



HIV Prevention Research Tools Participant Guide





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INTRODUCTION

Welcome to this workshop about HIV (Human Immunodeficiency Virus) prevention research tools. This important research is designed to find safe and effective methods to prevent HIV and AIDS (Acquired Immunodeficiency Syndrome). These prevention methods include:

- Biomedical (medicines, vaccines, and any equipment and tools to fight disease)
- Non-biomedical (behavioral)

Because this research is conducted by scientists who develop and test prevention approaches using drugs or other products, it is referred to as biomedical HIV prevention research.

Preventing HIV is our best hope for stopping the HIV epidemic.

What Will We Do in This Workshop?

In this workshop, we will provide basic information about HIV prevention research tools in simple terms. We will present important information and you will be able to ask questions. We will also do activities together to help you remember what you hear. The objective of this workshop is to define and describe HIV prevention tools and research and how they are used in HIV prevention research.

This workshop is designed to give you an opportunity to:

- Apply the information you learn in activities and discussions.
- Ask questions about information you do not understand.
- Practice what you learn.

This Participant Guide includes information, facts, and space to write your own notes, and a glossary. The glossary includes many words, abbreviations, and definitions that may not be familiar to you.

Notes



WHAT IS HIV PREVENTION AND THE HIV COMBINATION PREVENTION TOOLBOX?

Objectives

In this session, you will learn about:

- The qualities of high-impact HIV prevention
- The HIV combination prevention toolbox and what it contains

Introduction

HIV prevention includes medicines, medical devices, medical procedures, physical barriers, and behavioral approaches. Research is ongoing to identify new approaches to prevent HIV and to see if there are ways to combine approaches to improve prevention.

Comprehensive HIV prevention includes multiple approaches instead of just one or two approaches. Combination prevention incorporates biomedical, behavioral, and other interventions all designed to reduce HIV transmission.

No one HIV prevention approach will be acceptable to all people. HIV vulnerability also varies for each person and changes over time. Therefore, it is important that people have options for HIV prevention so they can choose the approach that is the best fit for them. The best option for one person may not be the best for others. Research is critical to develop and test new prevention options that offer people more choices. Finding clinical research participants who are willing and able to meet the rigorous clinical trial requirements is also important.

HIV prevention methods also need to be supported by the community at the local and national levels.

Notes



High-Impact Prevention

The U.S. Centers for Disease Control and Prevention (CDC) is using what they call high-impact prevention. High-impact prevention includes:

“...using combinations of scientifically proven, cost-effective, and scalable interventions targeted to the right populations in the right geographic areas.”¹

To make high-impact prevention work, the CDC is working to implement, evaluate, strengthen, and further develop effective HIV prevention efforts nationwide and globally. The CDC is also giving financial and technical support for:²

- Disease surveillance
 - HIV testing, counseling, and referral services
 - Street and community outreach
 - Risk-reduction counseling
 - Prevention case management
 - Prevention and treatment of other sexually transmitted infections (STIs)
 - Public information and education
 - School-based HIV/AIDS education
 - International clinical trials
 - Technology transfer systems
 - Organizational capacity building
-

Notes

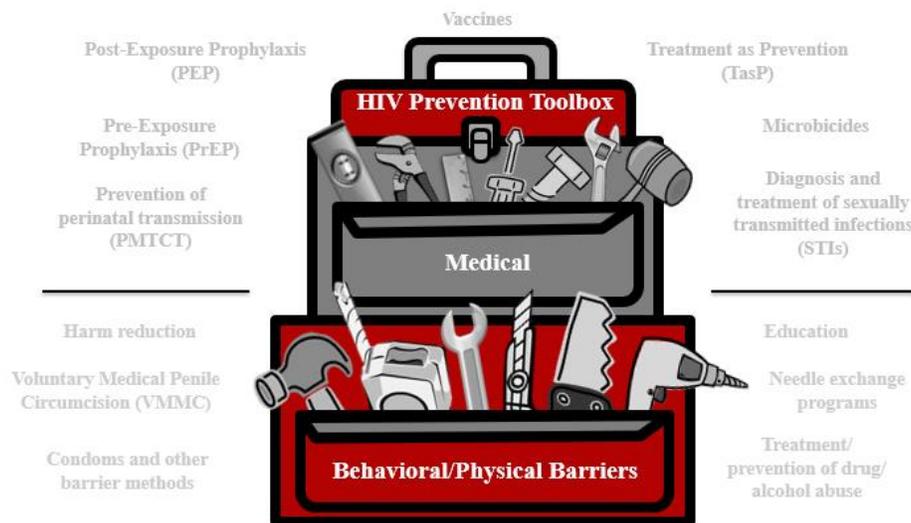


The HIV Combination Prevention Toolbox

The HIV combination prevention toolbox shows this kind of combination of approaches. The toolbox is organized into two sections:

- Tools and approaches that are “medical” in nature:
 - Medicines
 - Medical devices
 - Medical procedures
- Tools and approaches that are “behavioral” in nature are risk reduction counseling and effective behavioral interventions.

We have divided the combinations of interventions that can be used to prevent HIV infection into medical (meaning ones that generally would require a prescription or use of a biological product) and behavioral/physical barriers (meaning ones that are within the direct control of the person and hopefully readily available). It should be emphasized that all of these interventions are generally used in combination and all involve some behavioral activity on the part of the user. Most of the HIV prevention research being conducted by the NIH HIV/AIDS Clinical Trials Networks involves some type of medical intervention in combination with behavioral components.



The HIV combination prevention toolbox shows the importance of both medical and behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention. Some of these tools have both a medical and behavioral component. For example, PrEP is a medical tool because it involves antiretroviral medications, but there is also a behavioral component because people have to follow the prescribed plan and take the medication.



Effective HIV Prevention Programs

Effective HIV prevention programs are comprehensive and science-based. They include:³

- An effective community planning process
- Collection of data about HIV vulnerabilities, incidence, or prevalence
- HIV counseling, testing, and referral, and partner counseling and referral, linkage to medical care, prevention, and intervention services
- Health education and risk reduction activities, including individual-, group-, and community-level interventions
- Accessible services for diagnosis and treatment of other STIs
- Public information and education programs
- Comprehensive school health programs
- Training and quality assurance
- An HIV prevention technical assistance assessment and plan
- Evaluation of major program activities, interventions, and services
- Knowledge about HIV prevention research
- Knowledge about research outcomes in communities most impacted by HIV
- Two-way information:
 - Bringing scientific information to the community
 - Bringing community opinions, beliefs, and concerns to researchers
- Personal responsibility:
 - Know your HIV status.
 - Seek treatment if living with HIV.
 - Use combination treatments as prescribed for your own health and to prevent transmission to others.
 - If not living with HIV, use combination prevention strategies.
 - If not living with HIV, retest regularly. The CDC recommends that people who are vulnerable to HIV be tested every three months.



What Did You Learn?

In this activity, you will brainstorm how you can apply what you learned about HIV prevention by answering a question. With your group:

- Brainstorm the question you are assigned (you only need to brainstorm one of the questions).
- Share your answers with the whole group so they can hear your ideas.

1. How can you use what you have learned about HIV prevention in your daily life?

2. If someone you know wants more information about HIV prevention, what would you tell them?



3. If you were concerned about someone close to you becoming HIV-positive, what would you do?

4. In what ways has this information about HIV prevention impacted YOU?



Glossary

The following terms and abbreviations were used in this section:

AIDS	Acquired Immunodeficiency Syndrome
antibody	A protein molecule that can be found in the blood produced by a type of white blood cell that helps prevent against infection
ARV	Antiretroviral medications used for the treatment of HIV by blocking HIV replication in multiple phases in the reproductive cycle of the virus
CDC	Centers for Disease Control and Prevention
clean syringes (needle exchange programs)	A prevention approach that provides sterile needles to reduce HIV transmission through injecting drugs; needle exchange programs provide a safe way for people to turn in their used syringes for appropriate disposal and receive new sterile syringes in return; some programs also provide information on how to clean syringes using bleach and water
combination HIV prevention	Information, skills building, and access to preventive tools like condoms
condoms and other barrier methods	A behavioral/physical barrier prevention that prevents passage of blood, semen, or vaginal fluids from passing from one person to another
education	A prevention approach that includes knowing your status, encouraging testing, and knowing how the disease is transmitted
harm reduction	A way of dealing with behavior that damages the health of a person (and sometimes the health of their community). Harm reduction can include education about drug use, sex, and HIV.
high-impact prevention	Using combinations of scientifically proven, cost-effective, and scalable interventions targeted to the right populations in the right geographic areas
HIV	Human Immunodeficiency Virus



HIV prevention	Medicines, medical devices, medical procedures, behavioral approaches, and research to reduce HIV transmission
microbicides	Products being developed and tested for use in the vagina or rectum to reduce the likelihood of HIV transmission during vaginal and anal sex
needle exchange programs	A behavioral/physical barrier prevention that provides sterile needles to reduce the likelihood of HIV transmission through injecting drugs
PEP	Post-exposure prophylaxis is a medical prevention approach that includes taking anti-HIV drugs as soon as possible <i>after</i> exposure to HIV
PMTCT	Prevention of Perinatal Transmission is a medical prevention approach to reduce infant exposure to HIV during pregnancy, labor, and breastfeeding
PrEP	Pre-exposure prophylaxis is a medical prevention approach for people who do not have HIV but are vulnerable to contracting it; they take medication <i>before</i> exposure to HIV
sexually transmitted infections (STIs) diagnosis and treatment	A medical prevention approach to reduce STIs that can increase the likelihood of HIV transmission
STIs	Sexually Transmitted Infections
TasP	Treatment as prevention is a medical prevention approach that uses antiretroviral treatment for people living with HIV to decrease their chance of transmitting HIV, ideally to zero change under conditions of viral suppression (undetectable)
treatment/prevention of drug/alcohol abuse	A behavioral prevention approach that focuses on injection drug use, behavior while under the influence, and effects of drug use and addiction on a person's overall health
vaccine	A medical prevention substance that teaches the body's immune system to recognize and protect against a disease caused by an infectious agent or virus, often by stimulating the body to produce antibodies and T-cells against that infection



voluntary
medical penile
circumcision

A surgical procedure to remove the penis's foreskin; reduces the likelihood of the insertive partner acquiring HIV through the penis during vaginal sex by approximately 60%. "Voluntary medical" means the surgery is performed on adults who consent to the procedure for this medical purpose.

Frequently Asked Questions (FAQs)

How effective are
external and internal
condoms in preventing
HIV? ⁴

Condoms, when used consistently and correctly, are highly effective in preventing sexual transmission of HIV. The ability of condoms to prevent transmission has been scientifically established in laboratory clinical trials as well as in epidemiologic clinical trials of persons highly vulnerable to contracting HIV because they were involved in sexual relationships with partners living with HIV. It should be noted that condom use cannot provide absolute protection against HIV. For vaginal and anal sex, use a latex, polyurethane, silicone, or polyisoprene external or internal condom.

What are some
techniques to decrease
my chances of getting
HIV?

Be aware of your body and your partner's body. Cuts, sores, STIs, or bleeding gums increase the likelihood of spreading HIV. Rougher sex can cause bleeding or small tears that give HIV an easier way to enter the body. Use any of the biomedical or behavioral HIV prevention methods described in this training.

How can I get tested for
HIV?

There are several ways to test for HIV. Some take about a week to get the results. Other tests can give results in less than 20 minutes. Some require a blood draw from the arm or just a finger stick. Other tests use an oral swab. Some HIV tests look for antibodies to the virus rather than the virus itself. Antibodies almost always show up 1-3 months after transmission. See a doctor to find out which test is right for you. You can get HIV tests from your doctor, public health clinics and testing sites, and even over the counter from drug stores offering at-home tests.



Additional Resources

For more information about HIV prevention, go to:

www.bethegeneration.org

<http://www.thebody.com/>

<http://www.cdc.gov/hiv/>



WHAT ARE HIV PREVENTION TOOLS AND HOW ARE THEY USED IN HIV PREVENTION RESEARCH?

Objectives

In this session, you will learn about:

- Prevention research and HIV prevention research successes
- PrEP, TasP, and integrated strategies in HIV prevention research
- Microbicides in HIV prevention research
- Vaccines in HIV prevention research

Introduction

Research is looking at a number of ways to prevent the spread of HIV. It includes:

- Promoting awareness, understanding, and dialogue between researchers and members of impacted communities and advocates
- Encouraging support for ongoing HIV prevention research
- Developing and evaluating new HIV prevention tools and approaches
- Improving HIV treatment regimens

Three Important Medical Prevention Tools

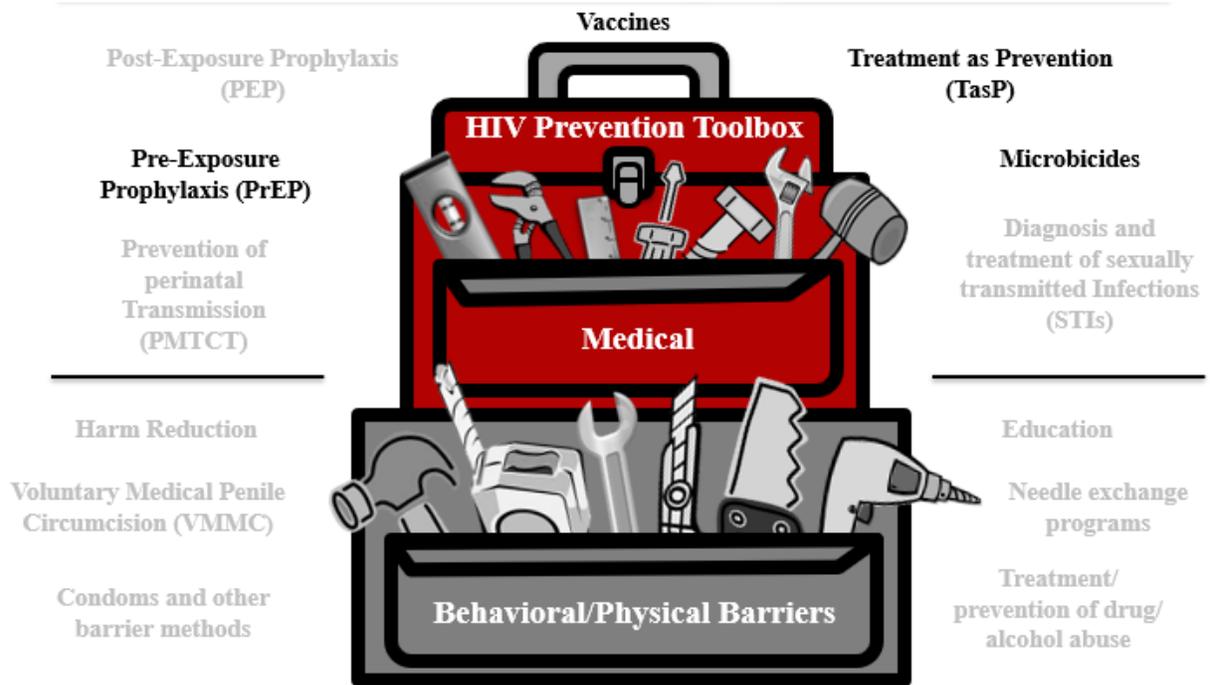
One of our goals today is to increase awareness of and knowledge about HIV prevention research. During this section of the course, we will focus on three important areas of biomedical prevention:

- **Pre-exposure prophylaxis (PrEP), TasP, & Integrated Strategies:** PrEP is an HIV prevention approach for HIV negative individuals to stay HIV-negative by taking anti-HIV medicines. There are two FDA approved medications for PrEP. One is called Truvada® and one that was approved in 2019 is Descovy®. These are pills that are approved for daily use in the US. TasP is the use of anti-HIV medicines among people with HIV to reduce the likelihood of transmission to others. “Integrated strategies” refers to other ways of administering PrEP that are currently under research, like injections.
- **Microbicides:** Microbicides are products being developed and tested in different forms like vaginal rings, rectal inserts, suppositories, douches, and gels that release drugs in the body over time. They are designed for people of all genders to be applied in the vagina or rectum to help prevent HIV during sex.



- Vaccines: An HIV vaccine would teach the body to recognize the virus and activate protective cells to prevent infection or control disease. There is no HIV vaccine right now. But some clinical trials have given hope that an effective vaccine could be developed, and newer trials are ongoing to find out.

We call these medical prevention tools “modalities.”





HIV Prevention Research Successes

A variety of HIV prevention research successes are creating a great deal of hope that we will soon be able to prevent the spread of HIV. Even when an approach or tool being tested does not work, researchers learn a great deal and can redirect their future efforts accordingly.

Prevention of perinatal transmission (PMTCT)	<ul style="list-style-type: none"> • PMTCT began as clinical research. • It is now considered regular care in the U.S. and much of the world. 	<ul style="list-style-type: none"> • Before 1994, women with HIV had at least a 25% chance of passing HIV to their babies. • Now, in the U.S., there is less than a 2% chance of HIV transmission when mothers with HIV and their babies receive HIV treatment.
The Thai HIV Vaccine Trial (RV144)	<ul style="list-style-type: none"> • RV144 was a clinical study from 2003-2009 testing a combination of two HIV vaccines (the “prime” and the “boost”). • The goal of the prime/boost approach is to stimulate different parts of the body’s immune system and increase the body’s overall immune response to HIV. 	<ul style="list-style-type: none"> • RV144 is the first clinical trial to show evidence of moderate protection and the possibility for an effective vaccine. • It provided a lot of new information about how antibodies form in response to the vaccine. • The prime/boost vaccine combination lowered the rate of HIV infection by about 31%.
CAPRISA 004 Microbicide	<ul style="list-style-type: none"> • CAPRISA 004 was a clinical trial from 2007-2010 testing the effectiveness of a microbicide gel product containing 1% tenofovir (an antiretroviral medication) in cisgender women used before and after vaginal sex. 	<ul style="list-style-type: none"> • CAPRISA 004 is the first clinical trial to show evidence of moderate protection and the possibility of an effective vaginal microbicide. • There were 39% fewer HIV transmissions among women who used the CAPRISA 004 microbicide.
iPrEx & Partners PrEP	<ul style="list-style-type: none"> • iPrEx was a clinical trial from 2007-2009 to test if taking a daily tablet containing two antiretroviral drugs could prevent HIV transmission through anal sex among cis men who have sex with men and transgender women who have sex with men. 	<ul style="list-style-type: none"> • Partners PrEP was a clinical trial from 2008-2010 for heterosexual couples where one partner had HIV and the other did not. • The medicine proved to be safe and well-tolerated.



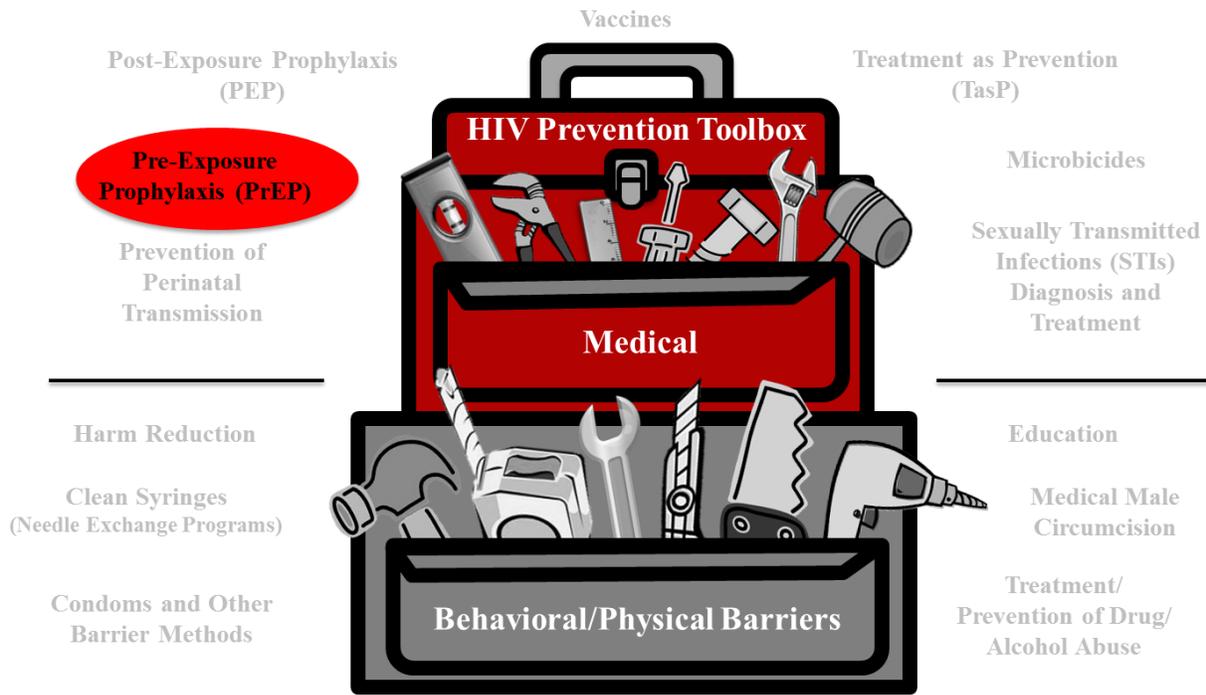
	<ul style="list-style-type: none">• These two trials helped pave the way for what we know today: oral PrEP is nearly 100% effective when taken as prescribed	<ul style="list-style-type: none">• The FDA approved this PrEP tablet for daily use in May 2012.
HPTN 052 (Treatment as Prevention)	<ul style="list-style-type: none">• HPTN 052 was a clinical trial from 2005-2010 for couples (mostly heterosexual) where one partner had HIV and the other did not.• It involved the person with HIV taking a combination of three or four drugs from a group of 11 HIV ARVs.	<ul style="list-style-type: none">• There was a 96% reduction in HIV transmission overall.• There was a 100% reduction in HIV transmission under conditions of viral suppression (undetectable).• HPTN 052 was the first randomized clinical trial to demonstrate that early antiretroviral therapy can improve health outcomes for people with HIV <i>and</i> prevent transmission of HIV to HIV-negative sex partners.⁵
ASPIRE, The Ring Study, & HOPE	<ul style="list-style-type: none">• ASPIRE and The Ring Study were two clinical trials (2012-2016) testing a monthly vaginal ring containing the ARV dapivirine for HIV prevention.• The two studies combined enrolled over 4,500 cisgender women in Africa and showed that the ring was safe and reduced HIV rates by 1/3.	<ul style="list-style-type: none">• Women who used the ring most had the greatest benefit: up to 75% reduction in HIV transmission.• HOPE was a trial in which former ASPIRE participants could use the ring open-label (there was no placebo). Results from 1,456 women showed high adherence and suggested a 39% reduction in HIV risk.⁶• The ring is under regulatory review.
HPTN 083 & HPTN 084 (Injectable PrEP)	<ul style="list-style-type: none">• HPTN 083 was a study from 2016-2020 testing an injection of the drug <i>cabotegravir</i> for HIV prevention among cisgender men and transgender women who have sex with men.• The injections were given in the buttock muscle once every other month.• The injections proved to be safe, well-tolerated, and equally as effective as oral PrEP.⁷	<ul style="list-style-type: none">• 083 was one of the first studies to set, meet, and exceed enrollment goals for Black MSM and transgender women.• HPTN 084 is testing the same injectable PrEP drug among cisgender women in Africa. Results are forthcoming.



Pre-Exposure Prophylaxis (PrEP)

Introduction

The PrEP prevention approach is focused on people who do not have HIV, but may be vulnerable to contracting HIV through sex and/or injection drug use (IDU). With PrEP, people who do not have HIV receive a prescription to take a medication. The medication may lower their likelihood of contracting HIV if they are exposed to it through sex or IDU. This approach is only effective if the medication is taken exactly as prescribed on a consistent, daily basis.⁸



The HIV combination prevention toolbox shows the importance of both medical and behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention. It is recommended that people who are prescribed PrEP also receive counseling as part of a comprehensive HIV prevention package and consistently use condoms.



PEP vs. PrEP

PEP (post-exposure prophylaxis) is the use of antiretroviral drugs *after* a possible HIV exposure to reduce the chance of HIV becoming established in your body. PEP must be started as soon as possible after HIV exposure to be effective. A combination of 2-3 antiretroviral medications is usually given for about 28 days to reduce the chance of HIV establishing itself in the body. These medicines keep HIV from making copies of itself and becoming permanently established. PEP is not always effective; it does not guarantee that someone exposed to HIV will not become HIV-positive.

PEP is in contrast to PrEP where medications are used *prior* to HIV exposure. People who take PrEP as prescribed greatly lower their likelihood of contracting HIV.

For more information, see: <http://www.fredhutch.org/en/research/divisions/vaccine-infectious-disease-division/research/immunology-and-vaccine-development/be-the-generation/prep-tasp.html>.

Oral PrEP Progress

One major milestone in HIV prevention was the first approval of a daily oral medication TDF/FTC in the United States. This happened for the first time in 2012, marketed under the name Truvada®. Truvada® is a combination of two antiretroviral drugs:

- Tenofovir disoproxil fumarate (also called TDF, or tenofovir)
- Emtricitabine (also called FTC)

Truvada® milestones are:

- January 2011: Interim guidance issued by the U.S. Centers for Disease Control and Prevention (CDC) for men who have sex with men and transgender women who are vulnerable to contracting HIV
- July 2012:
 - Approved by the U.S. Food and Drug Administration (FDA) for daily use
 - World Health Organization issued guidance on PrEP use
- August 2012: Interim guidance issued by the CDC for heterosexual men and women vulnerable to HIV, such as those in relationships where one person has HIV and the other does not
- June 2013: CDC adds injection drug use to the interim guidance on PrEP use based on the results of the Bangkok Tenofovir Study⁹
- October 2019: Descovy® was approved as another option for PrEP in the US. More PrEP options will continue to become available in years to come.



HIV Prevention Using Oral PrEP

We will focus on Truvada® because it is approved for use by anyone who is vulnerable to HIV acquisition. Truvada® (also known as TDF/FTC) is FDA-approved for daily use for HIV prevention (for HIV treatment, Truvada® is approved only in combination with other ARVs). Truvada® must be taken as prescribed to be effective as PrEP. Like any HIV prevention modality (including condoms), PrEP is not 100% effective in preventing HIV. And, because it does not prevent the transmission of other sexually transmitted infections such as syphilis, gonorrhea, and chlamydia, it is recommended that people who are prescribed PrEP continue to use condoms.

While the availability of Truvada® as a prescription for use as PrEP is a major breakthrough, it still has limitations (particularly around access), and there are specific guidelines for use.¹⁰

How Truvada® as PrEP works	Who should use Truvada® for HIV prevention?	Requirements for USE
<ul style="list-style-type: none"> • Truvada® is a pill consisting of two antiretroviral medications (ARVs) that protects people who do not have HIV if they are exposed to the virus • ARVs block HIV replication in multiple places in the reproductive cycle of the virus.¹¹ 	<p><u>Anyone</u> who is vulnerable to contracting HIV, including:</p> <ul style="list-style-type: none"> • Men who have sex with men • Transgender women who have sex with men • Couples where one partner has HIV and the other does not • People who inject drugs • <u>Anyone</u> who may benefit! 	<ul style="list-style-type: none"> • Be HIV-negative proven by testing prior to PrEP use • Test for HIV at least every three months while taking Truvada® • Take Truvada® as prescribed to achieve the maximum HIV prevention benefit



What Did You Learn?

In this activity, you will brainstorm how you can apply what you learned about PrEP by answering a question. With your group:

- Brainstorm the question you are assigned (you only need to brainstorm one of the questions).
- Share your answers with the whole group so they can hear your ideas.

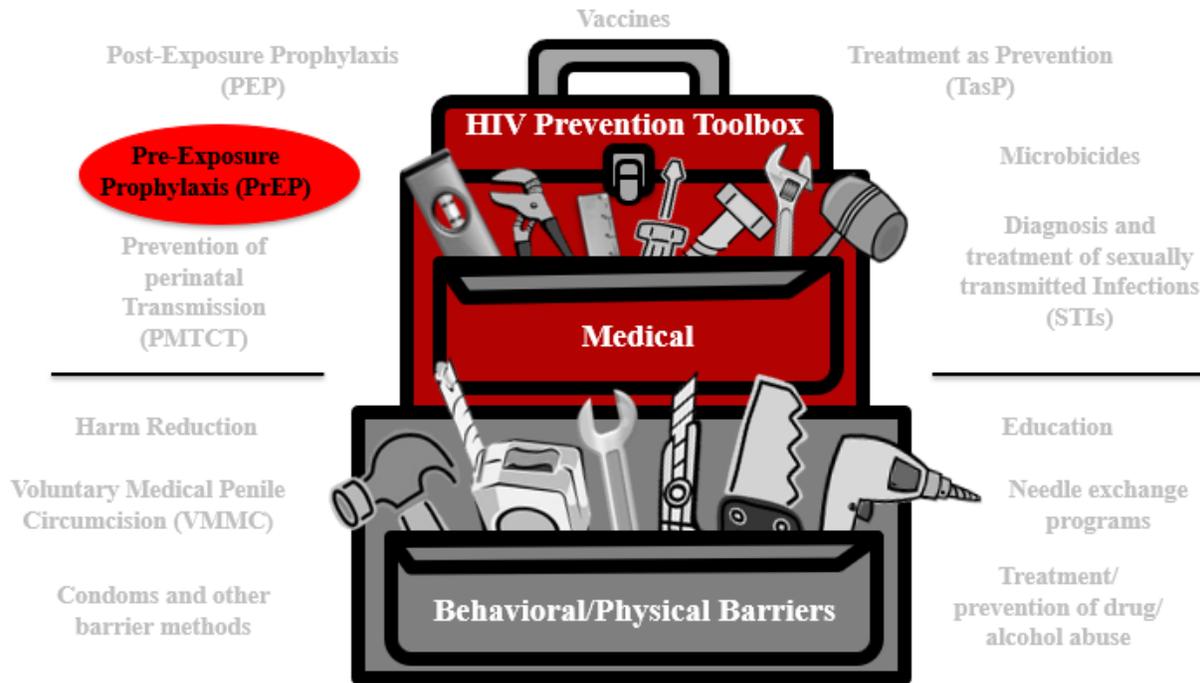
1. What thoughts, questions and concerns came to your mind about PrEP as you heard/read information about this HIV prevention modality?

2. If you were asked to speak to an audience about PrEP, what would be the three most important messages you would want to convey?



PrEP Summary

PrEP is a medical prevention approach for people who do not have HIV but are vulnerable to contracting HIV. It involves taking a specific medication on a daily basis to reduce the likelihood of contracting HIV through sex or injection drug use. Researchers are studying new PrEP approaches like injectables and implants that would theoretically last much longer than daily-dose pills.



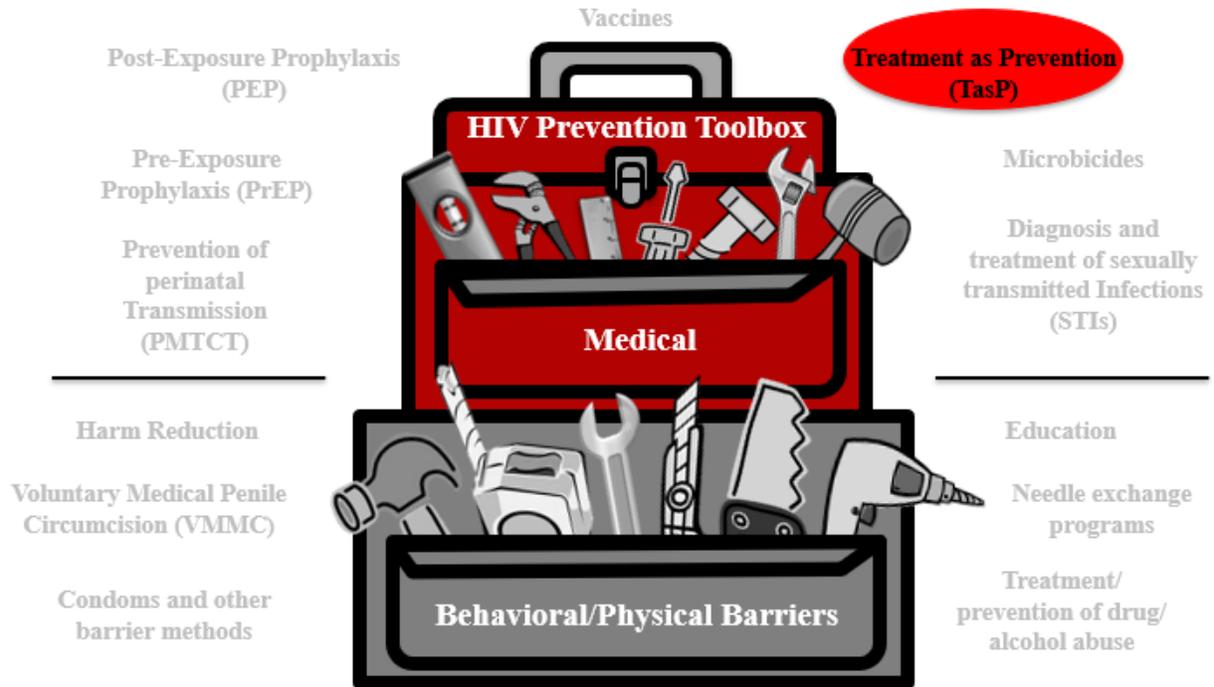
The HIV combination prevention toolbox reinforces the role of PrEP combined with other behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention.



Treatment as Prevention (TasP)

Introduction

We just talked about PrEP. Now let’s talk about another highly effective HIV prevention method: Treatment as Prevention, or “TasP.” While PrEP is only to be used by people who do not have HIV, TasP is an approach for people living with HIV to reduce the likelihood of passing HIV to others.



With TasP, people with HIV take medication. The medication controls the HIV in their bodies and keeps them healthy. The medication also lowers their likelihood of transmitting HIV to others through sex.

As discussed previously in the history of HIV, we have had effective combination anti-retroviral therapies for treating HIV since 1996. Today, many people with HIV take only one pill a day to successfully treat HIV and live healthy lives with life expectancy nearly equal to that of people who do not have HIV. There are now many different options for drug regimens prescribed to treat HIV, and the main purpose of anti-retroviral therapy is to control the amount of HIV in the body to keep the immune systems of people with HIV healthy, protecting against opportunistic infections and the development of AIDS. Additionally, we have learned through clinical research that ART is also highly effective in preventing the transmission of HIV to others. By successfully treating HIV in people living with the virus, we are also preventing new transmissions. This is why we call it Treatment as Prevention (TasP).



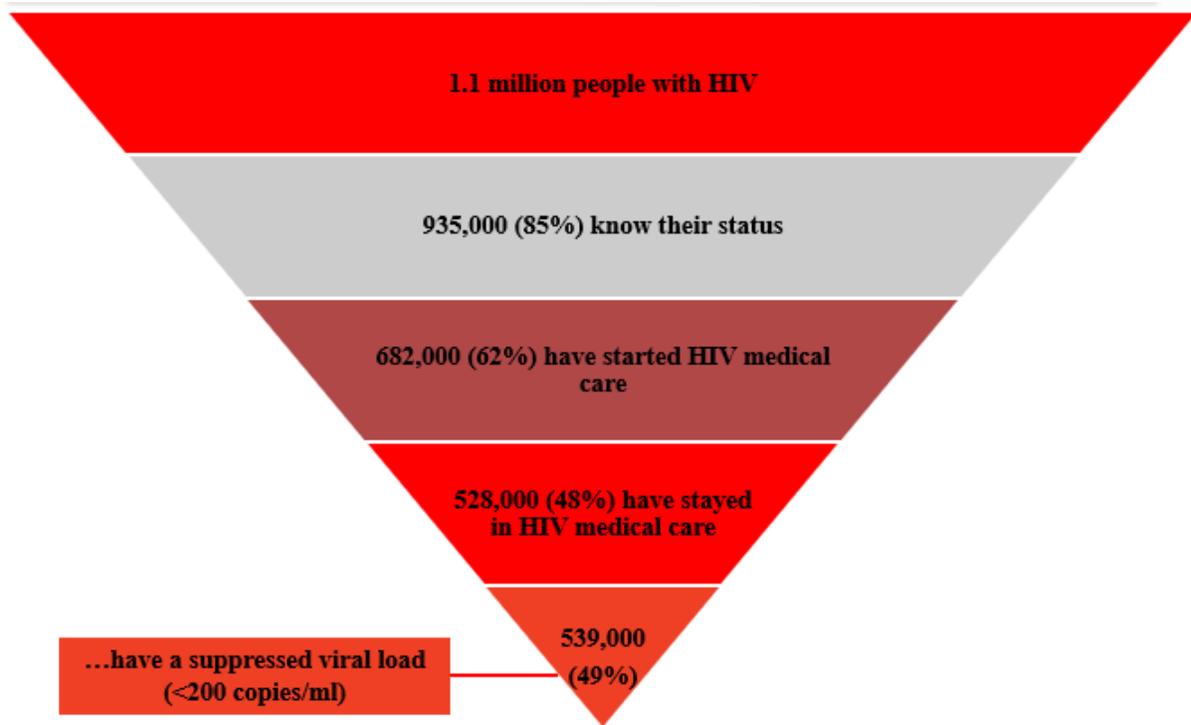
TasP Progress

- In 2011, the HPTN 052 study became the first randomized clinical trial to show that early ART improves health outcomes for people with HIV
 - It also showed that ART helps prevent transmission to HIV-negative sex partners. In the study, ART reduced HIV transmission by 96% overall. Stunningly, it also reduced HIV transmission by 100% when study participants taking ART had achieved viral suppression, meaning the ART was working such that the amount of HIV in the body had durably dropped below 200 copies per mm³. This is also known as “undetectable.”
 - This study paved the way for a massive global campaign called U=U, which means “undetectable equals untransmittable.” In other words, people with HIV who have an undetectable viral load cannot transmit HIV to their sex partners. The U=U concept applies only to sexual transmission of HIV; having an undetectable viral load is not 100% protective against HIV transmission by other means (e.g. injection drug use or breastfeeding). U=U was started by an organization called Prevention Access Campaign.
- In 2016, the PARTNER study showed zero HIV transmissions under conditions of viral suppression after at least 58,000 distinct acts of penetrative sex without condoms. This study reinforced what we learned from HPTN 052 about TasP and U=U.
- In 2016 and beyond, many organizations in the US and around the world began signing onto the U=U message: the US National Institutes of Health, US Centers for Disease Control and Prevention, state and local health departments, and many more.
- In 2017 and beyond, more studies with mixed HIV status couples continued to confirm that undetectable really does equal untransmittable. The earlier studies had enrolled mostly heterosexual couples, but the U=U message was shown to be true for cisgender gay male couples too in studies like Opposites Attract and PARTNER 2. Combined, these studies showed zero transmissions under conditions of viral suppression after nearly 100,000 acts of condomless anal sex without PrEP.





The Treatment Cascade in the US



The research findings about TasP have helped us to better understand the importance of the treatment cascade. About half of the people living with HIV in the US have a suppressed viral load, which means they cannot transmit HIV to others as long as their viral load stays suppressed. The better we can help more people know their status, link them to HIV care, start ART, and achieve viral suppression, not only will we help people with HIV stay healthy, but we will also drastically reduce rates of new HIV transmissions.

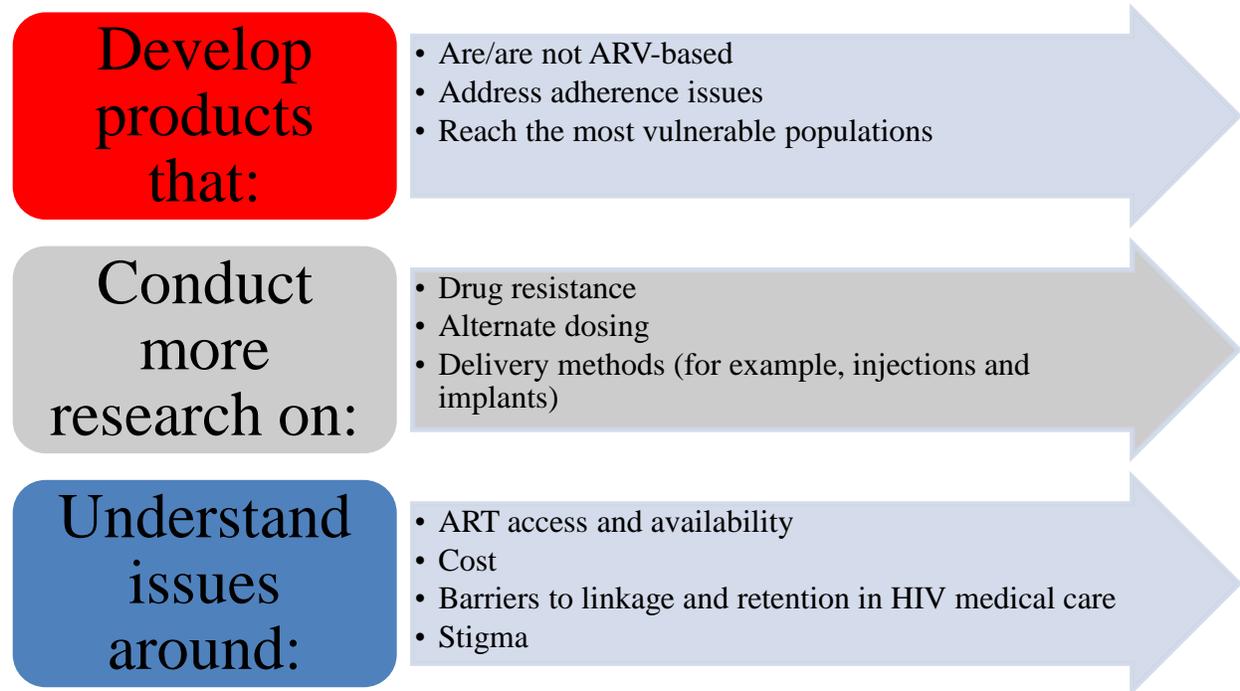
Adding PrEP into the landscape for people who do not have HIV but are vulnerable to getting it has the potential to turn around the trajectory of the epidemic. Using multiple strategies in combination has the best chance of ending the epidemic.

TasP is most effective if the medication is taken exactly as prescribed.



Continuing Research: Treatment as Prevention

Research into treatment for people with HIV continues, including research looking specifically at treatment as prevention. We know that only about half of people with HIV in the US have reached viral suppression, so additional strategies are needed to improve treatment. If every person with HIV in the US could reach viral suppression, we could effectively end the sexual transmission of HIV. But that is not the world we currently live in; we need a multitude of products, dosing, delivery methods, and so forth because no single product will be right for everyone.





What Did You Learn?

In this activity, you will brainstorm how you can apply what you learned about TasP by answering a question. With your group:

- Brainstorm the question you are assigned (you only need to brainstorm one of the questions).
- Share your answers with the whole group so they can hear your ideas.

1. What thoughts, questions and concerns came to your mind about TasP as you heard/read information about this HIV prevention modality?

2. If you were asked to speak to an audience about TasP, what would be the three most important messages you would want to convey?



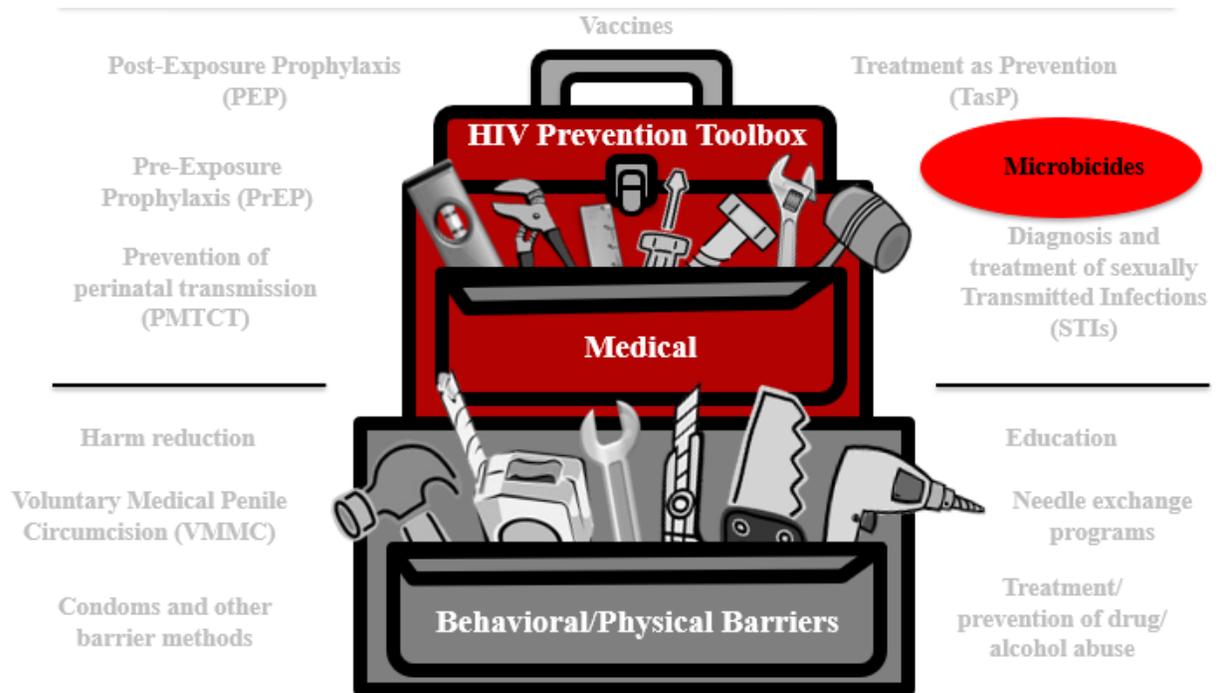
Microbicides

Introduction

Microbicides are products applied inside the vagina or rectum to protect against HIV through sex. They are different from other PrEP products because they only deliver anti-HIV drugs to the sites of potential HIV transmission with very little drug absorbed into the body, whereas pills, injectables, and implants deliver drugs systemically (throughout the entire body). Microbicides could fulfill the need for a non-systemic and/or short-acting method for HIV prevention that could be used around the time of sex. Microbicides being studied include:

- Films, gels, douches, fast-dissolving inserts, and suppositories
- Vaginal rings, which are furthest along in development and may be licensed soon

Most microbicides being tested today contain antiretroviral (ARV) drugs. ARVs block HIV replication in multiple places in the reproductive cycle of the virus. These drugs have been shown to protect people who do not have HIV if they are exposed to the virus by disrupting HIV's life cycle, thus preventing HIV from taking hold in the body.



The HIV combination prevention toolbox shows the importance of both medical and behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention.



Why Are Microbicides Important?

Microbicides are not yet available for use outside clinical trials. The microbicides under study are used vaginally and/or rectally to protect the user from HIV transmission during sex.

- Vaginal microbicides are designed to prevent HIV acquisition through the vagina:¹³
 - Cisgender women represent about 20 percent of new HIV cases in the U.S.
 - Cis women are more likely than cis men to contract HIV through heterosexual sex.
- Rectal microbicides are designed to prevent HIV among people of all genders during anal sex:¹⁴
 - An estimated 5-10% of the world’s population engages in anal sex.¹⁵
 - Because the lining of the wall of the rectum is different from the lining of the vagina, rectal-specific microbicides and formulations are being tested in clinical trials in addition to products for vaginal use.
 - The likelihood of contracting HIV during condomless/PrEPless anal sex is 10 to 20 times greater than condomless/PrEPless vaginal sex. Because the rectal lining is only one-cell thick, the virus can more easily reach cells.¹⁶

“If proven effective...microbicides could protect against HIV in people who are unable or reluctant to use condoms [or oral PrEP]. Unlike condoms, they could provide an alternative way to reduce risk that is not controlled by one’s sexual partner and possibly enhance sexual pleasure, helping to motivate consistent use.”¹⁷

Microbicides and women

For transgender and cisgender women around the world, some prevention tools are not practical. Because of gender-based violence and other factors it can be difficult for women to:

- Insist that partners use condoms
- Limit their or their partner’s HIV exposure
- Get themselves or their partners treatment for sexually transmitted infections (STIs)

There are many complex societal, economic, and cultural reasons why women specifically need multiple forms of HIV prevention tools.¹⁸

Microbicides and men

In the U.S., men who have sex with men:

- Make up about 70% of all new HIV cases
- Represent more than 50% of the people currently living with HIV
- Globally, are 19 times more likely to have HIV than the general population¹⁹

Consistent condom use doesn’t work for many men. Microbicides may offer an alternative and can be formulated like lubricants and douches, which many men already use for anal sex.



Challenges with Microbicides



HIV prevention in general has challenges, and microbicides are no exception:

- Dependence on human behavior requiring regular application
- Cultural and regional preferences
- Rectal microbicides research is in the early phase of clinical development due in part to scientific challenges related to the biology of the rectum and cultural reluctance to address anal sex. Several clinical trials evaluating the rectal safety of microbicides have been completed to date.²⁰



Microbicides Continuing Research

Next steps in vaginal and rectal microbicides research are to:²¹

- Develop products that:
 - Are/are not ARV based
 - Are contraceptive, non-contraceptive, and broad spectrum against several sexually transmitted diseases
 - Designed for vaginal and/or rectal use
- Conduct more research on drug resistance, alternate dosing, and delivery methods (for example, the vaginal ring), and effects on pregnancy and breastfeeding
- Understand issues around access and availability, cost, regular HIV testing requirements, and need for prescriptions for ARV-based microbicides

A number of public and private organizations, in partnership and individually, are working together to find microbicides 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.

Notes



What Did You Learn?

In this activity, you will brainstorm how you can apply what you learned about microbicides by answering a question. With your group:

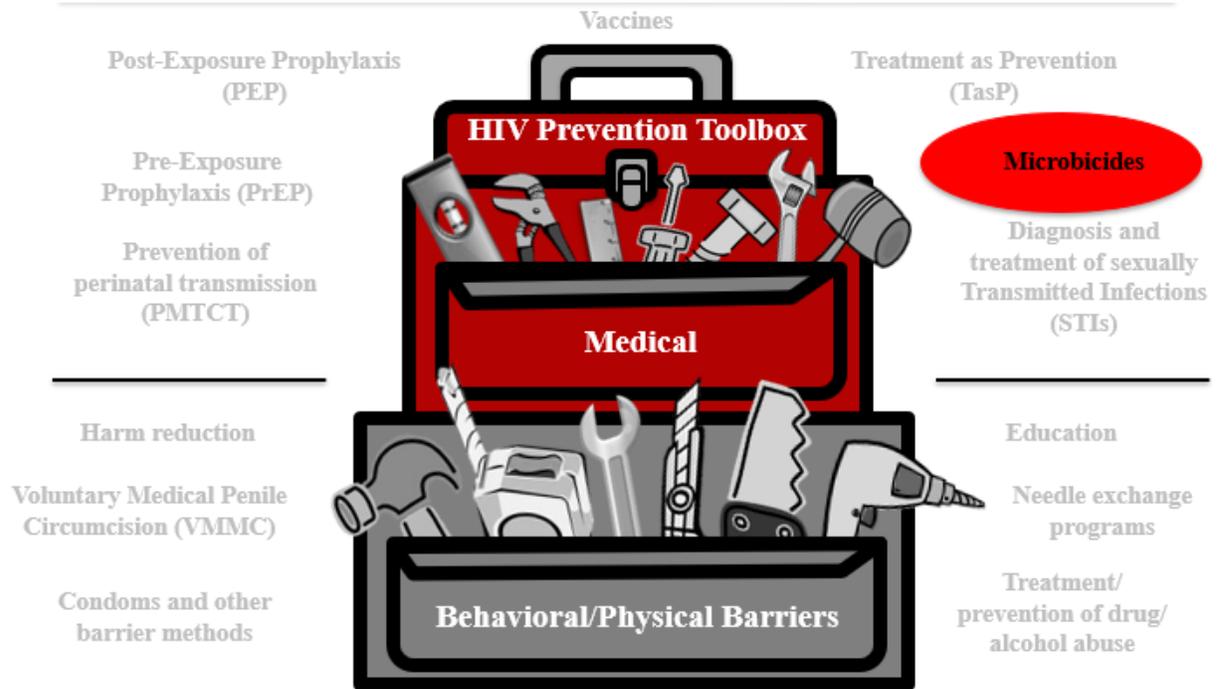
- Brainstorm the question you are assigned (you only need to brainstorm one of the questions).
 - Share your answers with the whole group so they can hear your ideas.
1. What thoughts, questions and concerns came to your mind about microbicides as you heard/read information about this HIV prevention modality?

2. If you were asked to speak to an audience about microbicides what would be the three most important messages, you would want to convey?



Microbicides Summary

Microbicides are products being developed and tested for use in the vagina or rectum to reduce the likelihood of HIV transmission during vaginal and anal sex.



The HIV combination prevention toolbox reinforces the role of microbicides combined with other behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention.

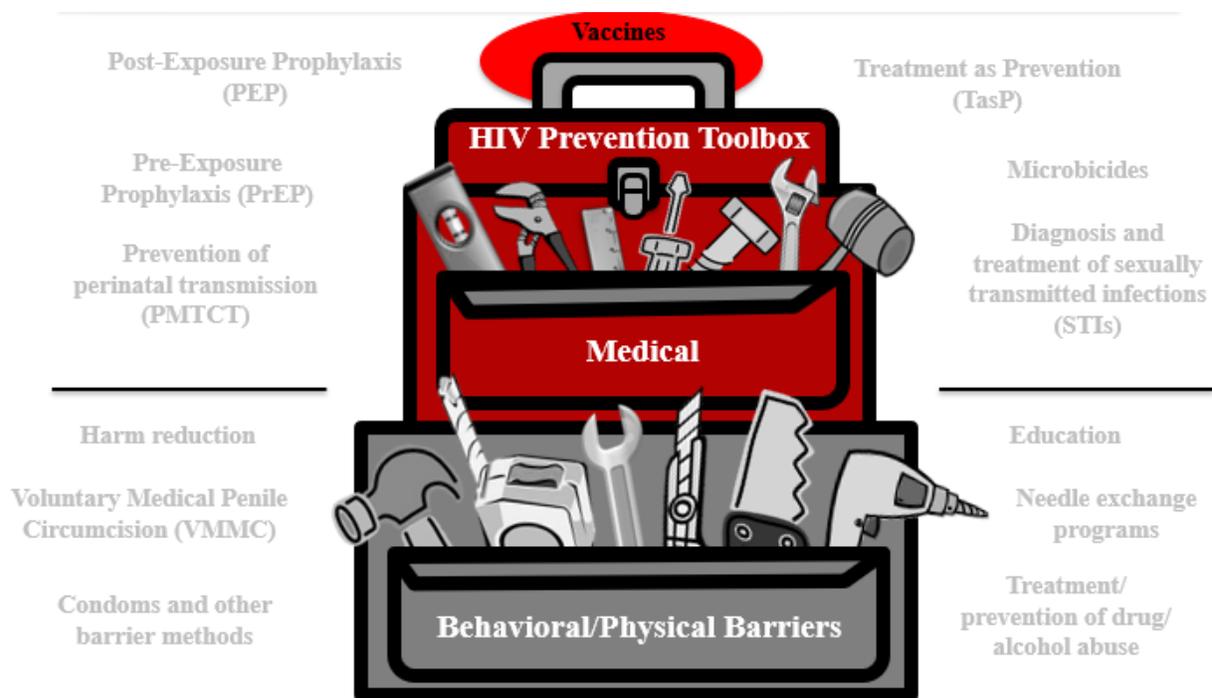


Vaccines

Introduction

A vaccine is a substance that teaches the body's immune system to recognize and protect against a disease caused by an infectious agent or virus, often by stimulating the body to produce antibodies and T-cells against that infection.

A safe and effective preventive vaccine is believed to be the best way to control the HIV/AIDS epidemic in the long term. There is a lot of important research going on to find a safe and effective HIV vaccine. However, there is currently no licensed vaccine against HIV or AIDS.

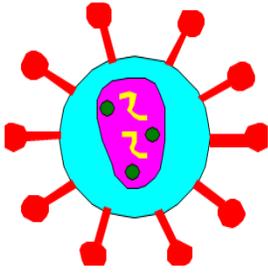
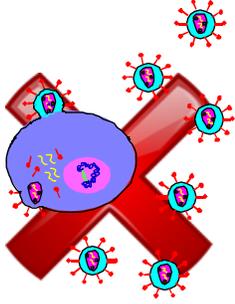


The HIV combination prevention toolbox shows the importance of both medical and behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention.



How Would a Vaccine Work?

HIV vaccines would work to:

Teach the body to recognize HIV	Tell the body to sound an alarm	Send fighter cells to go into action	Result: HIV is controlled or killed
			

Vaccines do not contain live or killed forms of a virus.

Why Do We Need a Vaccine?

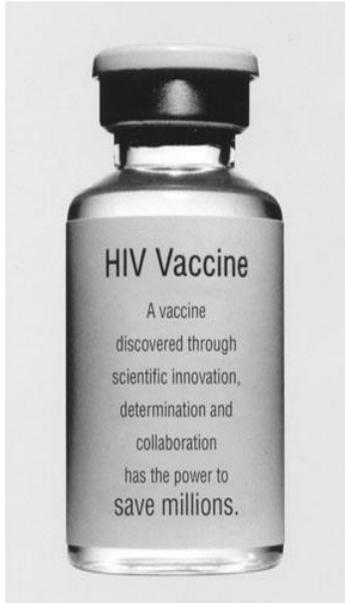
An HIV vaccine, even one that is only partially effective, is thought to be our best chance at long-term control of the HIV/AIDS epidemic. The HIV prevention tools we have now are limited in their ability to end the epidemic. For example,

- ART can be complex, costly, and have side effects
- HIV can develop resistance to ARVs
- ARVs and PrEP depend on long-term patient adherence; a vaccine could provide protection with minimal action from the patient
- A preventive HIV vaccine could help save millions of lives and billions of dollars each year in treatment costs



HIV Vaccines—the Future

Vaccines are important to control the spread of HIV. Preventive vaccines are tested with people who do not have HIV. HIV vaccines may one day be able to prevent or delay AIDS in people with HIV, too.



How an HIV vaccine might work	HIV vaccine possible benefits
<ul style="list-style-type: none">• Prevent HIV in most people• Prevent disease progression after people contract HIV	<ul style="list-style-type: none">• Even if a vaccine only protects some people, it would have a major impact on controlling the HIV/AIDS epidemic• A partially effective vaccine could decrease the number of people who contract HIV• There would be fewer people with HIV who would be able to pass the virus on to others



Important Numbers

Using current projections, the development of a safe and effective HIV vaccine remains a critical but elusive goal.

-25%

- An HIV vaccine with just 50% efficacy administered to 30% of the population of developing countries between 2015 and 2030 could prevent 25% of the new HIV cases that would otherwise occur.

+66%

- Without an HIV vaccine, the number of new HIV cases per year could increase from 6 million to 10 million by 2030.

Challenges in Developing an HIV Vaccine

Most vaccines we use today (polio, rubella, mumps) took more than 25 years to develop. Some challenges in developing HIV vaccines are:

- HIV can “hide” from the immune system that protects the body.
- HIV attacks the same immune cells that the body uses to defend itself against infections.
- There are many different varieties of HIV.
- HIV changes rapidly, even in a single person.
- There is no good model for testing HIV vaccines in animals, because HIV impacts people in ways that are different from the animal versions.
- The human immune system is not designed to clear HIV, so we are not sure what the immune response is that would be needed for protection; we have to do better than “mother nature.”



Vaccines Continuing Research

Some of the goals of ongoing HIV vaccine research include:

- Adapt the RV144 regimen for better protection
 - Adapt RV144 regimen: HVTN 702 was a clinical trial based on the Thai Trial (RV 144). The goal was to have greater and more sustained protection than that which was found in the Thai Trial. Researchers adapted this experimental vaccine to the HIV subtype that predominates in southern Africa, where it was tested. The research team had hoped for better results, but unfortunately, it was announced in January 2020 that the experimental vaccine being studied in HVTN 702 did not work to prevent HIV. While these results are disappointing, we can still learn from them. We now know that this particular vaccine design did not work in this particular context.
- We learned that the vaccine was highly safe and well-tolerated. The researchers will continue to analyze the data to learn more about what is needed for an HIV vaccine to work.
- Study “mosaic” vaccine candidates to cover a variety of global HIV strains
 - HVTN 705 is a clinical trial studying a “mosaic” vaccine to see if it will be safe and effective for protection against a variety of HIV strains, or “clades.” It is also being tested in southern Africa.
 - HVTN 706, known as “Mosaico,” is another study testing a “mosaic” vaccine. It is taking place in the US, Latin America, and Europe.
- Inform future prevention strategies via antibody-mediated prevention studies (AMP)
 - About 20% of people with HIV can develop broadly-neutralizing antibodies after several years living with the virus.²² Broadly neutralizing antibodies, or “bNAbs,” are produced by the immune system to attack or “neutralize” active HIV in the body. bNAbs cannot reach latent HIV, also known as the “reservoir” of HIV in a person’s body. The idea with AMP is to take some of these antibodies and manufacture more of them in labs so they can be given via IV infusion to HIV-negative people and observe how they do or do not protect against HIV taking hold in people who receive them. These studies may provide a proof-of-concept for future vaccine and other prevention strategies, showing how vaccines or other strategies might work if we can induce a preventive antibody response. Some bNAbs are also being studied for treatment to see if they can be used alongside ARVs to achieve viral suppression in people living with HIV.

A number of public and private organizations, in partnership and individually, are working together to find a vaccine that could end the 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 as rapidly as possible for prevention of HIV globally.

HVTN clinical research sites are located at leading research institutions throughout the world.



What Did You Learn?

In this activity, you will brainstorm how you can apply what you learned about vaccines by answering a question. With your group:

- Brainstorm the question you are assigned (you only need to brainstorm one of the questions).
- Share your answers with the whole group so they can hear your ideas.

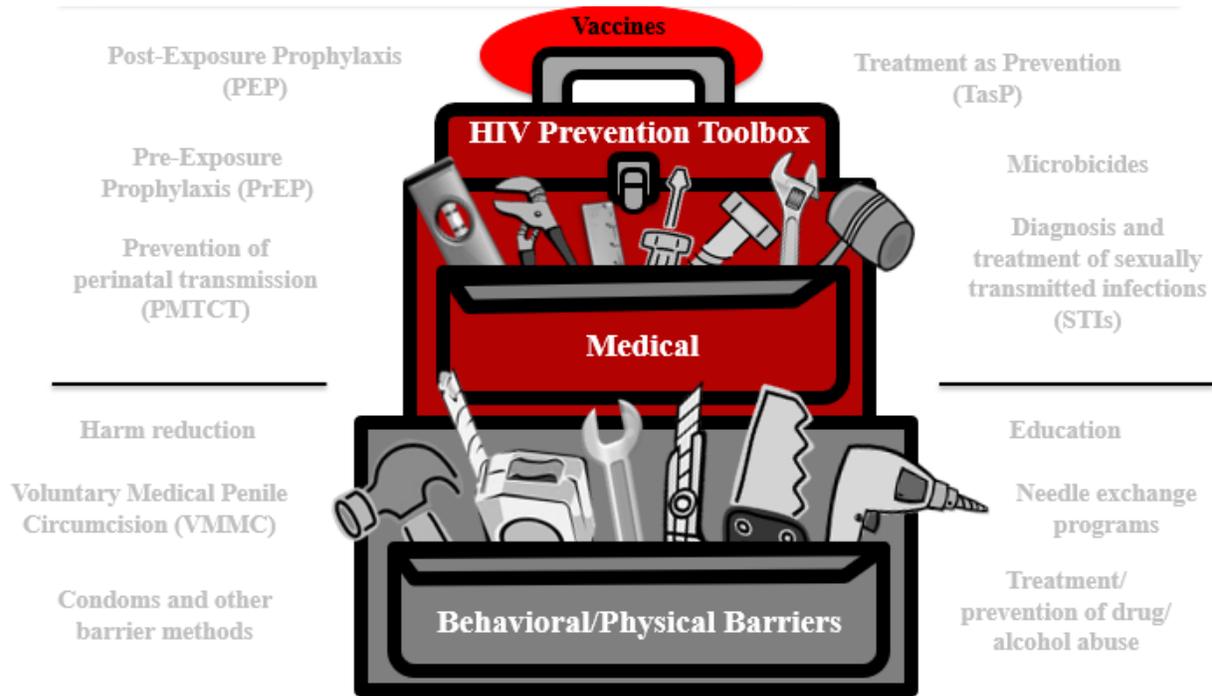
1. What thoughts, questions and concerns came to your mind about vaccines as you heard/read information about this HIV prevention modality?

2. If you were asked to speak to an audience about vaccines what would be the three most important messages, you would want to convey?



Vaccines Summary

A vaccine uses a substance that teaches the body's immune system to recognize and protect against a disease caused by an infectious agent or virus, often by stimulating the body to produce antibodies and T-cells against that infection.



The HIV combination prevention toolbox reinforces the role of vaccines combined with other behavioral/physical tools. Combining multiple tools may provide the best method for HIV prevention.



Prevention Tools Activity

In this activity, you will think about all of the different HIV prevention tools you have learned about.

You will receive a card with one of the tools from the HIV combination prevention toolbox.

1. What is your prevention tool?

2. Is your prevention tool (circle one):

Medical?

Behavioral/Physical Barrier?

Both?

If you selected both, why do you think so?

3. Now look at the list of words on the next page. Circle all words that you think are related to your prevention tool.

4. Cross off all words that you think are not related to the prevention tool.

5. Put a question mark next to all words that you are not sure about.



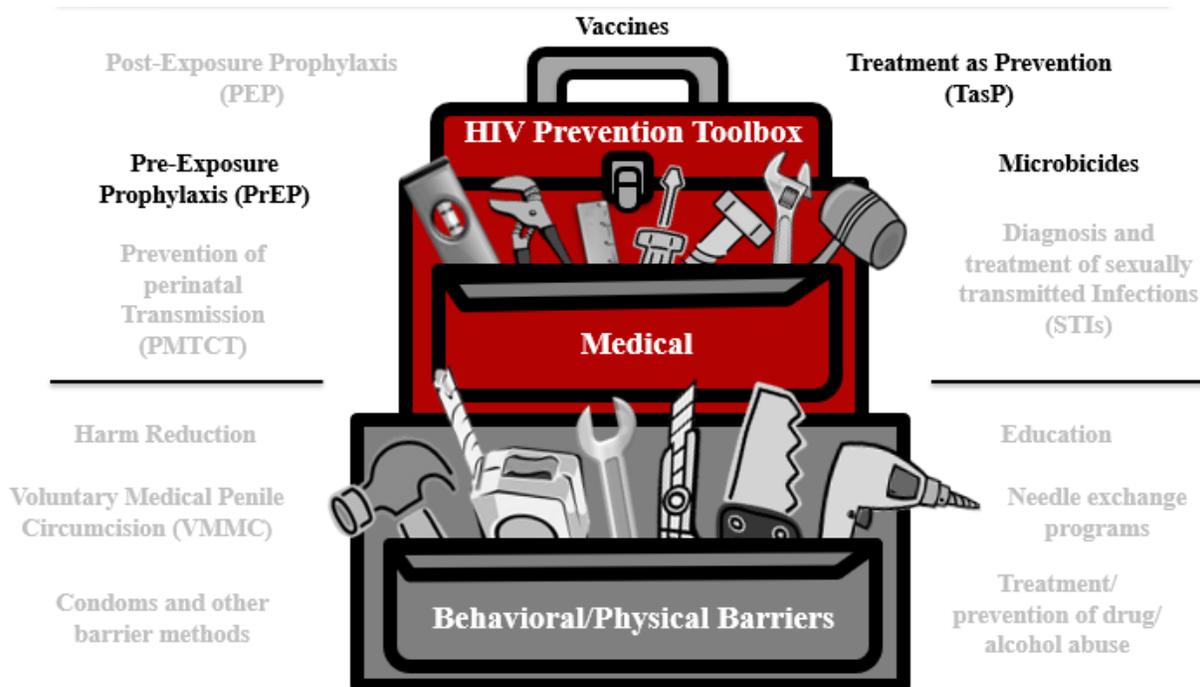
harm reduction	creams	sobriety
emtricitabine (FTC)	condom distribution	vaccines
raising awareness	antiretroviral medication (ARV)	microbicides
Treatment as Prevention (TasP)	research	TDF/FTC
education	drug abuse	reusable
HIV testing and counseling	mobile resources and tools	Prevention Training Centers
vaginal ring	gels	vaginal film
drug treatment programs	suppository	voluntary medical penile circumcision
latex	external condom	dialogue with your partners
internal condom	barrier methods	Truvada®
silicone	clean syringes	needle exchange programs
Sexually Transmitted Infection (STI) regular screening	sexually transmitted infections (STIs)	reducing stigma and discrimination
methadone as a substitute for heroin	Prevention of perinatal transmission (PMTCT)	Comprehensive Risk Counseling and Services (CRCS)
Tenofovir	post-exposure prophylaxis (PEP)	pre-exposure prophylaxis (PrEP)



Summary

HIV prevention research is important to find safe and effective approaches to prevent the spread of HIV. These approaches can include:

- Promoting awareness, understanding, and dialogue
- Supporting research
- Developing new prevention technologies



In this session, you learned about:

- Prevention research and HIV prevention research successes
- The role of pre-exposure prophylaxis (PrEP) in HIV prevention research
- The role of treatment as prevention (TasP) in HIV prevention research
- The role of microbicides in HIV prevention research
- The role of vaccines in HIV prevention research



Glossary

The following terms and abbreviations were used in this section:

antibody	A protein molecule that can be found in the blood, produced by a type of white blood cell; helps prevent against infections
ARV	Antiretroviral medications used for the treatment of HIV by blocking HIV replication in multiple places in the reproductive cycle of the virus
biomedical	Medicines, approaches, and tools to fight disease that include biological and medical characteristics
CDC	Centers for Disease Control and Prevention
clinical research	Research conducted in people that helps develop solutions to improve health all over the world; the formal evaluation of new interventions for both safety and efficacy that follows strict guidelines
clinical trial	Research that tests how safe and how well an intervention works in a group of people; it tests for new methods of screening, prevention, diagnosis, or treatment
epidemic	A disease affecting many people at the same time and spreading from person to person in a locality for a period of time
FDA	U.S. Food and Drug Administration
FTC	Emtricitabine (an antiretroviral drug)
Film	A dissolvable strip containing a drug
HIV	Human Immunodeficiency Virus
HIV-1	HIV-1 is the most common strain of the virus located throughout the world
HIV combination prevention toolbox	Medicines, medical devices, medical procedures, behavioral approaches, physical barriers, and other approaches to prevent HIV



HPTN	HIV Prevention Trials Network
HVTN	HIV Vaccine Trials Network
immune system	The body's system that fights diseases
implementation research	Research conducted to understand what happens after an intervention is shown to work in a clinical trial to confirm the effectiveness of the intervention in a large group of people in a real-world setting
IDU	Injection drug use
intervention	Any measure whose purpose is to improve health or alter the course of disease
microbicides	Products being developed and tested for use in the vagina or rectum to reduce the likelihood of HIV transmission during vaginal and anal sex
modalities	Medical prevention tools, such as pills, microbicides, and vaccines
MTN	Microbicide Trials Network
PEP	Post-exposure prophylaxis is a medical prevention approach that includes taking anti-HIV drugs as soon as possible after exposure to HIV
PrEP	Pre-exposure prophylaxis is a biomedical prevention approach for people who do not have HIV; they take medication before exposure to reduce their likelihood of acquiring HIV
PrEP-ception	Sero-discordant (mixed HIV status) couples using PrEP to reduce the likelihood of HIV transmission during conception; PrEP has been used by some couples who would like to have a child when one of the partners has HIV and the other does not (sero-discordant couples)
PMTCT	Prevention of Perinatal Transmission (formerly "Mother-to-Child Transmission," a term which many found stigmatizing, so "perinatal" and "vertical" were adopted)



“prime/boost” vaccine	A vaccine product that works with another vaccine product to stimulate different parts of the body’s immune system and increase the body's overall immune response to HIV
research	The gathering of data, information, and facts for the advancement of knowledge
retrovirus	A virus that converts its genes into DNA (a molecule that contains the hereditary material of the body) and then replicates and infects a host cell
STIs	Sexually Transmitted Infections
TasP	Treatment as Prevention is a medical prevention approach that uses antiretroviral treatment for people with HIV to decrease their chance of transmitting HIV, ideally to zero chance under conditions of viral suppression (undetectable)
T-cells	cytotoxic T-lymphocytes (cells that fight infection)
TDF	Tenofovir disoproxil fumarate; also called Viread (marketed name); an antiretroviral medication
TDF/FTC	A combination of two antiretroviral drugs: tenofovir (TDF) and emtricitabine or (FTC); also known as Truvada®; used for treatment of HIV as well as for HIV PrEP
vaccine	A medical prevention substance that teaches the body’s immune system to recognize and protect against a disease caused by an infectious agent or virus, often by stimulating the body to produce antibodies and T-cells against that infection



Frequently Asked Questions (FAQs)

How does PrEP prevent the spread of HIV?

Antiretrovirals (ARVs), if taken properly, block some of the steps that HIV uses to make copies of itself in a person's body. The best results for PrEP occur when a person who does not have HIV takes ARVs exactly as prescribed prior to being exposed to HIV.²³

Do people who are not vulnerable to HIV need an HIV vaccine?

Anyone can acquire HIV. A person may not be likely to contract HIV right now, but life situations can change. We all need a vaccine.

If my partner knows I am using a microbicide to prevent HIV, should he still use condoms?

Microbicides are not currently available for use outside of clinical trials. Condoms are still an important HIV and STI prevention option; people should still use a condoms if they can.²⁴



Additional Resources

www.bethegeneration.org

<http://www.thebody.com/>

www.avac.org

<http://www.niaid.nih.gov/topics/HIVAIDS/Research/prevention/Pages/art.aspx>

<http://www.hvtn.org/>

<http://www.mtnstopshiv.org/>

<http://www.hptn.org/>

<http://www.cdc.gov>



CONCLUSION

You have now completed the workshop about HIV (Human Immunodeficiency Virus) prevention research. This vital research is designed to find safe and effective methods to prevent HIV and AIDS (Acquired Immunodeficiency Syndrome). Preventing HIV is our best hope for ending the HIV/AIDS epidemic.

It is also important to promote awareness and understanding of this research and to build public support for this work. Researchers often partner with a variety of individuals and groups in the community for this awareness, understanding, and support. Successful partnerships among the following can make a difference:

- Community leaders
- Local and national organizations
- Health professionals
- Educators



What Is Clinical Research

Research is a systematic investigation to establish facts. Clinical research refers to clinical trials in people and helps develop solutions to improve the health of people all over the world. Clinical research includes:

- Development of new ways to treat, prevent, and control disease
- The evaluation of new interventions for:
 - Safety
 - Efficacy (the capacity to produce a desired effect/effectiveness)
 - Acceptability and adherence (whether or not people use the product as designed)
 - Preventing and controlling disease

Clinical research over the past 100 years has improved the health and lives of people around the world. Clinical research provides the means to make sure HIV research is conducted safely and effectively. Clinical research is an important step in finding ways to prevent and treat HIV/AIDS.

What Is Community Engagement?

Community engagement focuses on reaching and involving everyone from all walks of life and perspectives. Community engagement is especially important during clinical trials. During HIV/AIDS outreach activities, community engagement brings together those people affected and impacted by HIV/AIDS. Community engagement ensures that the:

- Community's concerns and needs are shared with researchers
- Community is aware of, can learn about, and have input into the research process



What Is HIV Prevention and the HIV Combination Prevention Toolbox?

Comprehensive HIV prevention includes treatment, information, skills, personal responsibility, and access to tools, products, and approaches.

Different HIV prevention approaches need to be tested to find out what works best. Identifying and offering more options will allow people to determine which options fit their lives, their needs, and the needs of their family and friends. Ongoing HIV prevention research supports:

- More HIV prevention options
- More combination HIV prevention options
- More diverse research participants to enlarge the understanding of what works

What Are HIV Prevention Tools and How Are They Used in HIV Prevention Research?

HIV prevention research is important to find safe and effective approaches to prevent the spread of HIV. These approaches can include:

- Promoting awareness, understanding, and dialogue
- Supporting research
- Developing new prevention technologies

Some important areas in biomedical HIV prevention are:

- The PrEP prevention approach is focused on people who do not have HIV, but may be vulnerable to exposure to HIV through sexual contact and injection drug use (IDU). With PrEP, people who do not have HIV receive a prescription to take a medication before exposure to HIV. If taken as prescribed, the medication lowers their likelihood of contracting HIV.
- Treatment as Prevention (TasP) is an approach for people living with HIV to reduce the likelihood of passing HIV to others. With TasP, people with HIV take medication. The medication controls the HIV in their bodies and keeps them healthy. The medication also lowers their likelihood of transmitting HIV to others through sex, ideally to zero chance when undetectable (U=U).
- Microbicides are designed to reduce HIV transmission during vaginal and anal sex. Most microbicides being tested today contain antiretroviral (ARV) drugs. These drugs have been shown to help prevent HIV acquisition if someone is exposed to the virus.
- A safe and effective preventive vaccine is believed to be the best way to control the HIV/AIDS epidemic in the long term. A vaccine uses a substance that teaches the body's immune system to recognize and protect against a disease caused by an infectious agent or virus, often by stimulating the body to produce antibodies and T-cells against that infection. There is a lot of important research going on to find a safe and effective HIV vaccine.



This project was originally supported through Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services Grant # UM01 AI068614: “Leadership Group for a Global HIV Vaccine Clinical Trials (Office of HIV/AIDS Network Coordination).” It has been independently operated by the Office of HIV/AIDS Network Coordination since 2014.

For More Information

For more information on HIV Prevention Research, visit:

- Be The Generation <http://www.bethegeneration.org/>
- The Legacy Project: <https://www.facebook.com/HANCLegacyProject/>
- Office of HIV/AIDS Network Coordination: <https://www.hanc.info>
- HIV Prevention Trials Network <http://www.hptn.org/>
- HIV Vaccines Trials Network <http://www.hvtn.org/>
- Microbicide Trials Network <http://www.mtnstopshiv.org/>
- AVAC <http://www.avac.org/>



Endnotes

¹<http://www.cdcnpin.org/scripts/hiv/prevent.asp>

²<http://www.cdcnpin.org/scripts/hiv/prevent.asp>

³<https://www.cdc.gov/hiv/policies/hip/works.html>

⁴<https://www.cdc.gov/condomeffectiveness/index.html>

⁵<https://www.hptn.org/research/studies/hptn052>

⁶ <https://mtnstopshiv.org/news/results-open-label-study-vaginal-ring-hiv-prevention-suggest-women-are-interested-and-willing>

⁷ <https://www.hptn.org/news-and-events/announcements/cab-la-proves-be-highly-effective-prevention-hiv-acquisition>

⁸<https://www.fredhutch.org/en/labs/be-the-generation/prep-tasp.html>

⁹<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm>

¹⁰<http://www.truvada.com/>

¹¹<http://aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/overview-of-hiv-treatments/>

¹²http://www.avac.org/ht/d/sp/i/262/pid/262/cat_id/458/cids/453,458

¹³<http://www.mtnstopshiv.org/node/706>

¹⁴<http://www.mtnstopshiv.org/node/706>

¹⁵<http://www.mtnstopshiv.org/node/2864>

¹⁶<http://www.mtnstopshiv.org/node/2864>

¹⁷<http://www.mtnstopshiv.org/node/2864>

¹⁸http://www.global-campaign.org/about_microbicides.htm

¹⁹<http://www.mtnstopshiv.org/node/2864>

²⁰ <http://www.fredhutch.org/en/research/divisions/vaccine-infectious-disease-division/research/immunology-and-vaccine-development/be-the-generation/microbicides.html>

²¹<http://www.global-campaign.org/EngDownload.htm#microbicides>

²²<https://www.hiv.gov/hiv-basics/hiv-prevention/potential-future-options/hiv-vaccines>

²³<http://www.fredhutch.org/en/research/divisions/vaccine-infectious-disease-division/research/immunology-and-vaccine-development/be-the-generation/prep-tasp.html>

²⁴<http://www.global-campaign.org/EngDownload.htm#microbicides>