



## Press release

### **A GLOBALLY EFFECTIVE HIV VACCINE REQUIRES GREATER PARTICIPATION OF WOMEN AND ADOLESCENTS IN CLINICAL TRIALS**

**Geneva, 31 August 2004** - Greater participation of women and adolescents is needed in HIV vaccine clinical trials, according to a group of international experts, who attended a consultation on HIV vaccine trials in Lausanne, Switzerland, from 26-28 August.

The meeting, organized by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), brought together for the first time 40 experts from around the world to address the issues of gender and age, as well as race in HIV vaccine-related research and clinical trials.

"We have identified measures aimed at rectifying the injustice stemming from the frequent exclusion or low participation of women and adolescents in HIV vaccine clinical trials. Clinical trial enrolment needs to be more inclusive, so the benefits of research are more fairly distributed," said Dr Ruth Macklin, co-Chair of the meeting and a bioethics professor at the Albert Einstein College of Medicine.

Studies show that women, when exposed to HIV, are at least twice as likely to become infected with HIV as their male counterparts. In parts of sub-Saharan Africa, girls and young women are up to six times more likely to be infected than their male peers. Girls and young women aged 15-24 make up 62% of the young people in developing countries living with HIV or AIDS. "Women and girls are particularly vulnerable to HIV infection for biological, social and economic reasons," said Dr Catherine Hankins, Chief Scientific Advisor at UNAIDS, who spoke at the opening of the meeting.

Young people are also at high risk of HIV -- about half of new HIV infections in the developing world occur among 15 to 24 year-olds.

"In spite of the epidemiological reality, women and adolescents, especially girls, have often had minimal involvement in clinical trials of HIV vaccines, as compared to men. This is in spite of the fact that they would be major beneficiaries of a future HIV vaccine," said Dr Saladin Osmanov, Acting Coordinator, WHO-UNAIDS HIV Vaccine Initiative, WHO. The Initiative promotes the development of an HIV vaccine, including through the facilitation of clinical trials.

Reasons for the lack of participation of women and young people in HIV vaccine clinical trials to date are numerous and include: lack of empowerment, independent decision-making and education in some settings; social isolation; discrimination; pregnancy and the potential effects of a candidate vaccine on a foetus; stigma associated with high-risk behaviour; trial enrolment criteria; and issues concerning confidentiality and informed consent. For instance, the participation of a minor in a clinical trial would require the parents' or guardian's consent, and youth must fully understand what receiving a candidate HIV vaccine does or does not mean for their health.

Experts agreed that these obstacles could and should be overcome because HIV vaccines need to be tested in a heterogeneous population, particularly in those most in need of a vaccine. Vaccines for several infectious diseases have shown varying levels of efficacy in different gender, age and racial or ethnic sub-groups. The 1998-2003 trial of VaxGen's AIDSVAX, the only candidate vaccine so far to reach Phase III efficacy testing in large numbers of people, found that although the vaccine was not effective overall, non-whites and women possibly had some degree of protection. This finding merits further investigation.

More than 30 promising, new candidate HIV vaccines are currently being tested in human clinical trials, the majority of which began in the past four years. The number of HIV vaccine candidates in small-scale human trials has doubled since 2000. The trials are taking place in 19 countries. A safe, effective and affordable vaccine against HIV would be a powerful arm against the AIDS epidemic which continues to infect five million adults and children and kill three million people every year.

The international HIV vaccine research mission is to develop HIV vaccines that are licensed, acceptable, available and accessible by all populations regardless of their gender, age, socio-economic status, race, ethnicity or country, and that are effective across the board. Special attention must be paid to ensure that vulnerable groups, particularly women and girls, benefit from an HIV vaccine.

Recommendations--covering ethics, policy, advocacy, community participation, clinical trial design and research gaps--issued at the consultation will form the basis of a policy document that will help guide those designing and conducting HIV vaccine clinical trials. An important suggestion for future work is to study HIV clinical trial sites with enrolments that include appropriate numbers of people from different sub-groups, and to try to better understand the barriers that have prevented wider participation.

The challenges to the creation of an HIV vaccine are mainly scientific and economic, primarily due to the lack of incentive by the private sector to engage in product development. However, new momentum has been generated in the field of HIV vaccine research. In June this year, the G8 countries endorsed a Global HIV Vaccine Enterprise to accelerate efforts to develop an HIV vaccine through an expanded capacity to test and manufacture vaccines, the establishment of vaccine development centres around the world and the development of an integrated global clinical trials system allowing laboratories to easily share data.

Represented at the consultation, co-sponsored by WHO and UNAIDS, were governmental public health research institutions in developing and industrialized countries, medical schools, industry, foundations and non-governmental organizations.

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