exposure and continues treatment for a month.

### **Issues in biomedical HIV prevention research**

- The current generation of microbicide and vaccine products are unlikely to be as effective as condoms.
- It is unknown whether PrEP is effective in humans, but even if effective it is likely to be less safe and considerably more expensive.
- HIV prevention trials are ethically complex, as access to treatment, care and best-practice prevention all need to be coordinated.
- Public health considerations flowing from biomedical HIV prevention research are complex: while additional tools are needed for the epidemic, additions to the toolbox are likely in the immediate future to be either/or less effective, more costly and, in the case of PrEP, have greater toxicity.
- Community participation in research receives lip service, but the reality is that such participation is often tokenistic or ineffective due to the complexity of the issues and the processes of research.

### **Community participation in research**

Increasingly genuine community participation in research is viewed as important, and in some cases where the research is controversial or raises difficult issues, necessary, for ethical and effective practice. Community participation can involve different roles:

- Participating in the development of research plans and protocols;
- Participating in decision-making processes and setting priorities for the kinds of research undertaken;
- Being consulted about research projects about to commence;
- Debating particular issues relevant to planned research
- Being asked to 'consent' to research planned in a community;
- Being asked to participate in educating individuals and groups and risks and benefits of research;
- Being asked to participate as volunteers in specific studies.

### **Background in community participation in HIV research in Australia**

- The Australian Federation of AIDS Organisations (AFAO) has extensive experience in community participation in research.
- AFAO nominees are involved in planning the research agenda of Australian's two National Centres in HIV Research
- All Australian HIV treatment trials run through the National Centre in HIV Epidemiology and Clinical Research include AFAO nominees
- The merits of research proposals are debated in publications edited by AFAO and/or its member organisations.

- AFAO participated as an equal partner in the Australia/Thailand Vaccine Consortium, with ran a trial of an HIV vaccine candidate in 2002.
- AFAO ran a consultation in Thailand, located a Thai community partner and facilitated/resourced that partner to participate actively in research proposed for Thailand.
- AFAO nominees were active members of an advisory taskforce planning the recent Step Study, of another HIV vaccine candidate.
- AFAO produced educational materials on the risks and benefits of trial participation ran consultations, community educational forums and facilitated the production of print media campaigns to avoid misinformation about both vaccine trials.

Developing the skills and the relationships to have this kind of input into research took many years and many lessons were learned along the way. AFAO is committed to building the capacity of other organisations and individuals in the Australia/Pacific region to have meaningful input into research planned for their communities.

**Proposal: the establishment of a community-centered coalition of health advocates**

AFAO proposes that a body needs to be created that has as its primary purpose the facilitation of effective community partnership and participation in HIV prevention research in the Asia Pacific region. This body, with a working title of Coalition to Empower Women In Research (CEWIR), would actively strengthen the linkages between HIV and sexual and reproductive health, in line with Article 21 of the UNGASS declaration.

With the aims of empowering communities outside Australia to participate in research, CEWIR would:

- Provide links between researchers and community groups
- Provide advice and assistance in the training of community representatives in research processes, including community advisory boards and lay members of ethics communities
- Develop, or assist with the development of, language-appropriate educational resources
- Provide independent review research protocols if required
- Advocate for the meaningful participation of communities and people living with HIV/AIDS in the development of research proposals.

This body would comprise:

- Women's sexual and reproductive health advocates (including Australian Reproductive Health Alliance)
- Representatives with clinical experience in women's sexual and reproductive health
- HIV sector advocates from Australia and the region (including AFAO, Asia and Pacific Council of AIDS Service Organisations (APCASO), the Thai organisations Path and Access)
- Organisations with an entrepreneurial interest in biomedical prevention, such as International AIDS Vaccines Initiative, Global Campaign for Microbicides, International AIDS Society
- Other activist organisations in the region, such as Womyn's Agenda for Change.

Its aim would be to extend these links beyond Australia's borders, in keeping with sentiments of Initiative Box 9 on HIV/AIDS from the White Paper on the Australian Government's Aid Program which lists "Strengthening capacity building research linkages between Australian HIV/AIDS organizations and their counterparts in the region in order to provide greater impetus to Australia's response".