

# Long-Acting Injectable PrEP is Here: Implementation and Capacity Building Opportunities

**September 27, 2022**

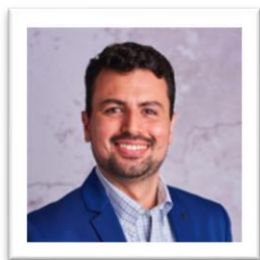
# NASTAD's PrEP Team



**Dori Molozanov**

Senior Manager, Health Systems Integration

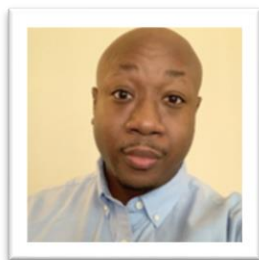
- Telehealth regulations
- Health plan coverage



**Edwin Corbin-Gutierrez**

Director, Health Systems Integration

- EHE systems coordination



**Kendrell Taylor**

Senior Manager, Prevention

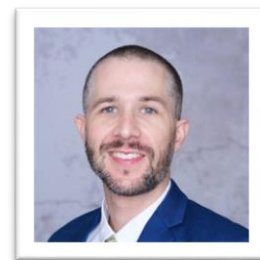
- PrEP implementation
- Take Me Home
- Self-testing



**Krupa Mehta**

Senior Manager, Prevention

- PrEP program implementation
- TelePrEP learning collaborative



**Mike Weir**

Associate Director, Policy & Legislative Affairs

- Federal and state policy
- Regulatory framework



**Nicole Elinoff**

Senior Manager, Prevention

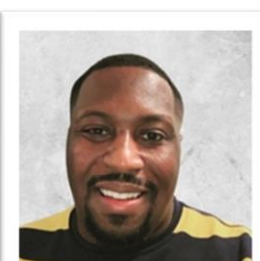
- PrEP implementation
- TelePrEP learning collaborative



**Tim Horn**

Director, Health Care Access

- 340B program income
- Generic drug market



**Will Lee**

Manager, Health Systems Integration

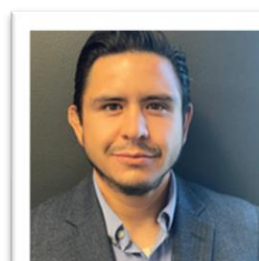
- PrEP policy research



**Rodderick Sheppard**

Manager, Prevention

- PrEP Navigation



**Ralph Moreno**

Consultant, TelePrEP Access

- TelePrEP learning collaborative
- 340B



**Cody Shafer**

Consultant, TelePrEP Access

- TelePrEP learning collaborative



**Brittany Sanders**

Consultant, TelePrEP Access

- TelePrEP learning collaborative

# Webinar Outline

---

- LAI for PrEP Overview
- Implementation Opportunities
- Cost and Coverage Considerations
- Capacity Building Opportunities
- Current LAI Resources
- Q+A

# Today's Speakers

---



**Rupa Patel, MD, MPH**  
Research Associate Professor (Voluntary)  
Division of Infectious Diseases  
Washington University School of Medicine



**Tim Horn**  
Director, Health Care Access  
NASTAD



**Benjamin Tsoi, MD, MPH**  
Director of HIV Prevention  
New York City Department of  
Health and Mental Hygiene

# LAI Overview and Implementation Opportunities

# Long Acting Injectable Pre-Exposure Prophylaxis for HIV Prevention (LAI PrEP)

Rupa R. Patel, MD MPH  
Research Associate Professor of Medicine (Voluntary)  
Washington University in St. Louis

# Disclosures

- Research Funding: Gilead Sciences, Inc., ViiV Healthcare

# Outline

- Review current PrEP options and practice guidelines
  - Advances in PrEP: Injectable option
- Implementation Workflows
  - Successes and Challenges



# PrEP Prescribing Options in 2022

- **FDA approved**
  - Daily oral PrEP with TDF/FTC (Truvada and generic)
    - ~99% effective for sexual transmission
    - ~74% for IDU transmission
    - All populations
    - CrCl > 60 mL/min
  - Daily oral PrEP with TAF/FTC (Descovy)
    - Cannot prescribe for cisgender women
    - CrCl > 30 mL/min
  - Injectable Cabotegravir (Apretude)
- **Not FDA approved:** On demand, event driven, 2-1-1 PrEP with TDF/FTC



# Prescribing National Resources

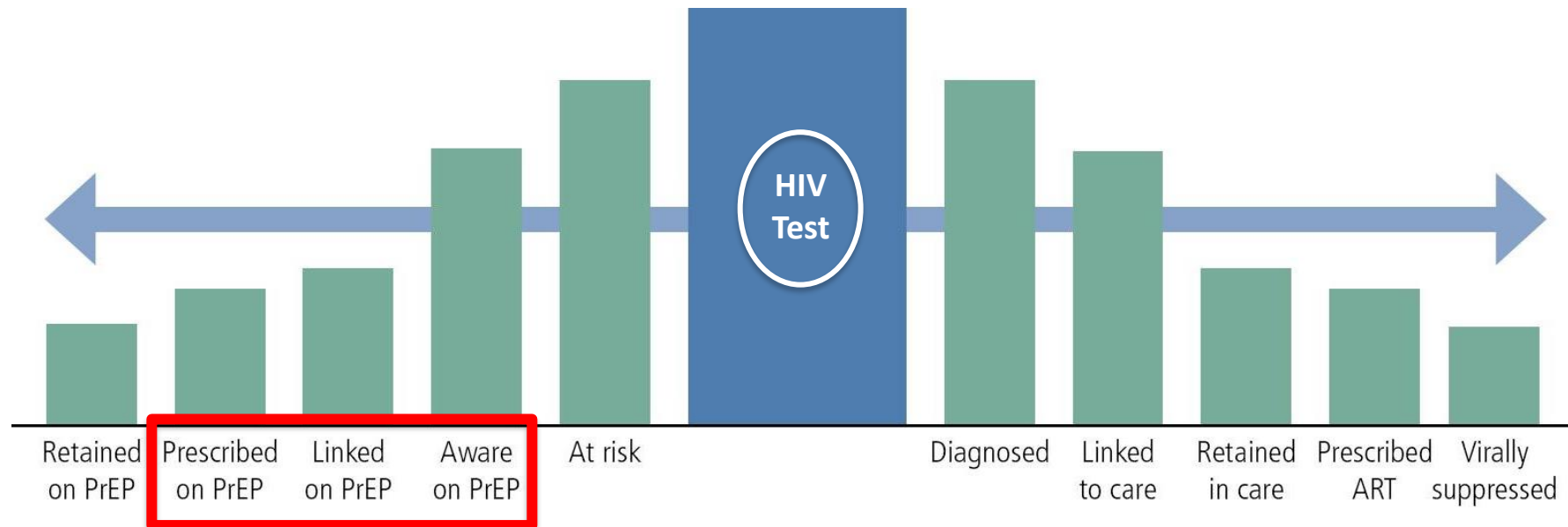
- CDC PrEP/PEP Hotline
  - 855-448-7737
  - <http://www.cdc.gov/hiv/living/treatment/hotline.html>
- UCSF Clinical Consultation Center (CCC)  
PrEPLine
  - 855-448-7737 (11 a.m. – 6 p.m. EST)
  - <http://nccc.ucsf.edu/clinical-resources/pep-resources/pep/>

# Status Neutral Continuum

What tools are needed to support implementing LAI PrEP

## PrEP Care Continuum

## HIV Care Continuum



Community Education  
Provider & Peer Navigator Education  
Tools for PrEP Retention

Buchbinder S and Liu A, Topics in Antiviral Medicine 2018

Nunn AC, et al. Defining the HIV pre-exposure prophylaxis care continuum. AIDS 2017

US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE



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

	Sexually-Active Adults and Adolescents <sup>1</sup>	Persons Who Inject Drug <sup>2</sup>
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"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>3</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	<p>HIV-positive injecting partner OR Sharing injection equipment</p>
Clinically eligible	<p><b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b></p> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• Estimated creatinine clearance <math>\geq 30</math> ml/min<sup>4</sup></li> <li>• No contraindicated medications</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>• Daily, continuing, oral doses of F/TDF (Truvada®), <math>\leq 90</math>-day supply</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), <math>\leq 90</math>-day supply</li> </ul>	
Follow-up care	<p><b><u>Follow-up visits at least every 3 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support</li> <li>• Bacterial STI screening for MSM and transgender women who have sex with men<sup>3</sup> – oral, rectal, urine, blood</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <p><b><u>Follow-up visits every 6 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for patients aged <math>\geq 50</math> years or who have an eCrCl <math>&lt; 90</math> ml/min at PrEP initiation</li> <li>• Bacterial STI screening for all sexually-active patients<sup>3</sup> – [vaginal, oral, rectal, urine- as indicated], blood</li> </ul> <p><b><u>Follow-up visits every 12 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for all patients</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> <li>• For patients on F/TAF, assess weight, triglyceride and cholesterol levels</li> </ul>	

<sup>1</sup> adolescents weighing at least 35 kg (77 lb)

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

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

<sup>4</sup> estimated creatine clearance (eCrCl) by Cockcroft Gault formula  $\geq 60$  ml/min for F/TDF use,  $\geq 30$  ml/min for F/TAF use

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

	Sexually-Active Adults	Persons Who Inject Drugs <sup>1</sup>
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>2</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• No contraindicated medications or conditions</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle                             <ul style="list-style-type: none"> <li>○ Initial dose</li> <li>○ Second dose 4 weeks after first dose (month 1 follow-up visit)</li> <li>○ Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)</li> </ul> </li> </ul>	
Follow-up care	<p><b><u>At follow-up visit 1 month after first injection</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay</li> </ul> <p><b><u>At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <p><b><u>At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Bacterial STI screening<sup>2</sup> for MSM and transgender women who have sex with men<sup>2</sup> – oral, rectal, urine, blood</li> </ul> <p><b><u>At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Bacterial STI screening<sup>1</sup> for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood</li> </ul> <p><b><u>At follow-up visits at least every 12 months (after the first injection) provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess desire to continue injections for PrEP</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> </ul> <p><b><u>At follow-up visits when discontinuing cabotegravir injections provide the following:</u></b></p>	

Injection window is +/- 7 days

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

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

**Table 7**      **Timing of CAB PrEP-associated Laboratory Tests**

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

\* HIV-1 RNA assay

X all PrEP patients

## 2.6 Recommended Dosing Schedule for Missed Injections

Adherence to the injection dosing schedule is strongly recommended. Individuals who miss a scheduled injection visit should be clinically reassessed to ensure resumption of APRETUDE remains appropriate [see *Dosage and Administration (2.2)*, *Warnings and Precautions (5.1, 5.2)*]. Refer to Table 3 for dosing recommendations after missed injections.

### Planned Missed Injections

If an individual plans to miss a scheduled every-2-month continuation injection visit by more than 7 days, take daily oral cabotegravir for a duration of up to 2 months to replace 1 missed scheduled every-2-month injection. The recommended oral daily dose is one 30-mg tablet of oral cabotegravir. The first dose of oral PrEP should be taken approximately 2 months after the last injection dose of APRETUDE. Restart injection with APRETUDE on the day oral dosing completes or within 3 days; thereafter, as recommended in Table 3. For oral PrEP durations greater than 2 months, an alternative oral regimen is recommended.

### Unplanned Missed Injections

If a scheduled injection visit is missed or delayed by more than 7 days and oral dosing has not been taken in the interim, clinically reassess the individual to determine if resumption of

---

injection dosing remains appropriate [see *Warnings and Precautions (5.1)*]. If the injection dosing schedule will be continued, see Table 3 for dosing recommendations.



**Table 3. Injection Dosing Recommendations after Missed Injections**

<b>Time since Last Injection</b>	<b>Recommendation</b>
<b>If second injection is missed and time since first injection is:</b>	
Less than or equal to 2 months	Administer 600-mg (3-mL) gluteal intramuscular injection of APRETUDE as soon as possible, then continue to follow the every-2-month injection dosing schedule.
Greater than 2 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by a second 600-mg (3-mL) initiation injection dose 1 month later. Then continue to follow the every-2-month injection dosing schedule thereafter.
<b>If third or subsequent injection is missed and time since prior injection is:</b>	
Less than or equal to 3 months	Administer 600-mg (3-mL) intramuscular injection of APRETUDE as soon as possible, then continue with the every-2-month injection dosing schedule.
Greater than 3 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by the second 600-mg (3-mL) initiation injection dose 1 month later. Then continue with the every-2-month injection dosing schedule thereafter.

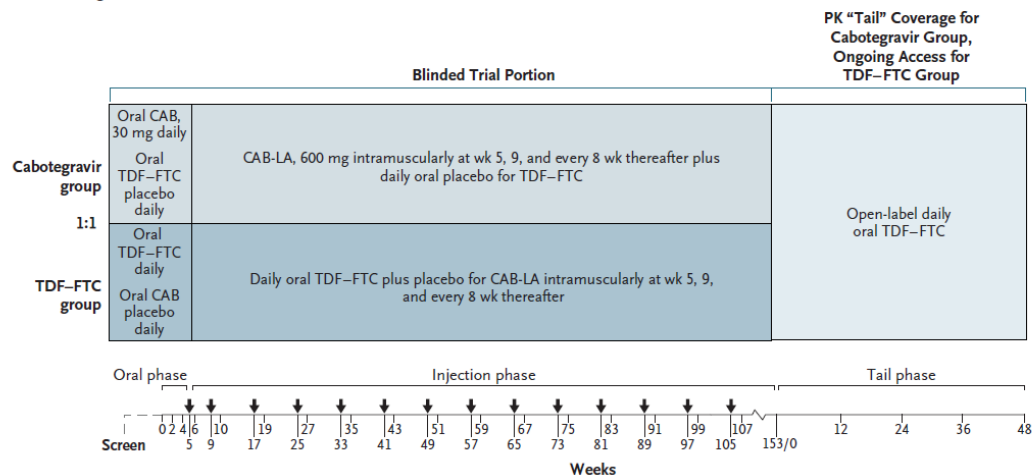
# The Science Behind LAI PrEP: HPTN 083 and HPTN 084

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\*

**A Trial Design**



PK "Tail" Coverage for Cabotegravir Group, Ongoing Access for TDF-FTC Group

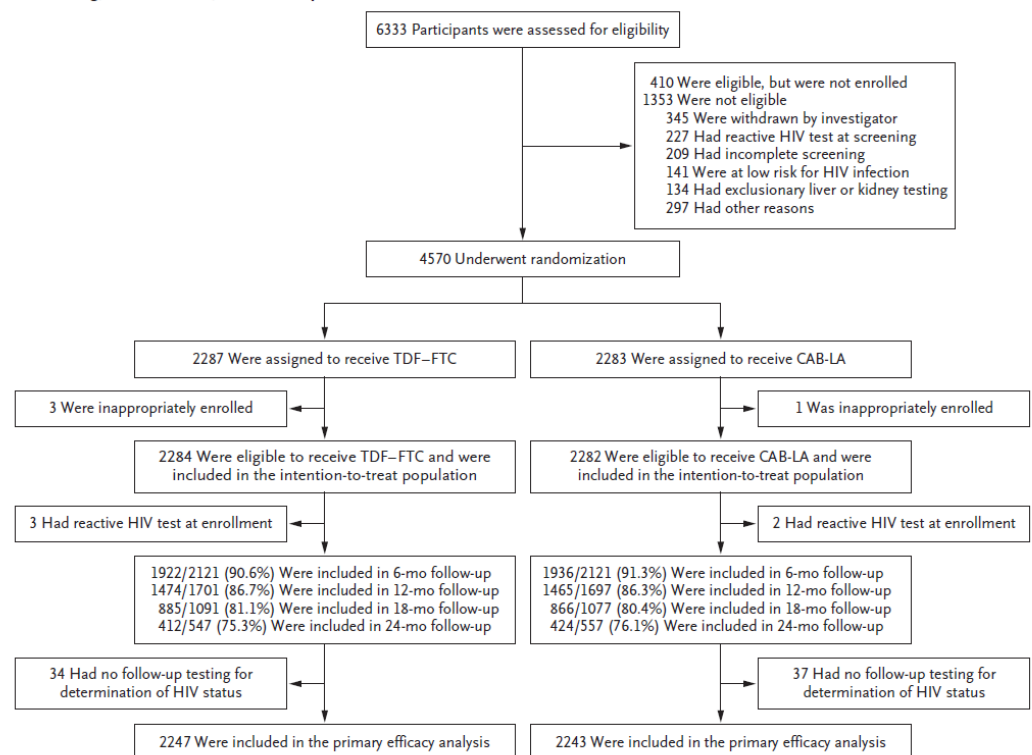
**Selected inclusion criteria:**

- HIV-1 negative at screening and enrollment<sup>1</sup>
- Age  $\geq 18$ <sup>2</sup>
- At high risk of sexually acquiring HIV-1 infection<sup>2</sup>

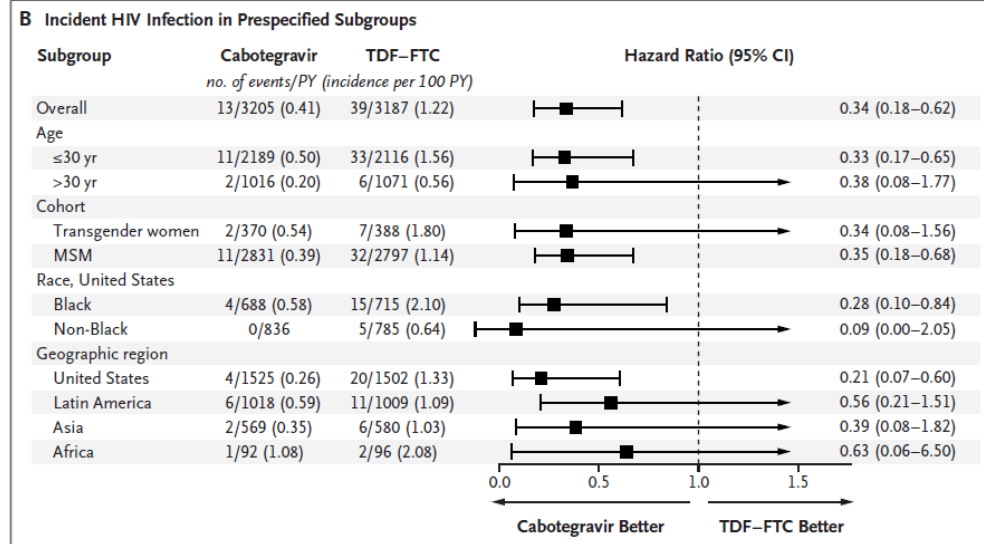
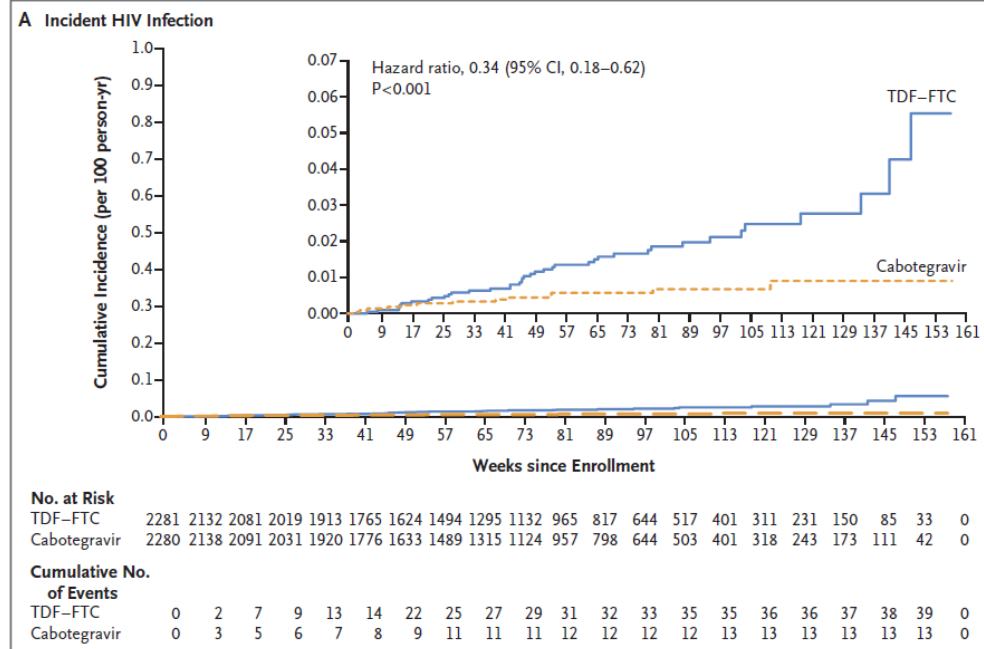
**Selected exclusion criteria:**

- Active or recent (90 days prior to enrollment) illicit intravenous drug use<sup>2</sup>
- Current or chronic history of liver disease<sup>3</sup>
- Surgically placed or injected buttock implants or fillers<sup>2</sup>

**B Screening, Randomization, and Follow-up**



Characteristic	Overall Trial Population <sup>†</sup>		
	Overall (%) N=4566	APRETUDE (%) n=2282	TDF/FTC (%) n=2284
<b>Gender and sexuality</b>			
Men who have sex with men	87	88	87
Transgender women who have sex with men	13	12	13
Preferred not to answer	0.1	0.1	<0.1
<b>Age</b>			
Median age, years (IQR)	26 (22-32)	26 (22-32)	26 (22-32)
18-29	68	69	66
30-39	23	22	24
≥40	10	9	10
Characteristic	US Sites Only		
	Overall (%) N=1698	APRETUDE (%) n=849	TDF/FTC (%) n=849
<b>Race</b>			
Black	50	49	51
Non-Black	50	52	49
<b>Ethnicity</b>			
Latinx	18	18	18



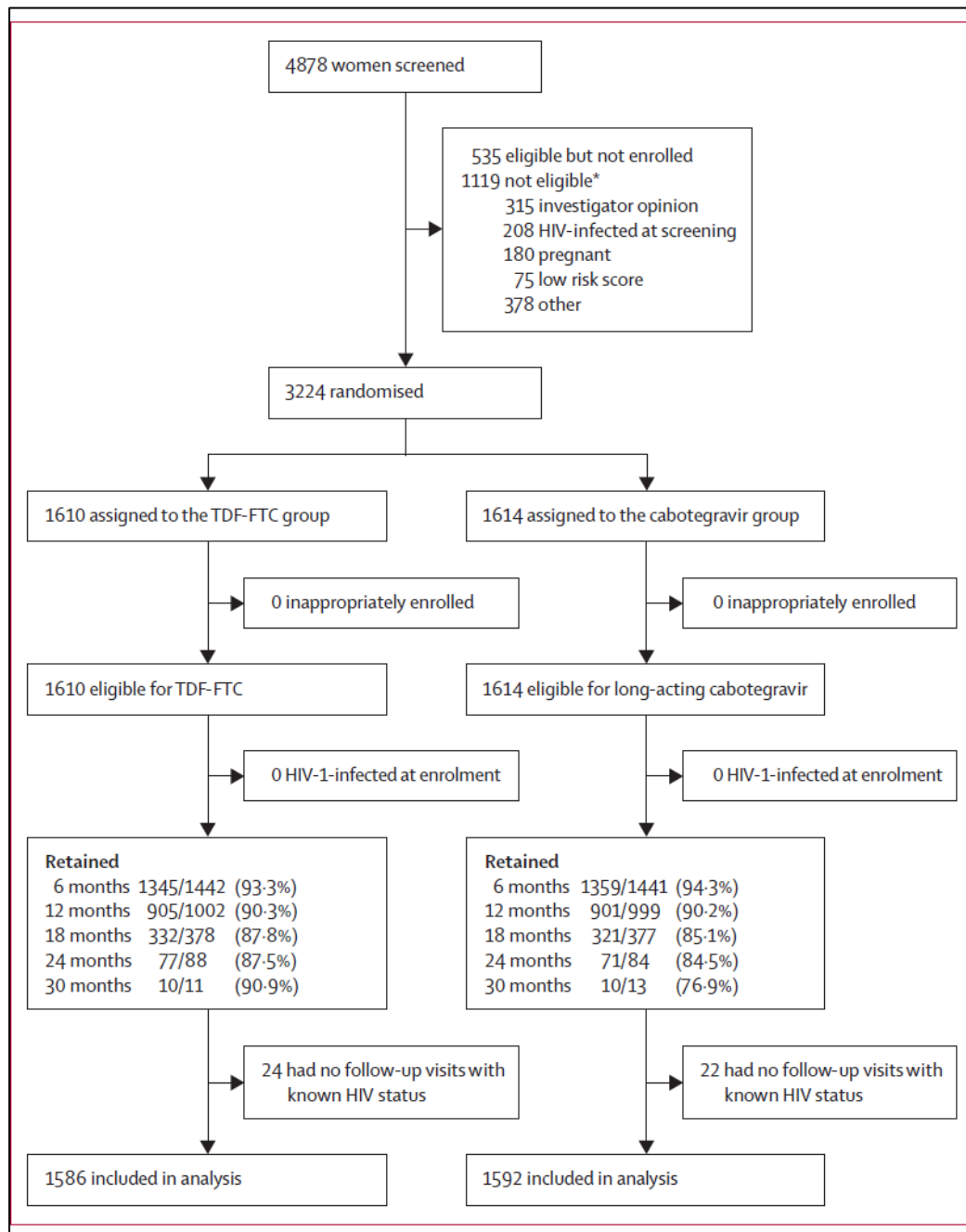
**Figure 2. Incident HIV infection.**  
Panel A shows Kaplan–Meier estimates of incident HIV infection. The inset shows the same data on an enlarged y axis. Panel B shows hazard ratios for incident HIV infection in the prespecified subgroups. Race was reported by the participant. MSM denotes men who have sex with men, and PY person-years.

High efficacy within subgroup analyses

---

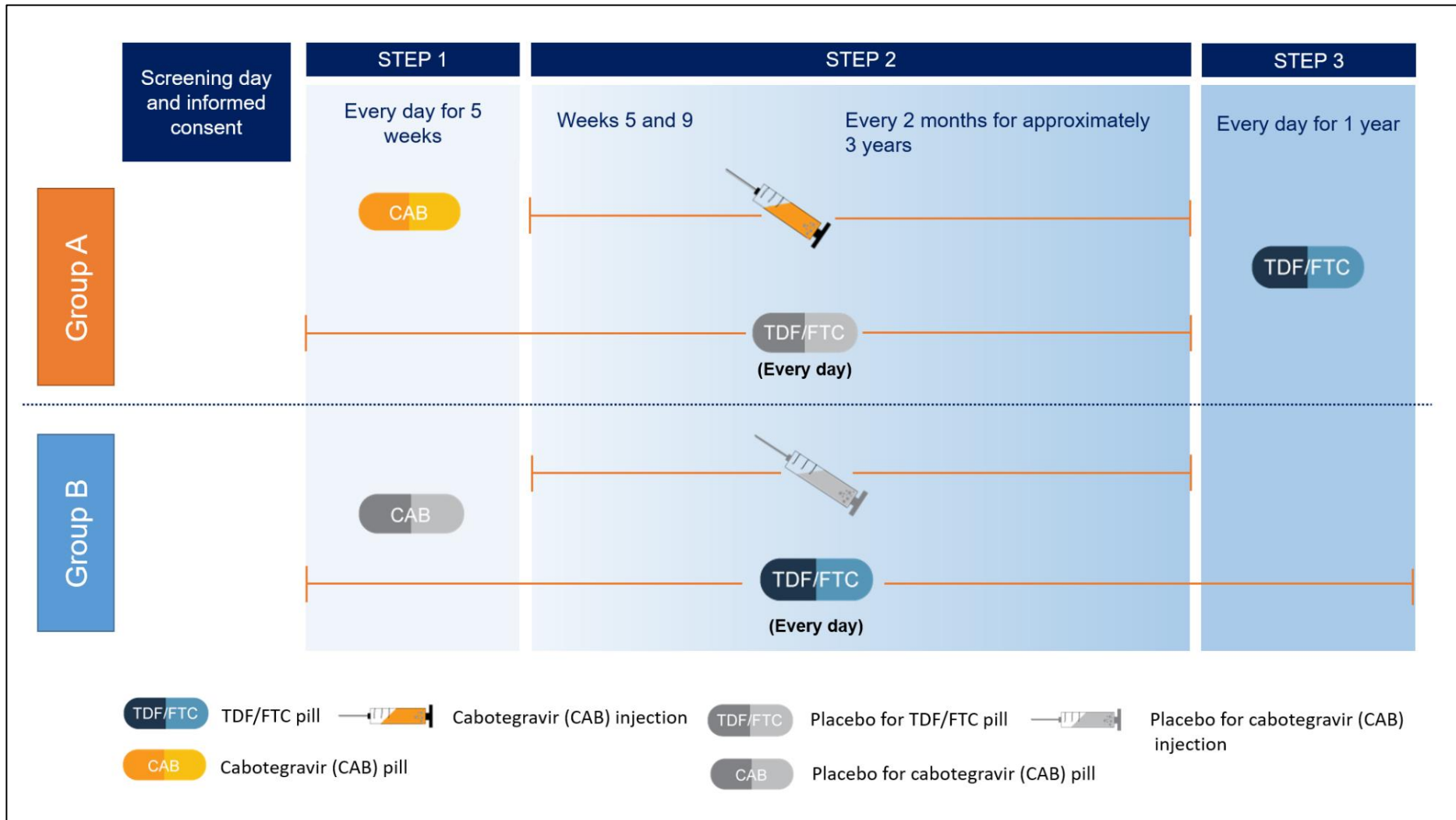
# Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial

*Sinead Delany-Moretlwe, James P Hughes, Peter Bock, Samuel Gurrion Ouma, Portia Hunidzarira, Dishiki Kalonji, Noel Kayange, Joseph Makhema, Patricia Mandima, Carrie Mathew, Elizabeth Spooner, Juliet Mpendo, Pamela Mukwekwerere, Nyaradzo Mgodzi, Patricia Nahirya Ntege, Gonasagrie Nair, Clemensia Nakabiito, Harriet Nuwagaba-Biribonwoha, Ravindre Panchia, Nishanta Singh, Bekezela Siziba, Jennifer Farrior, Scott Rose, Peter L Anderson, Susan H Eshleman, Mark A Marzinke, Craig W Hendrix, Stephanie Beigel-Orme, Sybil Hosek, Elizabeth Tolley, Nirupama Sista, Adeola Adeyeye, James F Rooney, Alex Rinehart, William R Spreen, Kimberly Smith, Brett Hanscom, Myron S Cohen, Mina C Hosseinipour, on behalf of the HPTN 084 study group*



- Selected inclusion criteria<sup>2</sup>:**
- Cisgender women, 18-45 years old
  - HIV-1 negative at screening and enrollment
  - At high risk of sexually acquiring HIV-1 infection
  - Negative pregnancy test (if of reproductive potential)
  - Use of long-acting contraception (if not sterile or with history of hysterectomy)
- Selected exclusion criteria<sup>2</sup>:**
- History of liver disease
  - Pregnant or currently breastfeeding





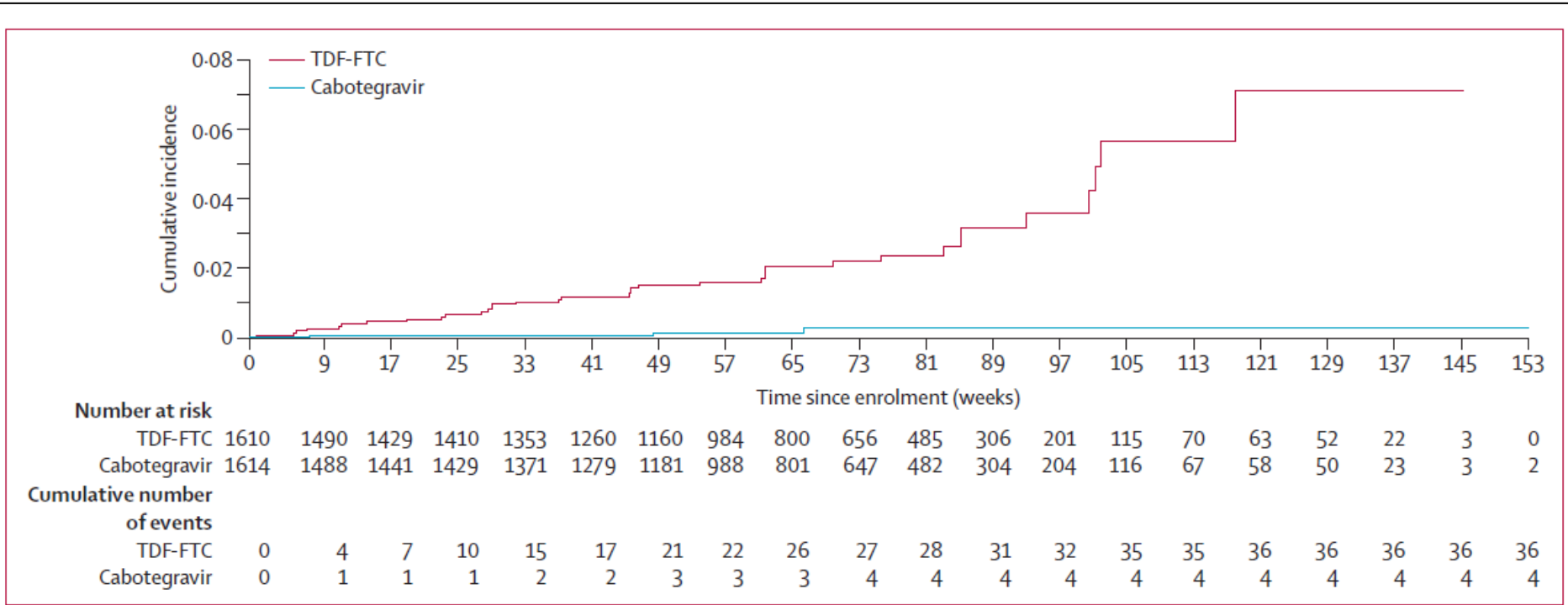
	Cabotegravir group (n=1614)	TDF-FTC group (n=1610)
Country		
Botswana	46 (2.9%)	45 (2.8%)
Eswatini	80 (5.0%)	80 (5%)
Kenya	31 (1.9%)	35 (2.2%)
Malawi	113 (7%)	111 (6.9%)
South Africa	653 (40.5%)	655 (40.7%)
Uganda	300 (18.6%)	296 (18.4%)
Zimbabwe	391 (24.2%)	388 (24.1%)
Age, years	25 (22-30)	25 (22-20)
Aged <25 years	814 (50.4%)	816 (50.7%)
Race or ethnicity (self-reported)		
Black African	1569 (97.2%)	1554 (96.5%)
Asian	2 (0.1%)	3 (0.2%)
Mixed race	2 (0.1%)	8 (0.5%)
White	0	1 (0.1%)
Other	41 (2.5%)	44 (2.7%)
Marital status		
Married, civil union, or legal partnership	169 (10.5%)	174 (10.8%)
Living with primary partner	106 (6.6%)	118 (7.3%)
Not living with primary partner	869 (53.8%)	860 (53.4%)
Single, divorced, or widowed	465 (28.8%)	454 (28.2%)
Other	5 (0.3%)	4 (0.2%)
Education		
No schooling	20 (1.2%)	12 (0.7%)
Primary school	251 (15.6%)	255 (15.8%)
Secondary school	1154 (71.5%)	1182 (73.4%)
Technical training	48 (3.0%)	41 (2.5%)
Tertiary education	141 (8.7%)	120 (7.5%)
Employed	451 (27.9%)	427 (26.5%)

(Continues in previous column)

	Cabotegravir group (n=1614)	TDF-FTC group (n=1610)
(Continued from previous column)		
Self-reported gender identity*		
Female	1612 (99.9%)	1607 (99.8%)
Male	0	3 (0.2%)
Transgender male	2 (0.1%)	0
Sexual activity in past month†		
≥2 sex partners	878/1609 (54.5%)	877/1600 (54.8%)
Transactional sex	658/1609 (40.9%)	655/1600 (40.9%)
Partner HIV-positive or unknown	542/1609 (33.7%)	558/1600 (34.9%)
Anal sex	90/1609 (5.6%)	95/1600 (5.9%)
Modified VOICE risk score‡	6 (5-7)	6 (5-7)
Body-mass index ≥30 kg/m²	465 (28.8%)	430 (26.8%)
Sexually transmitted infections		
<i>Chlamydia trachomatis</i> §	324/1602 (20.2%)	280/1587 (17.6%)
<i>Neisseria gonorrhoeae</i> §	112/1602 (7.0%)	98/1587 (6.2%)
<i>Trichomonas vaginalis</i> ¶	141/1578 (8.9%)	129/1555 (8.3%)
Positive syphilis serology	41/1611 (2.5%)	62/1608 (3.9%)

Data are mean (SD), n (%), or median (IQR). TDF-FTC=tenofovir disoproxil fumarate plus emtricitabine. VOICE=Vaginal and Oral Interventions to Control the Epidemic.<sup>11</sup>\* All participants were assigned female sex at birth. †15 missing (five in the cabotegravir group and ten in the TDF-FTC group) computer-assisted self-interview responses. ‡Modified risk score excludes variables for curable sexually transmitted infections and HSV-2 serostatus.<sup>11</sup> §35 results not done or invalid (12 in the cabotegravir group and 23 in the TDF-FTC group). ¶91 results invalid or not done (36 in the cabotegravir group and 55 in the TDF-FTC group). ||Five results missing or not done (three in the cabotegravir group and two in the TDF-FTC group); defined positive if both non-treponemal and treponemal test were reactive.

Table 1: Baseline characteristics of the intent-to-treat population



**Figure 3: Cumulative HIV incidence by study group**

Kaplan-Meier estimates of HIV infection are shown. Four HIV infections were observed in the cabotegravir group (HIV incidence 0.20 per 100 person-years [95% CI 0.06–0.52]) and 36 in the TDF-FTC group (1.85 per 100 person-years [1.3–2.57]). Participants in the cabotegravir group had an 88% lower risk of HIV infection than those in the TDF-FTC group (hazard ratio 0.12 [0.05–0.31];  $p < 0.0001$ ). TDF-FTC=tenofovir disoproxil fumarate plus emtricitabine.



## Long acting injectable cabotegravir: updated efficacy and safety results from HPTN 084

**S Delany-Moretlwe**, JP Hughes, P Bock, S Dadabhai, D Gadama, P Hunidzarira, S Innes, D Kalonji, J Makhema, P Mandima, C Mathew, J Mpendo, P Mukwekwerere, N Mgodhi, P Nahirya Ntege, C Nakabiito, H Nuwagaba-Biribonwoha, R Panchia, F Angira, N Singh, B Siziba, E Spooner, J Farrior, S Rose, R Berhanu, Y Agyei, SH Eshleman, M Marzinke, E Piwowar-Manning, S Beigel-Orme, S Hosek, A Adeyeye, J Rooney, A Rinehart, B Hanscom, M Cohen, M Hosseinipour  
on behalf of the HPTN 084 study team



AIDS 2022, Montreal, abstract #OALBX0108



Delany-Moretlwe S. et al. Long acting injectable cabotegravir: updated efficacy and safety results from HPTN 084. AIDS 2022, Montreal, abstract #OALBX0108

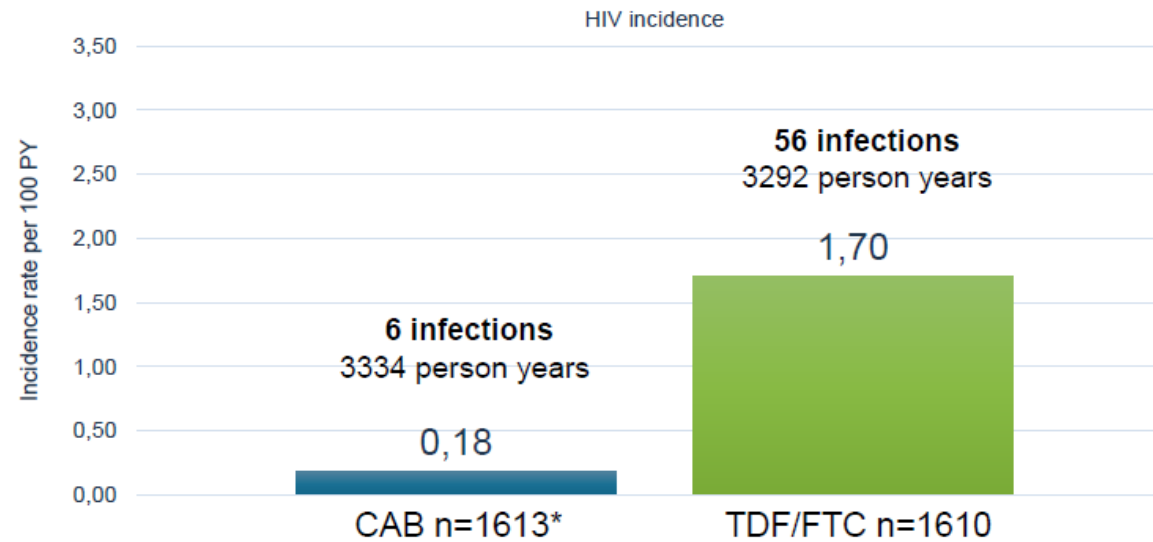
<https://www.hptn.org/research/studies/hptn084>

[https://www.hptn.org/sites/default/files/inline-files/220803%20IAS%202022%20HPTN%20084%20for%20HPTN%20website%20revised\\_0.pdf](https://www.hptn.org/sites/default/files/inline-files/220803%20IAS%202022%20HPTN%20084%20for%20HPTN%20website%20revised_0.pdf)

# HIV incidence: CAB vs TDF/FTC

Combined blinded and unblinded period, through Dec 2021

**HR 0.11; 95% CI 0.05 - 0.24**



\*Excludes 1 baseline infection from the blinded period

What's in the PrEP pipeline and implementing LAI PrEP today can help implement tomorrow's long-acting PrEP options

# Pharmacokinetics and Tolerability of Cabotegravir and Rilpivirine Long-Acting Intramuscular Injections to the *Vastus Lateralis* (Lateral Thigh) Muscles of Healthy Adult Participants

**Kelong Han**,<sup>1</sup> **Jafar Sadik Shaik**,<sup>1</sup> **Herta Crauwels**,<sup>2</sup> **Claudia Leemereise**,<sup>3</sup> **Gilda Bontempo**,<sup>4</sup> **Beta Win**,<sup>5</sup> **Ciara Seal**,<sup>1</sup> **Rebecca DeMoor**,<sup>1</sup> **Ojesh Upadhyay**,<sup>1</sup> **Vasiliki Chounta**,<sup>6</sup> **William R. Spreen**,<sup>4</sup> **Susan L. Ford**<sup>7</sup>

<sup>1</sup>GlaxoSmithKline, Collegeville, PA, United States; <sup>2</sup>Janssen Research & Development, Beerse, Belgium; <sup>3</sup>GlaxoSmithKline, Amersfoort, the Netherlands; <sup>4</sup>ViiV Healthcare, Research Triangle Park, NC, United States; <sup>5</sup>GlaxoSmithKline, Stevenage, United Kingdom; <sup>6</sup>ViiV Healthcare, Brentford, United Kingdom; <sup>7</sup>GlaxoSmithKline, Research Triangle Park, NC, United States

Evidence for strategies to promote self injection, partner injection, task shifting for injection administration, overcome gluteal fillers/body contouring, and provide varying body injection sites

# A Study Evaluating the Safety, Tolerability, and Pharmacokinetics of a High-Concentration (CAB 400 mg/mL) Cabotegravir Long-Acting Injectable Formulation Following Subcutaneous and Intramuscular Administration in Healthy Adult Participants

**Paul Benn,<sup>1</sup> Kelong Han,<sup>2</sup> Jörg Sievers,<sup>1</sup> Jafar Sadik Shaik,<sup>2</sup> Michael Warwick-Sanders,<sup>3</sup> Beta Win,<sup>3</sup> David Dorey,<sup>4</sup> Mark Baker,<sup>5</sup> Claudia Leemereise,<sup>6</sup> Kjersten Offenbecker,<sup>2</sup> Cindy Garris,<sup>7</sup> Darin B. Brimhall,<sup>8</sup> Craig Boyle,<sup>9</sup> Christian Schwabe,<sup>10</sup> Dale Taylor,<sup>11</sup> Michael A. Hassman,<sup>12</sup> Allen Wolstenholme,<sup>2</sup> Steve Knowles,<sup>13</sup> William R. Spreen,<sup>7</sup> Max Lataillade<sup>14</sup>**

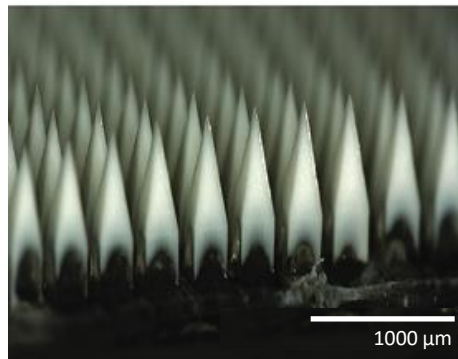
*<sup>1</sup>ViiV Healthcare, Brentford, United Kingdom; <sup>2</sup>GlaxoSmithKline, Collegeville, PA, United States; <sup>3</sup>GlaxoSmithKline, Brentford, United Kingdom; <sup>4</sup>GlaxoSmithKline, Mississauga, ON, Canada; <sup>5</sup>ViiV Healthcare, Nyon, Switzerland; <sup>6</sup>GlaxoSmithKline, Amersfoort, the Netherlands; <sup>7</sup>ViiV Healthcare, Research Triangle Park, NC, United States; <sup>8</sup>PPD, Inc., Las Vegas, NV, United States; <sup>9</sup>PPD, Inc., Austin, TX, United States; <sup>10</sup>New Zealand Clinical Research, Auckland, New Zealand; <sup>11</sup>PPD, Inc., Orlando, FL, United States; <sup>12</sup>Hassman Research Institute, Berlin, NJ, United States; <sup>13</sup>Halozyne Therapeutics, Inc., San Diego, CA, United States; <sup>14</sup>ViiV Healthcare, Branford, CT, United States*

Evidence for strategies to promote self injection, partner injection, task shifting for injection administration, overcome gluteal fillers/body contouring, and provide varying body injection sites



# Investigational Cabotegravir Formulations

## Microarray patch (long-acting for HIV PrEP)



Light microscopic image (x25)



## Cabotegravir LA (reformulation)

- Double-strength concentration (400 mg/mL)
- Phase 1 study of safety/ tolerability
  - Subcutaneous (abdominal)
  - Intramuscular (gluteus medius and vastus lateralis)

## Cabotegravir Implant (non-biodegradable, retrievable)



In collaboration with  
Northwestern University (NIH grant)

- Sustained long-acting protection from HIV (SLAP HIV) program

## NIAID is funding research on 4 types of long-acting HIV prevention.

### INTRAVAGINAL RING (IVR)



Polymer ring inserted into the vagina releases antiretroviral drug over time.

### IMPLANT



Device implanted in the body releases antiretroviral drug over time.

### INJECTABLE



Long-acting antiretroviral drug is injected into the body.

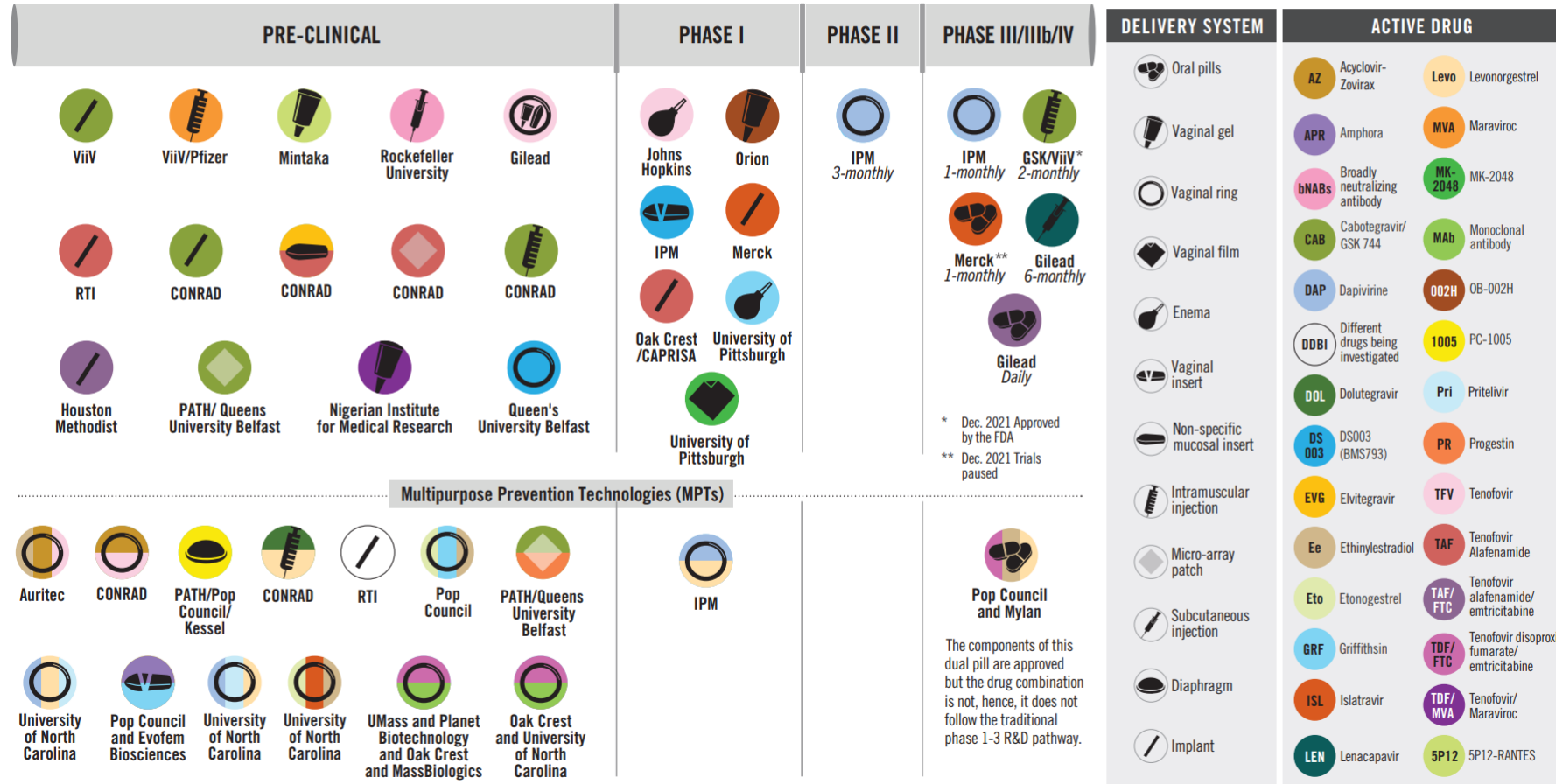
### ANTIBODY



Antibody is infused or injected into the body.

NIH National Institute of Allergy and Infectious Diseases: Long-Acting Forms of HIV Prevention

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women. (Visit [www.avac.org/hvad](http://www.avac.org/hvad) for vaccine and broadly neutralizing antibody pipelines.)



## What are MPTs?

Multipurpose prevention technologies (MPTs) are products designed to simultaneously address more than one sexual and reproductive health (SRH) concern. Male and female condoms—

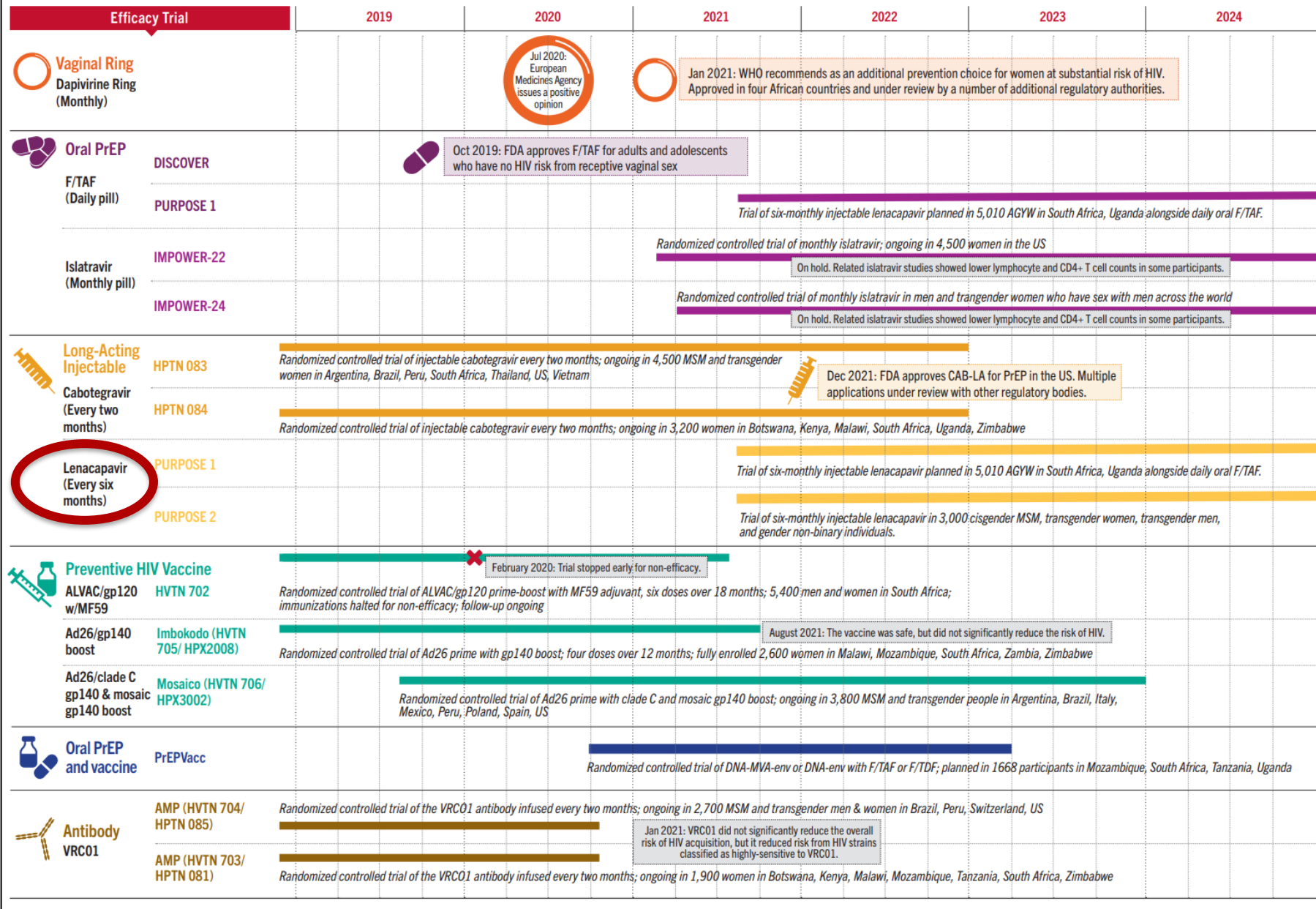
which protect against pregnancy as well as HIV and other sexually transmitted infections (STIs)—are great examples of MPTs that already exist. Many others are in development.

### AT A GLANCE: THE MPT R&D PIPELINE

Status of products in development



Adapted from: *The Initiative for MPTs (IMPT) Product Development Database; Treatment Action Group (TAG) 2020 Pipeline Report.*



# Implementing LAI PrEP: Workflow Challenges and Considerations

# Lessons Learned from Injectable Antiretroviral HIV Treatment

- Fatigue among clinics from implementing two antiretroviral injection modalities at the same time: *staffing for injection administration, documentation, follow up for missed injections, etc.*
- Implementation challenges exist at the levels of:
  - 1) client/patient: *retention/missed appointments*
  - 2) provider/support staff: *time/staffing for injections and follow up; fidelity to the clinical protocol*
  - 3) organizational/structural: *resources/staffing for billing/paperwork/medication acquisition, injection appointment slots, missed appointment follow up, and injection administration and record keeping*
- Notable challenges are medication acquisition in the setting of insurance turnover: *“Buy and Bill” and injection acquisition for the uninsured (medications shipped from an outside pharmacy)*

# Implementing LAI PrEP: Workflow Challenges

- Implementation challenges exist at the levels of:
  - 1) client/patient/community: *messaging, decision making, and retention/missed appointments*
  - 2) provider/support staff: *PrEP decision making; time/staffing for injections and follow up; fidelity to the clinical protocol*
  - 3) organizational/structural: *resources/staffing for billing/paperwork/medication acquisition, injection appointment slots, missed appointment follow up, and injection administration and record keeping; keeping up with patient insurance turnover and medication acquisition; receiving medications from an outside pharmacy for the uninsured*



# Implementing LAI PrEP: Workflow Considerations

- Creating LAI PrEP implementation workgroups:
  - Workgroups and related sub-workgroups should address clinical protocol creation, issues in billing (medical vs pharmacy benefit), staff injection education, injection record keeping (timing medication acquisition with each PrEP client appointment), medication stock and pharmacy relationships, and addressing missed client injection appointments
- “LAI PrEP Clinic” days and PrEP injection administration staff
  - Staff required for injection administration, injection pick up from the pharmacy with timing related to client appointments, injection administration documentation, and follow up for missed appointments (window period for each injection is +/- 7 days)
  - Due to the injection window period, there needs to be flexibility to schedule new appointments within 7 days for the same client

# PrEP Implementation Limitations at the Policy Level

- Policies needed to foster national PrEP scale up for LAI PrEP (legislation/billing) and allow us to reach those who are not able to come into a clinic routinely
  - Fosters non-traditional medicine (in-person provider in a clinic) --  
-----1) provider, 2) virtual/in-person, 3) location
    - **Task shifting** and onsite/offsite supervision requirements
      - Non-provider **injections** (self/partner/non-licensed professional)
    - **Telehealth**
    - **Locations:** street medicine, pharmacies, other
  - Fosters stable PrEP care coverage (office visit, labs, medications): coverage that accounts for insurance churning; national financing programs
    - USPSTF ratings for ALL PrEP options and ALL services
  - Other policies

# Conclusions

- HPTN 083 and HPTN 084 demonstrated the efficacy data for injectable cabotegravir for PrEP compared to daily oral TDF/FTC
- Implementation challenges exist at the client/patient, provider/support staff, and organizational level
- Today's implementation efforts and policy changes will accelerate the use of new PrEP products in the pipeline

# Acknowledgements

- PrEP Users
- Health support staff
- Providers

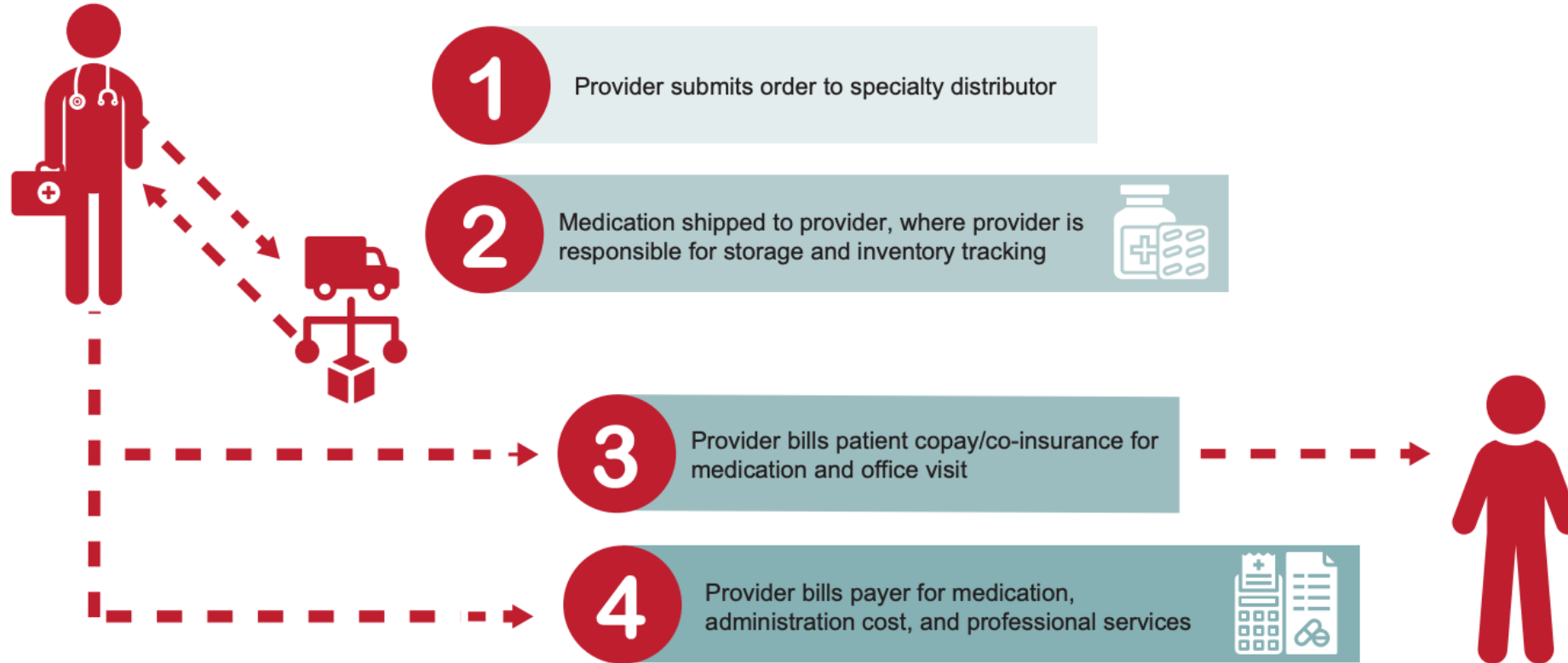
# Long-Acting Cabotegravir for PrEP: Access and Coverage Considerations

# Access and Coverage Overview

---

- Apretude wholesale acquisition cost is \$3,700 per 3 mL kit
  - Oral cabotegravir (Vocabria) for optional oral lead-in available free of charge
- Apretude is not available through retail community pharmacies, but rather through specialty distributors or specialty pharmacies
  - Can be procured by health care providers through “buy-and-bill”, “white bagging”, or “clear bagging” mechanisms
- As a provider-administered drug, insurers are most likely to cover Apretude as a medical benefit
  - Insurers may also cover it as a pharmacy benefit, or as both a medical and pharmacy benefit

# Buy-and-Bill



Source: ACE TA CENTER. Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients. <https://targethiv.org/ace/LAI-ART>

# White Bagging



Source: ACE TA CENTER. Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients. <https://targethiv.org/ace/LAI-ART>



# Coverage Considerations: Commercial Insurance

---

- Most commercial plans expected to cover Apretude as a medical benefit (vs. pharmacy benefit)
- May not appear on plan's traditional prescription drug formulary
- Apretude may be subject to utilization management (e.g., prior authorization)
- If covered as medical benefit, 20% cost share (coinsurance) may apply; if covered as pharmacy benefit, specialty drug tiering may apply; separate office visit/administration cost sharing may also apply
  - Some plans may apply USPSTF Grade A recommendation to PrEP (no cost sharing); updated USPSTF recommendation pending
  - ViiVConnect copay assistance program available (up to \$7,850 per year)

# Coverage Considerations: Medicaid

---

- Most Medicaid programs are expected to cover Apretude
- Coverage requirements, payment methods, and possible utilization management (e.g., prior authorization) vary state-to-state
- Cost sharing is typically nominal
  - ViiVConnect copay assistance program cannot be used for Medicaid cost sharing

# Coverage Considerations: Medicare

---

- Apretude is expected to be covered under Part B as a provider-administered drug
- Beneficiary may be responsible for up to 20% of the medication cost after the deductible requirement has been met
  - Supplemental insurance coverage, Medicaid dual-eligibility, or enrollment in the Qualified Medicare Beneficiary (QMB) program may defray cost-sharing requirements
  - ViiVConnect copay assistance program cannot be used
- Some Medicare Advantage plans that include prescription drug coverage (Part D) may opt to cover it as a pharmacy benefit

# Apretude Billing and Coding Reference

Code Category	Code Number	Description
NDC	49702-0244-23	Apretude 600 mg/3 mL kit
ICD-10	Z01.812, Z11.3, Z11.4, Z20.2, Z20.5, Z20.6, Z51.81, Z72.52, Z79.899	Multiple ICD-10 codes for HIV exposure and PrEP
ICD-10	B20	Human immunodeficiency virus (HIV) disease
CPT	96372	Therapeutic, prophylactic, or diagnostic injection (SQ or IM)
CPT Modifier	33	Commercial insurance only; in support of USPSTF Grade A recommendation for PrEP (no cost sharing); <i>may not accept</i>
HCPCS	J0739	Injection, cabotegravir, 1 mg

# Coverage Considerations: Low Income/Uninsured

Apretude may be available at no cost via ViiVConnect for individuals meeting the following criteria:

- Reside in one of the 50 states, the District of Columbia, or Puerto Rico
  - Have a household income <500% of the Federal Poverty Level (e.g.,: income that does not exceed \$91,550 in a household of two in 2022).
  - Not eligible for Medicaid (or Mi Salud, Puerto Rico's government-funded health plan)
- And either*
- Have no prescription drug coverage, or
  - Have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan, and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year, or
  - Have a private insurance plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of a drug

# Building Capacity for Injectable PrEP in New York City

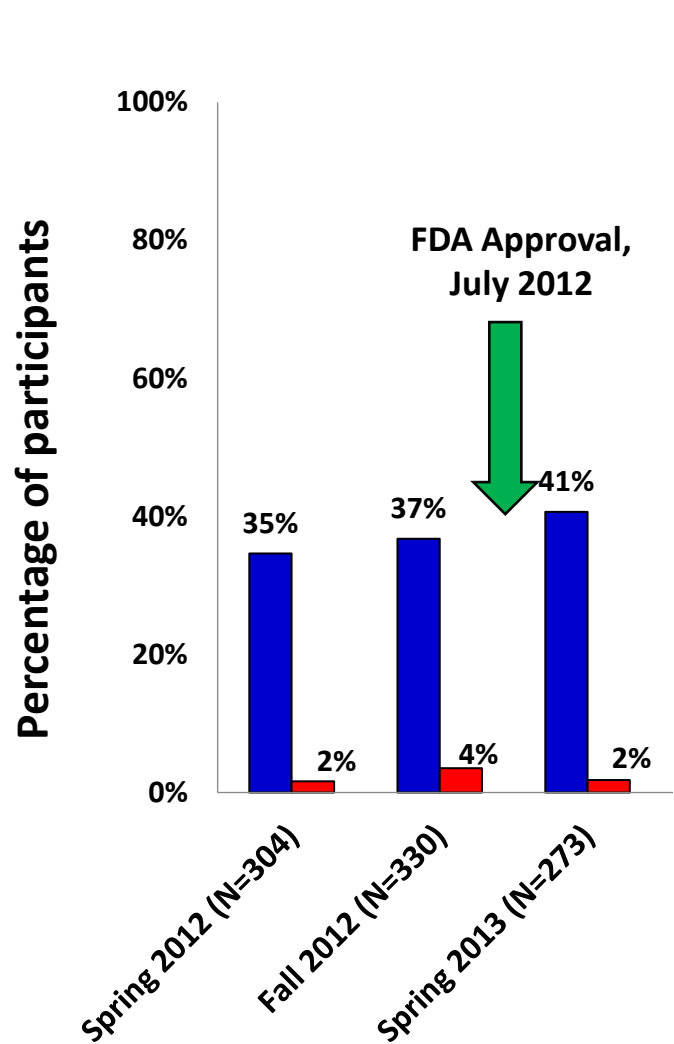
Benjamin Tsoi, MD, MPH  
Director of HIV Prevention, HIV Prevention Program

Bureau of Hepatitis, HIV, and Sexually Transmitted Infections, New York City Health Department  
*Envisioning a New York City without transmission or illness related to viral hepatitis, HIV, and sexually transmitted infections.*

# Learning from Implementation of Oral PrEP

- FDA approved TDF/FTC for PrEP in 2012





- When PrEP was initially approved in 2012,
  - Small proportion of gay men in New York City knew about it
  - Few providers were ready and willing to prescribe it

### Survey Cycle

\*Sample includes sexually active MSM aged 18-40 years and who do not report HIV-positive status



# Learning from Implementation of Oral PrEP

- FDA approved TDF/FTC for PrEP in 2012
- In 2012, demand exceeded supply
  - Many providers were reluctant to accept referrals for patients outside their network/practice
  - Many consumers were frustrated by lack of options and providers to offer PrEP



# Purview Paradox

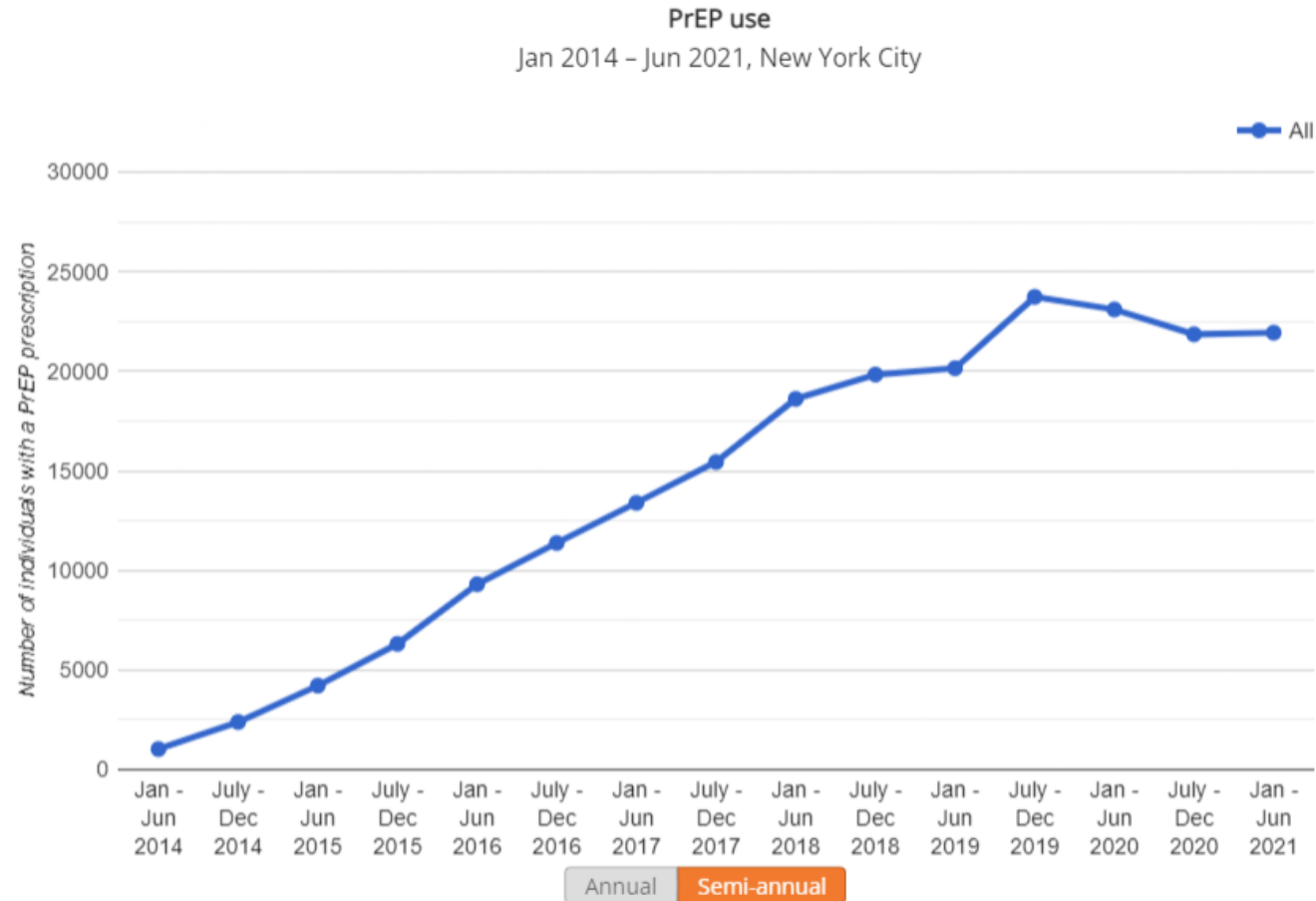
HIV Providers:  
PCP are in the  
best position to  
prescribe PrEP



Primary Care Providers:  
PrEP meds are too  
complicated

# Where Are We Now?

## PrEP prescriptions increasing (until COVID-19)

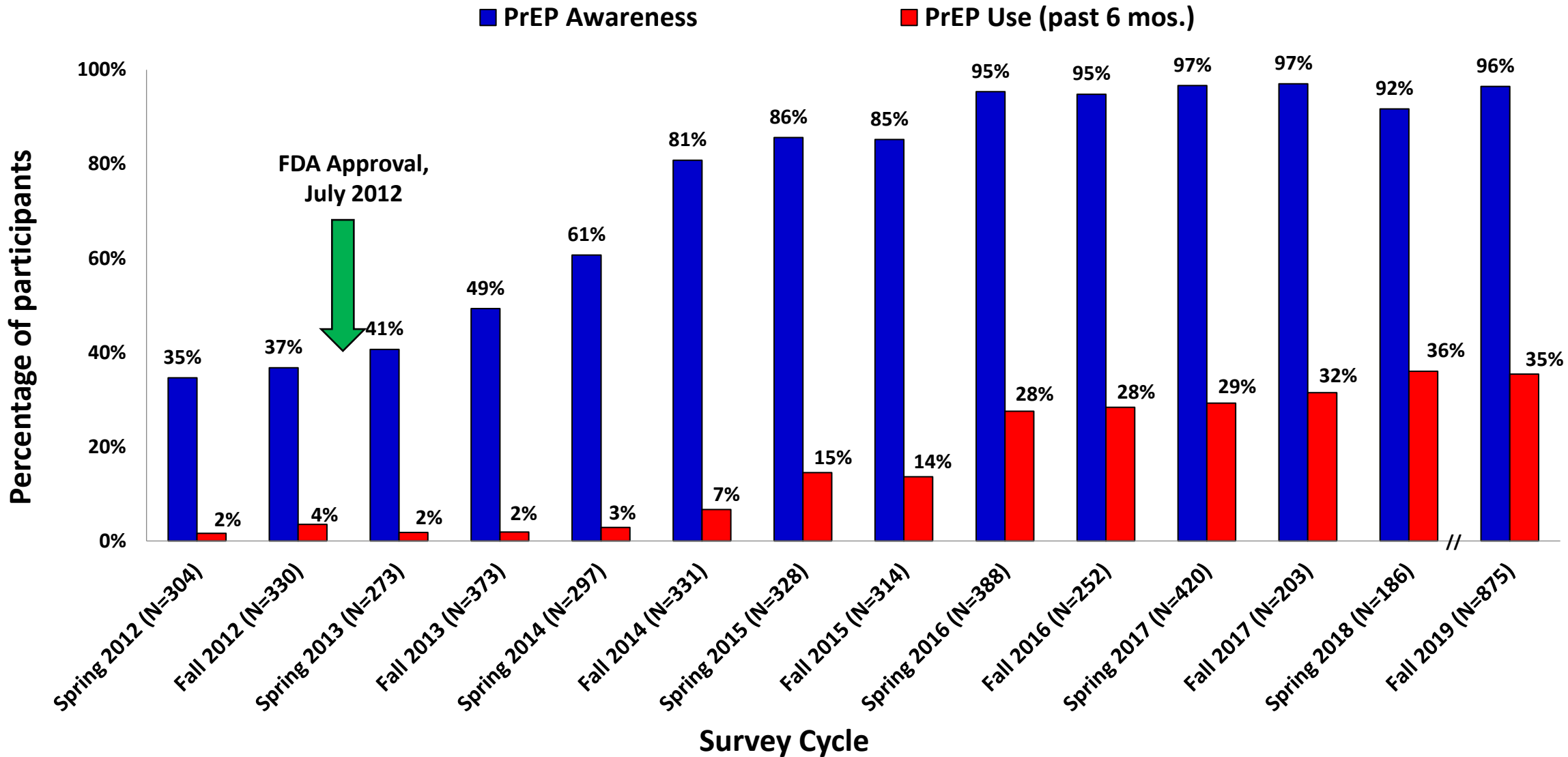


Data source: Source Healthcare Analytics (Symphony) and the NYS Medicaid Data Warehouse (MDW)



[etedashboardny.org](https://etedashboardny.org)

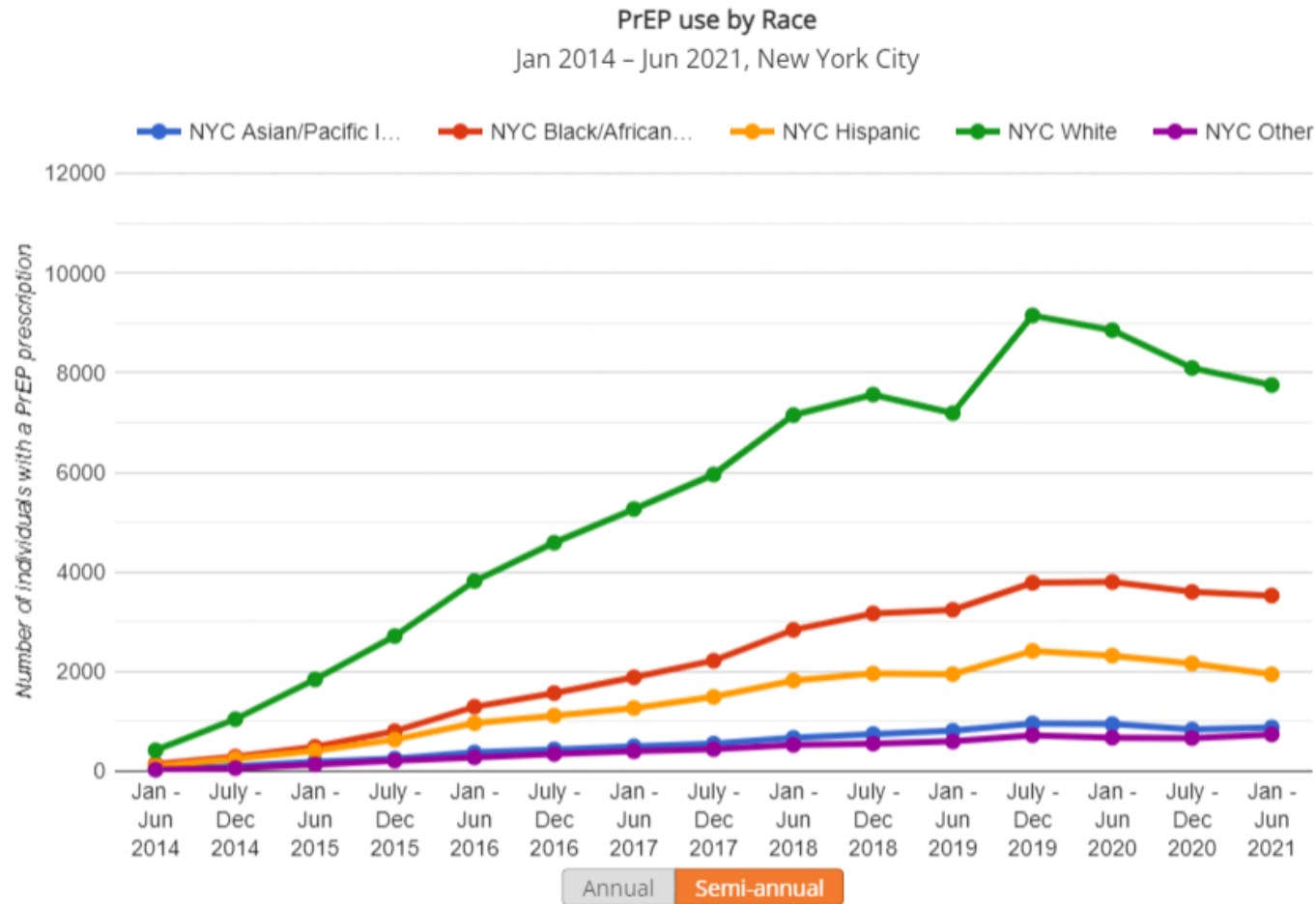




\*Sample includes sexually active MSM aged 18-40 years and who do not report HIV-positive status

# Where Are We Now?

## PrEP prescriptions increasing, but there are disparities in use



**More PrEP use among persons who are White than for persons who are Black or Latino**

Data source: Source Healthcare Analytics (Symphony) and the NYS Medicaid Data Warehouse (MDW)

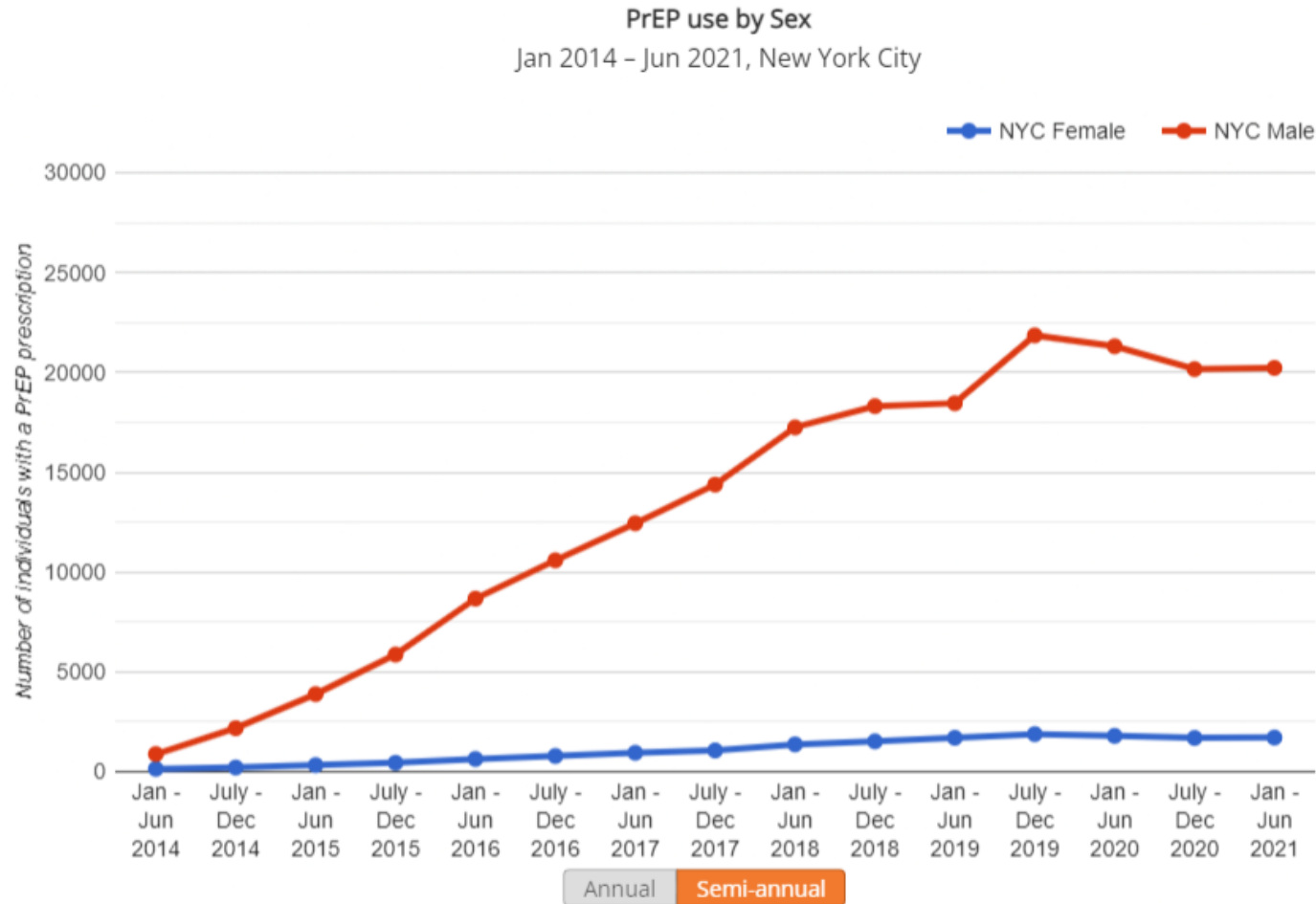


[etedashboardny.org](http://etedashboardny.org)



# Where Are We Now?

## PrEP prescriptions increasing, but there are disparities in use



**More PrEP use among males than among females**

Data source: Source Healthcare Analytics (Symphony) and the NYS Medicaid Data Warehouse (MDW)



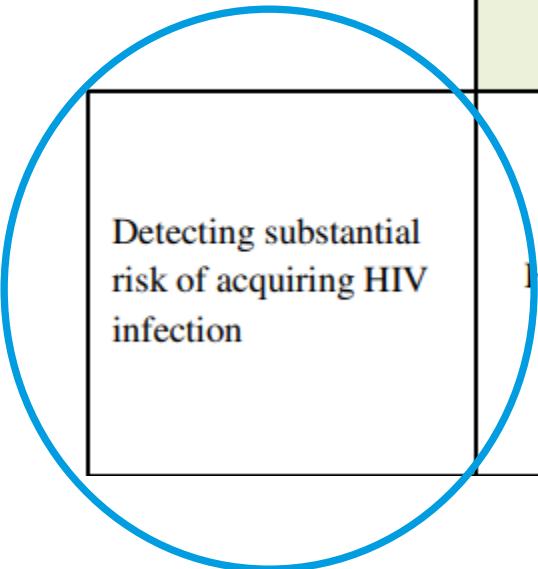
[etedashboardny.org](http://etedashboardny.org)



# Persons with Indications for PrEP

	<b>Men Who Have Sex with Men</b>	<b>Heterosexual Women and Men</b>	<b>Persons Who Inject Drugs</b>
Detecting substantial risk of acquiring HIV infection	<ul style="list-style-type: none"> <li>HIV-positive sexual partner</li> <li>Recent bacterial STI<sup>†</sup></li> <li>High number of sex partners</li> <li>History of inconsistent or no condom use</li> <li>Commercial sex work</li> </ul>	<ul style="list-style-type: none"> <li>HIV-positive sexual partner</li> <li>Recent bacterial STI<sup>‡</sup></li> <li>High number of sex partners</li> <li>History of inconsistent or no condom use</li> <li>Commercial sex work</li> <li>In high HIV prevalence area or network</li> </ul>	<ul style="list-style-type: none"> <li>HIV-positive injecting partner</li> <li>Sharing injection equipment</li> </ul>

# Persons with Indications for PrEP

	Men Who Have Sex with Men	Heterosexual Women and Men	Persons Who Inject Drugs
 <p>Detecting substantial risk of acquiring HIV infection</p>	<p>HIV-positive sexual partner Recent bacterial STI<sup>†</sup> High number of sex partners History of inconsistent or no condom use Commercial sex work</p>	<p>HIV-positive sexual partner Recent bacterial STI<sup>‡</sup> High number of sex partners History of inconsistent or no condom use Commercial sex work  In high HIV prevalence area or network</p>	<p>HIV-positive injecting partner Sharing injection equipment</p>



# Messaging about PrEP Resulted in Stigma



# PrEP Stigma Predicts PrEP Uptake and Adherence

Northwestern



Institute for Sexual  
and Gender Minority  
Health and Wellbeing

## PrEP Stigma Predicts PrEP Uptake and Adherence: Results from the RADAR Cohort Study (0988)

**Brian Mustanski, PhD; Michael E. Newcomb, PhD; Daniel T. Ryan, MS**

Northwestern University Feinberg School of Medicine and Northwestern Institute for Sexual and Gender Minority Health & Wellbeing

[brian@northwestern.edu](mailto:brian@northwestern.edu)

- **Young people who hold stigmatizing attitudes regarding the use of Truvada as PrEP are less likely to take the HIV prevention pill**
- **If they are on it, they are less likely to adhere to daily regimen**

Conference on Retroviruses and Opportunistic Infections 2019

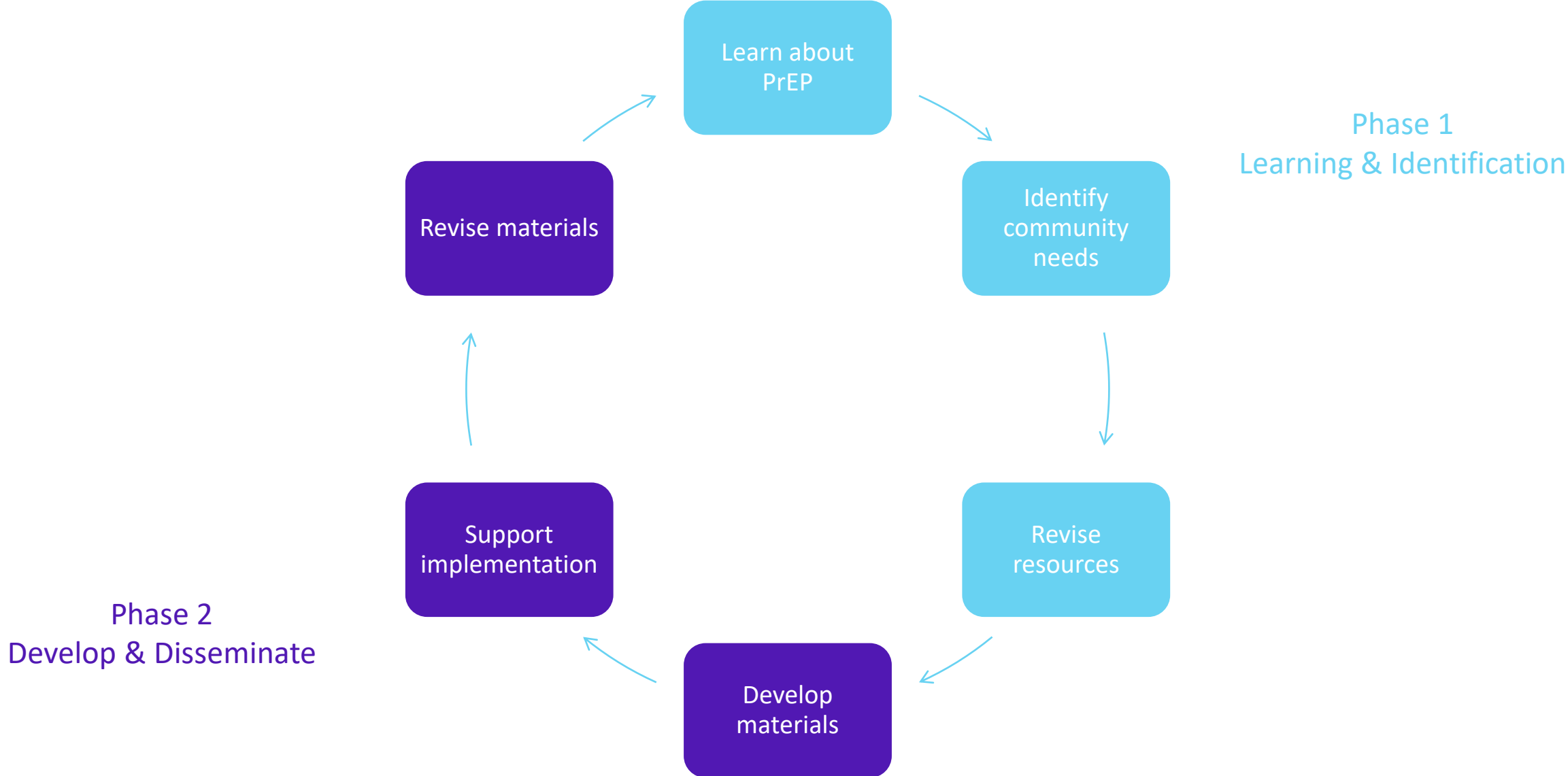
# Injectable PrEP Implementation Considerations

- Promote and support prescribers (Supply) to meet the needs of consumers
  - Increase number of providers who can prescribe PrEP
- Increase PrEP awareness and usage among persons who are Black and Latino, and among women
- Support consumers in
  - Understanding PrEP options
  - In deciding which option best suits their needs
- Promote and offer PrEP as a prevention option in a sex-positive and affirming manner

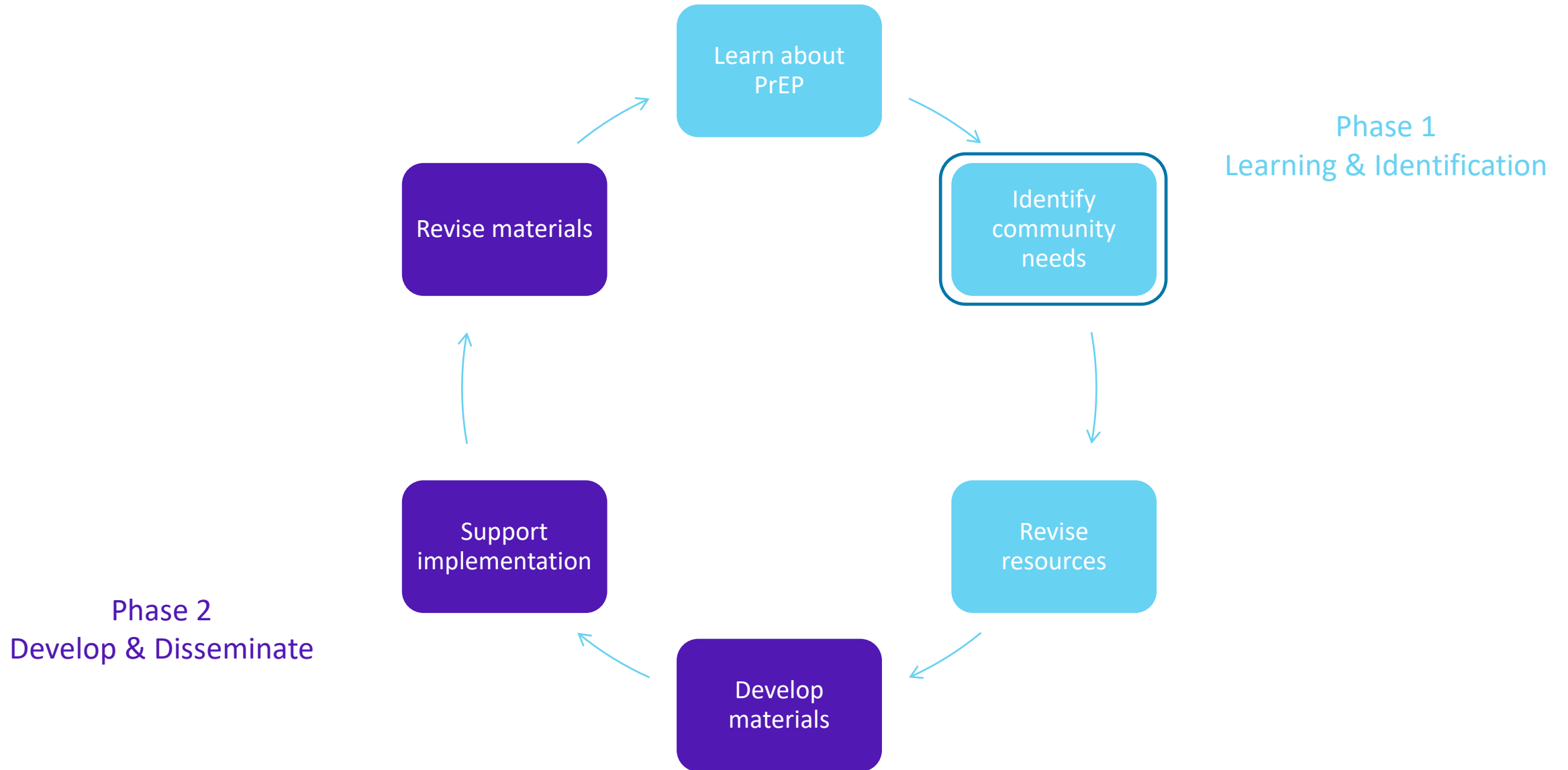


# INJECTABLE PrEP WORKPLAN

# Injectable PrEP Workplan



# Injectable PrEP Workplan



Injectable PrEP

Community

Needs

Assessment



[This Photo](#) by Unknown Author is licensed under [CC BY-NC](#)

- NYC Health Department conducted online needs assessment among staff of partner clinical and non-clinical agencies of community engagement initiative, New York Knows
- Needs assessment was conducted between March 14<sup>th</sup> to Apr 4<sup>th</sup> 2022
  - Sent to app

**89 online surveys were completed**

**43%** | of respondents worked at health center or clinic

**38%** | of respondents worked at CBO



# Needs Assessment Summary

- More than a third of respondents said that they have begun discussing implementing injectable PrEP at their agency
- Most respondents are either slightly prepared or not prepared at all to discuss injectable PrEP with their patients
- To make injectable PrEP available at their agency, respondents would need
  - Client education materials
  - Provider education materials, and
  - SOPs for agency staff to implement in the next 3 months

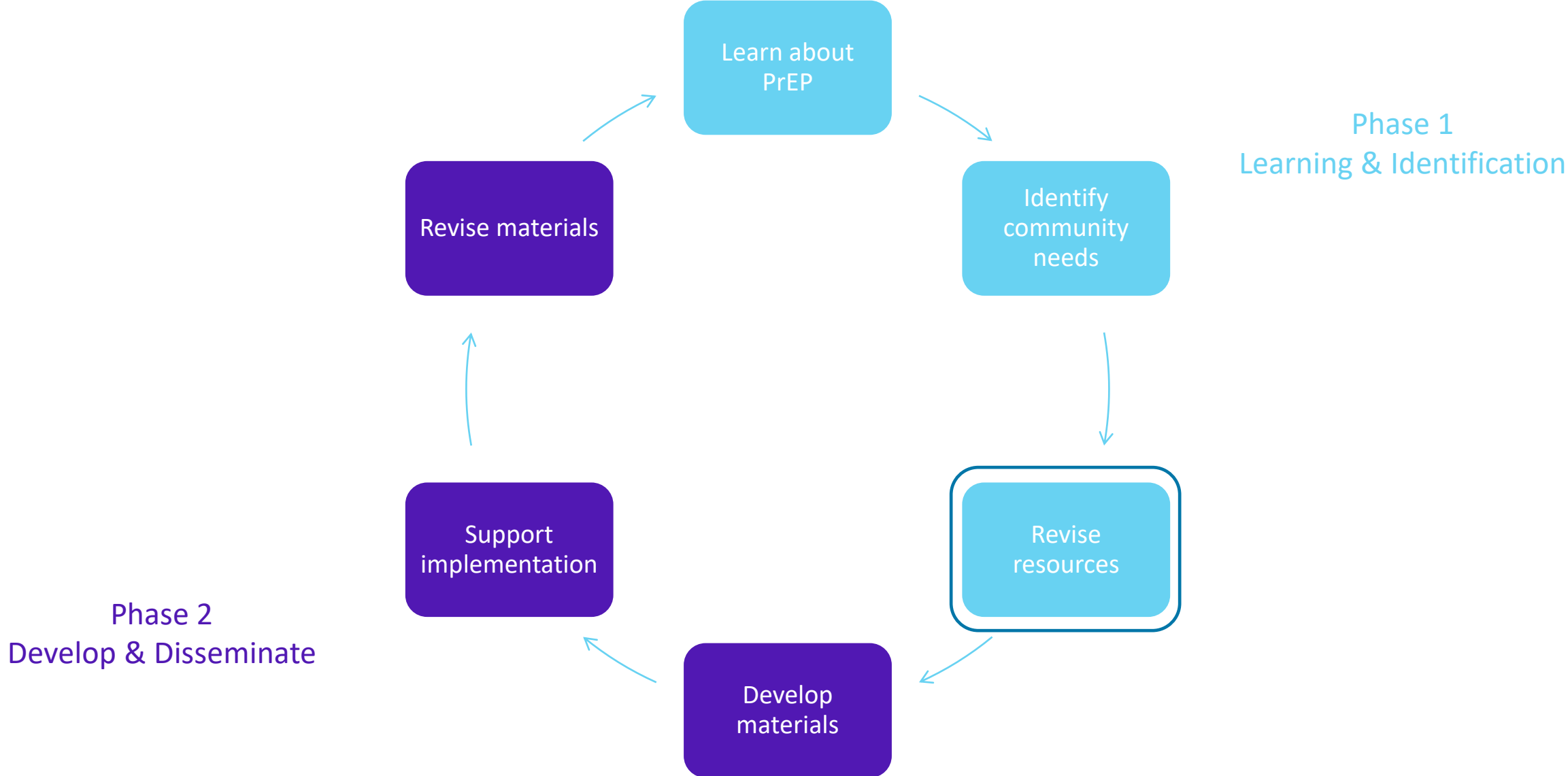
# Need Assessment Summary (cont.)

- Top three topics that respondents wanted to learn more about were:
  - Cost and insurance coverage
  - Eligibility requirements
  - Side effects
- Out of those that see clients, more than half reported clients interested in injectable PrEP
  - Of respondents that reported that their clients were disinterested in injectable PrEP the top three reasons were side effects, cost concerns and not knowing enough about CAB-LA

# Need Assessment Summary (cont.)

- Most reported challenges to implementing injectable PrEP were:
  - Insurance and prior authorization process
  - Billing and reimbursement
  - CAB-LA tail
    - Time period after injections have stopped, and slowly diminishing amount of cabotegravir remains in body of someone who received CAB-LA injections
    - Need for other preventive measure against HIV infection

# Injectable PrEP Workplan



# Updating Health Department Website

Get the latest on the COVID-19 Vaccine

NYC Health 311 Search all NYC.gov websites

Promoting and Protecting the City's Health

NYC Health 繁體中文 Translate Text-Size

Home COVID About Our Health Services **Providers** Data Business Search

Reporting and Services **Health Topics** Resources Emergency Prep

## By Disease or Condition

Immunizations

Alcohol and Drug Use

Smoking and Tobacco Use

Sexual and Reproductive Health

Children and Adolescents

## PrEP and Emergency PEP: Information for Medical Providers

### COVID-19 Update Information for Medical Providers

- [COVID-19: Information for Providers](#)
- [HIV PrEP and Emergency PEP: Best Practices During COVID-19](#) (PDF, June 2020)
- [Maintaining HIV and STI Services](#) (PDF)
- [NYC REACH Telehealth Support](#)

This page lists PrEP and emergency PEP resources for healthcare professionals in New York City. Please refer to the main [PrEP](#) and [PEP](#) webpage for general information and resources.



# CLINICAL GUIDELINES PROGRAM

Updated May 20, 2022



[JOIN OUR MAIL LIST](#) | [ABOUT US](#) | [POCKET GUIDES & SLIDES](#) | [HOME](#)

[HIV Testing and Acute HIV](#) [ART](#) [Primary HIV Care](#) [Perinatal HIV Care](#) [PrEP](#) [PEP](#) [Hepatitis Care](#) [STIs](#) [Substance Use](#)



## PREP TO PREVENT HIV AND PROMOTE SEXUAL HEALTH

The [Medical Care Criteria Committee \(MCCC\)](#) produced the *PrEP to Prevent HIV and Promote Sexual Health Guideline*

- The [NYSDOH Clinical Education Initiative \(CEI\)](#) provides CME on HIV, HCV, and STD care → [Learn More](#)
- [Subscribe to our mailing list](#) to be notified when new or updated guidelines are published → [Sign up now](#)

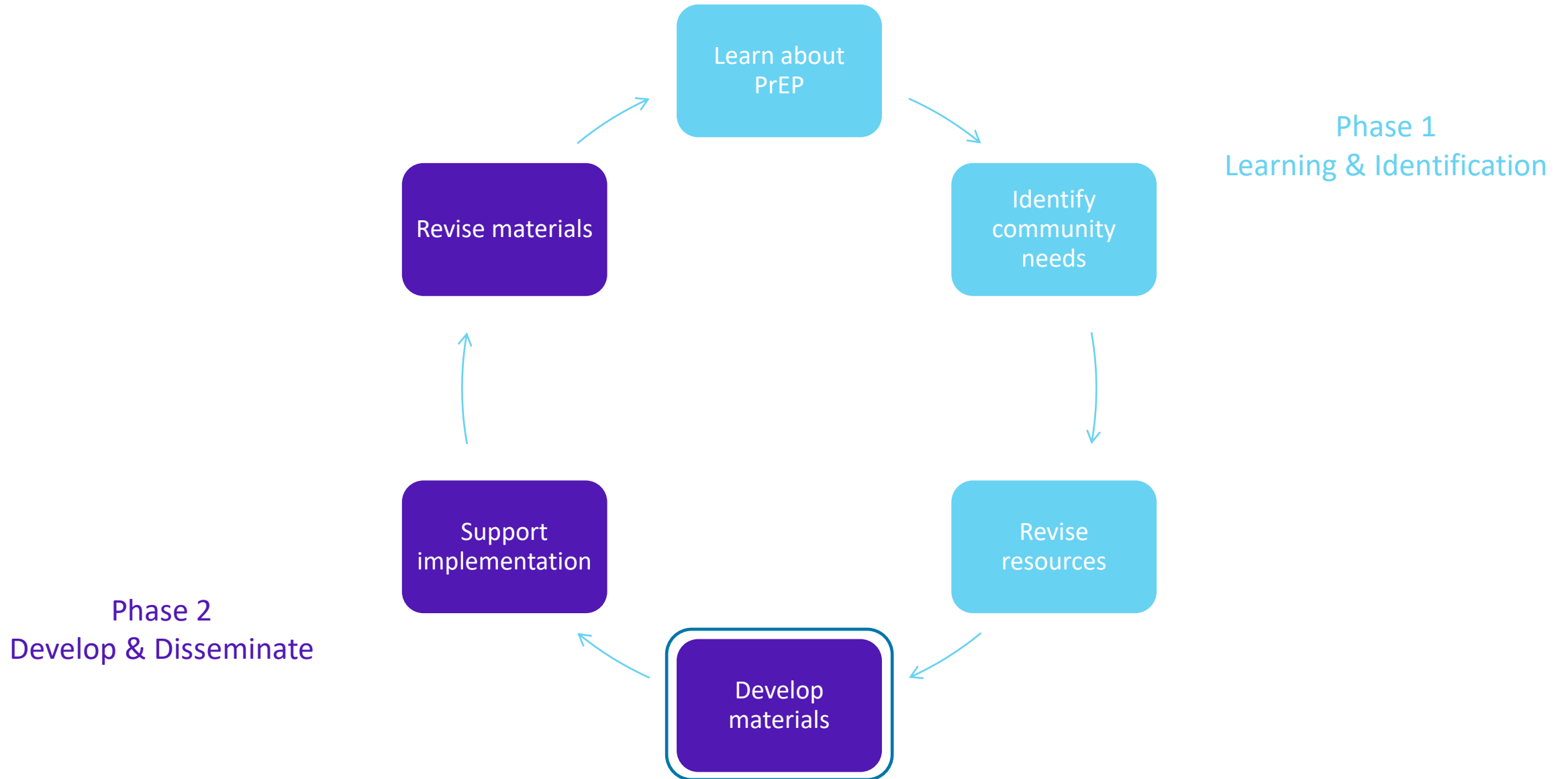
<https://www.hivguidelines.org/>

PrEP to Prevent HIV and Promote Sexual Health

PrEP Implementation

Resources for Care Providers

# Injectable PrEP Workplan



# Sending Updated PrEP Guidance to NYC Prescribers



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE

Ashwin Vasan, MD, PhD  
*Commissioner*

## Updated CDC Guidelines on PrEP to Prevent HIV

August 2, 2022

Dear Colleague,

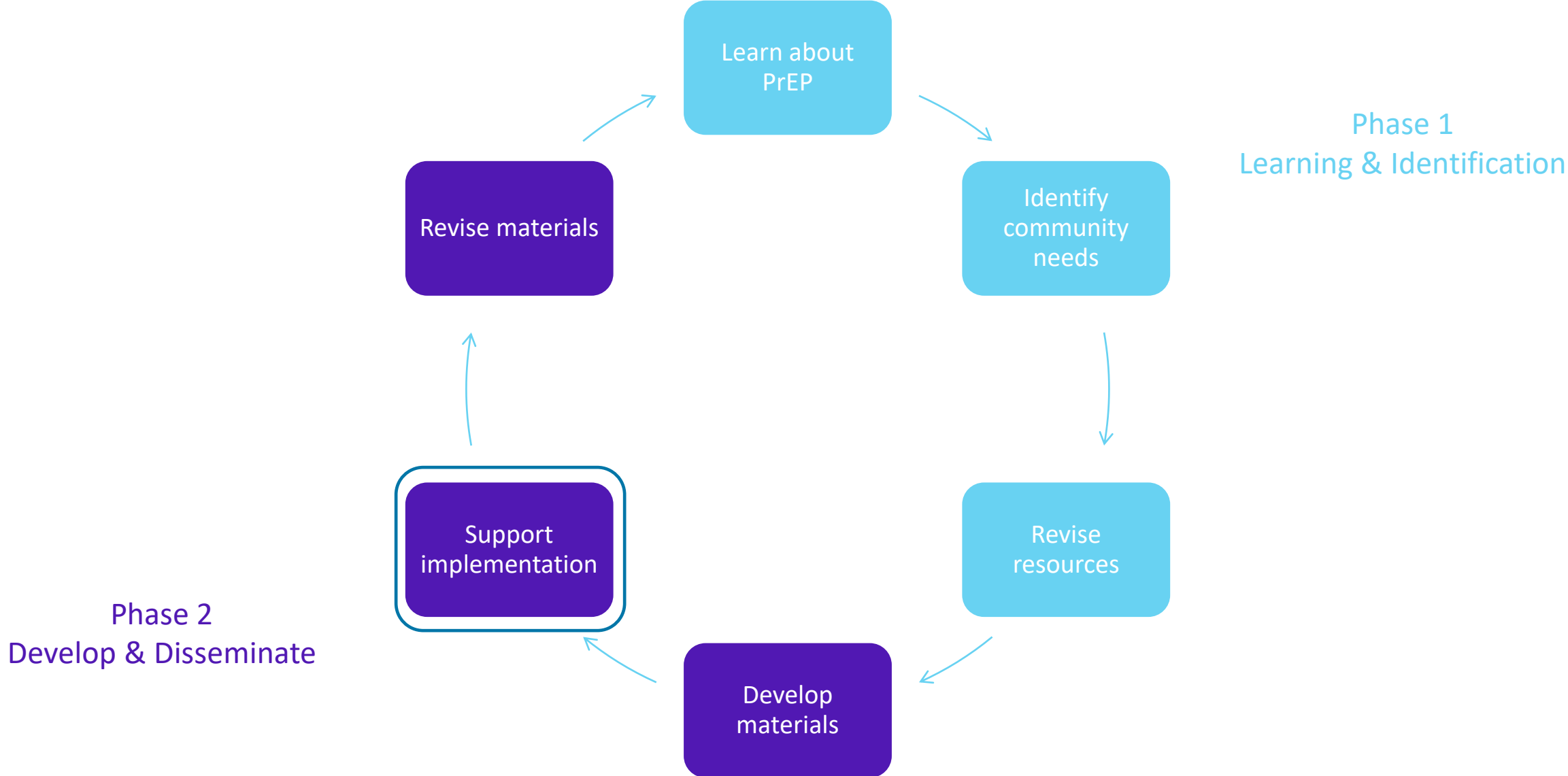
The U.S. Centers for Disease Control and Prevention (CDC) has updated its [guidelines](#) on the use of pre-exposure prophylaxis (PrEP) to prevent HIV. In this letter, we provide a summary of the major changes.

### **Injectable PrEP Is Now an Alternative to Daily Pills**

In December 2021, the U.S. Food and Drug Administration (FDA) [approved](#) long-acting cabotegravir (CAB-LA, or Apretude) as PrEP for use by adults and adolescents who weigh at least



# Injectable PrEP Workplan

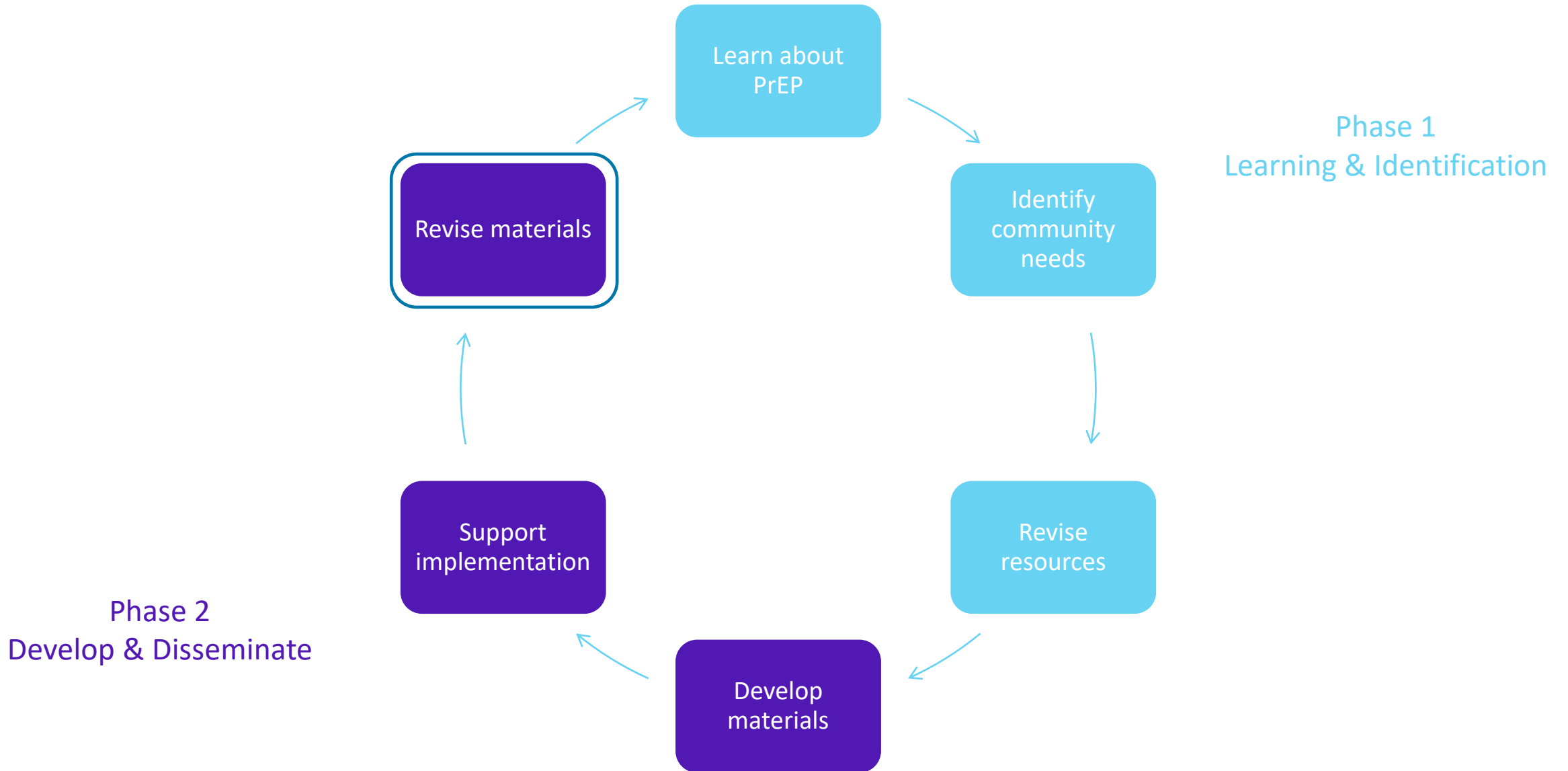


# Building Supply Side for Injectable PrEP

- Injectable PrEP requires more logistical support beyond writing prescriptions
- Create base of providers who can provide injectable PrEP (Supply)
  - Partnered with University of Rochester (CDC CBA provider)
  - Created a learning collaborative of agencies that can prescribe and offer injectable PrEP
    - Asked for commitment to implement injectable PrEP during the course of learning collaborative
    - Assemble implementation team
      - Prescriber
      - Someone who supports clients with education and navigation
      - Facility administrator
      - Pharmacist



# Injectable PrEP Workplan



# Next Steps

- From learning collaborative, we hope to gain information to inform
  - Creation of implementation checklist and support materials to help prescribers
  - Creation of patient education and social marketing materials
    - Promote sexual health model for PrEP use
    - Promote awareness of options and choice for clients
  - Support for community-based organizations that conduct outreach and navigation services to PrEP prescribers in community

# Acknowledgements

- Support for injectable PrEP was made possible only by the hard work of staff in the Bureau of Hepatitis, HIV, and STIs and our partners
- New York City Health Department
  - Alyson Clarke
  - Doienne Saab
  - Maria Ma
  - Patrick Padgen
  - Paul Kobrak
  - Sarah Braunstein
  - Stephanie Hubbard
  - Yanoh Jalloh
  - Yusyin Hsin
- University of Rochester
  - Daniela DiMarco
  - Juhua Wu
  - Mary Adams
  - Michael Wilson





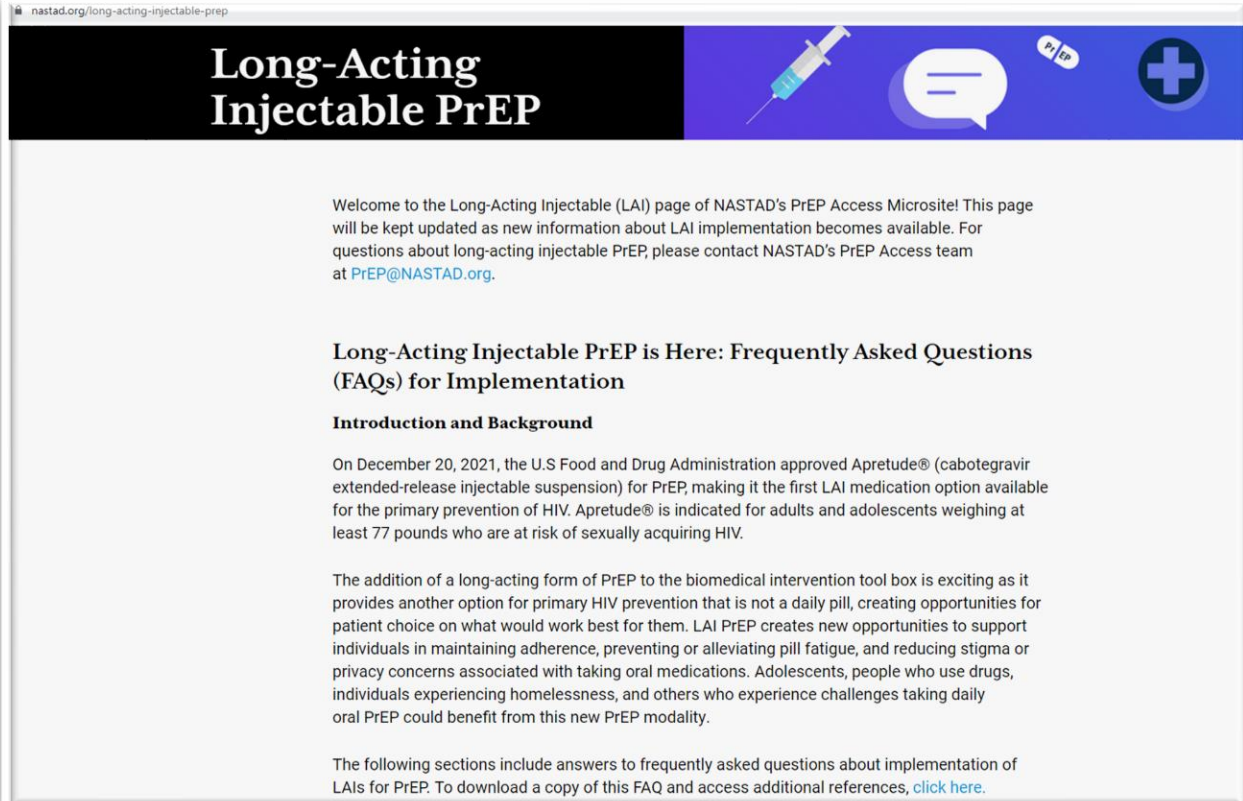
**Benjamin Tsoi, MD, MPH**  
Director, HIV Prevention  
Bureau of Hepatitis, HIV, and STIs  
[btsoi@health.nyc.gov](mailto:btsoi@health.nyc.gov)

# Current NASTAD LAI Resources

# Long-Acting Injectable PrEP is Here: Frequently Asked Questions (FAQs) for Implementation

## Resource reviews:

- Cost and coverage considerations
- Oral lead-in coverage
- Patient access
- Payment assistance available
- Stocking and storing Apretude®
- USPSTF and Apretude® Coverage
- Lab requirements and more



nastad.org/long-acting-injectable-prep

## Long-Acting Injectable PrEP

Welcome to the Long-Acting Injectable (LAI) page of NASTAD's PrEP Access Microsite! This page will be kept updated as new information about LAI implementation becomes available. For questions about long-acting injectable PrEP, please contact NASTAD's PrEP Access team at [PrEP@NASTAD.org](mailto:PrEP@NASTAD.org).

### Long-Acting Injectable PrEP is Here: Frequently Asked Questions (FAQs) for Implementation

#### Introduction and Background

On December 20, 2021, the U.S Food and Drug Administration approved Apretude® (cabotegravir extended-release injectable suspension) for PrEP, making it the first LAI medication option available for the primary prevention of HIV. Apretude® is indicated for adults and adolescents weighing at least 77 pounds who are at risk of sexually acquiring HIV.

The addition of a long-acting form of PrEP to the biomedical intervention tool box is exciting as it provides another option for primary HIV prevention that is not a daily pill, creating opportunities for patient choice on what would work best for them. LAI PrEP creates new opportunities to support individuals in maintaining adherence, preventing or alleviating pill fatigue, and reducing stigma or privacy concerns associated with taking oral medications. Adolescents, people who use drugs, individuals experiencing homelessness, and others who experience challenges taking daily oral PrEP could benefit from this new PrEP modality.

The following sections include answers to frequently asked questions about implementation of LAIs for PrEP. To download a copy of this FAQ and access additional references, [click here](#).

Visit [www.nastad.org/long-acting-injectable-prep](http://www.nastad.org/long-acting-injectable-prep)



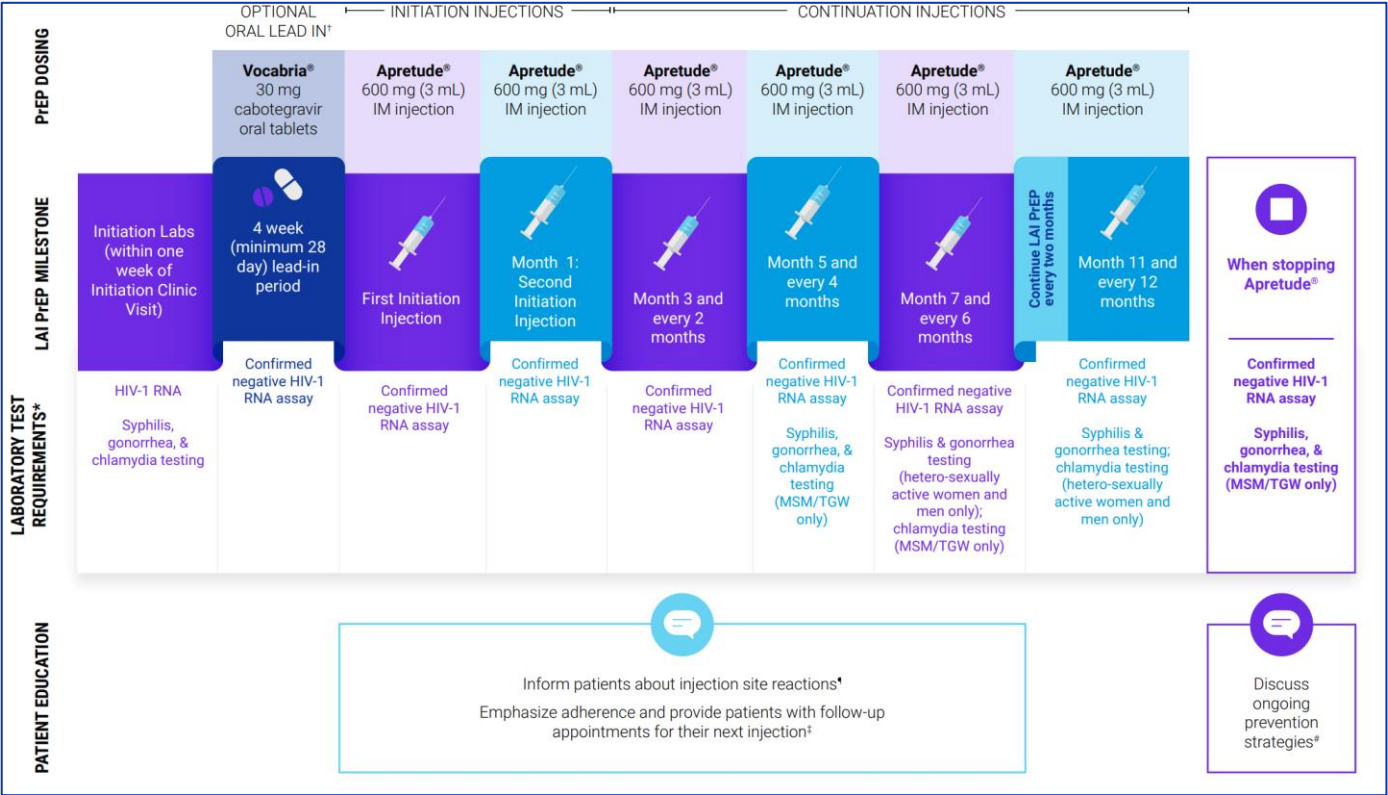
# Additional Provider Education Resources

Soon to be updated:

## Infographic: Long-Acting Injectable Cabotegravir Dosing

- Infographic walks through the required labs, initiation and dosing schedule for Apretude®.

What else would-be helpful resources for you?



# PrEP Access Resources

---

[PrEP Generics Entering the US Market: FAQs-](#)

[Billing Coding Guide for HIV Prevention: PrEP, Screening, and Linkage Services-](#)

[Infographic: Verifying PrEP as a Preventive Service-](#)

[NASTAD PrEP Coverage Brief: PrEP Services Covered with No Cost-Sharing](#)

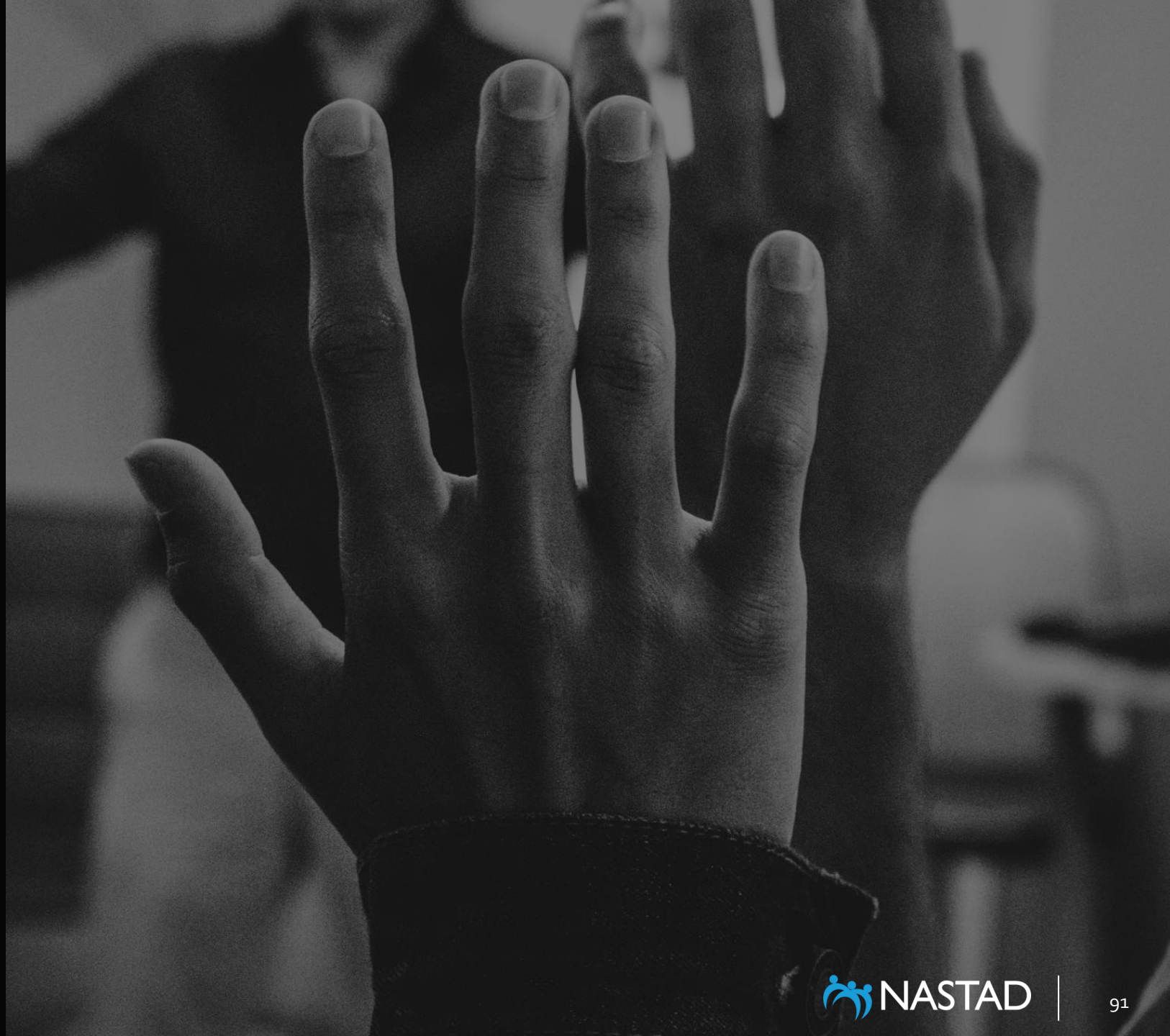
[NASTAD's PrEP Access Microsite](#)

[HIV BLUPrint \(Hunter Alliance for Research & Translation \(HART\) & Aaron Diamond AIDS Research Center \(ADARC\)](#)

[PrEPCoverageCheck.org](#)

[Diversifying PrEP Financing: Strategies to Leverage Funding across the PrEP Care Continuum](#)

Questions?



# Contact Information

---

PrEP@NASTAD.org

For more PrEP Access Updates, join  
[NASTAD's PrEP Access Listserv!](#)

