



HIV Pre-Exposure Prophylaxis (PrEP) Clinical Care and Updates

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Disclosures

- None

Objectives

- Describe the evidence for HIV PrEP
- List clinical considerations for oral and injectable PrEP medications
- Apply lessons learned to clinical work settings
- Incorporate quality improvement measures to increase PrEP implementation

PrEP:
***HIV PREVENTION
WITH JUST
1 PILL A DAY***

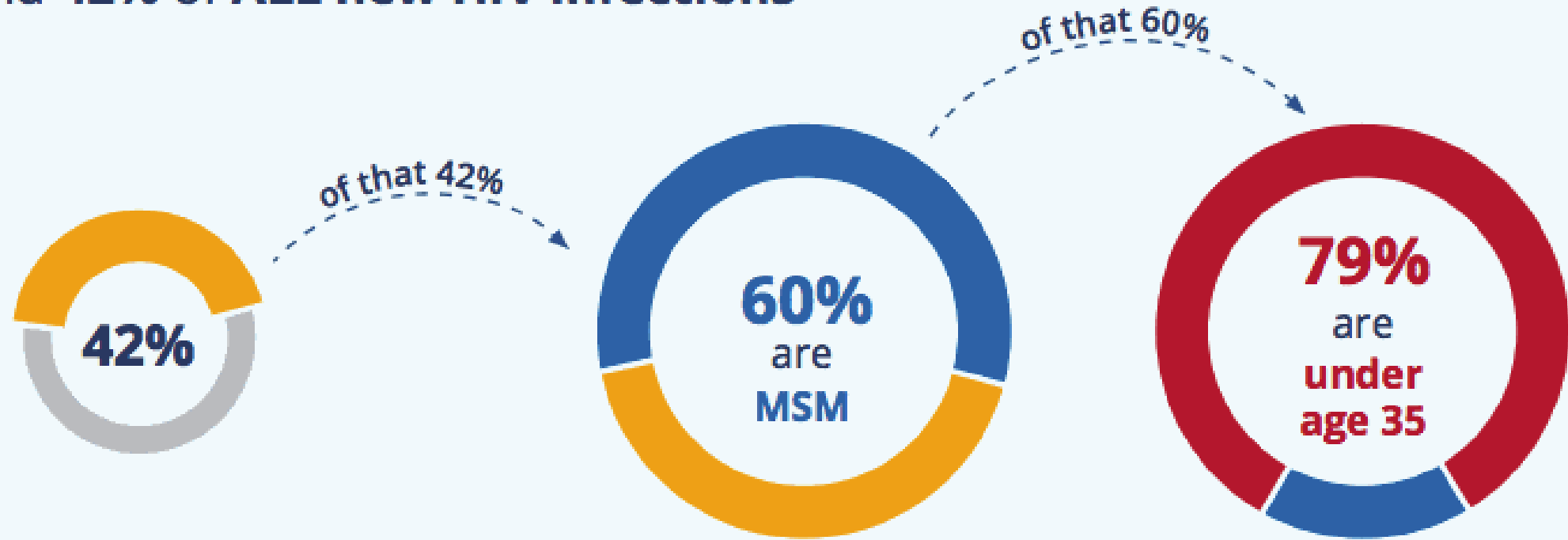


PrEP- Evidence For Prescribing



Disparities in Newly Diagnosed HIV Infections in U.S.

Blacks/African Americans account for 12% of the US population and **42% of ALL new HIV infections**



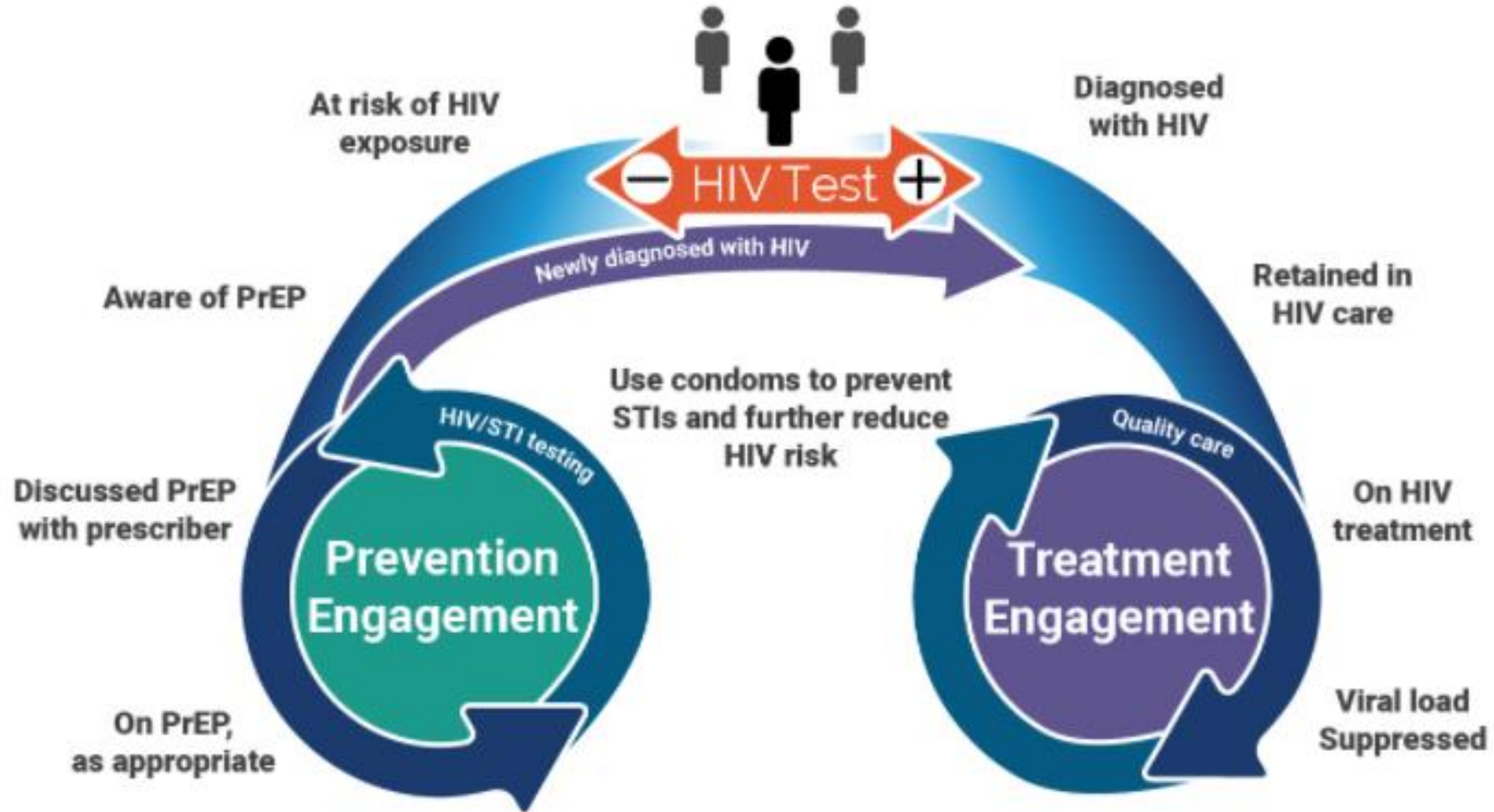
* Trends based on estimates for 2010 - 2015 / ** 2015 data / *** Other includes Asian and Multiple Races

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention



MidAtlantic AIDS Education and Training Center

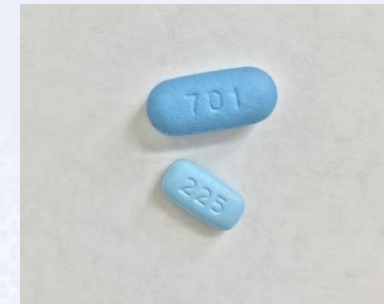
HIV Status-Neutral Service Delivery Model



Source: NYC Department of Health and Mental Hygiene

HIV Prevention Tools

- Condoms
- Syringe exchange
- Safe blood supply
- STI diagnosis and treatment
- pMTCT
- HIV testing, linkage to care, and U=U
- PrEP
- PEP



Medications Currently Used for PrEP

Drug name	Abbreviation	Form, Meds (Brand Name)
tenofovir alafenamide	TAF	Oral TAF/FTC (Descovy) Oral TDF/FTC (Truvada, Generic)
tenofovir disoproxil fumarate	TDF	
emtricitabine	FTC	
Cabotegravir	CAB	Injectable, CAB-LA (Apretude)



HIV Lifecycle & Major Classes of HIV Medications

NRTI (oral)

Nucleoside reverse transcriptase inhibitor

NNRTI

Non-nucleoside reverse transcriptase inhibitor

PI

Protease inhibitor

INSTI (injectable)

Integrase inhibitor

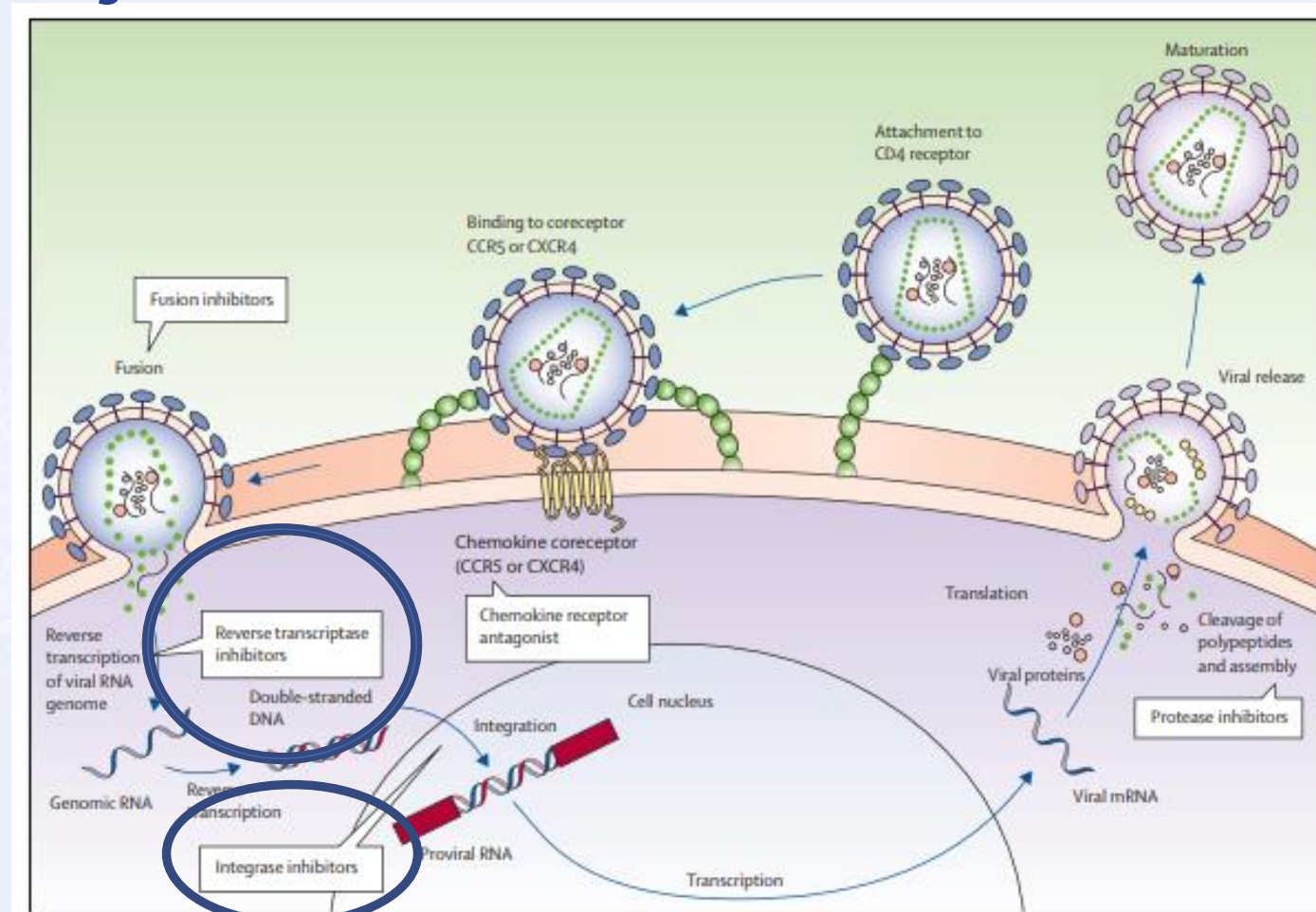
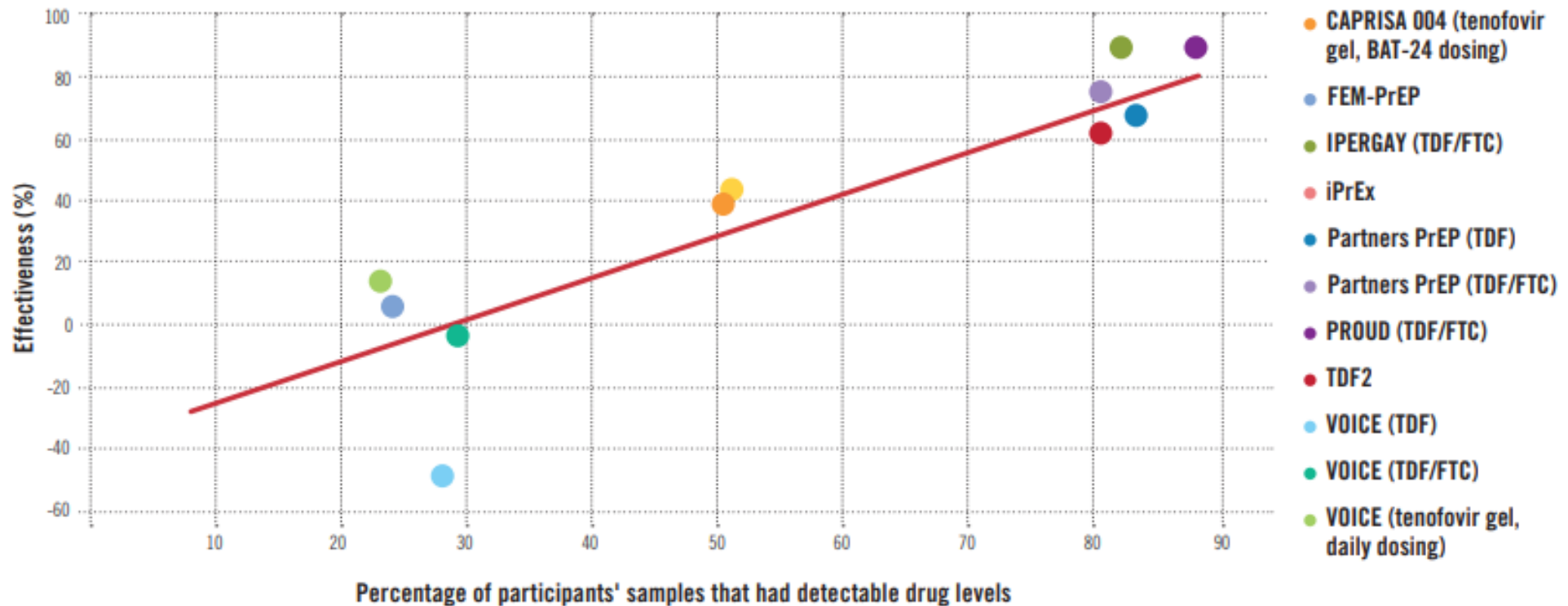


Figure 2: HIV life cycle showing the sites of action of different classes of antiretroviral drugs
Adapted from Walker and colleagues,⁷⁶ by permission of Elsevier.

Oral PrEP Works...If You Take It

PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



Oral PrEP Works If You Take It...For MSM/TW

According to **data analysis from the iPrEx study** that found PrEP to be effective:

- For people who take 7 PrEP pills per week, their estimated level of protection is 99%.
 - For people who take 4 PrEP pills per week, their estimated level of protection is 96%.
 - For people who take 2 PrEP pills per week, their estimated level of protection is 76%.
- **MSM/TW:** The 72-week iPrEx OLE demonstration project enrolled 1,603 participants without HIV formerly enrolled in the iPrEx trial.
 - OLE volunteers chose their study arm for themselves (non-randomized).
 - 76% opted to receive daily oral PrEP.
 - Adherence by drug levels in dried blood spots (DBS). Among participants who received PrEP:
 - Zero HIV infections were detected at study visits where DBS sampling signified use of four to seven pills per week.
 - DBS drug concentrations indicating two to three pills per week was associated with a 90% reduction in HIV acquisition risk.
 - **Heterosexual:** Less data
 - Partners PrEP suggests >80% adherence = 100% protection (Haberer et al. Plos Med 2013)

Oral PrEP For People Assigned Female at Birth?

- Meta-analysis of 5 RCTs of oral PrEP among women
 - 3 reported evidence of effectiveness and 2 did not
 - Estimates by adherence (based on plasma drug levels)
 - **25%** adherence: *no protection* (RR 1.19 95% CI: 0.89 – 1.61)
 - **50%** adherence: *32% protective* (RR 0.68 95% CI: 0.53 – 0.88)
 - **75%** adherence: *61% protective* (RR 0.39 95% CI: 0.25 – 0.60)

Hanscom B, Janes H, Guarino P. JAIDS 2016; 73(5):606-608



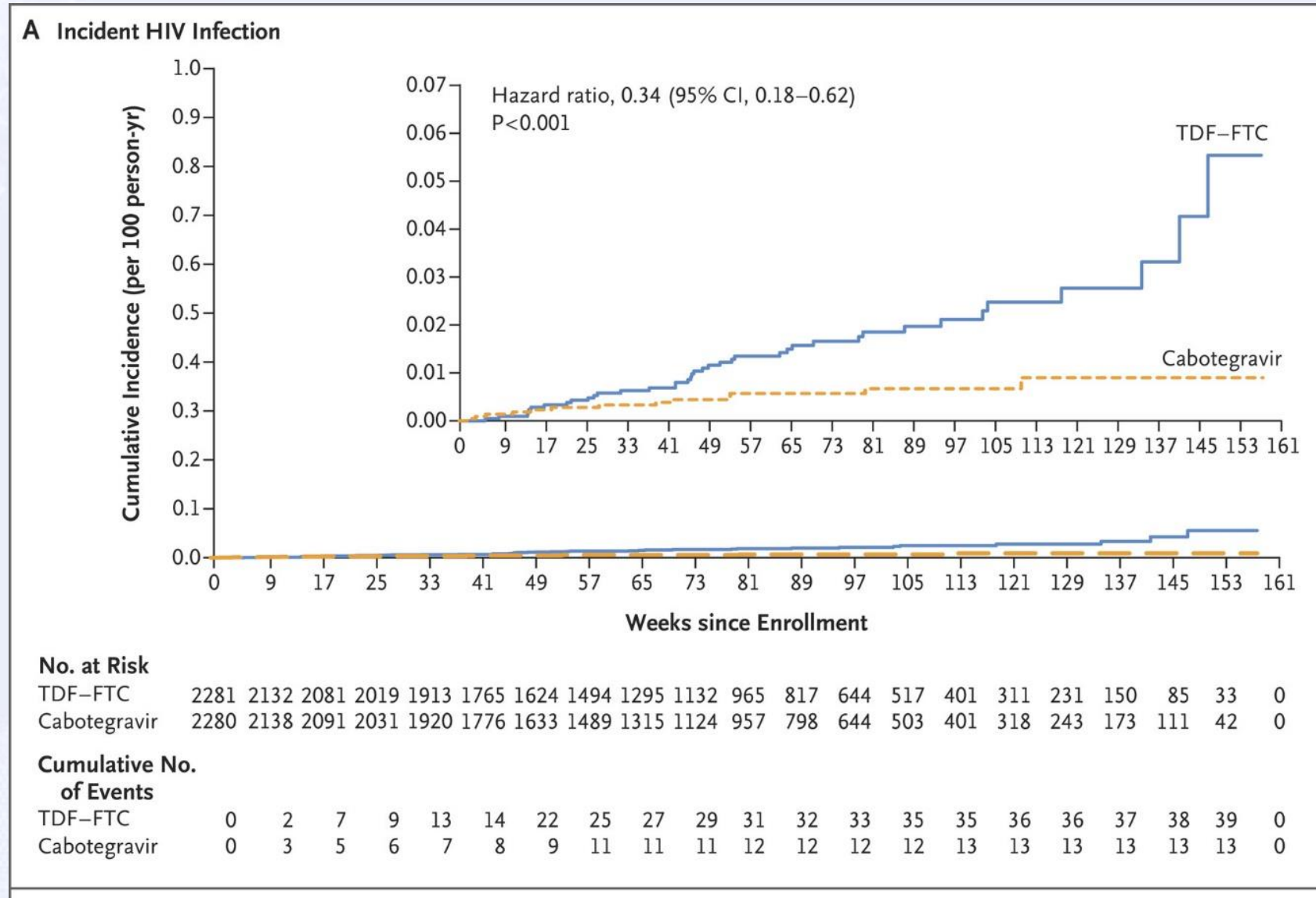
Injectable PrEP (CAB-LA): HPTN 083 Trial (cis men and TGW)¹

- RCT of CAB-LA vs Oral TDF/FTC in cis men and TGW over 18
- Study population was from USA, Latin America, Asia, and Africa
- N=4566
 - 2282 on CAB-LA
 - 2282 on TDF/FTC
- Outperformed oral PrEP in all populations
 - Overall risk of HIV infection 66% lower in CAB-LA group than TDF-FTC group
 - 4 incident infections observed despite on-time injections
 - Diagnosis delayed due to testing approach
 - Study ended early due to positive results
- Very safe
 - Most participants report injection site reaction
 - 2.4% chose not to continue as result¹
 - Weight difference?
 - Previous studies have shown weight gain with INSTIs
 - No difference or approx. 1kg weight loss in TDF/FTC group

¹Landovitz et al. (2021). Cabotegravir for HIV prevention in cisgender men and transgender women. *The New England Journal of Medicine*, doi: 10.1056/NEJMoa2101016



Injectable PrEP (CAB-LA): HPTN 083 Trial¹ (Cis Men and TGW)



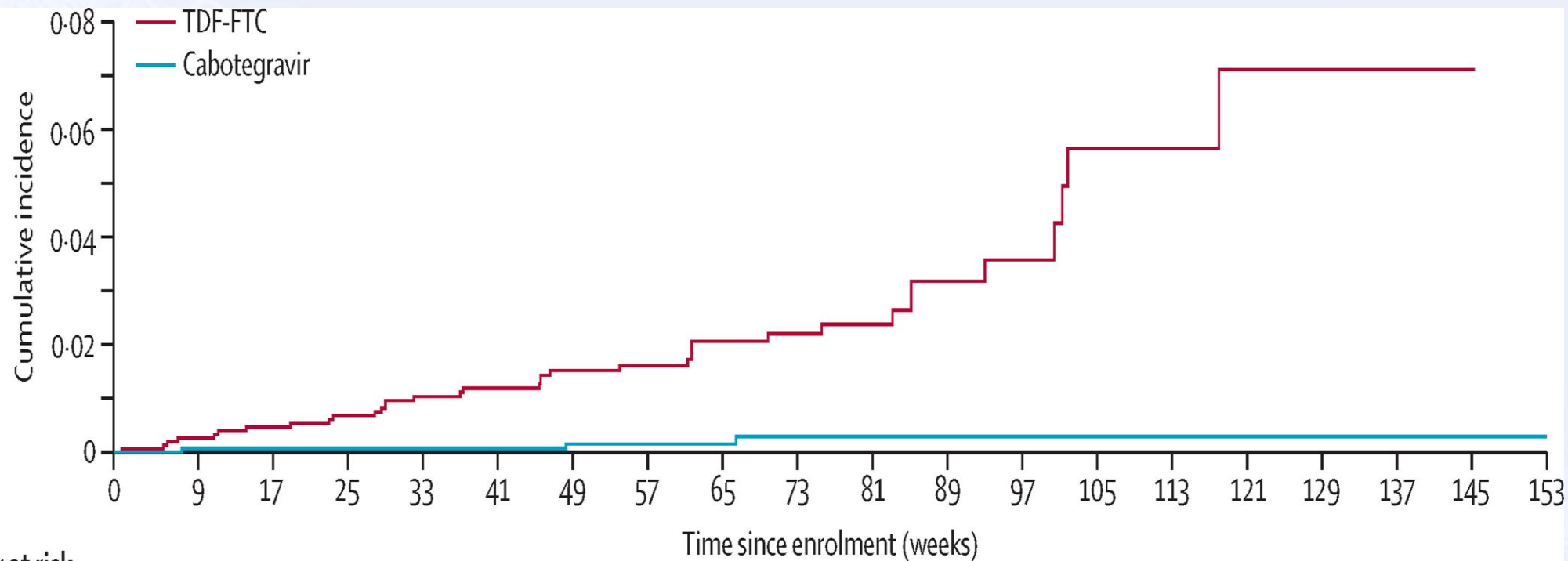
¹Landovitz et al. (2021). Cabotegravir for HIV prevention in cisgender men and transgender women. *The New England Journal of Medicine*, doi: 10.1056/NEJMoa2101016

Injectable PrEP (CAB-LA): HPTN 084 Trial (cis women)¹

- RCT of CAB-LA vs Oral TDF/FTC in cis women 18-45 y/o
- Study population was from 20 clinical sites in 7 countries in Africa
- N=3224
 - 1614 on CAB-LA
 - 1610 on TDF/FTC
- Injection at week 0, week 4, then every 2 months
- Outperformed oral PrEP in all populations
 - Overall risk of HIV infection 88% lower in CAB-LA group than TDF-FTC group
 - 4 incident infections observed despite on-time injections
 - Diagnosis delayed due to testing approach
- Very safe
 - 1/3 participants report injection site reaction
 - 0 chose not to continue as result¹
 - Weight difference?
 - Previous studies have shown weight gain with INSTIs
 - No difference observed in this study
 - 49 pregnancies during study, 29 in CAB-LA group (all women on LA contraception)
 - No neural tube defects or other congenital anomalies

¹Delany-Moretlwe, S. et al. (2022). Cabotegravir for the prevention of HIV-1 in women: results from HTPN 084, phase 3, randomized clinical trial. *The Lancet*, 300(10337)

Injectable PrEP (CAB-LA): HPTN 084 Trial (cis women)¹

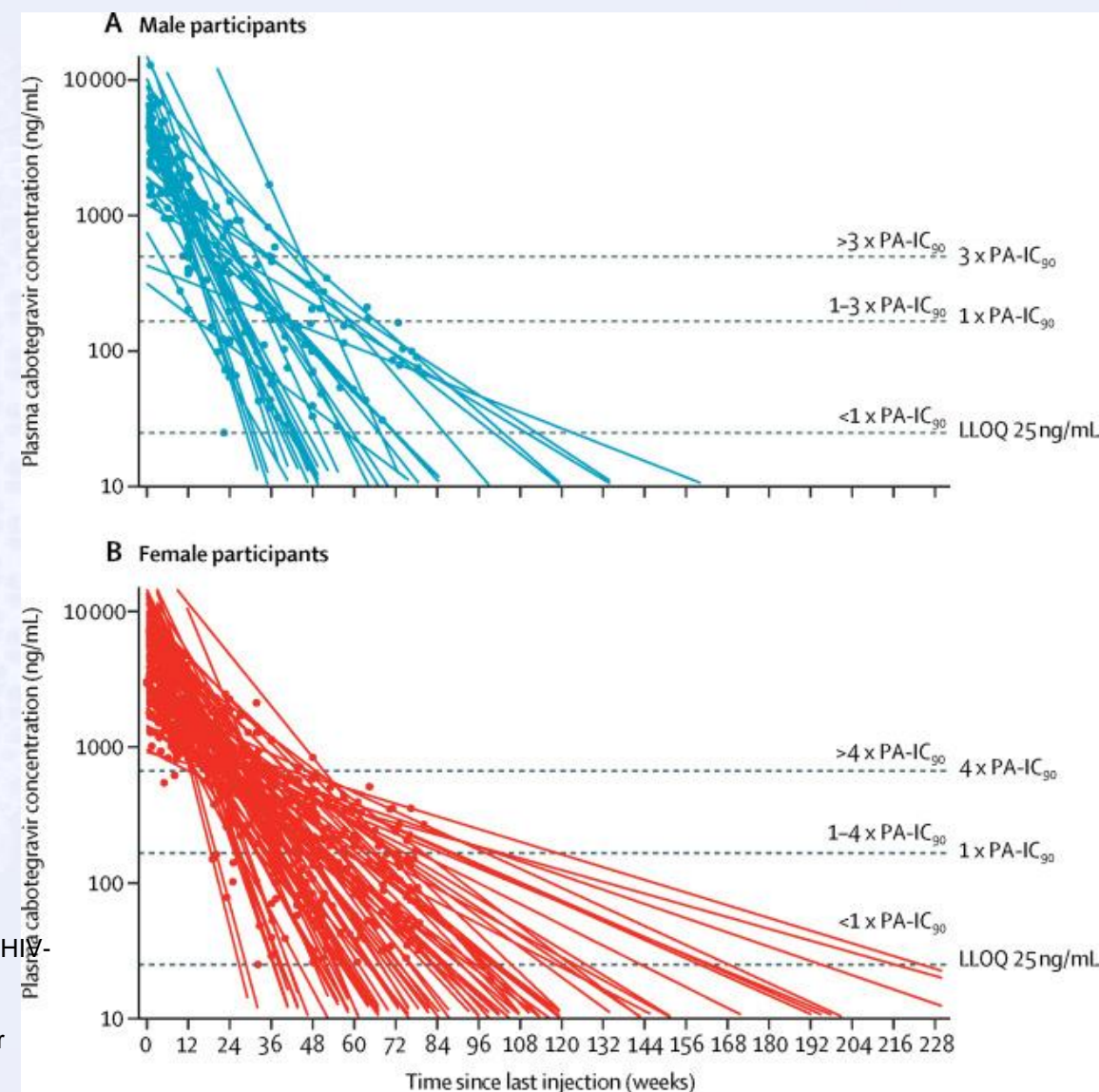


Number at risk		Time since enrollment (weeks)																			
		0	9	17	25	33	41	49	57	65	73	81	89	97	105	113	121	129	137	145	153
Cumulative number of events	TDF-FTC	1610	1490	1429	1410	1353	1260	1160	984	800	656	485	306	201	115	70	63	52	22	3	0
	Cabotegravir	1614	1488	1441	1429	1371	1279	1181	988	801	647	482	304	204	116	67	58	50	23	3	2
	TDF-FTC	0	4	7	10	15	17	21	22	26	27	28	31	32	35	35	36	36	36	36	36
	Cabotegravir	0	1	1	1	2	2	3	3	3	4	4	4	4	4	4	4	4	4	4	4

¹Delany-Moretlwe, S. et al. (2022). Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, phase 3, randomized clinical trial. *The Lancet*, 300(10337)

Injectable PrEP (CAB-LA): Tail

- Median time from last injection of CAB-LA below the lowest level of quantification¹:
 - Males: 43.7 weeks
 - Females: 67.3 weeks
- INSTI resistance during tail if acquire HIV?
 - There is a concern
 - In animal models, no resistance developed during tail phase
 - HPTN 083 found no INSTI resistance in HIV acquired during tail, but limited data²



¹Safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in low-risk HIV-uninfected individuals: HPTN 077, a phase 2a randomized controlled trial.

PLoS Med. 2018; 15:e1002690

²Landovitz et al. (2021). Cabotegravir for HIV prevention in cisgender men and transgender women. *The New England Journal of Medicine*, doi: 10.1056/NEJMoa2101016

Providing Oral PrEP- Who Should be Offered PrEP?



Who Should be Offered PrEP – CDC Guidelines

	Sexually-Active Adults and Adolescents ¹	Persons Who Inject Drug ²
Identifying substantial risk of acquiring HIV infection	<p>Anal or vaginal sex in past 6 months AND any of the following:</p> <ul style="list-style-type: none">• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)• Bacterial STI in past 6 months³• History of inconsistent or no condom use with sexual partner(s)	<p>HIV-positive injecting partner OR Sharing injection equipment</p>

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

Who Should be Offered PrEP – NYC Guidelines

☒ Candidates who should be offered PrEP include individuals who:

- Engage in condomless sex with partners whose HIV status is unknown, or who have untreated HIV, or who have unsuppressed virus while on treatment for HIV. [Smith, et al. 2012; Grov, et al. 2013].
- Are attempting to conceive with a partner who has HIV.
- Are at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus [Heffron, et al. 2016].
- Have, or are involved with partners who may have, multiple or anonymous sex partners.
- Engage in sexual activity at parties and other high-risk venues, or have sex partners who do so.
- Are involved, or have partners who may be involved, in transactional sex (i.e., sex for money, drugs, food, or housing), including commercial sex workers and their clients.
- Have been diagnosed with at least 1 bacterial sexually transmitted infection (STI) in the previous 12 months [Zetola, et al. 2009; LaLota, et al. 2011].
- Report recreational use of mood-altering substances during sex, including but not limited to alcohol, methamphetamine [Buchacz, et al. 2005; Zule, et al. 2007; Koblin, et al. 2011; Smith, et al. 2012; Grov, et al. 2013], cocaine, ecstasy, and gamma hydroxybutyrate.
- Report injecting substances or having sex partners who inject substances, including illicit drugs, hormones, or silicone.
- Are receiving non-occupational post-exposure prophylaxis (nPEP) and anticipate ongoing risk or have used multiple courses of nPEP [Heuker, et al. 2012].
- Request the protection of PrEP even if their sex partners have an undetectable HIV viral load (see the discussion of U=U, below).
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.

☒ Do not withhold PrEP from candidates who:

- Are pregnant or planning a pregnancy.
- Use other risk-reduction practices inconsistently, including condoms.
- Report substance use.
- Have mental health disorders, including those with serious persistent mental illness.
- Report intimate partner violence.
- Have unstable housing or limited social support.
- Report a recent STI.
- Request PrEP even in they have a partner living with HIV with an undetectable viral load.

Rapid PrEP



Rapid / Same-day / Immediate PrEP

- Start PrEP while awaiting baseline lab results if clinical criteria are met
- Reduce unnecessary barriers to PrEP initiation
- Engage patients more fully in care and reduce risk of HIV acquisition while awaiting test results
- Main concerns:
 - Starting a non-suppressive HIV regimen on someone who has HIV
 - Consider strategies for how to stop PrEP immediately if there are contraindications on baseline labs
 - HBV

Clinical Considerations

- Acute HIV infection
 - Signs/symptoms, sexual history
 - HIV testing (rapid and lab-based)
 - MUST HAVE – RAPID TEST
- Post-exposure prophylaxis (PEP)
 - If <72 hours from concerning exposure that merits 28-day course of PEP. Can transition to PrEP afterwards
- History of chronic Hepatitis B
 - TDF and TAF treat chronic Hepatitis B, discontinuation of PrEP can trigger a flare
- History of kidney disease
 - Do not use TDF if CrCl <60 and TAF if CrCl is <30
 - Consider risk factors for kidney disease (age, HTN, DM)

Rapid PrEP Evidence

- **PROUD Trial** (McCormack et al. (2016) Lancet 387:53-60)
 - 13 STI Clinics in the UK 2012-2014
 - RCT immediate vs. delayed start
 - 86% reduction in HIV incidence in immediate group compared to delayed group
- **NYC STI Clinics** (Mikati T, Jamison K, Daskalakis DC. CROI abstract, March 2019)
 - **Participants:**
 - Cis gender men and women >18
 - 1437 were evaluated
 - 1387 qualified for immediate PrEP (96.5%)
 - Of those with no contraindications but who delayed PrEP initiation, only **35% initiated PrEP within 60 days**, significantly lower compared to rapid PrEP
 - Very few immediate PrEP patients needed to discontinue due to medical contraindications
 - 4 participants d/c due to lab contraindications (0.2%)
- **Denver STI Clinic** (Kamis KF, et al. Open Forum Infectious Diseases. June 2019)
 - N=100
 - **Results:**
 - 78% attended at least one follow-up visit
 - 57% attended at least 2 f/u visits
 - No HIV seroconversion during 6-month follow up period
 - Higher income significantly associated with attending follow-up appointments

**Summary: Same-day
PrEP is acceptable,
feasible and safe**

Rapid PrEP, Acute HIV and Drug Resistance Kelly et al (2021), JAIDS, 87:2, p818-825

- PrEP and PEP users who started 2-drug regimens during undiagnosed acute HIV infection (AHI), followed for 2 years
- Of 1,758 same-day PrEP starts there were 7 AHI cases identified
- Of the 13 total AHI (PrEP/PEP users combined)
 - 100% were linked to HIV care, median time 1 week
 - >90% received ART Rx, median time 2 weeks
 - ~85% VL suppression within median of 2 months
- 3 developed (23%) M184V mutation within just 7-12 days of exposure to the 2-drug regimen
 - All 3 were linked to care, achieved viral suppression and remain virally suppressed

CDC 2021 Guidelines

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

To use a same-day PrEP initiation protocol, the clinic must be able to:

- Conduct point-of-care HIV testing, ideally with an antigen/antibody fingerstick or other blood test
 - Where same-day results can be obtained, laboratory-based antigen/antibody test or an HIV-1 RNA test can be used (and is preferred)
 - Oral fluid HIV testing should not be used in the context of PrEP initiation
- Draw blood for laboratory creatinine and HIV testing when same day HIV and creatinine test results are not available
- Provide assistance for eligible patients to enroll in health insurance, medication co-payment assistance, or medication assistance programs for those who are uninsured or underinsured
- Provide rapid follow-up contact for patients whose laboratory test results indicate HIV infection or renal dysfunction
- Provide scheduled follow-up care appointments
- Have clinicians available to dispense or prescribe oral PrEP medication, to administer a gluteal intramuscular injection of CAB, or optionally prescribe a daily oral CAB lead-in for 4 weeks.

Prescribing PrEP



PrEP Checklist

- ☐ History
- ☐ Rule out HIV infection
- ☐ Baseline labs
- ☐ Patient counseling/education
- ☐ Rx

History

- PrEP indication(s)
- Sexual health history
- Consider PEP eligibility
- Current medications
- Hepatitis B
- Kidney disease
- Symptoms of acute HIV in the last 4-6 weeks

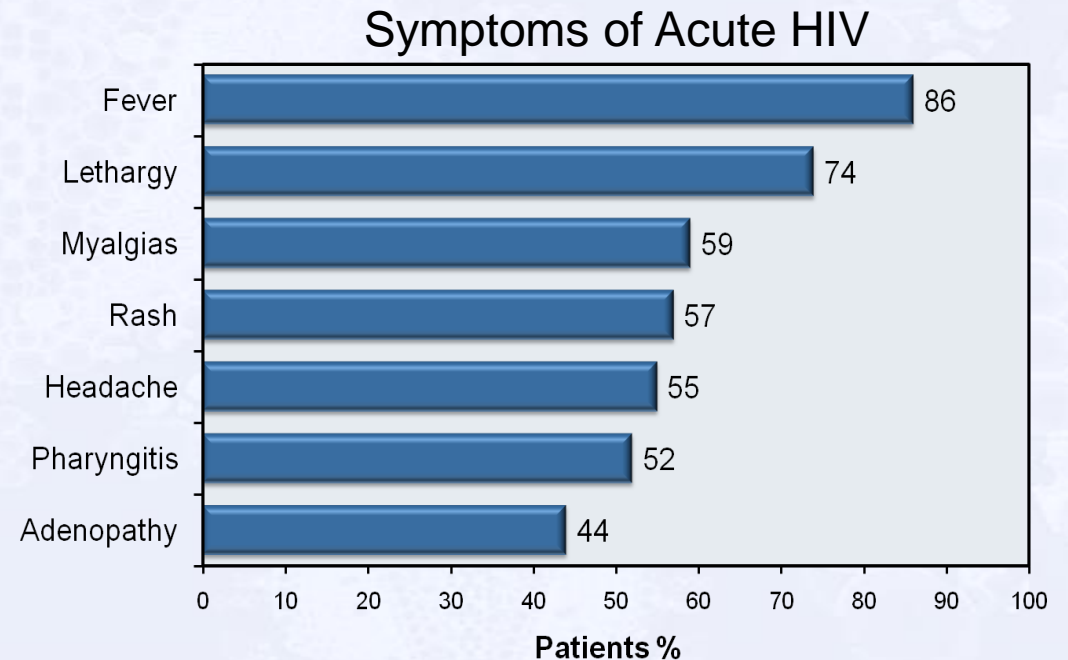
PrEP Checklist

History

- ☐ Rule out HIV infection
- ☐ Baseline labs
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Rule Out HIV Infection

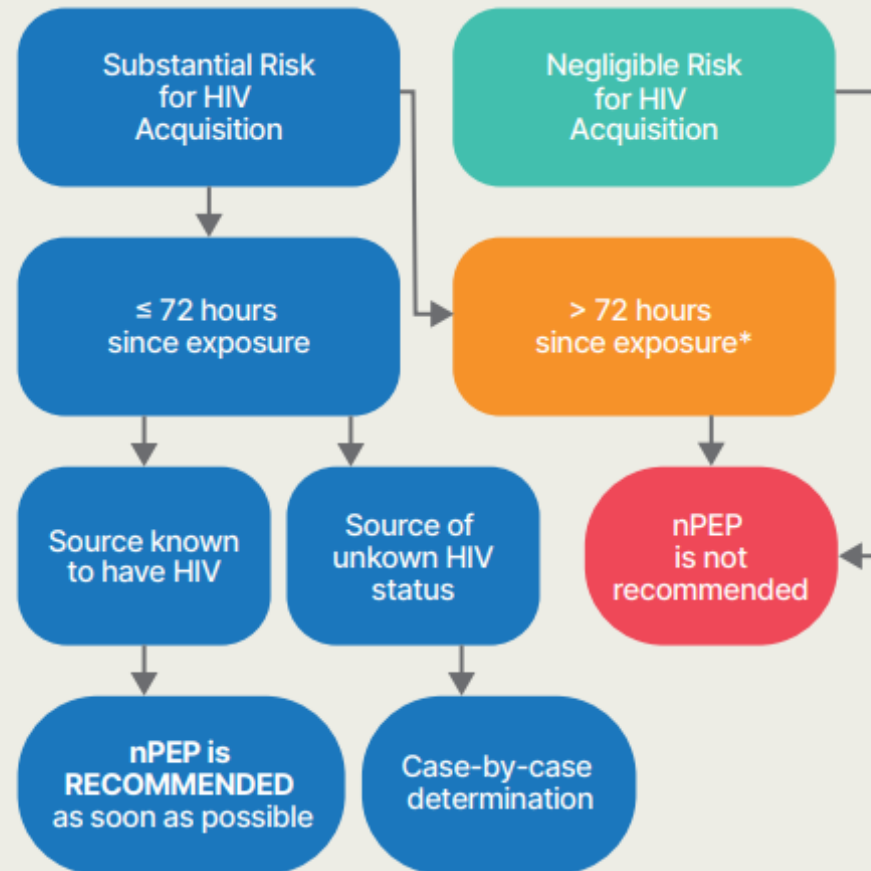
- Order a lab-based HIV 4th generation test even if a rapid POC result is negative
 - Can still prescribe same-day PrEP with rapid POC negative as long as labs are drawn and little concern for acute HIV
- In addition, order an HIV RNA if recent (within the last 4 weeks) high-risk exposure, or s/s of acute HIV infection “flu-like symptoms”
 - Fever
 - Lethargy
 - Myalgias
 - Rash
 - Headache
 - Pharyngitis
 - Lymphadenopathy



Vanhems P, et al. AIDS. 2000;14:375-81.

nPEP Risk Assessment

Risk Assessment



*Some clinicians would offer nPEP on a case-by-case basis.

Substantial Risk for HIV Acquisition

Exposure of: vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

With: blood, semen, vaginal secretions, rectal secretions, breast milk, any body fluid that is visibly contaminated with blood

When: the source is known to have HIV

Negligible Risk for HIV Acquisition

Exposure of: vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

With: urine, nasal secretions, saliva, sweat, tears (if visible blood, see "Substantial Risk for HIV Acquisition")

When: regardless of the known or suspected HIV status of the source

https://aidsetc.org/sites/default/files/resources_files/AETC-nPEP-guide-111721.pdf

Oral PrEP Checklist

- ☒ History
- ☒ Rule out HIV infection
- ☐ Baseline labs
- ☐ Patient counseling/education
- ☐ Rx

Baseline Labs

□ Oral PrEP Baseline labs

- Rapid HIV test (if Same-day)
AND
- HIV Ag/Ab*
- HIV RNA*
 - Can be qualitative or quantitative
- Metabolic panel (SCr) to calculate creatinine clearance
 - TDF/FTC should not be used if CrCl is <60mL/min
 - TAF/FTC should not be used if CrCl is <30mL/min
- HBsAg, anti-HBs, anti-HBc
- STI testing (GC/CT, Syphilis serology)*
 - Site specific
- Lipid panel (if prescribing TAF/FTC)
- Pregnancy test prn
- Take the opportunity to screen for HepC
- Consider Hep A based on sexual health history/IVDU

□ Injectable PrEP Baseline labs

- HIV Ag/Ab
- HIV RNA
 - Can be qualitative or quantitative
- STI testing (GC/CT, Syphilis serology)
 - Site specific
- Consider ordering all oral PrEP labs in case need to transition/start on oral PrEP at any time

Oral PrEP Checklist

- ☒ History
- ☒ Rule out HIV infection
- ☒ Baseline labs
- ☐ Patient counseling/education
- ☐ Rx

Patient Counseling/Education- Oral PrEP

- PrEP efficacy is highly dependent on adherence
- Time to protection:
 - Up to 1 week for receptive rectal exposure
 - Up to 3 weeks for all other exposure
- PrEP does not protect against other STIs. Encourage additional risk reduction
- Side effects are uncommon and usually resolve in the first month: headache and nausea can be managed by OTCs prn
- If HBV+, may have flare if PrEP is discontinued
- Discuss U=U
- Importance of routine follow up with HIV testing every 3 months
- Review how to navigate pharmacy refills and pay for PrEP
- Review PrEP discontinuation procedures

Patient Counseling/Education- Injectable PrEP

- Counsel on non-pharmacological HIV and STI risk reduction measures
- Review side effects and serious adverse effects
 - Hypersensitivity reaction
 - Injection site reaction
 - Liver impairment
 - Depressive Disorder
 - Does not treat HBV
- Review dose and lab requirements
- Review time to protection
 - Let patient know that there is no data on time to protection
 - Preliminary models estimate peak drug concentrations in about a week
- Review risks associated with non-adherence
 - HIV seroconversion
 - Developing INSTI resistant HIV mutation
- Review safe discontinuation in regards to long tail
- Patients considering PrEP should be informed of all FDA approved options
- Consider oral PrEP while working through injectable initiation

Side Effects

- Oral PrEP side effects:
 - Emergent (rare):
 - Lactic acidosis
 - Hepatotoxicity
 - Short term:
 - Headache
 - GI symptoms
 - Long Term (more common in TDF/FTC):
 - Renal impairment
 - Bone mineral density loss
 - Weight gain- TAF/FTC
- Injectable PrEP side effects:
 - Emergent (rare):
 - Allergic reaction
 - Hepatotoxicity
 - Short term:
 - Injection site reaction
 - GI symptoms
 - Headache
 - Fatigue
 - Decreased appetite
 - Myalgia
 - Other
 - Potential INSTI resistance if discontinued
 - Depression

Oral PrEP Checklist

- ☒ History
- ☒ Rule out HIV infection
- ☒ Baseline labs
- ☒ Patient counseling/education
- ☐ Rx

Prescription



❑ Rx- ORAL

- TDF/FTC (Truvada, generic) 300/200mg 1 tablet by mouth once daily
 - TDF/FTC should not be used if CrCl is <60mL/min
 - Now available in generic form
- TAF/FTC (Descovy) 25/200mg 1 tablet by mouth once daily
 - **Only for** people assigned male at birth with sexual risk for HIV
 - Do not prescribe TAF/FTC for those whose HIV risk includes receptive vaginal sex or injection drug use
 - TAF/FTC should not be used if CrCl is <30mL/min
- Take with or without food
- On demand dosing 2-1-1
 - 2 tablets of TDF/FTC 2-24 hours before sex, then 1 tab 24 hours later, and another 1 tab 24 hours later
 - Not recommended for receptive vaginal sex or IVDU
 - Only tested in MSM
- No more than 90 days at a time
 - example: #90, 0 refills or #30, 2 refills

❑ Rx- Injectable

- Cabotegravir 200mg/ml injection
 - Need negative HIV RNA within 7 days prior to starting
 - Contraindicated if previous hypersensitivity reaction to CAB
 - Contraindicated with receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine
 - Not for people below 35kg
 - Not fully studied in pregnant/ breast feeding people
 - TDF/FTC preferred
 - Weigh risk/benefit

Oral PrEP Initiation - Prescribing

	TRUVADA TDF/FTC	DESCOVY TAF/FTC
Effectiveness	>99% effective	
Safety: general	Both medicines have very low rates of side effects overall.	
Cost & affordability	Same cost; assistance programs available to cover costs of co-pays and medical care	
Regimen	Daily use & PrEP 2-1-1	Daily use (Although Descovy for PrEP 2-1-1 is being studied, there is inadequate clinical data to support this regimen now)
Show to be effective for	Everyone, including: Gay & bisexual cis men Trans women Trans men Cis women Heterosexuals People who inject drugs	Only: Gay & bisexual cis men Trans women (No clinical data to support use in people who may be exposed to HIV through vaginal sex or injection drug users)
Bone health	People with osteoporosis should avoid	Safer to take with osteoporosis
Kidney health	People with existing kidney issues or a strong family history of kidney disease should avoid	Safer to take with existing kidney issues or a strong family history of kidney disease, though monitoring still recommended
Weight gain & cholesterol	Small degree of weight loss and small decreases in LDL in some studies	Small degree of weight gain in some studies
Pill size (actual size)		

<https://gettingtozero.org/new-resource-which-prep-medication-is-best-for-me-truvada-and-descovy/>

Oral PrEP Checklist

- ☒ History
- ☒ Rule out HIV infection
- ☒ Baseline labs
- ☒ Patient counseling/education
- ☒ Rx

Oral PrEP Follow-up & Ongoing Monitoring

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	

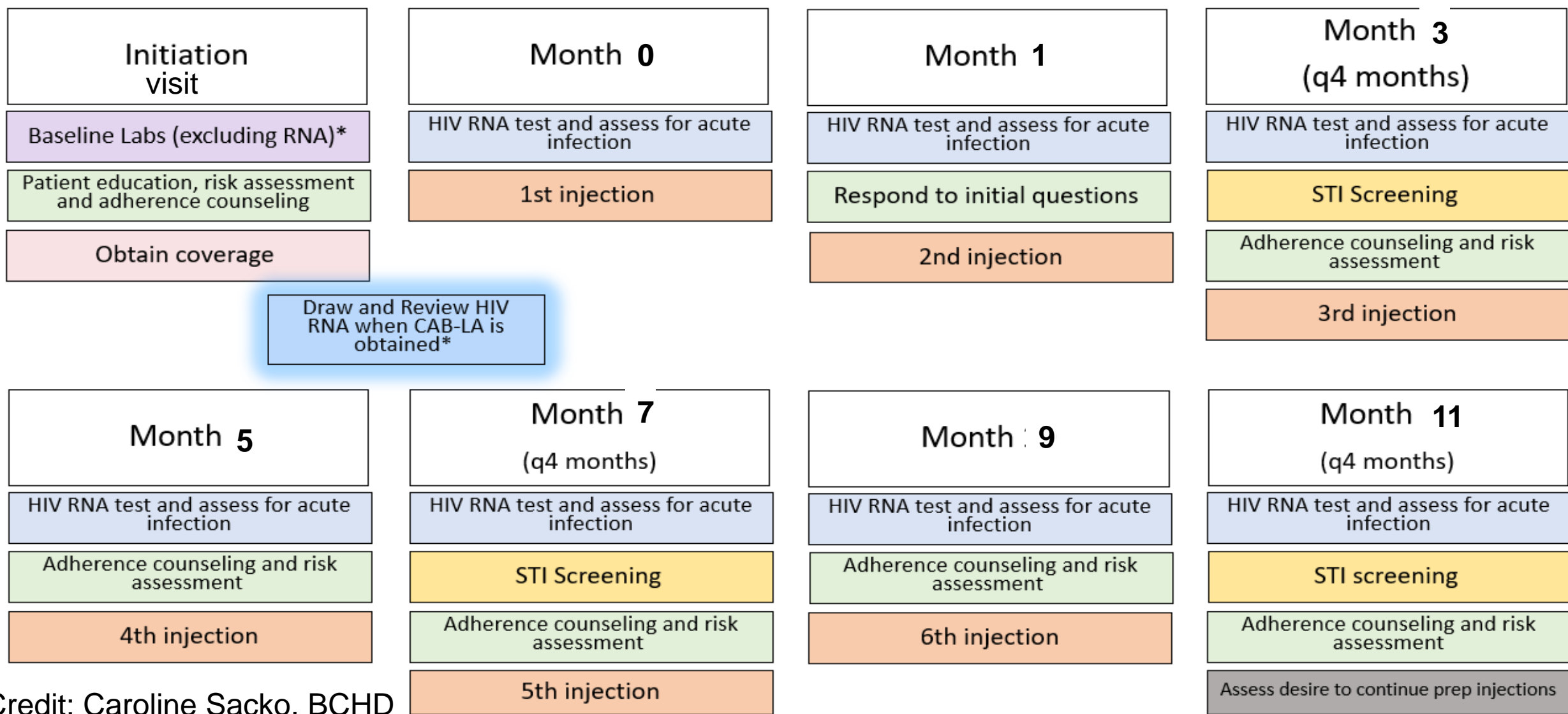
* Assess for acute HIV infection (see Figure 4)

Monitoring	Frequency
Assess medication adherence and provide behavioral risk reduction support	<ul style="list-style-type: none"> Every 3 months
For PWID: Assess access to syringe services	<ul style="list-style-type: none"> Every 3 months

* Routine STI screening may vary based on local data

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

CAB-LA Visit Schedule	
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Credit: Caroline Sacko, BCHD

PrEP During Pregnancy

- PrEP is indicated for those at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus
- Do not withhold PrEP from those who are pregnant or planning a pregnancy
 - TDF/FTC preferred, but weigh risk/benefit
 - CAB-LA not studied specifically in pregnant people, but no complications known
- Risk of perinatal transmission is significantly higher during acute seroconversion when a patient is pregnant or breastfeeding
- Tenofovir disoproxil fumarate (TDF) in combination with emtricitabine (FTC) is a preferred NRTI combination for use in treatment naïve pregnant women with HIV (<https://clinicalinfo.hiv.gov/en/guidelines/perinatal/overview-2>)
- There is limited data on the use of TAF during conception and during the first trimester. Remember not to use TAF/FTC for those whose HIV risk includes vaginal receptive sex

Paying for PrEP

- Insurance companies are required to cover at least one PrEP medication and PrEP related labs with no cost sharing
 - May require CPT modifier 33 for covered preventive services
- Oral PrEP:
 - Gilead Advancing Access Program
 - <https://www.gileadadvancingaccess.com/>
 - Co-pay Coupon Program
 - For those with copays through **private insurance**
 - » Medicare/Medicaid not eligible
 - up to \$7,200/yr
 - Enroll online or over the phone, immediate co-pay card to print or save, then show to the pharmacy
 - » Clinic: <https://advancingaccess.iassist.com/login>
 - » Phone: 1-800-226-2056
 - Ready, Set, PrEP
 - <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program>
 - For patients who don't have prescription drug coverage and have been prescribed PrEP
 - How to enroll:
 - Clinic: <https://getyourprephcp.iassist.com/login>
 - Patient: <https://getyourprepatient.iassist.com/>
 - Phone: (855) 447-8410
 - Injectable PrEP:
 - ViivConnect : <https://www.viivconnect.com/>
 - Suggest paper form at this time
 - Can also do insurance reviews
 - Esignature link: <https://www.viivconnectportal.com/viivprovider/s/esign-ondemand>

**ADVANCING
ACCESS®**

**AFFORDING
YOUR MEDICINE**

**UNDERSTANDING YOUR
COVERAGE**

UNINSURED 24/7 SUPPORT

Gilead's Advancing Access® Program Is Here to Help You

Gilead's Advancing Access program is committed to helping you afford your medication no matter your situation. Whether you have insurance or not, we can explore potential coverage options that might be right for you.

Our dedicated program specialists are here to help you. Talk to someone right away by calling **1-800-226-2056**. Advancing Access phone lines are open M - F 9am - 8pm ET. If you reach us after hours, leave a message, and we will call you back during the next business day.

The Advancing Access CO-PAY COUPON PROGRAM



The Advancing Access PATIENT SUPPORT PROGRAM



<https://www.gileadadvancingaccess.com/>

How You Can Get PrEP

Follow these steps to get PrEP medication to prevent HIV.

Is PrEP
right for
me?

PrEP is a safe and effective prevention option for people who are HIV-negative. PrEP medication works when taken as prescribed. Find local HIV testing sites at locator.hiv.gov.

1



GET READY

Talk to your health care provider. Find a provider who makes you feel comfortable and supported.

2

GET SET

Get tested to make sure you are HIV negative.



3



GET PrEP

Get your prescription filled at your local pharmacy or find one near you.

Staying
on PrEP

Take the medication as prescribed and see your provider every 3 months to get tested for HIV, STIs, check your kidneys, and get a refill.

<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program>



Not actual patients.



For Providers



Get Help



For Patients

https://www.viivconnect.com/for-providers/portal/?utm_source=bing&utm_medium=cpc&utm_term=viiv%20connect&utm_campaign=BS%20-%20Branded%20-%20ViiV%20Connect%20EX&gclid=7bb5ef2a42911d2ddccb8cac34d7dada&gclsrc=3p.ds&-

Mistr for PrEP: PrEP online

mistr

[HOW IT WORKS](#)

[OUR STORY](#)

[FAQ](#)

[BLOG](#)

[GET STARTED](#)

[LOGIN](#)

How it works?



1. HEALTH REVIEW

Answer some basic health questions and create a profile. Confidential and judgement free.



2. LABS

Simple at home testing. No needles, no doctor visit.



3. DOCTOR CONSULT

Our licensed physicians will review your results and prescribe PrEP if appropriate for you.



4. FREE DELIVERY

Our pharmacy network will ship your medication in our discreet packaging and refill automatically each month free of charge.



5. NO PAPERWORK

We'll work with your insurance company and the various patient assistance programs to ensure you have no out-of-pocket costs. We do everything for



6. FOLLOW-UP

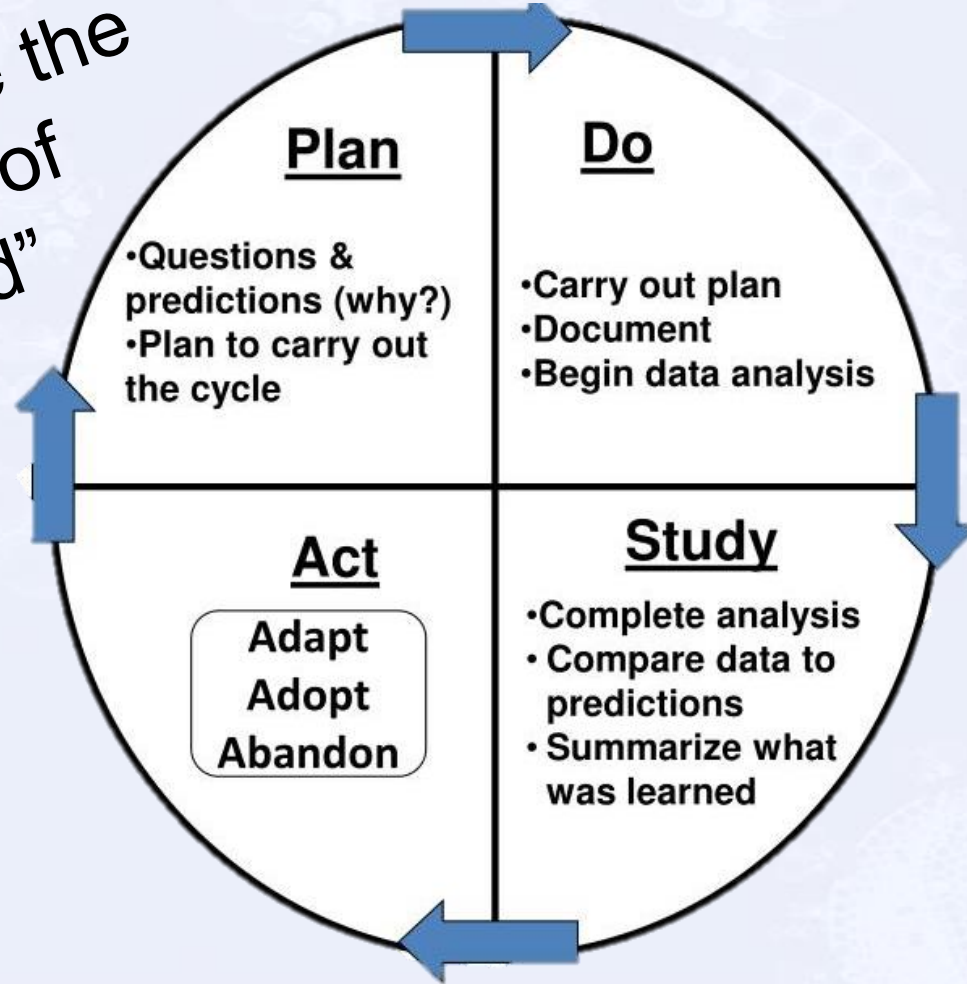
Prescription renewals every 3-months are even easier.



Implementing PrEP Programs

PDSA- Process For Implement QI

Don't let
“perfect” be the
enemy of
“good”



Sample Steps to implementing PrEP/QI

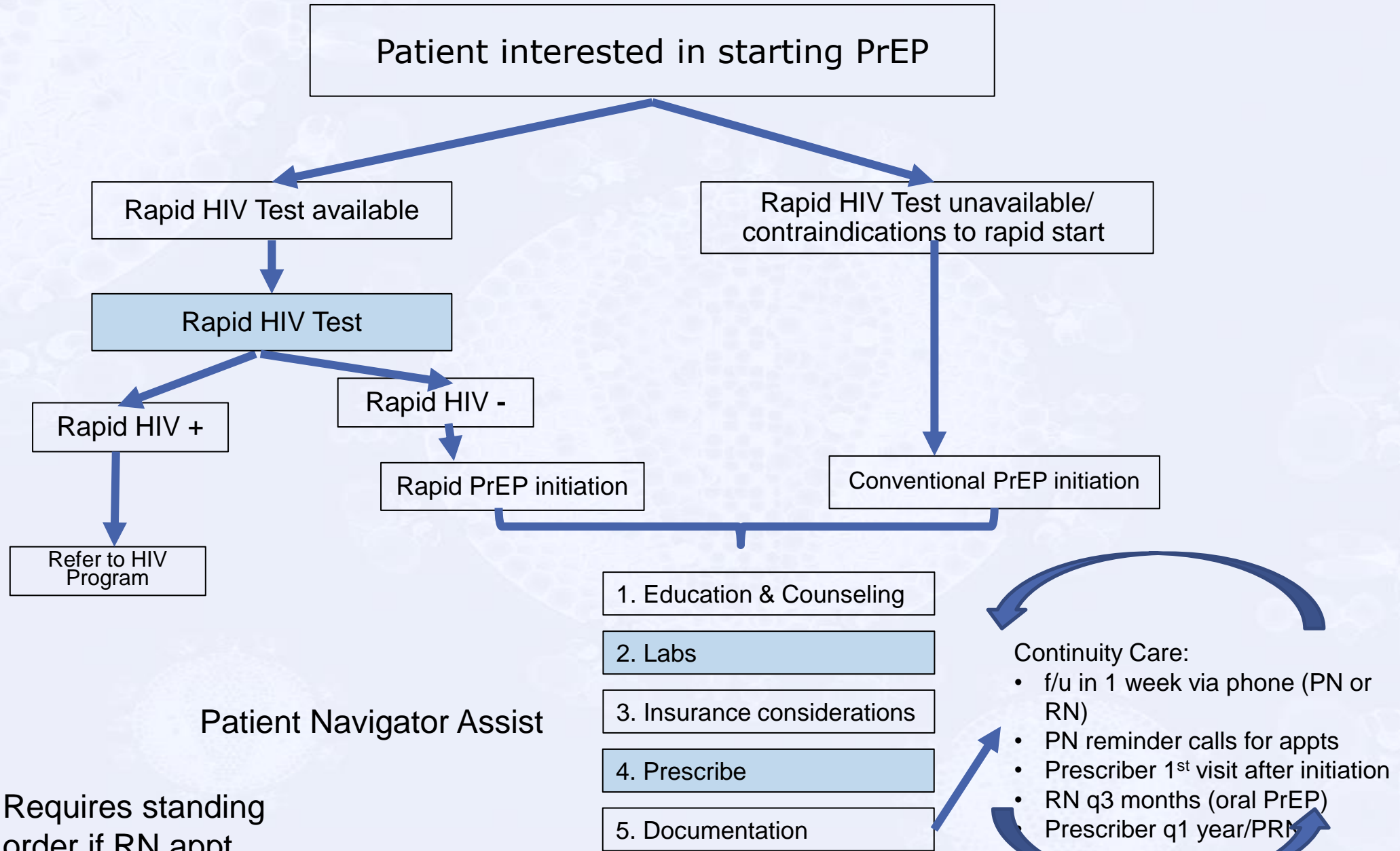
- Identify need for change/ intended impact
 - example: increase number of patients initiating PrEP
- Background research
- Establishment
 - Obtain buy-in from stakeholders
 - Plan for implementation
 - Timeline
 - Develop initial protocols/standing orders
 - Delineate roles
 - Identify measures/indicators
- Pilot
- Evaluation
- Standardization, Expansion, and scale-up
- Evaluation
- Maintenance and QI

Real World Example: RN- Led PrEP Care at an Urban Health Department

PrEP Clinic Model- RN Lead PrEP

- RNs manage PrEP panels using standing orders
- RNs initiate and provide routine continuity care under standing orders
 - Care provided via in-person, telephonic telehealth, and video telehealth
- Pts. See a provider (MD, PA, or NP) for first visit after initiation and at least annually
- RNs ensure pts. see providers, peer navigators, and social works as needed
- Task shifting allows providers to see more symptomatic/acute patients and increase # of people on PrEP

Sample Flow



Key

Requires standing order if RN appt

Other Considerations

- Level/position description of RNs
 - What do you need vs. what can you teach
- RN-led \neq RN does everything
 - Support staff very important
 - Prescriber still has important role
- Capacity/ staffing ratios
- Training

Future of PrEP delivery

- Long-acting PrEP
 - Islatravir- monthly pill/ implant
 - Lenacapavir injection q6 months
 - Broadly neutralizing antibodies (bNAbs) q6 months
- Pharmacist-delivered PrEP
- Telehealth options
 - Mistr

Training Resources



National **STD** Curriculum

www.std.uw.edu

This curriculum is funded by the U.S. Centers for Disease Control and Prevention (CDC) and developed by the University of Washington STD Prevention Training Center as part of the National Network of STD Prevention Training Centers (NNPTC).

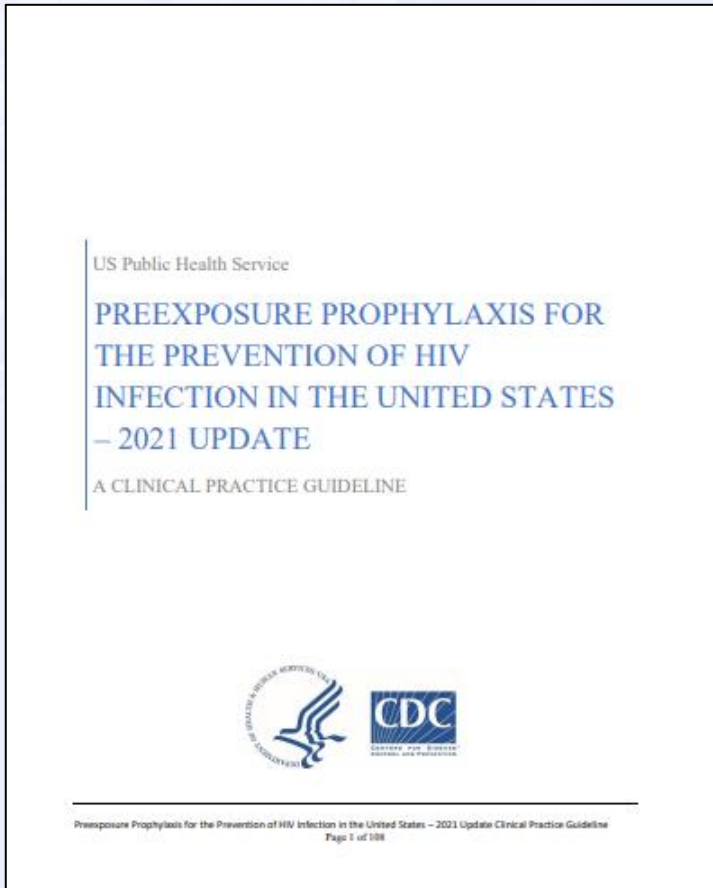


National **HIV** Curriculum

www.hiv.uw.edu

The National HIV Curriculum is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$1,021,448 with 0% financed with non-governmental sources.

Guidelines



NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE



**CLINICAL
GUIDELINES
PROGRAM**

<https://www.hivguidelines.org/>

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



Other Resources

- Current PrEP guidelines
 - <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>
- Current nPEP guidelines
 - <https://stacks.cdc.gov/view/cdc/38856>
- New York State clinical guidelines, includes HIV, PEP and PrEP
 - <https://www.hivguidelines.org/>
- Paying for PrEP
 - <https://www.nastad.org/prep-access/prep-assistance-programs>
 - <https://www.nastad.org/sites/default/files/resources/docs/nastad-prep-coverage-brief-on-prep-services.pdf>
- Warm line consultation from UCSF, also great resources
 - <https://nccc.ucsf.edu/>
 - (855) 448-7737 or (855) HIV-PrEP; Monday – Friday, 9 a.m. – 8 p.m. ET
- Aids Education and Training Center Program (AETC)
 - <https://aidsetc.org/>
 - Local: <https://aidsetc.org/aetc-program/johns-hopkins-university>
- National Network of Clinical Prevention Training Center (NNPTC)
 - National: <https://nnptc.org/>
 - Local: <https://www.stdpreventiontraining.com/about-us/>
- IAS-USA (good resource for free webinars, classes, conferences, etc.)
 - <https://www.iasusa.org/>

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SO...ANY QUESTIONS?



memegenerator.net

