HIV update: 2021

Vidhu Kariyawasam, MD
Assistant Professor of Medicine
Infectious Diseases and Global Medicine
University of Florida College of Medicine, Gainesville
Faculty, North Florida AETC

Continuing Education Disclosure
• The activity planners and speaker do not have any financial relationships with commercial entities to disclose.

This slide set has been peer-reviewed to ensure that there are no conflicts of interest represented in the presentation.

Objectives
• Recognize the global, national and local epidemiology of HIV
• Review “Ending the HIV Epidemic: A Plan for America”
• Recognize the impact COVID-19 has had on the diagnosis and treatment of HIV, and on those living with HIV
• Describe current HIV treatment guidelines
• Identify current HIV prevention strategies
38.0 million people living with HIV (31.6 million – 44.5 million)

1.7 million HIV-related deaths (0.5 million – 1.0 million)

0.7 million people newly infected (1.2 million – 2.2 million)

38.0 million people living with HIV globally

25.7 million Africa

3.7 million Eastern Mediterranean

2.6 million South-East Asia

2.2 million Western Pacific

2.0 million America

1.9 million Europe

Decline in HIV incidence and mortality over time

Source: UNAIDS/WHO estimates
HIV in the US

- In 2018, there were 37,286 new HIV diagnoses in the US
- 69% were among gay and bisexual men, 24% heterosexuals, 7% people who inject drugs (PWID)

Number of new HIV diagnoses was highest among people aged 25 to 34.

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 10 for estimates <1,000 and to the nearest 100 for estimates >1,000. Estimates for the year 2018 are preliminary and based on deaths reported to CDC through December 2019. Estimates for Alabama, Oklahoma, and South Carolina should be interpreted with caution due to incomplete death ascertainment.

†Total estimate for the United States does not include data for Puerto Rico.
Risk Factors for Severe COVID-19

- Cancer
- Heart disease
- COPD
- Chronic kidney disease
- Immuno compromise from solid organ transplant
- Obesity
- Sickle cell disease
- Smoking
- Type 2 diabetes

Is HIV a Risk Factor for COVID-19?

  - At Hospitalization for COVID-19
  - Prospective, observational study of people with COVID-19 infection (January-June 2020, 47,592 from 207 centers)
  - HIV coinfection (0.26%; 90% on ART) 123 people
  - Outcome: association between HIV status and mortality at day 28
  - Characteristics of persons with HIV (versus no HIV) at time of hospitalization for COVID-19
    - Younger
    - Fewer comorbidities
    - More systemic symptoms
    - Higher lymphocyte counts and C-reactive protein levels

Mount Sinai Hospital System:
Laboratory Confirmed COVID-19 and Persons With HIV on ART

- No difference in COVID-19 severity on admission by HIV status (P=0.15)
- Poor outcomes for hospitalized persons with HIV were frequent but similar in proportions with matched controls
- Similar cumulative incidence of death over time by HIV status (P=0.9)

COVID-19 Presentation and Adverse Outcomes

<table>
<thead>
<tr>
<th>With HIV (n=50)</th>
<th>Without HIV (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity_admission (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>18</td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
</tr>
<tr>
<td>Moderate/severe</td>
<td>44</td>
</tr>
<tr>
<td>Severe</td>
<td>17</td>
</tr>
<tr>
<td>Death</td>
<td>21</td>
</tr>
</tbody>
</table>

Adverse outcome:
- Mechanical ventilation
- Death
HIV Viral Suppression Rates During COVID-19: Ward 88, San Francisco

- HIV RNA <200 copies/mL pre shelter-in-place (n=1766): 81%
- Post shelter-in-place (versus pre)
  - Odds for patients having HIV RNA ≥ 200 copies/mL increased 31%
  - Increased odds among blacks versus white and homeless
  - Retention-in-care increased slightly
  - Facilitated by an increase in telehealth visits

Impact of COVID-19 on HIV PrEP Care at a Boston Community Health Center

- Fenway Health center (n=3520; January-April 2020)
- Baseline characteristics
  - Age (37 years), white/black/Hispanic/other (73%/6%/14%/7%)
  - Cisgender male (92%)
  - Public/private insurance (13%/86%)
- There was a major shift from in-person visits to telehealth (24 versus 1022 visits)
- PrEP refill lapses were associated with age (P=0.001), race (P=0.001), ethnicity (P=0.04), and insurance type (P=0.002)
- Limitation: cannot ascertain sexual and pill-taking behaviors
- Results indicate COVID-19 was associated with major disruptions in PrEP refills, new starts, and HIV/STI testing, despite near-complete shift to telehealth

Impact of COVID-19 Related Shelter-in-Place Orders on PrEP Access, Usage, and HIV Risk Behaviors

- Electronic convenience sample survey of PrEP users (n=344) and providers (n=182)
- Providers via email (Academy of HIV Medicine database) and users via social media
- Findings from this survey indicate that providers faced challenges adhering to CDC recommended monitoring and testing and that electronically-based critical monitoring has increased during shelter-in-place orders

<table>
<thead>
<tr>
<th>Main Changes in PrEP Care (January to April 2020)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>New PrEP users</td>
<td>20%</td>
</tr>
<tr>
<td>Patients with an active PrEP prescription</td>
<td>15%</td>
</tr>
<tr>
<td>Tests</td>
<td>46</td>
</tr>
<tr>
<td>HIV</td>
<td>35</td>
</tr>
<tr>
<td>Gonorrhea/Chlamydia</td>
<td>25</td>
</tr>
<tr>
<td>Percentage of patients who have had a test</td>
<td>25</td>
</tr>
</tbody>
</table>

Changes during shelter-in-place orders

- Among PrEP users
  -Stopped PrEP use: 32%
  -Missed appointments decreased perception of risk (88%), lack of
  -No change or increase in risk behaviors: 10% to 15%
  -Suggests ongoing PrEP access is important to mitigate HIV risk

- Among PrEP providers
  -Prescribed new PrEP prescriptions and refills: 55% (versus only 41%)
  -Reported at least 1 patient stopped PrEP
  -Encountered patients with providers who reported STI, but unable to test: 81%
  -Empirically treated patient for STI without seeing them or a test: 33%
Routine Screening for HIV During the COVID-19 Pandemic

- Urban ED preparations
  - Established in large temporary space for screening, testing, and Fever at time of first ED visit
  - Screening at time of discharge
  - COVID-19 screening of patients was incorporated into the design of the secondary ED space, with a station
  - HIV testing (percent of ED visits) was maintained during first 1.5 months
    - Through 4/18: 6 persons tested positive for HIV
  - It is important to maintain HIV screening and linkage to care, even in the face of the COVID-19 pandemic
  - HIV elimination initiatives nationwide require expansion and intensification of HIV screening and linkage to care efforts

Impact of COVID-19 on HIV diagnoses in Florida

- From January 1-September 25 2020, there were 3217 cases of HIV reported to the Florida Department of Health
- This is a 14% decrease in the number of HIV cases

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>N</th>
<th>% of Total</th>
<th>N</th>
<th>% of Total</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>901</td>
<td>24.1%</td>
<td>863</td>
<td>20.0%</td>
<td>-7.2%</td>
</tr>
<tr>
<td>Black</td>
<td>1,451</td>
<td>38.8%</td>
<td>1,217</td>
<td>28.6%</td>
<td>-16.1%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1,315</td>
<td>35.2%</td>
<td>1,085</td>
<td>27.3%</td>
<td>-17.7%</td>
</tr>
<tr>
<td>Other</td>
<td>72</td>
<td>1.9%</td>
<td>79</td>
<td>2.0%</td>
<td>9.7%</td>
</tr>
<tr>
<td>Total</td>
<td>3,798</td>
<td>100.0%</td>
<td>3,217</td>
<td>100.0%</td>
<td>-14.8%</td>
</tr>
</tbody>
</table>

Florida HIV Testing

- Publicly-funded HIV testing in Florida ranges from 310,000-340,000 annually
  - Average tests/month for 2019: 26,346
  - Average test/month for 2020: 15,217
PrEP Prescriptions

- 2019: 1574 prescriptions
- 2020: 1026 prescriptions
- 34.8% decrease in number of prescriptions Jan-Sept 2019 vs 2020

What’s next?

- Continue to monitor the impact COVID-19 is having on testing, diagnosis and treatment of HIV
- Evaluate innovative strategies/activities to help reduce disruptions in HIV care

Ending the HIV Epidemic: A Plan for America

**GOAL:**

HRSA will work with each community to establish local teams on the ground to tailor and implement strategies to:

- Diagnose all people with HIV as early as possible.
- Treat the infection rapidly and effectively to achieve sustained viral suppression.
- Prevent new HIV infections by using proven interventions, including pre-exposure prophylaxis (PrEP) and care, support, and linkage to care.
- Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.
When should I test for HIV?

- In 2006, the CDC issued guidelines advocating routine voluntary HIV screening of all patients aged 13 to 64 years as a normal part of medical care, without the need for signed consent or counseling:

  “Opt-out Testing”

- On July 1, 2015, a Florida law went into effect that removed need for written consent for HIV testing in healthcare settings.
Update – HIV Treatment

Antiretroviral Mechanism of Action

http://depts.washington.edu/nwaetc/Pill_Chart.pdf
Treatment Goals
- Maximally and durably suppress plasma HIV RNA
- Restore and preserve immunologic function
- Reduce HIV-associated morbidity and prolong the duration and quality of survival
- Prevent HIV transmission
  “Treatment as Prevention”

Considerations When Starting Antiretroviral Therapy
- Who to start on antiretroviral therapy:
  - Now DHHS, WHO and IAS-USA all recommend starting ART in everyone diagnosed with HIV irrespective of their CD4 count
- When to start antiretroviral therapy –
  - Now DHHS, WHO and IAS-USA all recommend starting ART as soon as possible
- Rapid start or initiating ART on same day as HIV is diagnosed is an emerging strategy to reduce loss to follow-up and decrease time to viral suppression
- What antiretroviral to start
- When to switch antiretroviral therapy
- What to switch to

What Antiretroviral Therapy to Start –Considerations:
- Viral load and CD4 count
- HIV resistance test result
- Drug interactions
- Potential side effects
- Pill burden
- Access and Cost
Table 1a. Recommended Antiretroviral Regimens for Initial Therapy

Recommended initial regimens for West People with HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use:

**INSTIs plus NNRTIs:**
- **Note:** For individuals of childbearing potential, see Table 1b before prescribing one of these regimens.
- **BCI/FTC/3TC** (ABC is preferred with lower resistance profile)
- **EFV/FTC/3TC** or **EFV/ABC/3TC**
- **RAL plus TVDR** or **TDF plus FTC/3TC or TDF/FTC**

**NNRTIs plus PI/HIbs**
- **DTI/3TC** (M), except for individuals with HIV RNA >50,000 copies/mL, where ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or NNRTI testing are available.

---

Example of Studies of Recommended INSTIs as First-Line ART Regimens

<table>
<thead>
<tr>
<th>Trial</th>
<th>INSTI Regimen</th>
<th>Comparator</th>
<th>Wks</th>
<th>Results</th>
<th>Outcomes vs Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS-18971</td>
<td>BIC/FTC/TAF</td>
<td>DTG/ABC/3TC</td>
<td>96</td>
<td>88 vs 90%</td>
<td>Noninferior</td>
</tr>
<tr>
<td>GS-18971</td>
<td>BIC/FTC/TAF</td>
<td>DTG + TAF</td>
<td>96</td>
<td>84 vs 86%</td>
<td>Noninferior</td>
</tr>
<tr>
<td>SINGLE2</td>
<td>DTI + ABC/3TC</td>
<td>EFV/FTC/TDF</td>
<td>144</td>
<td>71 vs 63%</td>
<td>Favors INSTI</td>
</tr>
<tr>
<td>FLAMINGO2</td>
<td>DTI + 2 NRTIs</td>
<td>DRV + RTV + 2 NRTIs</td>
<td>96</td>
<td>80 vs 68%</td>
<td>Favors INSTI</td>
</tr>
<tr>
<td>SPRING-211</td>
<td>DTI + 2 NRTIs</td>
<td>RAL + 2 NRTIs</td>
<td>96</td>
<td>81 vs 70%</td>
<td>Noninferior</td>
</tr>
<tr>
<td>GEMINI2</td>
<td>DTI + 3TC</td>
<td>DTI plus TDF/FTC</td>
<td>96</td>
<td>86 vs 88%</td>
<td>Noninferior</td>
</tr>
</tbody>
</table>

- No resistance mutations (INSTI or NRTI) in treatment naive studies of doubling INSTI/HIb turnover
- Rates of discontinuation for ABC numerically lower with INSTI/HIbs or PI over NRTIs
- Modest difference in adverse events between arms in head-to-head comparisons of disintegrative with Hlbi/insti given above

---

**Increased Persistence of Initial ART With INSTI-Containing Regimens**

Thibaut Dany, Bong Nkengadji, Okaloka, Zadoux, Dauteur J, et al.

---

Data from:
Low Virologic Failure and Treatment Emergent Resistance with Dolutegravir and Bictegravir

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>N/A</th>
<th>Treatment Arm</th>
<th>Virologic Failure, %</th>
<th>Treatment Emergent Resistance Mutations, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPREE 2T</td>
<td>96</td>
<td>DTG + r ALV</td>
<td>22 (12)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DTG + r NRTI</td>
<td>28 (15)</td>
<td>1 (10)</td>
</tr>
<tr>
<td>STRIVE 2T</td>
<td>189</td>
<td>DTG + r ALV</td>
<td>14 (8)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DTG + r NRTI</td>
<td>21 (11)</td>
<td>1 (11)</td>
</tr>
<tr>
<td>FLAMINGO 2T</td>
<td>96</td>
<td>DTG + r NRTI</td>
<td>10 (10)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DTG + r NRTI</td>
<td>33 (33)</td>
<td>0</td>
</tr>
<tr>
<td>GS 1408P</td>
<td>90</td>
<td>DTG + r NRTI</td>
<td>15 (16)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DTG + r NRTI</td>
<td>30 (30)</td>
<td>0</td>
</tr>
<tr>
<td>GS 1409P</td>
<td>90</td>
<td>DTG + r NRTI</td>
<td>20 (20)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DTG + r NRTI</td>
<td>30 (30)</td>
<td>0</td>
</tr>
<tr>
<td>Center 3 2T</td>
<td>144</td>
<td>DTG + r NRTI</td>
<td>0 (0)</td>
<td>0</td>
</tr>
</tbody>
</table>

Integrase Inhibitors Considerations

- There may be transmitted resistance with integrase resistance but very rare
- Women of childbearing potential – risk of birth defects continues to fall
- Possible weight gain – now convincingly associated with weight gain

Effect of Switching ART on Weight and Metabolic Changes

<table>
<thead>
<tr>
<th>Study</th>
<th>Switch</th>
<th>Weights/Metabolic Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPERA (observational)</td>
<td>TDF to TAF</td>
<td>2-4.5 kg/yr; greatest in those also switching to newer INSTI (DTG, BIC)</td>
</tr>
<tr>
<td>TRO (observational)</td>
<td>TDF or ABC to TAF</td>
<td>Greater weight gain after switching from TDF to TAF than after switching from ABC to TAF</td>
</tr>
<tr>
<td>TANGO (randomized)</td>
<td>TAF-based regimen to DTG/FTC</td>
<td>Weight: no difference DTG/FTC: improved lipids, insulin resistance, especially after switching from boosted regimen</td>
</tr>
</tbody>
</table>
Dual therapy

- **GEMINI-1,-2 and TANGO: Virologic Outcomes With DTG + 3TC as Initial or Switch Therapy**
  - **GEMINI-1,-2**: Initial therapy with DTG + 3TC noninferior to DTG + TDF/FTC for primary endpoint of HIV-1 RNA < 50 c/mL
  - **TANGO**: Switch to DTG/3TC noninferior to continued TAF-based ART for primary endpoint of HIV-1 RNA ≥ 50 c/mL

**Dual Therapy Treatment Option**

- Dolutegravir/lamivudine ➔ Dovato®
  - Treatment naïve
  - Switch from three drug regimen
  - No Hep B, NRTI/Integrase mutations or history of treatment failure

How Commonly Will 2 drugs Be Used

- Multiple unboosted combinations approved or in development (DTG/3TC, DTG/RPV and cabotegravir/RPV)
- Few differences yet in AE or long term outcomes
- No substantial cost differences
- Fewer metabolic effects – no TAF?
Florida’s Test and Treat Program:

- Instituted in February 2017 at community health departments
- Provides:
  1. Immediate linkage to HIV care
  2. Initiation of antiretroviral therapy (ART) at time of diagnosis and/or at the time of returning to care after a gap in services
- Eligibility:
  1. Newly diagnosed HIV
  2. Returning to care

Test and Treat Timeline:

- Day 1 (within 3 days):
  - HIV+ diagnosis or confirmive test
  - Enroll in care
  - Clinician visit to assess care status

- Day 4 (or within 10 days):
  - Initiation of ART
  - ART start

- Day 5-10 Follow Up:
  - Medication/medical initiation
  - Eligibility assessment
  - Obtain baseline labs
  - ART started (if applicable)
  - Counseling
  - Linkage to HIV primary care

- Linkage to Care:
  - Follow-up compliance with clinic visits and appointments
  - Transition to long-term primary HIV care

TAT Medications:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Therapeutic Class</th>
<th>Pharmacologic Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>B/LATAVY 34</td>
<td>lamivudine/tenofovir alafenamide</td>
<td>antiretroviral</td>
<td>INSTI/RTI combo</td>
</tr>
<tr>
<td>DESCOXY 34</td>
<td>emtricitabine/tenofovir alafenamide</td>
<td>antiretroviral</td>
<td>RTI/RTI combo</td>
</tr>
<tr>
<td>SYMTUZA 34</td>
<td>dolutegravir/lamivudine/tenofovir alafenamide</td>
<td>antiretroviral</td>
<td>INSTI/RTI combo</td>
</tr>
<tr>
<td>TRUXIMA 34</td>
<td>dolutegravir</td>
<td>antiretroviral</td>
<td>INSTI</td>
</tr>
<tr>
<td>TRUVADA 34</td>
<td>emtricitabine/tenofovir disoproxil fumarate</td>
<td>antiretroviral</td>
<td>INSTI/RTI combo</td>
</tr>
<tr>
<td>SENTRIS 34</td>
<td>raltegravir</td>
<td>antiretroviral</td>
<td>INSTI</td>
</tr>
</tbody>
</table>
Long acting antiretrovirals – cabotegravir

- Now FDA approved
- Integrase inhibitor similar to dolutegravir
- Similar resistance profile
- Initially will require an oral lead in
- Injected into Gluteus Medius
- Exciting -Nanotechnology formulation : SC and IM injections
- Safety- mostly injection site reactions and nodules with SC dosing
- RPV long acting needs cold chain

Cabotegravir: Phase 3 trials

<table>
<thead>
<tr>
<th>Study (reference)</th>
<th>Study population</th>
<th>Design</th>
<th>Result (week 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLAIR</td>
<td>Healthy adults (N=428)</td>
<td>ABC/3TC/TDF or CAB + RPV (oral/IV) then IM monthly</td>
<td>V≥95% CAB + RPV vs placebo</td>
</tr>
<tr>
<td>ATLAS-1</td>
<td>Adults with HIV-1 refractory to oral therapy (N=328)</td>
<td>CAB + RPV (oral/IV) then IM monthly</td>
<td>V≥95% CAB + RPV vs placebo</td>
</tr>
<tr>
<td>ATLAS-2M</td>
<td>Adults with HIV-1 refractory to oral therapy (N=328)</td>
<td>CAB + RPV (oral/IV) then IM monthly</td>
<td>V≥95% CAB + RPV vs placebo</td>
</tr>
</tbody>
</table>

Drugs in the Pipeline

- CAB – Prodrug in Rhesus Macaques – Nano formulated
- Has extended release Q6 month dosing
- Cabotegravir -- Micro needle Patches
Pre-exposure Prophylaxis

PrEP is an HIV prevention method in which people who do not have HIV infection take a pill daily to reduce their risk of becoming infected. ONLY PEOPLE WHO ARE HIV-NEGATIVE SHOULD USE PrEP. A NEGATIVE HIV TEST IS REQUIRED BEFORE STARTING PrEP AND THEN EVERY 3 MONTHS WHILE TAKING PrEP.

http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/

PrEP is an HIV prevention method in which people who do not have HIV infection take a pill daily to reduce their risk of becoming infected. ONLY PEOPLE WHO ARE HIV-NEGATIVE SHOULD USE PrEP. A NEGATIVE HIV TEST IS REQUIRED BEFORE STARTING PrEP AND THEN EVERY 3 MONTHS WHILE TAKING PrEP.

Why PrEP?

- Estimated 50,000 new HIV infections each year in the US
- No cure
- No effective vaccine yet
- In multiple studies, there is a significantly decreased risk of HIV acquisition in those who took PrEP consistently

<table>
<thead>
<tr>
<th>Transmission Route</th>
<th>Effectiveness Estimate</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual</td>
<td>~99%</td>
<td>Very high levels of adherence to PrEP ensure maximum effectiveness</td>
</tr>
<tr>
<td>Injection drug use</td>
<td>74% – 84%</td>
<td>These estimates are based on tenofivir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily.</td>
</tr>
</tbody>
</table>


Smith, DK., et al. CROI 2018; March 4-7, Boston, MA, USA.

ESTIMATED NUMBER OF ADULTS WHO COULD POTENTIALLY BENEFIT FROM PrEP, UNITED STATES, 2015

- Gay, bisexual, or other men who have sex with men
- Heterosexual adults
- Women who inject drugs

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Gay, bisexual, or other men who have sex with men</th>
<th>Heterosexual adults</th>
<th>Women who inject drugs</th>
<th>Total who could potentially benefit from PrEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/African-American, non-Hispanic</td>
<td>398,136</td>
<td>194,664</td>
<td>26,458</td>
<td>500,350</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>220,760</td>
<td>40,580</td>
<td>14,020</td>
<td>285,360</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>295,070</td>
<td>19,140</td>
<td>28,023</td>
<td>332,233</td>
</tr>
<tr>
<td>Total who could potentially benefit from PrEP</td>
<td>913,972</td>
<td>253,468</td>
<td>67,501</td>
<td>1,234,941</td>
</tr>
</tbody>
</table>

Notes: PrEP-exposure prophylaxis likely to be effective for some. Data are not shown.

Brooks, D.K., et al. CROI 2010; March 4-7, Boston, MA, USA.
2 FDA-Approved Medications for PrEP

Each consists of two drugs combined in a single oral tablet taken daily

1. Emtricitabine (F) 200 mg combined with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name Truvada®)
2. Emtricitabine (F) 200 mg combined with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name Descovy®)

Approved to prevent HIV infection in adults and adolescents weighing at least 77 pounds (35 kg)

Which medication should I prescribe for daily PrEP

![Comparison chart between TDF/FTC and TAF/FTC](chart.png)

<table>
<thead>
<tr>
<th></th>
<th>TDF/FTC</th>
<th>TAF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>14-21%</td>
<td>22-29%</td>
</tr>
<tr>
<td>Safety</td>
<td>≥ 14%</td>
<td>≥ 14%</td>
</tr>
<tr>
<td>Cost</td>
<td>$2,868/mo. in 2018</td>
<td>$1,158/mo. in 2018</td>
</tr>
<tr>
<td>Body Mass Index (kg)</td>
<td>34.3</td>
<td>45.1</td>
</tr>
</tbody>
</table>

Table 1: Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>How Will This Medication Help Prevent HIV infection?</th>
<th>How Will This Medication Help Prevent HIV infection?</th>
<th>How Will This Medication Help Prevent HIV infection?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive partner</td>
<td>HIV-negative partner</td>
<td>HIV-negative partner</td>
</tr>
<tr>
<td>High number of sex partners</td>
<td>No outbreaks of sexually transmitted infections and other complications</td>
<td>High number of sex partners</td>
</tr>
<tr>
<td>History of discordant or no condom use</td>
<td>History of discordant or no condom use</td>
<td>History of discordant or no condom use</td>
</tr>
<tr>
<td>Commercial sex work</td>
<td>Commercial sex work</td>
<td>Commercial sex work</td>
</tr>
<tr>
<td>In high HIV prevalence area or network</td>
<td>In high HIV prevalence area or network</td>
<td>In high HIV prevalence area or network</td>
</tr>
<tr>
<td>Clinically Eligible</td>
<td>Clinically Eligible</td>
<td>Clinically Eligible</td>
</tr>
<tr>
<td>Documented negative HIV test result before initiating PrEP</td>
<td>Documented negative HIV test result before initiating PrEP</td>
<td>Documented negative HIV test result before initiating PrEP</td>
</tr>
<tr>
<td>No signs or symptoms of acute HIV infection</td>
<td>No signs or symptoms of acute HIV infection</td>
<td>No signs or symptoms of acute HIV infection</td>
</tr>
<tr>
<td>Normal renal function, no cardiovascular or metabolic conditions</td>
<td>Normal renal function, no cardiovascular or metabolic conditions</td>
<td>Normal renal function, no cardiovascular or metabolic conditions</td>
</tr>
<tr>
<td>Documented hepatitis B virus infection or vaccination status</td>
<td>Documented hepatitis B virus infection or vaccination status</td>
<td>Documented hepatitis B virus infection or vaccination status</td>
</tr>
<tr>
<td>Prescription</td>
<td>Prescription</td>
<td>Prescription</td>
</tr>
<tr>
<td>Daily, non-stop, all of time</td>
<td>Daily, non-stop, all of time</td>
<td>Daily, non-stop, all of time</td>
</tr>
<tr>
<td>3 times a day</td>
<td>3 times a day</td>
<td>3 times a day</td>
</tr>
<tr>
<td>Other services</td>
<td>Other services</td>
<td>Other services</td>
</tr>
<tr>
<td>Follow-up visits at least every 3 months to guide the following:</td>
<td>Follow-up visits at least every 3 months to guide the following:</td>
<td>Follow-up visits at least every 3 months to guide the following:</td>
</tr>
<tr>
<td>HIV testing, medication adherence counseling, behavioral risk reduction support,</td>
<td>HIV testing, medication adherence counseling, behavioral risk reduction support,</td>
<td>HIV testing, medication adherence counseling, behavioral risk reduction support,</td>
</tr>
<tr>
<td>opportunistic infection assessment</td>
<td>opportunistic infection assessment</td>
<td>opportunistic infection assessment</td>
</tr>
<tr>
<td>At 1 month and every 6 months thereafter</td>
<td>At 1 month and every 6 months thereafter</td>
<td>At 1 month and every 6 months thereafter</td>
</tr>
<tr>
<td>HIV testing, opportunistic infection assessment</td>
<td>HIV testing, opportunistic infection assessment</td>
<td>HIV testing, opportunistic infection assessment</td>
</tr>
<tr>
<td>At 3 months and every 6 months thereafter</td>
<td>At 3 months and every 6 months thereafter</td>
<td>At 3 months and every 6 months thereafter</td>
</tr>
</tbody>
</table>

For women, access to pregnancy testing and pregancy counseling: 1 month

Access to clean needles and syringes and drug treatment services
**Ready, Set, PrEP**

- Launched by the US Department of Health and Human Services on 12/3/19
- To qualify, patients must:
  - Test negative for HIV
  - Have a valid prescription from a healthcare provider
  - Not have prescription drug coverage
- Beginning no later than March 30, 2020, patients may obtain PrEP through CVS, Walgreens, Rite Aid or mail order all at no cost
  - [https://www.getyourprep.com/](https://www.getyourprep.com/) or 855-447-8410
  - HIV.gov Locator

**HPTN 083- PrEP with IM CAB vs TDF/FTC**

- Phase 3 randomized double blinded HIV PrEP international study
- Study population: High risk adult MSM/TGW (n=4750)
- Study population 67% 30 years
- 12% TGW
- Cabotegravir oral lead in 5 weeks -> IM q2 months vs TDF/FTC po daily

**Results:**

- DSMB stopped study early
- New HIV infections 13 (CAB) vs 39 (TDF/FTC)
- HIV incidence 0.41(CAB) vs 1.22(TDF/FTC)

Conclusion CAB non inferior and superior
The PARTNER1 study looked at 888 couples where one was HIV positive and on antiretroviral treatment (ART) and who were already having sex without condoms:
- 548 heterosexual couples
- 340 MSM
They found that in more than 58,000 acts of condomless sex there were no HIV transmissions from the HIV positive partner among those on treatment with an undetectable viral load.
Couples were followed for a median of 1.3 years.

Partner2 Study:
- Prospective observational study in 14 European countries
- Enrolled 927 homosexual serodiscordant couples between September 2010 and July 2017
- Positive partner was on suppressive ART
- A total of 74,568 condomless-sex acts were reported, with 0 cases of within couple HIV transmission.

http://programme.aids2018.org/Abstract/Abstract/13470

QUESTIONS?
THANK YOU!