



AIDS RESEARCH Community Handbook

Tools for HIV/AIDS Treatment & Prevention Research Advocates

The Importance of Participant Diversity in HIV Clinical Trials

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Of all the challenges facing HIV researchers, one of the most significant is including persons of all genders and all racial and ethnic backgrounds in clinical trials. This challenge has emerged in many areas of medical research, but it is more pronounced in HIV research, where women and people of color historically have been under-represented.

There are many barriers to ensuring diversity in clinical trials. These include cultural and language issues, social stigma around HIV and the behaviors by which it is transmitted, and a history of ethical violations in research. Addressing these concerns does not happen overnight, but rather one person at a time, with lots of hard work. We also know that we must begin the work of addressing people's concerns early, before research in a particular location even begins. People need time to listen to the research messages, meet the researchers and other staff

members, ask questions, and make decisions about whether participating in a trial is something they want to do.

Community education efforts strive to move communities along a continuum, beginning with raising awareness and gradually moving ahead to knowledge, a willingness to participate, and, eventually, support for the research agenda. We seek to create communities where people understand the importance of the research agenda and are supportive of those who choose to volunteer. Even if some people decide that trial participation is not appropriate for them personally, it is important to create an environment that will be supportive for all, whether they choose to volunteer or not.

We often hear the question, "Why do I keep hearing about the need for women and minorities to participate?" There are some diseases where we already know that ethnicity matters. For example, African Americans are more susceptible to Sickle Cell Anemia, and Jewish people of Eastern European descent are more susceptible to Tay Sachs disease. We don't know the extent to which race or ethnicity makes a difference for HIV, so we need to involve people of many backgrounds in our research to make sure that the products will be safe and will work in diverse populations. This is true for all HIV research, whether the study product is a preventive or therapeutic vaccine, a vaginal or rectal microbicide, anti-HIV drugs, or treatments for opportunistic infections. Finally, diversity issues are also important for behavioral intervention studies where cultural norms may have an impact.

We also are not sure of the extent to which gender matters. In the first Phase III trial (7400 participants) of a preventive vaccine against herpes simplex virus type two, the type that typically affects the genitals, results appeared to indicate that the vaccine might be effective for women but not for men. However, there were not enough women enrolled in the trial to make this conclusion with certainty. As a result, researchers are now conducting another Phase III trial with 7550 women to assess the vaccine's effectiveness in women. Think of the time and money that could have been saved if only the first trial had enrolled enough women!

As the herpes vaccine trial demonstrates, we need to include women in HIV research so that scientists can examine how their immune responses may differ from those of men. Examples of these differences include the hormonal effects of estrogen, and the different dosages that women might require (since their body mass is typically lower than men's). Similar questions must also be addressed for transgender individuals. Including people of many backgrounds also underscores why we conduct our research in cities around the globe. Working globally helps researchers take into account the role of nutrition, living conditions, and other lifestyle factors on the immune system and how these factors might relate to the effectiveness of a study product.

At the HIV Vaccine Trials Network, we believe that by working with diverse communities now, earning their trust and their respect, we can create relationships that will ultimately benefit the communities themselves. Community Advisory Board members can play an important role in shaping these relationships. These may include

- advising research staff members on appropriate strategies for outreach and recruiting in various communities;
- reviewing the cultural competence of proposed advertising and study materials;
- helping researchers identify gatekeepers and other key members of the community; and
- making introductions: in some cases, the research staff members may not be the appropriate people to meet with a particular group, and CAB members can help to open doors and make connections that will facilitate a more productive interaction.

We must work to ensure that the history of under-representation of women and people of color in HIV research is not carried into the future. Instead, we want to create a new legacy of equal representation, where all are seated at the table. Advancing the HIV research agenda is something that scientists can't do alone, and it is the partnerships created now that will enable the delivery of successful interventions, both preventive and therapeutic, to all populations when they become available.

For more information

HIV Vaccine Trials Network (HVTN)

<http://www.hvtn.org>

The HVTN's mission is to facilitate the process of testing preventive vaccines against HIV/AIDS.

Related Fact Sheets

People of Color and HIV/AIDS Clinical Trials

<http://www.researchadvocates.org/article003.htm>

Women and HIV/AIDS Clinical Trials

<http://www.researchadvocates.org/article004.htm>