



Alternatives to Daily PrEP: Injectables and PrEP On-Demand

Dana Serafin, CRNP, FNP-BC
Associate Medical Director of PrEP Services
Philadelphia FIGHT
Philadelphia, PA

Speaker Disclosure

Dana Serafin, CRNP, FNP-BC has no commercial relationships to disclose.

CME Planning Committee Disclosures: Debra D'Alessandro, MPH and Jennifer Kolker, MPH have no relationships to disclose. Helena Kwakwa, MD, MPH discloses her institution formerly received a research grant from ViiV, however the financial relationship has since been divested.



In Order to Obtain CEs, You Must Do the Following:

- Be sure that the name that you're using in Zoom/RingCentral lists your **complete first name, last name, and degree.**
- Turn and keep your camera on and attend the entire duration of the program (full Zoom attendance reports are submitted to the accreditors).
- Complete the program evaluation form in the follow-up email within the deadline.

CME Credits

- Drexel University College of Medicine (DUCOM, our CME accreditation partner) issues all CME certificates once a year of the program, in the Fall/Winter.
- Certificates are issued to the email address that you provide on the evaluation form.



CNE Credits

- Within 3 Months of the program date, our CNE accreditor will send a link to a brief survey, that when completed, will allow you to print out your certificate.
- The link will be sent to the email address that you provide on the evaluation form.



Social Work Credits

- Bryn Mawr College (our social work accreditor) will send out certificates within 3 months of the program date.
- Certificates are issued to the email address that you provide on the evaluation form.

REMINDER

- Please complete the evaluation form that you receive in the follow-up email by ***Friday, 4/12/2024.***

Learning Objectives

- Review of currently approved PrEP options and brief review of updated PrEP guidelines
- Review alternatives to daily oral PrEP: eligibility, benefits and challenges, and how to counsel patients
- Communication with patients about PrEP options
- Lessons learned in implementing an injectable PrEP program in a primary care setting
- Take home points

Pre-Exposure Prophylaxis (PrEP)

- Approved to *prevent* HIV in at-risk adults and adolescents weighing at least 35kg
- **Grade A** recommendation by the USPSTF
- Current medication options for PrEP
 - Emtricitabine/tenofovir disoproxil fumarate (F/TDF) - brand name **Truvada**®
 - Emtricitabine/tenofovir alafenamide (F/TAF) - brand name **Descovy**®
 - Cabotegravir (CAB) - brand name **Apretude**®

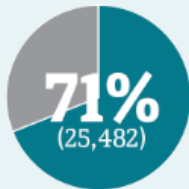
2021 Surveillance Data

Ending
the
HIV
Epidemic

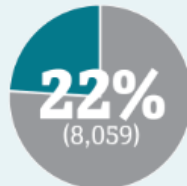
Overall Goal: Decrease the number of new HIV diagnoses to 9,588 by 2025 and 3,000 by 2030.



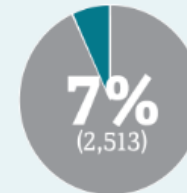
There were **36,136 new HIV diagnoses*** in the US and dependent areas in 2021. Of those:



were among gay, bisexual, and other men who reported male-to-male sexual contact[†]



were among people who reported heterosexual contact



were among people who inject drugs

*Among people aged 13 and older.

[†]Includes infections attributed to male-to-male sexual contact and injection drug use (men who reported both risk factors).

2021 Surveillance Data: “The PrEP Gap”

Ending
the
HIV
Epidemic

Overall Goal: Increase the estimated percentage of people with indications for PrEP classified as having been prescribed PrEP to at least 50% by 2025 and remain at 50% by 2030.



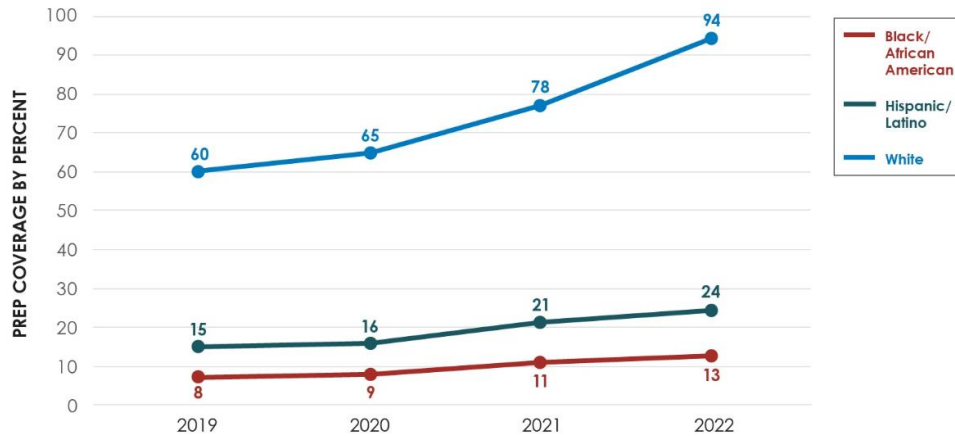
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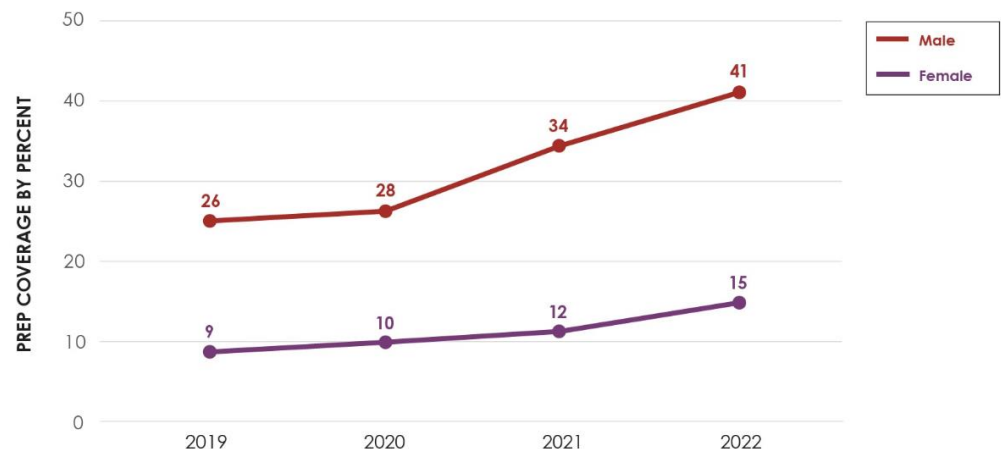
Of the 1.2 million people in the United States who could benefit from PrEP, only 30% were prescribed PrEP in 2021.

PrEP Disparities

TRENDS IN PREP PRESCRIPTIONS AMONG PEOPLE WHO COULD BENEFIT, BY RACE/ETHNICITY, 2019-2022*



TRENDS IN PREP PRESCRIPTIONS AMONG PEOPLE WHO COULD BENEFIT, BY SEX AT BIRTH, 2019-2022*



Major updates in 2021 Guidelines

- Inform all sexually active adults & adolescents about PrEP
- Simplified indications for PrEP use for sexually-active persons
- IM cabotegravir (CAB) included as an option for PrEP
- HIV testing algorithms for patients on or starting PrEP
- F/TAF as choice for cisgender men and transgender women
- Assess eCrCl every 12 months for persons < 50y old or with CrCl \geq 90, and every 6 months for all other patients

U.S. Centers for Disease Control and Prevention: U.S. Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published December 2021.

U.S. Centers for Disease Control and Prevention: U.S. Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: Clinical Providers' Supplement. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf>. Published December 2021.



Major Updates in 2021 Guidelines

- Outlined options for tele-PrEP initiation and follow-up
- Outlined procedures for same-day PrEP initiation
- Added section on primary care considerations for PrEP patients
- Outlined procedures for the off-label prescription of TDF/FTC to MSM and TGW on a non-daily regimen (“2-1-1”) and their follow-up care

U.S. Centers for Disease Control and Prevention: U.S. Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published December 2021.

U.S. Centers for Disease Control and Prevention: U.S. Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: Clinical Providers’ Supplement. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf>. Published December 2021.





Who should consider PrEP?



Individuals who have unprotected vaginal or anal sex



Someone in a sexual relationship with an HIV-positive partner



Individuals who inject drugs



People who have been prescribed multiple courses of non-occupational post-exposure prophylaxis (nPEP)



All sexually active adults and adolescents should be informed about PrEP, and offered if requested

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. Dec. 2021. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>



Available PrEP Medications



F/TDF (200mg/300mg)

- Two meds, **one pill daily or on-demand***
- Tenofovir disoproxil fumarate and emtricitabine (Truvada)
- Used in combination with other antiretrovirals to treat HIV
- Generic option available
- Has medications active against Hepatitis B



F/TAF (200mg/25mg)

- Two meds, **one pill daily**
- Tenofovir alafenamide and emtricitabine (Descovy)
- Used in combination with other antiretrovirals to treat HIV
- Has medications active against Hepatitis B

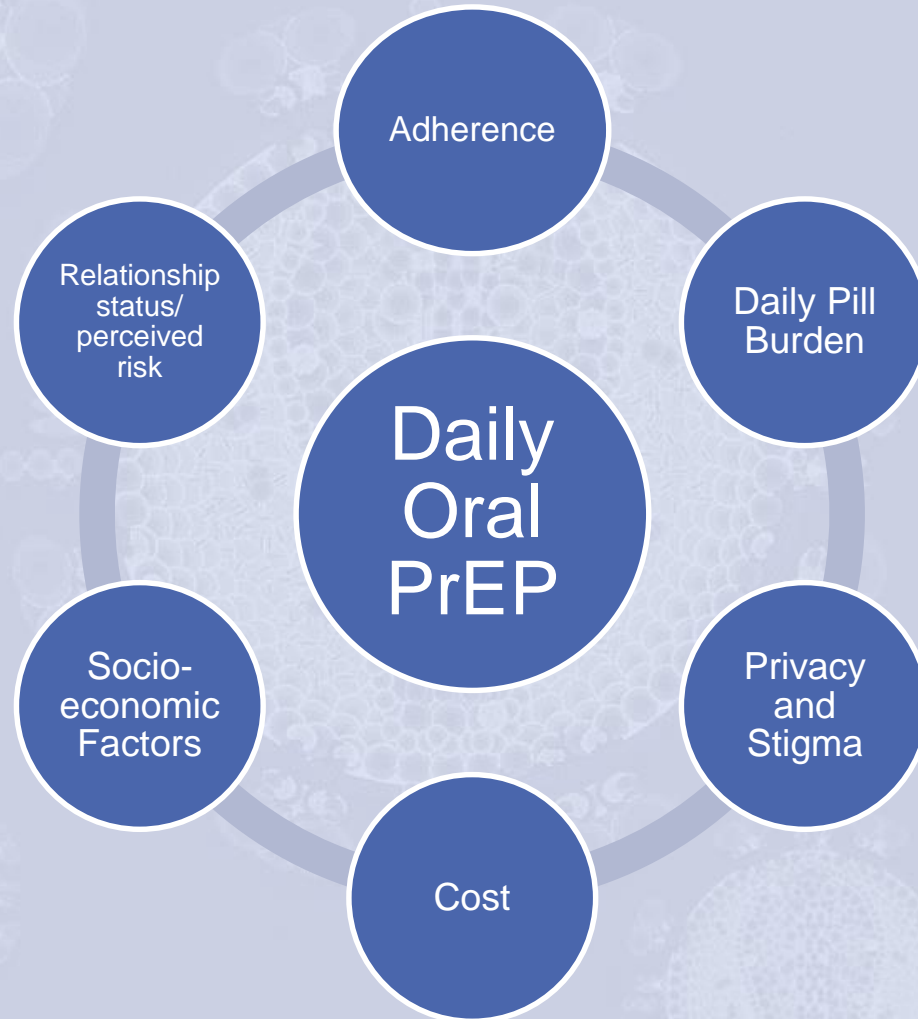


CAB-LA (600mg)

- One med, **one injection every 2 months**
- Cabotegravir extended-release (Apretude)
- Oral option for initiation (Vocabria) to assess tolerance
- Used in combination with other antiretrovirals to treat HIV

*Intermittent or "on-demand" dosing of F/TDF for PrEP is considered off label (not FDA approved)

Challenges with Daily Oral PrEP



Antonini M., Silva IED, 2023; Arnold et al., 2017

PrEP Paradigm Shift

Single PrEP
Option for all
to



Individualized
PrEP

Alternatives to daily oral PrEP

- ❖ Long-acting Injectable PrEP

- ❖ On-Demand (2-1-1) PrEP

Other Prevention Measures

- Post Exposure Prophylaxis (PEP)
 - Condom Use
 - Treatment as Prevention (U=U)
 - Partner Communication
- Needle and Syringe Exchange Programs

Injectable Cabotegravir



- Approved for PrEP in all adults and adolescents weighing at least 35 kg regardless of sex assigned at birth.
- 600 mg CAB administered intramuscularly in the gluteal muscle (ventrogluteal preferred) **monthly for 2 months, then every other month thereafter.** Optional oral lead-in available to assess tolerability
- Common side effects: injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.
- Available bridge with daily oral Cabotegravir 30 mg for up to 2 months for patients with planned missed doses (can replace 1 missed scheduled q2-month injection)
- Clinical trails (HPTN083 and HPTN084) showed superiority over daily oral PrEP with F/TDF. 66% in AMAB participants and almost 90% in AFAB participants

[APRETUDE \(cabotegravir\) Label \(fda.gov\)](#)

Who is a candidate for Injectable PrEP?



Negative HIV Ag/Ab test within 1 week of initiating Cabotegravir



No signs or symptoms of acute HIV infection



No contraindicated medications or conditions



Willingness and ability to make scheduled clinic visits for labs and injection every 2 months after a 1 month loading dose

Injectable PrEP: Counseling Patients

Long-acting IM injection for PrEP given monthly for 2 months, then every other month thereafter with a 14-day window for injection

Pain and swelling at injection site is the most common side effect

Time to effectiveness is about 7 days

“Tail” of medication for up to 1 year after discontinuation

More frequent visits
Ease of transportation every 2 months after loading dose
Working hours and clinic hours
Comfort with more frequent bloodwork
Planned and unplanned missed doses

Injection site pain remedies:


Movement after the injection, walk, stretch, ROM exercises
Do not massage the injection site
Ice before injection, after injection and intermittently for up to 2 days following the injection
Avoid warm compresses for 2 days after injection
Use OTC Tylenol/NSAIDS as needed for pain
Use of the preferred Ventrogluteal injection site

Can continue oral daily PrEP for 1 week if switching methods

Resistance risk with missed doses and after discontinuation
Family planning

Injection Window

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

 Target Injection Date

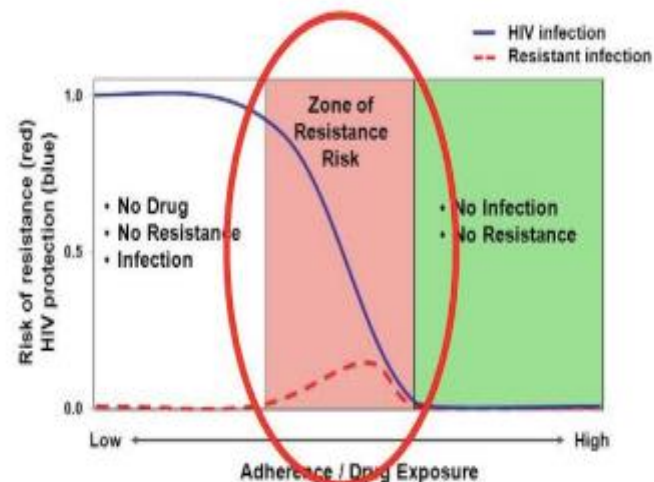
 Dosing Window



The “tail” phase and Resistance

- CAB levels slowly wane over many months after injections are discontinued, the median time to undetectable CAB plasma levels was 44 weeks for persons AMAB and 67 weeks for persons AFAB.
- During the “tail” phase, CAB levels will fall below a protective threshold and persist at non-protective levels
- Residual concentrations of CAB in systemic circulation may be sufficient to apply selective pressure for viral strains with mutations that confer resistance to CAB and other INSTI medications

PrEP and HIV resistance



Who is choosing Injectable PrEP?

- Struggling with adherence on daily oral PrEP
 - convenience
- Concerns about privacy and preference for discretion
 - Decreased concerns about how to carry and conceal PrEP pills
 - Reduction of social stigma
- Interested in the ease of a long-acting method for HIV prevention
- Reduced anxiety about missed doses of oral PrEP
 - “Less to think/worry about”
- Those that are unhoused
- Participating in more frequent sex or transactional sex
- Young cis gender women on Depo-provera for contraception
 - Injectable PrEP fit into existing family planning modalities
- Uptake of injectable PrEP more prominent in:
 - Higher education levels
 - Cisgender gay, bisexual and queer MSM
 - Younger individuals
 - People with injectable medication experience

Sciannameo S, Zalazar V, Spadaccini L (2024)
[J Int AIDS Soc.](#) 2023 Jul; 26(Suppl 2): e26107



Challenges to Injectable PrEP

Patient Concerns

- Frequent injections and blood draws
- Fear of needles/pain
 - Triggering for some former PWID
- More frequent visits to the clinic needed and logistical challenges
- Safety and efficacy of a new medication
- Waning of protection towards the end of the window
- Side effects and long-term health effects

Institutional Barriers

- Cost
 - Buy and Bill and reimbursement
- Insurance approval
 - Required to “fail oral PrEP”
- Capacity of staff for appointment requirements and tracking
- Higher specification HIV testing required

Coverage of Cabotegravir



Medicaid



Commercial payers

“try and fail” oral PrEP
Prior Authorizations, appeals
and letters of medical
necessity
Buy and Bill (through clinic
or through outside
pharmacies)
Copoly card



Uninsured

Patient Assistance Program
(PAP)
Foundational support

Cabotegravir Workflow at Philadelphia FIGHT

Initial Counseling with a Provider (PRC optional)

- Determine eligibility for Apretude
- Order baseline PrEP labs including HIV Ab/Ag and HIV RNA PCR if applicable
- Provider and patient to sign enrollment form

Initial Cabotegravir Visit: Provider and PRC

- Rapid HIV test – proceed if negative
- Draw labs for HIV Ab/Ag AND HIV RNA PCR
- Administer initial injection (RN)
- Counseling from PRC regarding persistence with appointments and missed injections
- Schedule for 4 weeks for loading dose

Loading dose (2nd injection) : Provider or RN and PRC

- Draw labs for HIV Ab/Ag AND HIV RNA PCR and appropriate STI screenings
- Discuss side effects, concerns about injection
- Administer Apretude loading dose
- Meet with PRC for counseling
- Scheduled 2 month continuation dose

Continuation Doses (every 7-9 weeks)

- Draw labs for HIV Ab/Ag AND HIV RNA PCR and appropriate STI screenings
- Discuss side effects, concerns about injection
- Administer Apretude loading dose
- Meet with PRC for counseling
- Scheduled 2 month continuation dose

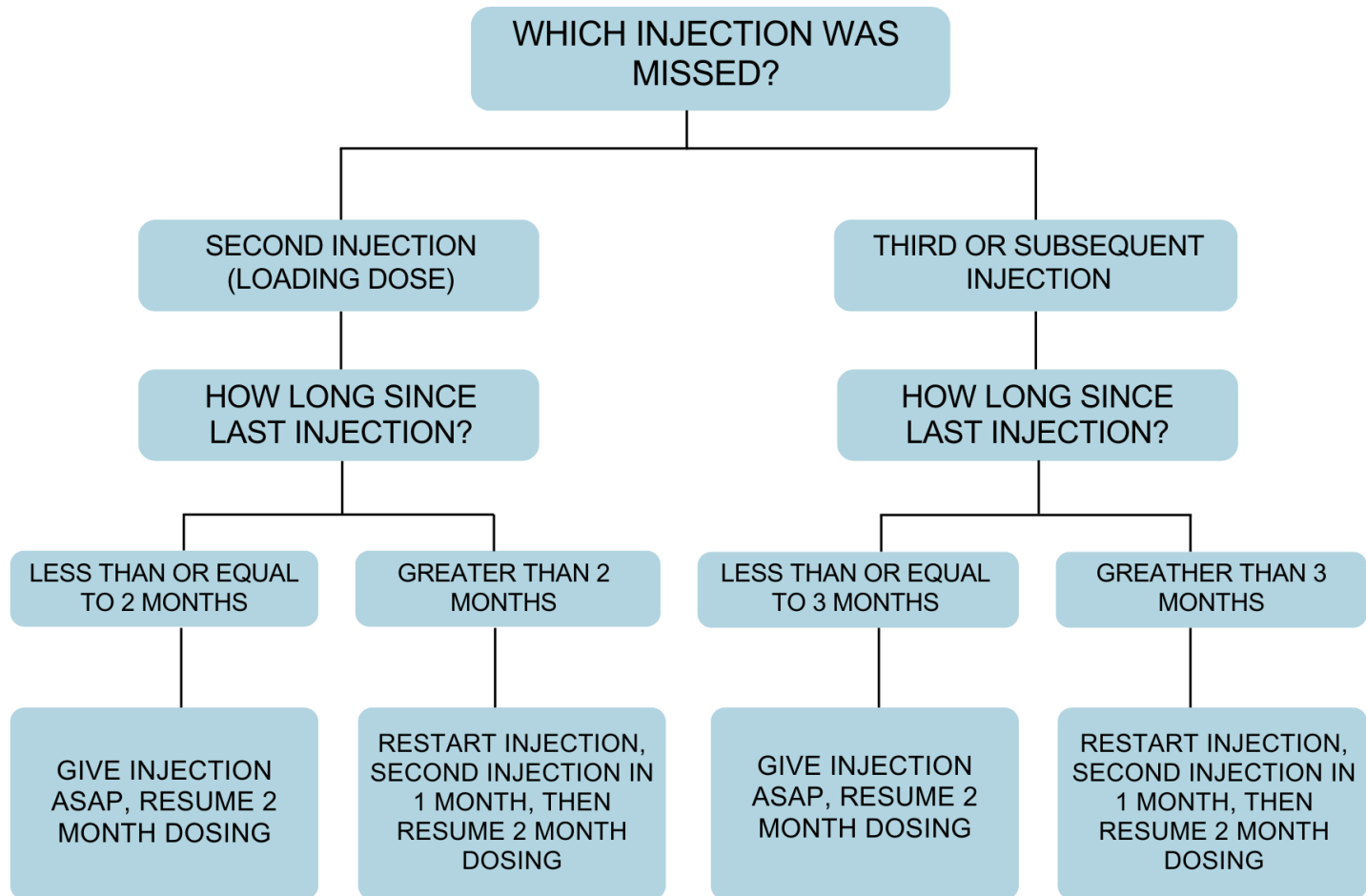
Apretude® Calendar

Apretude®
(Injectable PrEP)
continuing (3rd +) dose

Date of Injection or Date of Last Injection	Date Range to Receive Next Injection										
1-Jan	19-Feb	5-Mar	14-Feb	4-Apr	18-Apr	30-Mar	18-May	1-Jun	15-May	3-Jul	17-Jul
2-Jan	20-Feb	6-Mar	15-Feb	5-Apr	19-Apr	31-Mar	19-May	2-Jun	16-May	4-Jul	18-Jul
3-Jan	21-Feb	7-Mar	16-Feb	6-Apr	20-Apr	1-Apr	20-May	3-Jun	17-May	5-Jul	19-Jul
4-Jan	22-Feb	8-Mar	17-Feb	7-Apr	21-Apr	2-Apr	21-May	4-Jun	18-May	6-Jul	20-Jul
5-Jan	23-Feb	9-Mar	18-Feb	8-Apr	22-Apr	3-Apr	22-May	5-Jun	19-May	7-Jul	21-Jul
6-Jan	24-Feb	10-Mar	19-Feb	9-Apr	23-Apr	4-Apr	23-May	6-Jun	20-May	8-Jul	22-Jul
7-Jan	25-Feb	11-Mar	20-Feb	10-Apr	24-Apr	5-Apr	24-May	7-Jun	21-May	9-Jul	23-Jul
8-Jan	26-Feb	12-Mar	21-Feb	11-Apr	25-Apr	6-Apr	25-May	8-Jun	22-May	10-Jul	24-Jul
9-Jan	27-Feb	13-Mar	22-Feb	12-Apr	26-Apr	7-Apr	26-May	9-Jun	23-May	11-Jul	25-Jul
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12-Jan	2-Mar	16-Mar	25-Feb	15-Apr	29-Apr	10-Apr	29-May	12-Jun	26-May	14-Jul	28-Jul
13-Jan	3-Mar	17-Mar	26-Feb	16-Apr	30-Apr	11-Apr	30-May	13-Jun	27-May	15-Jul	29-Jul
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9-Feb	30-Mar	13-Apr	25-Mar	13-May	27-May	8-May	26-Jun	10-Jul	23-Jun	11-Aug	25-Aug
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12-Feb	2-Apr	16-Apr	28-Mar	16-May	30-May	11-May	29-Jun	13-Jul	26-Jun	14-Aug	28-Aug
13-Feb	3-Apr	17-Apr	29-Mar	17-May	31-May	12-May	30-Jun	14-Jul	27-Jun	15-Aug	29-Aug
						13-May	1-Jul	15-Jul	28-Jun	16-Aug	30-Aug
						14-May	2-Jul	16-Jul	29-Jun	17-Aug	31-Aug



Unplanned Missed Injections



Missed Injections

Unplanned Missed Injections

- **Assess patient for the need for PEP or any signs of acute HIV infection**
- Clinically reassess to determine if Apretude remains appropriate for the patient
- Confirm HIV-1 negative status
- Resume Cabotegravir injections according to timeline above
- Counseling on persistence with injection appointments



Planned Missed Injections

- If your patient plans to miss their Target Injection Date by >7 days, daily oral cabotegravir can be prescribed for a duration of up to 2 months to replace 1 missed scheduled every-2-month injection of injectable Cabotegravir
- The first dose of oral cabotegravir should be taken approximately 2 months after the last injection dose of injectable Cabotegravir
- Restart injections with Cabotegravir on the day oral dosing completes or within 3 days

Injectable PrEP: Lessons learned

Use a multidisciplinary team

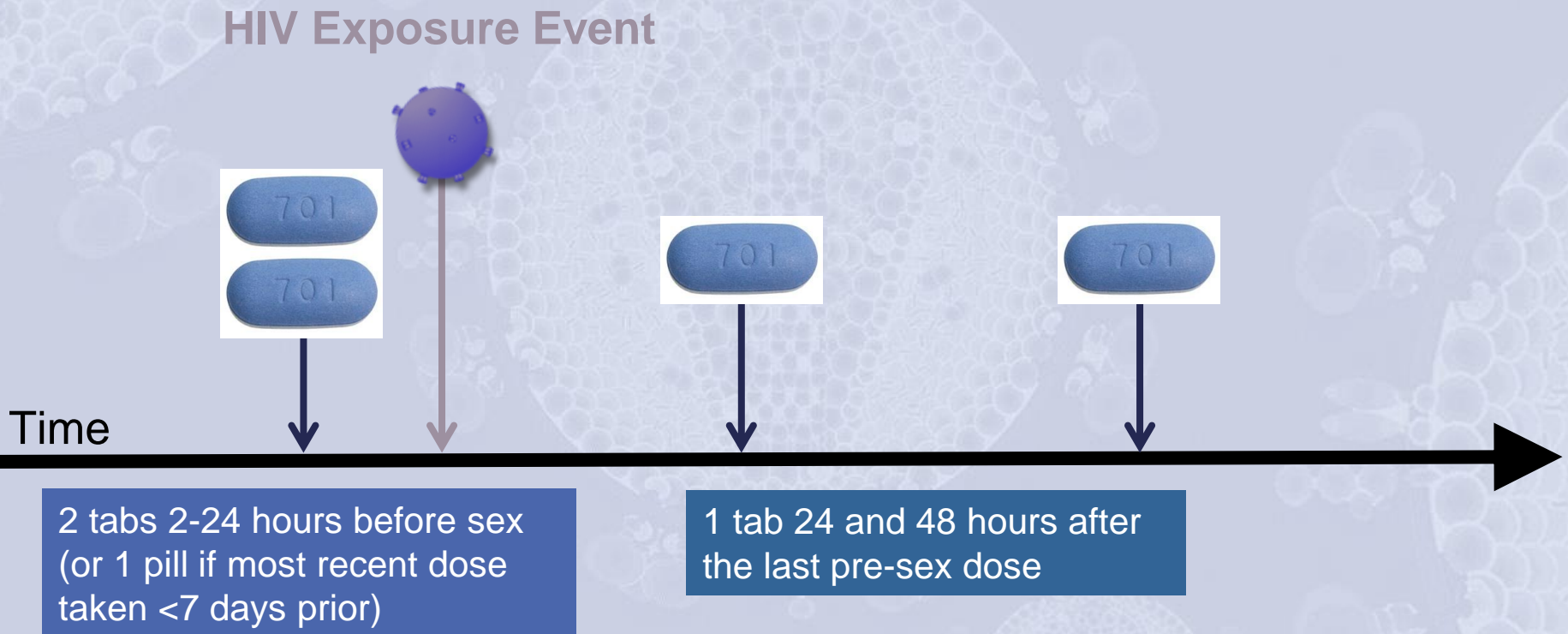
- PrEP Navigators
- Nurses/MA's/Phlebotomist
- Pharmacist – vital to help with insurance coverage of medication
- Provider
- Case Management
- Administrative support staff

Create a realistic and obtainable workflow

- Capacity of providers to see patients every 2 months
- Capacity of lab for bloodwork
- Capacity of trained injectors
- Tracking resources
- Medication storage

On-Demand PrEP for Men at High Risk for HIV IPERGAY: Design

IPERGAY On Demand Dosing Schedule



Who is a candidate for 2-1-1 PrEP?

- Off label using 2-1-1 dosing using F/TDF for:
 - **Cis gender MSM or trans-gender women who have sex with men**
 - **Those that can anticipate or plan for sex at least 2 hours in advance**
 - **Those who have sex <2 times per week**
 - **Those who fit the above criteria and would find intermittent PrEP more effective and convenient**
 - **No active HBV infection**

Efficacy of 2-1-1:

- Several studies around the world since IPERGAY have shown no significant difference in HIV incidence with on-demand PrEP users vs daily oral PrEP users

Molina J, Ghosn J, Assoumou L. ANRS-Prevenir. Lancet HIV 2022; Hojilla et al CID 2020. 71(10): 2710-2; Kwan JIAS 2021; Jongen JIAS 2021; Jongen JIAS 2021; 24(5); Laurent et al Lancet HIV 2021

World Health Organization. Technical brief: what's the 2+ 1+ 1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP. Geneva: World Health Organization; 2019.

Prescribing and Counseling on 2-1-1 PrEP

- Educate. Educate. Educate.
 - Ask for teach back, utilize visual aids, provide resources for patients to refer back to
- Stress importance of both pre and post sex dosing
- Counsel on “start up” symptoms that may occur
- Stress continued need for HIV/STI testing, Quarterly visits recommended
- Discuss how to switch back and forth safely
- Write Rx as 30-day daily dosing without refills

Disadvantages to 2-1-1:

- Lack of studies in cis gender women and transgender men
- Inability to predict sex, one study found 1/3rd of young MSM were unable to predict unprotected anal sex
 - Adherence to dosing schedule

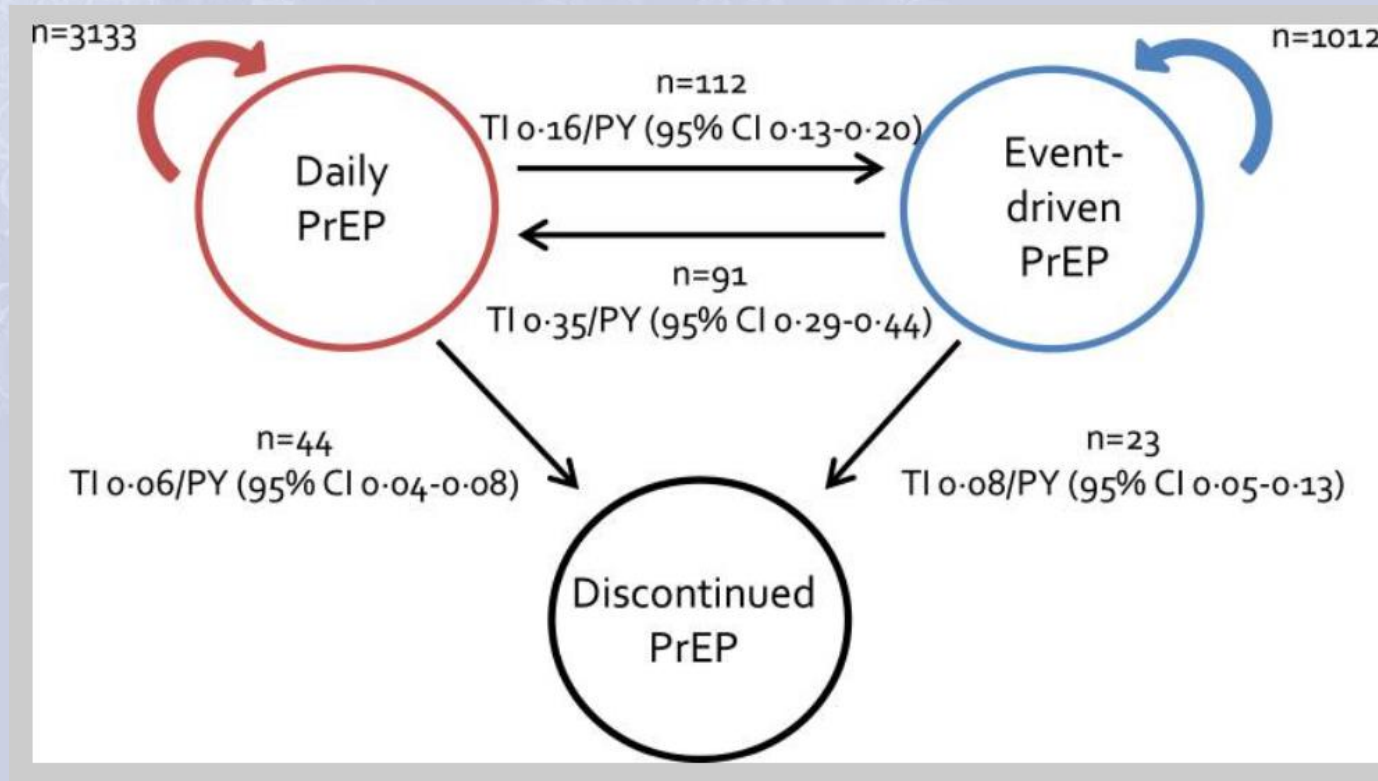
Why do people choose 2-1-1 dosing?

- Reasons for switching from daily to 2-1-1 dosing
 - Fewer sexual encounters (64%)
 - Desire for fewer pills (46%)
 - Reduced cost (22%)
 - Desire to reduce side effects (19%)
- Who is choosing 2-1-1 PrEP?
 - Those with barriers to daily PrEP
 - Those with lower comfort telling others about PrEP use
 - Those who identify as Bisexual
- Who is not choosing 2-1-1 that could benefit?
 - Those who are not aware of it as an option
 - ****Discuss as an option for patients who are thinking about discontinuing oral PrEP**

Camp & Saberi PLoS One 2021; 16(5); Liegeon J, Assoumou L, Ghosn J et al. ANRS-Prevenir Study. J Antimicrob Chemother 2022



Switching back and forth



121 switched their PrEP regimen at least once (34%)

67 participants discontinued PrEP (17.7%) with **no difference between regimens**

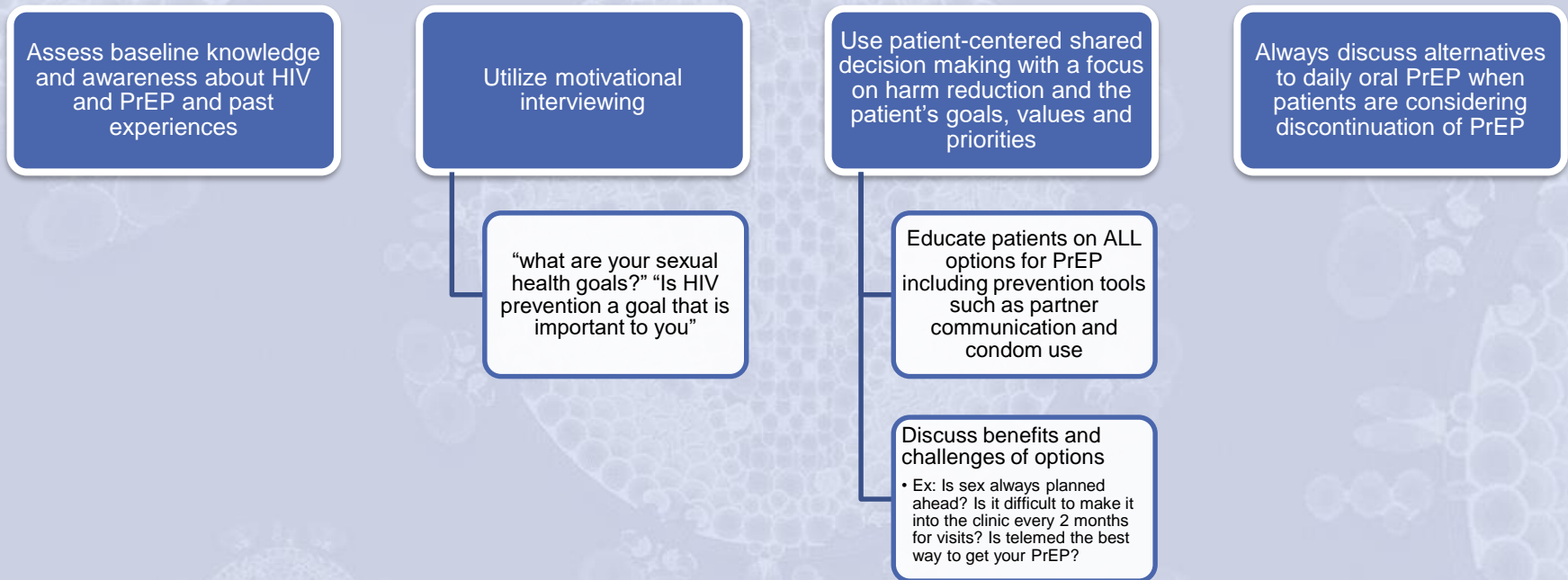
Coyer L, van den Elshout M, Achterbergh R. EclinicalMedicine 2020.

Post-Exposure Prophylaxis (PEP)

- 3-drug HIV regimen taken within 72 hours of a high-risk exposure
 - High-risk sexual exposure, including victims of sexual assault
 - Sharing needles and/or equipment to prepare drugs (i.e., cotton, cookers, water)
- Taken daily for total of 28 days
- Follow up after 4 weeks for repeat HIV/STI testing and to discuss transition to PrEP
- ****Educate patients on PEP whether they are on PrEP or not. This is vital information as an option following a possible exposure that they did not have protection for.**



Communication with patients: Which PrEP strategy to choose?



Incidence of HIV infection is 8 times higher in those who have discontinued PrEP

Future PrEP Options

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



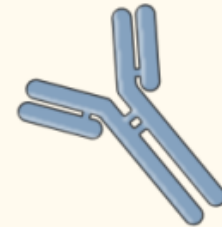
Device implanted in the body releases antiretroviral drug over time.

INJECTABLE



Long-acting antiretroviral drug is injected into the body.

ANTIBODY



Antibody is infused or injected into the body.

NIH/NIAID Infographic: Long-Acting Forms of HIV Prevention. Rev. Jul. 2019. <https://www.niaid.nih.gov/diseases-conditions/long-acting-forms-hiv-prevention>

MidAtlantic AIDS Education and Training Center - Contact Information

Regional Partner:

Debra D'Alessandro, MPH
MAAETC Regional Partner
Coordinator
Director of Public Health Training &
Technical Assistance
Health Federation of Philadelphia
215-567-8001
ddalessandro@healthfederation.org

Headquarters:

MidAtlantic AIDS Education and
Training Center
Department of Infectious
Diseases & Microbiology,
Graduate School of Public Health,
University of Pittsburgh
412-624-1895
maaetc@pitt.edu
www.maaetc.org

Linda Rose Frank, PHD, MSN, ACRN, FAAN
Principal Investigator and Program Director
Professor of Public Health, Medicine & Nursing
University of Pittsburgh

