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Making HIV trials work for women and adolescent girls

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Women are rarely included in HIV therapeutic trials in adequate numbers to draw conclusions about them. This has occurred for a number of reasons:

- concerns about possible dangers to their unborn babies
- women being considered as more 'difficult to study' because of hormone level changes with the menstrual cycle
- perceived barriers to participation such as stigma, the threat of violence, transportation and related personal costs, social and childcare responsibilities, pregnancy and contraception, lack of autonomy for consent, and concerns about undesirable effects specific to women such as reduced fertility or other harmful effects.
- **Trials designed for and with the full participation of women and girls are essential for an effective response to HIV.**

Adolescent girls, a priority population for effective HIV prevention tools, are not recruited to most biomedical HIV prevention trials. There will be significant delays in licensing effective products for adolescents. Adolescents have been excluded from trials due to:

- a lack of laws, policies, or precedent for participation in HIV trials
- age of consent – need for parental or guardian consent
- difficulties identifying the legal guardian
- challenges in protecting the adolescent's confidentiality
- stigma
- social obligations such as school
- approaches that are not age-appropriate or sensitive.
- **Concrete strategies and actions for including adolescent girls in trials need to be developed.**

- **Sex** refers to the biogenetic differences that distinguish females and males, such as anatomy and physiology.
- **Gender** refers to socially constructed notions of femininity and masculinity that translate into socially defined differences between men and women, including roles, behaviours, customs, relative power and influence, and access to the determinants of health.

Sex differences -women's body composition, hormonal cycle and metabolism are different to those of men and they react differently to drugs than men do. Therefore, scientific results from trials involving men cannot be assumed to apply to women. In fact, drugs tested on men could actually prove to be harmful to women.

- **More women and girls need to be involved in clinical trials to test the safety and efficacy of HIV drugs for women.**

Gender-related inequalities place women and adolescent girls at increased risk of acquiring HIV, failing treatment, or dropping out of trials. This warrants special measures to overcome barriers and facilitate enrolment and retention of women in biomedical HIV prevention and treatment.

- **The barriers to including women and adolescent girls in trials need to be identified.**
- **New ways should be sought to facilitate women's participation.**

Half of all people living with HIV and 62% of all young people living with HIV world wide are women. The epidemic now affects a greater number of women than ever before. Women and girls today do not have access to the tools to protect themselves from HIV as there are currently no HIV prevention methods that women can use to protect themselves without their partners' involvement and cooperation.

- **Research into new technologies to develop HIV prevention tools for women and girls is urgently needed to give women the choices necessary to protect themselves against HIV infection.**

Benefits for women if these measures are taken will be trials that address key questions of relevance and will be able to draw statistically significant conclusions about the implications for of biomarkers, biological responses, treatment efficacy, novel prevention technologies, and structural interventions. Such trials will offer

- **An important opportunity for women to access to free, high quality health care, information, counselling, and other services**
- **A safe, supportive environment**
- **A feeling of purpose and belonging to a group**
- **A sense of belonging to a community of support.**

Facilitating women's inclusion could be done by

- **Locating the research site in a setting that is safe and convenient**
- **Providing transportation or funds to cover this expense**
- **Scheduling flexible clinic times that are convenient for women**
- **Establishing child care or play spaces near the research site so that women can bring their children if they need to.**

Recommendations for policy and programming, a research agenda, and advocacy framework emerged from a consultation convened in Geneva in December 2007 by UNAIDS, GCWA, ICRW, and Tibotec Inc. The consultation gathered expert delegates from international organisations, governments, pharmaceutical industry, civil society, academic institutions, and research agencies.

- **The importance of placing women and girls at the centre of HIV research needs to be raised with policy makers and researchers.**
- **Research questions need to be defined in consultation with women, providers, and policymakers.**
- **Genuine partnerships need to be established between communities, international agencies, NGOs and the private sector to promote research of potential new advances.**
- **Mechanisms of accountability need to be built within regulatory frameworks and other standard setting bodies to require trials to include women subjects in sufficient numbers and to gather, analyze, and report sex-disaggregated data.**
- **Strategies need to be developed to identify and analyse "fugitive data" from research on HIV and women conducted by industry, public programmes, and other entities which is available today but rarely finds its way into scientific literature.**
- **Data on women and HIV outside the context of formal trials must be collected and in trials where women subjects are enrolled (i.e. in prevention of mother-to-child transmission), to encourage trial outcomes that will be specific to women's health.**

New norms need to be established, requiring active participation from all levels of the research society. Each research actor needs to make contributions in its field.

- **Research agencies** can contribute by ensuring that programmes and policy influence research.
- **Academic institutions** can lead the way by setting a research agenda that addresses needs of women and adolescent girls.
- **Researchers** have a responsibility to create trial sites that are inviting, facilitating, and supportive for women and girls, integrating basic, sexual, and reproductive health care.
- **Drug regulatory agencies'** guidelines on certification of drugs should include collecting and reporting on results specific to women, in particular adolescents and pregnant and breastfeeding women, and making the results available to the public.
- **The pharmaceutical industry** sets its own research agenda, but should be awake to the benefits of including women in trials and show ethical responsibility reaching beyond its immediate mercantile goals.
- **Scientific journal editors** can influence the research agenda by devoting editorials and thematic issues to the subject, and by establishing minimum standards for inclusion of women in trials that are to be published.
- **Community advocates and activists** should expand community research literacy by explicitly and consciously addressing sexual and reproductive health and rights and reaching out to women's groups.

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