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Staying PrEPped: Modern Prevention of HIV

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Objectives

- Outline the pharmacologic profile of emtricitabine/tenofovir disoproxil fumurate to emtricitabine/tenofovir alafenamide.
- Describe potential candidates for pre-exposure prophylaxis according to the Centers for Disease Control.
- Discuss emerging evidence for long acting injectable drugs for pre-exposure prophylaxis.

Key Definitions

- PrEP = Pre-Exposure Prophylaxis
- MSM = Men who have sex with men
- MTF = Male-to-female
- FTM = Female-to-male
- PWID = Persons who inject drugs
- STI = Sexually transmitted infection
- CAB = Cabotegravir
- ADAP = AIDS Drug Assistance Program

Epidemiology & Etiology

Over 1.2 million Americans are living with HIV

14% of these patients are unaware and need testing

HIV has a disproportionate impact on populations

- Age Group: Highest rate in persons aged **25-34 years**
- Race: Highest rate in **African Americans**
- Sex at birth: Rate for **males** was **5 times higher** than females
- Sexual orientation: Highest rate among **MSM** (69% of new cases)

All data collected in 2018*

U.S. Department of Health & Human Services. U.S Statistics | HIV.gov. 2020.

Epidemiology & Etiology

Transgender population has recently experienced an increase in HIV diagnoses

- Transgender MTF aged **25-29 years** accounted for **27%** of all HIV diagnoses
- Transgender MTF aged **20-24 years** accounted for **25%** of all HIV diagnoses

HIV diagnoses have increased among PWID

All data collected in 2018*

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U.S. Department of Health & Human Services. U.S Statistics | HIV.gov. 2020.

Risk Factors for Acquiring HIV

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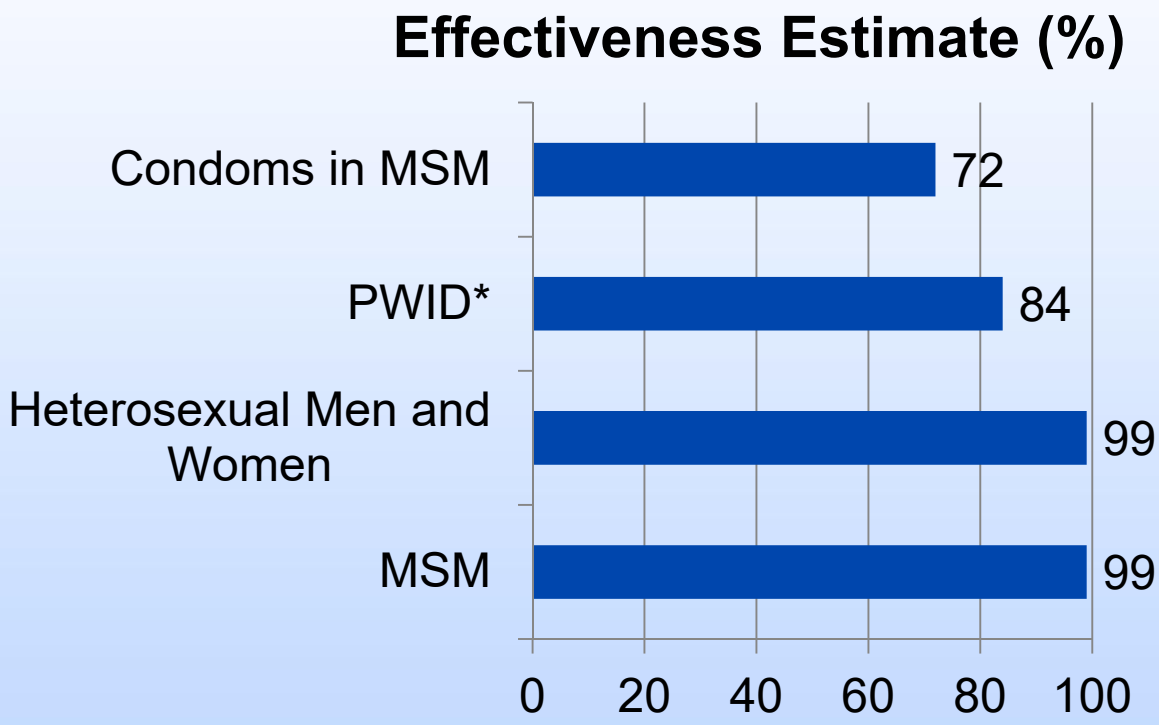
Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV



Condoms in MSM = 63-72%
PWID* = 74-84%

Assessed from https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html on 10/01/20

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Current Pharmacological Options for PrEP

Emtricitabine/tenofovir disoproxil fumurate (July 2012)

- PrEP in uninfected high-risk adults and in adolescents weighing 35 kg or more

Emtricitabine/tenofovir alafenamide (October 2019)

- PrEP in uninfected high-risk adults and in adolescents weighing 35 kg or more, **minus individuals** at risk from **receptive vaginal sex**

FDA Approved Indications

Truvada (emtricitabine/tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences; June 2020. Assessed on 10/01/2020
Descovy (emtricitabine/tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; January 2020. Assessed on 10/01/2020

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Comparing The Agents For PrEP

Truvada (emtricitabine/tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences; June 2020. Assessed on 10/01/2020

Descovy (emtricitabine/tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; January 2020. Assessed on 10/01/2020

Comparing The Agents for PrEP

Emtricitabine/tenofovir disoproxil fumurate (2012)

- **Boxed Warnings:**
  - HIV-1 and hepatitis B coinfection
  - Risk of medication resistance in HIV-1 positive patients
- **Strength:** 200mg/**300mg** of emtricitabine and tenofovir disproxil fumarate
- **Considerations:**
  - Renal impairment:
    - CrCl ≥60mL/min: No dosage adjustment necessary
    - CrCl <60mL/min: Not recommended

Emtricitabine/tenofovir alafenamide (2019)

- **Boxed Warnings:**
  - HIV-1 and hepatitis B coinfection
  - Risk of medication resistance in HIV-1 positive patients
- **Strength:** 200mg/**25mg** of emtricitabine and tenofovir alafenamide
- **Considerations:**
  - Renal impairment:
    - CrCl ≥30mL/min: No dosage adjustment necessary
    - CrCl 15-30mL/min: Not recommended
    - CrCl <15mL/min on chronic hemodialysis: One tablet after completion of hemodialysis on hemodialysis days

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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 (July 2020)

- **Objective:**
  - Determine efficacy and safety of emtricitabine/tenofovir alafenamide vs emtricitabine/tenofovir disoproxil fumarate for PrEP.

Outcomes:

Primary efficacy outcome: incidence of HIV infections

Secondary safety outcomes: Percent change from baseline to week 48 in bone mineral density of the hip and spine, urine B2-microglobulin to creatinine ratio, retinol-binding protein to creatinine ratio, distribution of urine protein to creatinine ratio, and serum creatinine

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Mayer KH, Molina JM, Thompson MA, 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;396(10246):239-254.

DISCOVER Trial (July 2020)

Baseline Characteristics	emtricitabine/tenofovir alafenamide (N=2694)	emtricitabine /tenofovir disoproxil fumarate (N=2693)
Average Age, y (median range)	34 (28-43)	34 (28-44)
Caucasian, N (%)	2264 (84)	2247 (87)
African American, N (%)	240 (9)	234 (9)
Transgender MTF who have sex with men, N (%)	45 (2)	29 (1)
Cisgender MSM, N (%)	2649 (98)	2664 (99)

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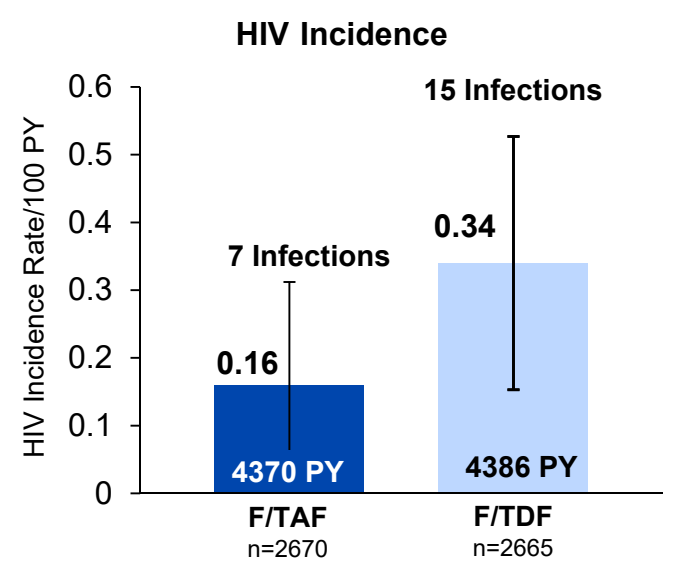
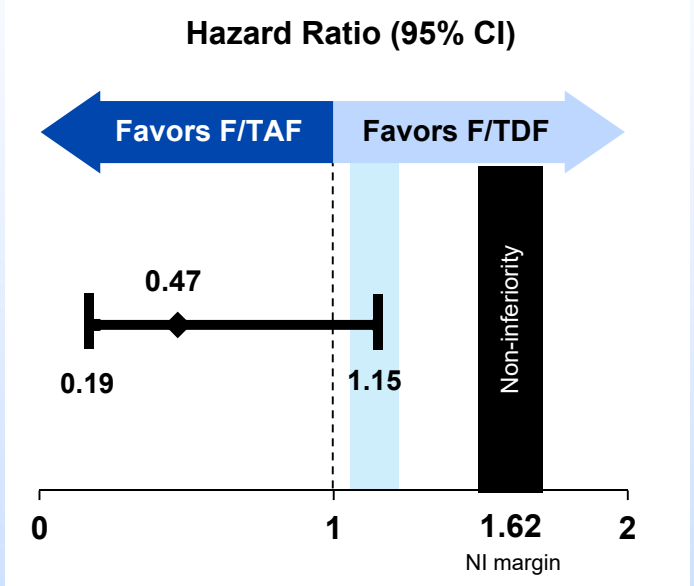
Mayer KH, Molina JM, Thompson MA, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. Lancet. 2020;396(10246):239-254.

F/TDF= emtricitabine/tenofovir disoproxil fumarate
F/TAF = emtricitabine/tenofovir alafenamide
PY = person-years
NI = Non-inferiority

Mayer KH, Molina JM, Thompson MA, 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;396(10246):239-254.

DISCOVER Trial (July 2020)





- Primary Outcome: (F/TAF vs. F/TDF) **0.16 infections** per 100-person years compared to **0.34 infections** per 100-person years, respectively. All but 2 of these participants had low [tenofovir]*

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DISCOVER Trial (July 2020)

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Adverse Events (Week 48)	F/TAF	F/TDF	P Value
HIP BMD (mean % change from baseline)	0.18	**-0.99**	P<0.0001
Spine BMD (mean % change from baseline)	0.50	**-1.12**	P<0.0001
Retinal-binding protein to creatinine ratio (median % change from baseline)	+0.2	**+19.9**	P<0.0001
β microglobulin to creatinine ratio (median % change from baseline)	-10.7	**+15.2**	P<0.0001
Δ UPCR from baseline (participants)	0	**+20**	P<0.0001
Δ SCr from baseline (mL/min)	-0.88	**+0.88**	P<0.0001

- Secondary Outcomes: In all six bone density and renal biomarkers, F/TAF showed superiority over F/TDF. Adverse events were considered similar among the two groups.

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F/TDF= emtricitabine/tenofovir disoproxil fumarate
F/TAF = emtricitabine/tenofovir alafenamide

SCr= Serum creatinine
UPCR= Urine protein to creatinine ratio

DISCOVER Trial (July 2020)

Conclusion:

The low incidence rate of acquired HIV while **adherent** to the studied regimens reinforces the true efficacy of both agents in high risk populations. Daily emtricitabine/tenofovir alafenamide showed **non-inferior efficacy** to daily emtricitabine/tenofovir disoproxil fumarate for **HIV prevention**. Adverse events were low and similar. **Emtricitabine/tenofovir alafenamide** was seen to have **more favorable effects** on **bone mineral density** and **less renal toxicity**.

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Mayer KH, Molina JM, Thompson MA, 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;396(10246):239-254.

Benefits of FDA Approved Agents for PrEP

Emtricitabine/tenofovir disoproxil fumarate recently became generic; will become widely available soon

Emtricitabine/ tenofovir disoproxil fumurate 2012

767 mm^3

Emtricitabine/ tenofovir alafenamide 2019

249 mm^3

US Dime

340 mm^3

*Pills shown are not actual size

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Images Reprinted with Permission from Gilead Sciences, Inc
Data on file. Gilead Sciences. 2019
DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.2017

Question 1

25 y/o cis-gender bisexual female presents after multiple sexual encounters in the past 6 months with inconsistent barrier protection. HIV status of partners are unknown. Pt currently taking drospirenone/ethinyl estradiol oral tablet daily. She has NKDA. PMH consists of previously treated gonorrhea x 2 (most recent 4 months ago). Denies any IVDU. HIV antibodies are negative and viral load was undetectable. All other labs are WNL.

Which of the following would be the most appropriate prophylaxis option for this patient?

a. Condom use alone

b. Emtricitabine/tenofovir alafenamide

c. Emtricitabine/tenofovir disoproxil fumurate

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Pre-exposure Prophylaxis For The Prevention Of HIV Infection In The United States – 2017 UPDATE Recommendations

HIV Diagnostic Testing

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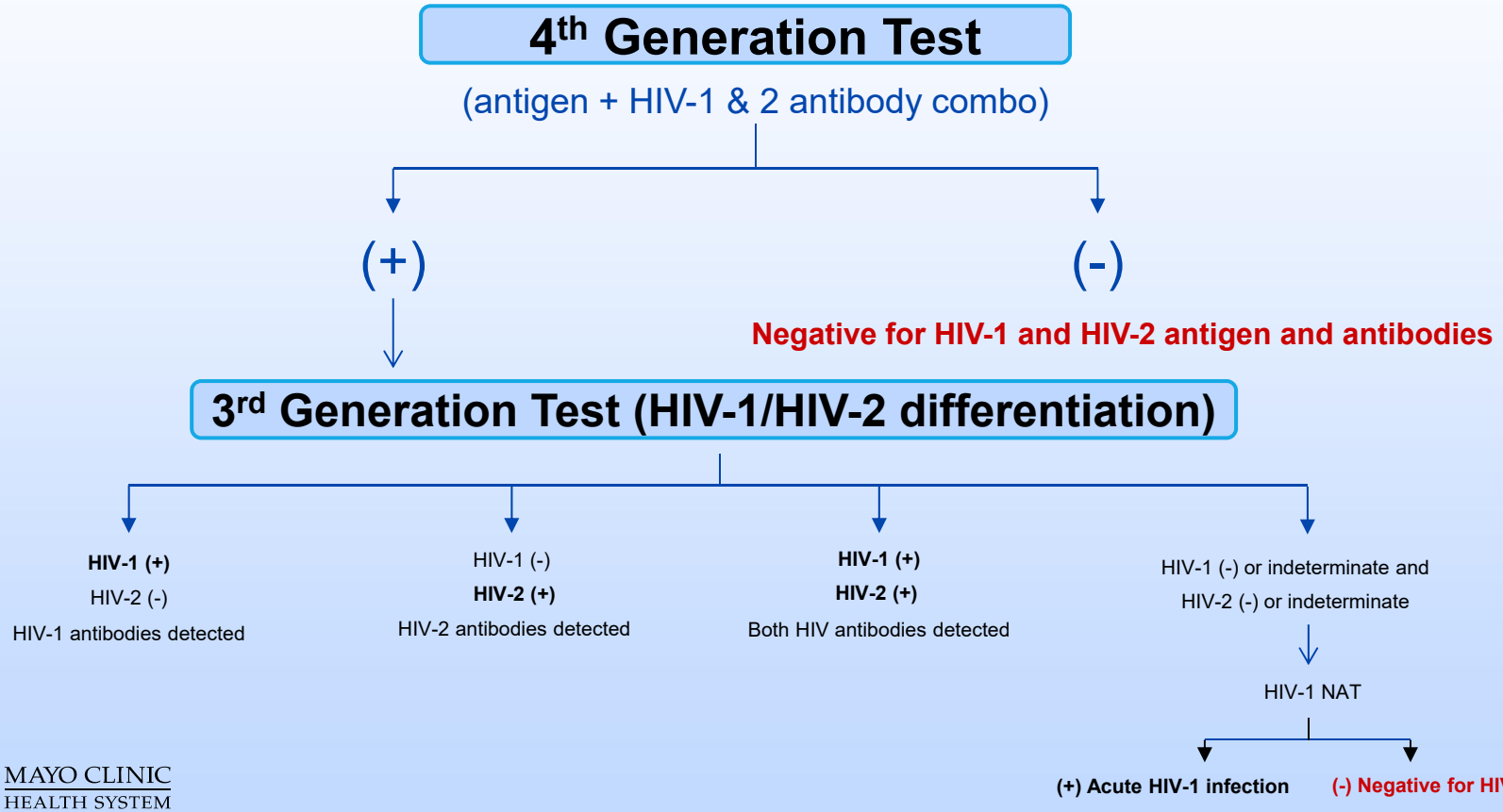
Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3



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HBV = Hepatitis B Virus
HCV = Hepatitis C Virus

Additional Testing Considerations

- Renal function:
  - Cockcroft-Gault Equation
- Hepatitis Serology:
  - Sexually active adults (especially MSM) and IVDU are at high risk of acquiring HBV and HCV infections

HBV infection is not a contraindication to PrEP use*

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Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

CDC Recommendations

Indications for PrEP use by MSM:

Any of the following:

1. Adult man (without HIV infection)
2. Male sex partner in past 6 months
3. Non-monogamous relationship with a recently tested HIV- negative man

AND at least one of the following

1. Any anal sex without condoms in past 6 months
2. Bacterial STI reported in past 6 months

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Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

CDC Recommendations

Indications for PrEP use by heterosexually active men and women:

Any of the following:

1. Adult person (without HIV infection)
2. Any sex with opposite sex partners in past 6 months
3. Non-monogamous relationship with a recently tested HIV-negative partner

AND at least one of the following

1. Is a bisexual man
2. Infrequent condom usage during sex with one or more partners of unknown HIV status who themselves are high risk
3. Is in an ongoing sexual relationship with an HIV-positive partner
4. Bacterial STI reported in past 6 months

Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

CDC Recommendations

Indications for PrEP use by PWID:

Any of the following:

- Adult person (without HIV infection)
- Any injection not prescribed by a clinician in the past 6 months

AND at least one of the following

- Any sharing of injection equipment in past 6 months
- Risk of sexual acquisition (See previous slide)

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Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

Testing For STIs

STI	Populations Recommended for Testing	Testing Frequency
Gonorrhea	Screen all sexually active adults prescribed PrEP	Baseline and at 6 months
Chlamydia	Screen all sexually active MSM	Baseline and at 6 months
Syphilis	Screen all adults prescribed PrEP	Baseline and yearly

Chlamydia testing not recommended for all sexually active women as a component of PrEP care

Follow 2015 CDC STI Guidelines for recommendations on testing frequency for women not using PrEP

Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3
https://www.cdc.gov/std/tg2015/screening-recommendations.htm

Clinical Monitoring and Follow-Up

	Every 3 months	Every 6 months	Every 12 months
Assess signs/symptoms	✖		
Repeat HIV testing	✖		
Repeat pregnancy test for women who may become pregnant	✖		
Provide additional prescriptions for no more than 90 days	✖		
Assess side effects, risk behaviors and ***adherence***	✖		
STI screening for symptomatic sexually active persons	✖		
STI screening for asymptomatic MSM at high risk of infection (i.e history of infection)	✖		
Monitor kidney function*		✖	
STI screening for all sexually active adolescents and adults		✖	
Evaluate the need to continue PrEP			✖

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All patients receiving PrEP

Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

Recommended PrEP Medications via CDC

- Tenofovir disproxil fumarate 300mg + emtricitabine 200mg once daily (as individual agents combined, or the combination tablet)
  - Approved in uninfected high-risk adults and in adolescents weighing 35 kg or more
- CDC guidelines have not yet been updated to include the recent FDA approval of emtricitabine/ tenofovir alafenamide (Guidelines published in March 2018)

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Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

Discontinuation and Reinitiation of PrEP

- Proper patient education on how to safely discontinue and restart PrEP is crucial
  - Conversation had at the start and end of PrEP therapy
- Protection will cease after 7-10 days of discontinuing therapy
- Patients who would like to restart PrEP must follow the initial PrEP workup

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Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

Centers for Disease Control and Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline.; 2018. doi:10.1016/S0040-4039(01)91800-3

PrEP in Special Populations

- **Pregnancy**
  - 2017 CDC Guideline recommendation varies on a case by case basis, balancing the risks and benefits with each patient
- **Lactation**
  - Emtricitabine and tenofovir disoproxil fumarate are present in the breast milk
- **Chronic HBV Infection**
  - Emtricitabine, tenofovir disoproxil fumarate, and tenofovir alafenamide are active against HIV and HBV (both prodrugs of tenofovir are FDA approved)

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Question 2

25 y/o cis-gender bisexual female presents after multiple sexual encounters in the past 6 months with inconsistent barrier protection. HIV status of partners are unknown. Pt currently taking drospirenone/ethinyl estradiol oral tablet daily. She has NKDA. PMH consists of previously treated gonorrhea x 2 (most recent 4 months ago). Denies any IVDU. HIV antibodies are negative and viral load was undetectable. All other labs are WNL.

Which of the following risk factors would make the patient recommended for PrEP according to the CDC recommendations?

a. IVDU
b. Adult person (without HIV infection) + Bacterial STI reported in past 6 months
c. Adult person (without HIV infection) + IVDU

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Primary Literature Review - Cabotegravir

Basics of Cabotegravir

- MOA: Integrase Strand Inhibitor
- Formulations: Oral Tablet and IM Injectable
  - IM Injection in clinic
- $t\frac{1}{2}$ = ~40 days

Cattaneo D, Gervasoni C. Pharmacokinetics and Pharmacodynamics of Cabotegravir, a Long-Acting HIV Integrase Strand Transfer Inhibitor. Eur J Drug Metab Pharmacokinet. 2019;44(3):319-327.
Image from https://en.wikipedia.org/wiki/Cabotegravir. Assessed on 10/01/20

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1. Safety and tolerability of long-acting cabotegravir injections in HIV-uninfected men (ECLAIR): a multicentre, double-blind, randomised, placebo-controlled, phase 2a trial **(August 2017)**

2. A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women Who Have Sex With Men **HPTN 083 (Preliminary Results July 2020)**

ECLAIR Trial (August 2017)

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Markowitz M, Frank I, Grant RM, et al. Safety and tolerability of long-acting cabotegravir injections in HIV-uninfected men (ECLAIR): a multicentre, double-blind, randomised, placebo-controlled, phase 2a trial. *Lancet HIV*. Published online 2017. doi:10.1016/S2352-3018(17)30068-1en-label, phase 2b, non-inferiority trial. *Lancet*. Published online 2017. doi:10.1016/S0140-6736(17)31917-7

ECLAIR Trial (August 2017)

Baseline Characteristics	CAB (N=106)	Saline placebo (N=21)
Average Age, y (median range)	31 (20-61)	30 (21-57)
Caucasian, N (%)	59 (56)	12 (57)
African American, N (%)	33 (31)	7 (33)
Cisgender MSM, N (%)	90 (85)	16 (76)
Body-mass Index kg/m^2 , median (range)	26 (18-48)	25 (18-40)

- Baseline characteristics equivalent (minus 5:1 randomization + Cisgender MSM population + BMI)
- Primary endpoint was safety and tolerability

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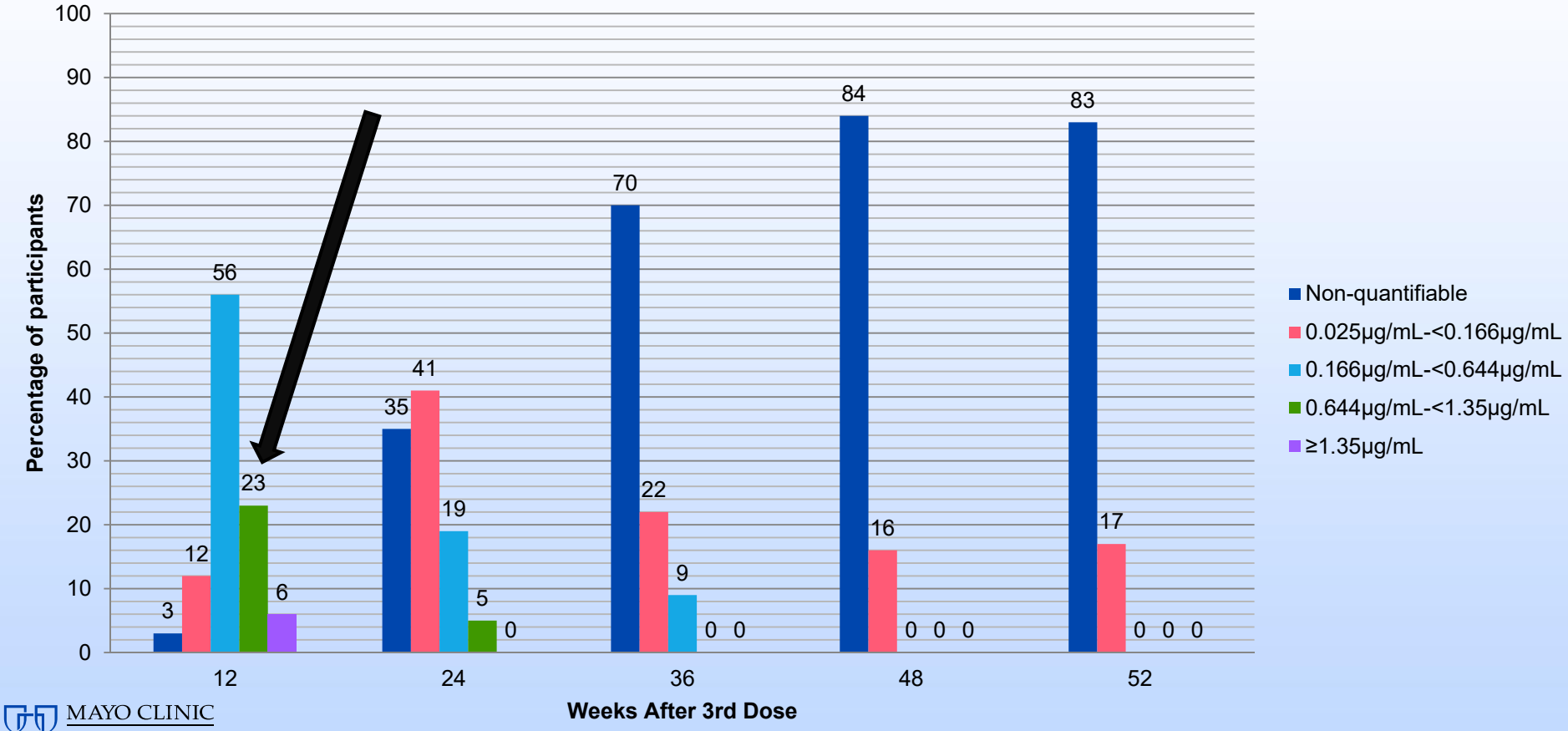

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ECLAIR Trial (August 2017)

Adverse Events	CAB	Placebo	P Value
Any event, n (%)	101 (96%)	20 (95%)	P=0.0049
Any grade 2 or higher event, n (%)	75 (80%)	10 (48%)	P=0.0049
Grade 2 or higher injection site pain, n (%)	55 (59%)	1 (5%)	P=0.0049

- **Safety Results:**
  - 2 MSM participants acquired HIV infection during the study (1 CAB 24 weeks after the final injection, 1 placebo during injection phase)
- **Discussion:**
  - When compared to saline placebo, CAB showed an acceptable safety profile
  - PK data suggests that BMI effects [CAB] and every 12 week dosing of CAB is suboptimal

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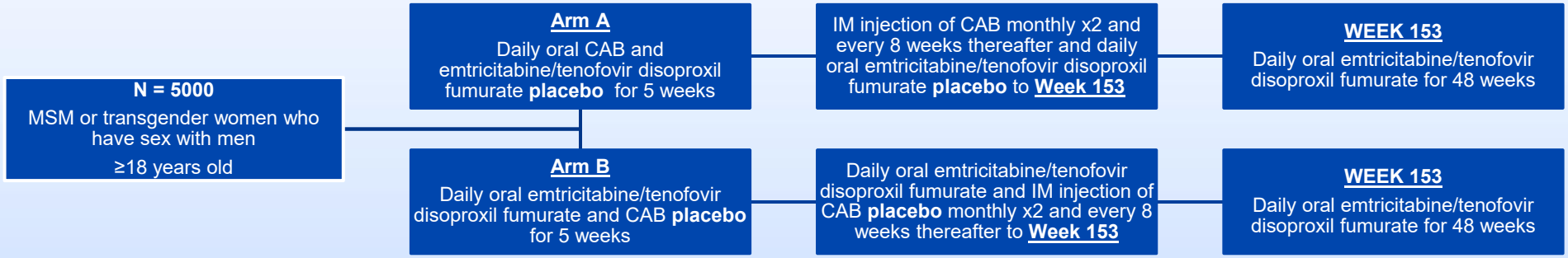
HPTN 083 (July 2020)

- **Objective:** To evaluate the safety and efficacy of cabotegravir for PrEP in HIV-uninfected cisgender men and transgender women who have sex with men



Interventions

1. CAB tablets 30mg
2. CAB IM injection 3mL 600mg
3. Emtricitabine/tenofovir disoproxil fumurate tablets 300mg/200mg
4. CAB IM + placebo tablets
5. Emtricitabine/tenofovir disoproxil fumurate tablets + IM placebo

Landovitz RJ. 2020.A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women Who Have Sex With Men. Retrieved from https://clinicaltrials.gov/ct2/show/results/NCT02842086

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- **Methods:**

HPTN 083 (July 2020)

F/TDF, emtricitabine/tenofovir disoproxil fumarate; CAB, cabotegravir
Landovitz R et al. AIDS 2020, OAXLB01
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	TOTAL (n=4566)	F/TDF (n=2284)	AB (n=2282)
Gender Identity, n (%)			
MSM	3995 (87.5)	1981 (86.7)	2014 (88.3)
TGW	**567 (12.4)**	302 (13.2)	265 (11.6)
Prefer not to answer	4 (0.1)	1 (<0.1)	3 (0.1)
Age, median (IQR)	26 (22, 32)	26 (22, 32)	26 (22, 32)
Age, n (%)			
18-29	**3079 (67.4)**	1508 (66.0)	1571 (68.8)
30-39	1049 (23)	550 (24.1)	499 (21.9)
40-49	315 (6.9)	170 (7.4)	145 (6.4)
50-59	110 (2.4)	50 (2.2)	60 (2.6)
≥60	13 (0.3)	6 (0.3)	7 (0.3)
Region, n (%)			
United States	1698 (37.2%)	849 (37.2%)	849 (37.2%)
Latin America	1964 (43.0%)	984 (43.2%)	980 (42.9%)
Asia	752 (16.5%)	377 (16.5%)	375 (16.5%)
Africa	152 (3.3%)	74 (3.2%)	78 (3.4%)
Race of US participants, n (%)			
Black/African-American	**844 (49.7)**	433 (51.0)	411 (48.9)
White/Asian/Native/Other	852 (50.2)	415 (48.9)	437 (51.5)
Other	2 (0.1)	1 (0.1)	1 (0.1)
Ethnicity of US participants, n (%)			
Latinx	303(17.8)	154 (18.1)	149 (17.6)

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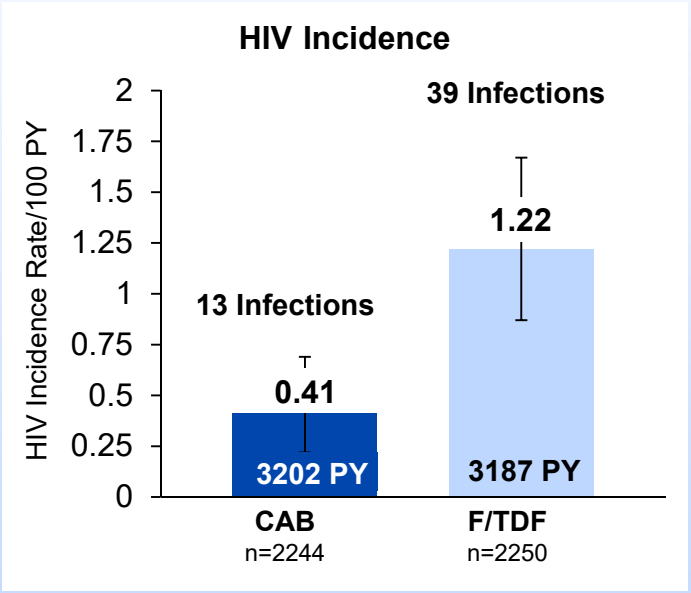
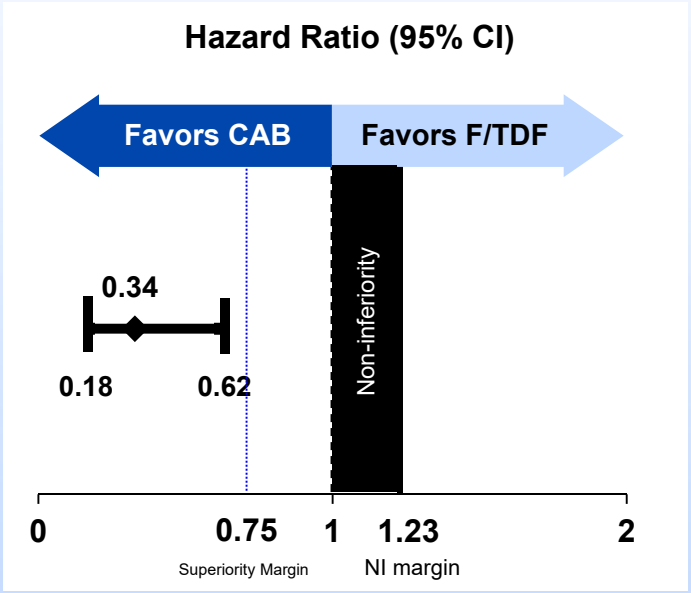
HPTN 083 (July 2020)

F/TDF, emtricitabine/tenofovir disoproxil fumarate; CAB, cabotegravir; CI, confidence interval
Landovitz R et al. AIDS 2020, OAXLB01
Graph Reprinted with Permission from Gilead Sciences, Inc

- **Preliminary Results:**





Conclusion: CAB is shown to be both superior and non-inferior when compared to daily emtricitabine/tenofovir disoproxil fumarate in MSM and transgender women

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Question 3

Following the results of the previous study, which of the following patients would be the best PrEP candidate for the long-acting injectable, CAB?

a. 33 y/o HIV negative cis-gender female with multiple sexual partners in the past year

b. 16 y/o HIV negative cis-gender female who presented to the ED post sexual assault

c. 28 y/o transgender woman in a monogamous relationship with an HIV+ male

Future Applications of CAB

There is limited yet emerging data on CAB monotherapy for PrEP

A monthly/bi-monthly injection option may **optimize therapy** for high risk patients in need of PrEP with adherence issues

CAB has also shown promising data in MSM and transgender women who have sex with men, suggesting it may become the first long-acting injectable recommended for PrEP

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Summary - Pharmacotherapy

- Currently, there are two FDA approved options for PrEP
- Emtricitabine/tenofovir alafenamide is associated with decreased effect on bone mineral density and less renal toxicity
- Although there are many benefits to emtricitabine/tenofovir alafenamide, CDC guidelines have yet to be updated to include it as an option for PrEP
- Emtricitabine/tenofovir disoproxil fumurate generic recently approved and will become available soon

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Staying PrEPped: Modern Prevention of HIV

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