



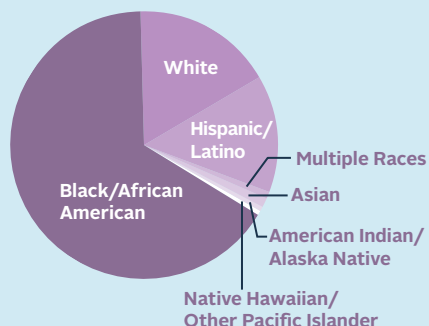
ISIS *a women's study*

ARTICLES

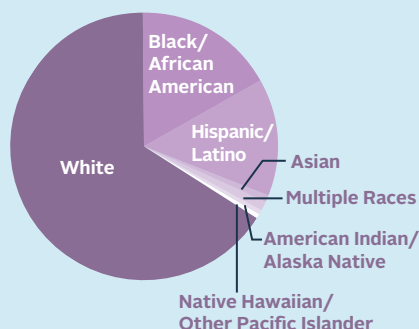
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Diagnoses of HIV Infection and Population among Adult and Adolescent Females, by Race/Ethnicity, 2009 — 40 States

DIAGNOSIS OF HIV INFECTION
N=9,973



FEMALE POPULATION, 40 STATES
N=102,041,789



Source: CDC

WOMEN AND HIV/AIDS IN THE UNITED STATES

Although men represent the majority of new HIV infections and AIDS diagnoses in the US, the impact on women has increased dramatically since the beginning of the epidemic. According to the Centers for Disease Control and Prevention (CDC), women represented 8% of the AIDS diagnoses in 1985, 20% in 1995 and 25% in 2009.

Women of color, particularly black women, have been the hardest hit by the disease and represent the majority of new HIV infections and AIDS diagnoses among women.

- HIV/AIDS is a leading cause of death among black women in the US.
- The estimated rate of HIV infection among black women is nearly 20 times higher than the rate for white women, and four times as high as that of Latina women.
- According to the CDC, many people are unaware of their HIV infection and may unknowingly transmit the virus to their partners. Research has shown that antiretroviral treatment that effectively suppresses the ability of the virus to multiply, greatly decreases the chances that HIV-infected people transmit the virus.

The concentration of new AIDS diagnoses among women is highest in the Northeast and the South. The District of Columbia tops the list with a rate 12 times the national average.

HIV Acquisition and Transmission

Women are much more likely to get HIV through heterosexual sex than any other route of transmission, accounting for 87% of new HIV infections in black women. Injection drug use is the second most common cause. Mother-to-child transmission of HIV in the US has decreased dramatically since its peak in 1992, thanks to the use of antiretroviral therapy which significantly reduces the risk of transmission from a woman to her baby. However, infections continue to occur, the majority of which are among black Americans.



Where did the study take place?

Ten communities in six distinct geographic areas participated in the study. HPTN 064 was conducted at the following clinical research sites:

EMORY UNIVERSITY, Atlanta, Georgia (Ponce de Leon Center CRS and Hope Clinic CRS)

GEORGE WASHINGTON UNIVERSITY, School of Public Health and Health Services, Washington D.C.

NEW JERSEY MEDICAL SCHOOL, Adult Clinical Trials Center, Newark, New Jersey

COLUMBIA UNIVERSITY, New York, New York (Bronx-Lebanon Hospital Center CRS and Harlem Prevention Center CRS)

JOHNS HOPKINS, Adult AIDS CRS, Baltimore, Maryland

UNIVERSITY OF NORTH CAROLINA-CHAPEL HILL, North Carolina (UNC AIDS CRS and Wake County Health and Human Services CRS)

HIV PREVENTION TRIALS NETWORK (HPTN) 064 ISIS STUDY

HPTN 064, or ISIS (The Women's HIV Seroincidence Study), is a federally funded study designed to estimate the overall new HIV infection rate in women at risk for HIV in the US. A total of 2,099 women between the ages of 18 and 44 years were enrolled over 14 months (from May 2009 to July 2010). Eighty-eight percent of the participants in the study were black, 12% identified as Hispanic/Latina.

The study generated a wealth of information. Focus groups and in-depth interviews with women in the study helped identify barriers to HIV prevention in the women's lives and communities, as well as other factors that may increase the risk of HIV. Ultimately, the ISIS study will provide information that may be used to design effective interventions to prevent HIV among US women most at risk. Information was also gathered from men living in the study site communities which identified what helps and hinders HIV testing. This information will help inform future trials that seek to incorporate a community-wide HIV counseling and testing initiative.

Why Is This Study Important?

HIV continues to spread. Despite the fact that black women make up just 14% of the US female population, they account for 66% of newly identified infections in women. There is an urgent need for an HIV prevention research agenda that is responsive to this epidemic's realities in the US. Specifically, better strategies for HIV prevention are needed, especially those that focus on US women most at risk for HIV. There is a limited understanding of which women are most at risk and why. The ISIS study seeks to accurately measure the rate of new infections in areas of the country where HIV infection occurs most commonly among women, as well as attempts to better understand the factors that impact their risk of infection.

STUDY PARTICIPANTS

2,099
WOMEN

18-44
YEARS OLD

88%
BLACK

12% HISPANIC/
LATINA



ISIS

You reached out to me and gave me hope,
you showed me
that somebody cared about my welfare,
by just being there....

You exemplified the meaning of ISIS,
which is Protector,
Goddess of women and children from which all beginnings arose,
Exceptionally wise with the knowledge and understanding to the highest degree....

Universal Mother which made me believe and discover
that I could recover
from low self-esteem and always dismissing
the fact that I am a queen with every ounce of my being....

Your symbol means life
which I was slowly taking away from myself
by risking suicidal decisions to my health....

You educated and empowered me on the facts about HIV
and how 50% of the ones infected look like me....

You gave me an outlet in which I could speak and tell my story on how things came to be
in my community....

You listened, intently, and gave me information
facilities, testing, counseling, even contacted me monthly
just to see how I was
Coping....

Even compensated me monetarily to show you valued my time and opinion,
treated us all with confidentiality, fairness, and equality....

"ISIS"
You revived my soul and re-birthed my spirit by nurturing
and releasing my captive mind
that longed to be freed...

And now, I can teach my seed,
and tell everyone how
ISIS has been immeasurably PRICELESS

— YASHIKA DICKERSON



YASHIKA'S STORY

Yashika Dickerson was homeless when she first met a member of the ISIS study. "They came to the women's shelter where I was living," says Ms. Dickerson. "I had just separated from my mate of 12 years and had just lost my job at the bank after 8 years. I was very broken in spirit and about to give up on life." Yashika says when the study team arrived they were all smiles and immediately connected with the women at the shelter and treated them with respect and dignity. "They didn't judge or turn their nose up at us. They wanted to help." She says the ISIS team explained that women could be a part of an important research study, one that could have a positive impact on the community. It was that incentive that convinced her to join the ISIS study.

"I wanted to be a part of something positive and meaningful."

Ms. Dickerson says the gift card incentives provided by ISIS were often how she was able to eat. While those cards were greatly appreciated, she says she is most thankful for the hope and rejuvenation that the wonderful women of ISIS provided. "I needed their energy to pick myself up and start over again.

I appreciate ISIS for everything!"



Harlem Prevention Center
at Columbia University



University of North
Carolina — Chapel Hill
ISIS team

STUDY SITE HIGHLIGHTS

The success of ISIS was attributed to the 3 Rs: recruitment, retention and resources. The HPTN O64 sites developed a variety of innovative strategies to successfully recruit and retain study participants. Special attention was paid to understanding site-specific cultural norms and identifying barriers to participating in clinical research within communities of color. Moreover, all sites worked with community stakeholders to assure effective support and engagement with each of the ISIS communities. Civic leaders, public health officials, AIDS community-based organizations and faith-based leaders were instrumental in ensuring robust community engagement and building a foundation of trust.

For example, one ISIS site worked closely with a community organization that is an international leader in HIV treatment and prevention in women. This organization helped the ISIS team gain entry into the community and assured rapid enrollment and community support for the trial. The organization provided safety and sensitivity training to help staff better understand the target community.

Community advisory boards were engaged and played a critical role in the study. All sites discussed the ISIS study with their CABs and each site had one or more community representatives working with the study.

Extensive field work was key to appropriate venue selection and convenient times for recruitment. ISIS staff tried to recruit and enroll women on the same day, including efforts to escort women from the recruitment venues directly to the study site for enrollment.

Study teams developed relationships between staff and participants and created comfortable and trusting environments. Recruitment pitches were unique, straightforward and honest. Resources were also provided to women and many were able to successfully connect with appropriate community services. This provided a sense of trust that research staff were genuinely interested in more than just answers to study questions and collecting data. HPTN O64 community engagement was guided by the RESPECT principle, an acronym created by one of the ISIS sites.

“The ISIS study was special. The team worked with communities in very effective ways. Everyone from stakeholders, to site investigators, to ISIS participants, all had the same important goal in mind to understand more about new HIV infections in US women.”

— SALLY HODDER
PROTOCOL CHAIR, HPTN O64 (ISIS)

- R** for Removing Barriers
- E** for Expressing Commonalities
- S** for Seeking Mutual Benefit
- P** for Presenting Yourself Often
- E** for Expecting the Best
- C** for Coming Through with Promises
- T** for Thanking Them!