- 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.

Next steps

Groups taking forward activities in the 'Action Plan for Making HIV Trials Work for Women and Adolescent Girls' have been developing a trials 'score card' to measure progress; working to define minimal standards for a sexual and reproductive health package for women and girls in HIV trials; assessing how to strengthen current guidelines for trial conduct; and advocating for changes in peer review criteria for publication of trial findings.

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If you would like to learn more, please visit: **http://www.unaids.org/en/PolicyAndPractice/ScienceAndResearch/womenHIVtrials.asp** or contact us at **womenandtrials@unaids.org**

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08 Making HIV trials work for women and adolescent girls

The HIV epidemic continues to be particularly devastating for women. More than 15.4 million women over the age of 15 are now living with HIV and in sub-Saharan Africa, 61% of adults living with HIV are women. HIV prevalence in young women is even more sobering: among people aged 15–24, the ratio of women to men with HIV infection is 3:1. Despite this there is still no HIV prevention method women can use without partners' involvement and cooperation.

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Women and HIV trials

Most HIV trials are not designed with women in mind. Women are considered "difficult" to study and enrol in trials given the complexities of their biology and their lives. When women are included in clinical trials, it is rarely in sufficient

numbers to be able to draw statistically significant conclusions about sex differences.

There is also little HIV research involving adolescent girls despite high HIV incidence in this population group, particularly in generalized epidemics. From this perspective, HIV trials clearly are not "working" for women and adolescent girls.

Making HIV Trials Work for Women and Girls

UNAIDS and other partners, including the Global Coalition on Women and AIDS, the International Center for Research on Women and Tibotec Inc., have come together to create a movement to 'Make HIV Trials Work for Women and Adolescent Girls'.

The movement has been established to review past participation of women and adolescent girls in clinical trials; to assess how well HIV trials are collecting, measuring, analysing and presenting data related to health determinants and health outcomes in women or adolescent girls; and to identify barriers to including women and adolescents in trials. An action plan, developed to address these concerns, is being implemented.

Ways forward

Women and girls are at the heart of any successful response. New and special measures to overcome the barriers that are preventing women from participating in biomedical HIV prevention and treatment trials are essential for an effective response.

- The importance of placing women and girls at the centre of HIV research needs to be raised with policy makers, research sponsors, and researchers so that trials will be designed and adapted to be relevant to women.
- 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 into new advances of interest to women and girls.
- Barriers to including women and adolescent girls in trials need to be identified and new ways sought to facilitate women's participation. Practical ways include:
  - 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, and
  - establishing child care or play spaces near the research site so that women can bring their children if they need to.
- Women need to be enrolled in trials in sufficient numbers to allow adequate conclusions to be drawn about sex differences and about their clinical and public health implications.
- 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, analyse, and report sex-disaggregated data.
- Strategies need to be developed to identify and analyse sex-disaggregated "fugitive data", that are available but rarely found in the scientific literature, from research conducted by industry, public programmes, and other entities.
- Data must be collected on women and HIV both outside the context of formal trials 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.
- More trials are needed to evaluate potential structural interventions, particularly addressing women and adolescent girls in the hyper-endemic areas of southern Africa.

Creating new norms

A "new norm" needs to be established that all research on critical health conditions experienced by women and all trials on drug interventions to address these conditions must include a scientifically meaningful number of women.

Creating this new norm would require reporting sex-disaggregated data by researchers, regulatory authorities, ethical review committees, host country governments, journal editors and peer reviewers, research sponsors, and donors.

It should simply no longer be acceptable to design studies that will not answer questions in a way that is relevant to women.

Benefits for women

If these measures are taken, trials addressing key questions of relevance for women and adolescent girls will be able to draw statistically significant conclusions about the implications for them of biomarkers, biological responses, treatment efficacy, novel prevention technologies, and structural interventions.

Such trials will offer an important opportunity for women to access free, high quality health care, information, counselling, and other services. They also will provide women with a safe, supportive environment, a feeling of purpose, and a sense of belonging to a community of support.

What needs to be done?

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.