Pre-exposure Prophylaxis for HIV

Sean Kelly, MD
Southeast AIDS Education and Training Center
Champion's Academy
April 12, 2024

Disclosures

- I have served on an advisory board for ViiV.

Objectives

- Learn from each other
- Describe the PrEP agents
- Describe PrEP dosing, adverse events, and monitoring
- Maximize HIV and STI risk reduction
- Describe principles of taking a sexual history
- Utilize a validated framework/blueprint to take an effective sexual history
- Utilize an effective script and verbiage when taking a sexual history

PrEP is primary prevention

It is intended to PREVENT the onset of a disease in those who are AT RISK

It is a concept, fulfilled by medication that has been FDA-approved for this purpose

Primary Prevention

	HIV	Myocardial infarction or Stroke
Assess risk	Take a sexual history	Take a past medical, family, social history, check cholesterol and screen for diabetes, calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines
Laboratory evaluation	Serum creatinine, HIV screen	Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c
Further risk reduction	Condom use, sexual health and substance use counseling, STI screening	Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation
Medication options	Truvada® Descovy®	Atorvastatin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin Aspirin

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PrEP IS EASY

PrEP efficacy studies summary

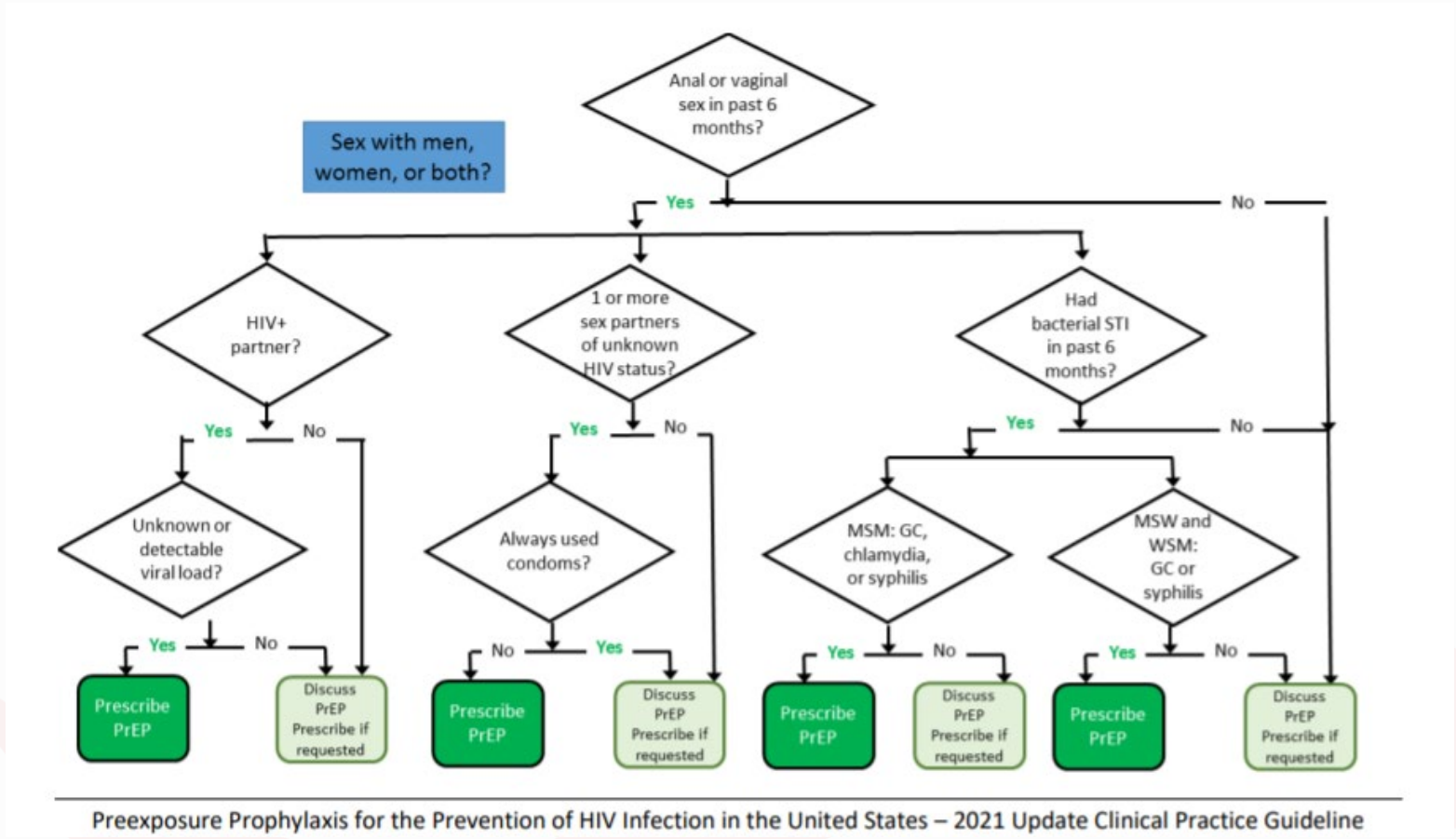
Study	Population	Dosing	Risk Reduction
iPrEX	MSM, transgender women	Daily	44% (92% with ideal adherence)
TDF2	Heterosexual men and women	Daily	62.2% (100% in open-label extension with regular follow-up)
Partners	Sero-discordant heterosexual couples	Daily	75% (90% with ideal adherence)
Bangkok Tenofovir Study Group	Intravenous drug users	Daily	48.9% (74% with ideal adherence)
IPERGAY	MSM	On-demand	86%

Case 1

- During a busy clinic day, you meet 4 new patients.
  - Linda, a Black cisgender woman with 5 cisgender male partners in the past 6 months
  - Skye, a White transgender woman with 2 cisgender male partners over the past 6 months
  - Mike, a White cisgender man who has had cisgender male and female partners in the past, but none in the past 2 years.
  - Tanner, a Hispanic cisgender man with one consistent cisgender male partner, who he married 18 months ago.

- With which of these patients should you discuss PrEP?

Discuss with everyone!



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

PrEP eligibility

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:	• Sexual partner with HIV • Recent bacterial STD • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• 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	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)
Clinically eligible:	• 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 doeses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	• 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		
	• Do oral/rectal STD testing	• Assess pregnancy intent • Pregnancy test every 3 months	• 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.

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility

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Detecting substantial risk of acquiring HIV infection:	• Sexual p • Recent b • High nu partners • History o no cond • Commer		
Clinically eligible:	• Do • No • No • Do		
Prescription			
Other services:	• Fol • HIV sid • At • Eve		
	• Do oral/re		

Source: US Public Health Service. Preexposure proph

HIRI-MSM Risk Index*

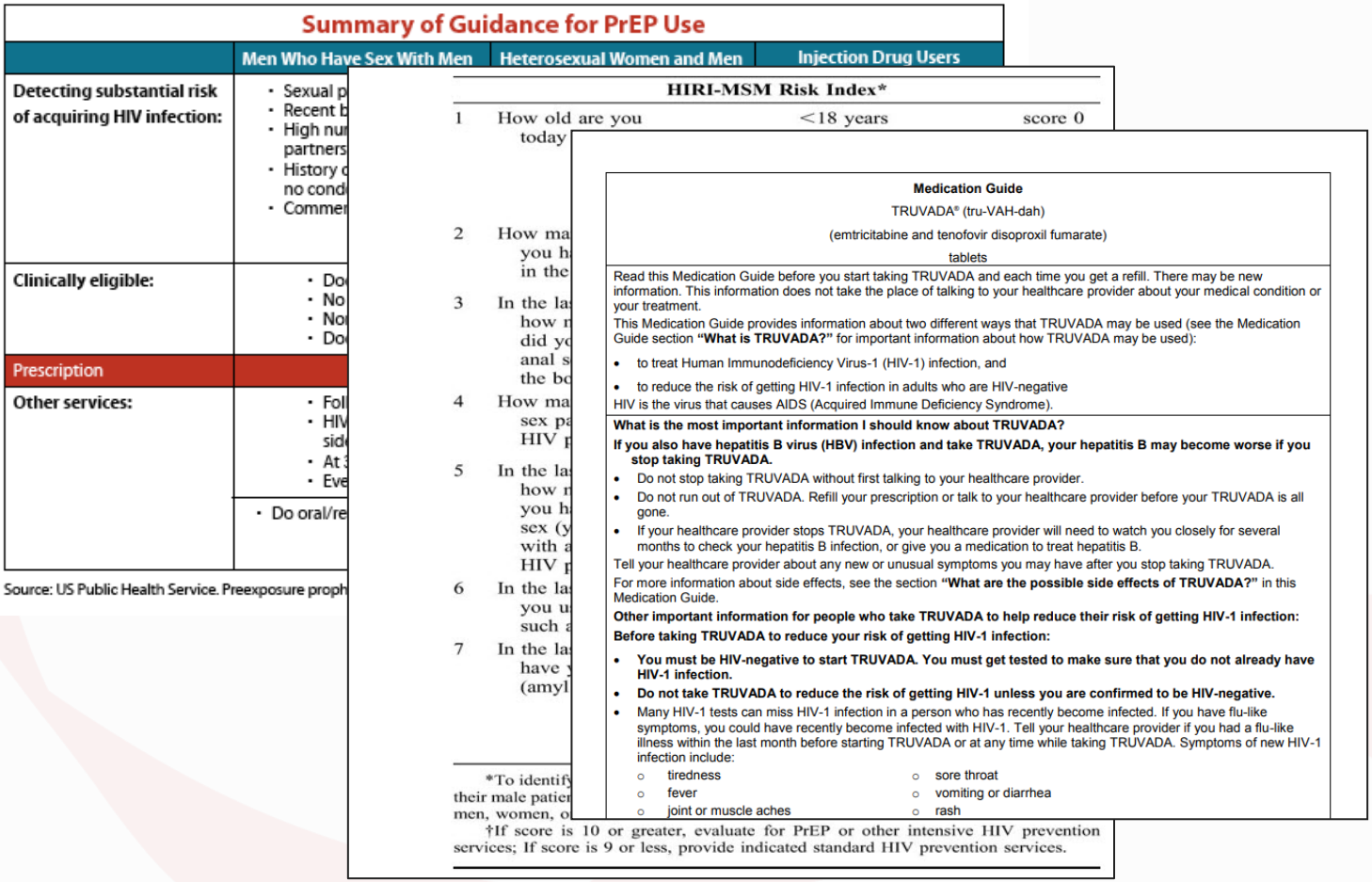
1	How old are you today (yrs)?	<18 years	score 0
		18–28 years	score 8
		29–40 years	score 5
		41–48 years	score 2
		≥49 years	score 0
2	How many men have you had sex with in the last 6 months?	>10 male partners	score 7
		6–10 male partners	score 4
		0–5 male partners	score 0
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?	1 or more times	score 10
		0 times	score 0
4	How many of your male sex partners were HIV positive?	>1 positive partner	score 8
		1 positive partner	score 4
		<1 positive partner	score 0
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times	score 6
		0 times	score 0
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes	score 5
		No	score 0
7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes	score 3
		No	score 0
		Add down entries in right column to calculate total score	Total score†

*To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: "In the past (time) have you had sex? (if yes), with men, women, or both?"

†If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility



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5	In the la how r you h sex (y with a HIV p		
6	In the la you u such a		
7	In the la have y (amyl		

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Medication Guide

TRUVADA® (tru-VAH-dah)

(emtricitabine and tenofovir disoproxil fumarate)

tablets

Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication Guide section **"What is TRUVADA?"** for important information about how TRUVADA may be used):

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and
- to reduce the risk of getting HIV-1 infection in adults who are HIV-negative

HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

What is the most important information I should know about TRUVADA?

If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.

- Do not stop taking TRUVADA without first talking to your healthcare provider.
- Do not run out of TRUVADA. Refill your prescription or talk to your healthcare provider before your TRUVADA is all gone.
- If your healthcare provider stops TRUVADA, your healthcare provider will need to watch you closely for several months to check your hepatitis B infection, or give you a medication to treat hepatitis B.

Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking TRUVADA.

For more information about side effects, see the section **"What are the possible side effects of TRUVADA?"** in this Medication Guide.

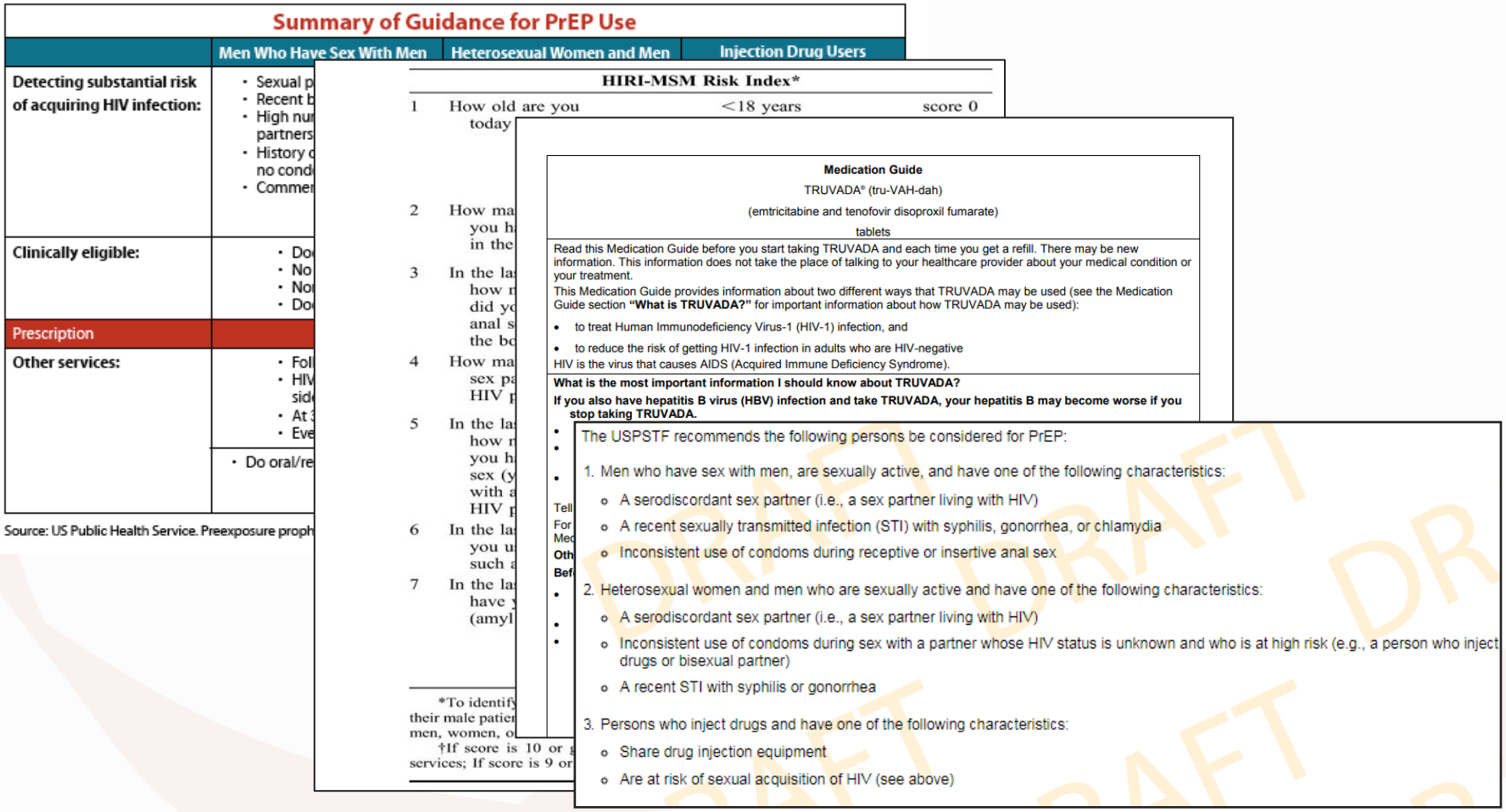
Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection:

Before taking TRUVADA to reduce your risk of getting HIV-1 infection:

- **You must be HIV-negative to start TRUVADA. You must get tested to make sure that you do not already have HIV-1 infection.**
- **Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.**
- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting TRUVADA or at any time while taking TRUVADA. Symptoms of new HIV-1 infection include:
  - tiredness
  - fever
  - joint or muscle aches
  - sore throat
  - vomiting or diarrhea
  - rash

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility



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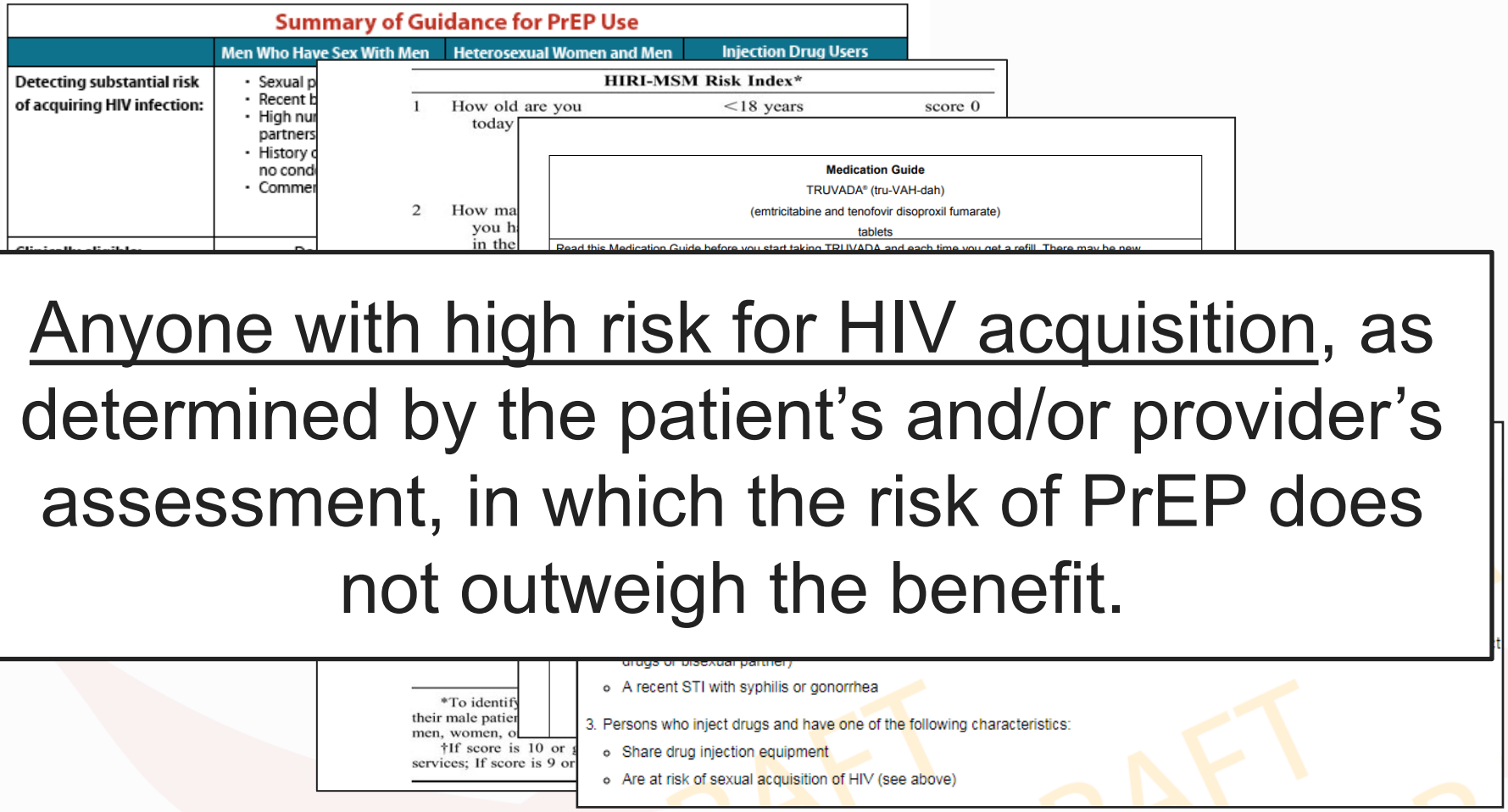
- Tell
- For
- Med
- **Oth**
- **Bef**

The USPSTF recommends the following persons be considered for PrEP:

1. Men who have sex with men, are sexually active, and have one of the following characteristics:
   - A serodiscordant sex partner (i.e., a sex partner living with HIV)
   - A recent sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia
   - Inconsistent use of condoms during receptive or insertive anal sex
2. Heterosexual women and men who are sexually active and have one of the following characteristics:
   - A serodiscordant sex partner (i.e., a sex partner living with HIV)
   - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who inject drugs or bisexual partner)
   - A recent STI with syphilis or gonorrhea
3. Persons who inject drugs and have one of the following characteristics:
   - Share drug injection equipment
   - Are at risk of sexual acquisition of HIV (see above)

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

PrEP eligibility



Anyone with high risk for HIV acquisition, as determined by the patient's and/or provider's assessment, in which the risk of PrEP does not outweigh the benefit.

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf
http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf

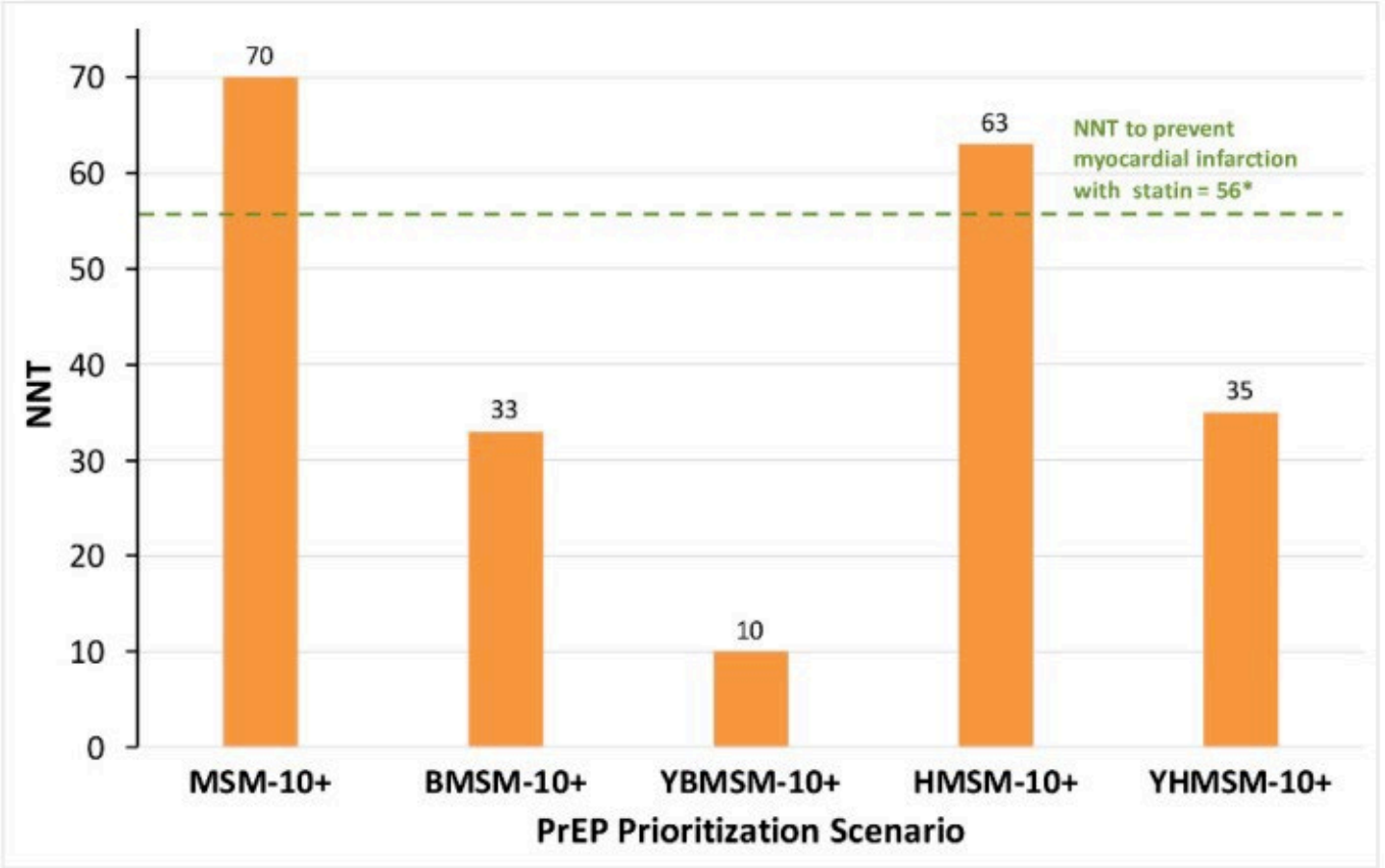
Recommendation comparisons

- 300 high risk young, black MSM (age 16-29) in Chicago
- 33 HIV acquisitions over 3 years
  - 52% met CDC eligibility for PrEP
  - 85% met HIRI-MSM eligibility for PrEP
  - 94% met drug company eligibility for PrEP

  - CDC guidelines: Low sensitivity, specificity (52%)
  - Drug company guidelines: High sensitivity, low specificity (15%)

Lancki N et al. AIDS, 2018

Number needed to treat



*MSM-10+ = PrEP prioritization scenario targeting all MSM with HIRI-MSM score of ≥10

Elion RA, Kabiri M, Mayer KH, Wohl DA, Cohen J, Beaubrun AC, Altice FL. Estimated Impact of Targeted Pre-Exposure Prophylaxis: Strategies for Men Who Have Sex with Men in the United States. Int J Environ Res Public Health. 2019 May 7;16(9):1592.

PrEP Inequity

- "*HIV prevention programs should be guided by PrEP use equity – the use of PrEP relative to the impact of the HIV epidemic on that group. Today's data shows that we have a long way to go.*"

- Patrick Sullivan, DVM, PhD,

Professor of Epidemiology at Emory University's Rollins School of Public Health.

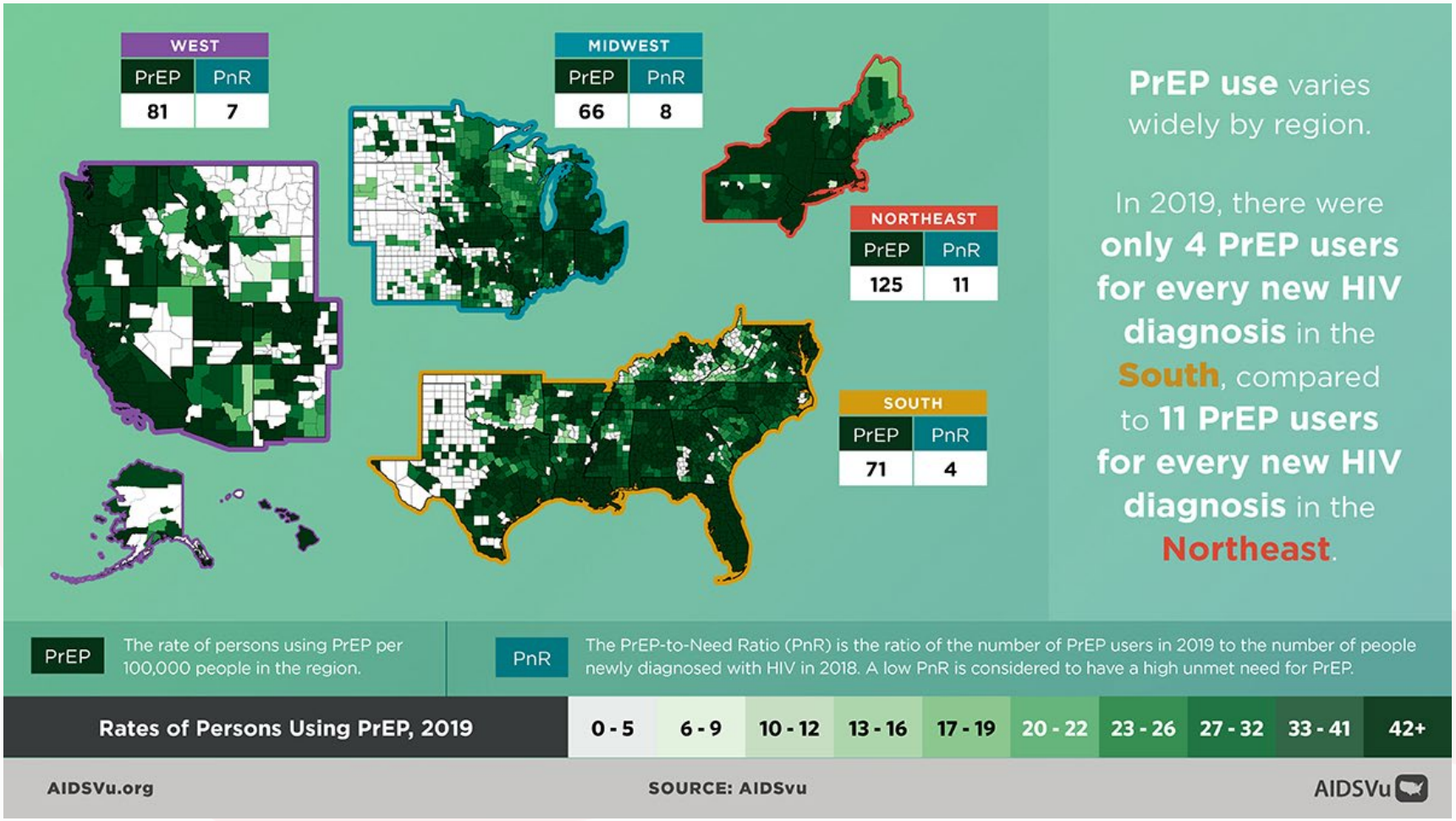
PrEP Inequity

- Black: 14% PrEP users, 42% of new HIV diagnoses
- Hispanic/LatinX: 17% of PrEP, 27% of new HIV diagnoses
- White: 65% of PrEP, 26% of new HIV diagnoses.

- Black persons made up 52% of new HIV diagnoses in the South, but only 21% of PrEP users in the South

AIDSVu.org [Accessed August 24, 2022]

PrEP-to-Need Ratio



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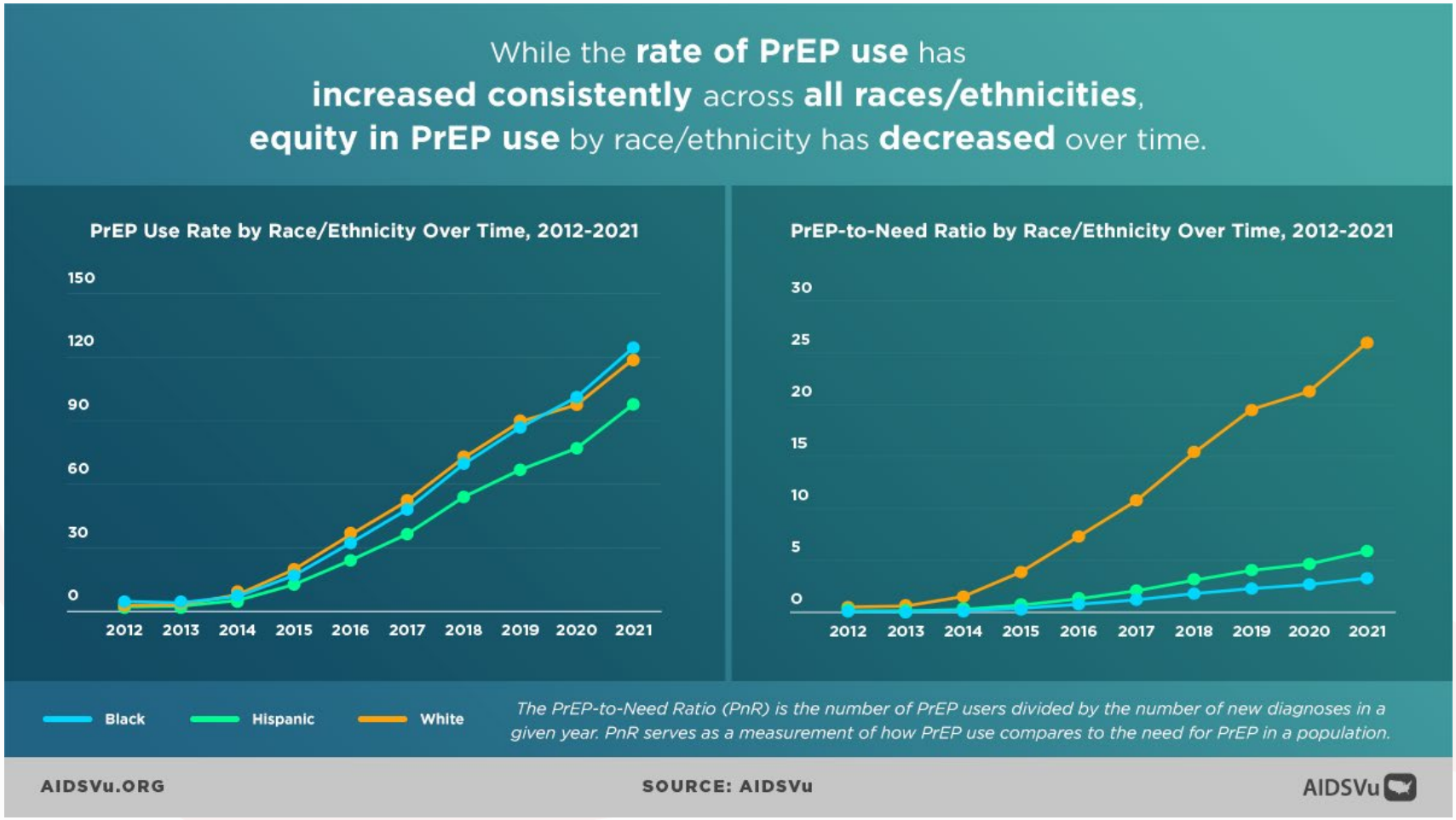

Case 2

- Alex is a 22-year-old cisgender man who has had sex with multiple male partners in the past 6 months with inconsistent condom and presents to you inquiring about starting PrEP. Last week, he underwent HIV, hepatitis C, tri-compartment GC/chlamydia, and syphilis testing at TDH, which were all negative. He has no significant past medical history, currently takes no medications, and does not inject drugs. He has employer-based insurance and is open to taking any PrEP agent that you recommend.

TDF/FTC (Truvada®)

- Fixed dose combination of tenofovir disoproxil fumarate (**TDF**) 300mg/emtricitabine (**FTC**) 200mg
- Developed by Gilead and marketed as Truvada®
- FDA-approved for use as PrEP for adults on June 6, 2012
- FDA-approved for use as PrEP for adolescents on May 15, 2018
- Generic TDF/FTC approved June 2017
  - Became available September 2020

TAF/FTC (Descovy®)

- Similar to TDF/FTC
  - Truvada® = tenofovir **disoproxil fumarate** (TDF) + emtricitabine
  - Descovy® = tenofovir **alafenamide** (TAF) + emtricitabine
- TAF/FTC demonstrated non-inferior to TDF/FTC in DISCOVER trial
- Approved for PrEP October 2, 2019 **for non-vaginal sex**
- TAF achieves high intracellular concentrations, but lower (>10-fold) plasma and tissue concentrations than TDF
  - Lower risk of BMD loss and reduced creatinine clearance
  - Can be used in chronic kidney disease (CrCl >30 mL/min)

LA cabotegravir

- Long-active injectable
  - Optional oral lead-in
  - 2 doses 1 month apart, then every 2 months
    - Consecutive doses can be given 7 days before or after target date
- Approved 12/20/21
- Demonstrated superiority to TDF/FTC
- Injection site reactions are common

https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF

Case 2

- Which agent do you recommend? Why?
  - TDF/FTC
  - TAF/FTC
  - LA cabotegravir

TAF/FTC vs TDF/FTC

TDF/FTC		TAF/FTC	
Pros	**Cons**	**Pros**	**Cons**
More data on efficacy, PK, dosing strategies…	Low risk of renal dysfunction	Lower risk of renal dysfunction	Fewer data, less experience
More experience	Reversible bone mineral density loss	Lower risk of bone mineral density loss	Can't be used for vaginal sex, IDU
Covered by all insurance	Larger pill size	Smaller pill size	Less insurance coverage
Can be used for vaginal and anal sex, IDU	Can't be used if eGFR <60	Faster time to therapeutic level	No data on 2-1-1 dosing
More brand recognition		Can be used if eGFR >30	Weight gain?
Generic available			Not cost effective

Case 2

- After discussion on all available agents used for PrEP, Alex is interested in the 2-1-1 dosing option.
- How does this work?

A. Start taking TAF/FTC before the potential exposure
B. Start taking TDF/FTC before the potential exposure
C. Start taking either TDF/FTC or TAF/FTC before the potential exposure
D. Start taking TDF/FTC PLUS dolutegravir after the potential exposure

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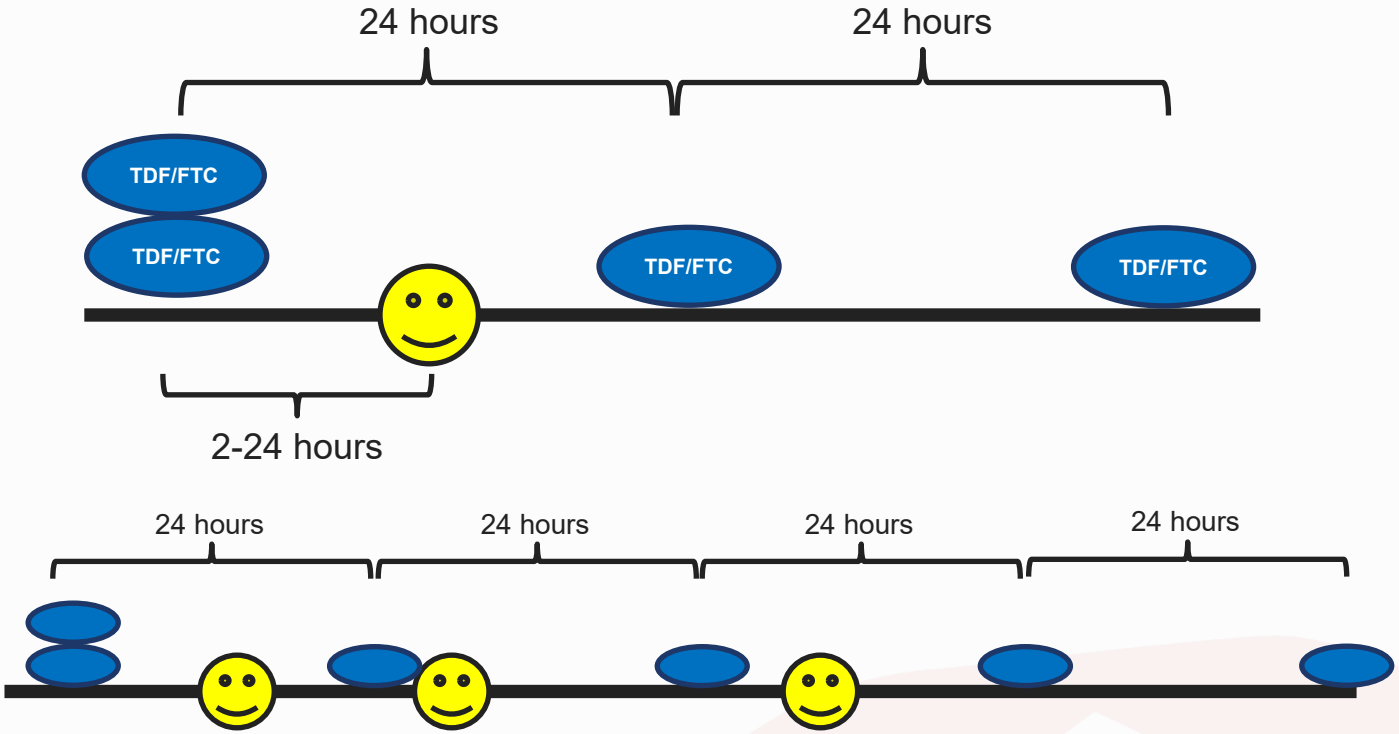
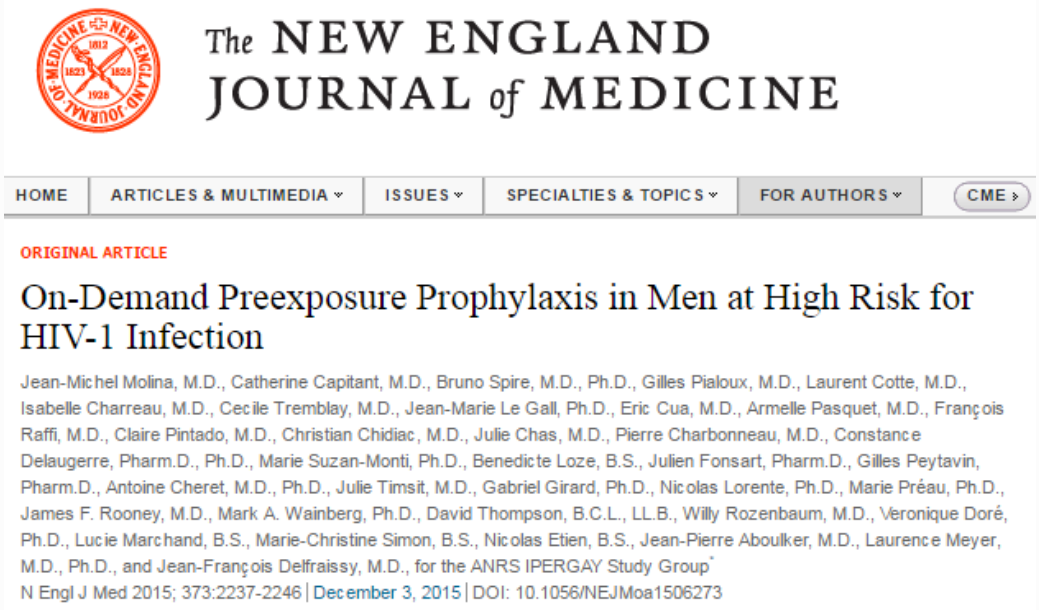
Event-Driven (2-1-1) Dosing – TDF/FTC ONLY!



- Continue 1 pill/day until 48 hours from event
- If <7 days between last pill and new event, resume one pill/24 hours (no need to double-dose)

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

IPERGAY



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ORIGINAL ARTICLE

On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

Jean-Michel Molina, M.D., Catherine Capitant, M.D., Bruno Spire, M.D., Ph.D., Gilles Pialoux, M.D., Laurent Cotte, M.D., Isabelle Charreau, M.D., Cecile Tremblay, M.D., Jean-Marie Le Gall, Ph.D., Eric Cua, M.D., Armelle Pasquet, M.D., François Raffi, M.D., Claire Pintado, M.D., Christian Chidiac, M.D., Julie Chas, M.D., Pierre Charbonneau, M.D., Constance Delaugerre, Pharm.D., Ph.D., Marie Suzan-Monti, Ph.D., Benedicte Loze, B.S., Julien Fonsart, Pharm.D., Gilles Peytavin, Pharm.D., Antoine Cheret, M.D., Ph.D., Julie Timsit, M.D., Gabriel Girard, Ph.D., Nicolas Lorente, Ph.D., Marie Préau, Ph.D., James F. Rooney, M.D., Mark A. Wainberg, Ph.D., David Thompson, B.C.L., LL.B., Willy Rozenbaum, M.D., Veronique Doré, Ph.D., Lucie Marchand, B.S., Marie-Christine Simon, B.S., Nicolas Etien, B.S., Jean-Pierre Aboulker, M.D., Laurence Meyer, M.D., Ph.D., and Jean-François Delfraissy, M.D., for the ANRS IPERGAY Study Group*

N Engl J Med 2015; 373:2237-2246 | December 3, 2015 | DOI: 10.1056/NEJMoa1506273

86% HIV risk reduction in MSM using event-driven PrEP

Event-Driven PrEP

- IPERGAY was discontinued early, all offered on-demand PrEP in open-label phase and more enrolled.
- Mean pill use: 18 pills/month (about 1 course/week)
- 97% reduction in relative risk of HIV in this extended arm versus the discontinued placebo arm

Event-Driven PrEP (ANRS IPERGAY substudy)

- Retrospective analysis of [prospectively-collected] IPERGAY data
  - Among patients who took ≤15 pills/month (~5 or fewer sex acts/month)
  - TDF/FTC vs. Placebo

	Person-Years (PY)	n HIV Infections	Incidence Rate /100 PY (95%CI)	RRR (95%CI)	p
Placebo	64.8	6	9.3 (3.4 ; 20.1)		
TDF/FTC	68.9	0	0.0 (0.0 ; 5.4)	**100% (39; 100)**	**0.013**

Antoni G, et al. Is on-demand PrEP with TDF/FTC effective among MSM with infrequent sexual intercourse? 9th IAS Conference on HIV Science (IAS 2017), July 23-26, 2017, Paris

Event-Driven (2-1-1) PrEP

- Offered by Kaiser Permanente SF since February 2019
  - Those using on-demand dosing:
    - Most cited infrequent sex as reason for this dosing (90%).
    - Some reported challenges, including difficulty planning sex in advance, adherence to the dosing schedule, and side effects (13%).
    - Few missed doses after their last sexual encounter (3%).

Case 2

- After further discussion, Alex recalls that his mother has osteoporosis, and is now concerned about bone density loss secondary to TDF/FTC.

- How do bone outcomes differ between TDF/FTC and TAF/FTC?

Bone Density Loss (TDF/FTC)

Table 3. Bone Mineral Density Scores.*

Assessment	Forearm			Hip			Lumbar Spine		
	TDF–FTC (N=109)	Placebo (N=112)	P Value	TDF–FTC (N=109)	Placebo (N=112)	P Value	TDF–FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001
Enrollment	−0.75	−0.58		0.44	0.53		−0.72	−0.59	
6 mo	−0.77	−0.50		0.33	0.57		−0.84	−0.45	
12 mo	−0.79	−0.48		0.33	0.54		−0.77	−0.56	
18 mo	−0.93	−0.27		0.17	0.77		−0.92	−0.43	
24 mo	−0.92	−0.13		0.21	0.74		−1.11	−0.37	
z Score			0.004			<0.001			<0.001
Enrollment	−0.70	−0.54		0.45	0.54		−0.67	−0.54	
6 mo	−0.73	−0.45		0.35	0.58		−0.80	−0.41	
12 mo	−0.72	−0.42		0.34	0.55		−0.74	−0.53	
18 mo	−0.88	−0.21		0.18	0.78		−0.88	−0.41	
24 mo	−0.87	−0.13		0.20	0.76		−1.09	−0.28	

* In the TDF–FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.

TDF2 Study Group, 2012

Grant RM, et al. Recovery of bone mineral density after stopping oral HIV pre-exposure prophylaxis. CROI 2016 Feb 20-24 Boston

Bone Density Loss (TDF/FTC)

Table 3. Bone Mineral Density Scores.*

Assessment	Forearm			Hip			Lumbar Spine		
	TDF–FTC (N=109)	Placebo (N=112)	P Value	TDF–FTC (N=109)	Placebo (N=112)	P Value	TDF–FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001
Enrollment	−0.75	−0.58		0.44	0.53		−0.72	−0.59	
6 mo	−0.77	−0.50		0.33	0.57		−0.84	−0.45	
6 mo	−0.73	−0.45		0.35	0.58		−0.80	−0.41	
12 mo	−0.72	−0.42		0.34	0.55		−0.74	−0.53	
18 mo	−0.88	−0.21		0.18	0.78		−0.88	−0.41	
24 mo	−0.87	−0.13		0.20	0.76		−1.09	−0.28	

* In the TDF–FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.

Significant decline in T scores and z scores for BMD at the forearm, hip, and lumbar spine in participants who received TDF/FTC, as compared with those who received placebo

TDF2 Study Group, 2012

Grant RM, et al. Recovery of bone mineral density after stopping oral HIV pre-exposure prophylaxis. CROI 2016 Feb 20-24 Boston

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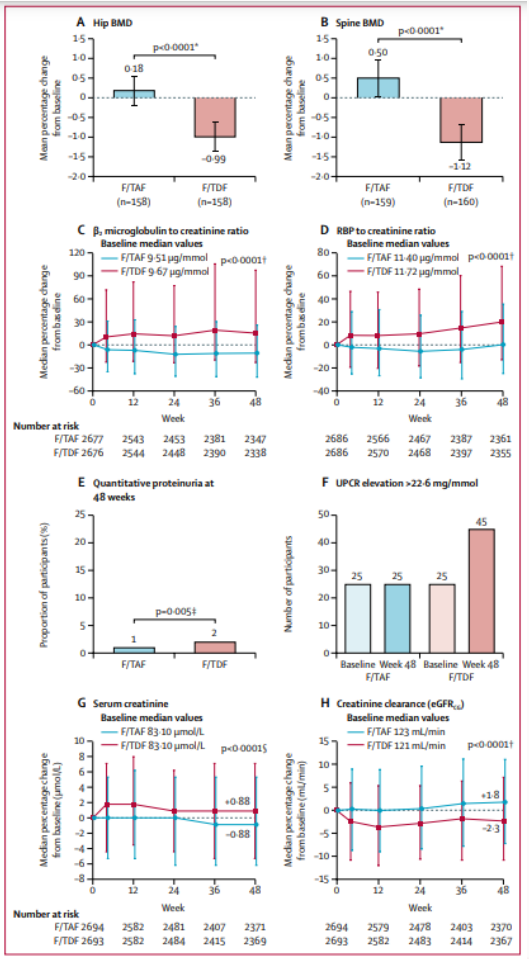
BUT THIS CAN RECOVER!

Bone mineral density recovered after 6 months of stopping TDF/FTC in both young and older adults.

TDF2 Study Group, 2012

Grant RM, et al. Recovery of bone mineral density after stopping oral HIV pre-exposure prophylaxis. CROI 2016 Feb 20-24 Boston

TAF/FTC vs TDF/FTC



Compared to TDF/FTC at 48 weeks, TAF/FTC demonstrated statistically significant, favorable outcomes in:

- Changes in hip BMD
- Changes in spine BMD
- Changes in β2 microglobulin to creatinine ratio
- Changes in retinol-binding-protein to creatinine ratio
- Quantitative proteinuria
- Changes in urine to protein creatinine ratio
- Changes in serum creatinine
- Changes in creatinine clearance

Mayer KH, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. Lancet. 2020 Jul 25;396(10246):239-254.

2-1-1 Dosing and Bone Loss

- TDF/FTC use has been associated with radiographically-significant bone density loss (osteopenia or osteoporosis) when taken daily (proportion of days covered ≥90%).
- 2-1-1 dosing is likely to avoid significant bone density loss, though further study is needed.

Chang J, Do D, Delgado H, Kanimian N, Huynh A. A retrospective analysis of bone loss in tenofovir-emtricitabine therapy for HIV PrEP. Int J STD AIDS. 2022 Dec;33(14):1183-1192. doi: 10.1177/09564624221130129. Epub 2022 Oct 11. PMID: 36220789.

Case 2

- Ultimately, Alex feels that daily TAF/FTC would be the best agent for him. You send a prescription to his preferred pharmacy. The next day, he sends you a message that this medication has a $200 copay and he cannot afford it.
- What would you do?

A. Prescribe TDF/FTC instead
B. Request a prior authorization
C. Send him information about copay assistance
D. Send him information about GoodRx.com

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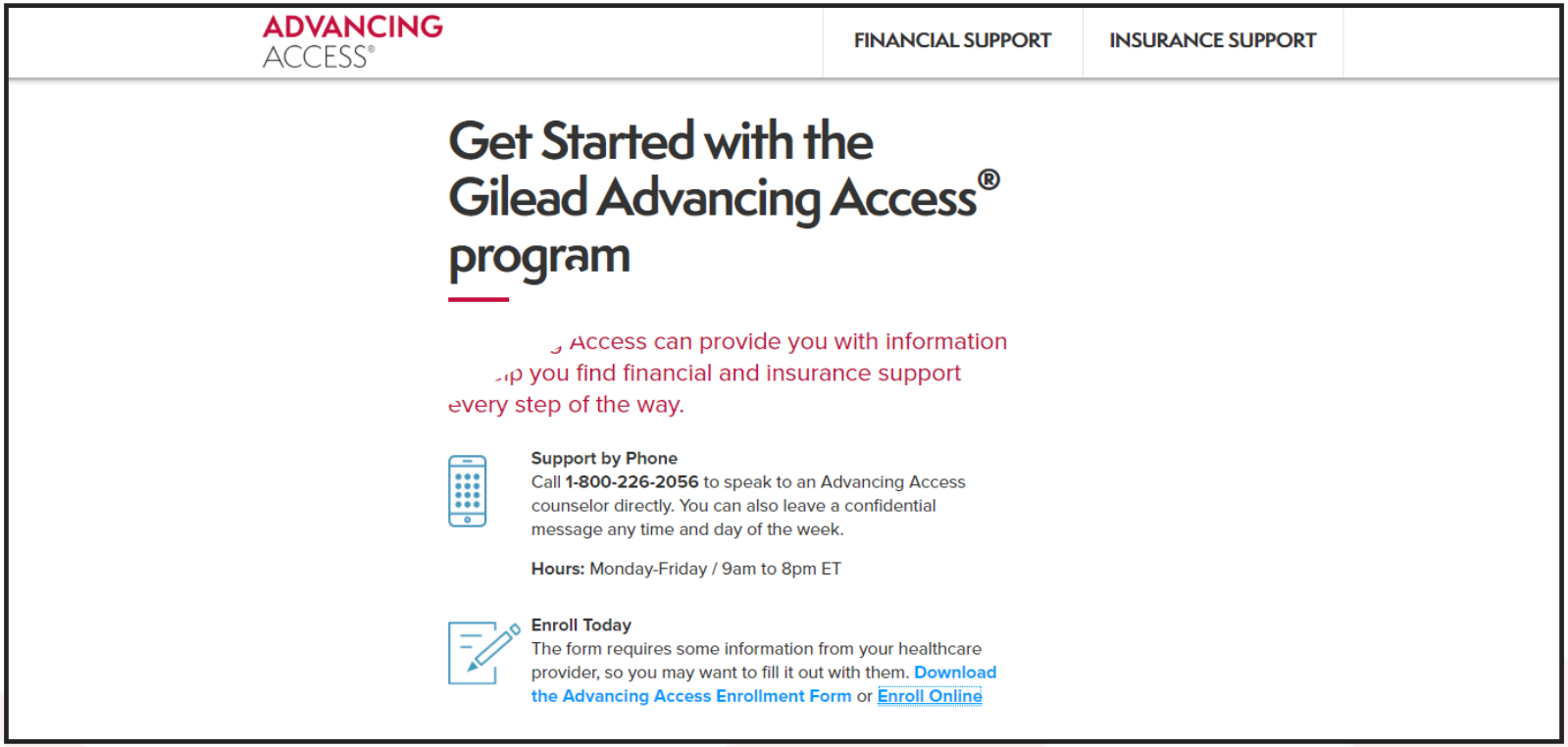
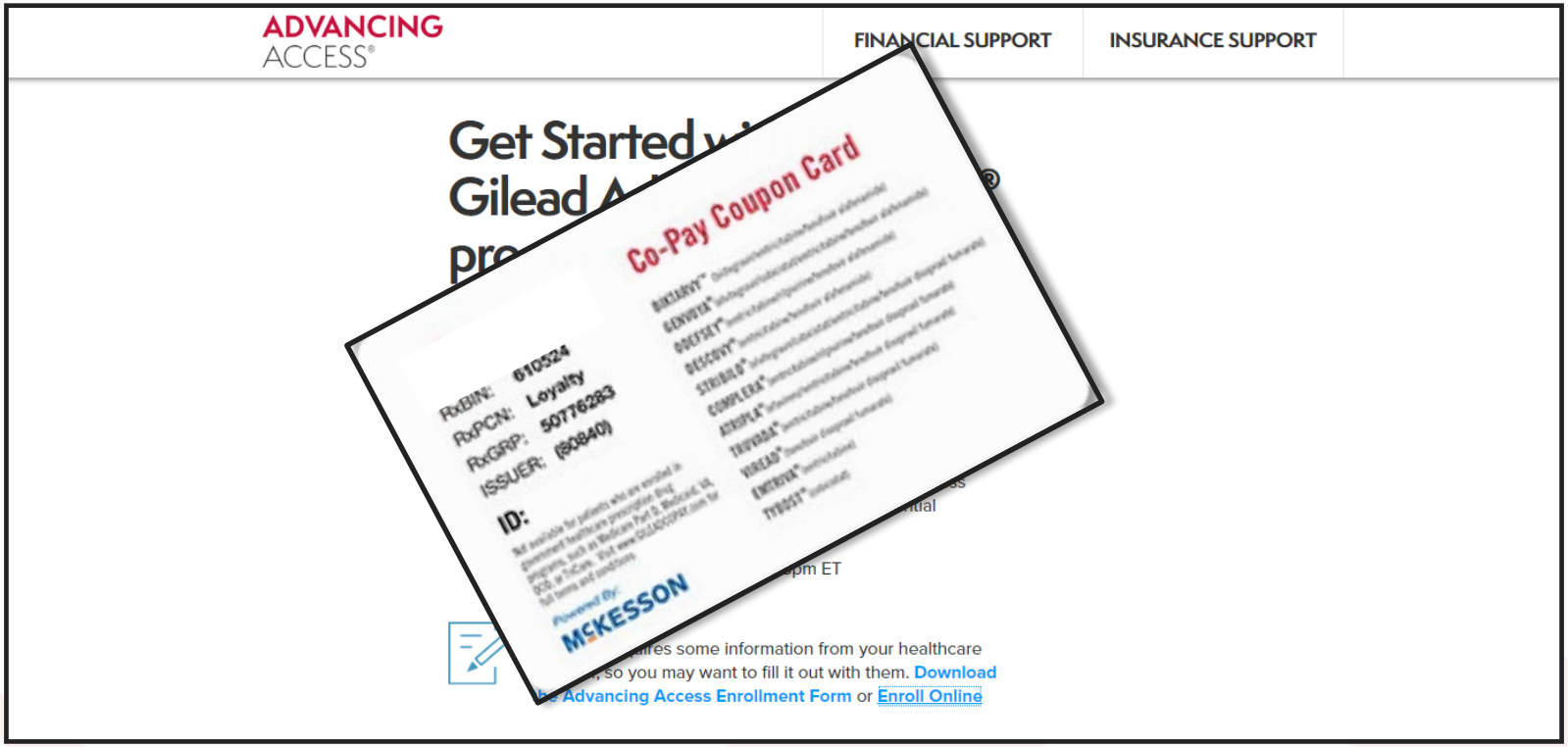
Copay Assistance



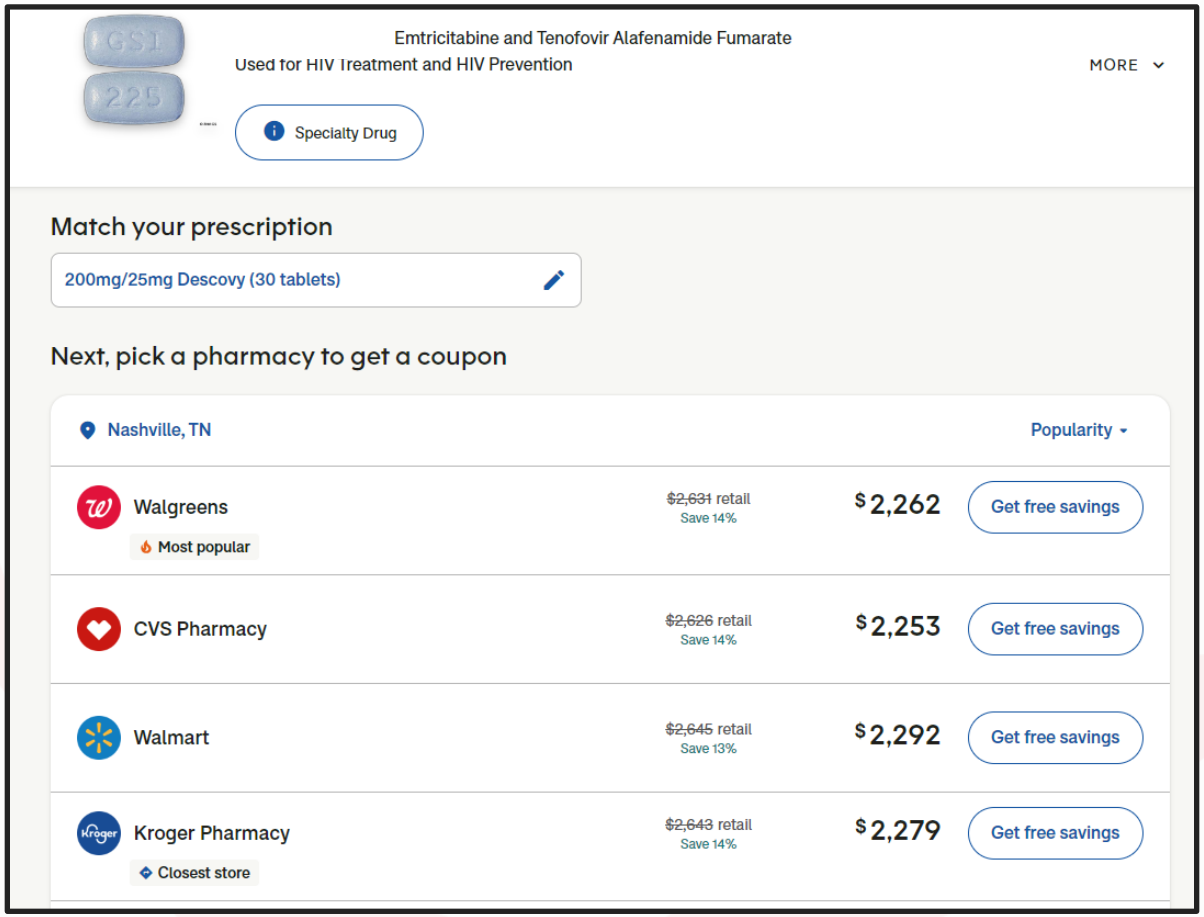
Copay Assistance



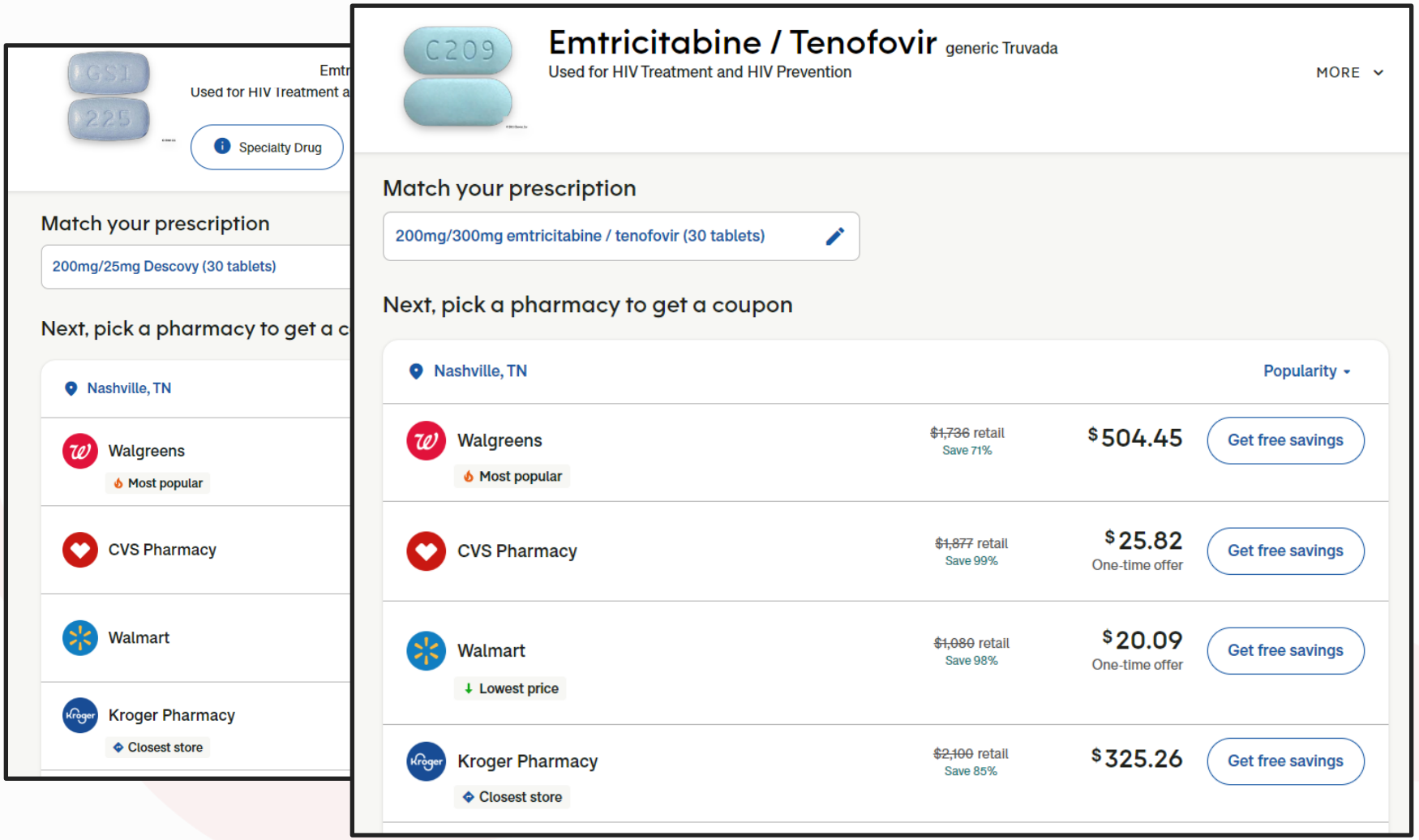
Advancing Access Program

- $7,200/calendar year benefit
- No income limitation
- Must be renewed each calendar
- Federal beneficiaries (Medicare, Medicaid) excluded

GoodRx


GSI
225
Emtricitabine and Tenofovir Alafenamide Fumarate
Used for HIV Treatment and HIV Prevention
MORE
Specialty Drug
Match your prescription
200mg/25mg Descovy (30 tablets)
Next, pick a pharmacy to get a coupon
Nashville, TN
Popularity
Walgreens
Most popular
$2,631 retail
Save 14%
$2,262
Get free savings
CVS Pharmacy
$2,626 retail
Save 14%
$2,253
Get free savings
Walmart
$2,645 retail
Save 13%
$2,292
Get free savings
Kroger Pharmacy
Closest store
$2,643 retail
Save 14%
$2,279
Get free savings

GoodRx


GSI
225
Used for HIV Treatment a
Specialty Drug
Match your prescription
200mg/25mg Descovy (30 tablets)
Next, pick a pharmacy to get a c
Nashville, TN
Walgreens
Most popular
CVS Pharmacy
Walmart
Kroger Pharmacy
Closest store
C209
Emtricitabine / Tenofovir generic Truvada
Used for HIV Treatment and HIV Prevention
MORE
Match your prescription
200mg/300mg emtricitabine / tenofovir (30 tablets)
Next, pick a pharmacy to get a coupon
Nashville, TN
Popularity
Walgreens
Most popular
$1,736 retail
Save 71%
$504.45
Get free savings
CVS Pharmacy
$1,877 retail
Save 99%
$25.82
One-time offer
Get free savings
Walmart
Lowest price
$1,080 retail
Save 98%
$20.09
One-time offer
Get free savings
Kroger Pharmacy
Closest store
$2,100 retail
Save 85%
$325.26
Get free savings

Case 2

- With the new prescription for TAF/FTC and recent negative STI testing, Alex feels confident in his sexual health and thanks you for your care.

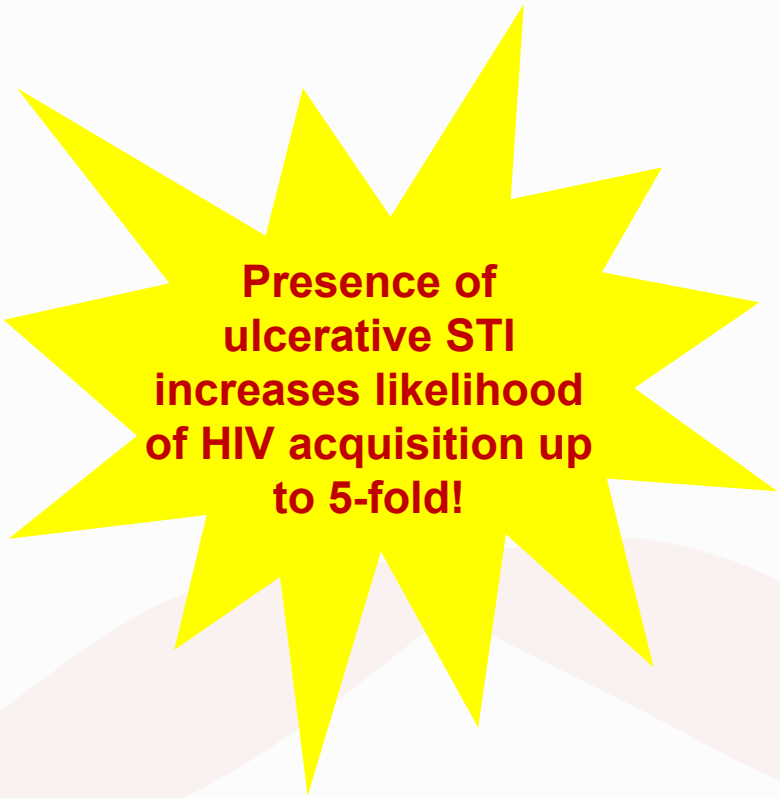
- What else would you do to provide Alex comprehensive sexual healthcare?

PrEP is a **PROGRAM**

- Not only HIV prevention
- Involves comprehensive sexual healthcare
  - Screening and treatment for STIs
  - Hepatitis A and B vaccination
  - HPV vaccination
  - Counseling on STI prevention strategies

STIs Facilitate HIV Transmission

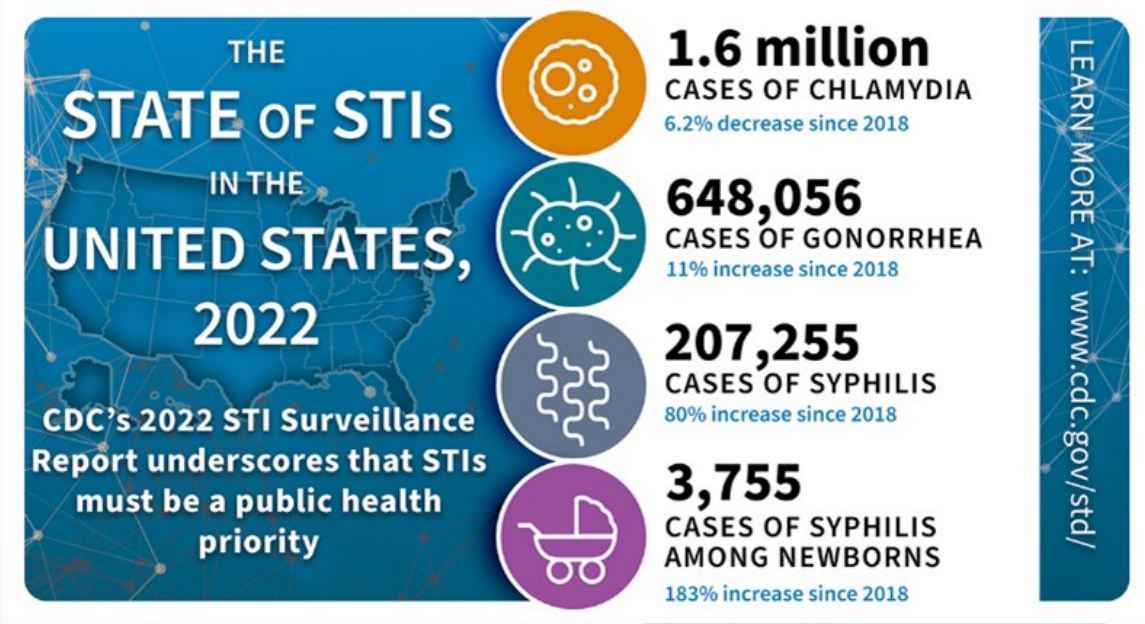
- Disruption of mucosal integrity
- Increase HIV target cells in genital tract due to immune reaction to infection
- STIs promote HIV shedding in the genital tract



https://www.cdc.gov/std/hiv/stds-and-hiv-fact-sheet-press.pdf

Be afraid!

- PrEP does NOT protect against bacterial and other STIs
- These are at record highs!
- We have yet to see the long-term effect of the COVID pandemic



DoxyPEP

- 501 participants with bacterial STI in the past year
  - 327 HIV-negative people using PrEP
  - 174 HIV-positive people
- 2:1 randomization: doxycycline vs placebo
  - **Doxycycline 200mg** taken (ideally) within 24 hours, but no more than 72 hours, of condomless sexual contact
- STI risk reduction
  - 66% reduction in HIV-negative
    - Chlamydia: 88% risk reduction
    - Syphilis: 87% risk reduction
    - Gonorrhea: 55% risk reduction
  - 62% reduction in HIV-positive
    - Chlamydia: 74% risk reduction
    - Syphilis: 77% risk reduction
    - Gonorrhea: 57% risk reduction

CNN health Audio Live TV Log In

STIs are on the rise in the US. A pill taken after sex could help slow them down

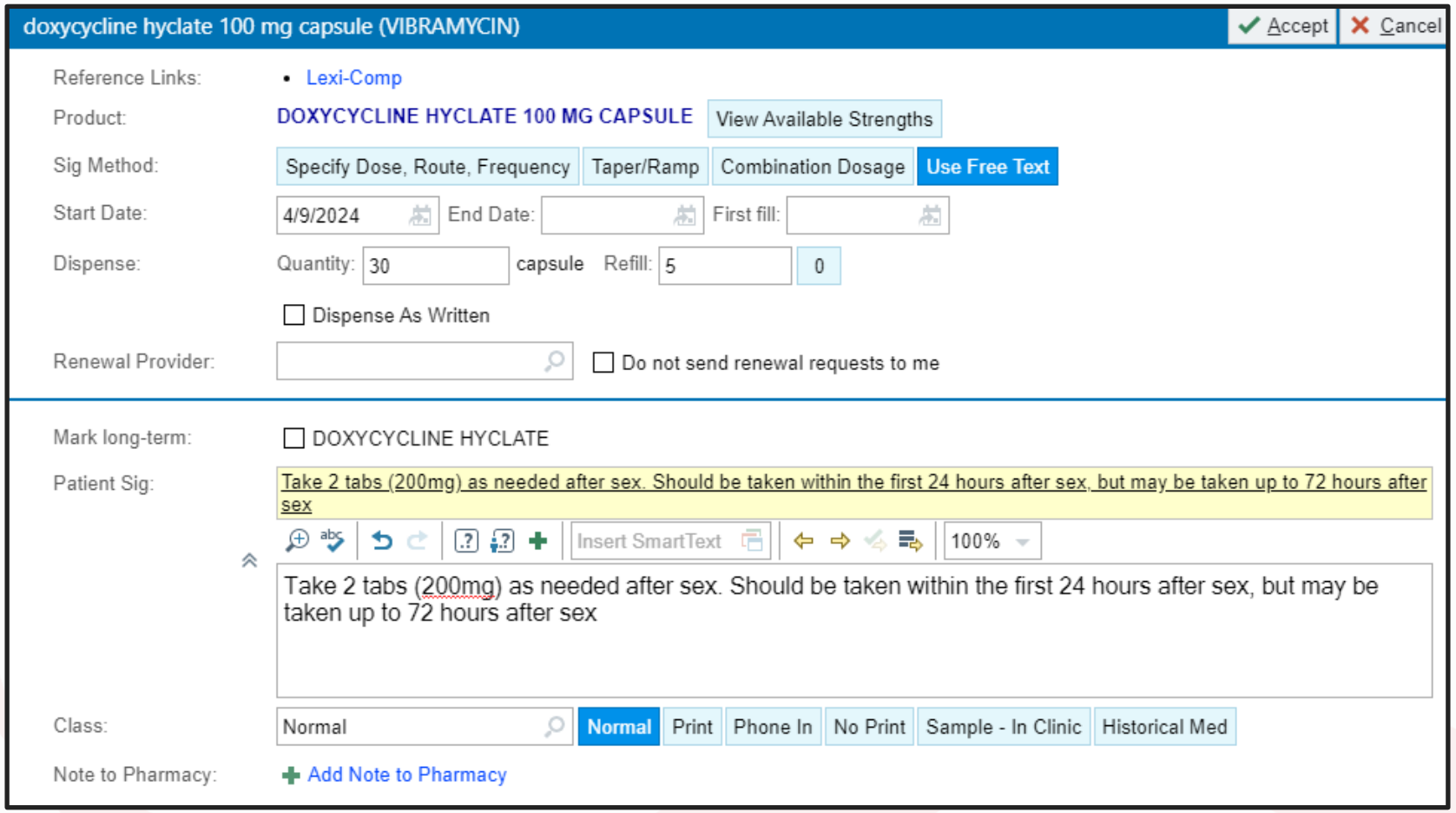
By Jacqueline Howard, CNN

Updated 8:22 AM EDT, Fri August 11, 2023

Rich Pedroncelli/AP

Recent research suggests a dose of doxycycline taken shortly after unprotected sex may help prevent STIs in some groups.

Luetkemeyer AF, Donnell D, Dombrowski JC, Cohen S, Grabow C, Brown CE, Malinski C, Perkins R, Nasser M, Lopez C, Vittinghoff E, Buchbinder SP, Scott H, Charlebois ED, Havlir DV, Soge OO, Celum C; DoxyPEP Study Team. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306. doi: 10.1056/NEJMoa2211934. PMID: 37018493; PMCID: PMC10140182.


doxycycline hyclate 100 mg capsule (VIBRAMYCIN)
Accept
Cancel
Reference Links:
Lexi-Comp
Product:
DOXYCYCLINE HYCLATE 100 MG CAPSULE
View Available Strengths
Sig Method:
Specify Dose, Route, Frequency
Taper/Ramp
Combination Dosage
Use Free Text
Start Date:
4/9/2024
End Date:
First fill:
Dispense:
Quantity:
30
capsule
Refill:
5
0
Dispense As Written
Renewal Provider:
Do not send renewal requests to me
Mark long-term:
DOXYCYCLINE HYCLATE
Patient Sig:
Take 2 tabs (200mg) as needed after sex. Should be taken within the first 24 hours after sex, but may be taken up to 72 hours after sex
Insert SmartText
100%
Take 2 tabs (200mg) as needed after sex. Should be taken within the first 24 hours after sex, but may be taken up to 72 hours after sex
Class:
Normal
Normal
Print
Phone In
No Print
Sample - In Clinic
Historical Med
Note to Pharmacy:
Add Note to Pharmacy

Case 2

- Alex returns after 3 months for his first follow-up visit. He reports complete adherence to TAF/FTC and has taken DoxyPEP after each sexual encounter.

- Which HIV testing strategy is recommended by CDC?

A. HIV-1 Ag/Ab assay
B. HIV-1 Ab oral swab
C. HIV-1 Ag/Ab assay AND HIV-1 RNA PCR
D. HIV-1 RNA PCR

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HIV screening

- At baseline, 4th generation HIV Ag/Ab combination assay
- During PrEP maintenance, HIV Ag/Ab **AND** HIV RNA PCR are now recommended
  - Incident HIV infections during PrEP use may exhibit lower viral replication and longer time to antibody production (seroconversion)
- Routine HIV RNA PCR may not be readily available or affordable
  - Providers should use tests that are available to them to continue PrEP provision

Donnell D, et al. The effect of oral preexposure prophylaxis on the progression of HIV-1 seroconversion. AIDS. 2017;31(14):2007. 78.

Marzinke MA, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. Infect Ds. 2021;

A year of oral PrEP

Encounter	To do
Month 0	• Screen for HIV • Confirm HBV and HCV status • Check serum creatinine • Screen for STIs • Counseling • Prescribe
Month 3	• Screen for HIV • Counseling • Prescribe
Month 6	• Screen for HIV • Screen for STIs • Counseling • Prescribe
Month 9	• Screen for HIV • Counseling • Prescribe
Month 12	• Screen for HIV • Screen for STIs • Check serum creatinine • Counseling • Prescribe

Labs*:
- HIV screen: 5
- Serum creatinine: 2**
- STI screen: 3***

***Lipids Q12 months if taking TAF/FTC**

****Serum creatinine should be done Q6 months if age ≥50 years or who have an CrCl <90 mL/min at initiation**

*****Tri-compartment GC/chlamydia, syphilis, HCV depending on risk**

Prescriptions/Refill authorizations: 5

Discussions: 5+

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Case 2

- After about a year of consistent follow-up, Alex reports that he has had one male partner over the past 7 months, Jesse. Jesse is HIV-positive, engaged in HIV care, and has been undetectable since shortly after his diagnosis 3 years ago. What recommendation should you give?

A. Alex should remain on PrEP
B. Alex should stop PrEP
C. Jesse should have HIV viral load checked more often
D. Alex should have HIV RNA PCR checked at each visit

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What about PrEP and U=U?

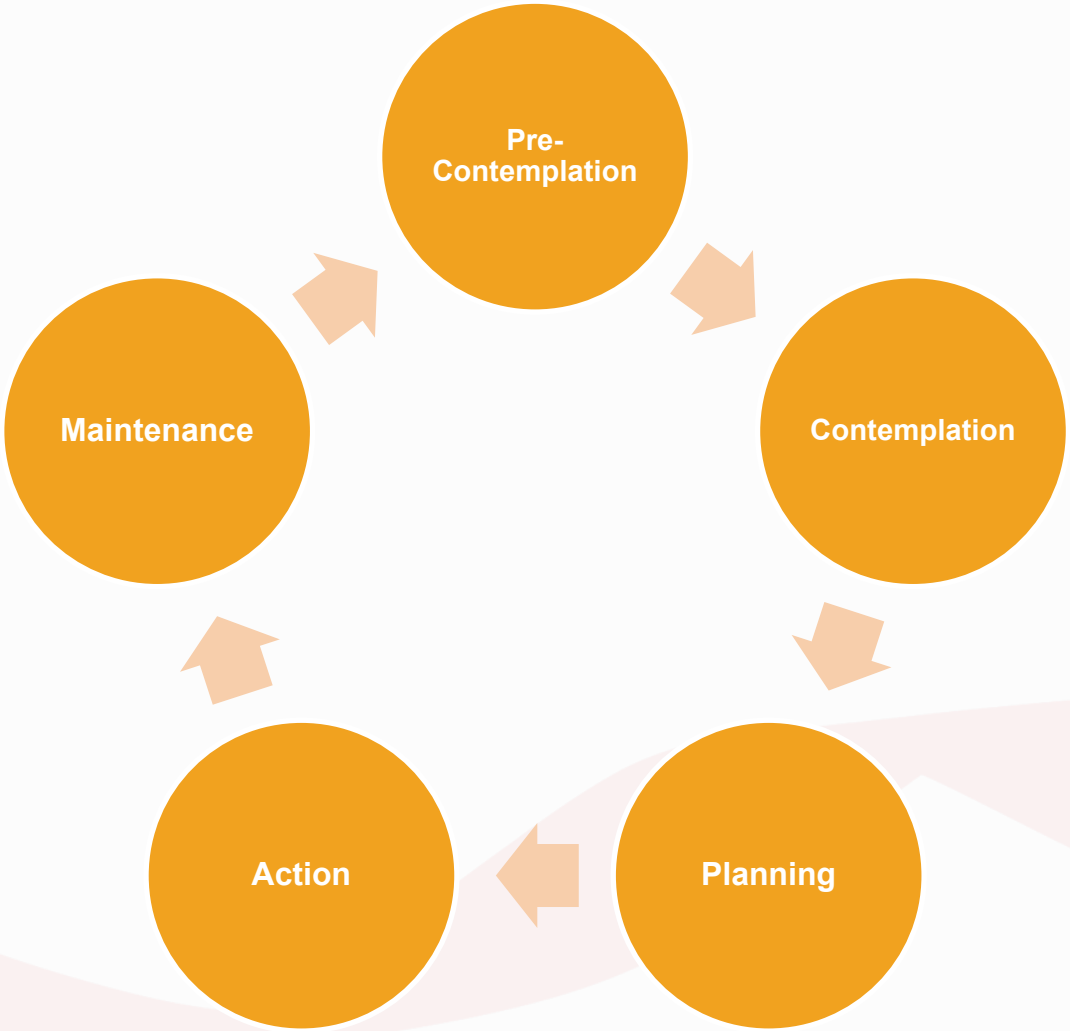
U=U

- Those who have an undetectable viral load have effectively no risk of transmitting the virus.
- This is a consensus of HIV experts worldwide, CDC, NIH, IDSA/HIVMA, common knowledge in the medical community.
- Combined data from 4 studies (HPTN 052, OPPOSITES ATTRACT, PARTNER and PARTNER2)
  - Among sero-discordant couples where the partner living with HIV had a durably undetectable viral load:
    - zero transmission among over a hundred thousand condomless sex acts
    - Results similar in both male-female and male-male partnerships

U=U

- Is PrEP necessary in this situation?
  - Consider *durable* viral suppression
    - Contributing factors include adherence, history of virologic failure, follow-up interval of the HIV-positive person
  - Consider non-monogamous sex
    - In U=U studies, HIV transmissions **DID** occur, but were linked to sex between HIV-negative participant and HIV-positive individual not involved in the study
  - *Always* weigh risks and benefits

The PrEP Stages of Change



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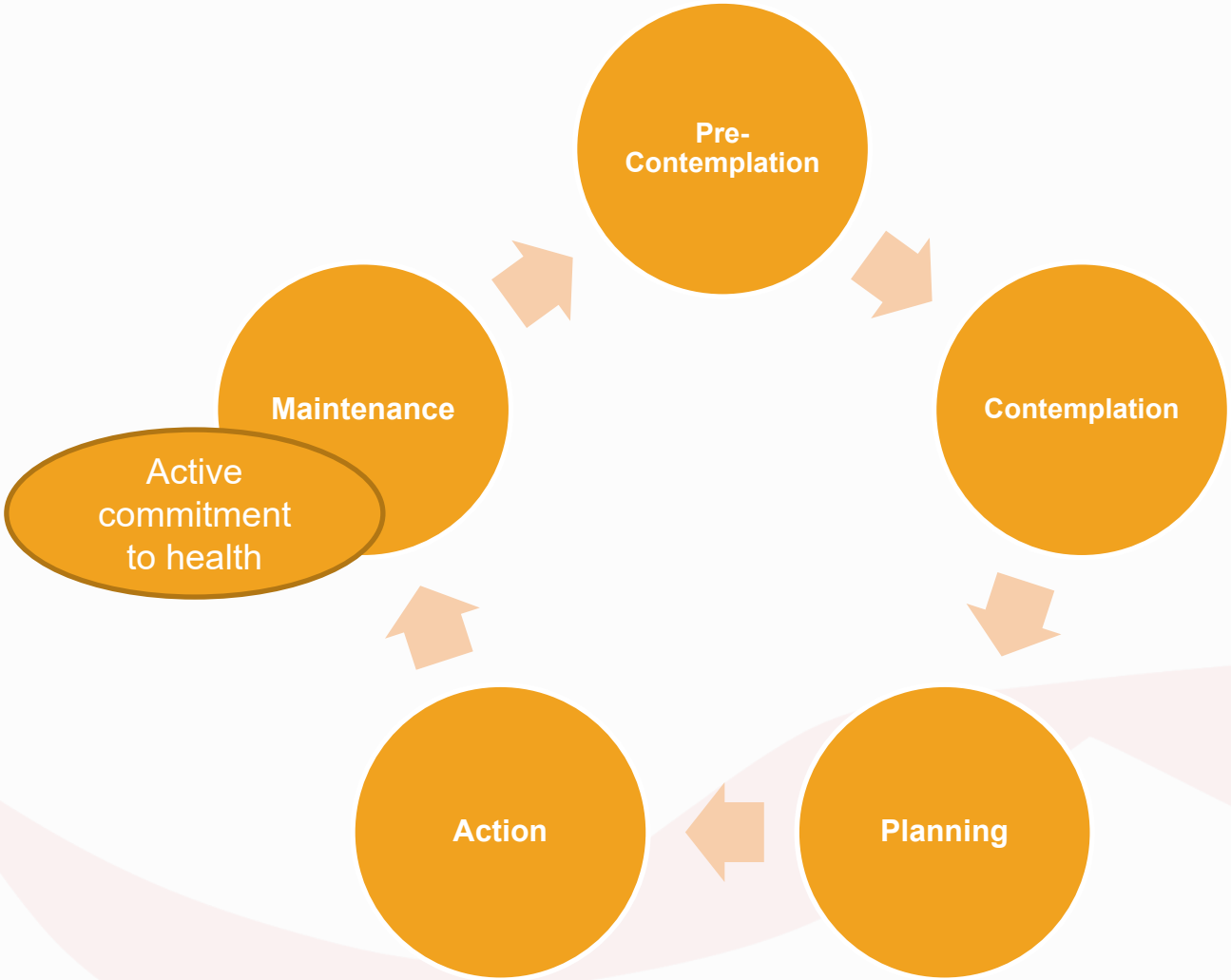

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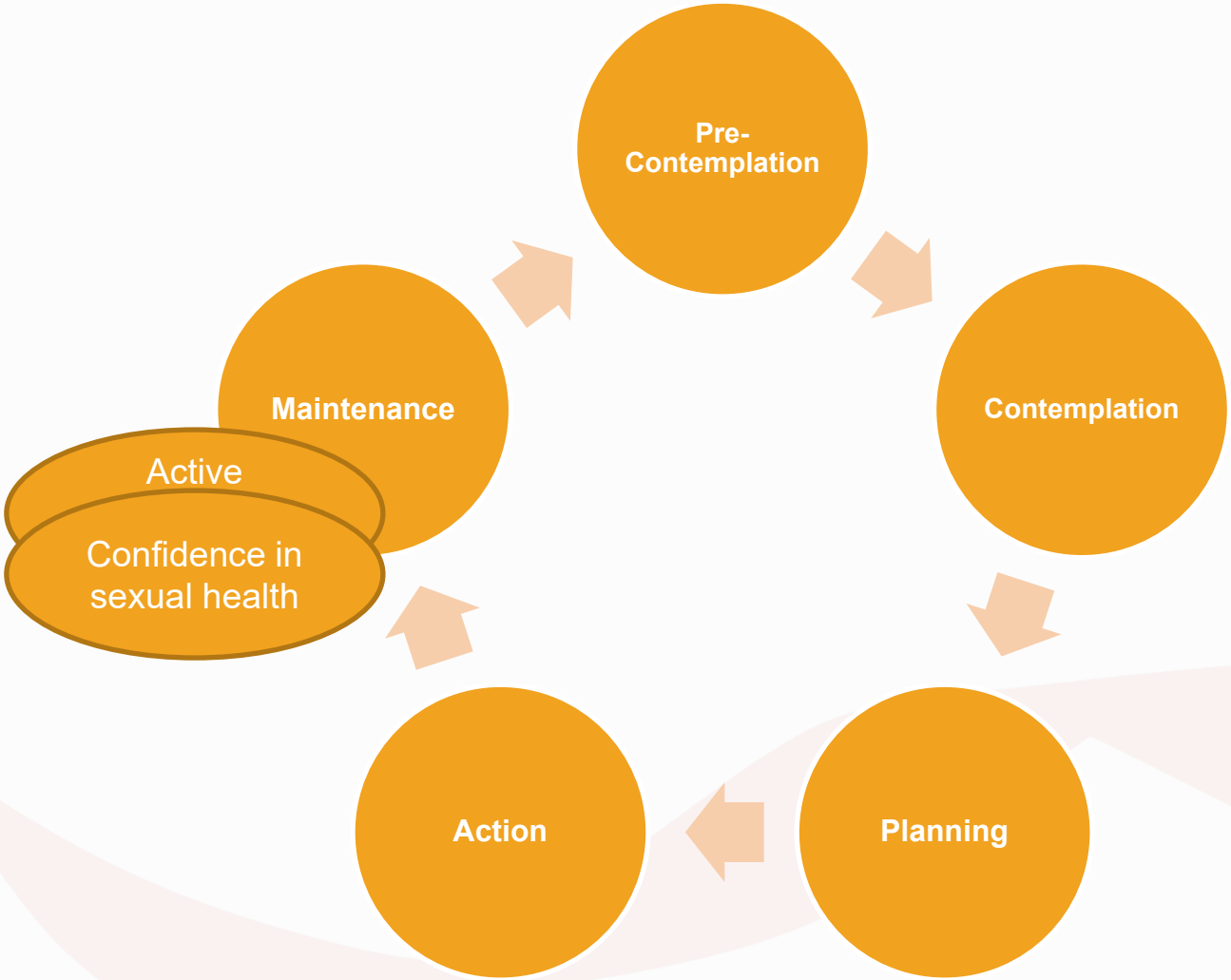

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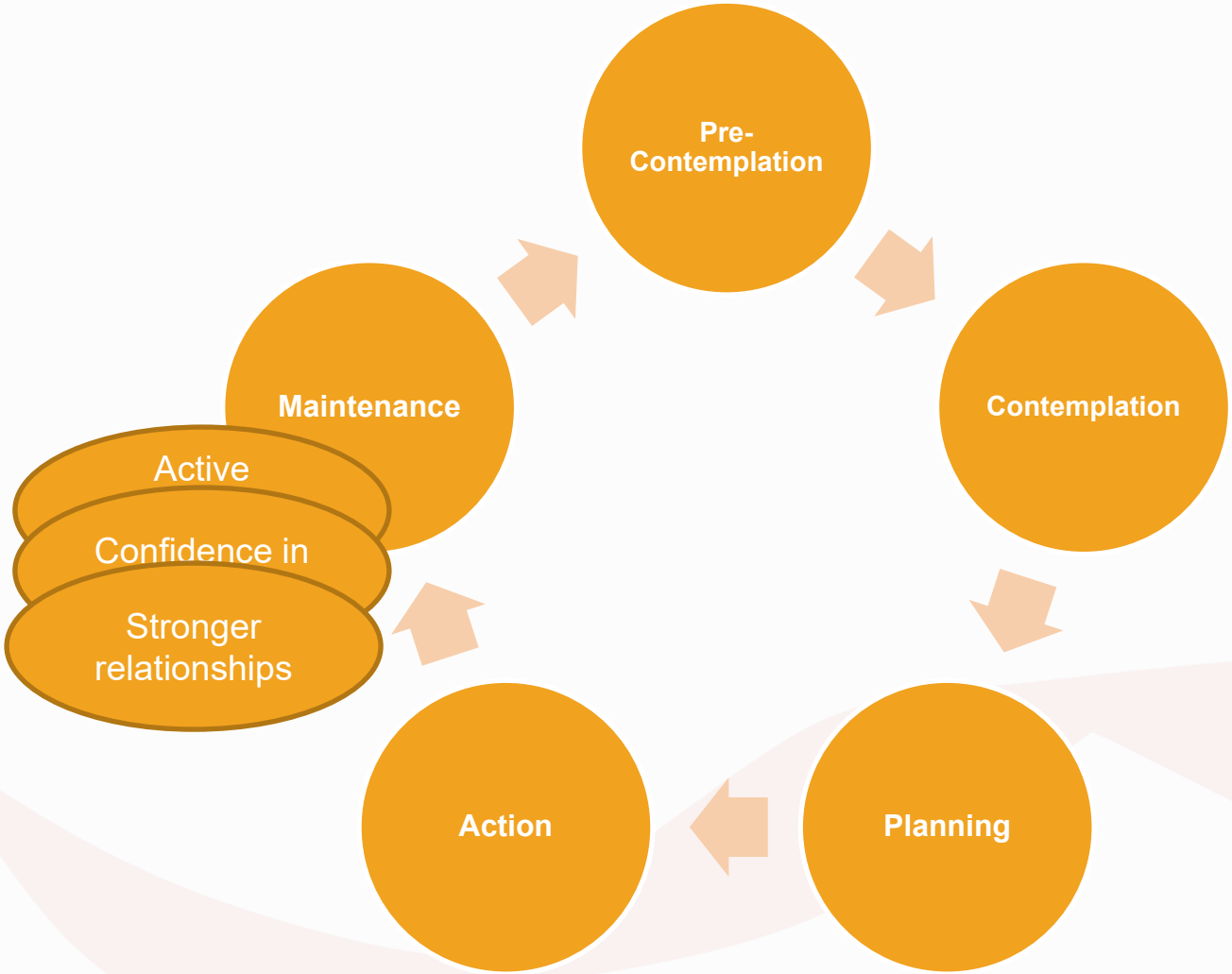

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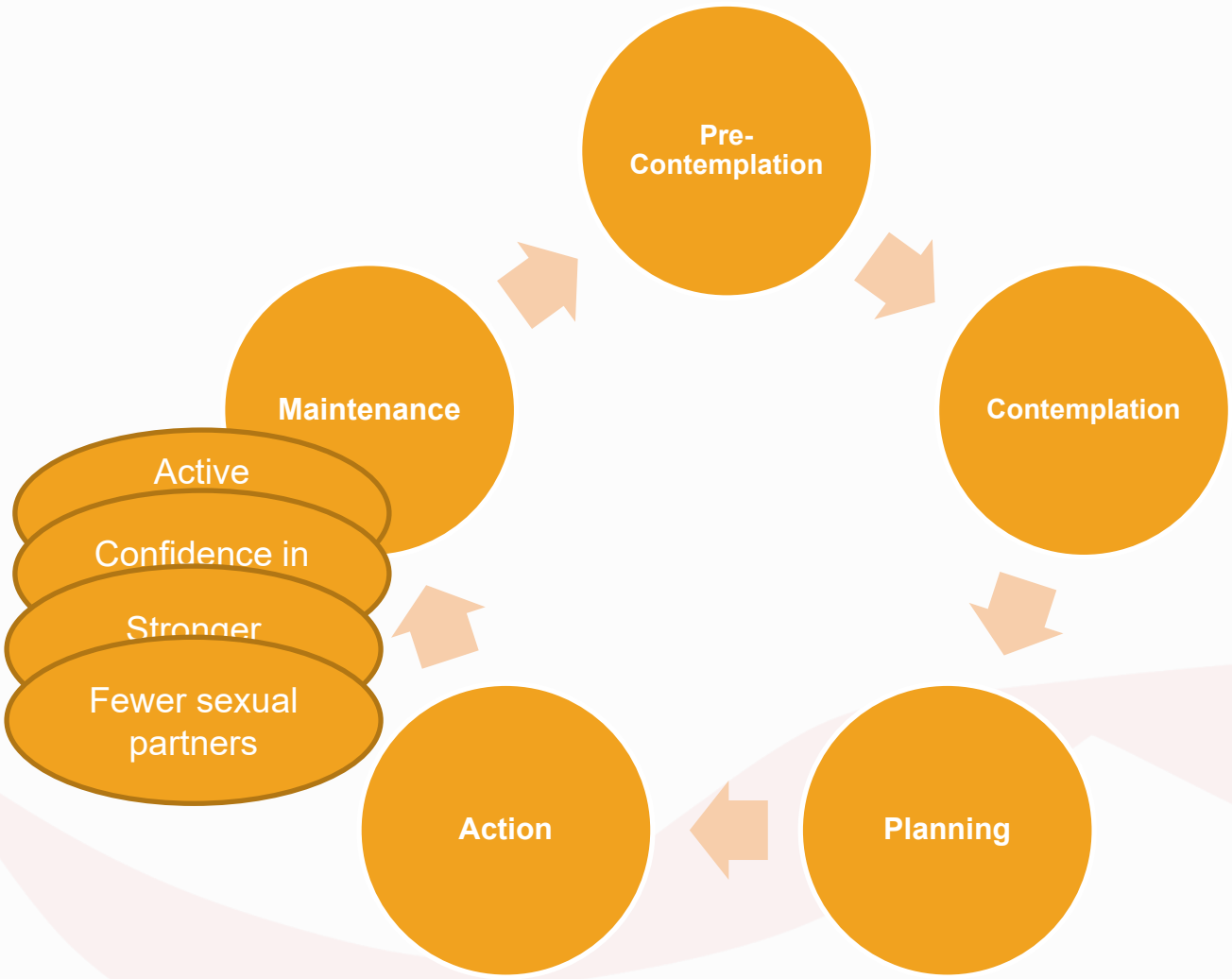

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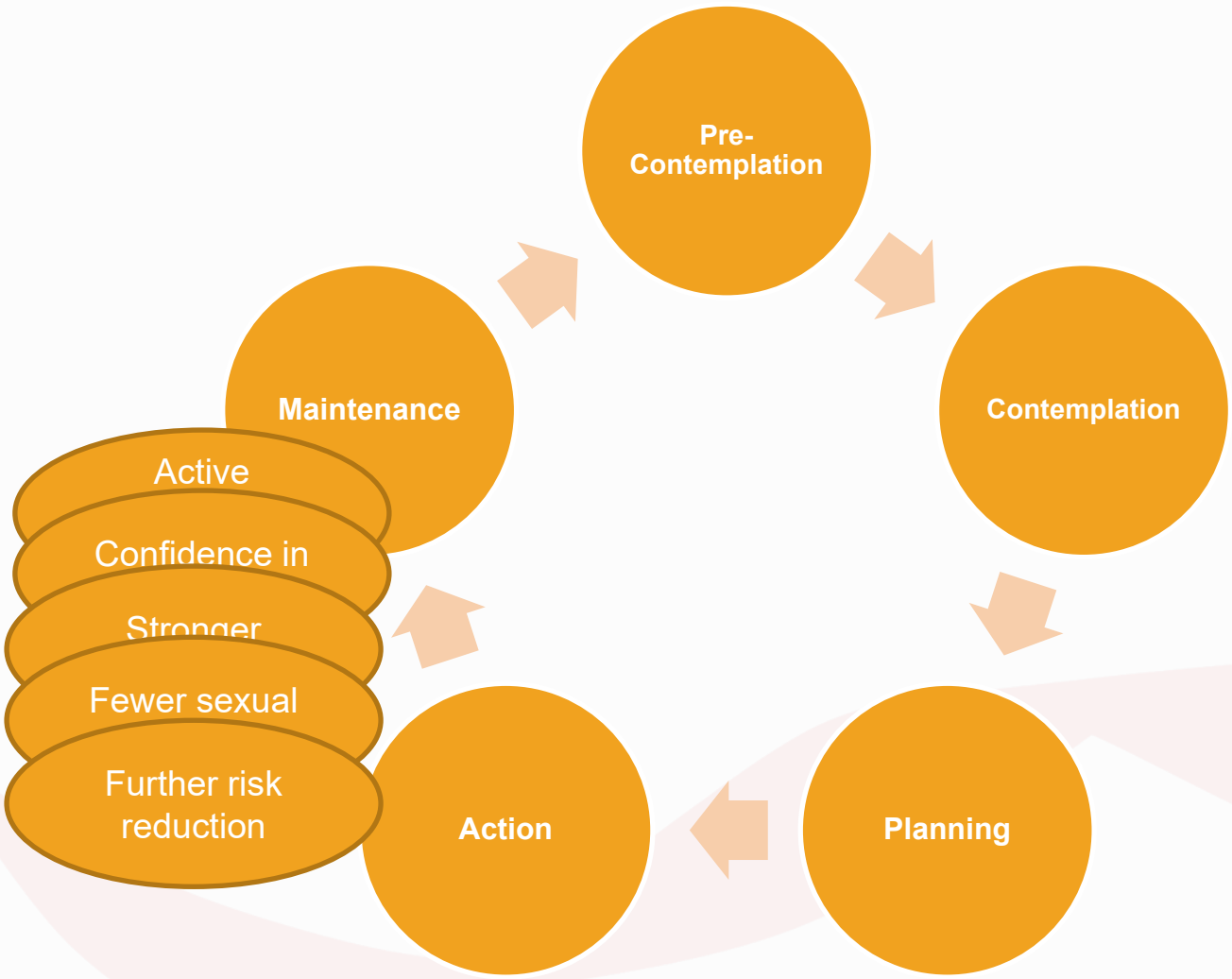

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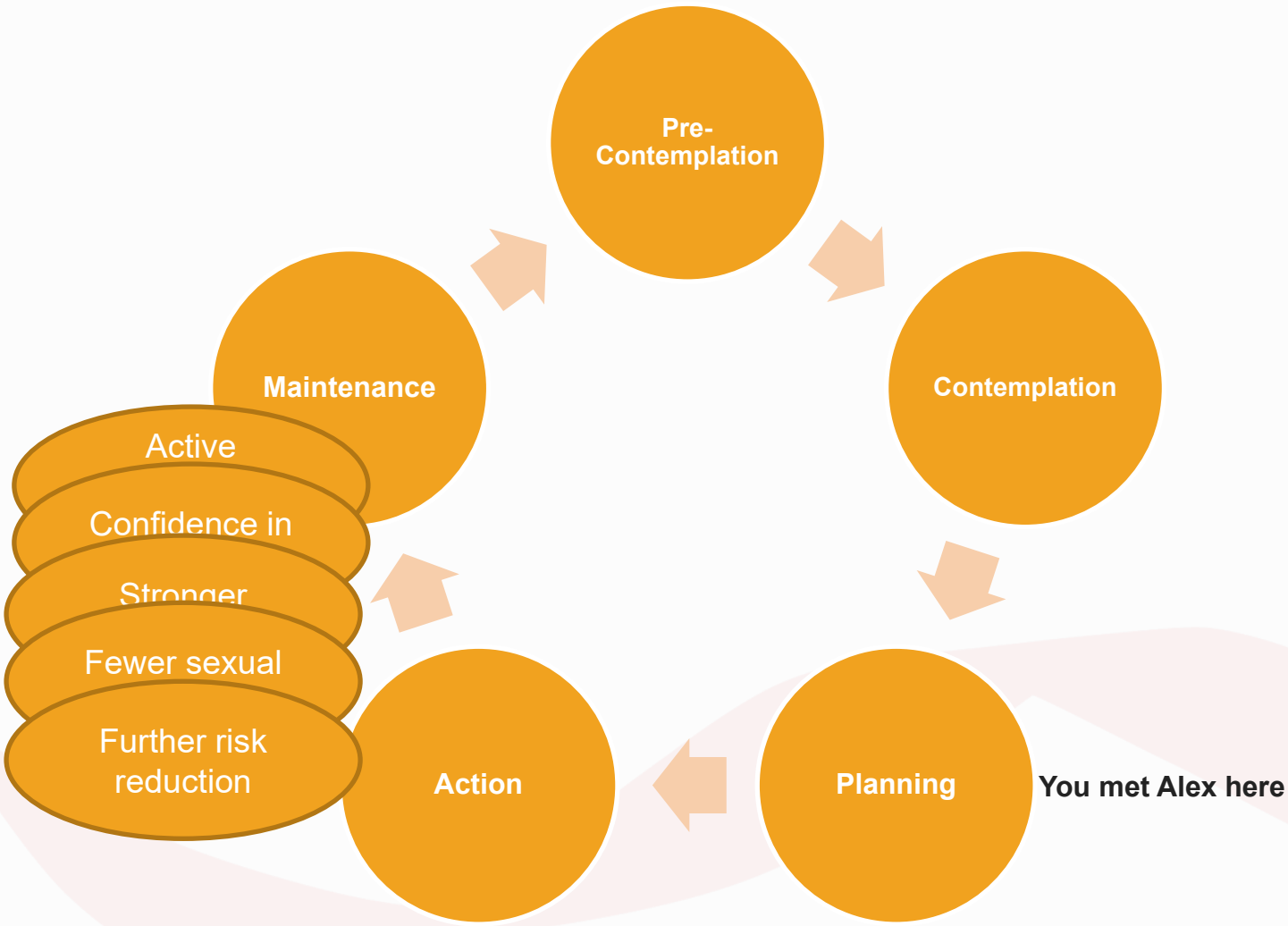

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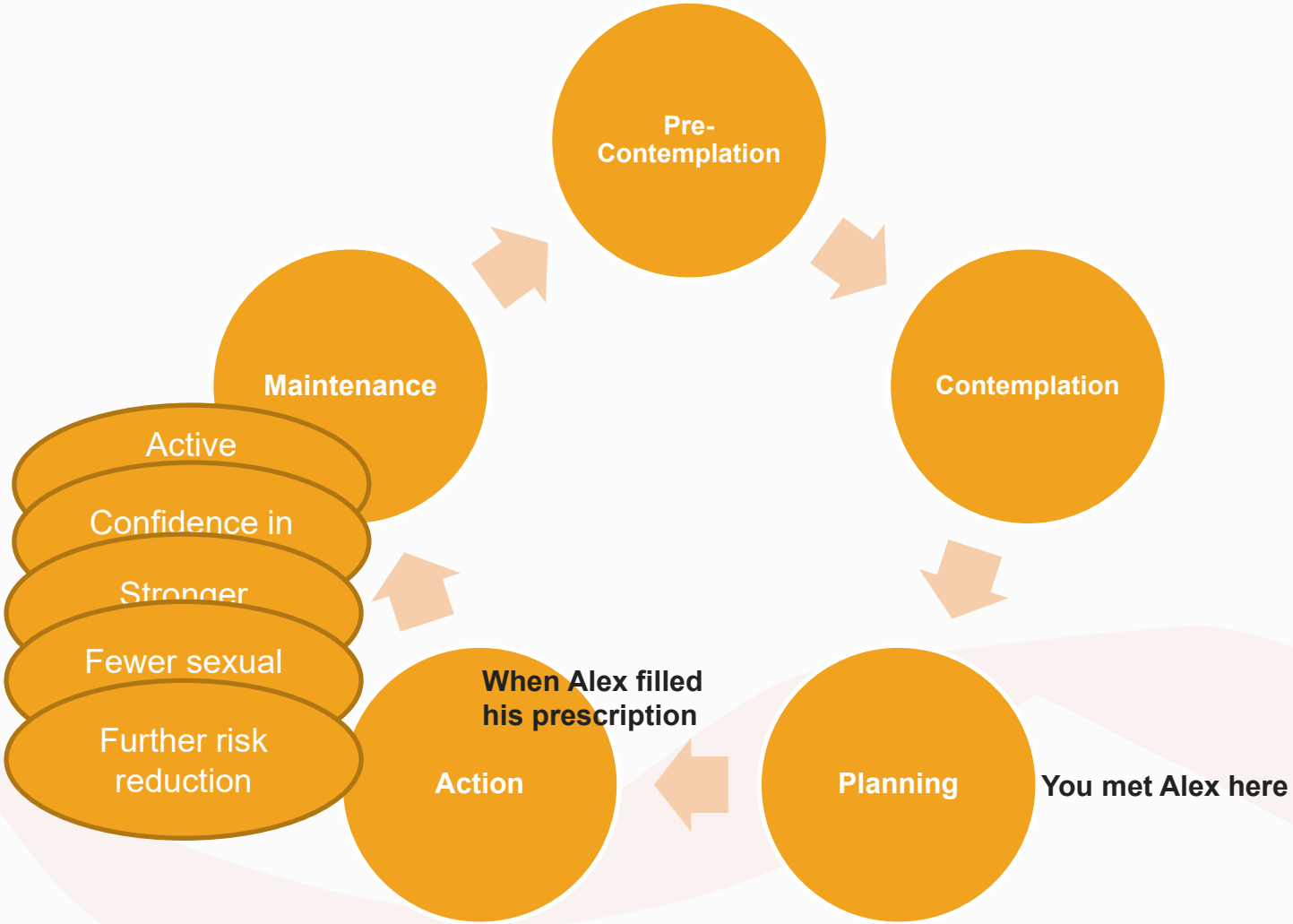

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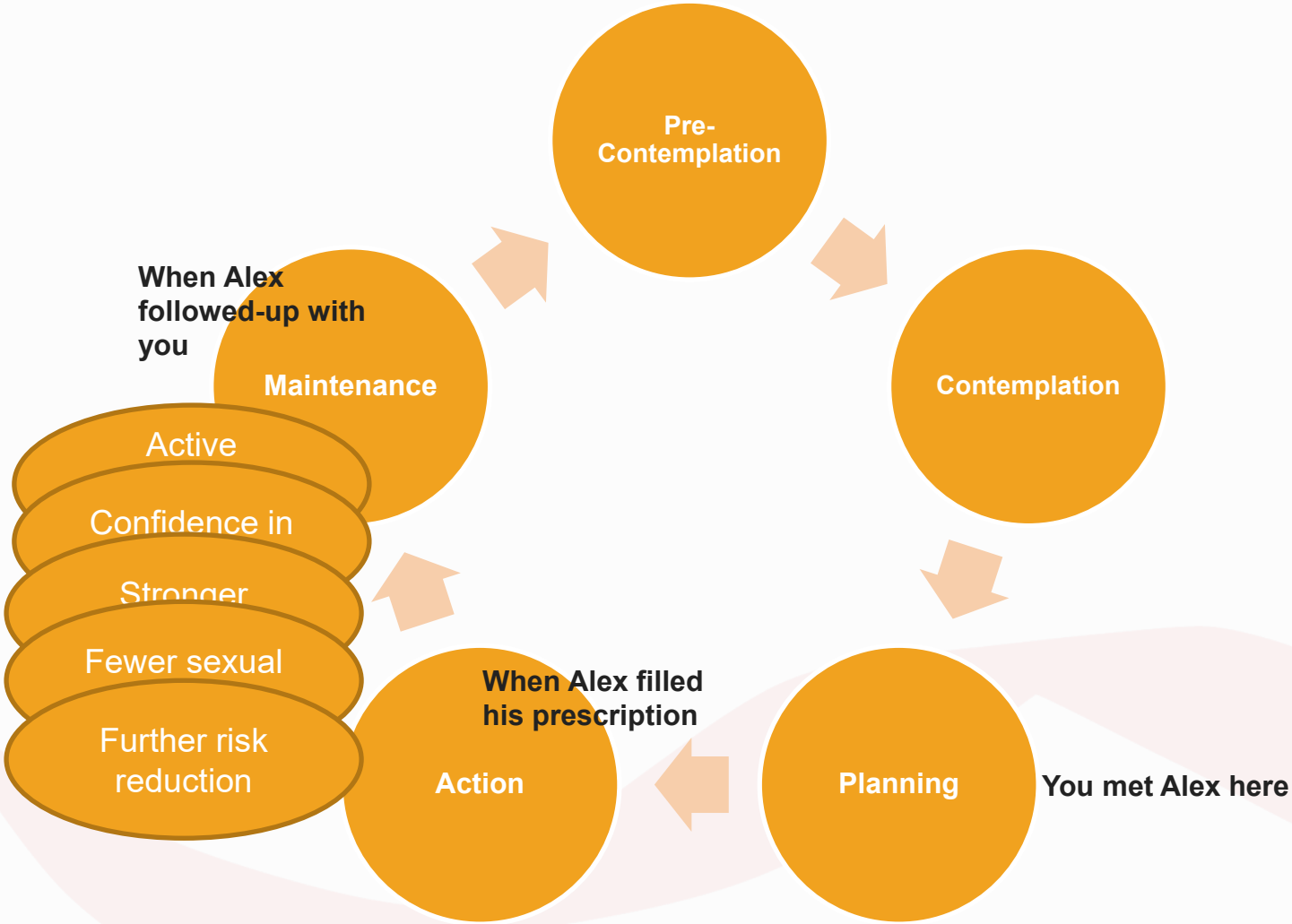

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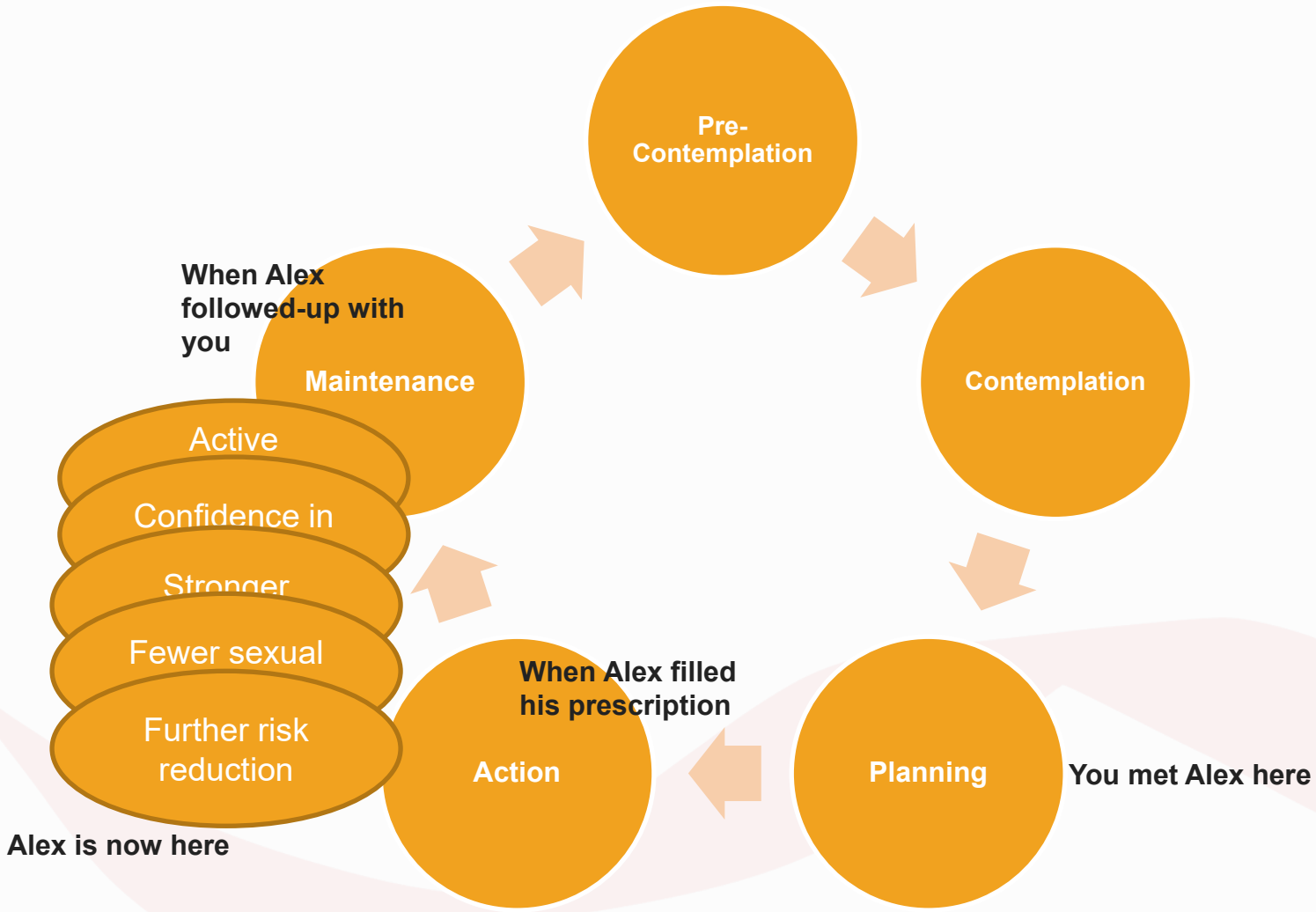


Case 3

- Mark is an 18-year-old cisgender man who presents to establish for primary care. He is a freshman in college. His previous medical provider was his pediatrician. Early in the conversation, he asks about STI testing. When you attempt to discuss this further, you notice that Mark seems uncomfortable and hesitant to divulge information.

- How do you approach the sexual history?

The Sexual History

- To learn about the patient's sexual health
  - This is more than just ascribing HIV/STI risk
    - People tend to underestimate/not believe their own risks
- To help the patient achieve the goals in their sexual health
    - Emphasizes benefits over risk, which can be more effective in motivating patients toward prevention and positive care behavior

Sexual History Misconceptions

- Married persons do not acquire STIs
- Persons who identify as “straight” only have sex with those of the opposite gender
- Persons who identify as “gay” or “lesbian” only have sex with those of the same gender
- Persons will an STI will have symptoms
- *Sexual risk compensation*
  - The concept that PrEP use will result in increased unprotected sex, which will undermine prevention efforts

Sexual risk compensation

- PrEP users will engage in higher risk sex than they previously had.
- This increased unsafe sex will undermine prevention efforts.
- Higher rates of bacterial STIs diagnosed among PrEP users may falsely support this.
  - PrEP users are screened for bacterial STIs frequently due to follow-up requirements.
- On a population level, sexual risk compensation is a fallacy.

The GOALS framework

- Considers the principle that sexual history-taking is an INTERVENTION that will:
  - Increase rates of routine HIV and STI screening
  - Increase rates of universal biomedical prevention and contraceptive education
  - Increase patients' motivation for and commitment to sexual health behavior
  - Enhance the patient-care provider relationship, making it a lever for sexual health specifically and overall health and wellness in general

Sarit A. Golub, PhD, MPH, Hunter College and Graduate Center, City University of New York, in collaboration with the NYC Department of Health and Mental Hygiene, Bureau of HIV, July 2019

The Sexual History

- Give a preamble/preface
- Offer opt-out HIV and STI testing
- Ask open-ended questions
- Listen for relevant information, and ask more pointed questions to fill in the blanks
- Suggest a course of action, highlighting benefits
  - Such as HIV and STI testing, PrEP, contraception counseling
  - Benefits include exerting greater control of their sexual health, decreasing anxiety about potential STI/HIV transmission

vs

- 5Ps (partners, practices, protection from STI, past history of STI, prevention of pregnancy)

The Sexual History

- Preamble
  - "*I talk to all of my patients about sexual health, because it's such an **important part of overall health**. Some of my patients have **questions or concerns** about their sexual health, so I want to make sure I **understand what your questions or concerns might be and provide whatever information or other help you might need**.*"

  - "Gonorrhea and chlamydia can also live in our rectums and throats, so it's important for me to test anywhere you might have had an exposure."

Opt-out HIV and STI screening

- Patients should be informed that screening will be included as part of their standard evaluations
  - *"I recommend HIV and STI screening to **all** my patients."*
- Patients may decline
- **Allow self-swabbing!**
- Risk-based screening (vs. opt-out screening) will miss new diagnoses among those who have a perceived low risk (Note: we all underestimate our own risks). It also allows:
  - Early linkage to care and treatment
  - Stigma reduction
  - Transmission reduction

The Sexual History Script

The Sexual History

- **"Tell me about your sex life."**
- "About how many partners have you had in the past 6 months?"
  - OR "Tell me about your sexual partners"
- "What gender are your partners?"
- "Are you a top, bottom, or vers?"
  - Top = anal insertive
  - Bottom = anal receptive
  - Vers/versatile = both insertive and receptive

The Sexual History

- “Do you have oral sex?”
- “What do you do to prevent STDs?”
- “How do you prevent pregnancy?”
- “Do you use condoms? What percentage of the time would you say you use condoms?”

The Sexual History

- “Are any of your partners HIV-positive?”
  - If so, “do you know if they’re undetectable?”
    - Reinforce U=U!
- “Have any of your partners recently had an STD?”
- “Have you ever had an STD”
- “Have you ever had HIV or STD testing?”

The Sexual History

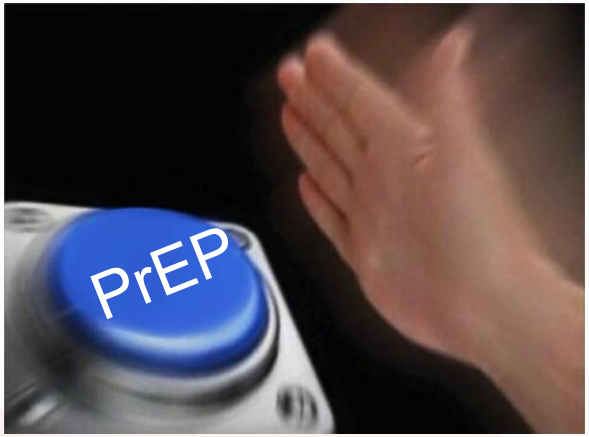
- “Do you ever use drugs, like poppers or meth, when you have sex?”
- “Do any of your partners make you scared or feel unsafe?”
- “Do you ever have to use sex for things you need, like food or to pay pills?”

The Sexual History

- Also a great time to discuss travel!
- During travel, patients may:
  - Meet sexual partners
  - Have sex with partners other than long-term partner
  - Engage in different risk behavior than when not traveling

Conclusions

- PrEP is a component of primary care
- PrEP is an extremely effective preventive strategy for both HIV and STIs
- Overcoming disparities in PrEP uptake is a critical goal of ending the HIV epidemic
- There are some adverse effects, but PrEP is generally very well-tolerated
- New agents will further expand the PrEP repertoire



Conclusions

- The Sexual History is a crucial part of delivering comprehensive primary care.
  - It's part of the job!
- Frame the sexual history in terms of benefits for the patient over risk factors.
- Include opt-out HIV and STI screening in the sexual history.
- The GOALS framework can provide a very useful guide to the conversation.