

An Introduction to PRE-EXPOSURE PROPHYLAXIS (PrEP)

- MICHAELA GREY, MPH – NNAAPC
- Mark Thrun, MD – Associate Professor, University of Colorado,
- Director, HIV/STD Prevention and Control, Denver Public Health
- Director, Denver Prevention Training Center

AGENDA

- I. Introductions
- II. NNAAPC Mission
- III. Objectives
- IV. PrEP Presentation: Beyond the Basics
- V. PrEP and the Indian Health Service

INTRODUCTIONS

- Michaela Grey, MPH – NNAAPC Deputy Director
- Mark Thrun, MD – Infectious Disease Clinician, Denver Health

National Native American AIDS Prevention Center NNAAPC

- National, Native-specific organization providing capacity building and technical assistance since 1987
- Our Mission:
- Eliminate HIV/AIDS and confront related health and social determinants that negatively impact American Indian, Alaska Native, Native Hawaiian and Indigenous peoples

Cooperative Agreement Partnership

- Indian Health Service via the National Indian Health Board (NIHB) maintain a cooperative agreement with NNAAPC
- Goal: To increase the capacity of Native communities to address HIV through technical assistance and community-based prevention materials developed through comprehensive community input and guidance of the IHS HIV/AIDS Program

OBJECTIVES

By the end of this webinar:

1. Participants will be able to describe the most frequently prescribed PrEP medication regimens
2. Participants will be able to list 2 advantages of using PrEP to prevent HIV infection
3. Participants will name the high risk populations for whom PrEP is recommended
4. Participants will be able to describe how to access PrEP through the Indian Health Service

Beyond the Basics: The Science of PrEP and PEP

- **Presented by:**
- Mark Thrun, MD
- Associate Professor, University of Colorado, Division of Infectious Diseases
- Director, HIV/STD Prevention and Control, Denver Public Health
- Director, Denver Prevention Training Center

Overview

- The Data Behind PrEP
- PrEP Research
- Key Points Related to PrEP
- PrEP Resources

Evolution of HIV Therapies Related to PrEP

- Highly active antiretroviral therapy (HAART)

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- Prevention of mother-to-child transmission (PMTCT)

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- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)

**Evolution of HIV Therapies
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- Highly active antiretroviral therapy (HAART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Pre-exposure prophylaxis (PrEP)

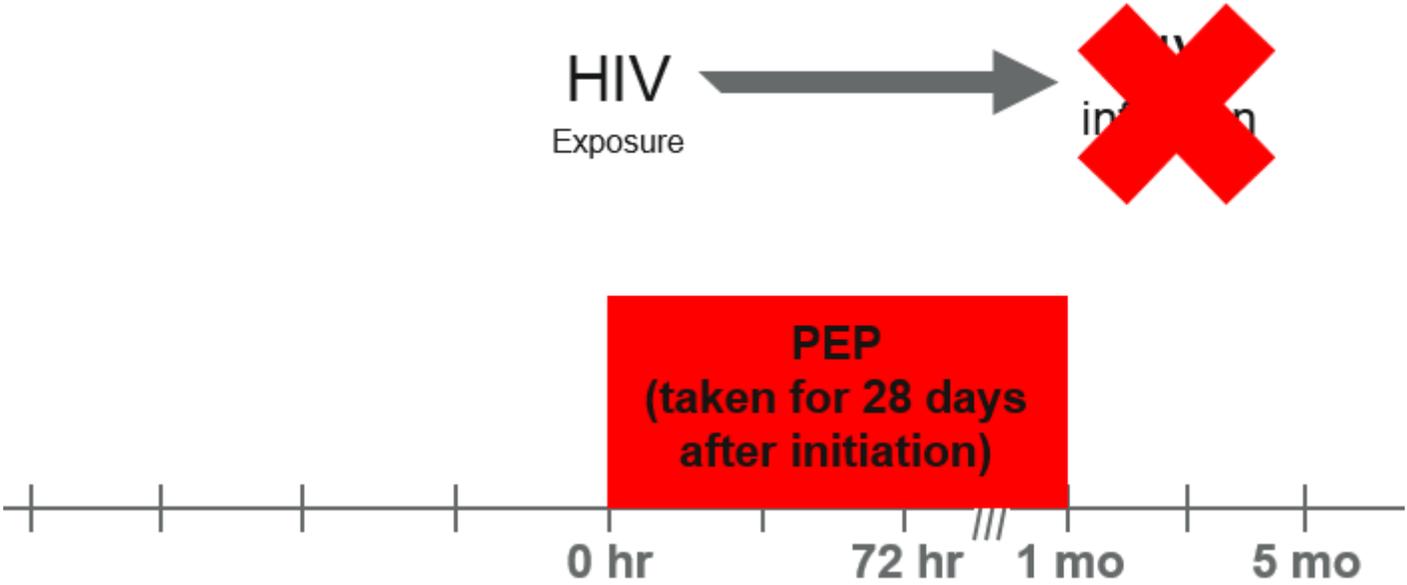
PEP and PrEP

- **PEP:** Utilizing antiretroviral HIV medications to prevent HIV infection following an exposure to HIV
- **PrEP:** Utilizing antiretroviral HIV medications to prevent HIV infection before an exposure to HIV

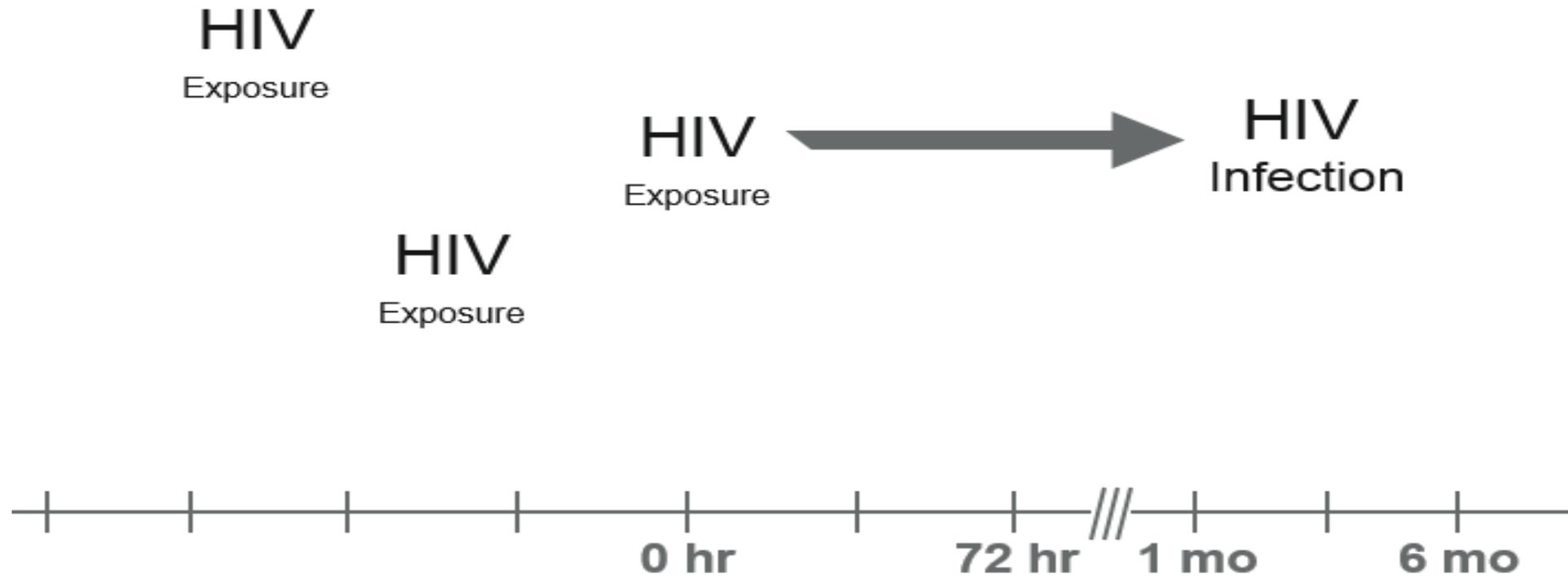
PEP: Isolated HIV Exposure



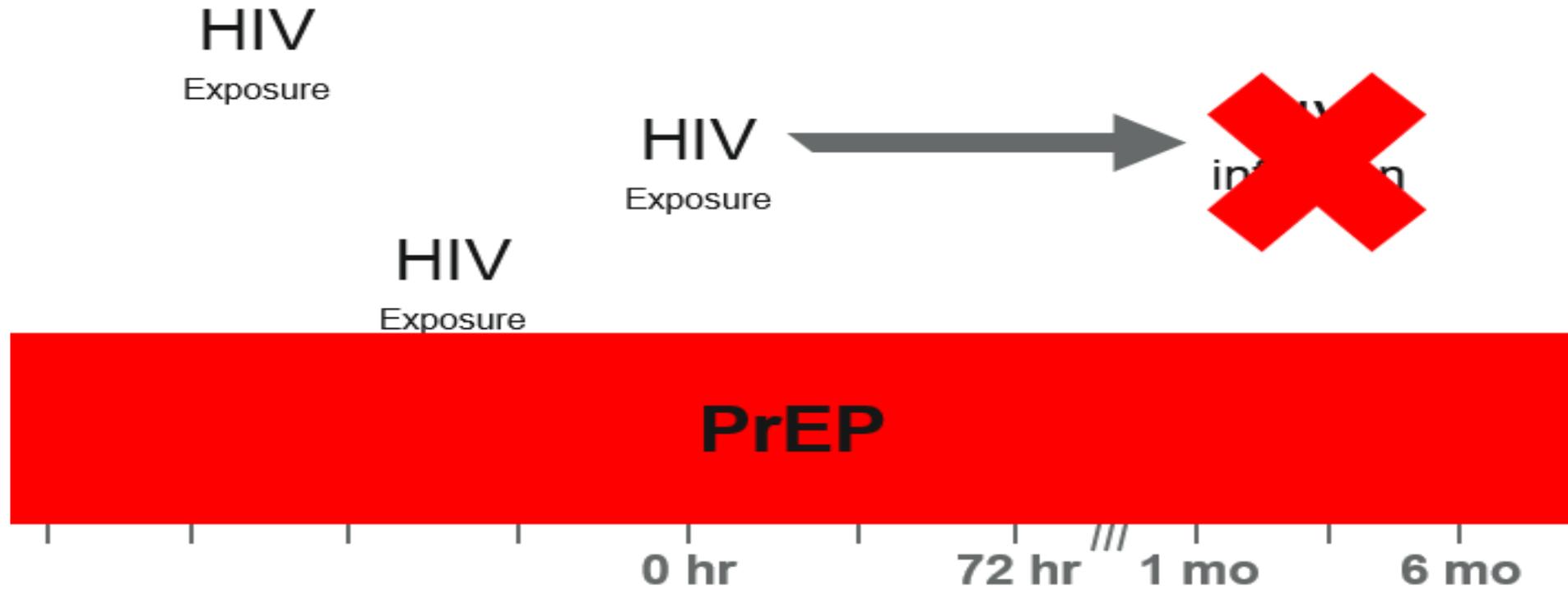
PEP: Prevents Infection After Isolated Exposure



PrEP: Multiple Exposures



PrEP: Prevents Infection Before Exposure

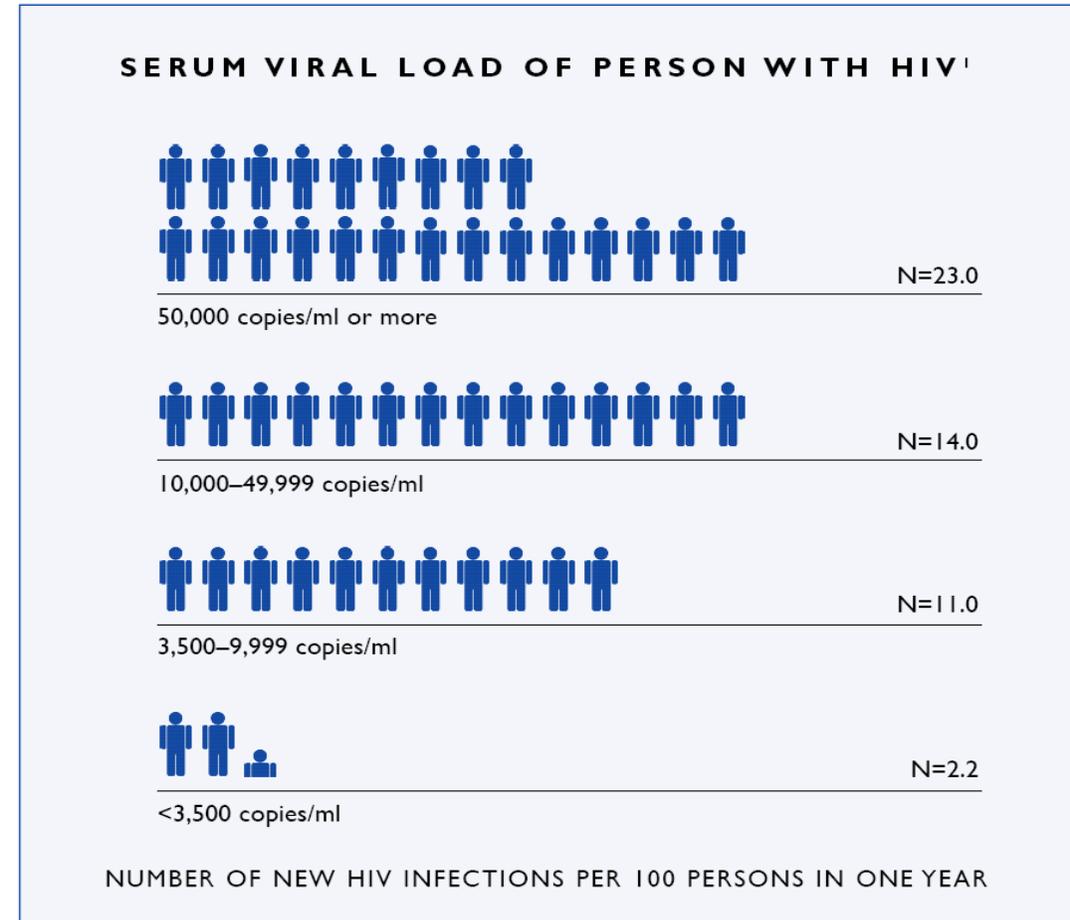


Treatment as Prevention

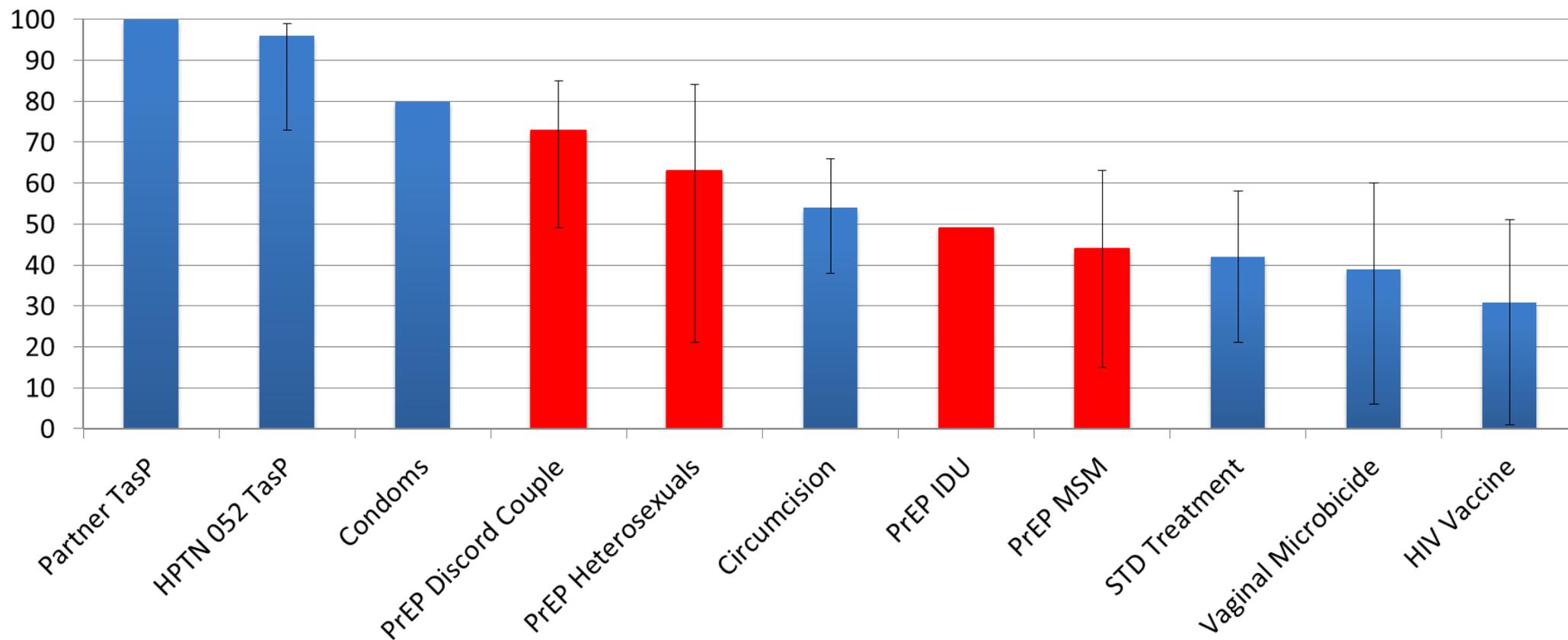
- People living with HIV use antiretroviral medications to reduce their viral load to undetectable levels.
- With an undetectable viral load, the likelihood of passing the virus on to another person is greatly reduced.

Relationship Between HIV Viral Load and HIV Transmission

- HIV viral load is closely associated with HIV transmission
- The lower the viral load, the less likely HIV is to be transmitted



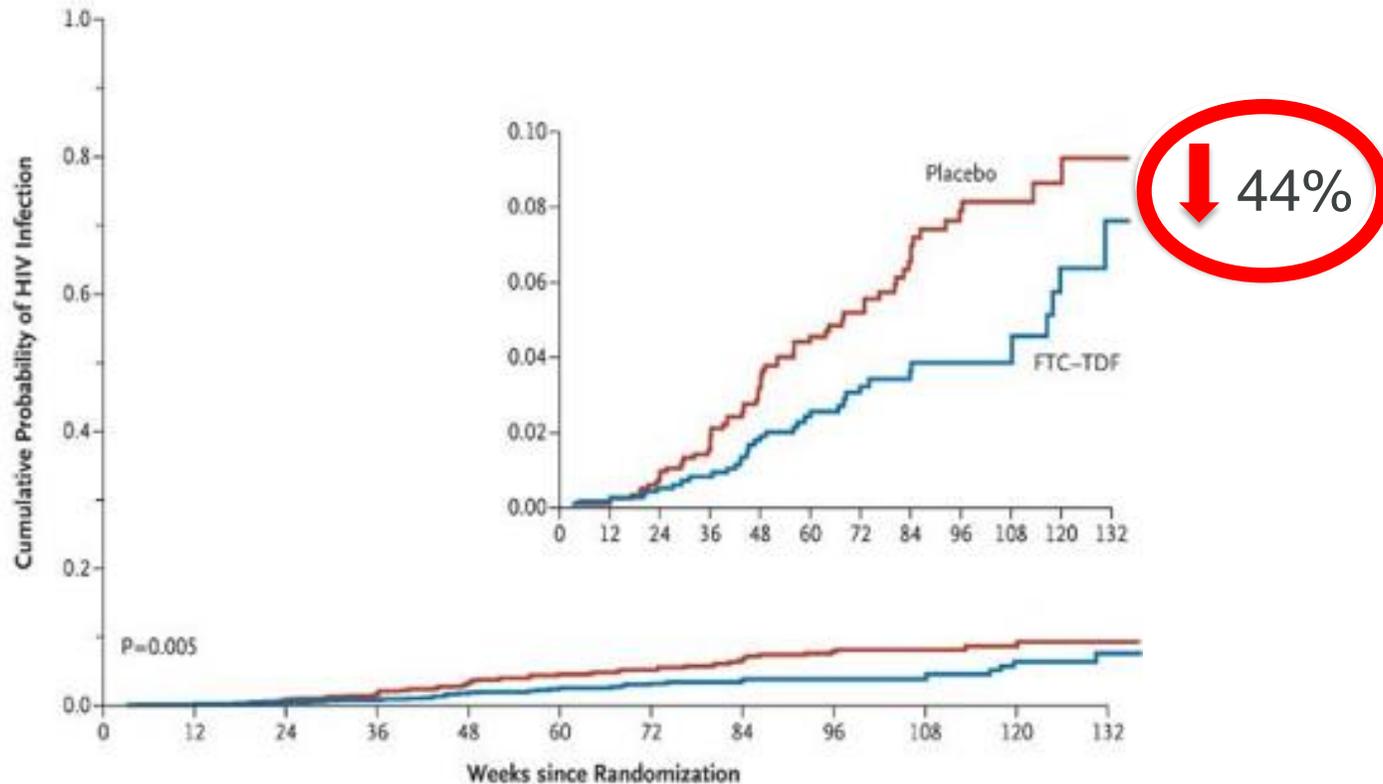
Prevention Science Overview: Biomedical Intervention Efficacy



PrEP

- Treatment before exposure to HIV

iPrEx Study: PrEP in MSM



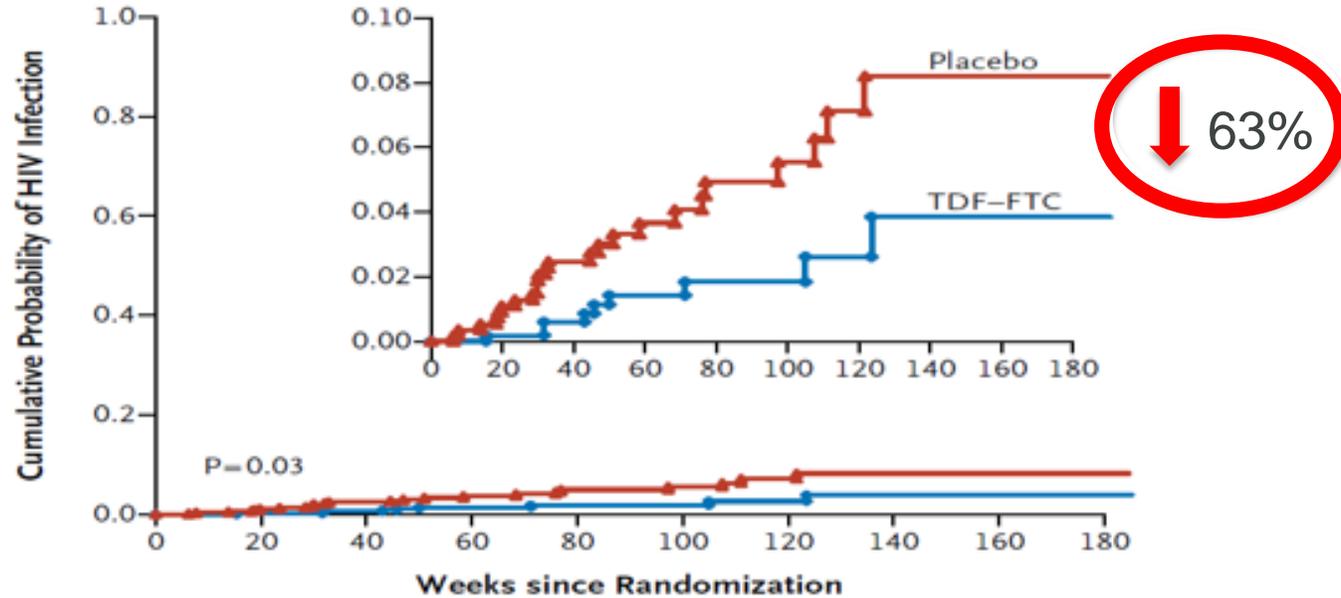
No. at Risk	0	12	24	36	48	60	72	84	96	108	120	132
Placebo	1248	1194	1108	1005	852	647	546	444	370	258	137	60
FTC-TDF	1251	1188	1097	988	848	693	558	447	367	267	147	65

HIV Infection
64
36

Among the men with detectable levels of medicine in their blood (meaning they had taken the pill

TDF2: Heterosexual PrEP Study

A Modified Intention-to-Treat Analysis



No. at Risk

Placebo	606	529	403	275	208	147	86	44	9	1
TDF-FTC	610	534	406	276	210	142	81	43	7	1

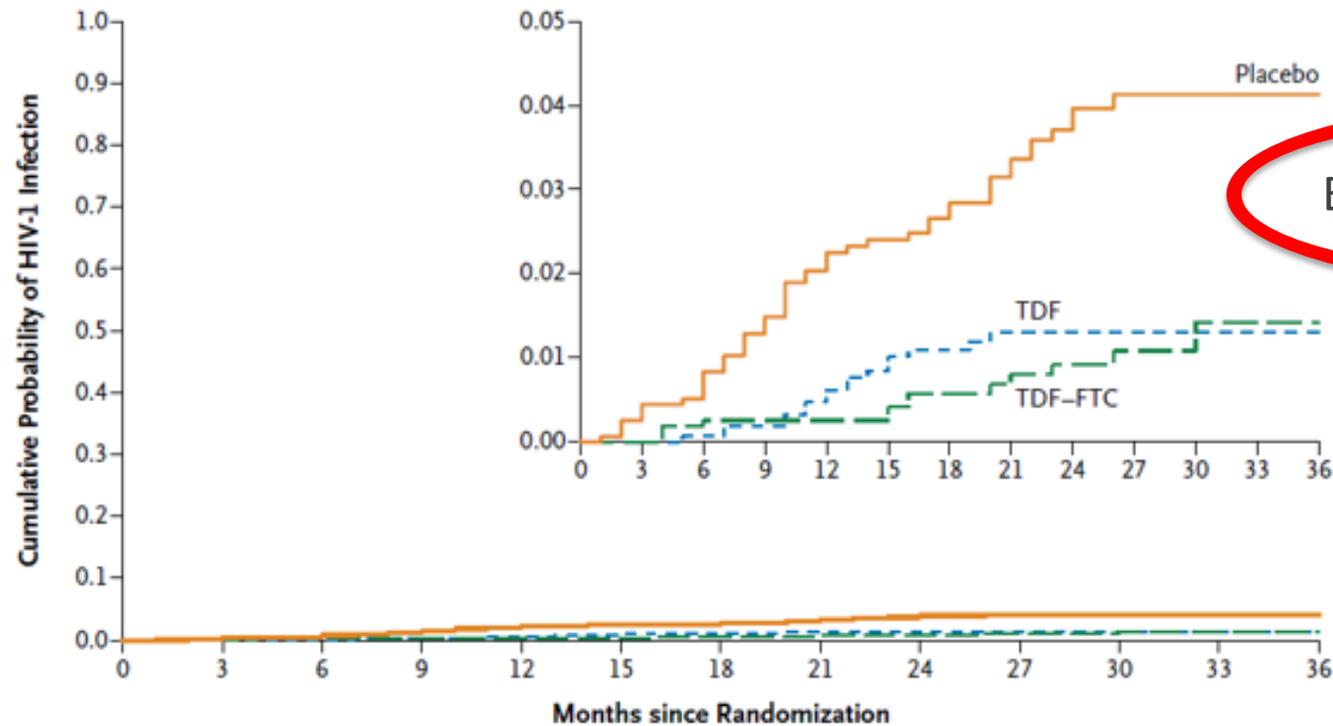
Cumulative No. of HIV Infections

Placebo	0	6	13	17	20	21	23	24	24	24
TDF-FTC	0	1	3	6	7	7	8	9	9	9

Participants who became infected had far less drug in their blood, compared with

matched

Partners PrEP Study: Heterosexual Serodiscordant Couples



Efficacy: 62 – 73%

Among those with detectable levels of medicine in their

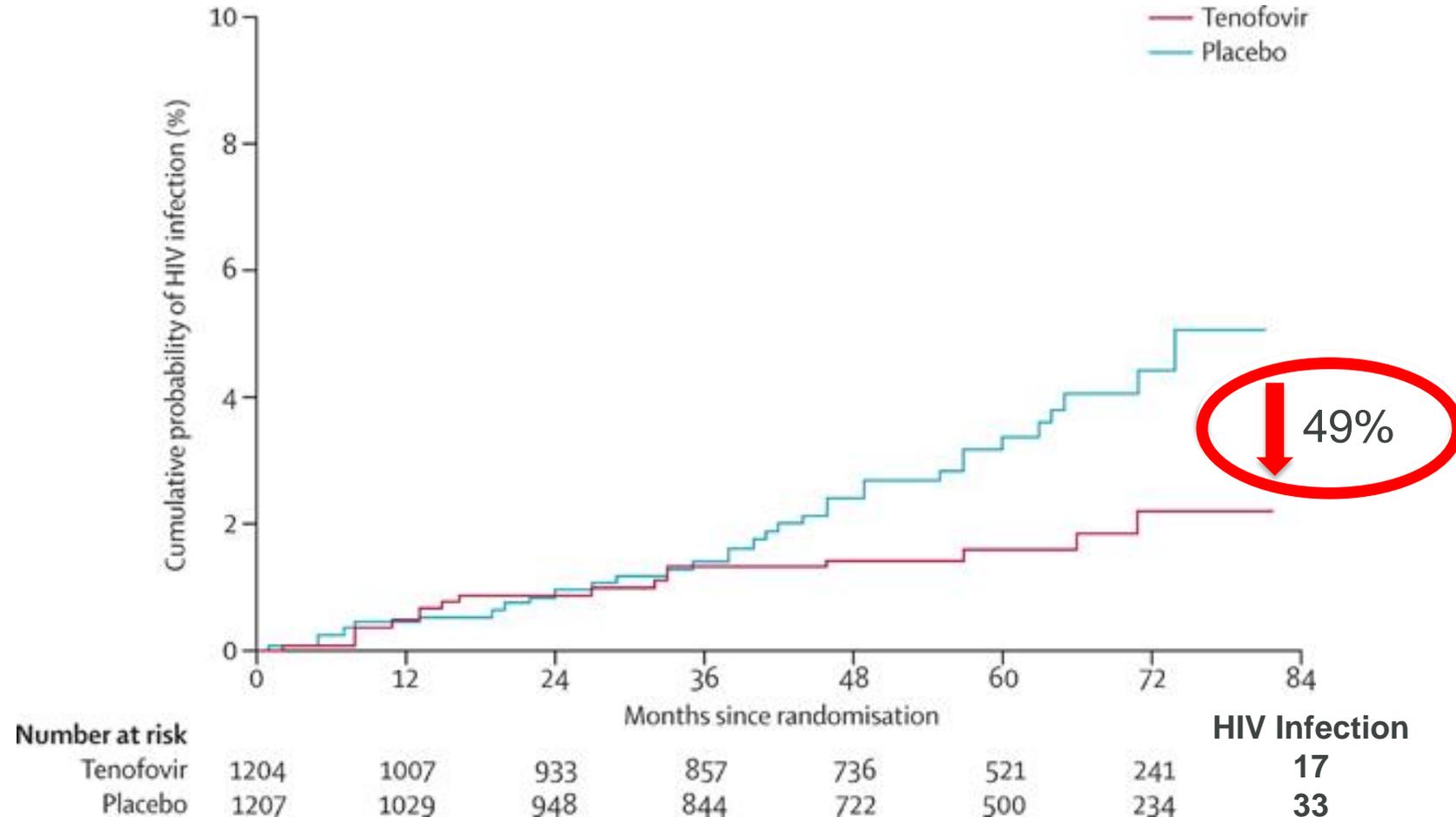
No. at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TDF	1572	1559	1547	1498	1350	1223	1062	902	735	510	287	108	15
TDF-FTC	1568	1557	1546	1493	1371	1248	1059	901	743	525	291	114	16
Placebo	1568	1557	1544	1487	1347	1224	1061	902	744	523	295	120	18

New Infection
17
13
52

without PrEP
reduced the risk of

HIV infection by up to 73%
N Engl J Med 2012;367:399-410.

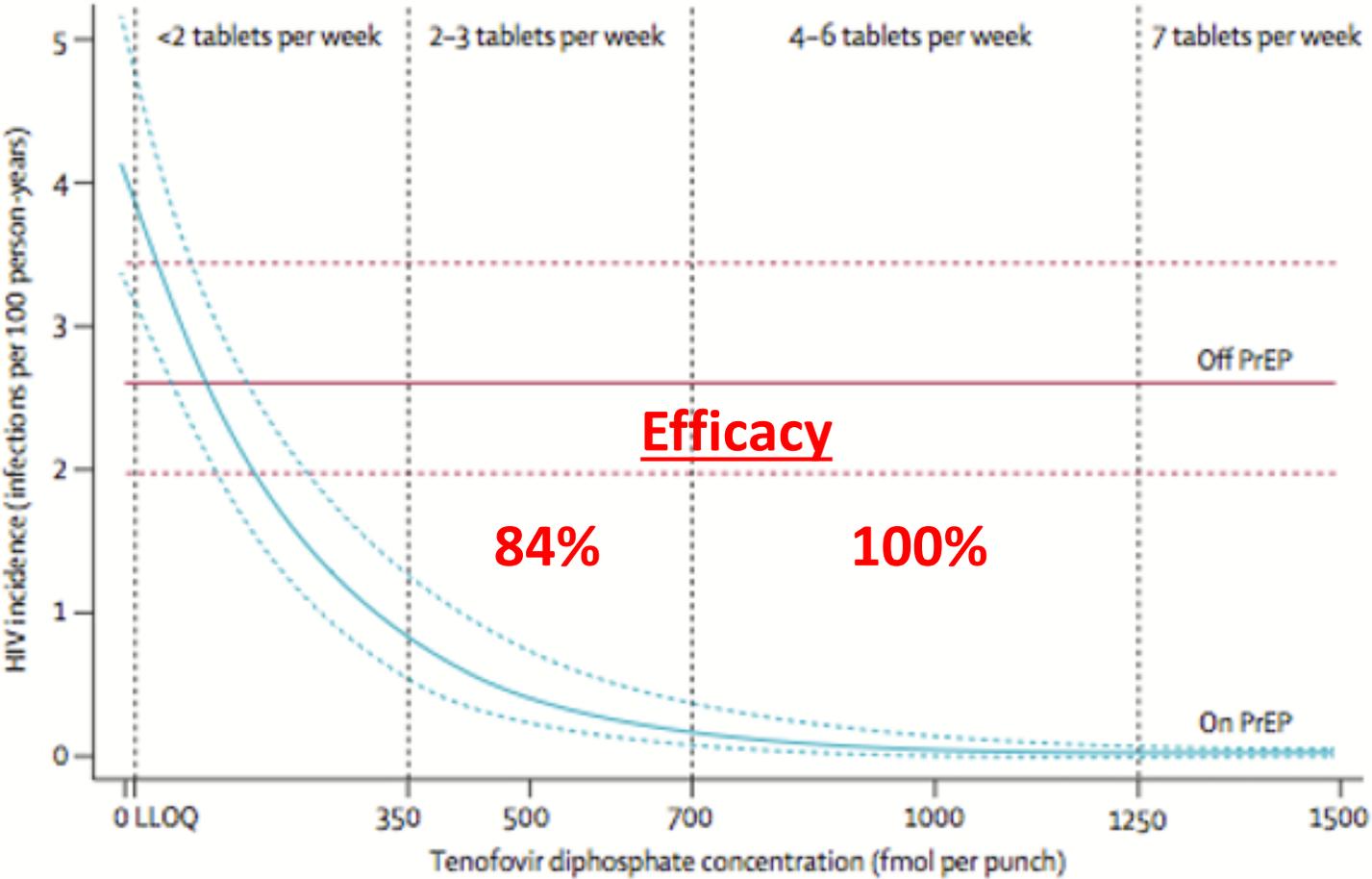
Bangkok Tenofovir Study: PrEP in Injection Drug Users



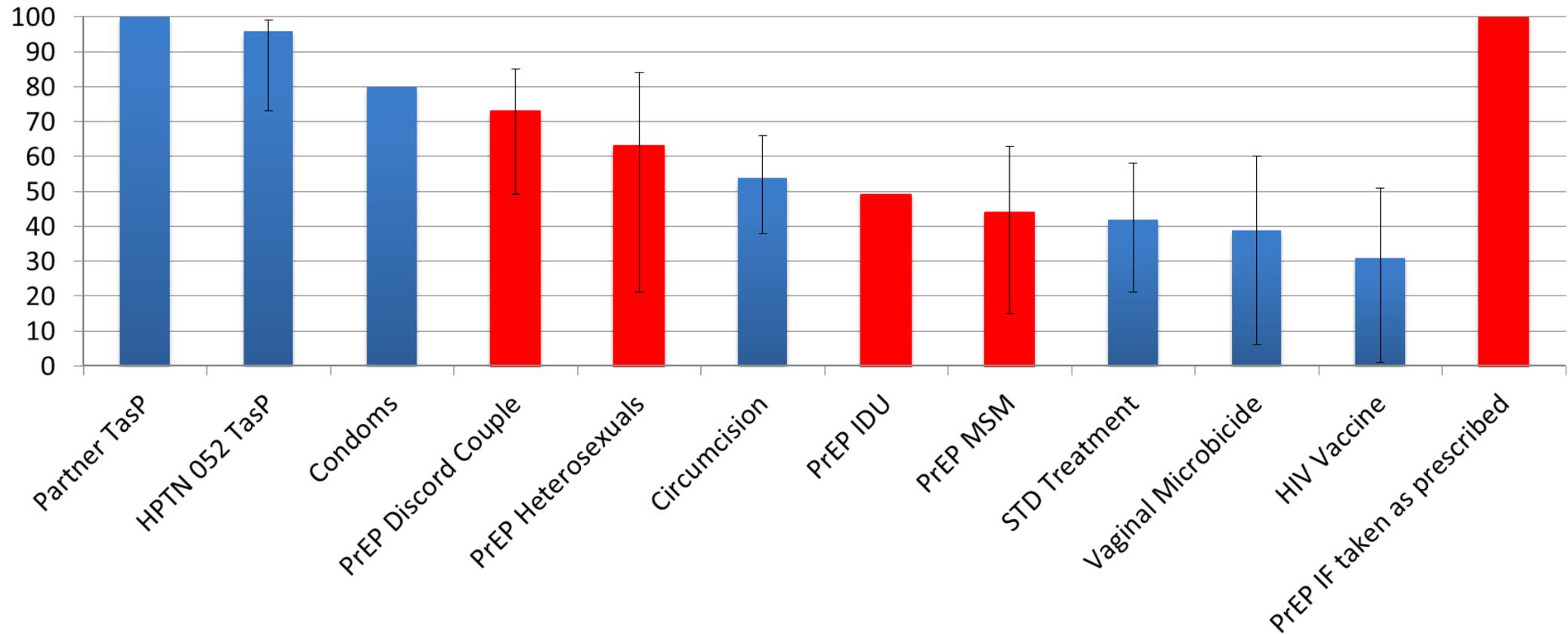
What else have the PrEP studies shown?

- Key points to remember about PrEP:
- Adherence is closely associated with PrEP efficacy
 - Though rare, side effects are possible
 - Undertake ongoing behavioral risk discussions

Increased Adherence Associated with Increased Efficacy



Prevention Science Overview: Biomedical Intervention Efficacy



Side Effects

Similar to those seen following years of antiretroviral use in persons living with HIV:

- Diarrhea
- Headache
- Nausea
- Renal dysfunction
- Antiretroviral resistance
- *Bone mineral density loss (has been noted in persons living with HIV, but not yet seen in persons taking PrEP)*

Behavioral Risk Discussions

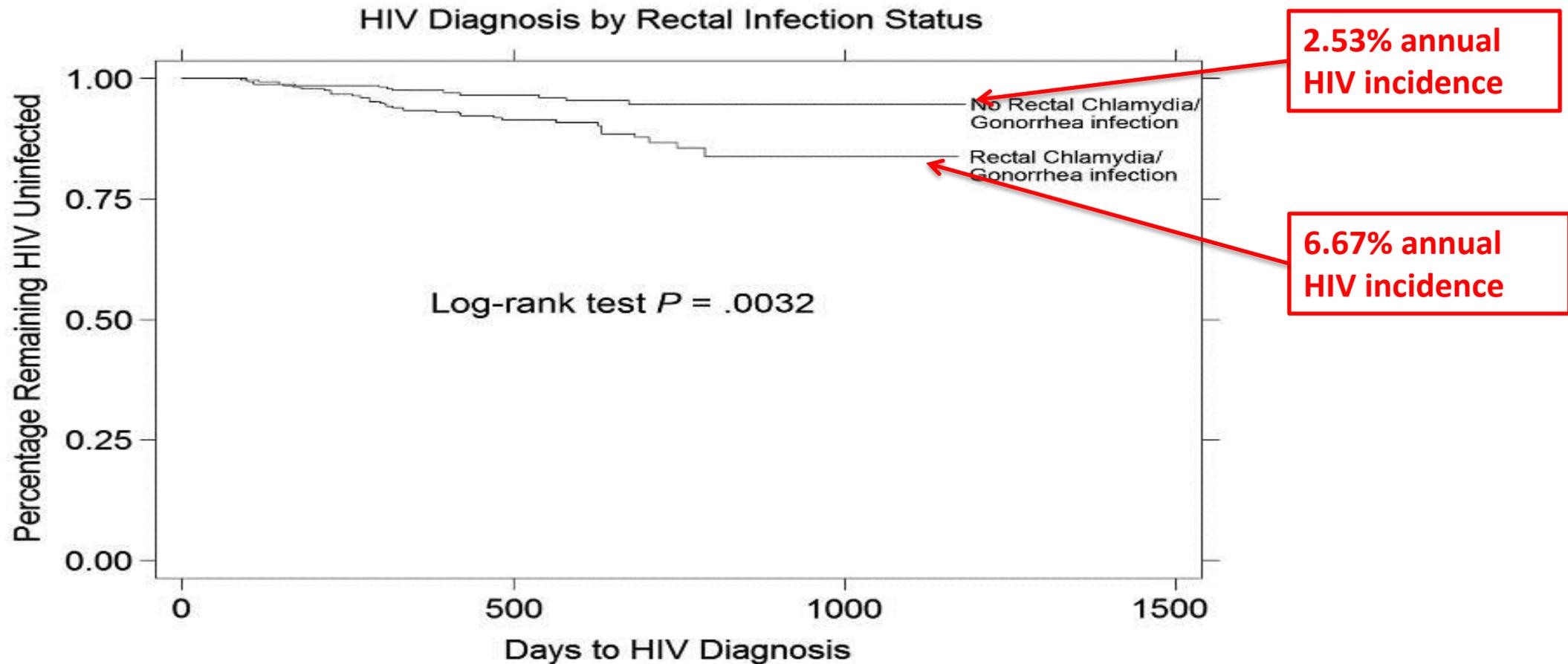
- PrEP is a biomedical AND a behavioral intervention
- Adherence is closely associated with efficacy
- Behavioral disinhibition – though not seen in the studies – could potentially negate PrEP benefits in real world use settings
- Ongoing risk discussions and risk reduction planning should be an integral component to PrEP

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

Ask about STDs: HIV Incidence Increased Following Rectal Bacterial Infections in MSM



Ask about STDs: HIV Incidence Increased in MSM with Prior Syphilis

- Results from the iPrEx study of PrEP in MSM:
 - 2.8 cases of HIV per 100 person-years follow up for those with ***no incident syphilis***
 - 8.0 cases of HIV per 100 person-years follow up for those with ***incident syphilis***
- Hazard ratio of 2.6 for acquiring HIV for those with syphilis

Denver Public Health Fact Sheet



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Pre-Exposure Prophylaxis (PrEP) for HIV

Pre-exposure Prophylaxis (PrEP) is one way to help prevent HIV infection. Prophylaxis means disease prevention. In this approach, people who do not have HIV infection take one pill once a day to reduce the risk of becoming infected. The pill includes two of the same medications used to treat HIV infection.

How does PrEP work to prevent HIV?

PrEP medicines limit HIV's ability to enter into and grow in the body.

- These medications are typically used to treat people living with HIV. They are very effective in keeping the virus under control by preventing it from dividing and spreading in the body.
- By stopping HIV virus from dividing and spreading, these medications also prevent new infection.
- Truvada® is the only current FDA-approved medication to be used for PrEP.

Who should use PrEP for HIV?

PrEP is recommended for people who do not have HIV infection and who are at increased risk for HIV. This includes, but is not limited to:

- Gay, bisexual, and other men who have sex with men who engage in unprotected sex.
- HIV-negative individuals (men and women) who have an HIV-positive sexual partner.
- Injection drug users.

How well does PrEP work?

- Several studies have shown PrEP to be more than 90% effective in preventing HIV when used daily. The level of protection will decrease if doses are missed.
- PrEP is most effective when combined with other prevention efforts, including using condoms and engaging in counseling.

Does PrEP prevent other sexually transmitted diseases (STDs)?

No, PrEP does not prevent other STDs. However, using safer sex practices, such as condoms, will prevent STDs and pregnancy while also adding more protection from HIV.

What should an individual expect if they use PrEP?

Taking PrEP for HIV requires a commitment to:

- Intake interview and counseling.
- Testing for HIV and STDs, hepatitis B, and kidney function before starting PrEP.
- Taking a pill every day.
- Regular medical visits every three months after starting PrEP for follow-up HIV tests and evaluation.

Are there side effects to taking PrEP?

- People living with HIV have used Truvada® and other similar medications for several years. They are generally easy and safe to take.
- Some people experience nausea, headaches, and loss of appetite. These can be treated and are not life threatening.
- Rare long-term side effects include loss of bone density and kidney problems.

Is PrEP covered by insurance?

Yes, most insurance and Colorado Medicaid cover the cost minus a co-pay or deductible.

Who can individuals contact to talk about using PrEP?

Individuals who think they are at increased risk for HIV should talk with the Linkage to Care team at Denver Public Health by calling (303) 602-3652 for information, questions about insurance coverage, and referrals.

SOURCES: AIDS InfoNet, Centers for Disease Control and Prevention, Denver Public Health

CDC Guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



Clinical Provider's Supplement

US PUBLIC HEALTH SERVICE

PREEXPOSURE PROPHYLAXIS
FOR THE PREVENTION OF HIV
INFECTION IN THE UNITED
STATES – 2014

CLINICAL PROVIDERS' SUPPLEMENT



NACCHO's Educational Series on PrEP

NACHHO.ORG/HIVPREP

Module 1

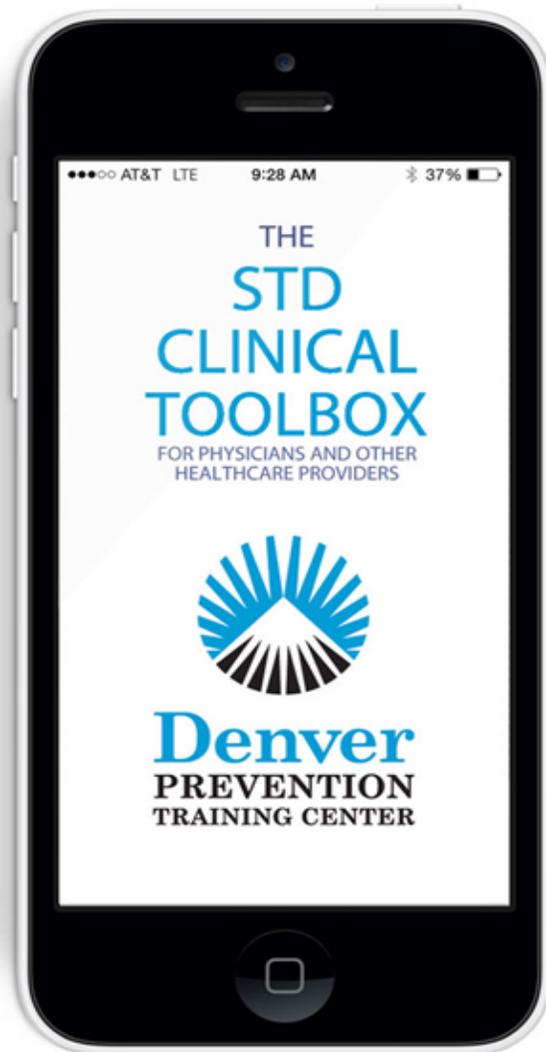
- PrEP for HIV Prevention: An Introduction
- **Beyond the Basics: The Science of PrEP**
- US Public Health Service Clinical Practice Guidelines for PrEP

Module 2

- Who Might Benefit from PrEP: Population-level Risk Assessments
- Who Might Benefit from PrEP: Individual-level Risk Assessments

Module 3

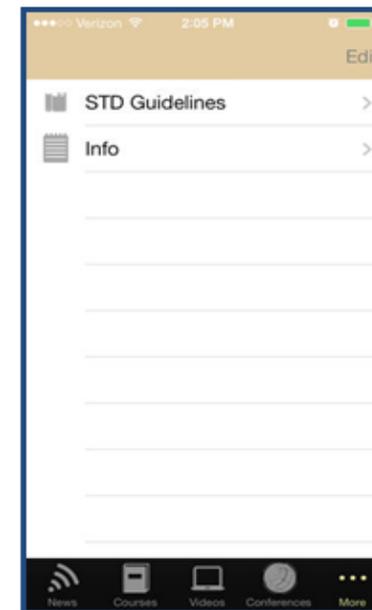
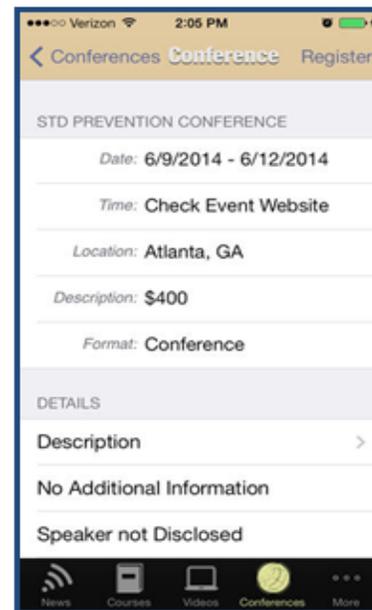
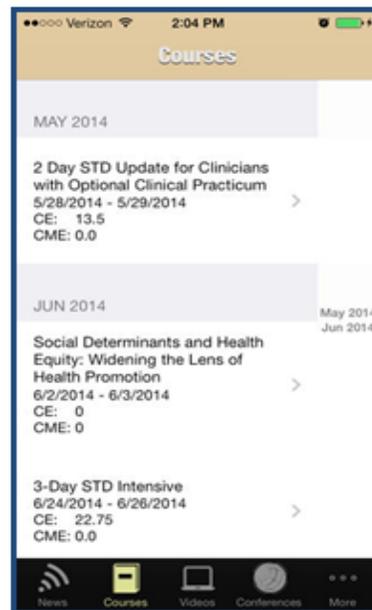
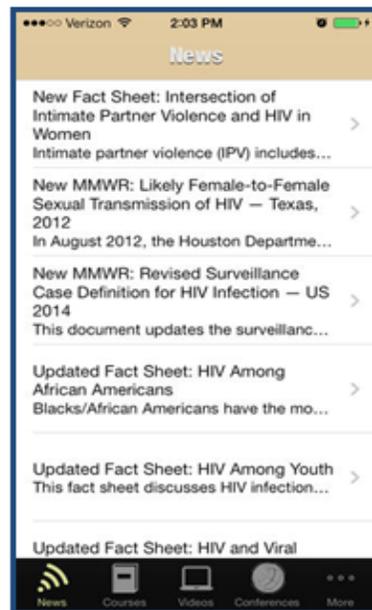
- Increasing PrEP Awareness and Knowledge in Your Jurisdiction
- Incorporating PrEP into Comprehensive HIV Prevention Programs



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A Brief Overview: PrEP and the Indian Health Service

Indian Health Service Units



Whose Eligible?

- Individuals engaging in high risk activity known to transmit HIV:
 - - unprotected anal/vaginal sex
 - - multiple partners
 - - injection drug use

Initiation

Discussions to begin PrEP may begin with:

- a) Patient request to obtain medication
- b) Introduction by the health care provider after risk assessment for HIV and/or STDs

Indian Health Service Pharmacies

- Although it may take some time, IHS Pharmacies can obtain and dispense PrEP medication to provided that:
 1. Patient is under the care of a IHS health care provider whose willing to manage that patients' care
 2. IHS provider(s) is/are aware of the indications of Truvada beyond HIV treatment and care

PrEP Maintenance

- Involves:
 - a) Regular clinic visits determined by a health care provider
 - b) Lab collection to test for HIV infection, STD infection and monitor liver function
 - c) Risk reduction for HIV and/or STD acquisition counseling
 - d) Explicit instructions on how to take PrEP properly

Who Pays for PrEP?

1. Prescriptions for PrEP are accepted by most insurance programs
2. If insurance is not an option, Medication Assistance Programs are available

Practical Tips for Patients

1. PrEP is a medication that requires adherence
2. PrEP requires regular visits to the doctor for lab collection, brief physical exam and risk assessment
3. Condom use is strongly suggested even while taking PrEP
4. PrEP is not an HIV Vaccine; when used as prescribed by your provider can prevent HIV infection among those who don't have HIV

Questions?

Thank You!

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- Ph# (720) 382-2244

- Mark Thrun, MD – University of Colorado, Division of Infectious Diseases
- Director, HIV/STD Prevention and Control, Denver Public Health
- Director, Denver Prevention Training Center