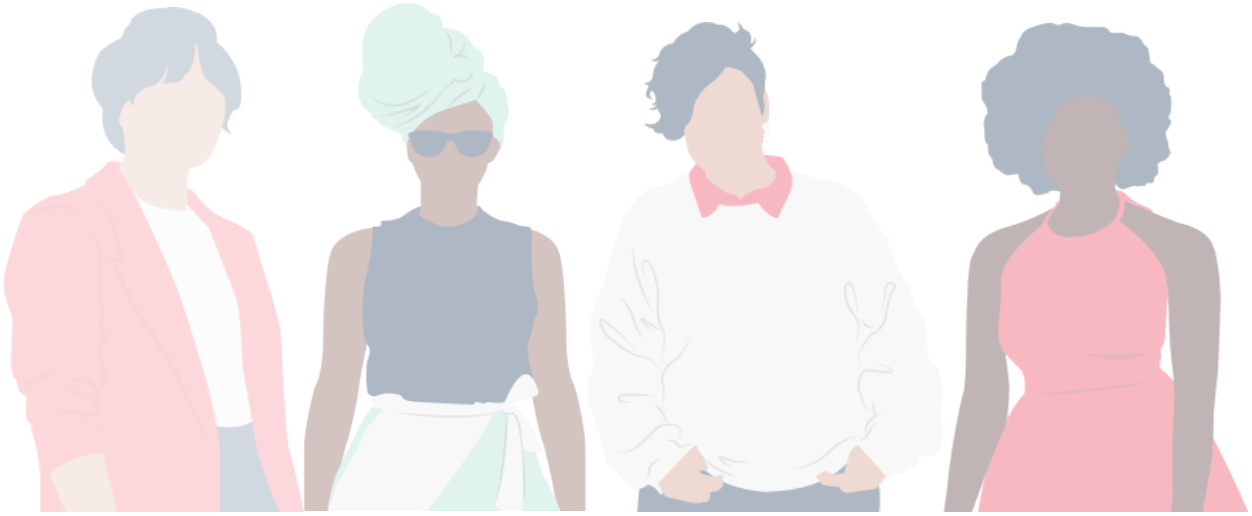
FACILITATOR'S GUIDE

BIOMEDICAL HIV PREVENTION FOR WOMEN



THE WOMEN'S HIV RESEARCH COLLABORATIVE (WHRC)

HANC HIV/AIDS Network Coordination

WHRC

HOW TO USE THIS GUIDE

This facilitator's guide has been developed as a tool for people leading community discussions or workshops using *Biomedical HIV Prevention for Women*, a training on biomedical HIV prevention for cisgender and transgender women developed by the Women's HIV Research Collaborative (WHRC), a working group of the Legacy Project at the Office of HIV/AIDS Network Coordination. The guide has been designed for facilitators as a tool to prepare for presenting the training at a workshop or other venue. The information provided here includes details about the training as well as frequently asked questions that may be helpful for facilitators who are less familiar with biomedical HIV prevention research. If you find yourself unable to answer an audience question that comes up during a training, don't worry. No one is expected to know the answers to every potential question. Just be sure to tell the person who asked the question that you don't know, and that you will get back to them with an answer once you find it. Remember to get the individual's email address so you can follow up. Send an email to bminalga@fredhutch.org with the question, and we will get back to you with the answer as soon as possible.

The guide also includes two forms that are important for obtaining feedback about the training.

Facilitator Utilization Form: to be filled out by the facilitator, scanned, and emailed to the WHRC at bminalga@fredhutch.org after each training.

Attendee Evaluation Form: to be printed off and distributed to each person at the workshop/presentation session where the training is conducted. Please ask the attendees to complete this short form, and please scan and email them to the WHRC at bminalga@fredhutch.org.

WE THANK YOU IN ADVANCE FOR SHARING YOUR EXPERIENCE AND FEEDBACK ON THE TRAINING!

I. *BIOMEDICAL HIV PREVENTION FOR WOMEN*: INTRODUCTION

QUICK FACTS ABOUT THE TRAINING

Biomedical HIV Prevention for Women was developed by the Women's HIV Research Collaborative (WHRC), a group of women who are leaders in women's health and HIV from around the United States. With community and staff representatives from all five National Institute of Health (NIH)-funded HIV/AIDS clinical trials networks, this group provides guidance and leadership in the HIV response focused on the research needs of cisgender and transgender women in the United States. While the WHRC focuses on advocating for HIV research with women living in the US, the organization operates with a comprehensive awareness of the potential for American women to benefit from HIV research that is being conducted internationally. To that end, WHRC's focus is domestic, but its interests are global.

This training was developed to address cisgender and transgender women's contributions to HIV prevention research, and current and future biomedical HIV prevention options for women. It is intended for anyone to be able to present. The primary information is included on each slide, with supplemental information and suggestions on how to present the information in the speaker notes of each slide.

The training was pilot-tested at the United States Conference on AIDS in September 2019.

WHY THIS TRAINING IS IMPORTANT

Since the beginning of the epidemic, cisgender and transgender women have been affected by HIV. Yet there has been little attention paid to the development and distribution of comprehensive informational resources on women-focused biomedical approaches to HIV prevention. To fill this gap, the WHRC developed *Biomedical HIV Prevention for Women* as a training resource for promoting awareness of the urgency for HIV prevention in women. Information presented in the training is based on research conducted by three NIH-funded HIV prevention-focused networks: the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN), and the Microbicide Trials Network (MTN). The training addresses the following topics:

- The need for accurate, timely and understandable information on biomedical HIV prevention relevant to cisgender and transgender women.
- The vital role cisgender and transgender women have played in achieving scientific advances in biomedical HIV prevention research.
- Ongoing research in biomedical HIV prevention relevant to cisgender and transgender women, including PrEP (oral, injectable and implants), vaccines and antibody mediated prevention, and topical products (vaginal and rectal microbicides).
- The need to advocate for continued biomedical HIV prevention research among all women.

HOW TO USE THIS TRAINING

Biomedical HIV Prevention for Women can be presented by any individual or group interested in sharing information and knowledge about cisgender and transgender women and biomedical HIV prevention. The training takes approximately 90 minutes to present, with time included for exercises (ice breakers,

audience response system questions, etc.) and for attendees to ask questions. Presenters may want to include additional time to facilitate in-depth discussion, or, alternatively, may want to shorten the training as needed.

WHAT TRAINING ATTENDEES CAN BE EXPECTED TO LEARN

- The basics of HIV incidence among women who bear a disproportionate burden of HIV: women of color, transgender women, and women from the southern region of the U.S.
- Women's contributions to HIV prevention research – as participants, researchers, and advocates
- The diverse biomedical HIV prevention modalities & research relevant to women – both present and future
- The need for advocacy and continued biomedical HIV research among women

II. *BIOMEDICAL HIV PREVENTION FOR WOMEN*: TRAINING STRUCTURE

The training is divided into five sections in a single power point presentation. Sections include the following:

- Women's Contributions to HIV Prevention Research – addresses the many and varied roles cisgender and transgender women have played in all aspects of HIV research
- The Urgency for HIV Prevention for Women – outlines the dire need for HIV prevention in cisgender and transgender women, including the social and structural issues relevant to HIV vulnerability
- HIV Prevention for Women: The Present – provides information on biomedical options for HIV prevention currently available to women
- HIV Prevention for Women: The Future – addresses areas of ongoing biomedical HIV prevention research, including new approaches under development and testing
- How You Can Get Involved – provides information on joining the WHRC and additional resources for advocating for continued HIV prevention research among women

Each section of the training provides data and information relevant to both cisgender and transgender women. At any point during the training, facilitators should feel free to include time for exercises, Q&A, or a break.

III. FREQUENTLY ASKED QUESTIONS

HIV & BIOMEDICAL HIV PREVENTION

Q: Does Truvada as PrEP work to prevent HIV for women?

A: Yes, Truvada as PrEP is nearly 100% effective at preventing HIV for cisgender and transgender women if taken every day as prescribed. Some research indicates that cisgender men can get away with missing a few doses per week without losing the effectiveness of Truvada as PrEP, while cisgender and transgender women must adhere to the daily regimen more strictly to maintain the maximum HIV prevention effect. Some research also indicates that it might take longer for Truvada as PrEP to become fully protective in the vagina. Don't let this information confuse you, though! The answer is a resounding *yes* that Truvada as PrEP is nearly 100% effective for *everyone*, including cis and trans women, if taken as prescribed in the US.

Q: I hear that "PrEP" and "PEP" can both prevent HIV. What's the difference?

A: *PrEP* stands for Pre-Exposure Prophylaxis. It involves taking a pill every day before being exposed to HIV. *PEP* stands for Post-exposure prophylaxis. This involves taking a series of pills after someone thinks they may have been exposed to HIV (within 72 hours of the potential exposure). Both PrEP and PEP are highly effective at preventing HIV if taken as prescribed.

Q: How do I know if PrEP is right for me?

A: More than 7,000 women are diagnosed with HIV every year in the US. It is estimated that half a million women in the US could benefit from taking Truvada as PrEP, but less than 1% of those 500,000 women are actually taking it. You are the best judge of whether or not you should take PrEP to prevent HIV. Start a conversation with your doctor if you'd like to explore it further.

Q: I heard that people living with HIV can't pass HIV to others through sex if they're "undetectable." What does that mean?

A: Being "undetectable" means that the amount of HIV in someone's body is so low that it can't be measured or "detected" in regular lab tests. Someone who is undetectable cannot pass HIV to others through sex. This is why we say "U equals U," or "undetectable equals untransmittable." People living with HIV can be undetectable by taking their HIV medications as prescribed.

Q: Why are women of color so much more vulnerable to HIV than white women?

A: Systemic racism affects all aspects of the lives of women of color, including their health. It creates disparities in income, wealth, opportunity, housing, mental health, physical health, and access to healthcare, among many other disparities. Women of color live at the intersection of racism and misogyny, and many women of color also live with transgender antagonism, disabilities, and other factors that compound their disenfranchisement in our society that systemically discriminates against people with these factors. This situation creates an environment of privilege and oppression in which women of color face heightened social and structural vulnerability to HIV.

MICROBICIDES RESEARCH

Q: Is there need for the dapivirine vaginal ring when oral PrEP is already available in the U.S.?

A: PrEP is highly effective with consistent use, but taking a daily tablet can be difficult for some people. No one method will suit everyone, nor suit everyone at all times. As with contraception, the more HIV prevention options available to women, the more likely one will and can be used. If approved, the monthly dapivirine ring would be the first biomedical HIV prevention product developed specifically for cisgender women. Importantly, it would represent another option from which they may choose. Women need and deserve a range of safe and effective approaches to protect themselves against HIV.

Q: Is it safe to conduct biomedical HIV prevention research in pregnant and breastfeeding women?

A: Pregnant and breastfeeding women are typically excluded from participating in clinical trials, especially from trials of new medicine. Though women of reproductive age may enroll, they often must use contraception throughout participation, and if they become pregnant, must stop using the study product immediately. Such measures are intended to protect the fetus and baby from potential harm, but they also make certain that a drug's safety cannot be determined in this population. As a result, a drug that receives regulatory approval will be contraindicated (not

recommended) in women during pregnancy and lactation. Drugs are often used during pregnancy and breastfeeding anyway – without knowing if the drug will be safe or effective.

Knowing whether daily PrEP and the monthly dapivirine ring are safe during pregnancy and breastfeeding is vitally important. The MTN is planning two studies, DELIVER (MTN-042), for pregnant women, and B-PROTECTED (MTN-043), for women who are breastfeeding, so that regulatory authorities and national programs have the kind of information they need to consider making these HIV prevention methods available to pregnant and breastfeeding women. These studies were designed in a stepwise, backward fashion, beginning with women late in pregnancy, to assure they are conducted as safely and ethically as possible.

Q. Why does the MTN conduct HIV prevention studies in teens and young girls? Aren't they too young to have to worry about HIV?

A. Around the world, adolescent girls and young women are among those most impacted by HIV due to vulnerabilities created by unequal cultural, social, and economic status. Studies have shown that adherence to HIV prevention can be particularly challenging for younger women. Reducing HIV incidence in this population is a global priority. MTN's REACH (Reversing the Epidemic in Africa with Choices in HIV Prevention) study will help answer key questions about the safety and use of Truvada as daily oral PrEP and the monthly dapivirine ring by adolescent girls and young women in Africa ages 16-21, as well as their preferences for either or both approaches. The MTN has already completed a study that evaluated the dapirivine vaginal ring in 96 teens in the U.S., finding it safe and acceptable to use.

Q: Why are rectal microbicides needed?

A: Anal sex is practiced by people of all genders and sexualities around the world. According to some estimates, the risk of acquiring HIV through anal sex is 20 times greater than vaginal sex because the rectal lining, the mucosa, is thinner and much more fragile than the lining of the vagina. If proven effective, rectal microbicides could expand choices for HIV prevention by providing methods that are short-acting, non-systemic and used around the time of sex.

Q. Why are some rectal microbicides being tested as placebo products?

A: A well-made shirt can look great on a hanger, but it can be an entirely different experience when you're in the fitting room trying it on. It could be the fit or even the fabric. The same is true of HIV prevention. A product may seem great sitting on your medicine cabinet shelf, but if it's not the right fit for your lifestyle, you probably won't use it at all.

DESIRE (Developing and Evaluating Short-acting Innovations for Rectal Use) is a rectal microbicide study that gives participants the opportunity to "try on" potential HIV prevention methods and share their experiences before specific products have been developed. The study is asking cisgender and transgender people to use and compare three different placebo approaches to delivering a rectal microbicide -- a douche, suppository and fast-dissolving insert. By engaging with communities early on, products can be developed that better address their needs and offer choice in HIV prevention.

HIV VACCINE RESEARCH

Q: Why do we need a preventive HIV vaccine?

A: There is no cure to end the HIV epidemic. Although the availability of antiretroviral therapy has dramatically reduced AIDS-related deaths, these treatment regimens can be complex and costly, and some people experience side effects. In addition, HIV can become resistant to the drugs, particularly if individuals do not take them consistently over time. HIV treatment depends on long-term patient adherence; a vaccine could provide protection with minimal action on the patient's part.

A preventive HIV vaccine could help save millions of lives and billions of dollars each year in treatment costs. Safe, effective, and affordable vaccines that can prevent HIV are the best long-term hope for controlling and/or ending the HIV/AIDS epidemic.[1] [2]

1 Ending AIDS — Is an HIV Vaccine Necessary? Anthony S. Fauci, M.D., and Hilary D. Marston, M.D., M.P.H. N Engl J Med 2014; 370:495-498February 6, 2014DOI: 10.1056/NEJMp1313771
2 Interview with Dr. Anthony Fauci on the need for an HIV vaccine and the advances that will help fulfill that need. Supplement to the N Engl J Med 2014; 370:495-498

Q: Can a trial participant get HIV from the vaccine?

A: No. There is NO risk of getting HIV from the preventive vaccines being tested because they do not contain HIV. They contain only lab-made, synthetic copies that look like pieces of HIV. These synthetic copies are not able to cause infection.[3] We do not know if study vaccines will decrease, increase, or not change a participant's chance of contracting HIV if they are exposed to the virus.

Several studies have tested whether HIV vaccines can reduce the risk of getting HIV from another person. In some studies, people who got the vaccine seemed to have the same risk of contracting HIV as people who did not get the vaccine. In one study, people who got the vaccine were at lower risk of contracting HIV than people who did not get the vaccine. In another study, some men who got the vaccine had a higher risk of contracting HIV than men who did not get the vaccine. As soon as researchers noticed this trend, they stopped giving the vaccine. The vaccine in that trial, however, did not cause people to contract HIV; participants in the study who contracted HIV got the virus from another person who had HIV.

3 Cooper, C. J., Metch, B., Dragavon, J., Coombs, R.W., Baden, L. R. (2010). Vaccine-induced HIV seropositivity/reactivity in noninfected HIV vaccine recipients. JAMA, 304.

Q: How will you know if an HIV vaccine works?

A: Studies that test whether an experimental vaccine works are called efficacy studies. Not all vaccine studies are efficacy studies. Early vaccine studies test if the study vaccine is safe to give to people, and whether people are able to take the study vaccine without becoming too uncomfortable. Another important goal of early studies is to test if people's immune systems respond to the study vaccines. Efficacy studies are done after these smaller, early studies show the vaccine is safe and the immune system reacts to it in the desired ways.

When you go through the informed consent process, you will find out if the study you want to join is an early study or an efficacy study. With all studies, it may take several years before the results are known. Efficacy studies can last as long as 5 years.

Regardless of what the study is looking for (whether it is safety or efficacy), all HIV vaccine studies teach us something important and bring us closer to finding a vaccine that works.

Q: How will the health and rights of participants be protected?

A: Protecting the health and respecting the rights of participants are top priorities. Without volunteers, we would never be able to find effective prevention methods or an HIV vaccine.

A first step in protecting the rights of study participants is to give them information about the study before they join. Clinic staff will give people information about the study products and procedures, the possible risks and benefits to participants, and the rights that they have. These include the right to receive any new information about the study that could affect whether they want to stay in it, and the right to leave the study at any time.

During the study, the clinic staff will monitor participants to make sure the study vaccines or bnAbs are not causing any health problems. The clinic staff will also ask participants about any social problems they may experience from being in the study. If a participant has a health or social problem related to being in the study, clinic staff will help them.

There are also several groups involved in protecting participants' rights and well-being:

- A study safety review team and an independent safety monitoring board regularly look at the health information from the study to decide whether it appears safe to continue giving study injections or IV infusions.
- An Institutional Review Board (IRB) or Ethics Committee (EC) reviews and monitors the study plan for each clinic doing the study, including the information that is given to people about the study, study progress, and health problems in participants. The IRB/EC also looks at whether participant rights are being respected.
- The US Food & Drug Administration (FDA) also reviews the study. The FDA enforces US laws about research in humans and the use of study vaccines and bnAbs in research.
- Each study clinic has a Community Advisory Board (CAB). Its members are local people who bring the concerns and interests of the community and study participants to the researchers. CAB members are part of the team that develops each study. They also help develop or review the information that is given to participants.

The NIH-funded HIV/AIDS Clinical Trials Networks have a policy that outlines the rights and responsibilities of study participants. It is given to every person during the informed consent process.

Q: Where can I find more information about HIV vaccines?

A: You can find information about…

- HIV vaccine and bnAb clinical studies: www.clinicaltrials.gov
- The HIV Vaccine Trials Network: www.hvtn.org
- The HIV Prevention Trials Network: www.hptn.org
- Your rights and responsibilities as a study participant: http://www.hvtn.org/en/participants/participants-rights.html
- And if you have additional questions about HIV vaccines that were not answered, please email us at info@hvtn.org or contact the study clinic near you.

IV. SUGGESTED QUESTIONS FOR DISCUSSION

These suggested questions for discussion have no "right" or "wrong" answers. The goal is to spark discussion among training attendees on issues related to women and HIV prevention. Facilitators may choose to use these questions or ask their own depending on the audience and their specific interests.

1. How might you respond if someone tells you cisgender and transgender women don't need additional options for biomedical HIV prevention because they can just take oral PrEP?
2. How can we encourage women to become more active and involved in biomedical HIV prevention as advocates? As researchers? As study participants?
3. Imagine a "perfect" tool for biomedical HIV prevention for women. What qualities would that tool have? How would it be used? What would be important to ensure that it is used?
4. Sexual health is often a neglected area of women's health. How can we improve this situation? How important is sexual health in the context of biomedical HIV prevention for cisgender and transgender women?
5. Would you personally choose to participate in a clinical trial of a tool for biomedical HIV prevention? Why or why not?

V. EVALUATION FORMS

The next two pages contain two different evaluation forms. For every training, please fill out the Facilitator Utilization Form, and ask attendees to fill out the Attendee Evaluation Form. Please send the completed forms by email to WHRC at bminalga@fredhutch.org. This important data will help determine the impact of the training and will aid in future efforts on similar topics.

Thank you in advance for your support!

FACILITATOR UTILIZATION FORM

Date of training

_____

Location of training

_____

Name of event

_____

Type of event

_____

Audience numbers (how many people were there?)

_____

Describe the audience, e.g. demographics, level of HIV knowledge)

_____

_____

_____

_____

_____

_____

Please briefly describe audience feedback, positive or negative, and note any questions you found Interesting or were unable to answer:

_____

_____

_____

_____

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ATTENDEE EVALUATION FORM

Date of training _____

Location of training _____

Name of event _____

Please circle the number that best describes your opinion and experience:

1. The training was informative.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

2. The training was interesting.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

3. The training was the right length (not too long or too short).

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

4. The training increased my awareness of women and biomedical HIV prevention.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

5. The scientific information in the training was easy to understand.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

6. The information in the training seemed trustworthy to me.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

7. I will recommend this training to friends, colleagues.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

8. After taking part in this training, I am interested in getting more involved in women & HIV research.

1 (completely disagree) 2 (somewhat disagree) 3 (neutral) 4 (somewhat agree) 5 (completely agree)

Please share other feedback/opinions regarding the training:

_____

_____

_____

VI. OTHER RESOURCES

- HIV Prevention Trials Network (HPTN) – www.hptn.org, @HIVptn
- HIV Vaccine Trials Network (HVTN) – www.hvtn.org, @HelpEndHIV
- Microbicide Trials Network (MTN) – www.mtnstophiv.org, @HIVMTN
- Office of HIV/AIDS Network Coordination (HANC) – www.hanc.info