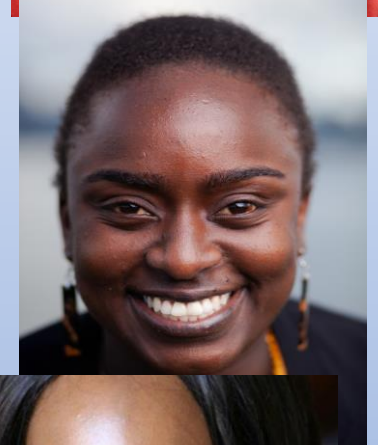




# **Biomedical HIV Prevention for Women**

**The Women's HIV Research Collaborative**

# The Women's HIV Research Collaborative



# The Women's HIV Research Collaborative



# Presentation Overview

- Women's Contributions to HIV Prevention Research
- The Urgency for HIV Prevention for Women
- HIV Prevention for Women: The Present
- HIV Prevention for Women: The Future
- How You Can Get Involved!

# **Women's Contributions to HIV Prevention Research**

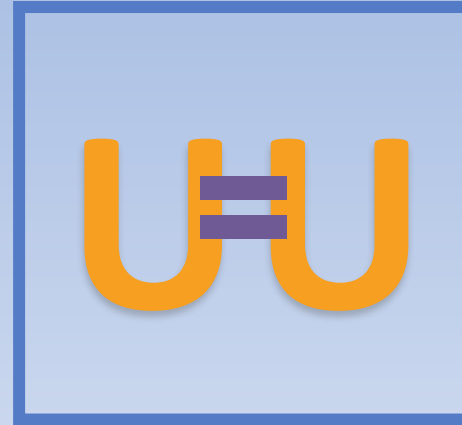


# Women Play Vital Roles in Every Aspect of HIV Research

- All 5 NIH-funded research networks are led / co-led by women as Network Principal Investigators / Chairs
- Network Directors
- Laboratory Center Principal Investigators
- Statistical and Data Management Center Principal Investigators
- Women's Health Inter-Network Scientific Committee
- Advocates
- Front desk
- Managers
- Recruiters
- Community Educators
- And many more

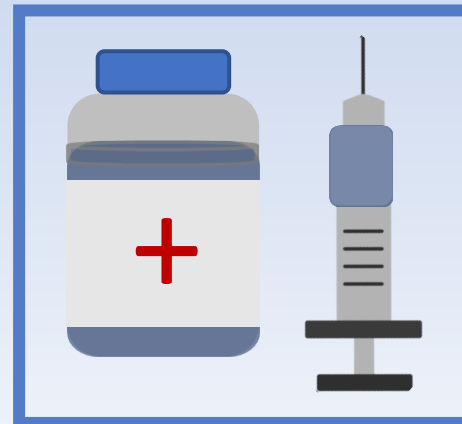
# Women Advance HIV Prevention as Research Participants

Dapivirine Vaginal  
Ring



TasP / U=U

Oral PrEP



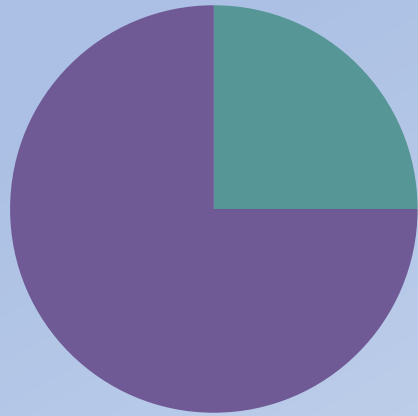
Experimental Vaccine

*“This is our struggle--we want to be free from HIV.”*

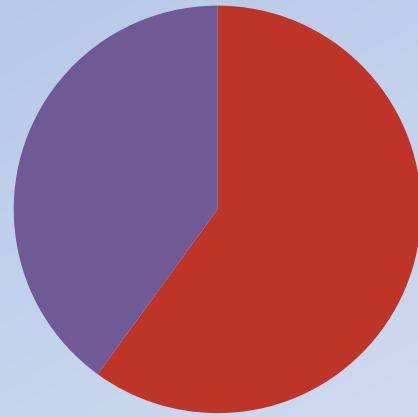
# **The Urgency for HIV Prevention for Women**



# HIV Among Transgender Women in the US



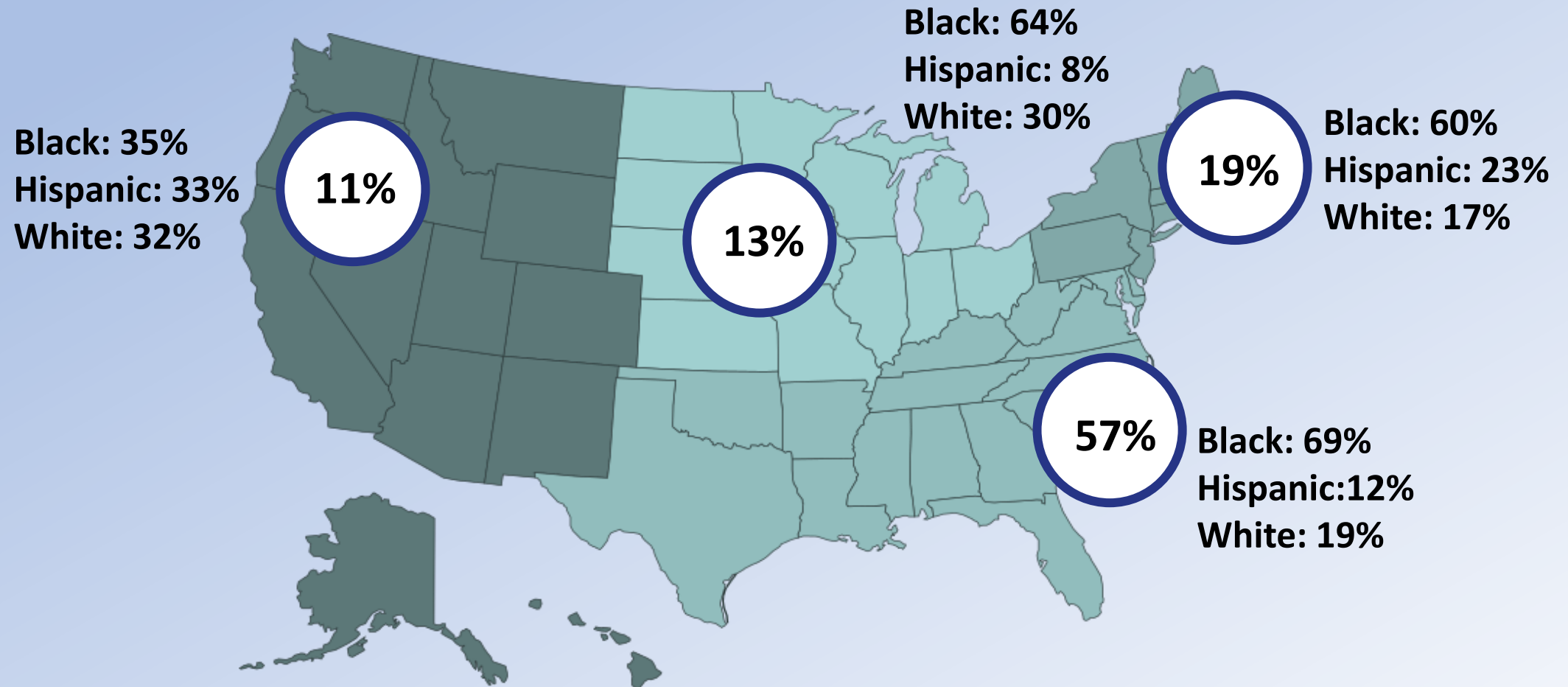
ABOUT **1/4** of all  
transgender women



MORE THAN **1/2** of all  
**Black transgender women**

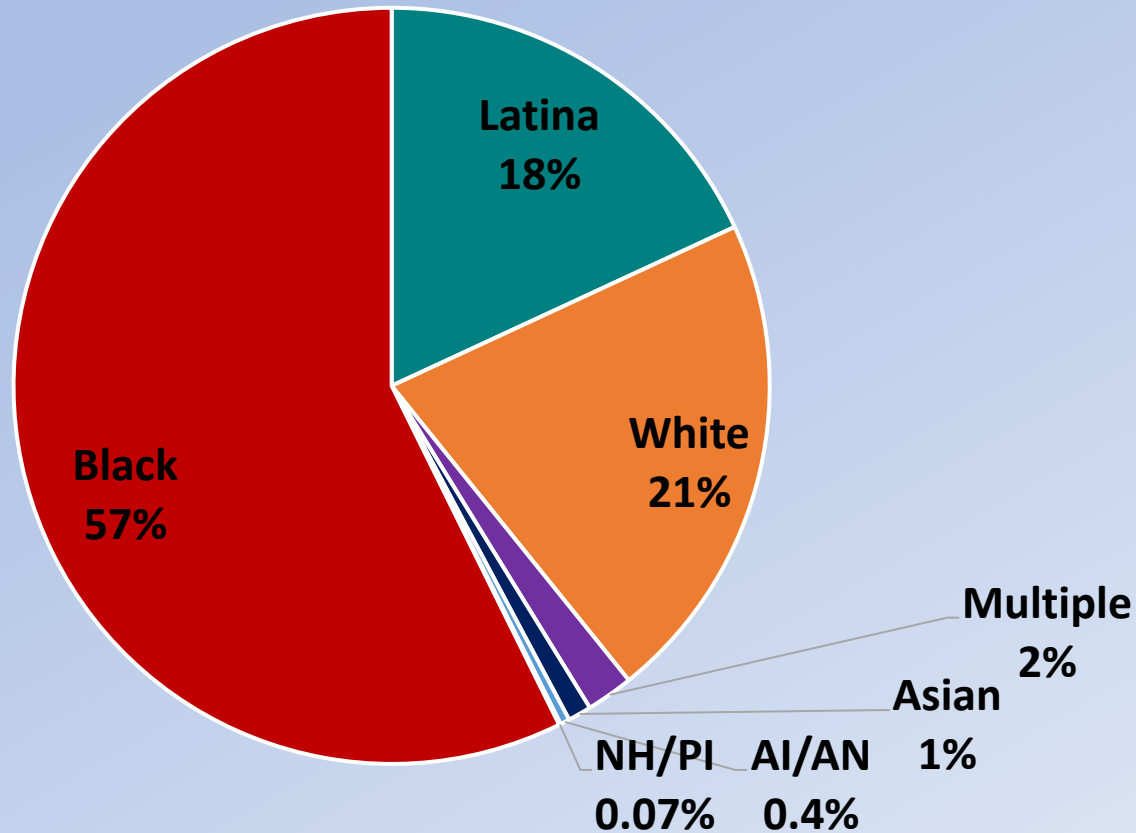
are  
estimated  
to be living  
with HIV.

# HIV Diagnoses Among Cisgender Female Adults & Adolescents in 2017



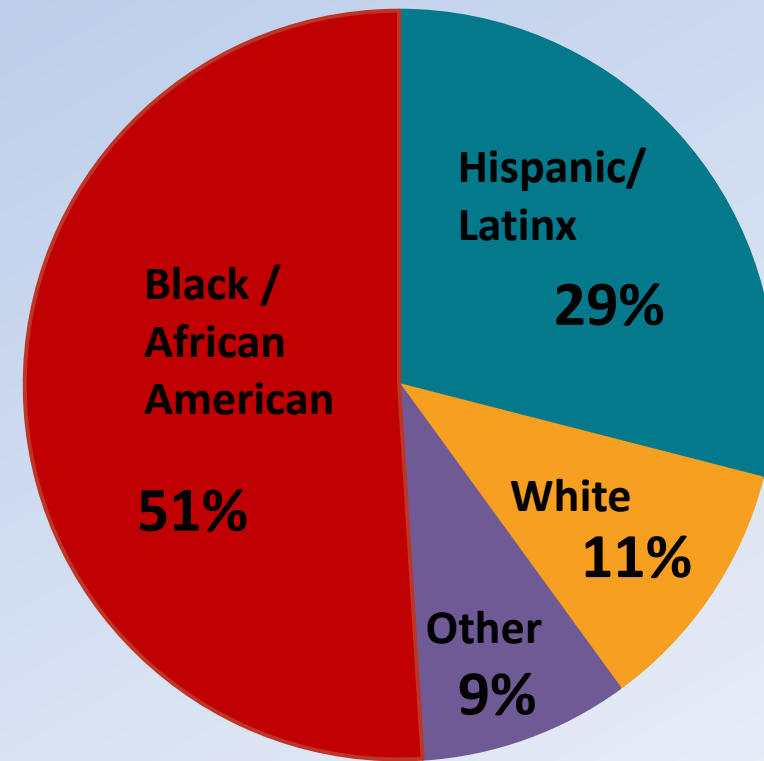
# Diagnoses by Race: Women in the US

CISGENDER WOMEN, 2018  
(N= 7,220)



Source: <https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf>

TRANSGENDER WOMEN , 2009-2014  
(N= 1,974)



Source: Centers for Disease Control and Prevention; H Clark et al. Diagnosed HIV Infection in Transgender Adults and Adolescents: Results from the National HIV Surveillance System, 2009-2014. December 2016.

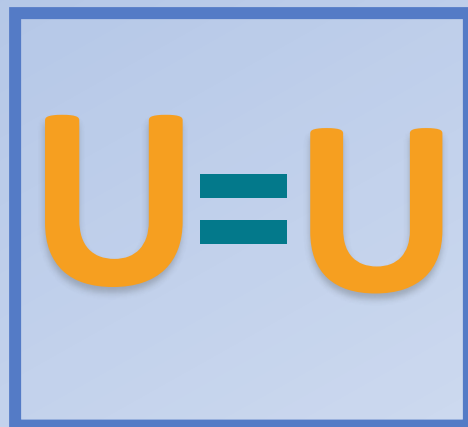
*“It’s time we placed our own health above our partner’s desires.”*

# **HIV Prevention for Women: The Present**

# Available Now



Post Exposure  
Prophylaxis  
(PEP)

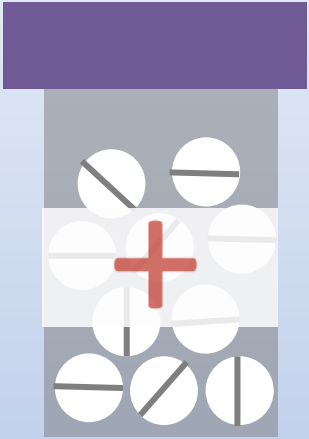


Treatment as  
Prevention  
(TasP)



Pre-Exposure  
Prophylaxis  
(PrEP)

# Post-Exposure Prophylaxis (PEP)



The use of antiretroviral medicines *after* being potentially exposed to HIV to prevent the virus from taking hold in the body

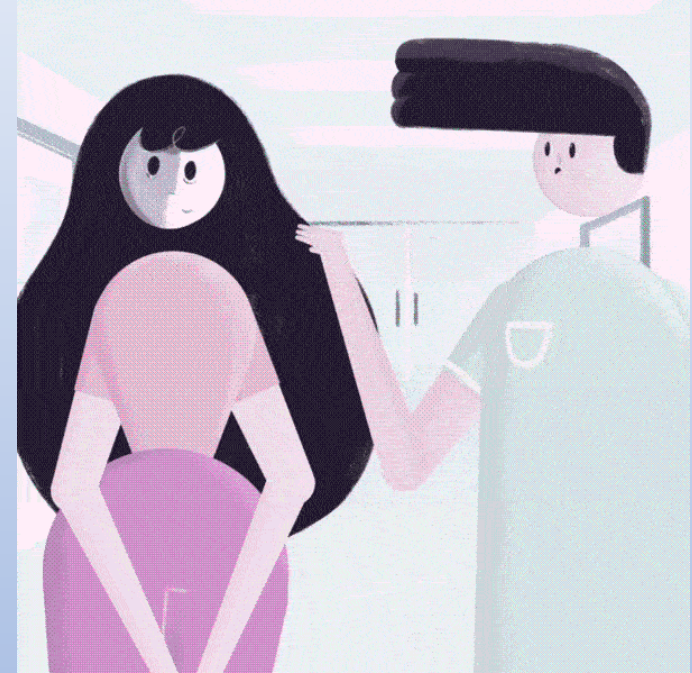
- Must be started within 72 hours after exposure in order to be effective
- The sooner PEP is started, the better
- Usually prescribed to be take once or twice daily for about a month

**If someone thinks they may have been exposed to HIV, they should talk to their health care provider or an emergency room doctor about PEP right away.**



# Treatment as Prevention (TasP)

- The use of antiretroviral drug therapy (ART) by someone who has HIV
- By taking ART as prescribed, people living with HIV can reduce the amount of virus in their bodies to “undetectable” levels
- Under conditions of viral suppression, the chance of transmission to others through sex is ZERO
- U=U





# Oral PrEP (Pre-Exposure Prophylaxis)

- A pill approved for daily use to prevent HIV
- Nearly 100% effective when taken daily as prescribed
- Must be HIV-negative to take it
- Contains two anti-HIV drugs
- Prevents HIV only (not other STIs)
- Self-administered; you're in control



# Who Should Take Truvada as PrEP?

- Anyone who is HIV-negative and vulnerable to acquiring HIV (Centers for Disease Control and Prevention or CDC). Including (but not limited to):
  - Cis and trans women who do not use condoms during sex with partners of unknown HIV status
  - Cis and trans women in a sexual relationship(s) with a partner(s) who has HIV
  - People in sero-different relationships – one partner has HIV, the other does not – including those who are considering getting pregnant or breastfeeding
  - Women who would feel more comfortable and confident using it

**The CDC estimates that nearly 500,000 women in the US could benefit from taking PrEP. However, less than 1% of those 500,000 women are taking it!**



# Does Truvada as PrEP Work for Trans Women?

- The CDC recommends PrEP for all HIV-negative persons who are vulnerable to getting HIV, including transgender women.
- Research is ongoing with regard to interactions between hormone therapy and oral PrEP, but the CDC does not recognize any drug conflicts or interactions.
  - If you're worried that PrEP will affect your hormone therapy, ask your health care provider to check your hormone levels.
- Everyone taking PrEP should see their health care provider every 3 months for follow up, HIV tests, and prescription refills.
  - Combine PrEP visits with hormone therapy appointments.



# **HIV Prevention for Women: The Future**

# Still Under Research

## New PrEP & Integrated Strategies



New formulations and delivery methods to reduce the likelihood of transmission.

## Microbicides



Products applied vaginally or rectally that may prevent HIV transmission.

## Vaccines



Harnessing the immune system to help prevent a person from contracting HIV.

# Continuing Research: PrEP & Integrated Strategies

The HIV Prevention Trials Network (HPTN), funded by the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health, and the National Institute on Drug Abuse, is dedicated to discovering and developing new and innovative strategies to reduce the acquisition and transmission of HIV.

# Integrated Strategies

- No single HIV prevention intervention will work for all women.
- Effective HIV prevention programs require a combination of behavioral, biomedical and structural interventions.
- Evidence-based and cost-effective strategies to meet women's needs.





# Advancing HIV Prevention Research

Oral PrEP is an available option for HIV prevention. What's next?

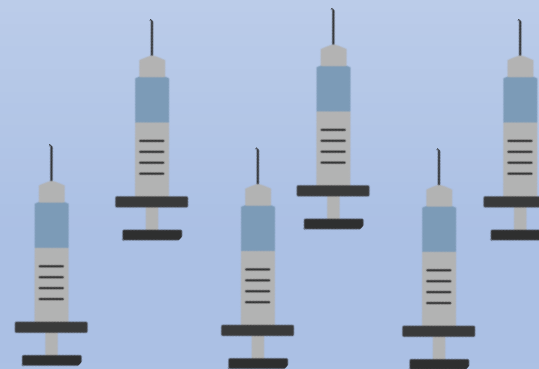
- Improving PrEP and evaluating new PrEP agents and delivery methods
- Developing and evaluating integrated combination prevention strategies
- Optimizing application of new knowledge to women (and other key populations)

# PrEP 2.0

- **PrEP as a Shot**
  - HPTN 083
    - 43 sites in 7 countries (including US)
    - Minimum recruitment target of 10% transgender women (**>450 transgender women**)
  - HPTN 084
    - **3,200 cisgender women** in 7 African countries



**VS.**



# PrEP 2.0

- **Implantable PrEP Studies**
  - Implantable products for HIV prevention similar to Norplant for birth control
- **Longer Acting Oral PrEP Studies**
  - Studies looking at options for oral PrEP that may only need to be taken once a week.



# Different PrEP Concepts

<u>Oral PrEP</u>	<u>Injectable PrEP</u>	<u>Implantable PrEP</u>
<ul style="list-style-type: none"> <li>• User-controlled</li> <li>• Different dosing schedules</li> <li>• Some people may not like taking pills</li> <li>• Stigma associated with HIV meds</li> <li>• May be expensive</li> </ul>	<ul style="list-style-type: none"> <li>• Clinician-administered</li> <li>• Dose every 8 weeks</li> <li>• Could help address adherence issues</li> <li>• Different side effects than oral PrEP</li> <li>• Medicine cannot be removed once given</li> <li>• Some women may not like injections</li> <li>• Potential long-lasting side effects (medicine may stay in body for ~52 weeks)</li> </ul>	<ul style="list-style-type: none"> <li>• Clinician-administered</li> <li>• Insertion every 6 months or yearly</li> <li>• Could make it easier to take medicine</li> <li>• Fewer (or different) side effects than oral PrEP</li> <li>• Can be removed</li> <li>• Annual removal, if not biodegradable</li> <li>• Some women may not like having implants</li> </ul>

# Additional Information

- [www.hptn.org](http://www.hptn.org)
- [www.facebook.com/HIVptn](https://www.facebook.com/HIVptn)
- [www.twitter.com/HIVptn](https://www.twitter.com/HIVptn)
- [www.bethegeneration.org](http://www.bethegeneration.org)
- [www.nih.gov](http://www.nih.gov)

# Continuing Research: Microbicides

A number of public and private organizations, in partnership and individually, are working together to find microbicides that can help prevent HIV.

The Microbicide Trials Network (MTN), funded by the National Institute of Allergy and Infectious Diseases (NIAID), brings together international investigators, community stakeholders, and industry partners who focus on developing and evaluating microbicides.

The MTN is focused on evaluating non-systemic and multi-purpose products with studies designed to support potential regulatory approval of products.

# What Are Microbicides?

- Microbicides are products applied inside the vagina or rectum to protect against HIV through sex.
- They deliver high levels of anti-HIV drugs to the site of potential HIV transmission, with very little drug absorbed into the body.
- Microbicides formulated as vaginal rings, films, gels, douches, fast-dissolving inserts, and suppositories are being developed and tested to provide additional options to prevent HIV acquisition during sex.
- These products could fulfill the need for a non-systemic and/or short-acting method for HIV prevention that can be used around the time of sex.

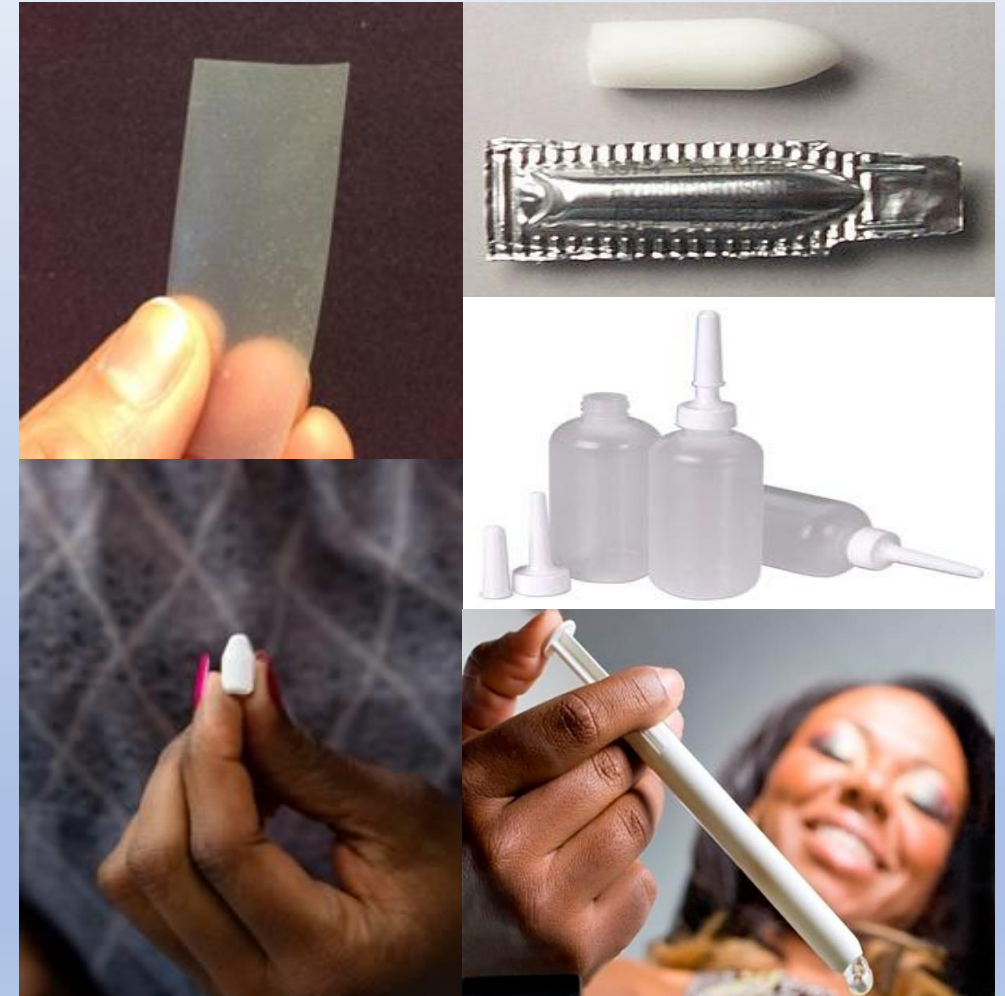


Image courtesy of Conrad



# Why Microbicides?

- Oral PrEP is a safe and very effective method to prevent HIV, but taking pills daily may not be possible or desirable by everyone.
- To make a global impact on the HIV epidemic among cisgender and transgender women who may have vaginal and/or anal sex, we need new and creative ways to prevent HIV that recognize diverse preferences and choices.
- Products that could be used around the time of sex or that conform to already practiced sexual behaviors might be desirable to some women, giving them more control over their own health and sex lives.

# Dapivirine Vaginal Ring

- Flexible silicone monthly ring that slowly releases Dapivirine inside the vagina, with low systemic absorption.
- WHO-recommended based on multiple studies with more than 6,600 cisgender women, finding:
  - strong safety profile; reduces HIV transmission; more effective when used consistently – not used consistently by younger women & girls
- Ongoing study with cisgender girls and young women in Africa will provide more information on ring use in this population, as well as daily PrEP, and assess their preferences for the approaches.
- Other studies being planned will evaluate the safety of the ring in women who are pregnant and breastfeeding.



Image credit: IPM

# Next Generation Rings

- Rings that can be used for up to 3 months
- Rings that can also prevent unintended pregnancy
- Rings that could protect against both HIV and other sexually transmitted infections, such as herpes



# Rectal Microbicides

*“Just treat me with respect. Treat me like any other woman. Women have anal sex. It’s not only guys.”*

- Anal sex is a common sexual practice enjoyed by cisgender and transgender women around the world.
- Currently being developed and tested, rectal microbicides could...
  - Provide protection around the time of anal sex (“on-demand” products)
  - Conform to already practiced sexual behaviors such as rectal lubes and/or douches (“behaviorally-congruent” products)
  - Encourage a feeling of safety & confidence by recognizing the importance of pleasure in the lives of cisgender and transgender women
- Several early rectal microbicide studies have been completed to date that have enrolled more than 100 cisgender and transgender women.



Image credit: IRMA

# Rectal Microbicides & DESIRE

- DESIRE (Developing & Evaluating Short-acting Innovations for Rectal Use) launched in 2019 and is the first study to explore multiple placebo methods for delivering a rectal microbicide – a douche, suppository, and fast-dissolving rectal insert.
- DESIRE, whose results are expected in 2020, will:
  - Include 210 transgender men and women and cisgender men who have sex with men from Malawi, Peru, South Africa, Thailand, and the U.S. (Birmingham, Pittsburgh and San Francisco)
  - Aid in the design of HIV prevention products that fit into people's lives, rather than expecting their lives to fit into standard prevention methods
  - Directly impact the development of intervention strategies for future studies of rectal microbicides



# Additional Information

- [www.mtnstophiv.org](http://www.mtnstophiv.org)
- <https://www.facebook.com/microbicidetrialsnetwork/>
- [www.bethegeneration.org](http://www.bethegeneration.org)
- [www.nih.org](http://www.nih.org)



# Continuing Research: HIV Vaccines

A number of public and private organizations, in partnership and individually, are working together to find a vaccine that could end the HIV epidemic.

The HIV Vaccine Trials Network (HVTN), funded by the National Institute of Allergy and Infectious Diseases (NIAID), is an international collaboration that conducts all phases of clinical trials to test HIV vaccines.

The HVTN's mission is to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates with the possible goal of developing a safe, effective vaccine as rapidly as possible for prevention of HIV globally.







# Preventive Vaccines Historically Have Ended Epidemics



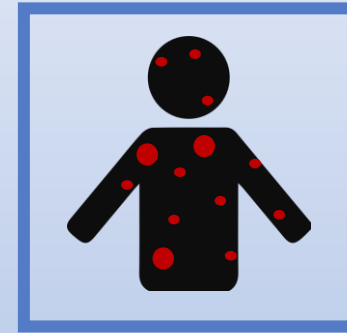
Used for decades around the world, most commonly in children



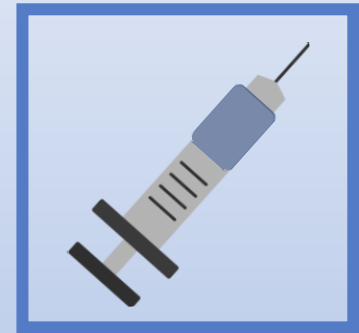
Very safe when manufactured and used properly



Very cost-effective compared to treatment



Eliminated smallpox worldwide, soon polio



2006: 1<sup>st</sup> vaccine for girls and young women against a cancer-causing virus, human papilloma virus (HPV), and 2009-10 approval for boys and young men.



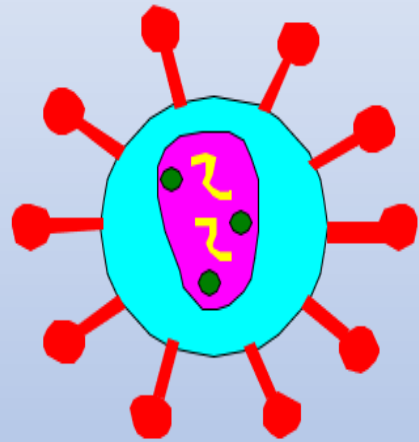
# Vaccine Research in Perspective

VACCINE	DISCOVERY OF VIRUS	VACCINE DEVELOPED FOR HUMAN USE	YEARS TO VACCINE
H. Influenzae-B	1892	1985	93
Herpes (HSV-1)	1919	Not available	>90
Pertussis	1906	1926	20
Polio	1909	1954	47
Yellow Fever	1900	1935	35
Influenza	1933	1945	12
Measles	1911	1957	46
Hepatitis A	1973	1995	22
Hepatitis B	1967	1984	17
HPV	1974	2007	33
HIV	1983	Not available	>30



# How Do Vaccines Work?

By teaching the body to recognize and fight invaders.



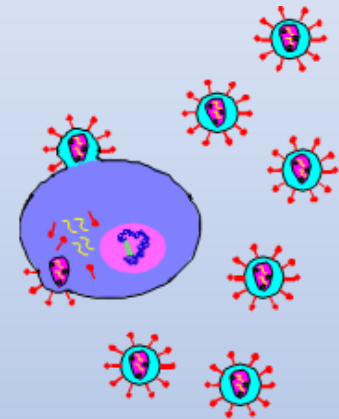
Body  
recognizes  
virus



Body sounds  
alarm



Fighter cells and  
proteins go into  
action



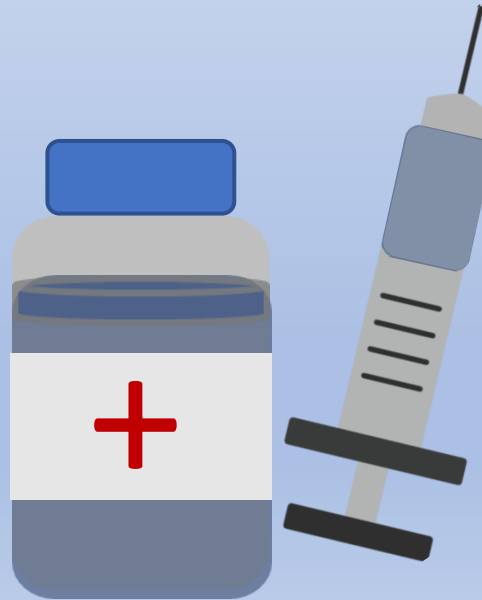
Goal: virus is  
controlled or  
killed



# Does an HIV vaccine already exist?

# NO

Research is being conducted today to find a safe and effective HIV vaccine!

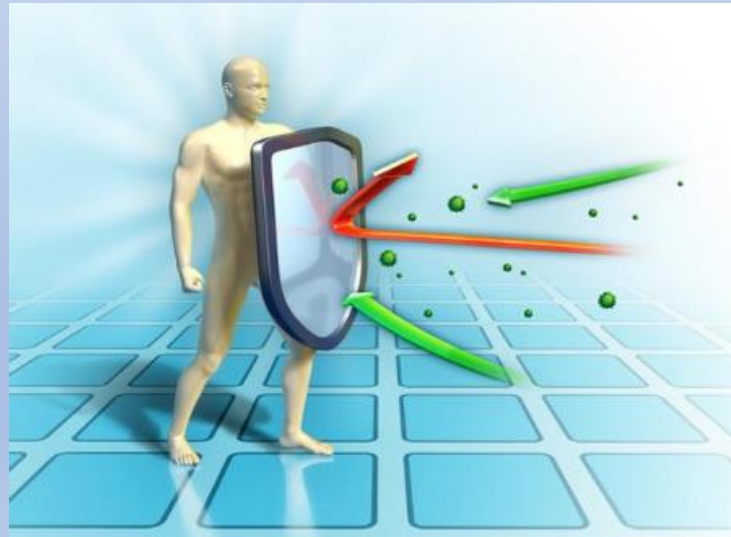




# An HIV Vaccine is More Challenging



- We have to outperform Mother Nature by inducing “unnatural” protective immunity.
- This immunity needs to be a rapid response, and in all the right locations.
- The only people who have a *natural* protective immunity to HIV are those with a genetic mutation to their CCR5 receptor (mostly of Western European ancestry).





# What Might a Preventive HIV Vaccine Do?

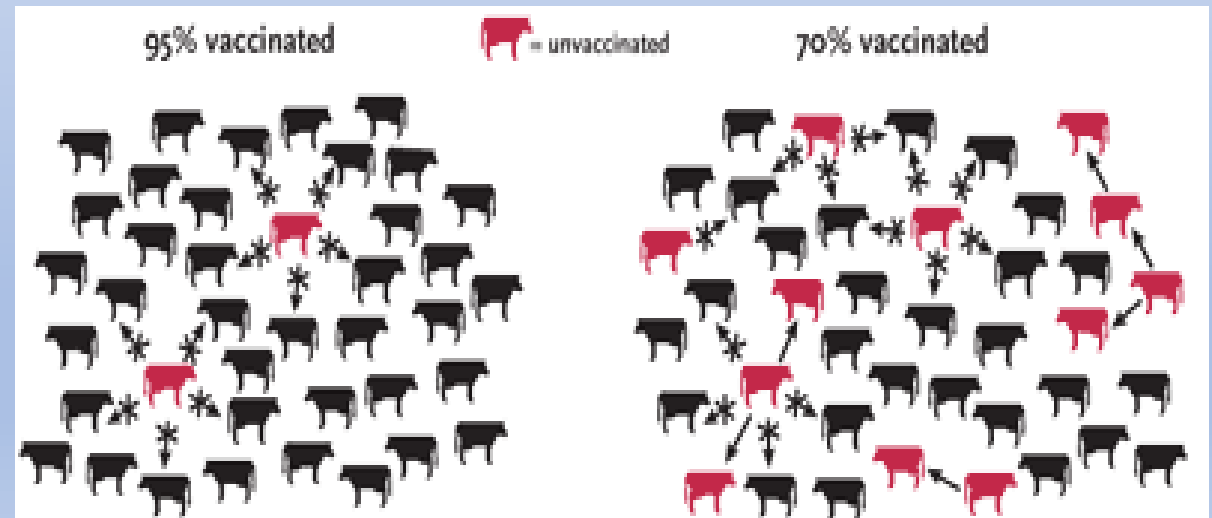
Benefits for the person who gets the vaccine

- ✓ Prevent infection
- ✓ Prevent disease
- ✓ Delay disease progression



Benefits for the entire community

- ✓ Prevent further transmission
- ✓ Create “herd immunity”



# HVTN Phase 1/2A Studies

- Phase I Trials study the safety of a product. The goal is to determine the maximum tolerated dose and/or to determine the dose that elicits the best immune response.
- More than 1,200 women have participated in Phase I Vaccine and Broadly Neutralizing Antibody Trials in the U.S.
- They have paved the way by helping to prove that products are safe and merit further study to see if they will prevent HIV, which is done in Phase 2B and 3 trials.



# HVTN Phase 2B/3 Studies

The HVTN also has a portfolio of global Phase 2B and Phase 3 efficacy studies. These trials aim to determine whether the products can prevent HIV. They also continue to evaluate safety in a larger group of people. Cisgender and transgender women from around the world are part of the journey to find an HIV vaccine. More than 7,600 women have enrolled in these groundbreaking studies.



HVTN 706 / HPX3002





# HVTN Exploratory Studies

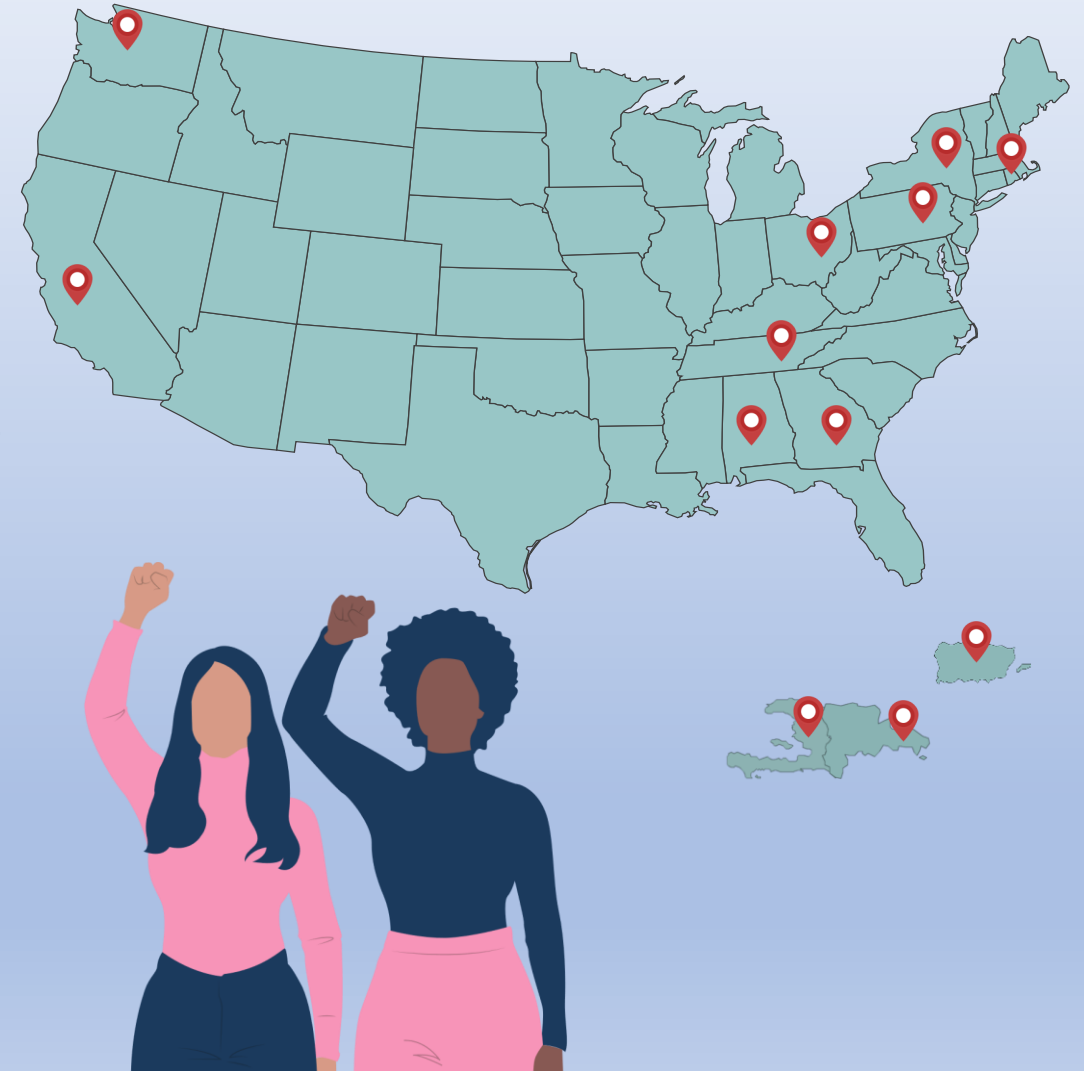
The HVTN conducts several exploratory studies to help us plan future trials that test whether an experimental HIV vaccine works. For example:

## HVTN 906 Objectives:

- To determine the feasibility of recruiting and retaining cisgender women who are highly vulnerable to HIV acquisition.
- To determine if the HIV incidence among cisgender women in the US is at least 1% per year.

## HVTN 907 Objectives:

- To determine the most effective ways to identify cisgender women in the US and Caribbean who are vulnerable to HIV acquisition and maintain contact with them.
- For women we determine to be vulnerable to HIV acquisition, to determine whether they actually contract HIV despite our efforts to prevent it.



# Women Around the Globe

Women around the globe continue to contribute to helping us find new ways to prevent HIV.



*“She can’t help but start a movement that does more than just wear red t-shirts on December 1<sup>st</sup>.”*

*—Mary Bowman,*

*“I Know What HIV Looks Like”*

# Get Involved!

# Join the WHRC!

Contact Brian Minalga:



[bminalga@fredhutch.org](mailto:bminalga@fredhutch.org)



[www.facebook.com/HANCLegacyProject](https://www.facebook.com/HANCLegacyProject)



Recent Topics:

- HIV prevention research for cis and trans women
- Women and HIV cure research
- Pregnancy and lactation in HIV clinical trials
- Mental health, HIV, and gender
- Screening for intimate partner violence in HIV research
- Women of color in research
- Building partnerships with other women-centered organizations

# Advocate for Women in HIV Research

## *Get Informed!*

- AVAC: Global Advocacy for HIV Prevention – [www.avac.org](http://www.avac.org)
- Positive Women's Network – [www.pwn-usa.org](http://www.pwn-usa.org)
- SisterLove, Inc. – [www.sisterlove.org](http://www.sisterlove.org)
- The Well Project – [www.thewellproject.org](http://www.thewellproject.org)
- US Women and PrEP Working Group – [www.prepwatch.org/us-women-prep-working-group](http://www.prepwatch.org/us-women-prep-working-group)

## **AND MORE!**

# Advocate for Women in HIV Research

## Apply for a scholarship to attend a meeting:

- CDC National HIV Prevention Conference – [www.cdc.gov/nhpc](http://www.cdc.gov/nhpc)
- United States Conference on AIDS & Biomedical HIV Prevention Summit – [www.nmac.org](http://www.nmac.org)
- International Workshop on HIV and Women – [www.virology-education.com/event/previous/international-workshop-hiv-women](http://www.virology-education.com/event/previous/international-workshop-hiv-women)

## Engage with the HIV prevention networks and related CABs:

- HIV Prevention Trials Network (HPTN) [www.hptn.org](http://www.hptn.org), @HIVptn
- HIV Vaccine Trials Network (HVTN) [www.hvtn.org](http://www.hvtn.org), @HelpEndHIV
- Microbicide Trials Network (MTN) [www.mtnstophiv.org](http://www.mtnstophiv.org), @HIVMTN, @microbicidetrialnetwork
- Join a Community Advisory Board (CAB) in your area

## Volunteer to participate in a clinical trial on HIV prevention.

# Acknowledgements

The Women's HIV Research Collaborative is grateful to the Division of AIDS at the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, for making this research possible by funding the vital work of the biomedical HIV prevention networks.

A special thanks to the following individuals who developed this training:

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**Clare Collins**, Microbicide Trials Network

**Christopher Hucks-Ortiz**, HIV Prevention Trials Network  
Black Caucus

**Brian Minalga**, Office of HIV/AIDS Network  
Coordination

**Linda Oseso**, HIV Vaccine Trials Network

**Kacie Sadorra**, Office of HIV/AIDS Network  
Coordination

**Stephaun Wallace**, HIV Vaccine Trials Network