



Pre-Exposure Prophylaxis for HIV

Patient Education, Adherence and Risk Reduction

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Disclosures

- None Declared



A Tale of Two Clinics

Vanderbilt
Comprehensive Care
Clinic



Infectious disease experts Katie White, M.D., Ph.D., and Sean Kelly, M.D., are working to raise awareness of effective ways to prevent HIV infection, including the combination drug therapy called pre-exposure prophylaxis, or PrEP. (photo by Daniel Dubois)

Katie White MD Sean Kelly MD

My House

Neighborhood Health
HRSA Supported Health Center



Kim Rivers FNP-C



Agenda

- Building Trust
- Why Adherence Matters
- Barriers to Adherence
- Patient Education
- Financial Support



Building Trust

- Building trust is crucial to patient education, adherence and risk reduction.
- Starts at the Call Center
 - Create an environment of safety and trust throughout your clinic.



Building Trust

INTERNATIONAL JOURNAL
of NURSING PRACTICE

 Full Access

The importance of the patient–clinician relationship in adherence to antiretroviral medication

Alex Molassiotis RN PhD , Kate Morris B. Pharm,
Ian Trueman RN MSC

First published: 15 November 2007

| <https://doi.org/10.1111/j.1440-172X.2007.00652.x> | Cited by:13



CDC Emphasizes Importance of Building Trust

<https://effectiveinterventions.cdc.gov/docs/default-source/pfh-ma/medadherencewaysbuildtrust.pdf?sfvrsn=2>

Partnership for Health - Medication Adherence

Ways to Build Trust and Communication



One goal of the Partnership for Health - MA strategy is to increase your patients' knowledge about ART and the importance of adherence. Patients may not fully understand or have misconceptions about how ART works to keep them healthy. This lack of understanding or misconceptions about ART and adherence could lead to skipped doses or stopping medication. In addition, side effects associated with ART may also lead to skipped doses. Describing how the medication works, possible side effects and their duration, and the consequences of missed doses engages the patient as an informed participant in this partnership.

Establishing trust and communication is a core component of the Partnership for Health - MA strategy. Fostering a respectful, open, and honest relationship will enhance your patients' willingness to speak truthfully about their struggles with adherence. Ways to encourage open communication and build trust include the following.



Barriers to Adherence

- Stigma
- Educational
- Motivation
- Financial
- Social Determinants of Health
 - Be aware of local resources for transportation, housing, food, etc
- Mental Health / Substance Abuse Concerns
 - Don't assume that mental illness will result in poor adherence
 - Know local resources for substance abuse and mental health services



Barriers to Adherence - Stigma

- Stigma regarding HIV in general
- Stigma regarding PrEP
 - Judgment from providers
 - Judgment from partners
 - Partner could find out about sex outside of the relationship
 - Partner would misinterpret taking PrEP as having HIV



Stigma

A preventative measure against the consequences of sexual activity

... *condones* sexual activity

... *promotes* sexual activity

... *causes* sexual activity



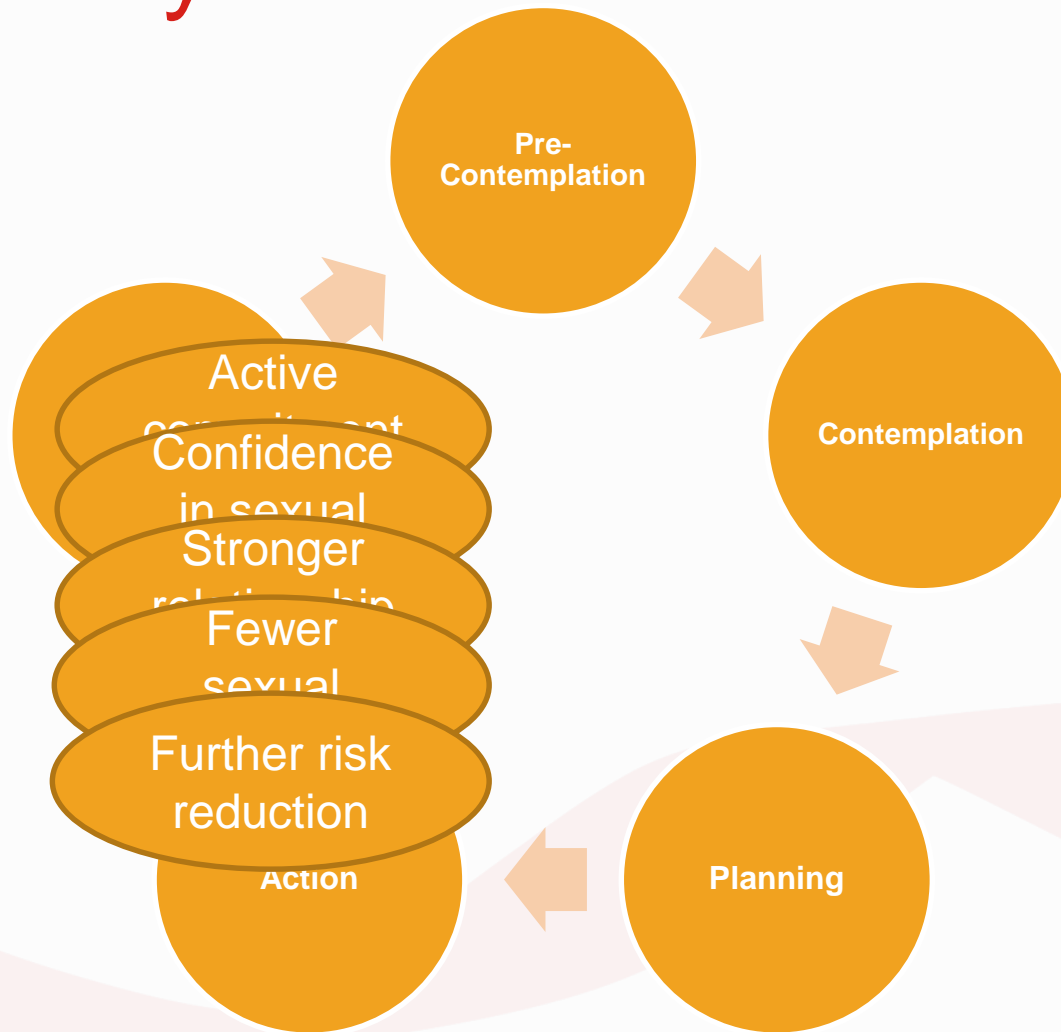


Stigma

- PrEP is a “party drug”
- PrEP promotes “bareback sex”
- PrEP users will stop using condoms
- PrEP users will acquire more STIs

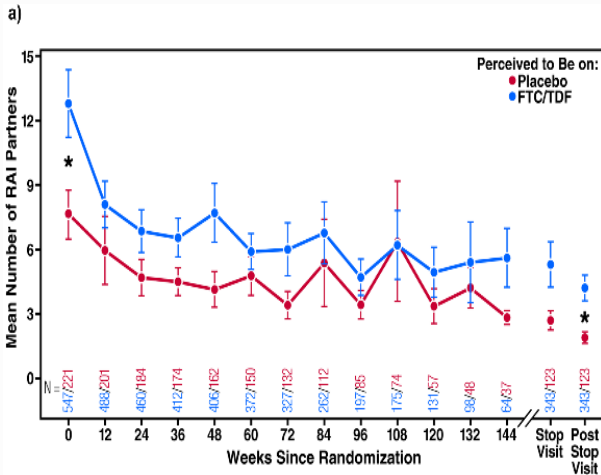


But actually...



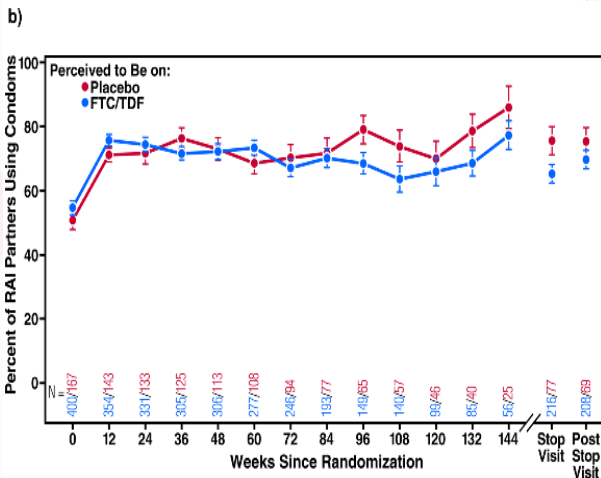


No evidence of sexual risk compensation in the iPrEx trial of daily oral PrEP



For patients believing they were on PrEP, the number of receptive anal intercourse partners decreased.

For patients believing they were on PrEP, condom use increased.



Syphilis incidence also decreased in both study arms

Julia L. Marcus, David V. Glidden, Kenneth H. Mayer, Albert Y. Liu, Susan P. Buchbinder, K. Rivet Amico, Vanessa McMahan, Esper Georges Kallas, Orlando Montoya-Herrera, Jose Pilotto, Robert M. Grant. PLoS One. 2013 Dec 18;8(12):e81997



Stigma

As a society, we treat any HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.

Sean Kelly, MD

Assistant Professor

Vanderbilt Division of Infectious Diseases



Risk Reduction

Set realistic expectations.

My personal mantra:

People are people and they are going to have sex.



Risk Reduction

Role of Adherence

PrEP Works.....WHEN YOU TAKE IT

Risk Reduction

iPrEX



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ORIGINAL ARTICLE

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., Valdílea G. Veloso, M.D., Ph.D., Susan P. Buchbinder, M.D., Suwat Charialertsak, M.D., Dr.P.H., Mauro Schechter, M.D., Ph.D., Linda-Gail Bekker, M.B., Ch.B., Ph.D., Kenneth H. Mayer, M.D., Esper Georges Kallás, M.D., Ph.D., K. Rivet Amico, Ph.D., Kathleen Mulligan, Ph.D., Lane R. Bushman, B.Chem., Robert J. Hance, A.A., Carmela Ganoza, M.D., Patricia Defechereux, Ph.D., Brian Postle, B.S., Furong Wang, M.D., J. Jeff McConnell, M.A., Jia-Hua Zheng, Ph.D., Jeanny Lee, B.S., James F. Rooney, M.D., Howard S. Jaffe, M.D., Ana I. Martínez, R.Ph., David N. Burns, M.D., M.P.H., and David V. Glidden, Ph.D., for the iPrEX Study Team*

N Engl J Med 2010; 363:2587-2599 | December 30, 2010 | DOI: 10.1056/NEJMoa1011205


44% HIV risk reduction

But, 92% risk reduction when taken consistently
among MSM and transgender women



Risk Reduction

TDF2 Study Group



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ORIGINAL ARTICLE

Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana

Michael C. Thigpen, M.D., Poloko M. Kebaabetswe, Ph.D., M.P.H., Lynn A. Paxton, M.D., M.P.H., Dawn K. Smith, M.D., M.P.H., Charles E. Rose, Ph.D., Tebogo M. Segolodi, M.Sc., Faith L. Henderson, M.P.H., Sonal R. Pathak, M.P.H., Fatma A. Soud, Ph.D., Kata L. Chillag, Ph.D., Rodreck Mutanhaurwa, M.B., Ch.B., Lovemore Ian Chirwa, M.B., Ch.B., M.Phil., Michael Kasonde, M.B., Ch.B., Daniel Abebe, M.D., Evans Buliva, M.B., Ch.B., Roman J. Gvetadze, M.D., M.S.P.H., Sandra Johnson, M.A., Thom Sukalac, Vasavi T. Thomas, M.P.H., R.Ph., Clyde Hart, Ph.D., Jeffrey A. Johnson, Ph.D., C. Kevin Malotte, Dr.P.H., Craig W. Hendrix, M.D., and John T. Brooks, M.D., for the TDF2 Study Group*

N Engl J Med 2012; 367:423-434 | August 2, 2012 | DOI: 10.1056/NEJMoa1110711

62.2% HIV risk reduction among heterosexual men and women

(100% in open-label extension with regular follow-up)



Risk Reduction

Partners PrEP Study Team



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ORIGINAL ARTICLE

Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women

Jared M. Baeten, M.D., Ph.D., Deborah Donnell, Ph.D., Patrick Ndase, M.B., Ch.B., M.P.H., Nelly R. Mugo, M.B., Ch.B., M.P.H., James D. Campbell, M.D., Jonathan Wangisi, M.B., Ch.B., Jordan W. Tappero, M.D., M.P.H., Elizabeth A. Bukusi, M.B., Ch.B., Ph.D., Craig R. Cohen, M.D., M.P.H., Ely Katabira, M.B., Ch.B., Allan Ronald, M.D., Elioda Tumwesigye, M.B., Ch.B., Edwin Were, M.B., Ch.B., M.P.H., Kenneth H. Fife, M.D., Ph.D., James Kiarie, M.B., Ch.B., M.P.H., Carey Farquhar, M.D., M.P.H., Grace John-Stewart, M.D., Ph.D., Aloysious Kakia, M.B., Ch.B., Josephine Odoyo, M.P.H., Akasiima Mucunguzi, M.B., Ch.B., Edith Nakku-Joloba, M.B., Ch.B., Ph.D., Rogers Twesigye, M.B., Ch.B., M.P.H., Kenneth Ngure, Ph.D., Cosmas Apaka, B.Sc., Harrison Tamooch, M.B., Ch.B., Fridah Gabona, M.B., Ch.B., Andrew Mujugira, M.B., Ch.B., Dana Panteleeff, B.S., Katherine K. Thomas, M.S., Lara Kidoguchi, M.P.H., Meighan Krows, B.A., Jennifer Revall, B.A., Susan Morrison, M.D., M.P.H., Harald Haugen, M.S., Mira Emmanuel-Ogier, B.A., Lisa Ondrejcek, M.A., Robert W. Coombs, M.D., Ph.D., Lisa Frenkel, M.D., Craig Hendrix, M.D., Namandjé N. Bumpus, Ph.D., David Bangsberg, M.D., M.P.H., Jessica E. Haberer, M.D., M.P.H., Wendy S. Stevens, M.D., F.C.Path., Jairam R. Lingappa, M.D., Ph.D., and Connie Celum, M.D., M.P.H., for the Partners PrEP Study Team*

N Engl J Med 2012; 367:399-410 | August 2, 2012 | DOI: 10.1056/NEJMoa1108524

75% HIV risk reduction among heterosexual sero-discordant couples

90% among those with detectable drug levels



Risk Reduction

Bangkok Tenofovir Study Group

THE LANCET

Volume 381, Issue 9883, 15–21 June 2013, Pages 2083–2090



Articles

Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, MD^a, Dr Michael Martin, MD^{b, c}, Pravan Suntharasamai, MD^a, Udomsak Sangkum, MD^a, Philip A Mock, MAppStats^b, Manoj Leethochawalit, MD^d, Sithisat Chiamwongpaet, MD^d, Praphan Kitisin, MD^d, Pitinan Natrujirote, MD^d, Somyot Kittimunkong, MD^e, Rutt Chuachoowong, MD^d, Roman J Gvetadze, MD^e, Janet M McNicholl, MD^{b, c}, Lynn A Paxton, MD^e, Marcel E Curlin, MD^{b, c}, Craig W Hendrix, MD^f, Suphak Vanichseni, MD^a, for the Bangkok Tenofovir Study Group

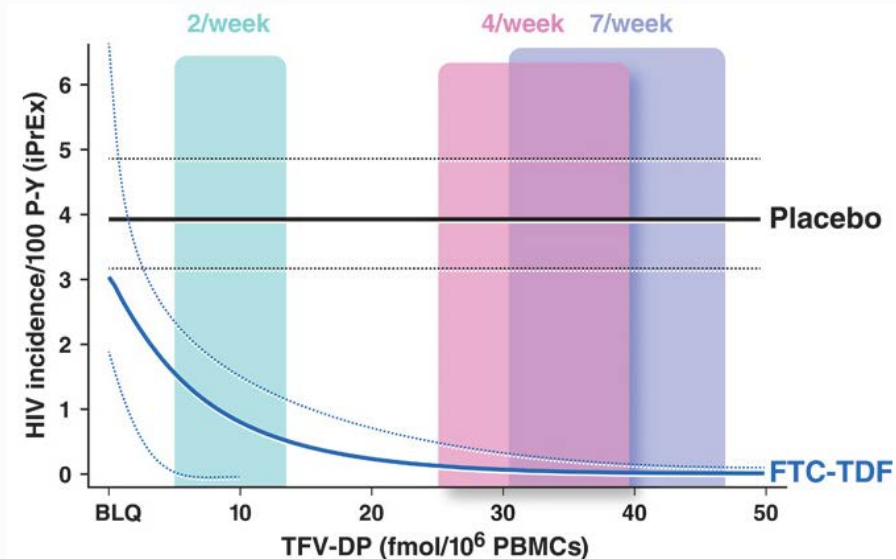
48.9% risk reduction

But, 74% HIV risk reduction when taken consistently, among IDUs (TDF only)



Risk Reduction

Dosing matters



Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict:

76% risk reduction with 2 doses/week

96% with 4 doses/week

99% with 7 doses/week.

Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Sci Transl Med.* 2012;4: 151ra125. doi: 10.1126/scitranslmed.3004006. pmid:22972843



Risk Reduction

Studies Summary

| Study | Population | Dosing | Risk Reduction |
|-------------------------------|--------------------------------------|--------|---|
| iPrEX | MSM | Daily | 44% (92% with ideal adherence) |
| TDF2 | Heterosexual men and women | Daily | 62.2% (100% in open-label extension with regular follow-up) |
| Partners | Sero-discordant heterosexual couples | Daily | 75% (90% with ideal adherence) |
| Bangkok Tenofovir Study Group | Intravenous drug users | Daily | 48.9% (74% with ideal adherence) |



Risk Reduction

Probability of Acquiring HIV from an Infected Source

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

| Type of Exposure | Risk per 10,000 Exposures |
|--|---------------------------|
| Parenteral | |
| Blood Transfusion | 9,250 |
| Needle-Sharing During Injection Drug Use | 63 |
| Percutaneous (Needle-Stick) | 23 |
| Sexual | |
| Receptive Anal Intercourse | 138 |
| Insertive Anal Intercourse | 11 |
| Receptive Penile-Vaginal Intercourse | 8 |
| Insertive Penile-Vaginal Intercourse | 4 |
| Receptive Oral Intercourse | Low |
| Insertive Oral Intercourse | Low |
| Other[^] | |
| Biting | Negligible |
| Spitting | Negligible |
| Throwing Body Fluids (Including Semen or Saliva) | Negligible |
| Sharing Sex Toys | Negligible |

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[^] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Source

- Patel P, Borkowf CB, Brooks JT, Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human Immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.



Risk Reduction

Probability of Acquiring HIV from an Infected Source

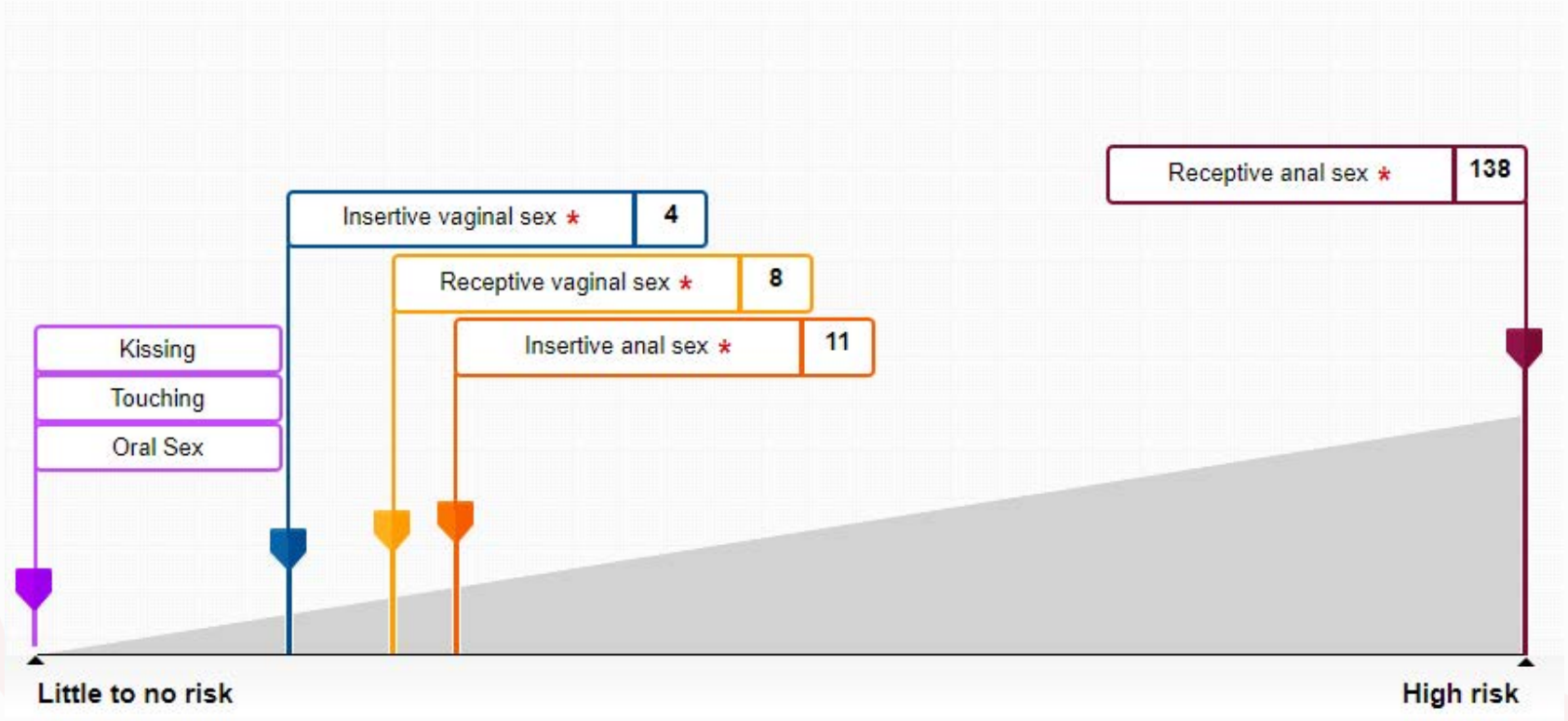
| Sexual | |
|--------------------------------------|-----|
| Receptive Anal Intercourse | 138 |
| Insertive Anal Intercourse | 11 |
| Receptive Penile-Vaginal Intercourse | 8 |
| Insertive Penile-Vaginal Intercourse | 4 |
| Receptive Oral Intercourse | Low |
| Insertive Oral Intercourse | Low |

<https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>



Risk Reduction

Probability of HIV Transmission per every 10,000 sex acts without protective barriers



<https://wwwn.cdc.gov/hivrisk/estimator.html#--~sb>



Risk Reduction

Receptive Vs Insertive Sex

Receptive Versus Insertive Sex

During anal sex, the partner inserting the penis is called the insertive partner (or top), and the partner receiving the penis is called the receptive partner (or bottom).

Receptive anal sex is much riskier for getting HIV. The bottom partner is 13 times more likely to get infected than the top. However, it's possible for either partner to get HIV through anal sex from certain body fluids—blood, semen (*cum*), pre-seminal fluid (*pre-cum*), or rectal fluids—of a person who has HIV. Using condoms or medicines to protect against transmission can decrease this risk.

- **Being a receptive partner during anal sex is the highest-risk sexual activity for getting HIV.** The *bottom's* risk of getting HIV is very high because the lining of the rectum is thin and may allow HIV to enter the body during anal sex.
- **The insertive partner is also at risk for getting HIV during anal sex.** HIV may enter the *top* partner's body through the opening at the tip of the penis (or urethra) or through small cuts, scratches, or open sores on the penis.

<https://www.cdc.gov/hiv/risk/analsex.html>



Risk Reduction

Condom Use

- Education from a perspective of pleasure / quality of life vs fear.





Risk Reduction Barrier to Condom Use

- Power issues and self esteem are often barriers to condom use.
 - Dominant partner
 - Domestic violence
 - Sex workers
 - People trading sex for housing, food or drugs
- Teach negotiation skills
 - International Planned Parenthood Federation
 - <https://www.ippf.org/blogs/condom-negotiation>



Risk Reduction

Condom Negotiation

Here are some lines you could use to persuade a partner to use a condom:

She says, "I'm on the pill, don't worry."

You say, "I trust you. But I want to protect both of us just in case."



He says, "We already did it without a condom once."

You say, "And that was a mistake. I worried about being pregnant all month!"



She says, "What — a condom? Are you trying to say that I've cheated on you?"

You say, "I trust you. I use condoms because I care about you, and me, and our future together."

He says, "I always pull out in time, don't worry."

You say, "I know, but when we use a condom you don't have to pull out. It can feel even better."

She says, "I can't feel anything when you wear a condom."

You say, "That's awful! Let's wait then and try another brand or size that fits me better and some special 'warming' lubricant tomorrow."



He says, "I can't keep a hard on with a condom."

You say, "I can't relax and enjoy sex without a condom. So I'll help you stay hard."



Risk Reduction

Ineffective Strategy

Serosorting for HIV-Negative Persons

| Population | Effectiveness Estimate | Source | Interpretation |
|----------------------------|------------------------|---------------|--|
| MSM | 54% | Kennedy, 2013 | When compared to condomless anal sex with either HIV-positive or unknown status partners, HIV-negative MSM who self-report serosorting reduce their risk of HIV acquisition by 54%. When compared to no condomless anal sex, serosorting results in increased risk of acquiring HIV. |
| Heterosexual Men and Women | 54% | Kennedy, 2013 | There is no direct evidence for effectiveness of serosorting in reducing the risk of acquiring HIV among HIV-negative heterosexual men and women. There is no reason, however, to believe serosorting wouldn't also be effective in heterosexual men and women. When compared to condomless sex with either HIV-positive or unknown status partners, HIV-negative heterosexual men and women who self-report serosorting may reduce their risk of HIV acquisition by 54%. When compared to no condomless sex, serosorting may result in increased risk of acquiring HIV. |

<https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>



Risk Reduction Ineffective Strategy

| Circumcision of Adult Males | | | |
|-----------------------------|------------------------|--|--|
| Population | Effectiveness Estimate | Source | Interpretation |
| MSM, Insertive Anal Sex | Inconclusive | Wlysonge, 2011; Sanchez, 2011; Doerner, 2013 | Based on observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision reduces the risk of the insertive partner acquiring HIV during anal sex among MSM. |
| MSM, Receptive Anal Sex | Inconclusive | Wlysonge, 2011; Schneider, 2012 | Based on observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision (of the insertive partner) reduces the risk of the receptive partner acquiring HIV during anal sex among MSM. |
| Heterosexual Men | 50% | Siegfried, 2009 | Based on trials of circumcision among adult males, male circumcision reduces the risk of heterosexual men acquiring HIV during sex by 50%. |
| Heterosexual Women | Inconclusive | Wawer, 2009; Weiss, 2009; Baeten, 2010 | Based on several trials and observational studies of circumcision among adult males, there is insufficient evidence at this time to conclude that male circumcision reduces the risk of heterosexual women acquiring HIV during sex. |

<https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>



Patient Education

- Establish Trust
- Assessment
- Face to Face
- Tailor the education to your patient
- Printed Material / Web Resources
- Life happens – situations change



Patient Education - Assessment

- Great education starts with a great assessment.
- Get to know your patient and establish trust.
- Things to look for:
 - Cognitive Barriers
 - Stigma
 - Treatment Concerns
 - Social Support
 - Mental Health Concerns
 - Structural Barriers
 - i.e. housing, transportation, insurance, etc
 - Baseline Knowledge of HIV and how to prevent it



Patient Education - Face to Face

- Pick up on visual cues.
- Helps to establish rapport.
- Helps to engage patient is communicating about their care.
- Helps make active listening more effective.



Patient Education – Face to Face

<https://effectiveinterventions.cdc.gov/docs/default-source/pfh-ma/medadherencewaysbuildtrust.pdf?sfvrsn=2>

| Key Elements of Active Listening | |
|----------------------------------|---|
| Ask open-ended questions | <p>Closed-ended questions make it easy for patients to dismiss concerns or questions they may have had about their treatment or adherence. Closed-ended questions also make it easy for the provider to quickly assess the patient's immediate needs and make it possible to keep the visit and conversation short. However, open-ended questions invite the patient to discuss their concerns. Providers might ask:</p> <p>“What makes it difficult to take every dose, every day?”</p> <p>“Tell me more about what has changed in your daily routine that may be making it difficult for you take every dose, every day.”</p> <p>“What could you do to help remind yourself to take every dose, every day?”</p> |
| Reflect | “I understand how frustrating it can be to forget taking your doses every day.” |
| Restate | “You’re finding it difficult to take your pill with food because you’re not able to wake up early enough to fix breakfast.” |
| Redirect | Redirecting involves bringing the patient back to the discussion when he or she has strayed off track. Most providers are quite skilled at redirecting. The trick is to redirect, so that the patient feels like he or she is still being heard. |
| Affirm | “You recognized the importance of getting back to taking your dose every day.” |
| Non-verbal communication | Maintain eye contact when the patient speaks, nod your head, and wait for him or her to finish speaking before responding. |



Patient Education Materials

CDC Downloadable Documents

PrEP 101

PrEP Basics

PrEP stands for **Pre-Exposure Prophylaxis**. PrEP is an HIV prevention medicine that you take every day. PrEP can help prevent you from getting HIV if you are exposed to the virus.

How Does It Work?

PrEP works by blocking HIV from getting into your body. It is 92% effective at preventing HIV from getting into your body.

PrEP Access

How Can I Start PrEP?

Talk with your doctor or health care provider to determine if PrEP is right for you.

Is PrEP Right For Me?

I am thinking about PrEP to prevent HIV. What now?

Frequently Asked Questions

If you decide PrEP is right for you

Take your pill every day.

GET INFORMED. MAKE THE RIGHT CHOICE FOR YOU.

YOU ARE IN CONTROL

ARE YOU READY FOR PrEP?

Start Talking. Stop HIV.

AETC Southeast

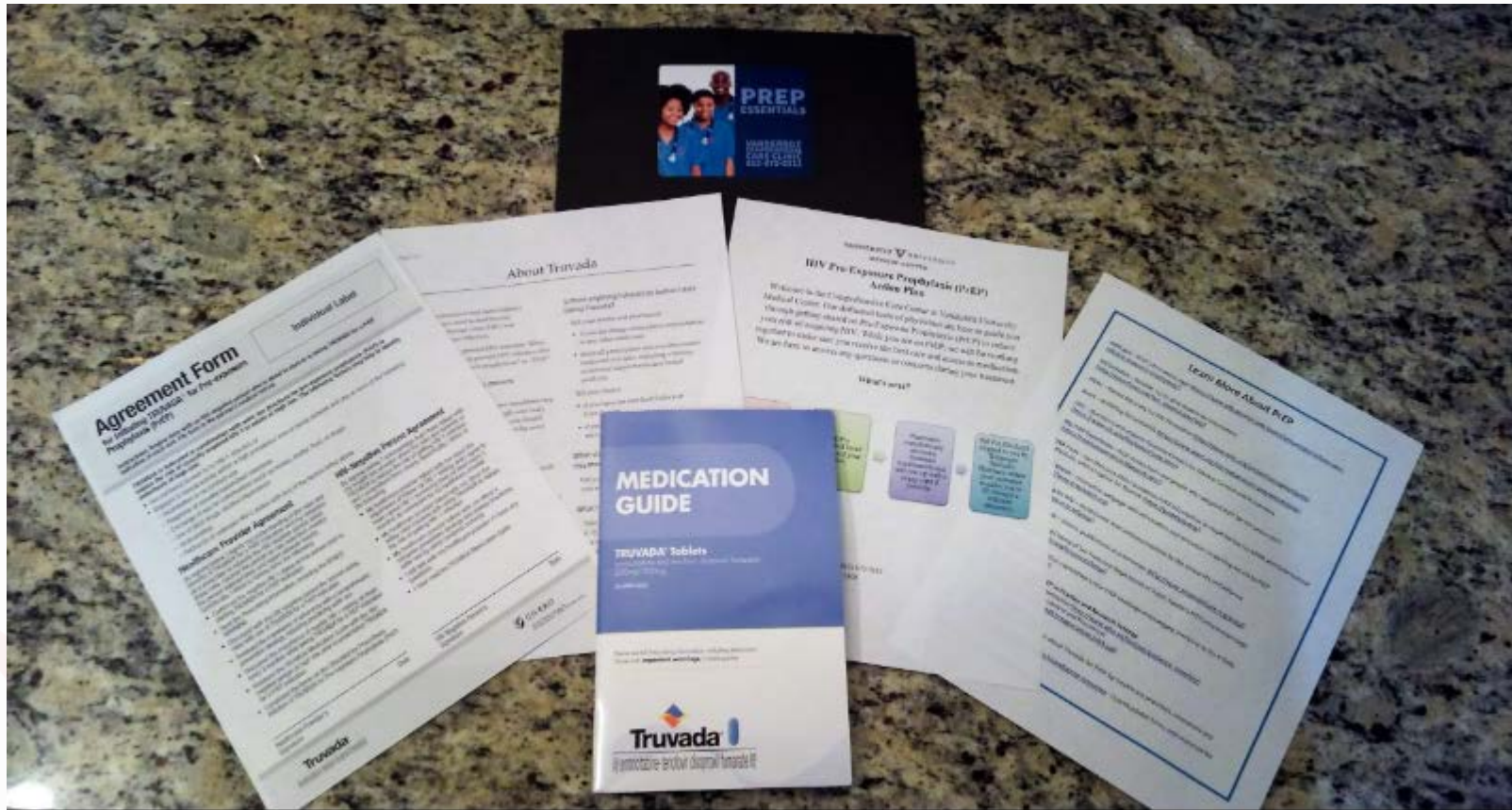
CDC

<https://www.cdc.gov/actagainstaids/campaigns/starttalking/materials/prepresources.html>



Patient Education Materials

New Patient Folder





Patient Education Materials

AIDSinfonet.org

AIDS InfoNet www.aidsinfonet.org Fact Sheet Number 160

TREATMENT TO PREVENT HIV INFECTION (PrEP)

WHAT IS PRE-EXPOSURE PROPHYLAXIS?
PrEP stands for Pre-exposure prophylaxis. Prophylaxis means disease prevention. PrEP is a new HIV prevention option for HIV-negative individuals to reduce their risk of HIV infection. PrEP for HIV prevention is the use of antiretroviral medications (ARVs) by HIV-negative individuals to reduce risk. Large research studies showed that PrEP could help prevent new HIV infections when used by people at high risk of getting HIV.

The only research on PrEP is based on using the combination pill Truvada (see fact sheet 421). Research showed over 90% reduction in HIV infections when taken four times a week. PrEP taken daily reduced HIV infections by 99%. There is not enough information on other medications. We don't know yet if other drugs or dose timing (like a few times a week instead of every day) might also be a good way to reduce risk of HIV.

Truvada as PrEP was studied in people who were at high risk of HIV infection. HIV-negative men who have sex with men, transgender women and heterosexuals at high risk were studied. Results in these studies have varied. The studies showed that PrEP worked best for people who took the medication every day.

HOW IS PrEP TAKEN?
PrEP is currently one tablet of Truvada daily. It can be taken with food, or between meals. There is research ongoing to look at other medications for PrEP.

Truvada contains two medications, tenofovir (Viread) and emtricitabine (Emtriva). Truvada is only available with a prescription.

WHO SHOULD USE PrEP?
PrEP is more than simply taking HIV pills. The US Centers for Disease

Control and Prevention (CDC) has issued guidelines for the use of PrEP. One set of guidelines is for men who have sex with men. Another is for heterosexuals.

- PrEP should be used by people who are at high risk of becoming infected with HIV by sexual activity
- PrEP should be part of an overall HIV prevention program including condoms and counseling
- Before taking PrEP, people should be tested to confirm that they are not already infected with HIV
- People using PrEP should continue to be tested to make sure they have not been infected
- They should also be tested for kidney damage, hepatitis B and any sexually transmitted diseases

HOW SHOULD PEOPLE USING PrEP BE MONITORED?
The CDC guidelines recommend that people taking PrEP be seen every 2-3 months in order to:

- Test for HIV infection
- Check for side effects of Truvada
- Check for problems taking PrEP every day
- Reinforce condom use and other prevention messages

WHAT ARE THE LIKELY SIDE EFFECTS?
The most common side effects seen in the studies of Truvada as PrEP include headache, nausea, vomiting, rash and loss of appetite. In some people, tenofovir can increase creatinine and transaminases. These are enzymes related to the kidneys and liver. High levels can indicate damage to these organs. Long-term use of tenofovir can damage the kidneys.

Tenofovir can reduce bone mineral density (see fact sheet 557). Calcium or vitamin D supplements may be helpful. This is especially true for people with osteopenia or osteoporosis.

Levels of lactic acid in the blood (lactic acidosis, see Fact Sheet 556) increase in some people taking tenofovir and emtricitabine. Liver problems including "fatty liver" may also occur.

In rare cases, people taking emtricitabine had some temporary changes in skin color.

DOES PrEP HAVE RISKS?
People with HIV have used Truvada, tenofovir and emtricitabine, for several years. They are generally easy to take. Possible long-term side effects include loss of bone mineral density and kidney damage.

Some people worry that people taking PrEP might think they are totally protected. They might be less careful about their sexual behavior. So far, this does not appear to be true.

THE BOTTOM LINE
Pre-exposure prophylaxis (PrEP) is the use of the antiretroviral medication Truvada before exposure to HIV, to reduce the risk of HIV infection. When Truvada as PrEP is used correctly and consistently, it can reduce the rate of HIV infection by sexual activity by as much as 90%.

The benefits of PrEP are potentially very high for reducing new HIV infections in people who recognize their risk of infection and can take Truvada to protect themselves. Some people fear PrEP may encourage unsafe behaviors, but this has not been seen.

FOR MORE INFORMATION
CDC guidelines on PrEP are on the Internet at: <http://www.cdc.gov/hiv/prep/>. Additional information on PrEP is at www.prepwatch.org.

Reviewed August 28, 2014

A Project of the International Association of Providers of AIDS Care. Fact Sheets can be downloaded from the Internet at <http://www.aidsinfonet.org>

AIDS InfoNet www.aidsinfonet.org Fact Sheet Number 421

TRUVADA (Tenofovir + Emtricitabine)

WHAT IS TRUVADA?
Truvada is a combination pill that contains two drugs used to fight HIV: tenofovir DF (Viread) and emtricitabine (Emtriva). Truvada is manufactured by Gilead Sciences. Generic versions are approved under PEPFAR (see fact sheet 925.)

The drugs in Truvada are called nucleoside analog reverse transcriptase inhibitors, or nukes. These drugs block the reverse transcriptase enzyme. This enzyme changes HIV's genetic material (RNA) into the DNA. This occurs before HIV's genetic code gets inserted into an infected cell's chromosome.

WHO SHOULD TAKE TRUVADA?
Truvada was approved in 2004 for treatment of people with HIV infection in combination with other antiretroviral drugs.

Truvada is also approved for daily use by adults confirmed to be HIV negative, don't have symptoms of recent HIV infection and at high risk of becoming infected. PrEP should be used in combination with safer sex practices. This use is called pre-exposure prophylaxis (PrEP, see fact sheet 160).

While antiretroviral therapy is recommended for all persons living with HIV, there are no absolute rules about when to start antiretroviral therapy (ART). You and your health care provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking ART. Fact Sheet 404 has more information about guidelines for the use of ART.

If you take Truvada with other antiretroviral drugs (ARVs), you can reduce your viral load to undetectable levels, and increase your CD4 cell counts. This should mean staying healthier longer.

Truvada is not approved for treating people who have hepatitis B infection (HBV). Some people with HBV get worse after they stopped taking Truvada. Get tested for hepatitis B before you start taking Truvada to treat HIV.

Truvada provides two drugs in one pill. It can be more convenient to use Truvada than some other combinations of drugs. This could mean fewer missed doses and better control of HIV.

WHAT ABOUT DRUG RESISTANCE?
Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance."

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS TRUVADA TAKEN?
Truvada is taken by mouth as a tablet. The normal adult dose is one tablet, once a day. Each tablet includes 300 milligrams (mg) of tenofovir DF (Viread) and 200 mg of emtricitabine (Emtriva).

Truvada can be taken with or without food. If you have kidney problems, you may need to take Truvada less often.

WHAT ARE THE SIDE EFFECTS?
When you start any ART, you may have temporary side effects such as headaches, high blood pressure, or a general sense of feeling ill. These side effects usually get better or disappear over time.

Truvada is usually very well tolerated. The most common side effects of Truvada are the same as with tenofovir DF (Viread) and emtricitabine (Emtriva). They include headache, nausea, vomiting, rash and loss of appetite. In some people, tenofovir can increase blood chemicals called creatinine and transaminases. High levels can indicate injury to kidneys or the liver.

Tenofovir DF can cause bone problems by reducing bone mineral density (BMD). This is especially true for people an issue for people with osteopenia or osteoporosis (see fact sheet 557). BMD tests should be considered in people taking Truvada who have had bone fractures or other risks for osteoporosis.

Levels of lactic acid in the blood (lactic acidosis, see Fact Sheet 556) increase in some people taking nucleoside analog drugs. Liver problems including "fatty liver" may also occur.

In rare cases, people taking emtricitabine had some limited changes in skin color.

HOW DOES TRUVADA REACT WITH OTHER DRUGS?
Truvada can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your health care provider knows about ALL drugs and supplements you are taking.

Tenofovir DF levels can be increased with the HCV drug ledipasvir/sofosbuvir (Harvoni, see fact sheet 686), especially when given with a boosted protease inhibitor. Kidney function should be monitored before and during HCV treatment in people taking this combination of medications.

Tenofovir DF increases levels of ddi (Videx). The dose of ddi taken with Truvada should be reduced to 250 mg for people weighing 60 kg (132 lbs) or more. There is no information on ddi dosing for people weighing less than this.

Truvada should not be used with tenofovir (Viread), emtricitabine (Emtriva, FTC), Descovy or with drugs containing lamivudine (EpiViv, 3TC) including Combivir, Trizivir or Epivior.

There are no data on interactions between emtricitabine and methadone. Tenofovir does not affect blood levels of methadone.

Tenofovir lowers the levels of the HIV protease inhibitor atazanavir (Reyataz). When taken with Truvada, atazanavir should be taken with ritonavir (Norvir).

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Patient Education

Adherence Tools

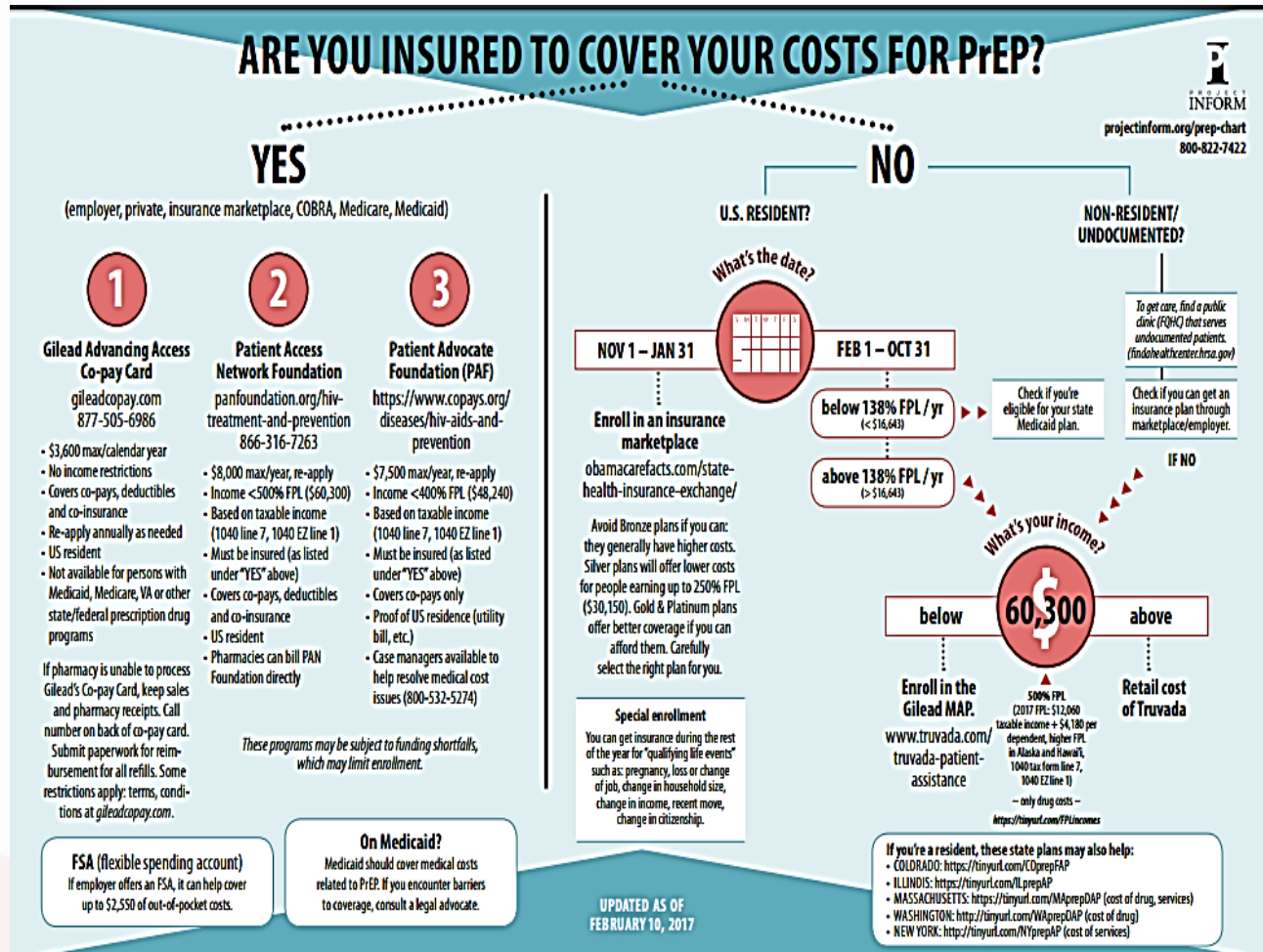
- Med boxes
- Key fobs
- Cell phone reminders
- Apps
- Accountability partner





Patient Education

Financial Support



PROJECT INFORM

projectinform.org/prep-chart
800-822-7422



Patient Education

Co Pay Card

- Assess your patient's ability to facilitate obtaining a co pay card.
 - They may need assistance navigating this process.

- Two ways to obtain a co pay card:
 - Phone
 - 1-877-505-6986
 - On line
 - www.gileadadvancingaccess.com



Patient Education

Co Pay Card

Your personal information is required for security purposes and is used to confirm your identity as a cardholder.

Are you a current resident of the United States, Puerto Rico, or U.S. Territories? **Yes** **No**

Are your prescriptions paid for in part or in full under any state or federally funded program, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, or TRICARE? **Yes** **No**

Are you in the Medicare Part D coverage gap (Donut Hole)? **Yes** **No**

If you begin receiving prescription benefits from such state, federal, or government-funded program at any time, you will no longer be eligible to use the Gilead Advancing Access[®] co-pay coupon card. **Yes** **No**

Do you acknowledge your agreement with this statement?



Patient Education

Co Pay Card

| | | |
|------------------------------|--------------------------|------------------|
| ADVANCING ACCESS® | FINANCIAL SUPPORT | INSURANCE |
|------------------------------|--------------------------|------------------|

Enrollment

Step 2 of 3

*First name:

*Last name:

*Date of birth: MM DD YYYY

*Address 1:

Address 2:

*City:

*State:

*Zip code:

*E-mail:

*Phone number: () -

*Required fields

Gender:

[Optional]



Additional Adherence Tactics

- Follow up phone calls
 - My House
 - Walgreens Specialty Pharmacy
 - PrEP Navigator
- Appointment Reminders
 - VCCC – automated text messaging



Conclusion

In order for any of this to work, building a trusting relationship with your patient is essential.



Conclusion

- PrEP is an extremely effective preventive strategy
- Look at the whole person
- Above all – create a culture of safety and trust
- Ask for help! Sherise.stogner@vumc.org



Thank You!!

Questions??



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