HIV PREVENTION (PEP/PREP/ON DEMAND PREP AND DOXY-PEP)

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DISCLOSURE

- **Gilead Pharmaceuticals – NOVA Grant – Studying PrEP in the BDSM/Kink Community**
- **Speaker TASHRA**

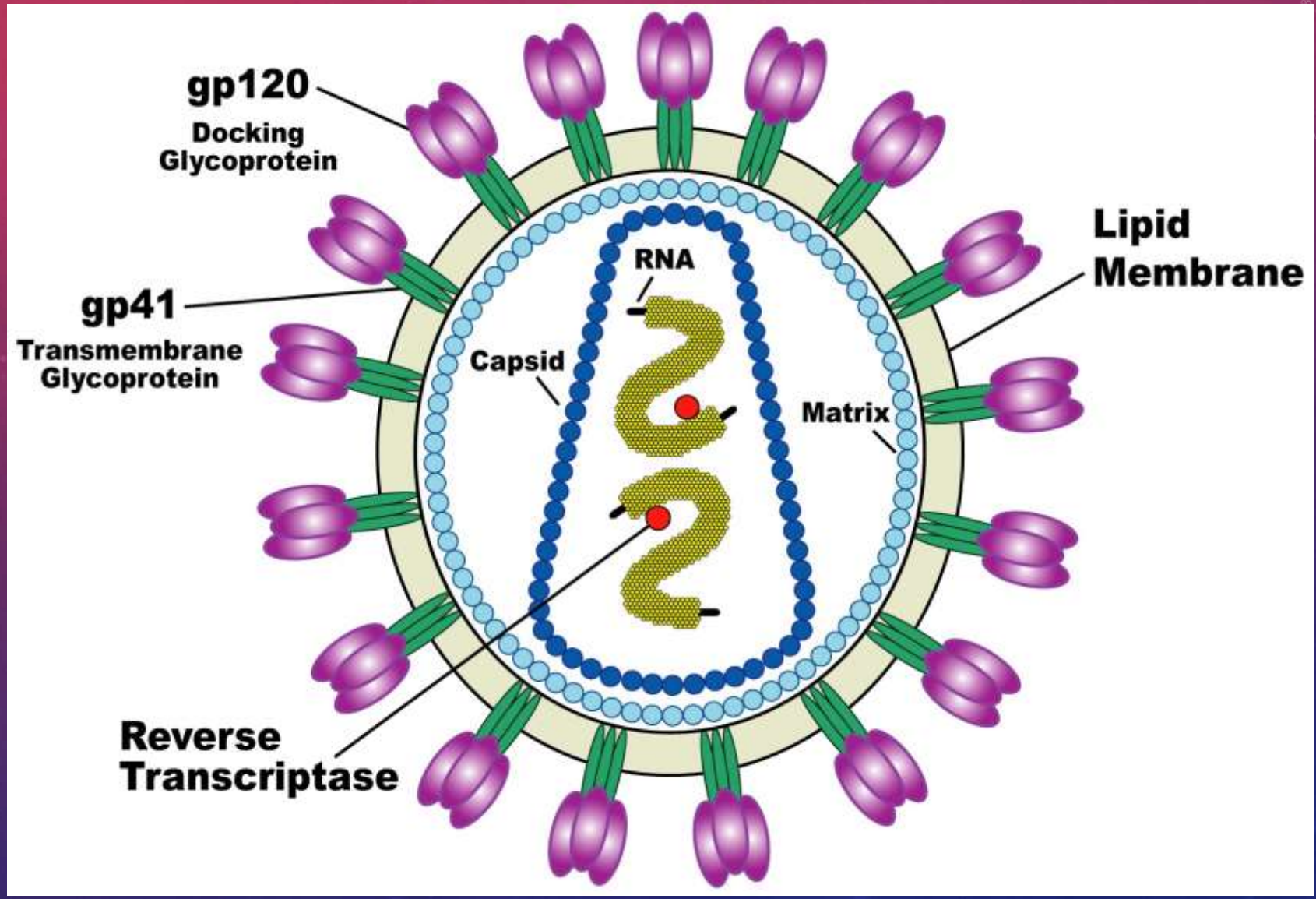
GOALS

- To understand Treatment as Prevention (TaSP)
- To understand the use of Post-Exposure Prophylaxis (PEP)
- To understand the use of Pre-Exposure Prophylaxis (PrEP)
- To understand the use of Intermittent on demand PrEP
- To discuss the use of DOXY-PEP (Doxycycline as Post Exposure)
  - This is a rather new topic

TERMINOLOGY

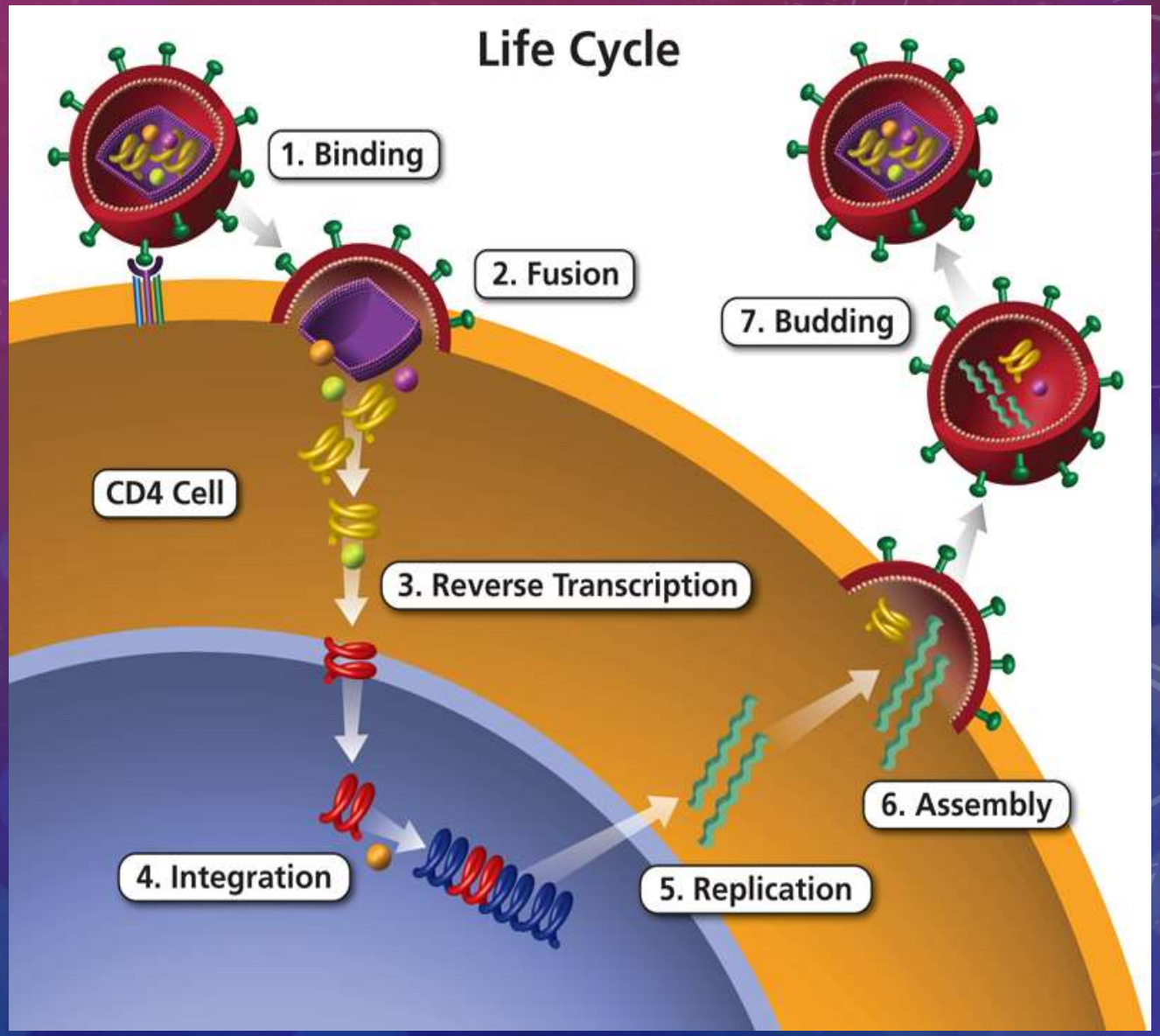
- TASP = Treatment as Prevention
  - U=U = Undetectable = Un-transmittable
- PEP = Post Exposure Prophylaxis
- PrEP = PreExposure Prophylaxis
  - Truvada = FTC/TDF (TDF) - oral – TDF from this point on
  - Descovy = FTC/TAF (TAF) – oral – TAF from this point on
  - Apertude = Cabotegravir (CAB) – injectable – CAB –
  - From this point on to prevent any concerns about medication and bias
- DOXY-PEP – new concept/not fully embraced yet but from data shows promise

THE ENEMY


gp120
Docking
Glycoprotein
gp41
Transmembrane
Glycoprotein
RNA
Capsid
Matrix
Lipid
Membrane
Reverse
Transcriptase

THE ENEMIES ATTACK

- I will only focus on where the PrEP medications work
- Just remember it hijacks our own cellular function
- RNA Virus
- Entry of virus – conversion to RNA to DNA by RT current medication for PrEP attack this enzyme
- RNA converted to DNA must integrates into our DNA – current medication for PrEP drugs



SEXUAL HISTORIES

- We need to get over our discomfort about talking about sex - normalize it – GET OVER IT
- ALL PATIENTS should be evaluated – not only unmarried/people with an STI – ALL patients
- Do brief check on alcohol and illicit drugs (alkyl nitrite/meth)
  - Increases the risk
- Consider alternative sexual dynamics
  - We know gender, sexual orientation and gender expression are not binary – neither are relationship dynamics now
  - We also have stop considering monogamy as the default
  - CNM
  - Polyamory

- **HIGH RISK**
  - Exposure of vagina, rectum, eye, mouth, mucosal membranes, non-intact skin, percutaneous contact
  - With blood, semen, vaginal secretions, rectal secretions, and any body fluid with visible blood

- **Negligible RISK**
  - Urine, nasal secretions, saliva, sweat, tears - if not visibly contaminated with blood

DEMOGRAPHIC DATA

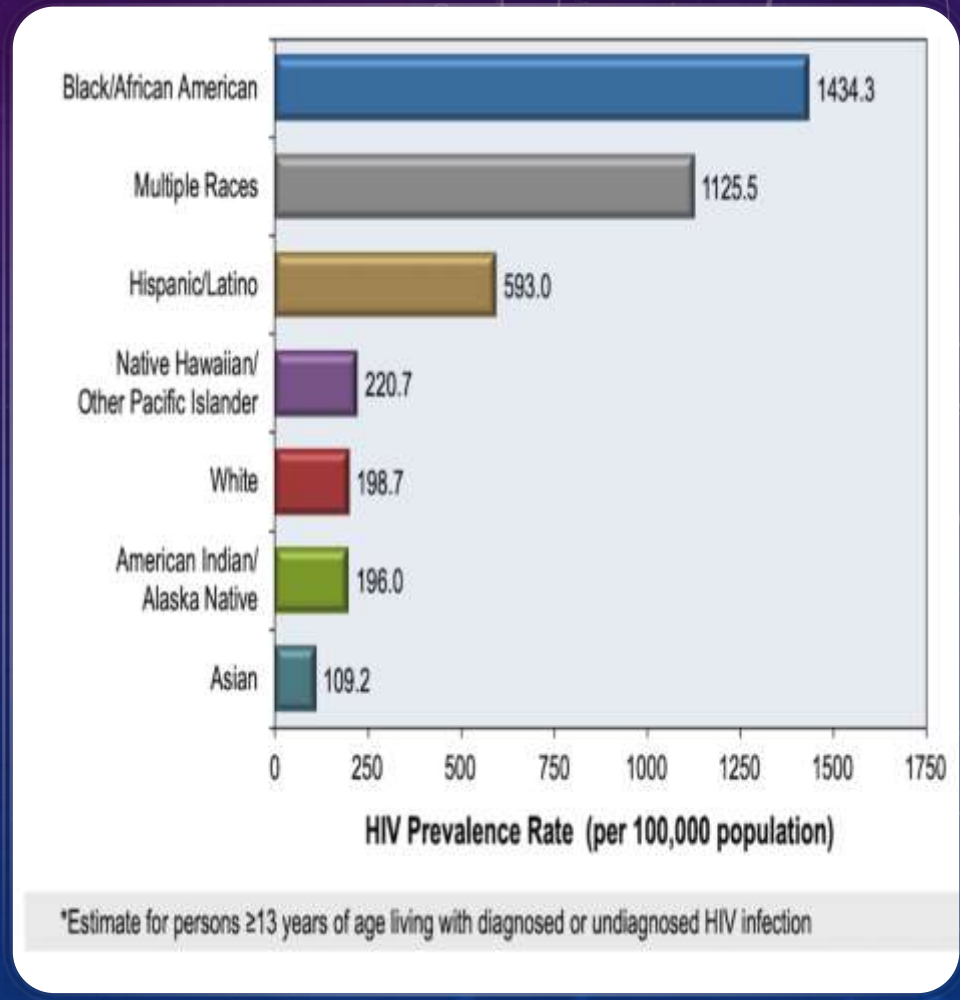
- **World Wide women constitute highest burden of HIV**
- **PrEP was indicated in 2021/2012**
  - **2018**
    - **Only 6% of Black persons were on PrEP**
    - **Only 10% of Latino/hispanic**
- **2018 Data New 39K**
  - 67% were in MSM – w/o IUD
  - 3% were MSM/IUD
  - 24% in Heterosexual (male-female) w/o IUD
  - 6% male-female w IUD
  - 2% Transgender individuals - but consider the number of individuals who identify as trans

SEXUAL ORIENTATION AND HIV INFECTION

Estimated New HIV Infections in United States, 2018	
Transmission Category	Estimated Number of New HIV Infections
Male-to-Male Sexual Contact	24,400
Male Injection Drug Use	1,400
Female Injection Drug Use	1,000
Male-male sexual and Injection Drug Use	1,400
Males with Heterosexual Contact	2,500
Females with Heterosexual Contact	5,700
Total	36,400

RACE/SOGI

- Black population
  - Higher rates in Black MSM 1:2
  - Among the individual with heterosexual activities which is 24% - 67% Black men/women
- Hispanic MSM : 1:4/5
  - White MSM : 1/11
- Aging
  - Higher number seen in Black Women
- Transgender individuals have a disproportionately higher number of individuals living with HIV relative to population



RISK FOR INDIVIDUALS WHO ARE BLACK/AFRICAN AMERICAN

HIV Infection Cases and Rates (Adults)

Estimated number of diagnosed cases and rates (per 100,000) of HIV infection, 2020			
	# Cases	Rate	African American/ White Ratio
African American males	9,859	60.9	7.8
White males	6,542	7.8	
African American females	2,965	16.4	10.9
White females	1,289	1.5	
African American (total, all ages)	12,856	31.0	7.8
White (total, all ages)	7,843	4.0	

- Black/African American make up 14% of the US population but account for 43% of new cases of HIV
- Black/African America women are 15x more likely to contact HIV then white women
- Higher rates seen in the southern states

TRANSGENDER DATA

- Only 2% of individuals who identify as transgender
- In USA 21% of transgender women are living with HIV
- Limited data for transgender men, but predictions it is higher then their cis-gender counterparts

HIV Prevalence Among Transgender Women in 7 US Cities, 2019-2020*

Racial and ethnic disparities exist among transgender women with HIV.

Among transgender women interviewed, 42% had HIV.

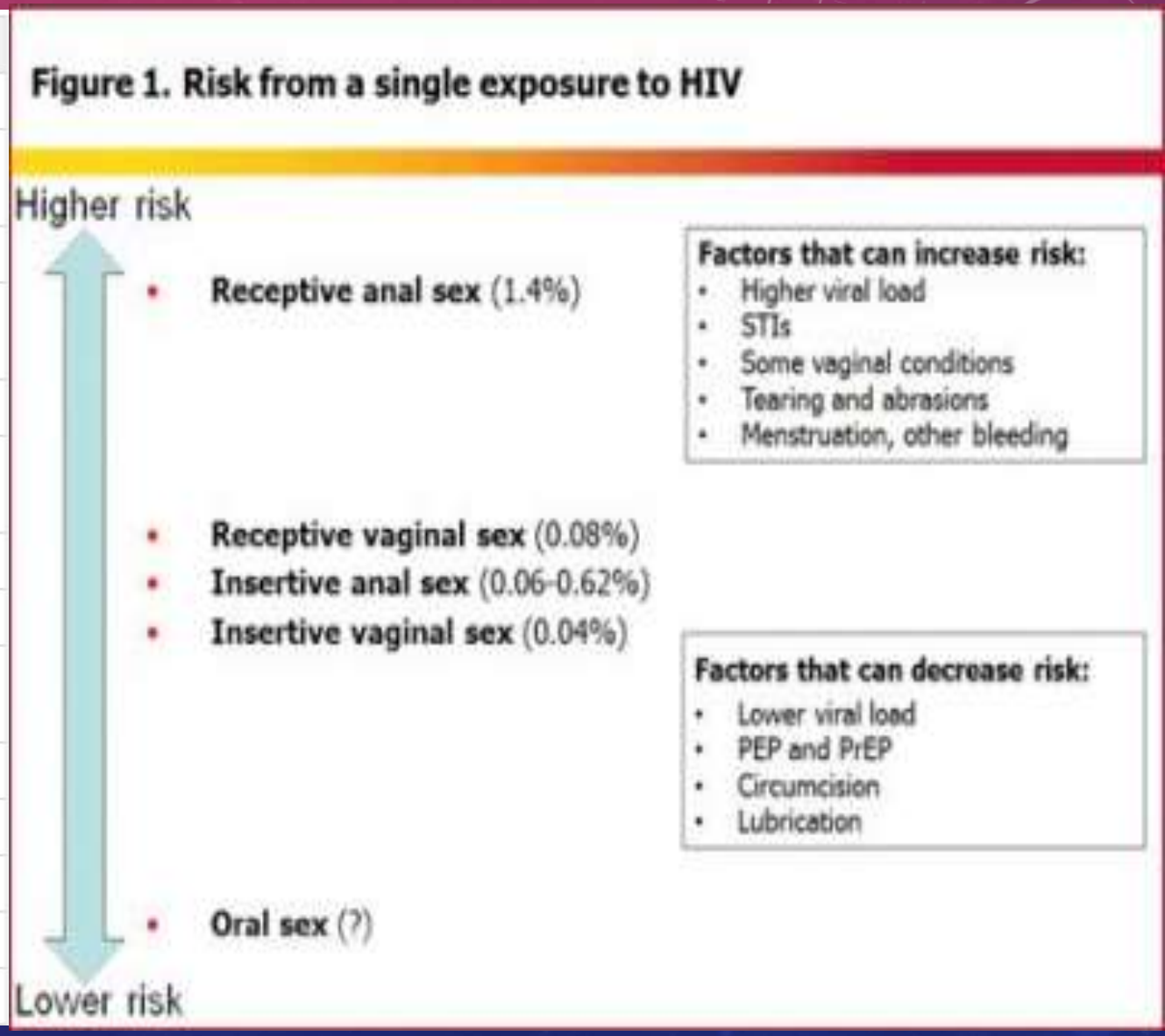
- 62% of Black/African American transgender women had HIV
- 35% of Hispanic/Latina transgender women had HIV
- 17% of White transgender women had HIV

* Among people aged 18 and older.

Source: CDC. HIV infection, risk, prevention, and testing behaviors among transgender women–National HIV Behavioral Surveillance–7 U.S. Cities, 2019-2020 [PDF – 2 MB]. *HIV Surveillance Special Report* 2021.

RISKS

Activity	Risk-per-exposure
Vaginal sex, female-to-male, no condom	0.04% (1 in 2380)
Vaginal sex, female-to-male, no condom, undetectable viral load	0%
Vaginal sex, male-to-female, no condom	0.08% (1 in 1234)
Vaginal sex, male-to-female, no condom, undetectable viral load	0%
Receptive anal sex, no condom	1.38% (1 in 72)
Receptive anal sex, no condom, undetectable viral load	0%
Insertive anal sex, no condom	0.11% (1 in 909)
Insertive anal sex, no condom, undetectable viral load	0%
Receptive fellatio, no condom, viral load not known	Estimates range from 0.00% to 0.04% (1 in 2500)
Pregnancy and childbirth, no preventative measures	22.6% (1 in 4)
Pregnancy and childbirth, undetectable viral load	0.14% (1 in 715)
Injecting drug use	0.63% (1 in 158)
Needlestick injury with contaminated blood	0.23% (1 in 435)
Blood transfusion with contaminated blood	92.5% (9 in 10)



CDC STATEMENT

- 1.2 million people are eligible for PrEP
- Increasing use is one of the Goals of “Ending the Epidemic”
- 2012 – only approximately 8K now 2018 – 220K – we are not reaching people
- Everyone is eligible MSM, Heterosexual men/women, IUD
- Lack data small numbers of Transgender women non on transgender men – does not matter use it

WHY THE ISSUE WITH DETECTION?

- How many of you know your HIV status?
- Vague symptoms
- Fear of knowing their status
- Fear of rejection
- Fear of legal issues repercussions
- Recommendation is everyone should have one HIV test once within their lifetime (13y/o—65y/o)
- All pregnant patients should have an HIV test during intake, and possible at 36 weeks
- As a friend of mine says, “there is nothing sexier than going on your first date and getting an HIV test“

WHY ITS HARD TO TELL

DURING THE INITIAL INFECTION YOU MAY NOT KNOW

SYMPTOMS ARE PRETTY VAGUE

CAN LOOK LIKE THE FLU

IT LOOKS LIKE ANY VIRAL ILLNESS

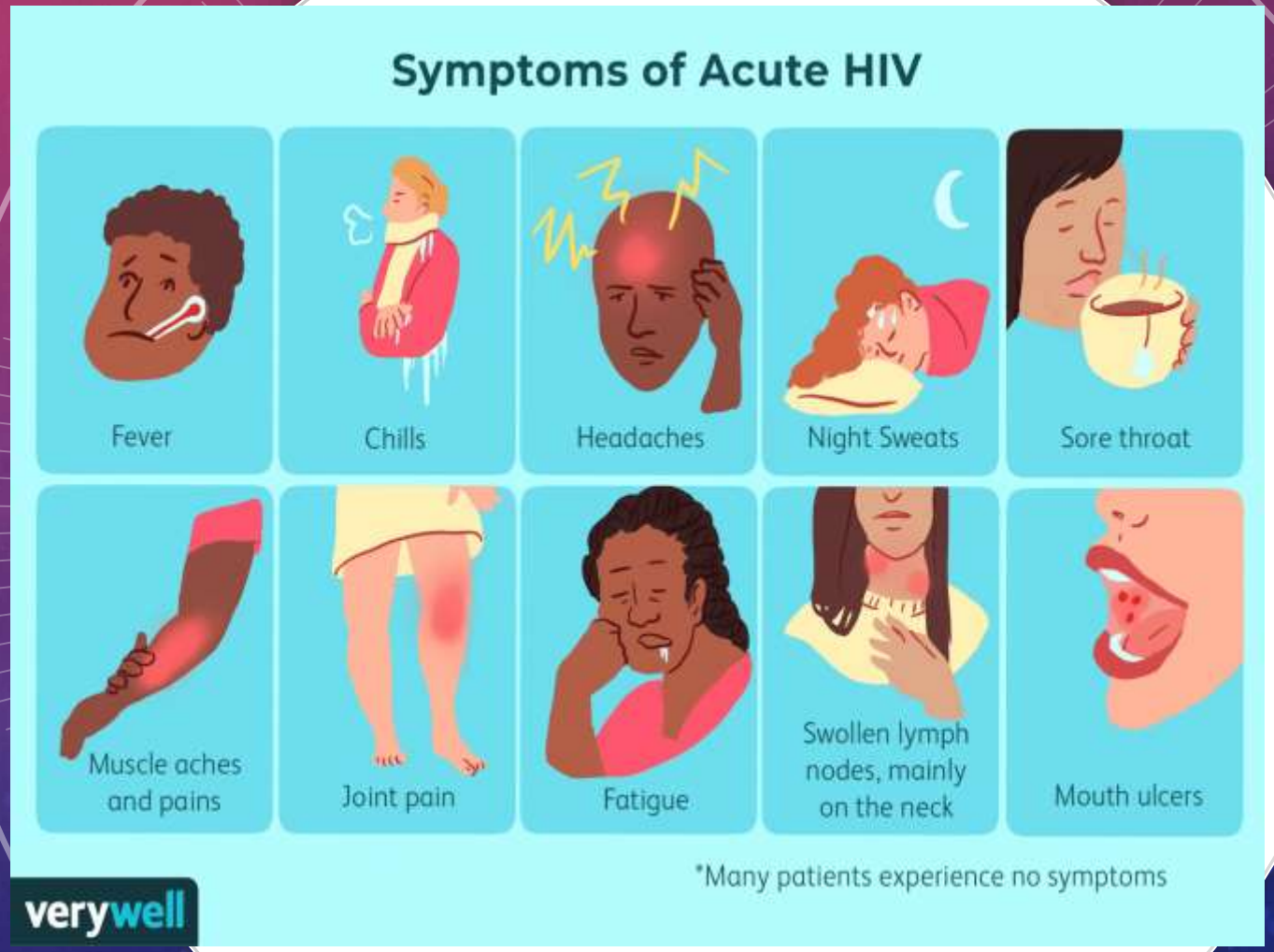


Table 2: Clinical Signs and Symptoms of Acute (Primary) HIV Infection[71]

Features	Overall (n = 375) %	Sex		Route of transmission	
		Male (n = 355) %	Female (n = 23) %	Sexual (n = 324) %	Injection Drug Use (n = 34) %
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

Figure 4a below illustrates the recommended clinical testing algorithm to establish HIV status before the initiation of PrEP in persons without recent antiretroviral prophylaxis use. Laboratory

SIGNS AND SYMPTOMS

- As you see vague symptoms
- Most common fevers and fatigue

INSIDE YOUR CELLS

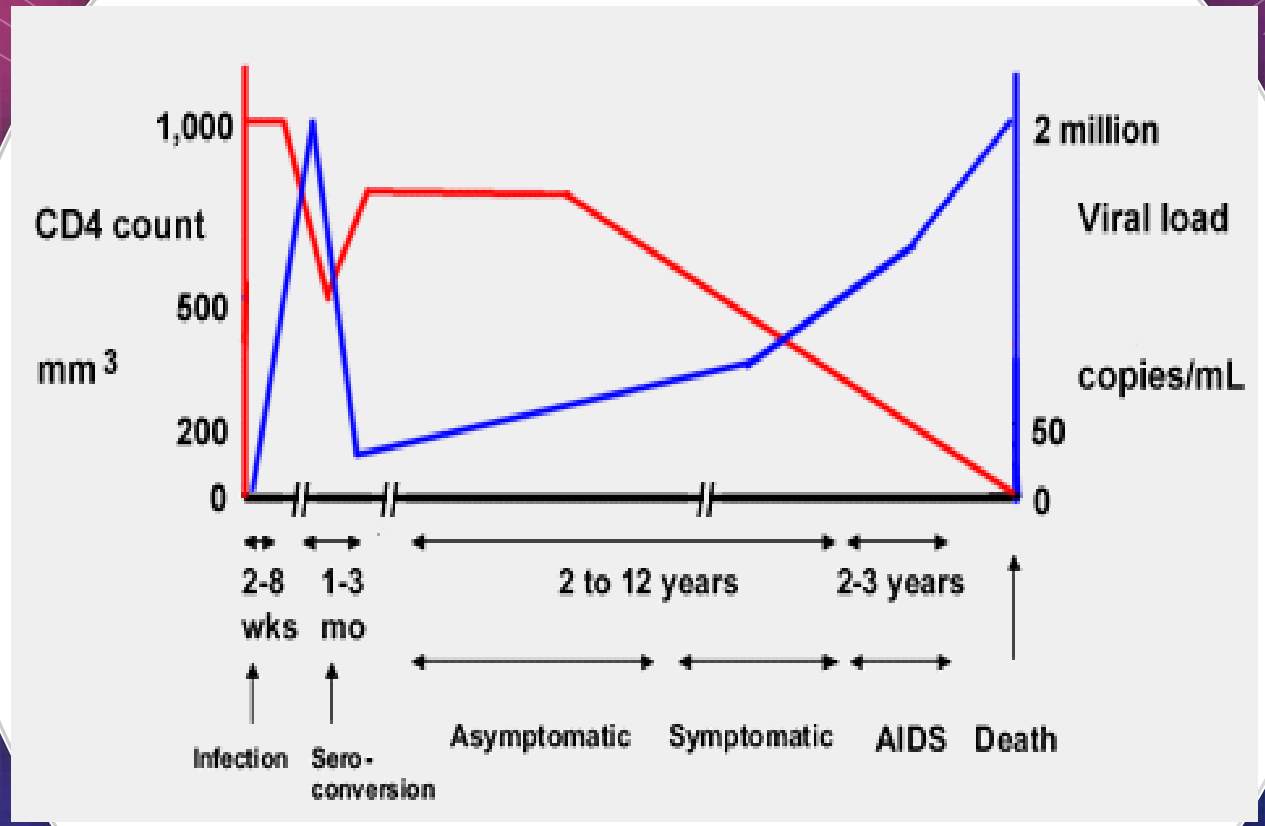
THIS IS HOW IT LOOKS FOR THE ACUTE SERO-CONVERSION

DURING ACUTE HIV YOU GET A MASSIVE REPLICATION AND SPIKE IN THE VIRUS

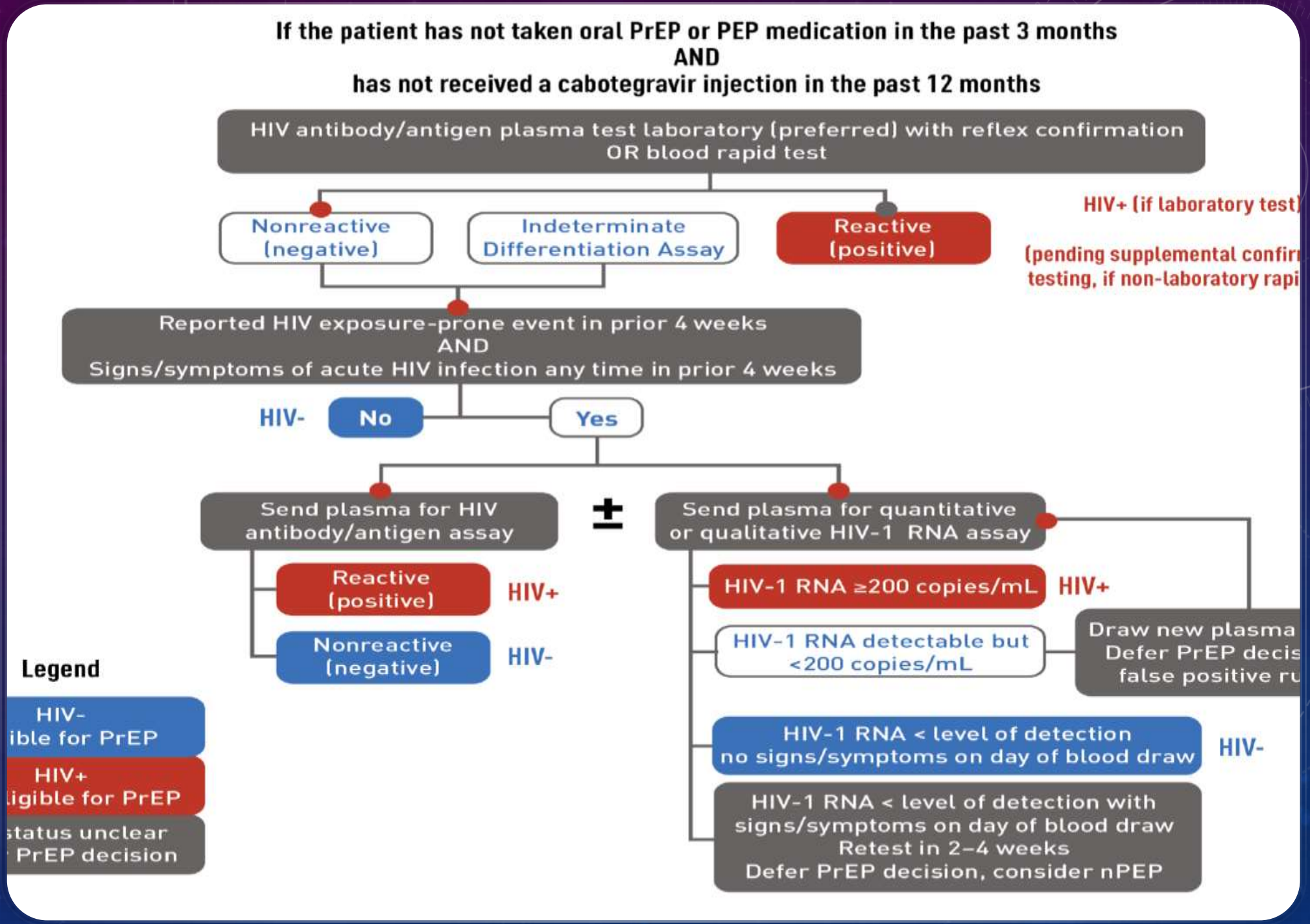
ACUTE RETRO VIRAL SYNDROME

THE VIRUS THEN GOES TO A STABLE POINT AND REMAINS IN THE CELLS REPLICATING AND DAMAGING THE SPECIAL CELLS CALLED CD4

AS THE CD4 CELLS DROP THE VIRUS INCREASE AND YOU GO INTO AIDS DEFINING ILLNESS



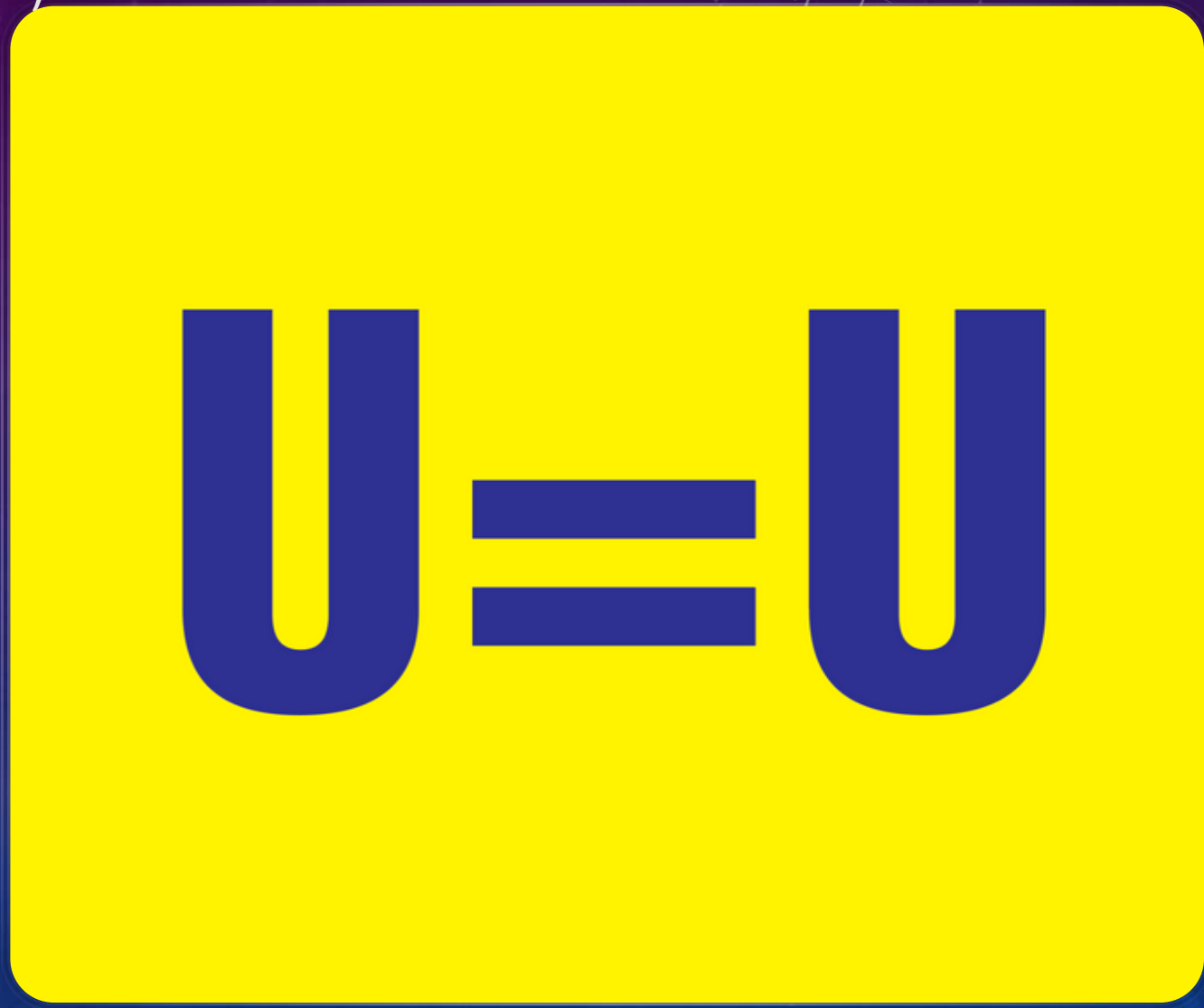
ALGORITHM


If the patient has not taken oral PrEP or PEP medication in the past 3 months
AND
has not received a cabotegravir injection in the past 12 months
HIV antibody/antigen plasma test laboratory (preferred) with reflex confirmation
OR blood rapid test
Nonreactive (negative)
Indeterminate Differentiation Assay
Reactive (positive)
HIV+ (if laboratory test)
(pending supplemental confir
testing, if non-laboratory rapi
Reported HIV exposure-prone event in prior 4 weeks
AND
Signs/symptoms of acute HIV infection any time in prior 4 weeks
HIV-
No
Yes
Send plasma for HIV antibody/antigen assay
±
Send plasma for quantitative or qualitative HIV-1 RNA assay
Reactive (positive)
HIV+
Nonreactive (negative)
HIV-
HIV-1 RNA ≥200 copies/mL
HIV+
HIV-1 RNA detectable but <200 copies/mL
Draw new plasma
Defer PrEP decis
false positive ru
HIV-1 RNA < level of detection
no signs/symptoms on day of blood draw
HIV-
HIV-1 RNA < level of detection with signs/symptoms on day of blood draw
Retest in 2–4 weeks
Defer PrEP decision, consider nPEP
Legend
HIV-
ible for PrEP
HIV+
igible for PrEP
status unclear
PrEP decision

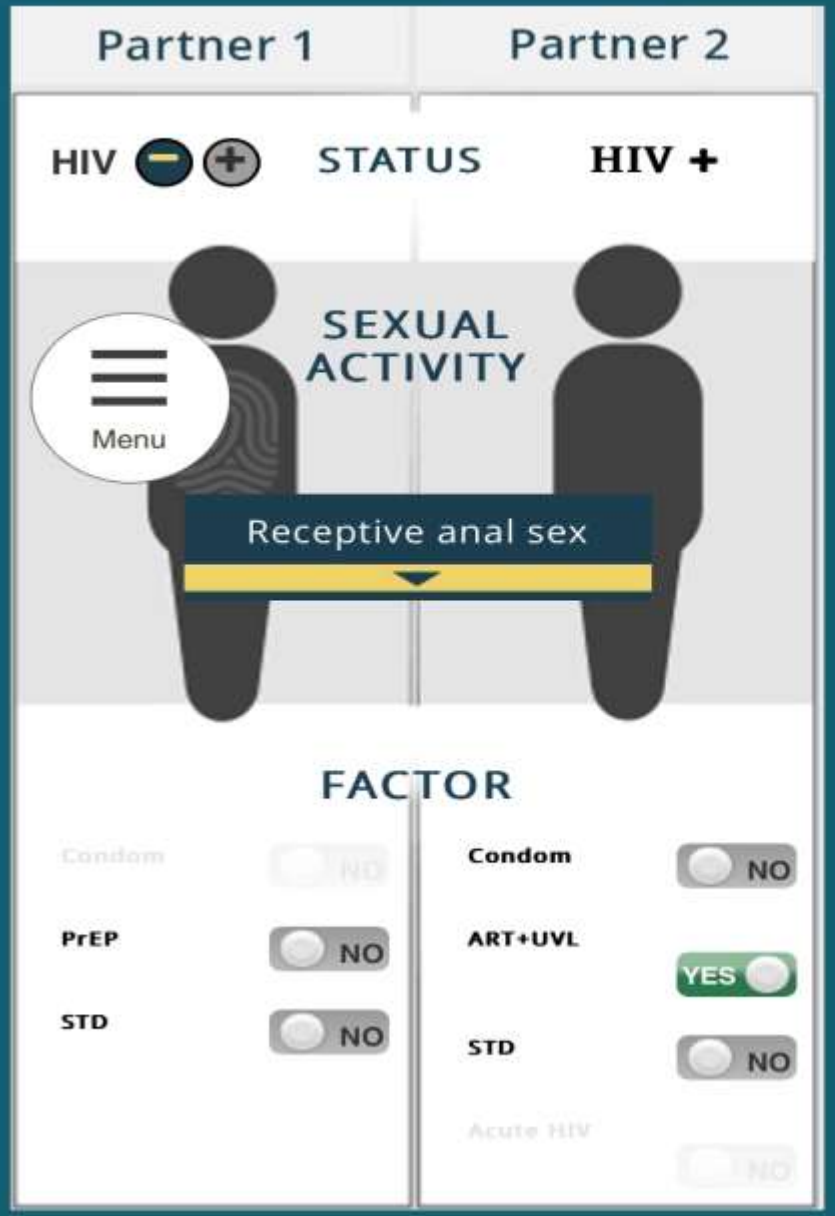
STOP THE STIGMA
STOP THE FEAR OF HIV
STOP SEXUAL HEALTH SHAMING

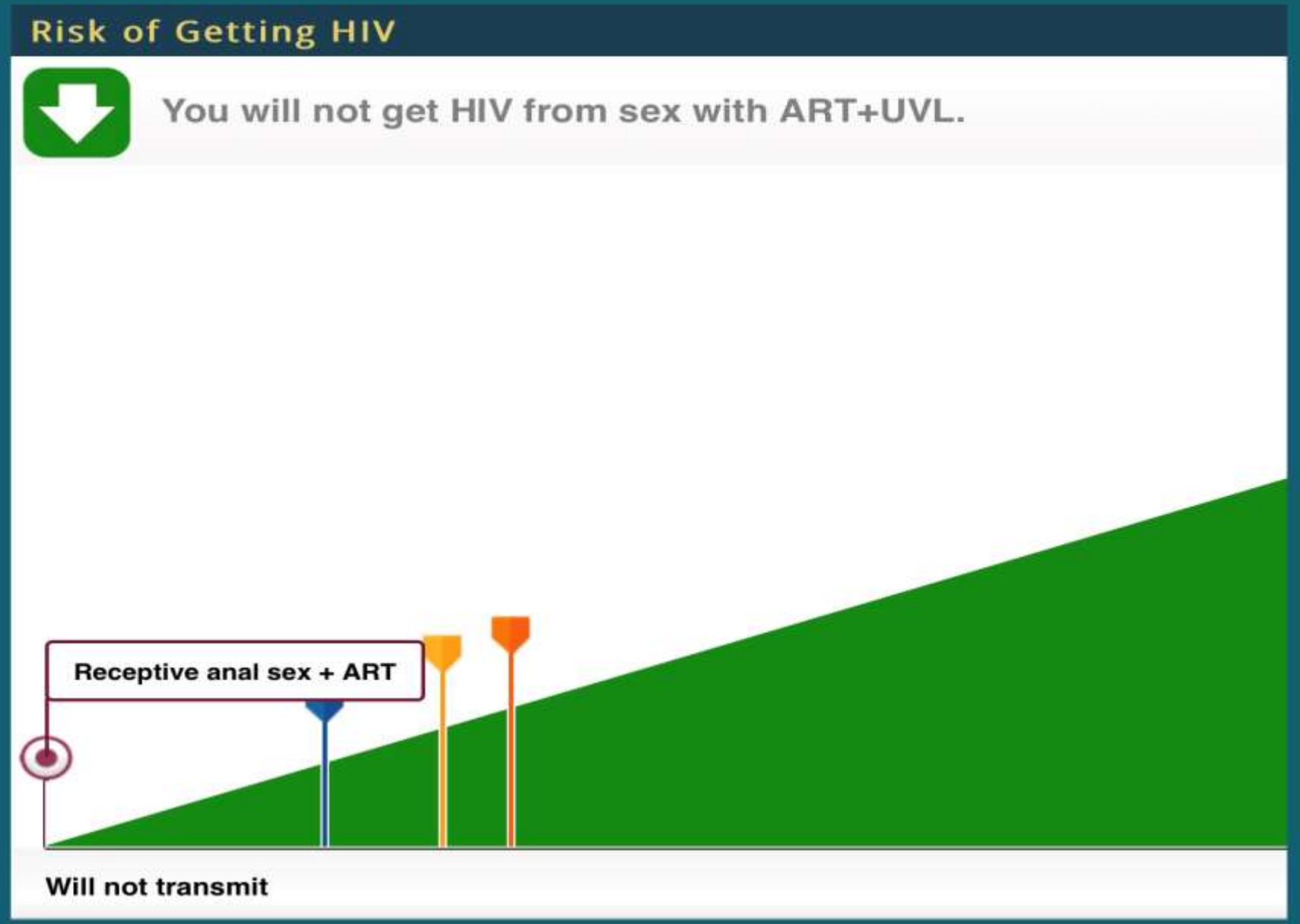
TREATMENT AS PREVENTION (TASP)

- This is an individual who is HIV positive
- They are taking their medications as prescribed, following with their doctor
- With proper medication adherence suppression can occur within 6 weeks
- If after suppression we can maintain viral suppression for 6 months, and viral load is less then 200copies (WHO), this individual becomes undetectable and therefore Un-transmittable – they CAN NO LONGER TRANSMIT HIV
- Opposites attract, partners 1&2, UPTN 052
- U=U – when talking to patients focus on the positive aspects of viral suppression – STOP THE STIGMA



U=U (CDC/NIH)


Partner 1
Partner 2
HIV
STATUS
HIV +
SEXUAL ACTIVITY
Menu
Receptive anal sex
FACTOR
Condom
NO
PrEP
NO
STD
NO
Condom
NO
ART+UVL
YES
STD
NO

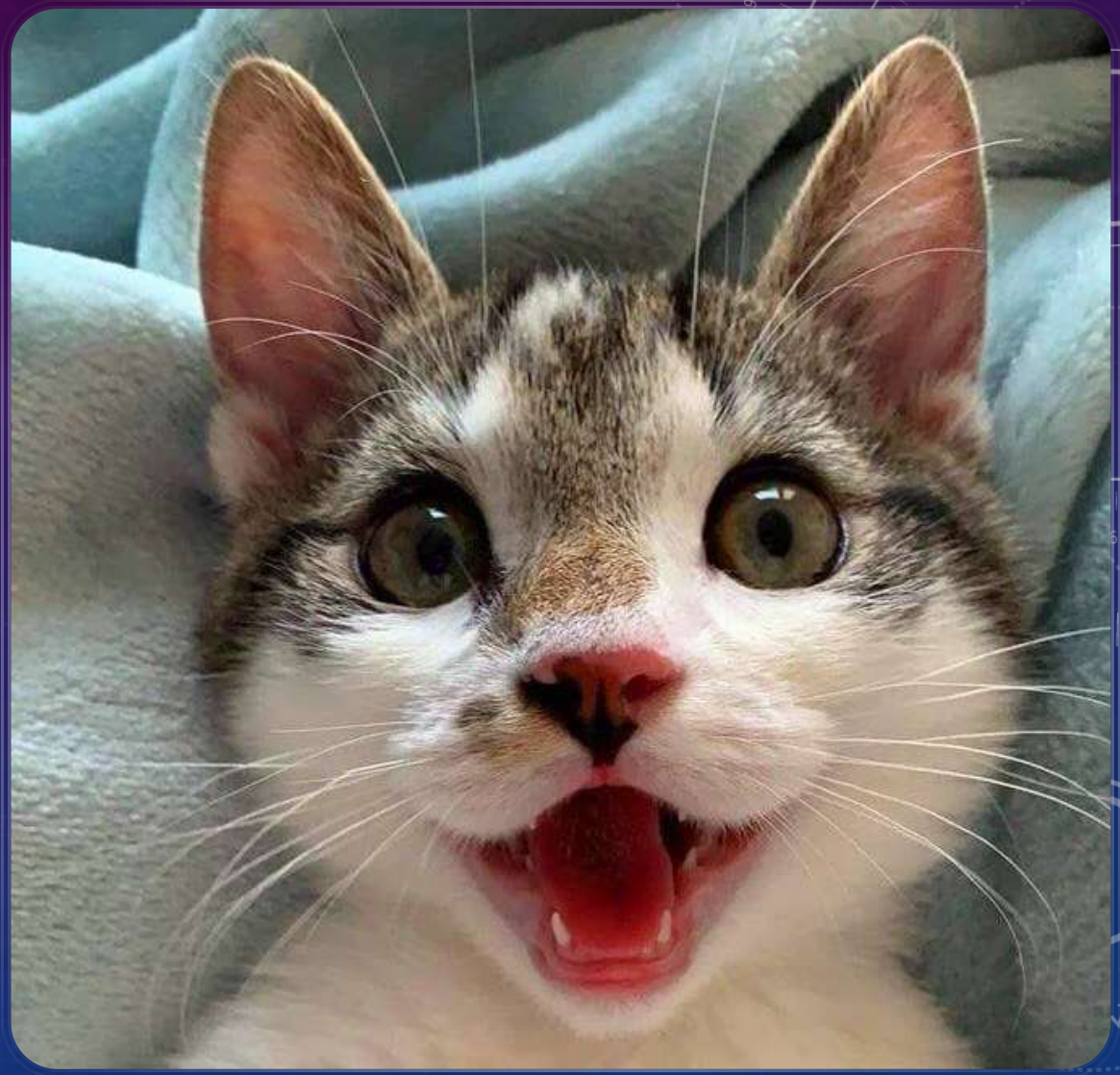

Risk of Getting HIV
You will not get HIV from sex with ART+UVL.
Receptive anal sex + ART
Will not transmit

YOUR PATIENT HAS A HIGH RISK EXPOSURE

- They use IUD
- You never asked what their partners HIV status was or they did discuss
- You had unprotected sexual intercourse or IUD
- Your patient is not on HIV prevention medications

ALL IS NOT LOSS

- Seek medical assistance – Talk to you patients about this options consider the risk we dicussed
- Protective medication are possible



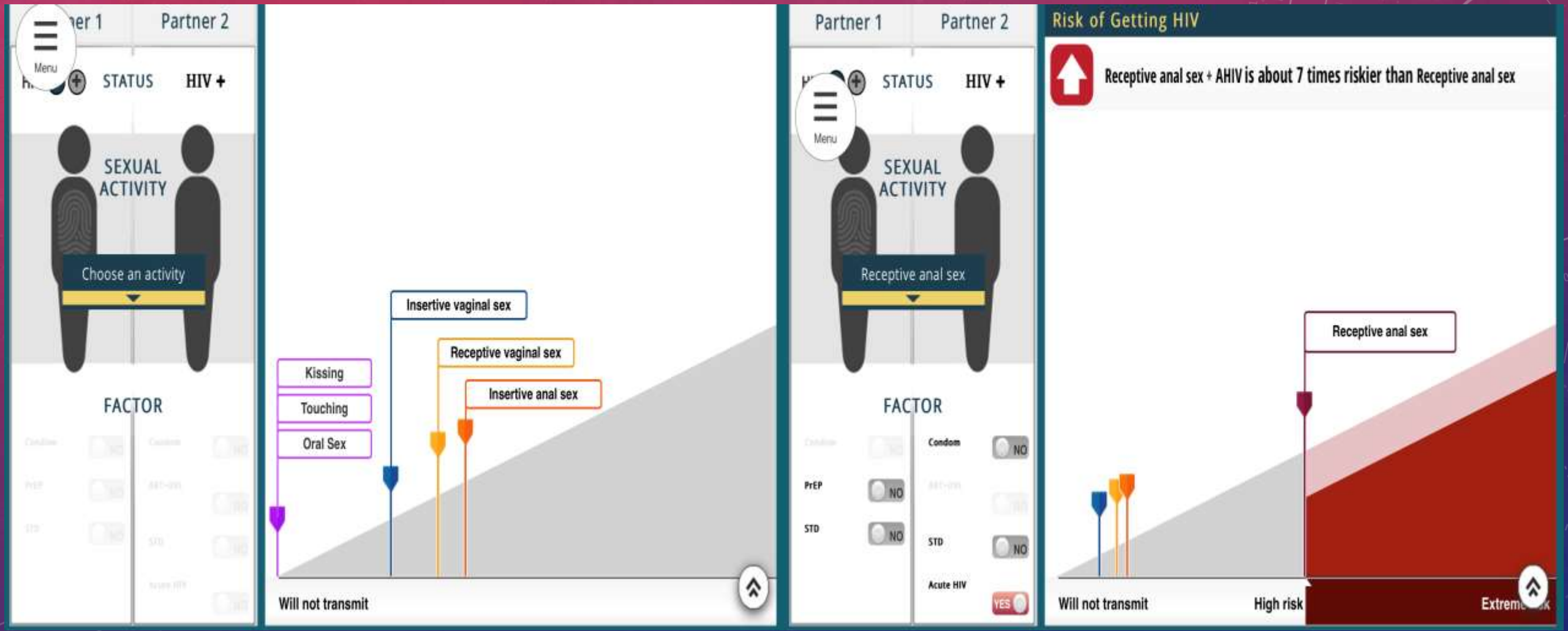
POST EXPOSURE PROPHYLAXIS

- Medications that will reduce their risk of HIV
- It's usually either:
  - FTC/TDF + DTG or RAL HD
  - FTC/TAF + DTG or RAL HD
  - Other medications at the discretion of the provider (study underway with a 3 medication in one pill)
- The issue you only have **72 hour window** from the time of exposure, if greater then 72 not recommended
- 28 Days of medication
- You need bloodwork then needs to be repeated in 1 month
  - The first draw is to determine your own status at point 1, then point 2 after that some recommendation would be monitor repeat in three month and some recommend up to 6 Months

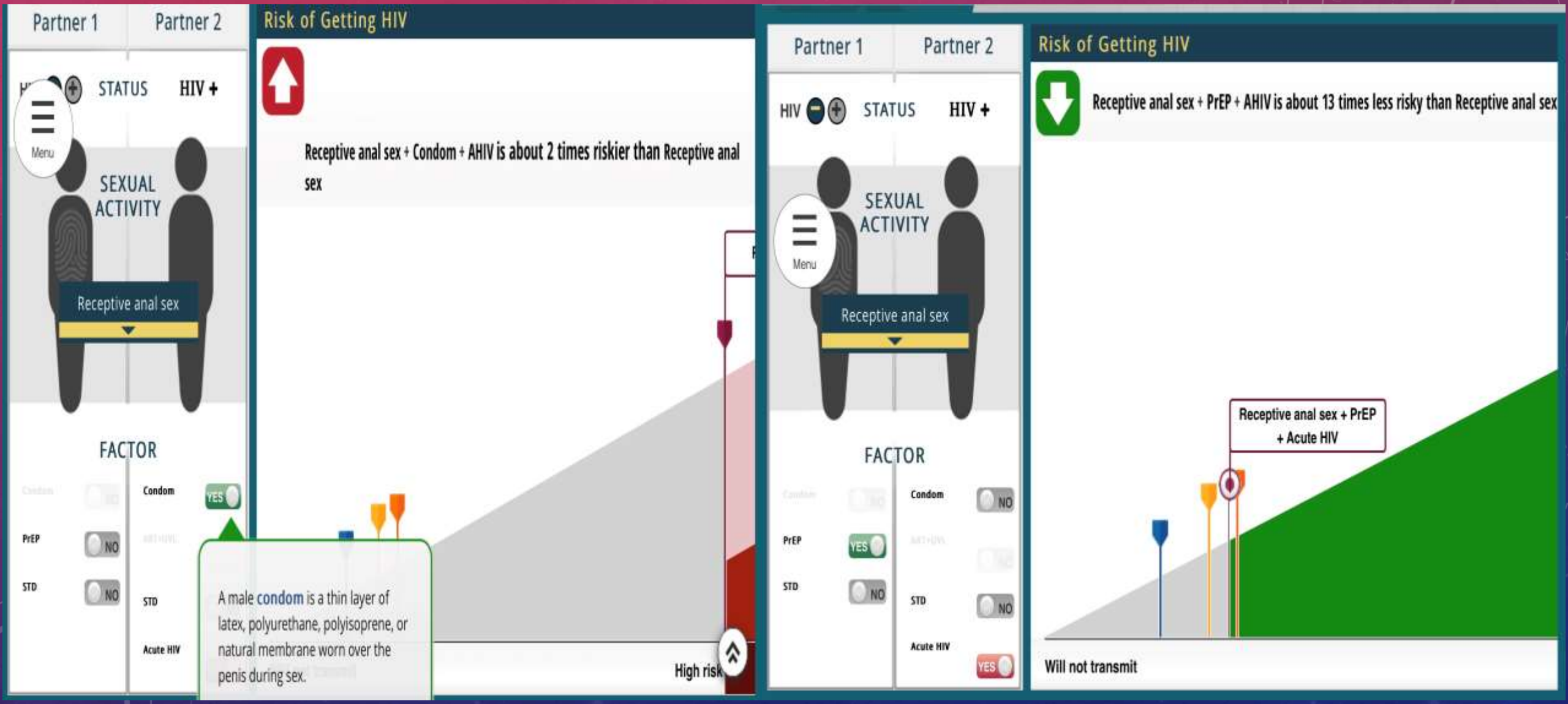
WHAT TO DO NEXT AFTER PEP

- If you do not know how to do PEP call someone who is more comfortable - there are hotlines to do it
- This should start the talk about PEP—> PrEP
- Information is also in your Sanford guide

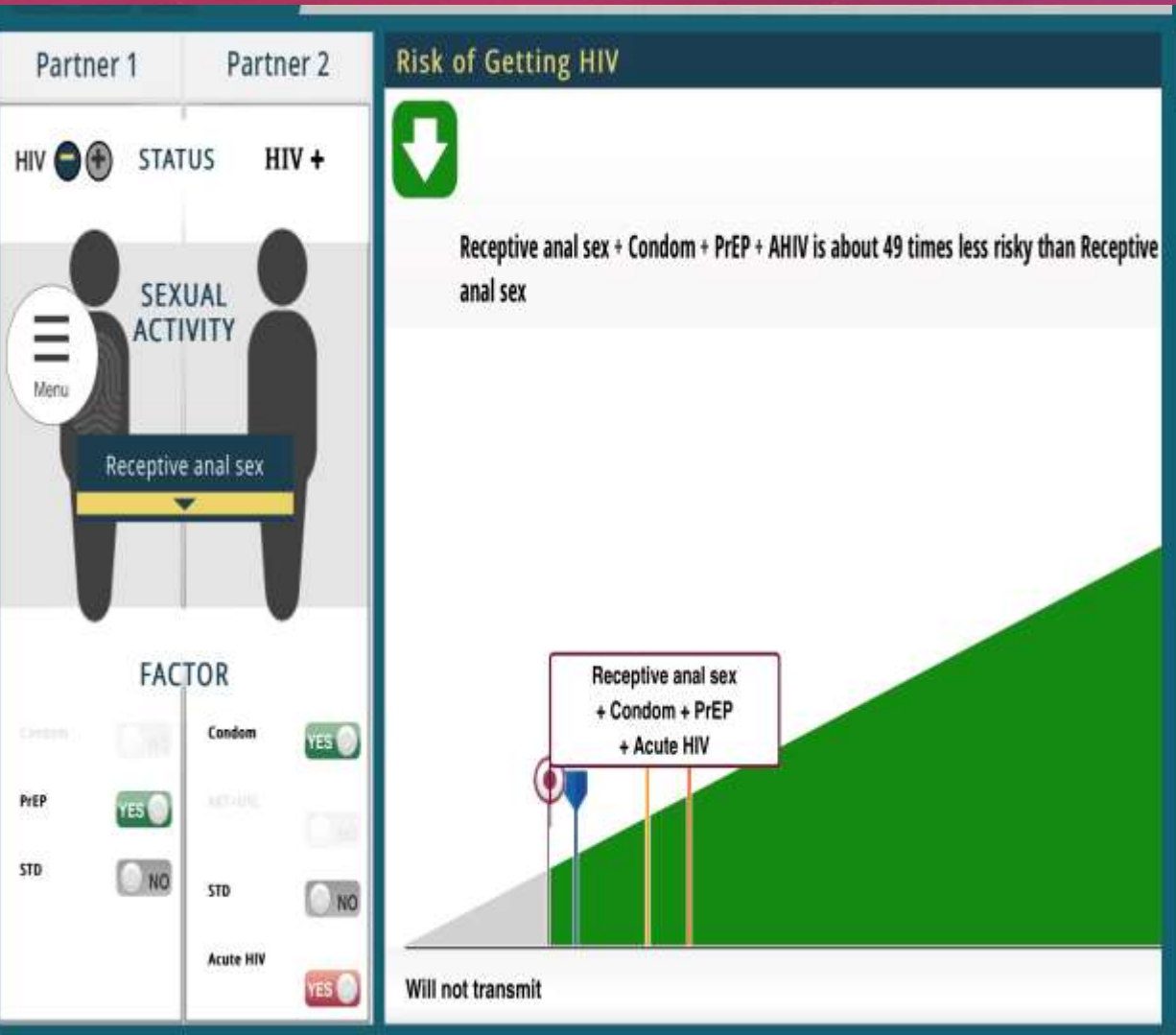
HIGHEST RISKS – ACUTE HIV INFECTON

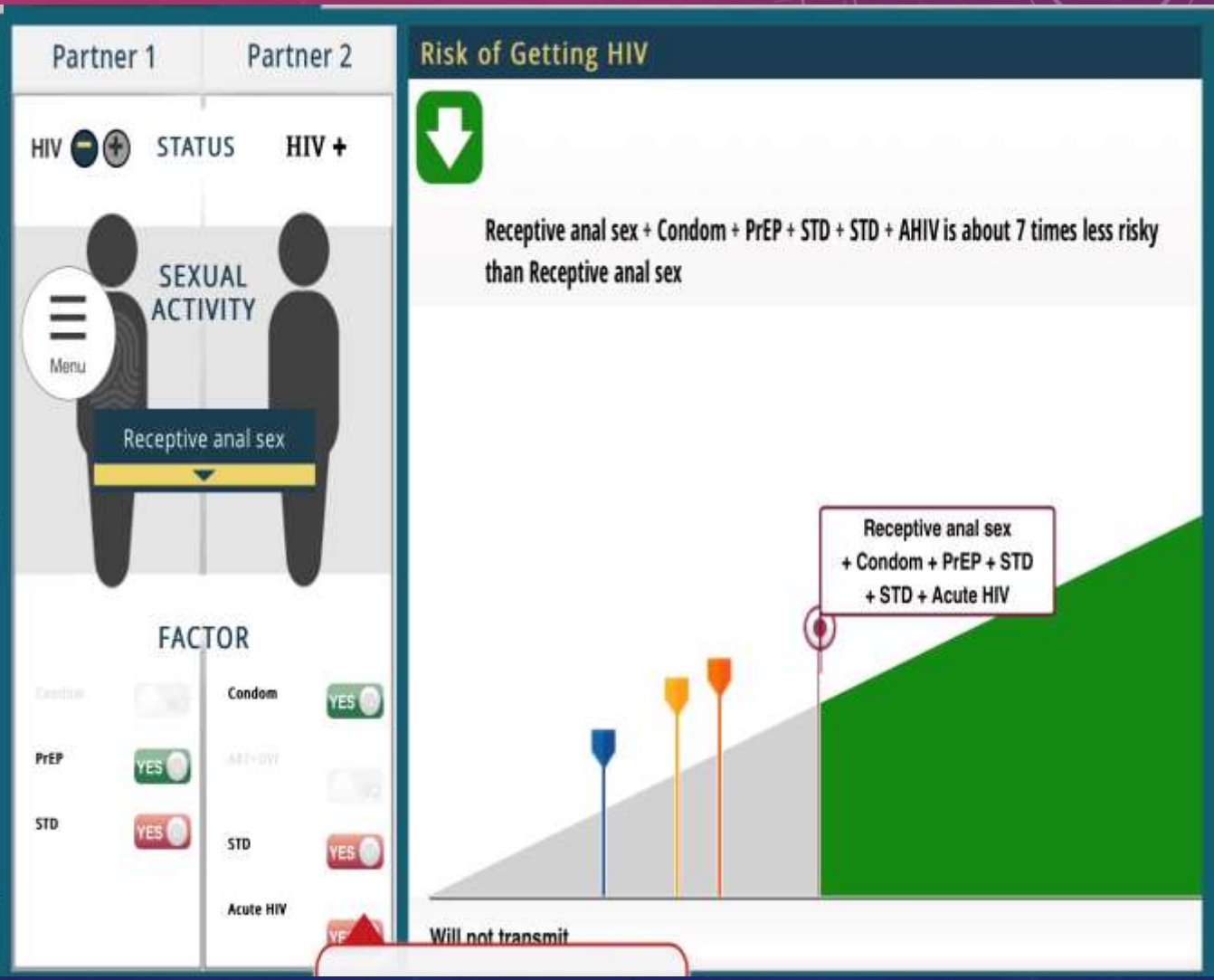


RISKS (CONDOMS VS PREP)

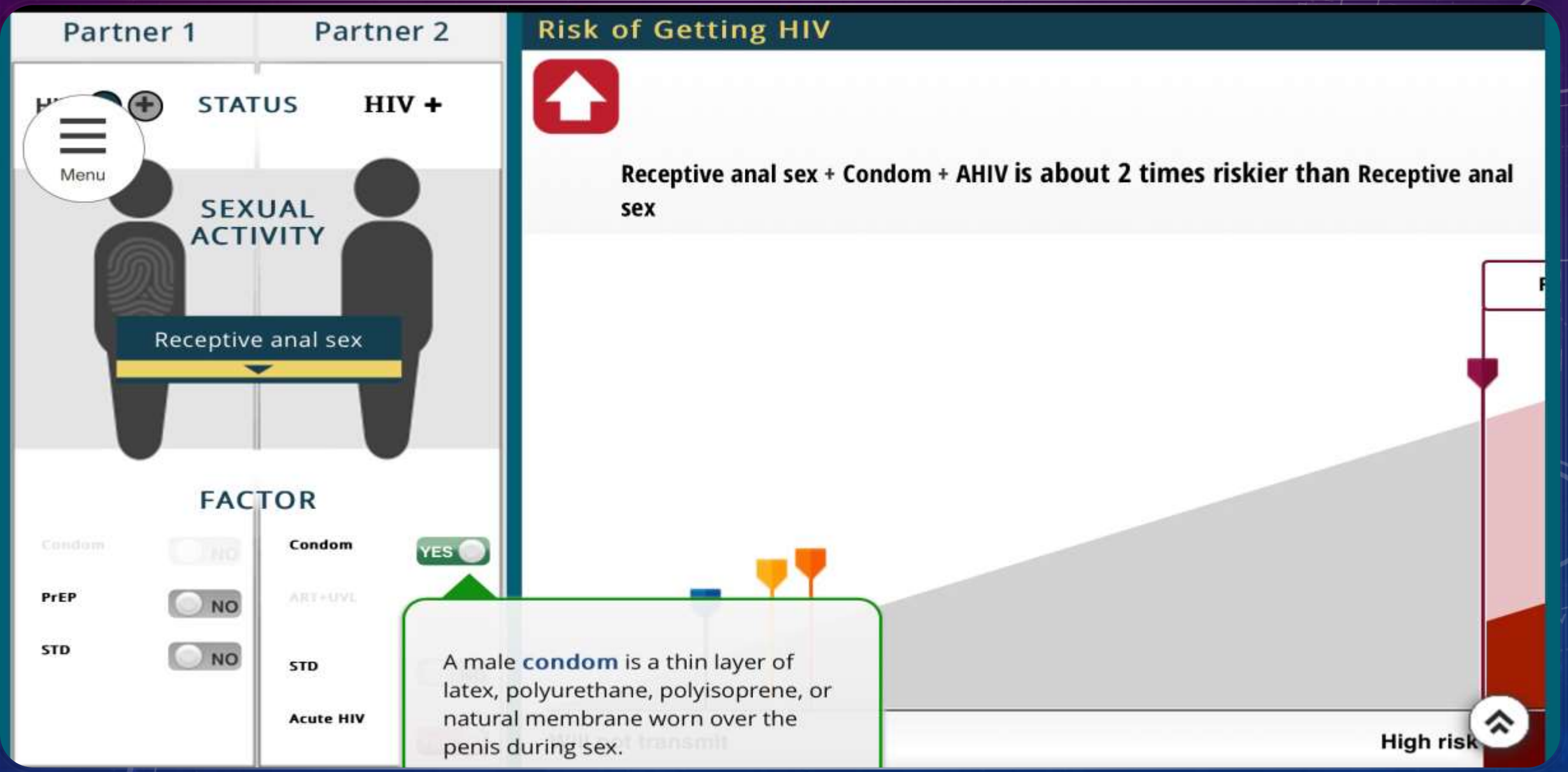


RISKS (PREP + CONDOM) VS. PREP + CONDOM+ STI





ACUTE HIV AND CONDOMS ALONE



OUR FRIEND THE CONDOM

- Reported consistent use of condoms in the heterosexual individual is only 80% reduction
- Reported consistent use of condoms in the MSM individual is only 70% reduction
  - CDC PREEXPOSURE PROPHYLAXIS FOR HIV PREVENTION 2021 pg: 26/108
- **@@@@ CONDOMS for HIV prevention**
- DO NOT GET ME WRONG THEY ARE GOOD STI but not acute HIV or through condom use
- FYI condoms were never studied in anal sex, we now have a condom specific for anal
- Be carful not to shame individuals for not using – sex shaming is counter productive to you and the patient – you could have just lost someone you could help

IUD

- Number of new case of HIV have dropped
- Receptive sharing syringes was 33% and equipment was 55%
- Males: Increased rates of HIV when not using condoms with female partners but lower with male partners (anal)
- Females: higher rates of condom less vaginal and anal
- The study for PrEP for IUD only used TDF although we tend to use dual agents
- Some cases occur in transgender patients due to non-prescribed medications –
- Besides PrEP also consider medication assisted therapy/mental health services and syringes services programs for sterile needles.

PREEXPOSURE PROPHYLAXIS (PREP)

- **Multiple form of PrEP**
  - Oral Forms
    - FTC/TDF
    - FTC/TAF
  - IM CAB
- Essentially taking the medications it will reduce patients risk by 99%

WHERE DID PREP COME FROM

- Ipex/Ipex (OLE) – showed incident of HIV was 1:8/100 pay vs 2.6/100 people year (FTC/TDF)
- PROUD – England – stopped early due to interim analysis showing superiority of PrEP (FTC/TDF)
- DEMO – showed 2 seroconversions but individuals were taking less then 2 doses (FTC/TDF)
- Partners (PREP) heterosexuals – cis males/females was only either TDF or FTC or FTC/TDF – stopped interim analysis showed benefits – Even had sero-discordant couples
- ATN – Adolescent trial – confirmed the use in individuals >35kg
- FEM-PrEP – heterosexual cis-women – did not show benefit with FTC/TDF - low levels <50% drug
- Other studies using vaginal ring did not show significance
- Bangkok – IUD – when levels were detected it did show about a 73% reeducation – only TDF
- Discover – TAF as PrEP showed effectiveness
- HPTN 083 – looked at CAB vs TDF – did have oral lead in – not required now – CAB non-inferior to TDF
- HPTN 084 – did the every 2 month comparing the monthly vs ever 2 which was just as effective

DATA SHOWED CONSISTENT USE OF FTC/TDF OR FTC/TAF OR CAB REDUCES RISK HIV ACQUISITION

PICTURES OF THE DRUGS

IN 2011 CDC INTERIM APPROVAL/2012 FULL GUIDELINES – UPDATED FOR TAF

- **FTC/TDF**
  - Does not matter sexual orientation or gender identity or IUD
  - Can only give if renal function > 60ml/min
  - There can be some incremental rise in Cr and minimal bone density changes
  - ONLY FIXED DOSE MEDICATION ALLOWED
  - Variation on therapeutic doses in tissues (rectal (7d) /vaginal (20d)/ blood (about 20d)
- **FTC/TAF**
  - Limited to cis-gendered or transgender women
  - Can be given if renal function > 30 or <15
  - Some incremental rise in cr and bone density changes
  - Fixed dosed

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

INDICATIONS

- Pretty Broad indications
- U=U ??? Patient decision?
- You do need to follow up every 3 months
- I personally disagree with some aspect - (asymptotic)

Table 5 Timing of Oral PrEP-associated Laboratory Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

VISITS/TEST

- Screening should include all locations you are having sex with
- Hepatitis B serology has to be checked since TDF/TAF can be used to treat active hepatitis b or chronic hepatitis b – Stop issues
- TAF is only indicated for MSM or Transgender women – was not studied with significant cis-women or Transgender men
- Provider allowed to modify
- Variation from CDC other statements

	TDF	TAF
Buprenorphine	No significant effect No dosage adjustment necessary	
Methadone	No significant effect No dosage adjustment necessary	
Oral contraceptives	No significant effect No dosage adjustment necessary	
Feminizing hormones (Spironolactone, estrogens)	Lower tenofovir-diphosphate rectal tissue levels (unknown if it affects PrEP effectiveness). TDF does not affect hormone levels	*No data available*
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion	Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities	*No data available*
Adefovir	**Do not co-administer with TDF** Serum concentration of TDF may be increased, monitor for toxicities	*No data available*
Ledipasvir, sofosbuvir, velpatasvir, voxilaprevir	Serum concentrations of TDF may be increased. Monitor for toxicities	No significant effect
St John's Wort	No significant effect	**Do not co-administer with TAF** Decrease in TAF concentration possible
Rifampin	No significant effect	**Do not co-administer with TAF unless benefits outweigh risks**
Rifabutin, Rifapentine	No significant effect	**Do not co-administer with TAF**

INTERACTIONS

- Interaction with medications can occur but clinical significance is questionable
- Always ask your patients about otc medications
  - These drugs can sometimes create more problems with how the drug acts or metabolizes

INITIATION ISSUES

Table 3: Recommended Oral PrEP Medications

Generic Name	Trade Name	Dose	Frequency	Most Common Side Effects[109,110]
F/TDF	Truvada	200 mg/300 mg	Once a day	Headache, abdominal pain, weight loss
F/TAF	Descovy	200 mg/25 mg	Once a day	Diarrhea

- TDF – Cr and BMD (1%) issues can happen but it's monitored – when stopped returns to normal
- TDF some question about younger MSM
- TAF – slightly lower Cr and Bone increased in BMD
- TAF may increase TG, increase CVD check Lipids
- Study ATN 110 (18-22) larger bone decline in age 15-19, then 20-22 – bone density decrease more in younger patients – recommendation by CDC is TAF compounds

CRITICAL:

Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV Incidence per 100 person/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

- Has to be taken daily to be fully effective
- Effectiveness drops with missed pills (well duh)
- Time to tissue detection varies
- If you do not take it will not help

CAB

- Hard to cover
- Have to fail oral medication
- It’s 3cc of medication in you bum
- Month ½ then every 2 month
- Ideally same day, but 7 days before or after date allowed
- If need you can give up to 2 months of oral as backup
- Common side effect are more site location – recommend NSAID prior and warm compress area

Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually-Active Adults	Persons Who Inject Drugs[1]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle ○ Initial dose ○ Second dose 4 weeks after first dose (month 1 follow-up visit) ○ Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)	
Follow-up care	**At follow-up visit 1 month after first injection** • HIV Ag/Ab test and HIV-1 RNA assay **At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:** • Bacterial STI screening[2] for MSM and transgender women who have sex with men[2] – oral, rectal, urine, blood **At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:** • Bacterial STI screening[1] for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood **At follow-up visits at least every 12 months (after the first injection) provide the following:** • Assess desire to continue injections for PrEP • Chlamydia screening for heterosexually active women and men – vaginal, urine **At follow-up visits when discontinuing cabotegravir injections provide the following:**	

[1] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[2] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

CAB START

- Very similar indicated
- +/- initiation with oral lead in
- The oral medication cannot be used for PrEP
- You have to come to office or center
- One benefit it can be given independent of SOGI to everyone
- Issue is the medication cannot be used to
- Possible for housing instability issues, sex workers
- U=U ????

MONITORING

- You do not need all the baseline labs: LFT, lipids, renal function or hepatitis B serology
- Personally I do not agree if you are trying risk mitigation – NOT CHECKING HEPATITIS B STATUS
- Common issues site location reaction – NSAID prior and warm compress after
- BIG ISSUE IS IF YOU STOP LONG TAIL – CAN INCREASE RISK OF INFECTION DEVELOPMENT OF POSSIBLE RESISTANT STRAIN – NEED TO BE ON ANOTHER FORM OF PrEP if at risk 8 week up to 67 weeks still detectable
- SCREENING THEN VARIES ON SOGI ????
- We also do not know how long until protection

Table 7 Timing of CAB PrEP-associated Laboratory Tests

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW⁻ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay
X all PrEP patients
^ men who have sex with men
⁻ persons assigned male sex at birth whose gender identification is female

Table 6 Cabotegravir PrEP Drug Interactions (https://www.hiv-druginteractions.org/)

Rifampicin, rifapentin	**Do not co-administer with CAB** Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB [142, 143]
Rifabutin	**Co-administer with caution** Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB[144]
Hormonal contraceptives	No significant effect[145]
Feminizing hormones (Spironolactone, estrogens)	No data yet available[146]
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	**Do not co-administer with CAB** Concern that these anticonvulsants may result in significantly reduced exposure to protective levels of CAB but strength of evidence is weak

CAB INTERACTIONS

- Seizure meds NO
- TB meds NO

INTERMITTENT USE PREP

- CDC 2011 guidelines changed
- Prior this was not allowed, but they now say with shared decision making between provider and patient this is an option – this has been common in many countries for years
- This is not daily PrEP oral PrEP – TDF – but as needed or event driven
- For individuals whose exposure to HIV with a lower risk profile - where use of daily PrEP would not be advantageous
- Issue it was only studied in MSM by extension transgender women and adult > 18 yes old
- It is not FDA approved
- 2/1/1
  - You take 2 pills ideally 24 before sex, but minimally 2 hours before
  - Then you take 1 pill each of the following days

Table 8 Primary Care Health Measures

		MSM	MSW*	Women*	PWID
Vaccines# (if not previously vaccinated)	Hepatitis A vaccine	Yes	Yes	Yes	Yes
	Hepatitis B vaccine	Yes	Yes	Yes	Yes
	HPV vaccine	Through age 26	Through age 26	Through age 26	Through age 26
	Meningococcal B vaccine	Ages 16-18	Ages 16-18	Ages 16-18	Ages 16-18
	Influenza vaccine	Yes	Yes	Yes	Yes
General Health	Hepatitis C infection^	Ages 18-79	Ages 18-79	Ages 18-79	Ages 18-79
	Screen for depression^	Yes	Yes	Yes	Yes
	Screen for unhealthy alcohol use^	Ages 18 and older	Ages 18 and older	Ages 18 and older	Ages 18 and older
	Screen for smoking^	Yes	Yes	Yes	Yes
	Screen for Intimate Partner Violence^	Yes		Yes	If female, Yes
Women's Health	Mammography^			Ages 50-74 every two years	If female, Ages 50-74 every two years
	Screen for cervical cancer^~			Ages 21-65 every three years	If female, Ages 21-65 every three years
Men's Health	Screen for prostate cancer^	Ages 55-69	Ages 55-69		If male, Ages 55-69

*"screen what you have" principle for transgender persons
per ACIP recommendations
^per USPSTF recommendations
~per ASCCP (American Society of Colposcopy and Cervical Pathology} guidelines[198]

WAYS TO GET PREP

- Primary Care (study out of Fenway, using PCP increased overall health – decreased smoking, better control of chronic conditions
- Infectious Disease helpful, only if PCP is unwilling you may be referred
- Some STI departments may do it
- Telemedicine – useful in some areas where you do not want to disclose
- MONKEYPOX Vaccine is not listed
- HPV up to age 45 now
- Do not agree with MSM not being screened for partner violence
- Transgender individuals should be screened by organ inventory

DOXY-PEP

- **OFF LABEL USE**

- Bacterial STI are increasing in last 10 Years in MSM/Bisexual men/Transgender women
- STUDY out of Kenya has show insufficient benefit in cis-gender women
  - If given to women pregnancy test has to happen
  - Shared decision making between providers and patient
  - Target population individual who have had an STI in last 6months
- Reduce STI acquisition and transmission
  - Gonorrhea
  - Chlamydia
  - Syphilis
- Doxycycline 200mg given as a single dose within 72 hours of unprotected sexual intercourse

- **Concern development of antibiotic Resistance**

DATA

- Study from San Francisco Department of Public Health/University of Washington
  - Reduction rate by 66% with DOXY-PEP and people on PrEP/3months (per quarter)
    - Decrease syphilis by 87%
    - Decrease Chlamydia by 87%
    - Decrease gonorrhea by 55%
  - Reduction rate by 62% using DOXY-PEP in people living with HIV/3month (per quarter)
    - Decrease syphilis by 77%
    - Decrease Chlamydia by 74%
    - Decrease gonorrhea by 57%

PLUG TO HELP US UNDERSTAND THE NEEDS OF THE COMMUNITY

- **International Kink Health Survey**
  - *https://www.tashra.org/ikhs/*
- **PrEP4Kink**