



# HIV/AIDS Clinical Trials & the Transgender Community

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## Getting Started: Terms to Know

Many of us have not had to spend a lot of time thinking about our own sex and gender; we were either: born female, raised as a girl, and think of ourselves as a woman; or born male, raised as a boy, and think of ourselves as a man. This is not the case for everyone. In order to talk about transgender issues it's important to understand the differences between birth sex, gender identity, and gender roles.

- **Birth Sex** refers to the biological characteristics of a person at birth.
- **Gender Identity** refers to an individual's own sense of themselves as being male or female
- **Gender Role** refers to the expressions, behaviors and mannerisms that we use to be viewed as masculine or feminine by a particular culture.

## Understanding 'Transgender'

Transgender is a broad term that includes a variety of people who all have one thing in common; their gender identity, expression, or behavior is not traditionally associated with their birth sex.<sup>1</sup> This term includes those born male who identify as female (male-to-female) and those born female who identify as male (female to male). Transgender includes cross-dressers, individuals who like to wear the clothes of another gender, but while they enjoy exploring this gender role, it is not their gender identity. Transgender also includes those who do not strongly identify with either the male or female gender.

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"Sex and gender are two closely related yet distinct concepts that affect HIV/AIDS at virtually every level."

- Forum for Collaborative HIV Research  
Report on Sex and Gender Issues in HIV Disease

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Some transgender individuals are transsexuals; meaning their gender identity is opposite their birth sex, and they live their lives consistent with their gender identity. Transsexual individuals may choose to change their bodies to make them more consistent with their gender identity. This could include taking hormones, or having surgery.

## Intersex

You may also hear the term Intersex, which is different from Transgender. An intersex individual is born with an anatomy, or birth sex, that cannot be easily categorized as male or female.

## HIV/AIDS in the Transgender Community

There is no national data on the prevalence of HIV in the transgender community, due to a lack of data collection by the Centers for Disease Control and Prevention (CDC) and other federal agencies. Smaller regional studies, however, indicate that the transgender community has been one of the communities hit hardest by this epidemic.

- A Centers for Disease Control and Prevention (CDC) review of an outbreak of tuberculosis among a group of 26 transgender persons in Baltimore and New York City found that 62% were HIV infected.<sup>2</sup>
- In a Washington DC Survey of the transgender community, 25% of all participants self-reported as HIV positive, while 22% said they did not know their HIV status.<sup>3</sup>

## Barriers for the Transgender Community

Transgender individuals often face stigma and discrimination, which increases their HIV risk while at the same time makes it more difficult for them to access HIV prevention and treatment services. Few transgender sensitive prevention and treatment programs exist.<sup>4</sup>

Many socioeconomic factors in the transgender community negatively impact access to health care, including HIV prevention and treatment services. These factors include a higher unemployment rate, and lack of health insurance.<sup>3</sup>

## Hormone Therapy

Some transgender individuals take hormones like estrogen or testosterone. More research on how HIV/AIDS treatments may interact with hormone therapy is needed. The enrollment of transgender people in clinical trials affords an opportunity to collect this important information regarding their care. While some clinical trials may exclude participants who are taking hormones, many need not unless it is medically necessary. Trials that exclude transgender people who take hormones must clearly explain the medical reasons in the exclusion criteria section of their protocols.

## Most HIV/AIDS Research Fails to Accurately Collect Data on Sex and Gender

There is a clear understanding in the HIV/AIDS research community that birth sex and gender identity are two clearly separate concepts.<sup>5</sup> Still, the majority of HIV/AIDS research fails to accurately collect information on sex and gender. Sadly, most studies still have one box for 'male' and one box for 'female'.

## DAIDS Research Networks Fail to Accurately Collect Data on Sex and Gender

Among the AIDS research networks supported through the NIH NIAID Division of AIDS, or DAIDS, data collection on sex and gender is sorely lacking. There is inconsistent use of terminology such as the words 'sex' and 'gender' across the research networks. There are inconsistent methods for collecting information on gender and sex across AIDS research networks. In many cases, no information about gender identity is collected.

With incomplete data collection forms, and a general lack of understanding of transgender issues in society at large, it is not uncommon for a transsexual woman to be labeled as 'male' in order to participate in a study, or for a transsexual man to be labeled as a 'woman' in order to participate. Even if it is just a check-mark on a form, not respecting someone's gender identity in this manner is inappropriate, insensitive, and a significant barrier to their trial participation.

## Making a Difference

As a concerned community member involved in HIV/AIDS research, you have a tremendous opportunity to be an ally to the Transgender Community. Here are some things you can do:

- Make sure information about birth sex and gender identity is included in each and every research study you review.
- Encourage the research networks you work with to develop consistent guidelines for collecting information about birth sex and gender identity. Ask them to incorporate this into their template documents, so that future studies are consistent with these guidelines.
- Reach out to transgender organizations in your community and encourage their participation in research advocacy.
- Make sure researchers you work with, and your local research site, are sensitive to the needs of transgender trial participants. A training kit "Living Out Loud: How to Serve Transgender Clients Where They Are" is available from Diversity Works ([www.dwmm.org](http://www.dwmm.org), 410 235-1600)

### For more information

#### ***For information on the Transgender Community***

##### **Gender Education & Advocacy**

<http://www.gender.org>

Gender Education and Advocacy (GEA) is a national organization focused on the needs, issues and concerns of gender variant people in human society.

##### **National Center for Transgender Equality**

<http://www.nctequality.org>

The National Center for Transgender Equality (NCTE) is a social justice organization dedicated to advancing the equality of transgender people through advocacy, collaboration and empowerment.

##### **National Coalition for LGBT Health**

<http://www.lgbthealth.net>

The National Coalition for LGBT Health is committed to improving the health and well-being of lesbian, gay, bisexual and transgender individuals and communities through public education, coalition building and advocacy that focuses on research, policy, education and training.

#### ***For information on Intersexuality***

##### **Intersex Society of North America**

<http://www.isna.org>

The Intersex Society of North America (ISNA) is devoted to systemic change to end shame, secrecy, and unwanted genital surgeries for people born with an anatomy that someone decided is not standard for male or female.

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<sup>1</sup> Lawrence, A. A., Shaffer, J. D., Snow, W. R., Chase, C., & Headlam, B. T. (1996). Health care needs of transgendered patients [Letter to the editor]. *JAMA*, 276, 874.

<sup>2</sup> HIV-Related Tuberculosis in a Transgender Network: Baltimore, Maryland, and New York City Area, 1998-2000." *MMWR*. April 20, 2000.

<sup>3</sup> The Washington Transgender Needs Assessment Survey. Jessica M. Xavier, Principal Investigator, Gender Education and Advocacy, Inc., [Jessica@gender.org](mailto:Jessica@gender.org). Implemented by Us Helping Us-People into Living, Inc., Ron Simmons, PhD., Executive Director, Funded by the Administration for HIV and AIDS of the District of Columbia Government.

<sup>4</sup> HIV/AIDS and Transgender Persons, The Leadership Campaign on AIDS, Office of HIV/AIDS Policy, Department of Health and Human Services (DHHS)

<sup>5</sup> Sex and Gender Issues in HIV, The Forum for Collaborative HIV Research, The George Washington University Medical Center School of Public Health and Health Services, Department of Health Policy, Center for Health Services Research and Policy, A Project Co-Sponsored by: The National Institutes of Health Office of AIDS Research and the Centers for Disease Control and Prevention, November, 2002.