

# Medication Prophylaxis

## Medication Prophylaxis

1. HIV post-exposure prophylaxis (PEP)
2. **HIV pre-exposure prophylaxis (PrEP)**



# Updated PrEP Recommendations

US Public Health Service

## PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

- Discuss PrEP with **more** people
- Do **more** HIV testing
- Expand PrEP options to appeal to **more** people
  - Tailored recommendations for initiation and follow-up care

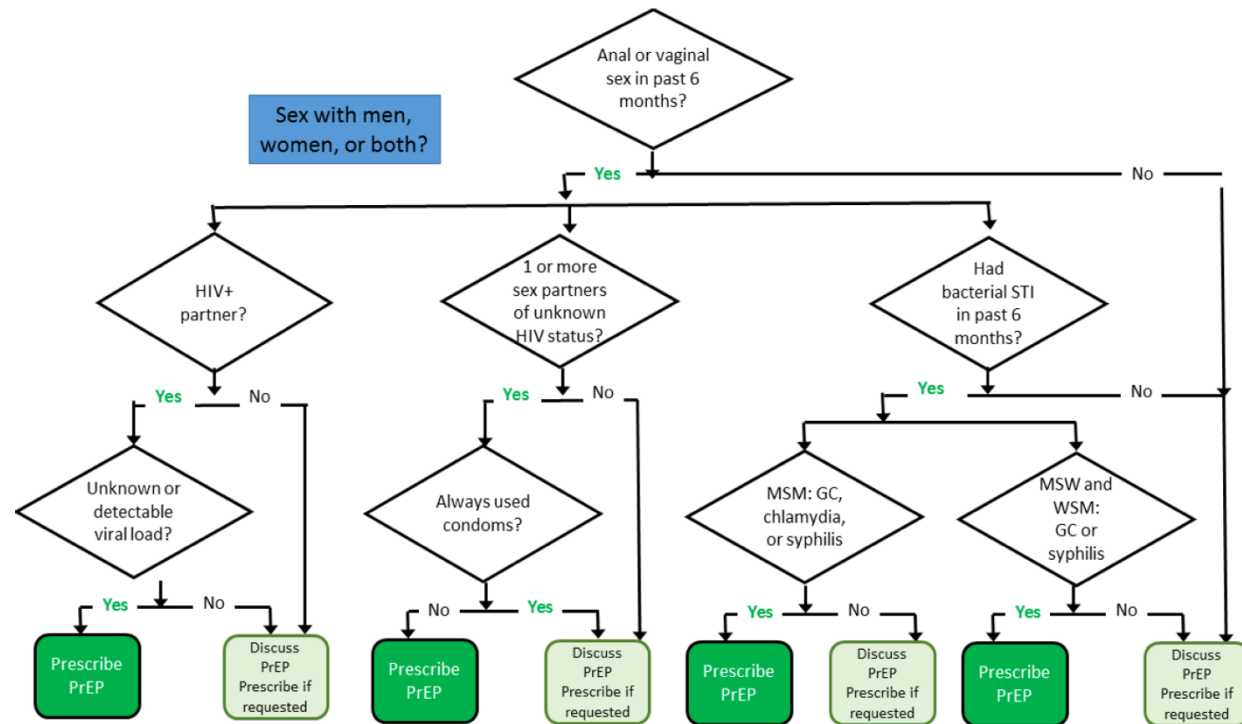
# Updated Recommendations



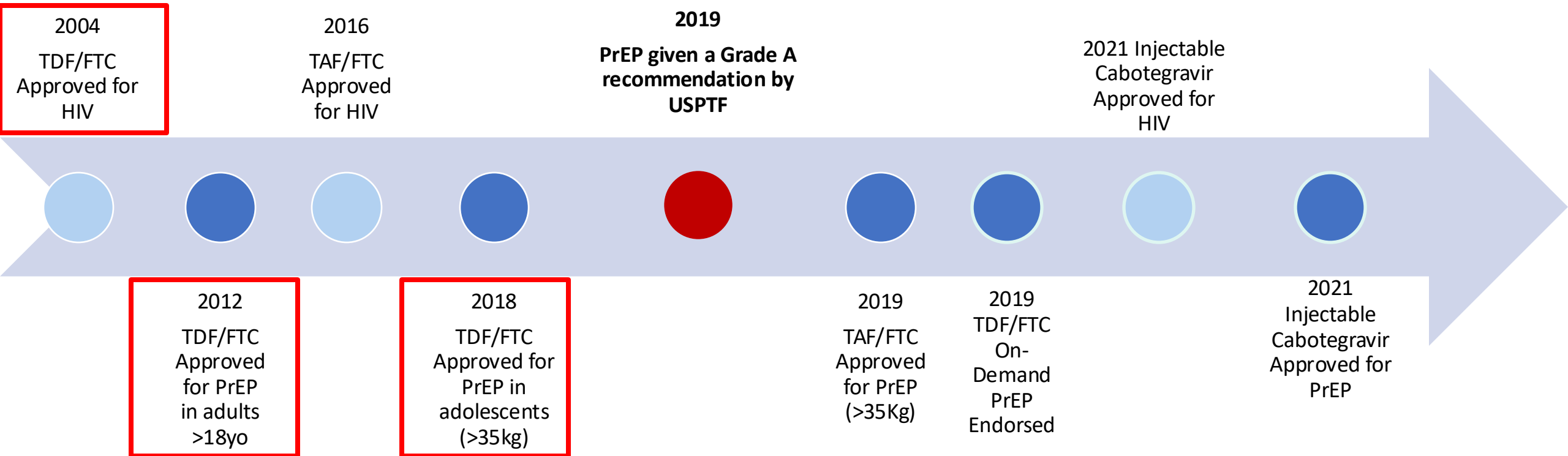
- Inform **all** sexually active adults and adolescents about PrEP
  - Risk-based screening tools and algorithms don't work and stigmatize patients
  - Universal HIV/STI screening and PrEP education is more beneficial and cost effective than risk-based screening

# Updated Recommendations

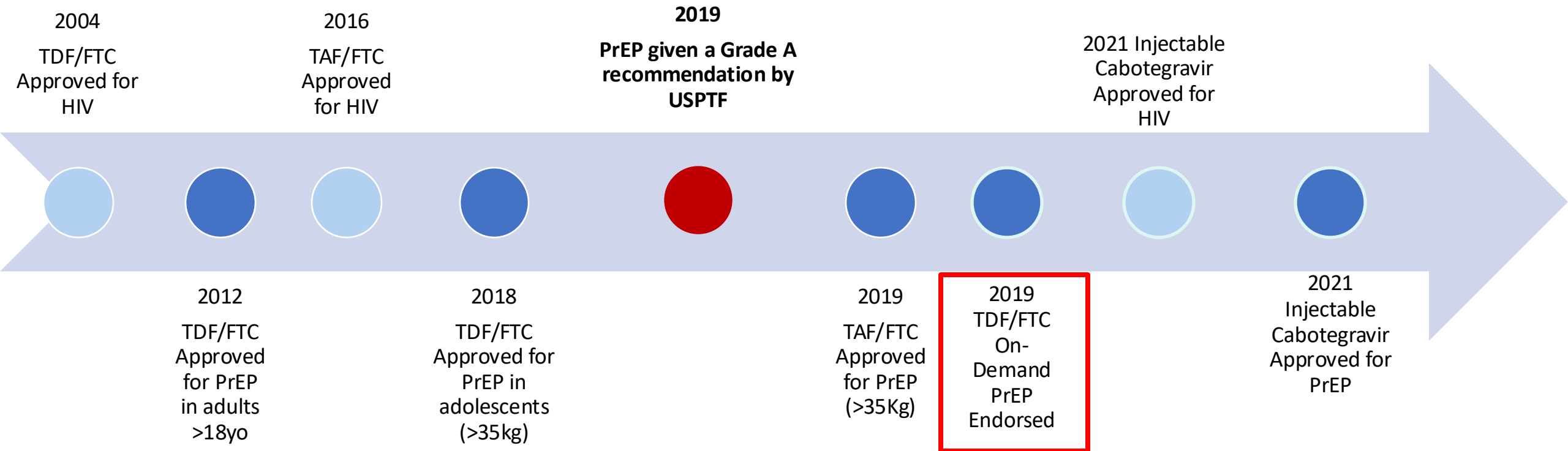
## PrEP Indications for Sexually Active Persons



# The Era of PrEP Choice



# The Era of PrEP Choice



# On-Demand PrEP Works

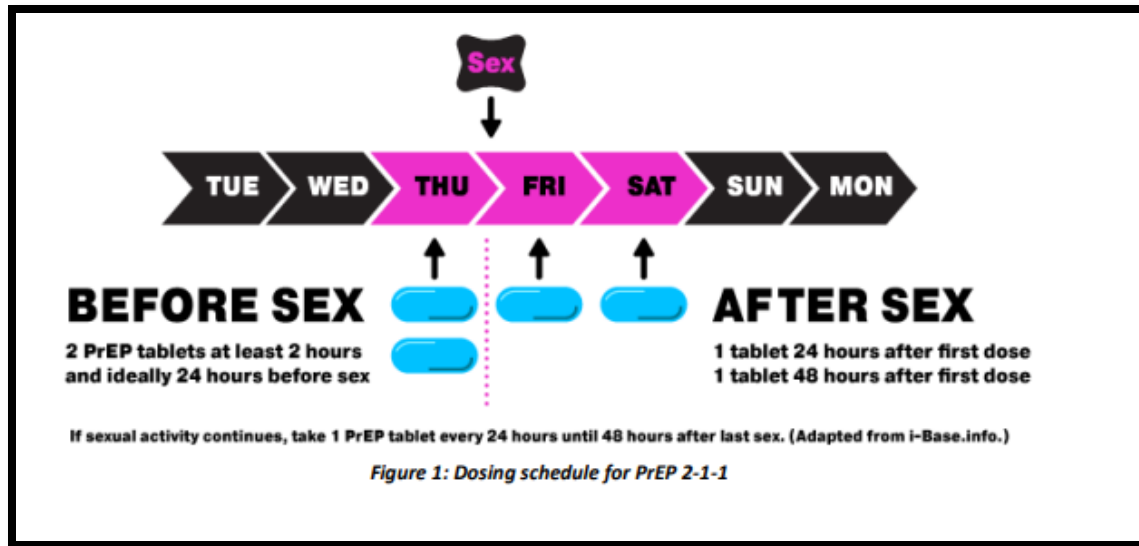
ORIGINAL ARTICLE

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

J.-M. Molina, C. Capitant, B. Spire, G. Pialoux, L. Cotte, I. Charreau, C. Tremblay, J.-M. Le Gall, E. Cua, A. Pasquet, F. Raffi, C. Pintado, C. Chidiac, J. Chas, P. Charbonneau, C. Delaugerre, M. Suzan-Monti, B. Loze, J. Fonsart, G. Peytavin, A. Cheret, J. Timsit, G. Girard, N. Lorente, M. Préau, J.F. Rooney, M.A. Wainberg, D. Thompson, W. Rozenbaum, V. Doré, L. Marchand, M.-C. Simon, N. Etien, J.-P. Aboulker, L. Meyer, and J.-F. Delfraissy, for the ANRS IPERGAY Study Group\*

- 414 patients randomized to placebo vs on-demand PrEP
- 86% relative reduction in HIV incidence compared with placebo
- **The use of TDF-FTC before and after sexual activity provided protection against HIV-1 infection in men who have sex with men.**

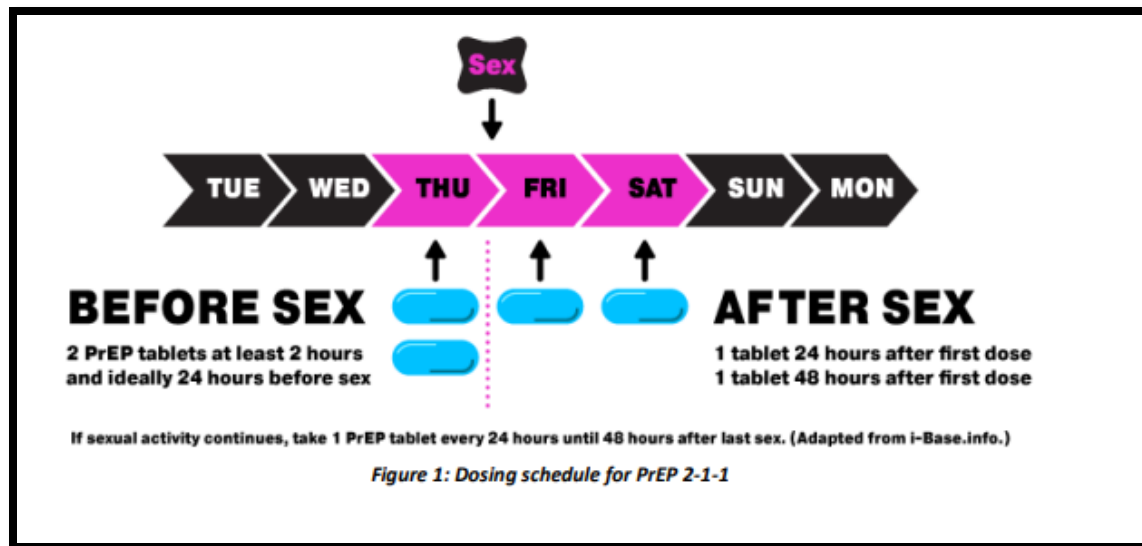
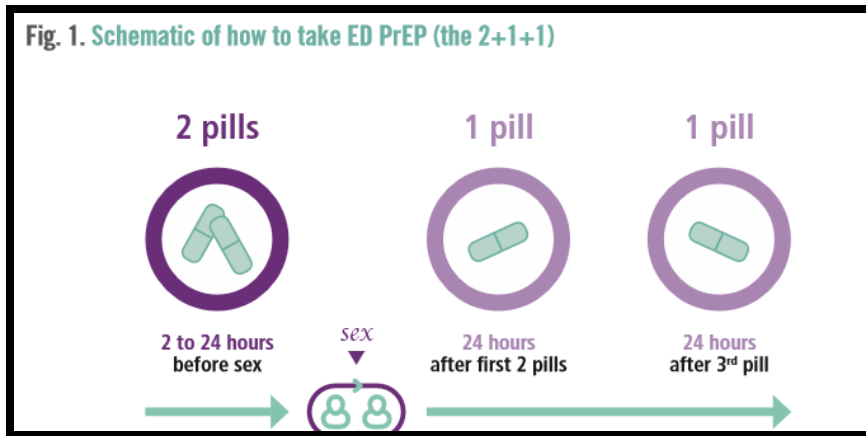
# On-Demand PrEP



1. First dose: 2 tablets 2-24 hours (ideally 24 hours) before sex
2. Second dose: 1 tablet 24 hours after the first dose
3. Third dose: 1 tablet 48 hours after the first dose
4. If you have sex later than planned or multiple times:
  1. Keep taking additional tablets until you have taken two tablets in the 48 hours (once every 24 hours) after your last sexual encounter
5. If you have sex more than twice a week, take daily PrEP instead

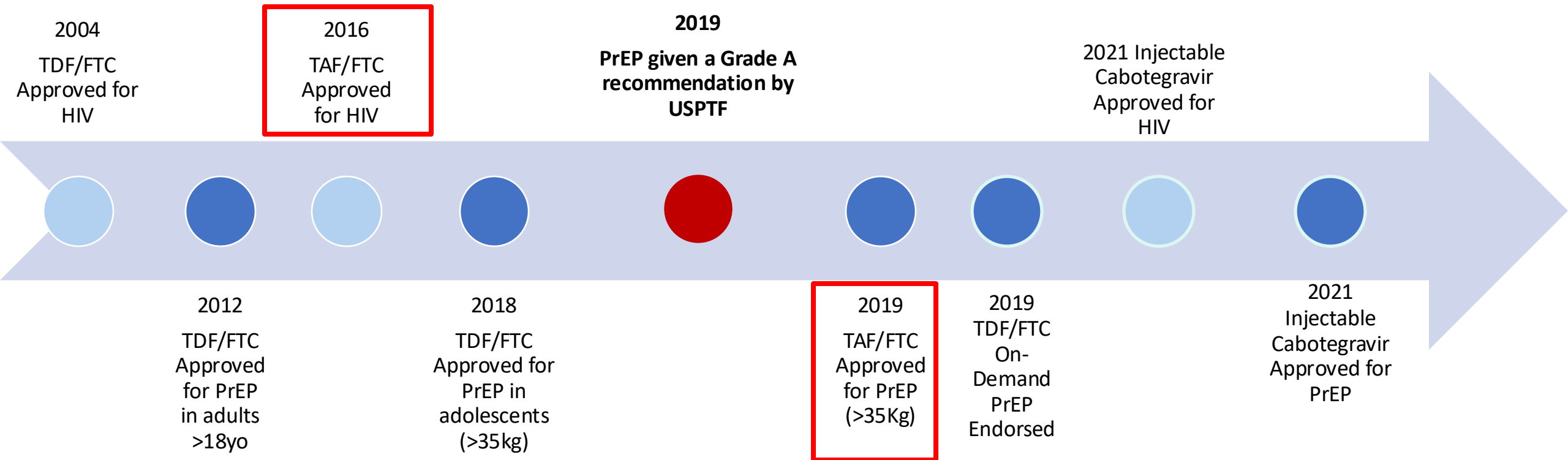


# On-Demand (Great For Starts and Stops)



- Only for men who have sex with men
  - Limited data for cisgender women, transgender women, and transgender men having vaginal/frontal sex
- Infrequent sex
- Able to plan for sex at least 2 hours in advance
- Contraindicated in Hepatitis B infection

# The Era of PrEP Choice



# TDF vs TAF

1. There is a robust evidence base for the use of TDF/FTC as PrEP
2. TAF/FTC has not been shown to be more effective than TDF/FTC
3. TDF/FTC is extremely safe
4. Continuing to prescribe TDF/FTC may allow us to expand PrEP use

## Tenofovir Alafenamide for HIV Preexposure Prophylaxis — What Can We DISCOVER About Its True Value?

Douglas S. Krakower, MD<sup>1,2,3</sup>, Demetre C. Daskalakis, MD<sup>4</sup>, Judith Feinberg, MD<sup>5</sup>, Julia L. Marcus, PhD<sup>2,3</sup>

<sup>1</sup>Beth Israel Deaconess Medical Center, Boston, MA, USA

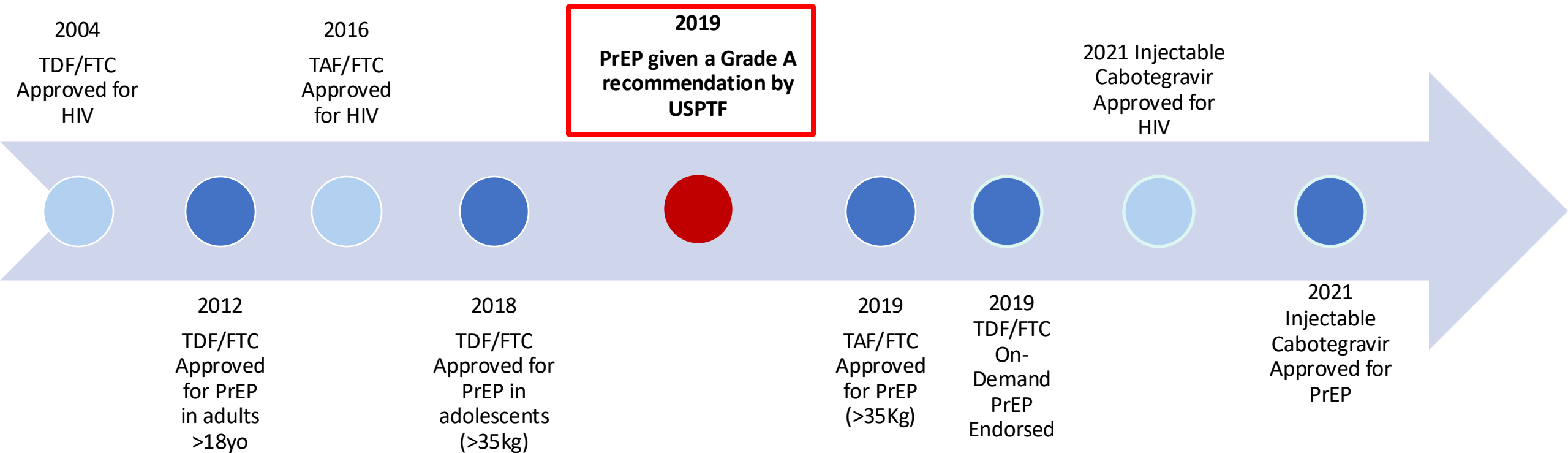
<sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

<sup>3</sup>The Fenway Institute, Boston, MA, USA

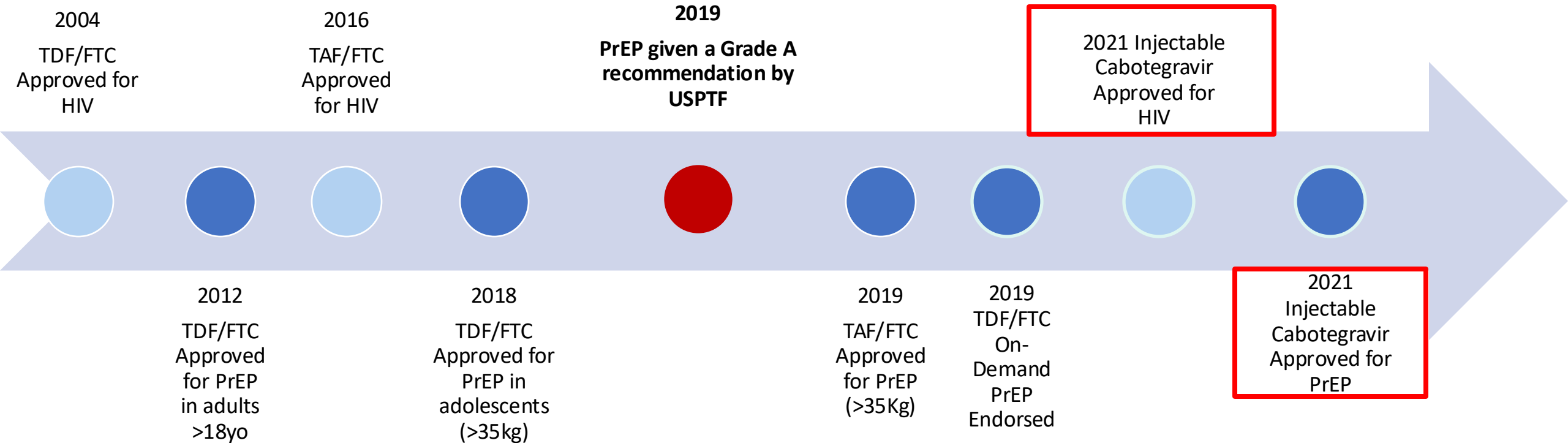
<sup>4</sup>New York City Department of Health and Mental Hygiene, New York, NY, USA

<sup>5</sup>West Virginia University, Morgantown, WV, USA

# The Era of PrEP Choice



# The Era of PrEP Choice



# Injectable PrEP

## HPTN083

ORIGINAL ARTICLE

### Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women

R.J. Landovitz, D. Donnell, M.E. Clement, B. Hanscom, L. Cottle, L. Coelho, R. Cabello, S. Chariyalertsak, E.F. Dunne, I. Frank, J.A. Gallardo-Cartagena, A.H. Gaur, P. Gonzales, H.V. Tran, J.C. Hinojosa, E.G. Kallas, C.F. Kelley, M.H. Losso, J.V. Madruga, K. Middelkoop, N. Phanuphak, B. Santos, O. Sued, J. Valencia Huamaní, E.T. Overton, S. Swaminathan, C. del Rio, R.M. Gulick, P. Richardson, P. Sullivan, E. Piwowar-Manning, M. Marzinke, C. Hendrix, M. Li, Z. Wang, J. Marrazzo, E. Daar, A. Asmelash, T.T. Brown, P. Anderson, S.H. Eshleman, M. Bryan, C. Blanchette, J. Lucas, C. Psaros, S. Safren, J. Sugarman, H. Scott, J.J. Eron, S.D. Fields, N.D. Sista, K. Gomez-Feliciano, A. Jennings, R.M. Kofron, T.H. Holtz, K. Shin, J.F. Rooney, K.Y. Smith, W. Spreen, D. Margolis, A. Rinehart, A. Adeyeye, M.S. Cohen, M. McCauley, and B. Grinsztejn, for the HPTN 083 Study Team\*

- CAB-LA was **superior** to daily oral TDF–FTC in preventing HIV infection among MSM and transgender women

## HPTN084

The Journal of Infectious Diseases

MAJOR ARTICLE



### Characterization of Human Immunodeficiency Virus (HIV) Infections in Women Who Received Injectable Cabotegravir or Tenofovir Disoproxil Fumarate/Emtricitabine for HIV Prevention: HPTN 084

Susan H. Eshleman,<sup>1</sup> Jessica M. Fogel,<sup>1</sup> Estelle Piwowar-Manning,<sup>1</sup> Gordon Chau,<sup>2</sup> Vanessa Cummings,<sup>1</sup> Yaw Agyei,<sup>1</sup> Paul Richardson,<sup>1</sup> Philip Sullivan,<sup>1</sup> Casey D. Haines,<sup>1</sup> Lane R. Bushman,<sup>3</sup> Christos Petropoulos,<sup>4</sup> Deborah Persaud,<sup>5</sup> Ryan Kofron,<sup>6</sup> Craig W. Hendrix,<sup>7</sup> Peter L. Anderson,<sup>3</sup> Jennifer Farrior,<sup>8</sup> John Mellors,<sup>9</sup> Adeola Adeyeye,<sup>10</sup> Alex Rinehart,<sup>11</sup> Marty St Clair,<sup>11</sup> Susan Ford,<sup>12</sup> James F. Rooney,<sup>13</sup> Carrie-Anne Mathew,<sup>14</sup> Portia Hunidzarira,<sup>15</sup> Elizabeth Spooner,<sup>16</sup> Juliet Mpendo,<sup>17</sup> Gonasagrie Nair,<sup>18</sup> Myron S. Cohen,<sup>19</sup> James P. Hughes,<sup>20</sup> Mina Hosseinipour,<sup>19</sup> Brett Hanscom,<sup>2</sup> Sinead Delany-Moretlwe,<sup>14,a</sup> and Mark A. Marzinke<sup>1,7,a</sup>

- **Superiority** of Injectable Cabotegravir to Oral TDF/FTC for the Prevention of HIV in Cisgender Women in Sub-Saharan Africa

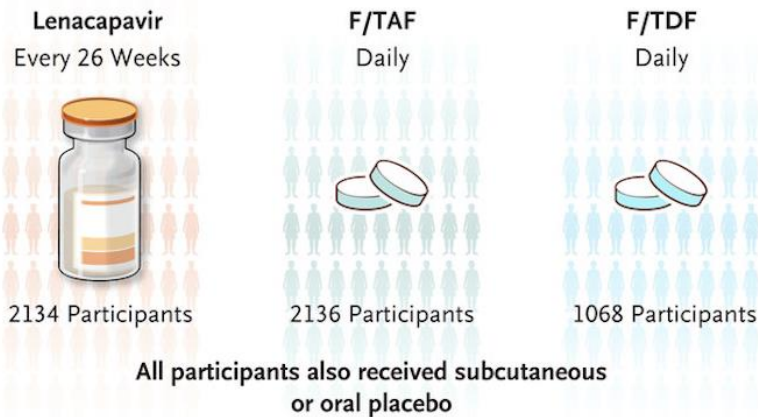


# Twice-Yearly Lenacapavir for HIV Prevention

A PLAIN LANGUAGE SUMMARY

## HOW WAS THE TRIAL CONDUCTED?

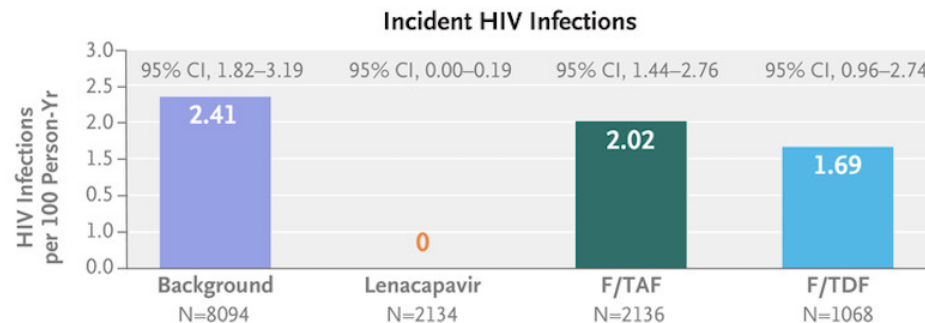
Adolescent girls and women who were HIV-negative at baseline were assigned to receive subcutaneous lenacapavir every 26 weeks, daily oral F/TAF, or daily oral emtricitabine–tenofovir disoproxil fumarate (F/TDF; active control) for 104 weeks. All participants also received the alternate subcutaneous or oral placebo. The primary objective was to determine the efficacy of lenacapavir and F/TAF by comparing the incidence of HIV infection among participants with the estimated background incidence in a cross-sectional screened incidence cohort.



## RESULTS

Twice-yearly lenacapavir reduced HIV incidence by 100% as compared with background HIV incidence and by 100% as compared with daily oral F/TDF. No adolescent girls or young women who received lenacapavir acquired HIV infection.

HIV incidence with F/TAF did not differ significantly from background HIV incidence, and there was no meaningful difference in HIV incidence between F/TAF and F/TDF.



## CONCLUSIONS

In a randomized, controlled trial involving cisgender adolescent girls and young women in South Africa and Uganda, twice-yearly subcutaneous lenacapavir was superior to daily oral emtricitabine–tenofovir disoproxil fumarate in preventing HIV infection.

# PrEP Choice Considerations

|  | How do you take it? | Frequency              | Visit Interval | Approved for                             | Cost     | Side Effects              | “Tail” |
|--|---------------------|------------------------|----------------|--|----------|---------------------------|--------|
| TDF/FTC  | Oral                | Daily or On-Demand*    | Q3 months      | Everyone                                 | \$       | GI, Renal, BMD            |        |
| TAF/FTC  | Oral                | Daily                  | Q3 months      | Men and transgender women at sexual risk | \$\$\$   | GI, Renal, BMD, Metabolic |        |
| Cabotegravir - LA  | Injectable          | 4 weeks then Q2 months | Q2 months      | Everyone at sexual risk                  | \$\$\$\$ |                           | X      |
| *Not FDA approved but endorsed by WHO, State DOH's, and in the updated CDC HIV prevention guidelines |                     |                        |                |  |          |                           |        |



# PrEP Initial Labs

## (Additional Choice Considerations)

|                   | HIV Testing | STI Testing | Cr Cl   | Hepatitis B | Lipid profile |
|-------------------|-------------|-------------|---------|-------------|---------------|
| TDF/FTC           | X           | X           | X (>60) | X           |               |
| TAF/FTC           | X           | X           | X (>30) | X           | X             |
| Cabotegravir - LA | X           | X           |         |             |               |

# PrEP Initial Screening

## Initial Screening

- Substance Use Screen
- Mental Health Screen
- Partner information
- Housing Status
- Benefits status
- For people who can become pregnant:
  - Pregnancy status
  - Reproductive plans

## Health Maintenance

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

# Prescribing PrEP To Your Patients

|  | Dose          | Frequency                    | Pills         |
|--|---------------|------------------------------|---------------|
| TDF/FTC daily                                | 200 mg/300 mg | Once a day                   | 90-day supply |
| TDF/FTC On Demand                            | 200 mg/300 mg | PRN                          | 30 pills      |
| TAF/FTC Daily                                | 200 mg/25 mg  | Once a day                   | 90-day supply |
| Cabotegravir-LA                              | 600mg         | 4 weeks then every 2 months* |               |
| *Optional 30-day lead in prior to injections |               |                              |               |

# PrEP Follow-up

| Oral PrEP   | Injectable PrEP   |
|---|---|
| Every 2 months  | <ul style="list-style-type: none"> <li>HIV testing: HIV Ag/Ab test and <b>HIV-1 RNA assay*</b></li> </ul>   |
| Every 3 months <ul style="list-style-type: none"> <li>HIV testing: HIV Ag/Ab test and <b>HIV-1 RNA assay*</b></li> <li>Bacterial STI screening: MSM and transgender women who have sex with men**</li> </ul>  |   |
| Every 4 months  | <ul style="list-style-type: none"> <li>Bacterial STI screening: all sexually-active patients (if not needing Q2 month screening)**</li> </ul>   |
| Every 6 months <ul style="list-style-type: none"> <li>Creatinine clearance for those age &gt;50 or CrCl &lt;90</li> <li>Bacterial STI screening: All sexually-active patients (if not needing Q3 month screening)*</li> </ul>   | <ul style="list-style-type: none"> <li>Bacterial STI screening: All heterosexually-active women and men*</li> </ul>   |
| Every 12 months <ul style="list-style-type: none"> <li>Creatinine clearance for all patients</li> <li>Bacterial STI screening: Chlamydia screening for heterosexuals*</li> <li>Hepatitis C (MSM, TGW, PWID only)</li> <li><b>F/TAF:</b> Weight, triglycerides and cholesterol levels</li> </ul> | <ul style="list-style-type: none"> <li>Bacterial STI screening: Chlamydia screening for heterosexuals*</li> </ul>   |
| Discontinuation   | <ul style="list-style-type: none"> <li>Re-educate patients about the “tail”</li> <li>If PrEP indicated, prescribe daily oral PrEP within 8 weeks after last injection</li> <li>HIV testing: HIV Ag/Ab test and <b>HIV-1 RNA assay*</b> quarterly for 12 months</li> </ul> |
| <p>*Repat HIV Ag/Ab test and <b>HIV-1 RNA assay</b> at one month visit as well</p> <p>**Consider STI screening at every visit, and with extra-genital testing, as per the CDC STI Guidelines</p>  |   |

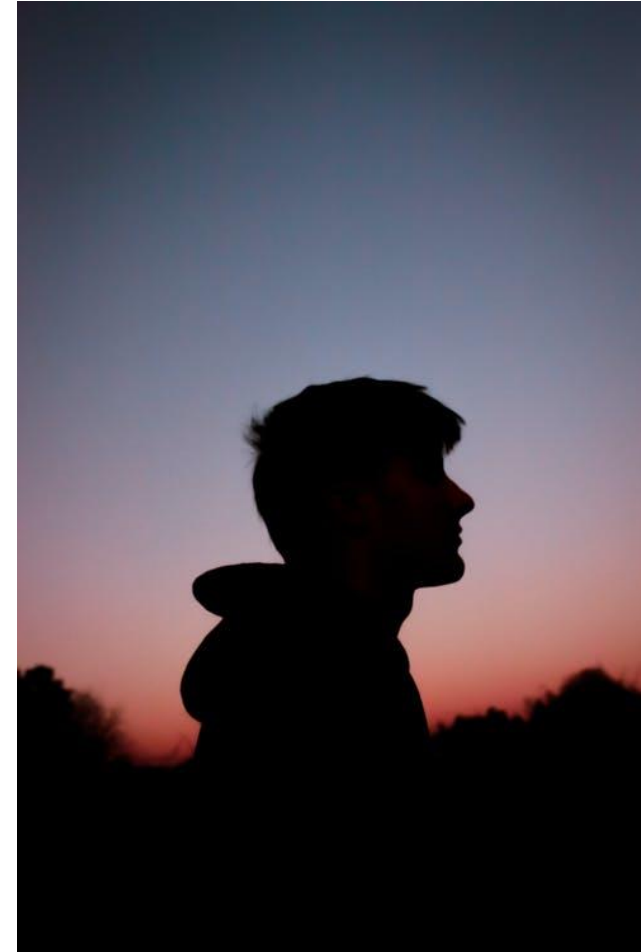
# Common PrEP Concerns

- PrEP Choices
- PrEP Engagement
- Resistance
- Frequent STIs (risk compensation)
- Insurance/Medication Payment barriers



# Meet Marcus

- 29-year-old male in New York City
- Takes HIV PrEP for HIV prevention
- Sexually active with men
  - Four partners since his last visit, no condom usage
- Walks in to clinic due with 2 days of green penile discharge
- **Routine testing for HIV, syphilis, and three-site gonorrhea/chlamydia testing performed**
- **Treated empirically with Ceftriaxone and Doxycycline**



# Marcus's Prevention Plan



## Primary Prevention

### **Vaccination**

- HPV
- Hepatitis A/B
- Meningococcal ACYW
- Mpox

### **Medication**

- HIV PrEP



## Secondary Prevention

### **Routine screening**

- Q3 Month Screening

### **Syndromic testing/treatment**

### **Presumptive treatment**

# Marcus's Results

## Lab results:

HIV Ab/Ag - Negative

Urine GC/CT – GC positive

Pharyngeal GC/CT – GC positive

Rectal GC/CT – GC positive

RPR – 1:128

- 1:4 - 2 months ago

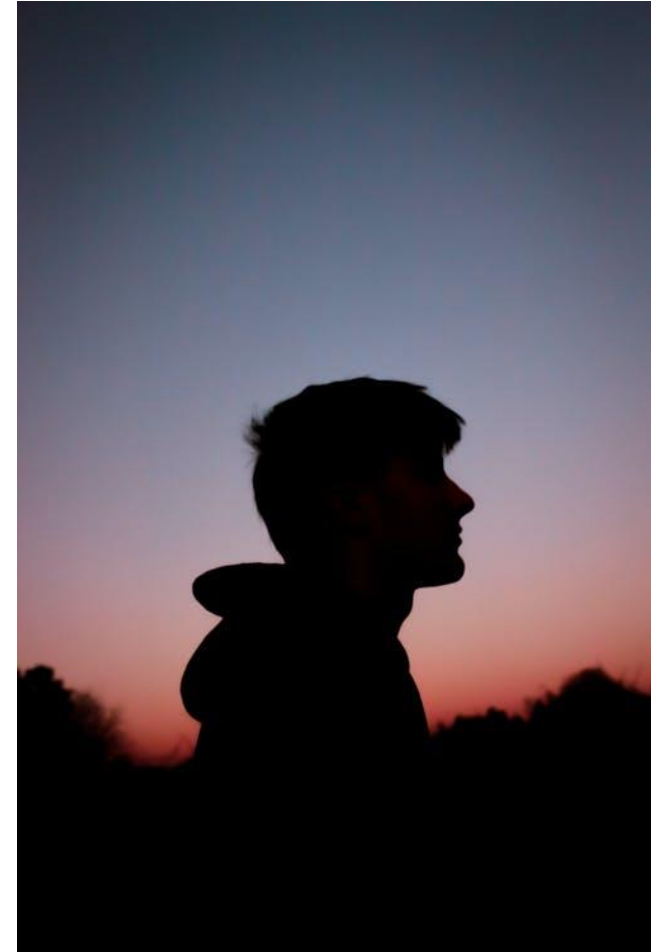


Received additional 7 days (total 14 days) of Doxycycline for early latent syphilis



# Marcus

- Returned 6 weeks later
- **“I got totally better but now it hurts again when I pee”**
  - Seven partners since his last visit
  - Is sure that his regular partners got treated for gonorrhea and syphilis
  - Repeat routine testing for HIV, syphilis, and three-site gonorrhea/chlamydia testing was performed
  - Treated empirically with Ceftriaxone and Doxycycline



# Marcus's Results

## Lab results:

HIV Ab/Ag - Negative

Urine GC/CT – GC positive

Pharyngeal GC/CT – GC positive

Rectal GC/CT – CT positive

RPR – 1:32

- 1:128 – 6 weeks ago



# Marcus

- Called to give Marcus his results and he was pretty upset
- **“This is frustrating, is there anything I can do so I stop getting STIs?”**

