



# Biomedical HIV Prevention Research Assessment

The following assessment measures knowledge of Biomedical HIV Prevention modalities. It includes questions on **Vaccines, Pre-Exposure Prophylaxis (PrEP),** and **Microbicides**. This assessment contains key questions and expanded explanations of the answers.

When using this tool as a pre-post assessment, or when linking demographics to responses please have respondents include an ID (e.g. a number, initials, etc) in the boxes labeled "ID."

This assessment was developed by Be the Generation Bridge, a collaborative project between the Legacy Project and FHI360, in conjunction with HPTN, HVTN, and MTN. For more information, contact Legacy Project at 206-667-1194 or visit [www.hanc.info](http://www.hanc.info).

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(Version 4.1, 15-Item)



Clinical studies assessing how well new medicines or medical devices help prevent new HIV infections are called *biomedical HIV prevention research*. Please indicate whether you believe the following statements to be true or false about these clinical studies. If you are unsure, feel free to select “don’t know.”

		True	False	Don't know
1.	Scientists test how well drugs and vaccines prevent HIV by encouraging study volunteers to engage in high-risk behavior.	T	F	DK
2.	Before people volunteer for HIV prevention clinical studies, they are given detailed information on the side effects they might experience.	T	F	DK
3.	Representation from diverse racial and ethnic groups as volunteers in clinical studies is a priority for researchers.	T	F	DK
4.	Scientists have already developed a vaccine that prevents HIV infection.	T	F	DK
5.	Volunteers for preventive HIV vaccine studies can get HIV from the vaccines being tested.	T	F	DK
6.	HIV vaccines train the body to recognize the HIV virus if a person gets infected.	T	F	DK
7.	HIV vaccines contain live HIV virus.	T	F	DK
8.	PrEP is a way to prevent HIV by taking HIV treatment medication after exposure to the virus.	T	F	DK
9.	PrEP has been shown to reduce the risk for HIV infections among gay men.	T	F	DK
10.	PrEP is an HIV prevention method intended for use by HIV-positive people.	T	F	DK
11.	Researchers do not know whether there are health risks from using PrEP for long periods of time.	T	F	DK
12.	Microbicides refer to pills taken orally to prevent HIV infection.	T	F	DK
13.	Microbicides are only being tested among women.	T	F	DK
14.	Most microbicides tested today contain HIV antiretroviral drugs which are used to treat people living with HIV/AIDS.	T	F	DK
15.	There are possible health risks associated with participating in HIV microbicides clinical studies.	T	F	DK

Please complete this form so that data may be analyzed accurately.



Event \_\_\_\_\_ Date \_\_\_\_\_

With which racial or ethnic groups do you identify? (Check all that apply)

- African American/Black
- Alaska Native (Tribal Affiliation(s): \_\_\_\_\_)
- American Indian (Tribal Affiliation(s): \_\_\_\_\_)
- Asian American
- Latino/Latina/Hispanic
- Native Hawaiian or Other Pacific Islander
- White Caucasian
- Other (Specify: \_\_\_\_\_)
- Decline to State

How old are you?

- Under 18 years old
- 18-20 years old
- 21-24 years old
- 25-29 years old
- 30-39 years old
- 40-49 years old
- 50 years old or older

What is the highest level of education you have completed? (Check one)

- No High School Degree or GED
- High School Degree or GED
- Some College, Did Not Receive Degree or Certificate
- AA degree/Vocational Certificate
- 4-Year College Degree (BA/BS)
- Master's Degree
- Doctorate/Medical/Law Degree

What is your gender? (Check all that apply)

- Man/Male
- Woman/Female
- Transgender
- Genderqueer
- Gender Non-Conforming

What is your sexual identity?

- Straight or Heterosexual
- Gay, Lesbian, or Homosexual
- Bisexual
- I do not identify with any sexual identity
- Other (Please specify: \_\_\_\_\_)

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## KEY GUIDE

1. **Scientists test how well drugs and vaccines prevent HIV by encouraging study volunteers to engage in high-risk behavior.** F

All clinical trial volunteers receive extensive counseling about safe behaviors and what they can do to reduce their risk of HIV infection. Volunteers are reminded that we do not know if the medication is effective and they should not assume they are protected by it. Some will receive a placebo. Placebos are inactive substances used in studies to compare the effects of with tested drug. Even when an HIV vaccine is developed, education and other prevention efforts will be needed so that people continue to practice safe behaviors.

2. **Before people volunteer for HIV prevention clinical studies, they are given detailed information on the side effects they might experience.** T

Some studies test new treatments or devices to test their safety. In these cases, volunteers are told to report on any side effects they experience. Participants in these trials are closely watched for all possible side effects. Studies that test whether a treatment or device works to prevent HIV (efficacy studies) are only conducted after determining that the product is safe. Even safe products may carry some side effects (e.g. nausea, headaches, etc.). Volunteers are informed about known side effects that were seen in earlier studies of the treatment or device, and are monitored for any side effects throughout trial participation

3. **Representation from diverse racial and ethnic groups as volunteers in clinical studies is a priority for researchers.** T

Diverse representation among clinical trial volunteers is important to researchers for several reasons. Some biological traits may affect how well a medicine works. Sometimes these traits may differ based on ethnic heritage. Racial and ethnic groups may also differ in the environmental conditions in which they live. Diverse participation will help determine if these environmental conditions influence how well new prevention methods work. Racial and ethnic diversity is important to helping researchers ensure approaches are culturally appropriate, and that diverse racial and ethnic groups are aware of new research being conducted.

4. **Scientists have already developed a vaccine that prevents HIV infection.** F

Currently, there is not a licensed vaccine to prevent HIV. Research is being conducted to find a safe and effective preventive HIV vaccine. In order to find one, researchers will need thousands of volunteers to participate in clinical trials.

5. **Volunteers for preventive HIV vaccine studies can get HIV from the vaccines being tested.** F

The HIV vaccines used in clinical trials cannot cause HIV infection or AIDS, and volunteers are not exposed to the HIV virus through the study. However, volunteers in clinical trials can get HIV from other people through unprotected sex or drug use.

6. **HIV vaccines train the body to recognize the HIV virus if a person gets infected.** T
- Vaccines would teach the body to recognize the virus, sounding an internal “alarm” which calls the fighter cells into action, and ultimately helps prevent or control an infection.
7. **HIV vaccines contain live components of the HIV virus.** F
- HIV vaccines do not contain either live or killed forms of the virus. The vaccines are synthetic (man-made) compounds designed to trigger immune responses that will help your body recognize and fight the HIV virus. There is no real virus or infected material in the vaccine, so there is no way that it can cause HIV/AIDS.
8. **PrEP is a way to prevent HIV by taking HIV treatment medication after exposure to the virus.** F
- Pre-exposure prophylaxis (PrEP) involves prescribing HIV-negative people medicine to prevent rather than treat a disease or condition. People would consistently take a single drug or combination of drugs with the hope that it would lower their risk of infection if they later get exposed to HIV.
9. **PrEP has been shown to reduce the risk for HIV infections among gay men.** T
- The iPrEx PrEP trial for gay men, transgender women, and men who have sex with men was a landmark in HIV prevention research. Results showed use of PrEP was 44% effective in reducing the risk of HIV infection among trial participants.
10. **PrEP is an HIV prevention method intended for use by HIV-positive people.** F
- PrEP is an HIV prevention strategy in which HIV-negative people are prescribed a daily dose of the antiretroviral medication (ARV) Truvada® to reduce risk of HIV infection.
11. **Researchers do not know whether there are health risks from using PrEP for long periods of time.** T
- To date, PrEP studies have been relatively short in duration (e.g. 12-18 months). Medications tested as PrEP are the same used to treat people with HIV. Some of these medications carry health risks (e.g. kidney damage) among HIV-positive people when used over several years. Researchers do not know whether similar or other health risks will occur among HIV-negative people if used over a long time or when used only occasionally.
12. **Microbicides refer to pills taken orally to prevent HIV infection.** F
- Microbicides are being developed to reduce a person’s risk of HIV or other sexually transmitted infections when applied topically inside the vagina or rectum. Microbicides could take the form of gels, lubricants, rings or films. Oral pre-exposure prophylaxis (PrEP), on the other hand, is an HIV prevention approach that involves use of an antiretroviral pill by HIV-negative people.
13. **Microbicides are only being tested among women.** F

Although the majority of microbicides research has focused on products to be used in the vagina, research is also underway on products that men and women could use during anal sex. According to estimates, 5 to 10 percent of the world's population engages in anal sex.

14. **Most microbicides tested today contain HIV antiretroviral drugs which are used to treat people living with HIV/AIDS.** T

Different types of microbicides are being tested in clinical trials, but those that incorporate antiretroviral (ARV) drugs are furthest along in development and testing. The idea behind ARV-based microbicides is that some of the same drugs used to treat HIV may also help prevent infection in people who are HIV-negative.

15. **There are possible health risks associated with participating in HIV microbicide clinical studies.** T

There are risks involved in participating in any clinical trial. Researchers in the HIV prevention field strive to minimize these risks by incorporating a multi-tiered safety review process into clinical studies, and by conducting them under the watchful eye of regulatory and research authorities.

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