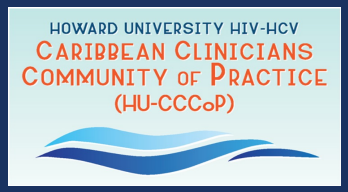
LONG-ACTING INJECTABLES FOR HIV TREATMENT AND PrEP: WHAT CLINICIANS NEED TO KNOW

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CME Disclosures:
Planning Committee And Speaker

Speaker: The following speaker has nothing to disclose in relation to this activity: Orlando O. Harris, Ph.D., RN, FNP, MPH, FAAN

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Goulda A. Downer, PHD, RD, LN, CNS – Principal Investigator/Project Director

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Goulda A. Downer, PhD, RD, LN, CNS
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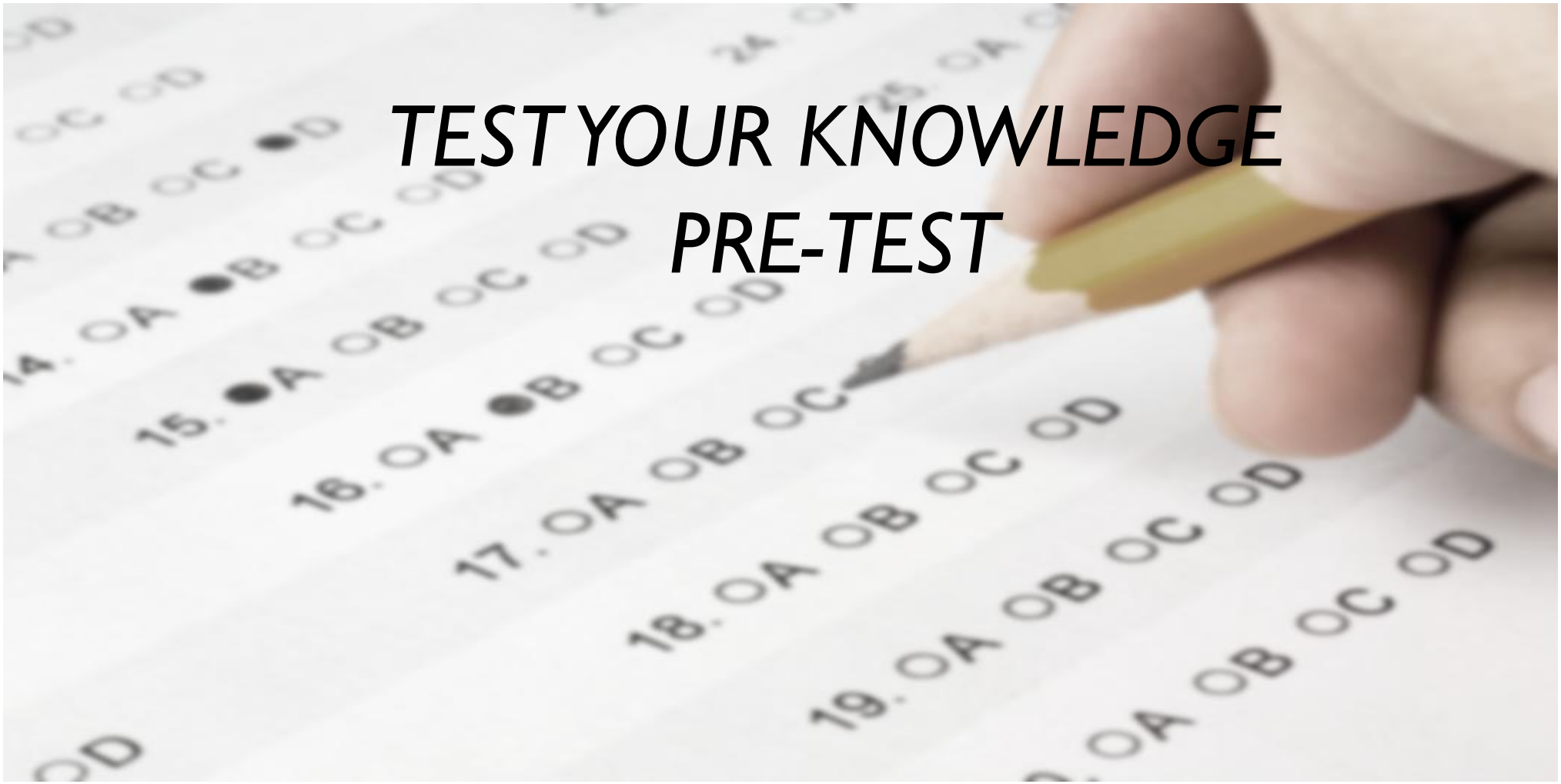
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TEST YOUR KNOWLEDGE
PRE-TEST

Test Your Knowledge
Question #1

Which of the following is NOT a component of a comprehensive HIV prevention plan to reduce HIV infection?

A. Consistent and correct use of condoms to avoid STIs

B. Risk reduction behavioral counseling

C. Biomedical interventions (i.e., PrEP, microbicides, and vaccines)

D. Testing once yearly for HIV and other STIs

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Test Your Knowledge
Question #2

Which of the following medication is NOT approved for HIV prevention?

A. Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)

B. Cabotegravir (200mg/ml)

C. Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose vial

D. All of the above

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Test Your Knowledge
Question #3

Which of the following injectable medications require a lead-in period prior to the first injection?

A. Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)

B. Cabotegravir (200mg/ml)

C. Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose vial

D. All of the above

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Test Your Knowledge
Question #4

Cabotegravir (200mg/mL)/rilpivirine (300mg/mL) or Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose can be used for the prevention of HIV?

A. True

B. False

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LONG-ACTING INJECTABLES FOR HIV TREATMENT AND PREP: WHAT CLINICIANS NEED TO KNOW

LEARNING OBJECTIVES

1. Identify and review current advances in biomedical interventions for the treatment and prevention of HIV (i.e., long-acting injectable ART and PrEP) and implications for use with high-risk sexually active adults
2. Identify barriers and challenges in the implementation of long-acting injectables for use in the Caribbean
3. Discuss the clinical significance for the use of long-acting injectables in sub-populations of high-risk sexually active adults in the Caribbean
4. Discuss potential strategies to maximize optimum uptake of long-acting injectables in accomplishing the UNAID 95-95-95 goals

State of the HIV/AIDS Epidemic in the Region – Epidemiology

HIV AND AIDS IN THE CARIBBEAN

- The Caribbean has the highest incidence of reported AIDS cases in the Americas
- With between 350,000 and 590,000 Caribbean people living with HIV/AIDS, the region has an adult HIV prevalence rate between 1.9% and 3.1% -
  - Second only to Sub-Saharan Africa (7.5% and 8.5%)
- The Caribbean has what is considered to have a mosaic-style epidemic
  - A mixed picture of generalized and concentrated epidemics.
  - Substantial differences exist within countries and across the region

CDC, 2023; UNAIDS 2023

HIV AND AIDS IN THE CARIBBEAN

- In 2019, 77% of people living with HIV in the Caribbean knew their status
  - This compares to the worldwide average of 81%
- Over 81% of diagnosed Caribbean people were on treatment in 2018
- Of those who are on antiretroviral medication, over 80% are virally suppressed.
  - This is slightly under the global average which was significantly higher at 88%
- The percentage of women with HIV who are getting lifelong antiretroviral treatment, which decreases the risk of their children being infected, rose to 86% in 2019 in the Caribbean, compared to 42% in 2010
- The percentage of children with HIV who are receiving antiretroviral treatment rose from 42% in 2017 in the Caribbean to 44% in 2019

Source: PANCAP, 2019; PAHO, 2020

AIDS-RELATED DEATHS IN THE REGION

- In 2018, there were 6,900 AIDS-related deaths in the region
- Deaths due to AIDS decreased by 37% since 2010
- Total antiretroviral treatment coverage for the region was 63%-71% for women and 56% for men



RATES OF NEW HIV INFECTIONS IN THE REGION

- New HIV infections decreased by 29% in the region since 2010
- One-third of new HIV infections in the Caribbean in 2019 were among young people ages 15 to 24
- Males ages 15 to 24 accounted for 57% of new infections



ACHIEVING THE 90-90-90 TARGETS

- Some countries have achieved elements of the 90-90-90 targets
  - 90% of PLHIV aware of their HIV status, 90% of diagnosed people on antiretroviral treatment and 90% of those on treatment virally suppressed
- Barbados has reached the target for testing while Guyana has exceeded it with 94% of PLHIV diagnosed
- Haiti has gotten 98% of diagnosed people on treatment
- Suriname and Trinidad have achieved viral suppression among at least 90% of PLHIW who are on treatment

CDC, 2023; PAHO, 2023

HIV AND AIDS IN THE CARIBBEAN – SELF-TESTING STRATEGIES

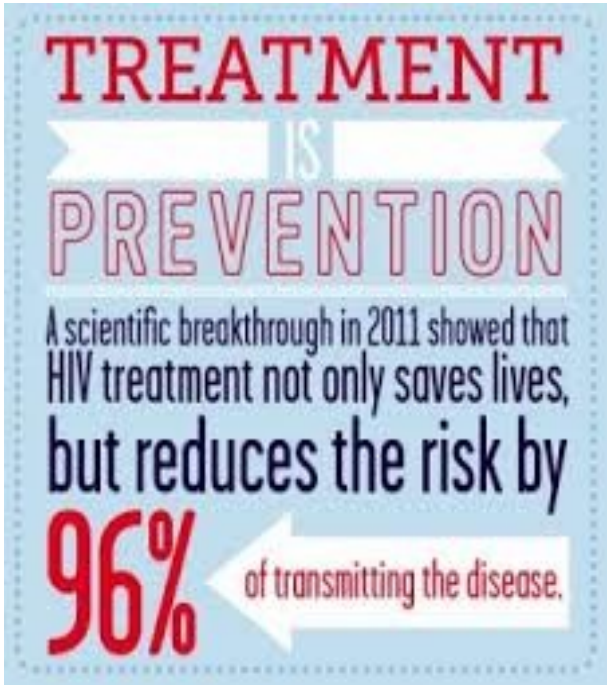
- HIV self-testing has emerged as a significant strategy to for reaching the UN goal of having 90% of people with HIV know their status.
  - Self-testing increases patient autonomy, decentralizes HIV services, and creates demand for HIV testing among those who have not been reached by other services.
  - Self-testing also opens the door for other opportunities to demedicalized PrEP and ARTs.



PAHO, 2020

HISTORICAL CONTEXT FOR TREATMENT AS PREVENTION

BIOMEDICAL ADVANCES



HISTORICAL CONTEXT OF TREATMENT AS PREVENTION AND BIOMEDICAL ADVANCES FOR PrEP

- In the early 1990s, medications were given to HIV positive expecting mothers to prevent HIV from being transmitted to their unborn child.
  - This innovative approached led to a 90% decrease to maternal-to-child transmission of HIV in the United States
    - As a result, today, infected moms have a less than 1% chance of infecting their baby
- In the mid-1990s, the introduction of highly active antiretroviral therapies (HAART) expanded the life expectancy in people living with HIV
- In the 1990s, post-exposure prophylaxis was used for the prevention of HIV in persons who were occupationally exposed to HIV

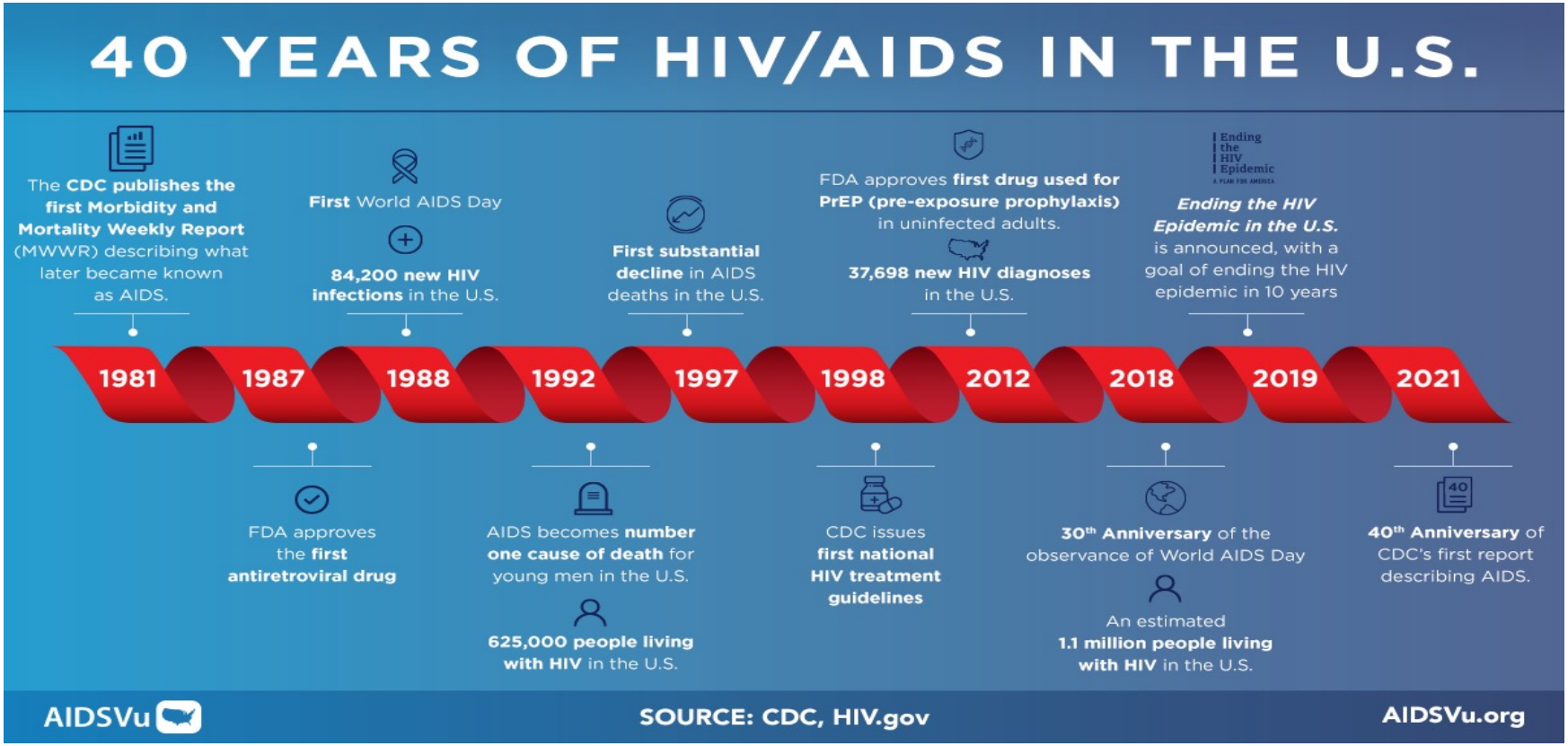
Grant et al., 2010; UCSF, 2015

HISTORICAL CONTEXT OF TREATMENT AS PREVENTION AND BIOMEDICAL ADVANCES FOR PrEP

- In the early parts of 2000s, research evidence emerged that showed that treatment of HIV-positive people could keep their HIV-negative partners uninfected.
  - This supported the rational for treatment as prevention
  - HIV Prevention Trials Network (HPTN) 052 study (2011) found a 96% reduction in HIV acquisition in sero-discordant relationships.

Grant et al., 2010; UCSF, 2015

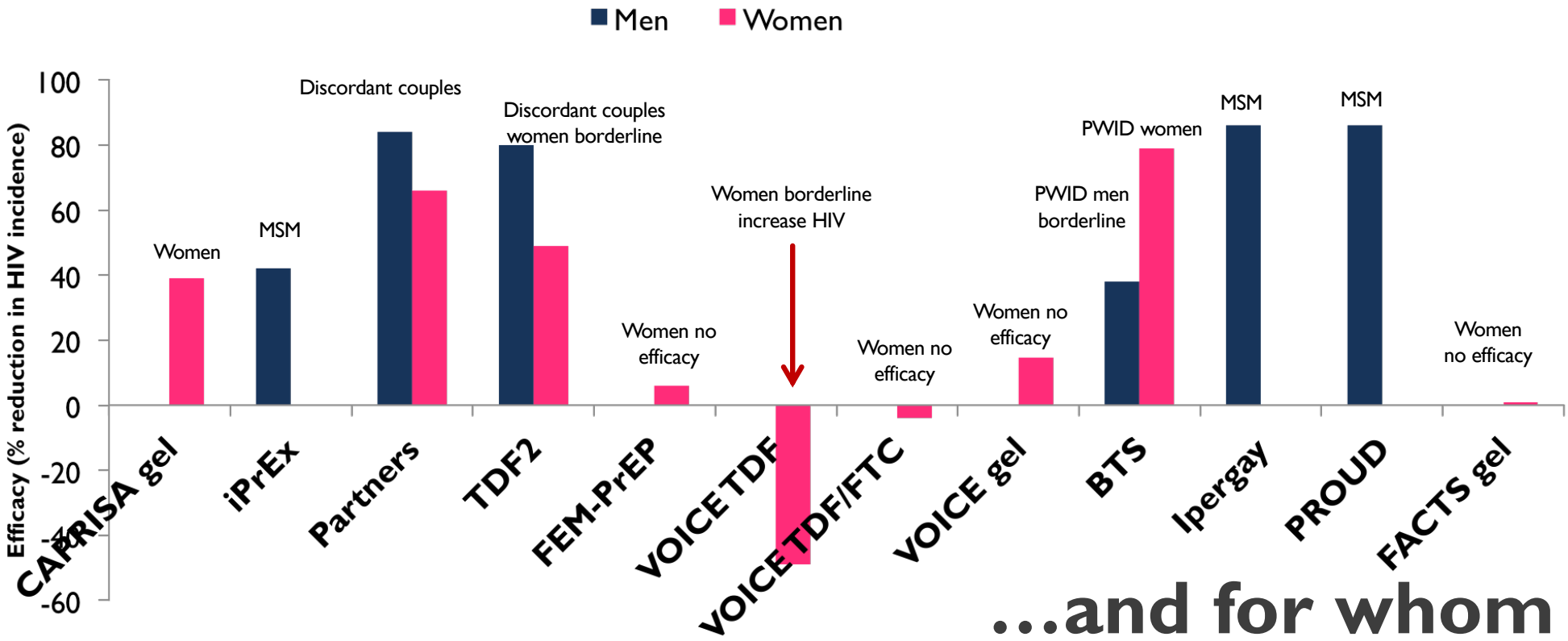
TIMELINE OF THE HIV CRISIS – FROM DEVASTATION TO THE END



RESEARCH SUPPORTING THE EVIDENCE FOR PrEP

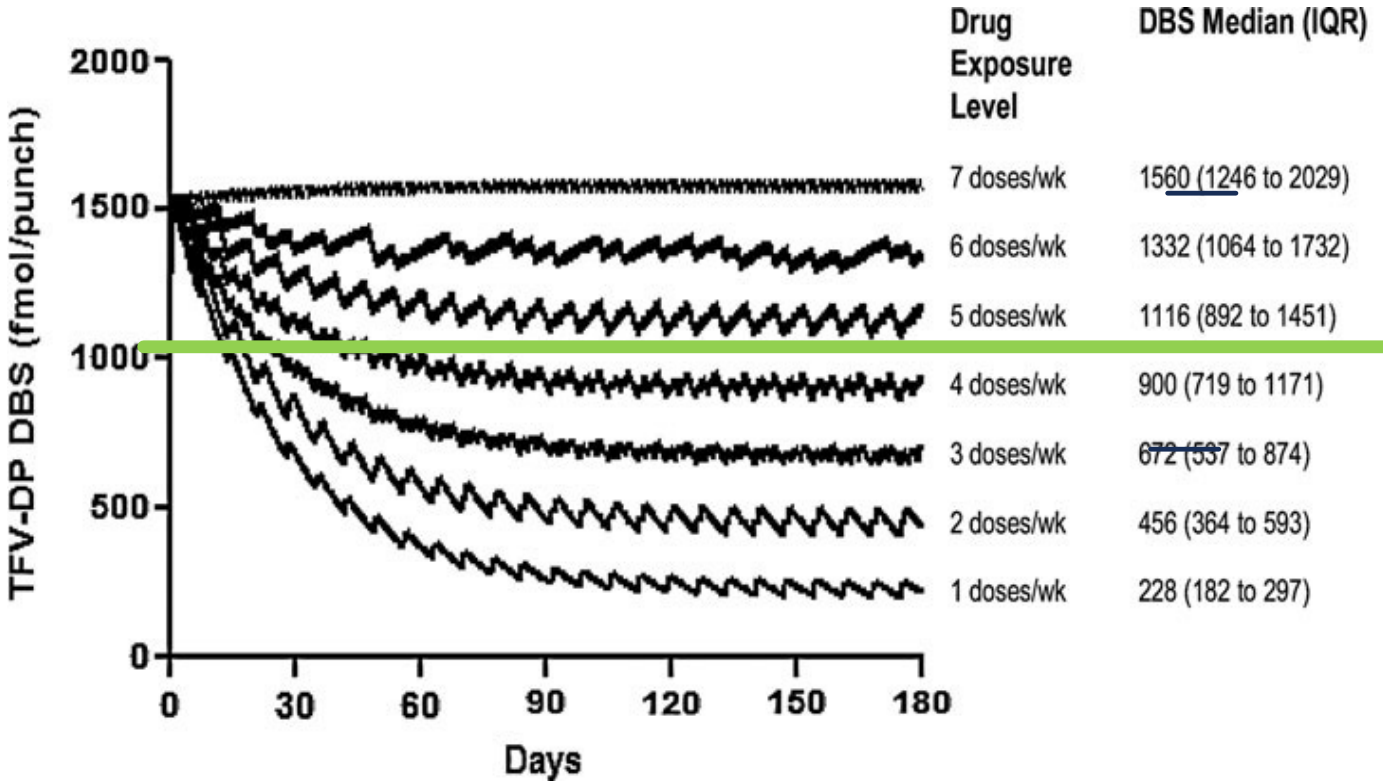


Evidence that PrEP works…



…and for whom

Need ≥4 of 7 daily pills per week



TFV-DP (fmol/punch)	Adherence Interpretation
>1250	daily dosing
>700 to 1250	4-6 doses/wk
350 to 700	2-3 doses/wk
<350	< 2 doses/wk

Castillo-Mancilla. 2012 AIDS Res Hum Retroviruses (PMID 22935078)

ADHERENCE CHALLENGES WITH ORAL PrEP

- Daily oral ART regimens have several inherent challenges for some people with HIV (PWH) or those at-risk, including:
  - Fear of disclosure
  - Stigmatization
  - Anxiety related to staying adherent
  - The daily reminder of HIV status
- Patients and providers have expressed interest in long-acting (LA) ART treatments with reduced dosing frequencies



CASE STUDY #1

CASE #1: MARCIA

Marcia is a 26-year-old transgender woman who was diagnosed with HIV one year ago. She is in her final year at the community college and has been working at a restaurant for the past six months. She lives with her parents. Marcia receives her HIV care at a community clinic that serves the LGBTQ community. She has been faithful in keeping appointments but not consistent with taking her ARTs. She admits to having multiple sex partners in the past but is now in a monogamous relationship for over a year with her partner, Jessie, a 32-year-old cisgender construction worker. On further assessment, she admits to socially using alcohol and marijuana– "mostly when I go to parties." While Jessie is aware of her alcohol and marijuana use, he has no knowledge of her HIV status. She has a history of depression, which is managed with medication. During her most recent visit to the clinic, her latest labs were as follows:

CD4+ T cell count: 410 cells/mm3
HIV RNA: 79,000 copies/mL
*Hepatitis C Antibody: Negative

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DISCUSSION

1. How would you proceed?
2. What factors need to be addressed to help Marcia stay adherent and virally suppressed?
3. Is she a good candidate for injectable ART medication?
4. Are there any ethical concerns that need to be addressed during this encounter?
5. What ethical responsibilities, if any, does the clinic have to Marcia?
6. How do we support her in disclosing her HIV status with her partner?
7. Discuss other cultural competence issues that may impact adherence to injectable ART and her ongoing retention in HIV care.

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Long-Acting Injectables for HIV Treatment and PrEP: What Clinicians Need to Know

LONG-ACTING HIV INJECTABLES – THE EVIDENCE

- Cabotegravir (CAB), an integrase strand transfer inhibitor (INSTI), and rilpivirine (RPV), a non-nucleoside reverse transcriptase inhibitor, have been developed for LA administration as intramuscular injections
- CAB+RPV LA has been approved for monthly dosing and every 2 months (Q2M) dosing in Australia, Canada, the European Union, and the United States (U.S.)
- Q2M dosing is commercially available in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hong Kong, Ireland, Italy, Japan, Norway, Poland, Sweden, Switzerland, Taiwan, the Netherlands, the United Kingdom
- The US. Approval of monthly dosing was based on the ongoing Phase 3 ATLAS (NCT02951052) and FLAIR (NCT02938520) studies, which demonstrated CAB+RPV LA dosed every 4 weeks (Q4W) was noninferior to daily oral ART over 48 weeks, with continued high rates of virologic suppression through 96 weeks of treatment

LONG-ACTING HIV INJECTABLES – THE EVIDENCE

- ATLAS-2M is a Phase 3b, randomized, multicenter study assessing the efficacy and safety of CAB+RPV LA every 8 weeks (Q8W) vs. 4 weeks (Q4W)

- Approval of Q2M dosing was based on the ongoing Phase 3b ATLAS-2M (NCT03299049) study, which demonstrated CAB+RPV LA dosed every 8 weeks (Q8W) was noninferior to Q4W dosing over 48 and 96 weeks, with similar safety profiles
  - Most participants preferred Q8W dosing over Q4W dosing and oral ART

- Virologically suppressed (HIV-1 RNA <50 copies/ml) individuals were randomized to receive CAB+RPV LA every 8 weeks (Q8W) or Q4W
  - Endpoint included the proportion of participants with plasma HIV-1 RNA ≥50 copies/mL and <50 copies/m/L, incidence of confirmed virologic failure (CVF; two consecutive measurements of ≥200 copies/mL), safety, and tolerability

LONG-ACTING HIV INJECTABLES – THE EVIDENCE

- 1045 participants received Cab+RPV LA (Q8W, n=522; Q4W, n=523). CAB+RPV LA Q8W demonstrated noninferior efficacy vs. Q4W dosing, with 2.7% (n=14) and 1.0% (n=5) of participants having HIV-1 RNA ≥50 copies/mL, respectively
- The adjusted treatment difference in proportions was 1.7% (95% CI 0.1 to 3.3), meeting the pre-specified noninferiority threshold of 4%. At week 152, 87% of participants maintained HIV-1 RNA <50 copies/mL (Q8W, 87% [n=456]; Q4W, 86% [n=449])
- Overall, 12 (2.3%) participants in the Q8W arm and two (0.4%) participants in the Q4W arm had CVF. Eight and 10 participants with CVF had treatment-emergent resistance-associated mutations to RPV and integrase inhibitors, respectively
- Safety profiles were comparable, with no new safety signals observed since week 48

LONG-ACTING HIV INJECTABLES – THE EVIDENCE

Lenacapavire in multidrug resistant HIV (CAPELLA Study)

- Phase 3, randomized, trial with oral and subcutaneous lenacapavir, a first-in-class capsid inhibitor, versus optimized background therapy (OBT)
- Enrollment Criteria:
  - Age ≥12 years
  - Virologic failure on current ART
  - HIV RNA >400 copies/mL for ≥8 wks
  - Documented HIV drug resistance to at least 2 HIV medications from at least 3 of the 4 main classes
  - At least one fully active agent available for HIV treatment

Source: Segal-Maurer S, et al. N Engl J Med. 2022;386:1793-1803.

LONG-ACTING HIV INJECTABLES – CAPELLA STUDY

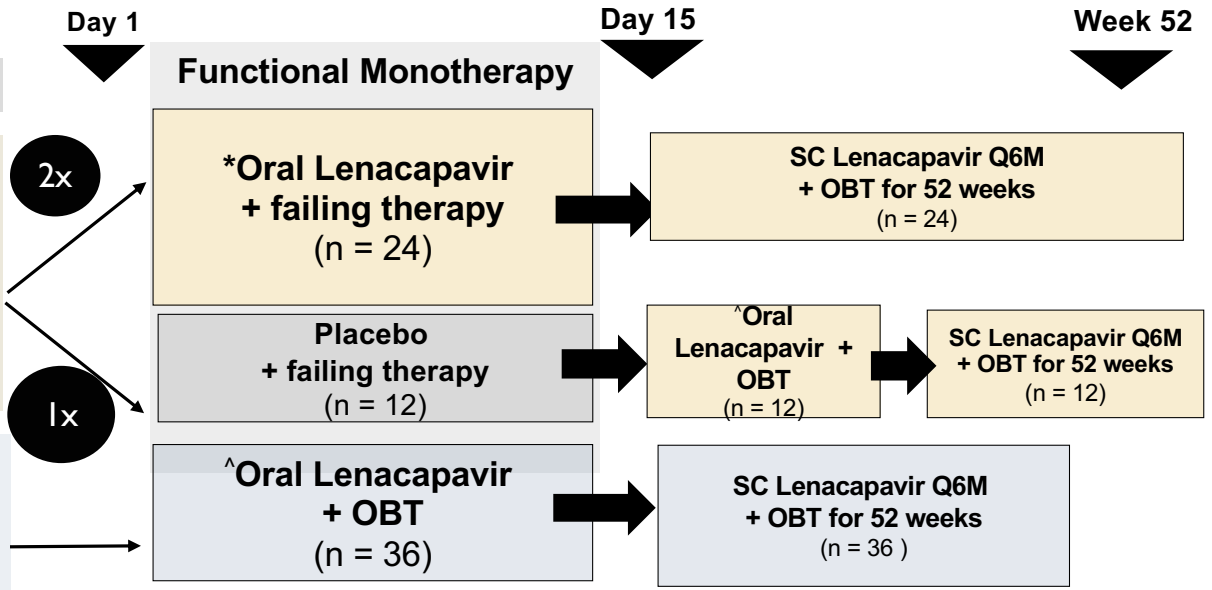
Study Cohorts

Cohort 1 (Randomized, Stable Viremia)

- First 36 participants with:
  - HIV RNA decrease <0.5 log between the screening and cohort-selection visits
    and
  - HIV-1 RNA ≥ 400 copies/mL during screening

Cohort 2 (Nonrandomized, Reduced Viremia)

- Participants with:
  - HIV RNA decrease ≥0.5 log between the screening and cohort-selection visits
    or
  - HIV-1 RNA <400 copies/mL during screening



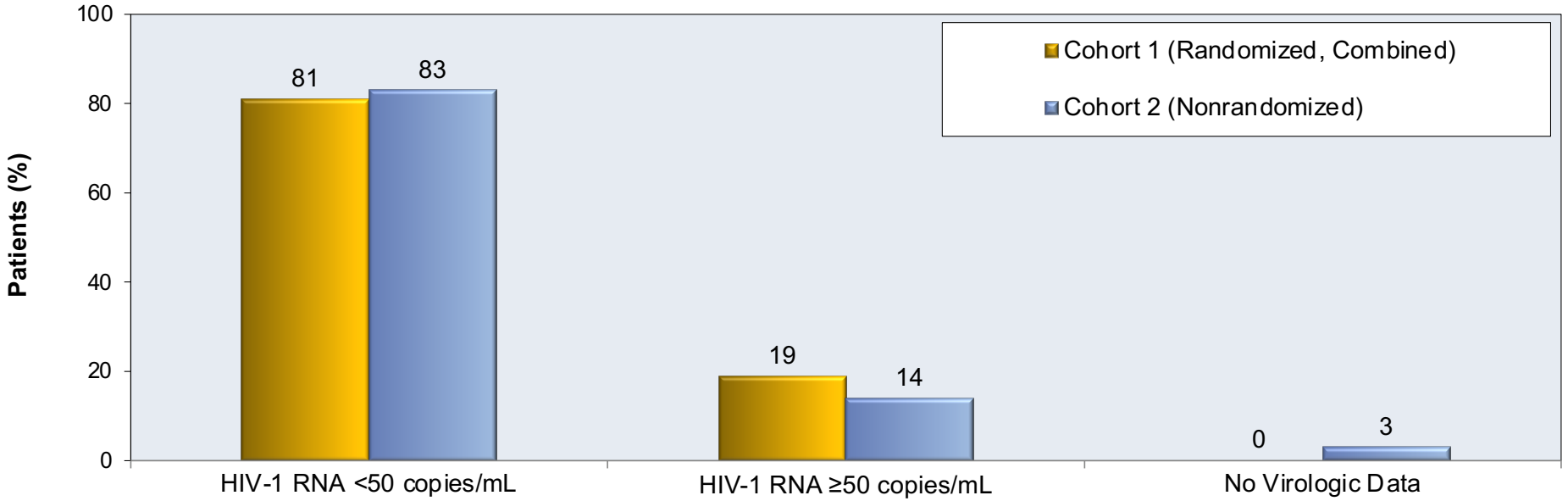
OBT = optimized background regimen

*Oral lenacapavir = 600 mg days 1 and 2, 300 mg day 8
^Oral lenacapavir = 600 mg days 15 and 16, 300 mg day 22
SC Lenacapavir = 927 mg every 6 months

- Source: Segal-Maurer S, et al. N Engl J Med. 2022;386:1793-1803.

LONG-ACTING HIV INJECTABLES – CAPELLA STUDY

- Virologic Responses at 26 Weeks



Source: Segal-Maurer S, et al. N Engl J Med. 2022;386:1793-1803.

LONG-ACTING HIV INJECTABLES – CAPELLA STUDY

- **Conclusions**: "In patients with multidrug-resistant HIV-1 infection, those who received lenacapavir had a greater reduction from baseline in viral load than those who received placebo."

Source: Segal-Maurer S, et al. N Engl J Med. 2022;386:1793-1803.

LONG-ACTING HIV INJECTABLES – HIV TREATMENT

- Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)
  - Approved to treat HIV-1 infection in people 12 years and older
  - It is a co-packaged antiretroviral medication.
  - The package consist of cabotegravir and rilpivirine with two separate injection vials.
    - Administered as two separate intramuscular injections every other month

LONG-ACTING HIV INJECTABLES – HIV TREATMENT

- Common side effects of Cabotegravir/rilpivirine:
  - Pain and tenderness, hardened mass of lump, swelling, redness, itching, bruising, and warmth at the injection site
  - Fever
  - Tiredness
  - Headaches
  - Muscle or bone pain
  - Nausea
  - Dizziness
  - Sleep problems

LONG-ACTING HIV INJECTABLES – HIV TREATMENT

Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)

- Cost:
  - $4,456.20 ($1,114.05 per unit) – 4 milliliters
  - $6,679.54 ($1,113,26 per unit) – 6 milliliters

- Storage: 2°C to 8°C (36°F to 46°F) in the original carton until ready to use. Do not freeze

LONG-ACTING HIV INJECTABLES – HIV TREATMENT

Monthly injection		≤ 2 months	Resume monthly injection as soon as possible.
		> 2 months	Re-initiate 1 injection of 600 mg cabotegravir and 1 injection of 900 mg rilpivirine and then continue with 400 mg of cabotegravir and 600 mg of rilpivirine.
2-month injection	Missing the second dose	≤ 2 months	Resume 2-month injection as soon as possible.
		> 2 months	Re-initiate 1 injection of 600 mg cabotegravir and 1 injection of 900 mg rilpivirine and then continue with the initiation dose 1 month later. Then, continue with 2-month schedule.
	Missing the third or later dose	≤ 3 months	Resume 2-month injection as soon as possible.
		> 3 months	Re-initiate 1 injection of 600 mg cabotegravir and 1 injection of 900 mg rilpivirine and then continue with the initiation dose 1 month later. Then, continue with 2-month schedule

LONG-ACTING HIV INJECTABLES – HIV TREATMENT AND PrEP

- Lenacapavir
  - Approved by the FDA in 2022 for the treatment and prevention of HIV-1 infection in in people 12 years and older
  - Indicated for treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant infection

LONG-ACTING HIV INJECTABLES – HIV TREATMENT AND PrEP

- Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose vial
  - Approved by the FDA in 2022 for the treatment and prevention of HIV-1 infection in in people 12 years and older
  - Each kit contains 2 single-dose vials, each containing sufficient volume to provide 927mg dose
  - Administered as one single subcutaneous injection (927mg) every 6 months

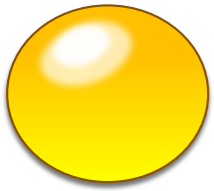
LONG-ACTING HIV INJECTABLES – LENACAPAVIR

- **Type of Medication**
  - HIV capsid inhibitor
- **Indication**
  - Treatment of HIV-1 in combination with other antiretroviral medications in heavily treatment-experienced adults with multidrug resistant HIV
- **Preparations**
  - Oral: 300 mg tablets
  - Subcutaneous injection: 463.5 mg/1.5 mL vial
- **Adverse Reactions**
  - Most common adverse effects are nausea and injection site reactions
- **Contraindications**
  - Contraindicated to give with strong CYP3A inducers

Source: Lenacapavir Prescribing Information.

LONG-ACTING HIV INJECTABLES – LENACAPAVIR

Oral Lenacapavir



300 mg tablets

Take with or without food

Subcutaneous Lenacapavir



Each 1.5 mL vial = 463.5 mg

Administer as Subcutaneous Injection

Source: National HIV Curriculum; Lenacapavir Prescribing Information

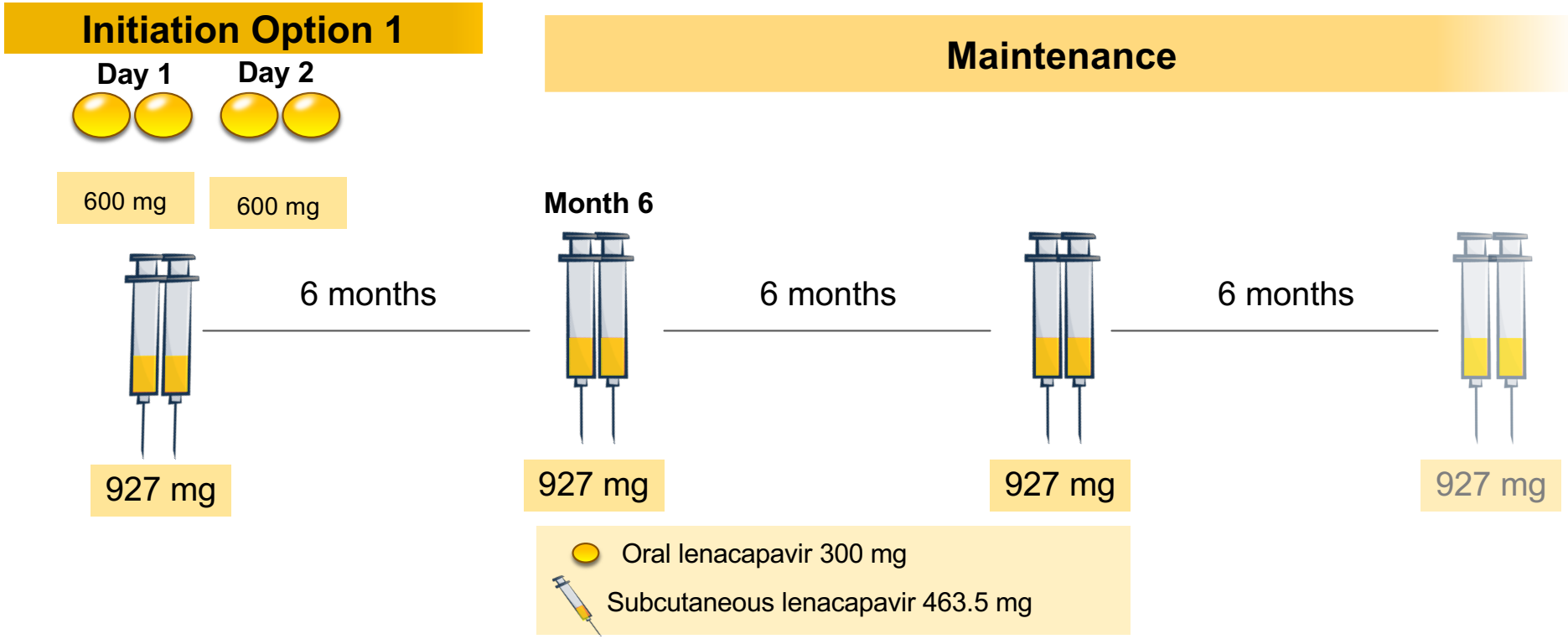
LONG-ACTING HIV INJECTABLES – LENACAPAVIR

Lenacapavir Dosing Schedule

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) + 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Initiation Option 2	
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	300 mg orally (1 x 300 mg tablets)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance	
927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from date of the last injection +/-2 weeks	
Missed dose: If more than 28 weeks since last injection and clinically appropriate to continue lenacapavir, restart initiation from Day 1, using either Option 1 or Option 2	

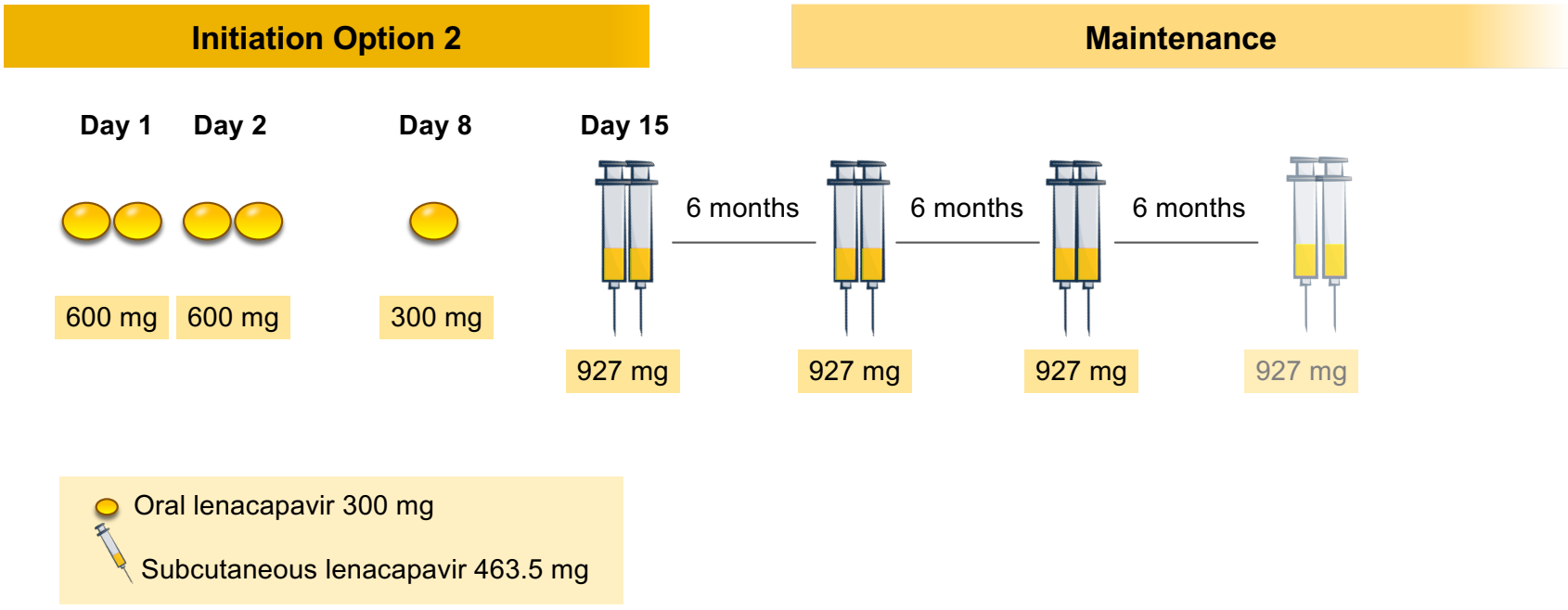
Source: National HIV Curriculum; Lenacapavir Prescribing Information

LONG-ACTING HIV INJECTABLES – LENACAPAVIR – OPTION 2



Source: National HIV Curriculum; Lenacapavir Prescribing Information; David H. Spach, MD

LONG-ACTING HIV INJECTABLES – LENACAPAVIR – OPTION 2



Source: National HIV Curriculum; Lenacapavir Prescribing Information; David H. Spach, MD

LONG-ACTING HIV INJECTABLES – LENACAPAVIR

- Cost: $42,250 in first year of treatment (injection and oral tablets); $39,000 annually
- Storage: Dry, dark and at 0 - 4 C (32 – 39 F) for short term (days to weeks) or -20 C (-4 F) for long term (months to years)



LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

- The FDA in 2021 approved cabotegravir for the prevention of HIV in at-risk adults and adolescents weighing at least 77 pounds
- The medication is administered every 2 months after two initial injections that are given 1 month apart



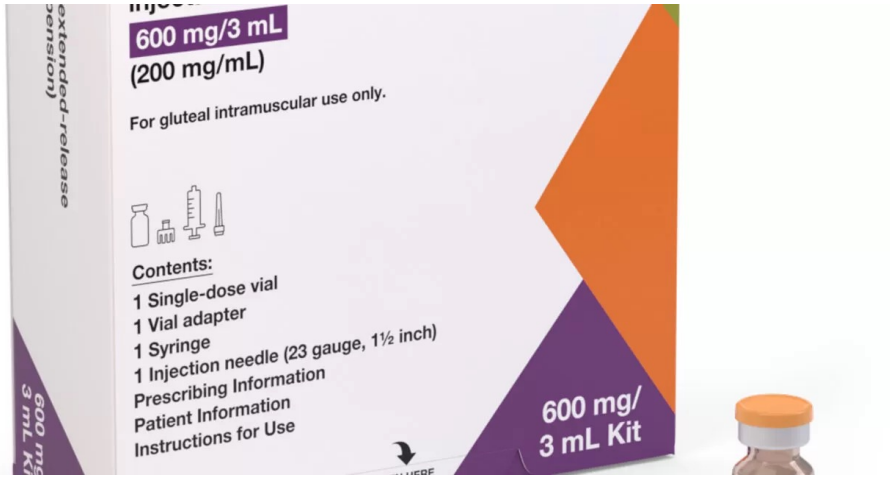
LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

- Cabotegravir 200mg/ml
  - Approved to prevention of HIV-1 infection in people 12 years and older who weigh at least 77 pounds
  - It is an extended-release injectable suspension antiretroviral medication for PrEP
  - The package consist of cabotegravir medication injection vial
  - Administered as an intramuscular injection every other month
    - After 2 initial injections given 1 month apart



LONG-ACTING HIV INJECTABLES – HIV TREATMENT

- Common side effects of Cabotegravir:
  - Pain and tenderness, hardened mass of lump, swelling, redness, itching, bruising, and warmth at the injection site
  - Fever
  - Tiredness
  - Headaches
  - Muscle or bone pain
  - Nausea, dizziness, sleep problems
  - Abscess and discoloration
  - Diarrhea



LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

Cabotegravir 200mg/ml

- Cost:
  - $3,964.04 ($1,321.35 per unit) – 3 milliliters

- Storage: 2°C to 25°C (36°F to 77°F). Exposure up to 30°C (86°F) permitted



LONG-ACTING HIV INJECTABLES – TREATMENT AND PREVENTION

- Who is injectable for?
  - Injectables are for people who are living with HIV or are at risk for getting HIV from sex or injection drug use
  - Injectables are highly effective at protecting patients from HIV or to treat HIV in treatment experience patients
  - Injectables can be an excellent option for people who:
    - Have problems taking oral pills as prescribed
    - Prefer getting an injection every 2-6 months instead of daily oral pills
    - Have serious kidney disease that prevents use of oral medications

LONG-ACTING HIV INJECTABLES – TREATMENT AND PREVENTION

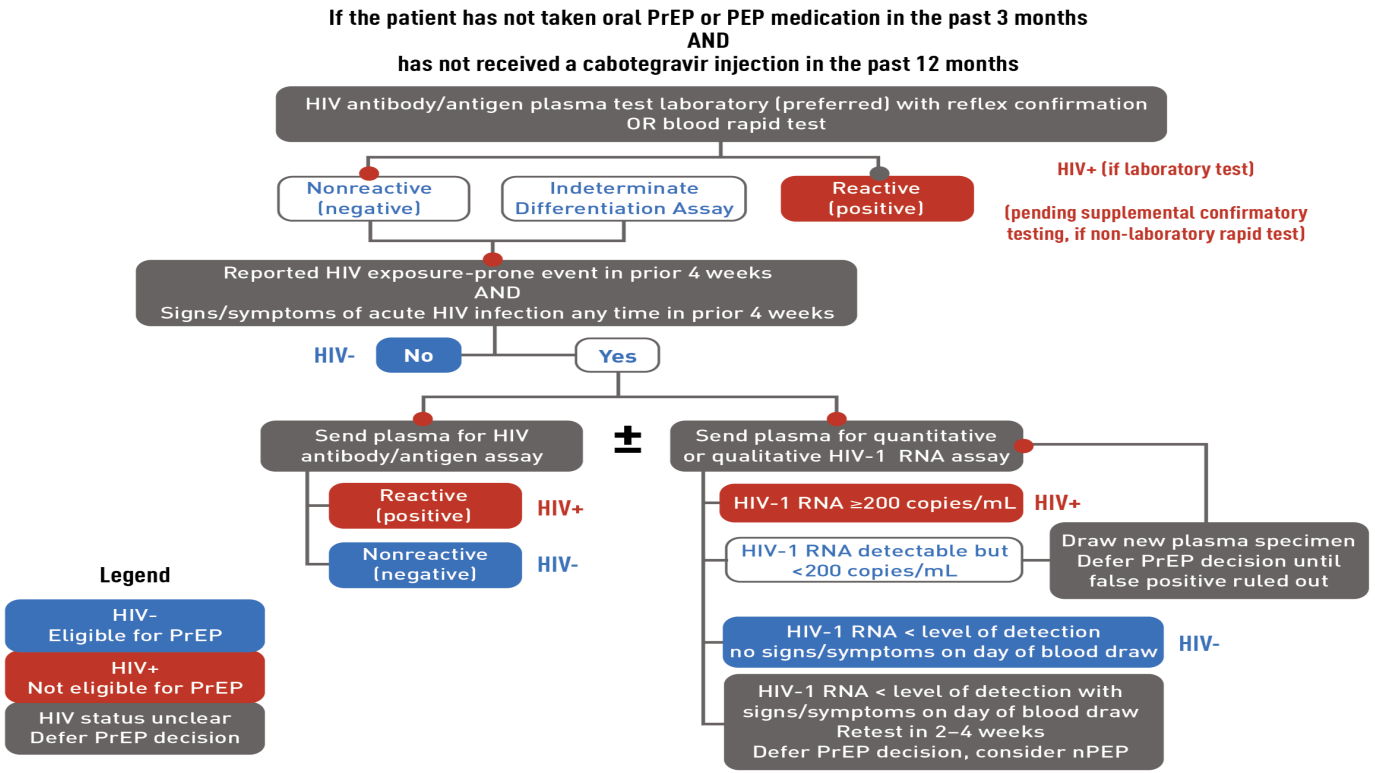
- Injectables are approved as an intramuscular injection in the buttocks or subcutaneous
- A 4-week lead-in period of 30mg daily oral CAB prior to the first injection is optional for patients who are worried about side effects.
- Lanacapavir is approved for twice yearly injections (Q6 months) for the prevention and treatment of HIV-1 infection.

LONG-ACTING HIV INJECTABLES – PREVENTION AND TREATMENT

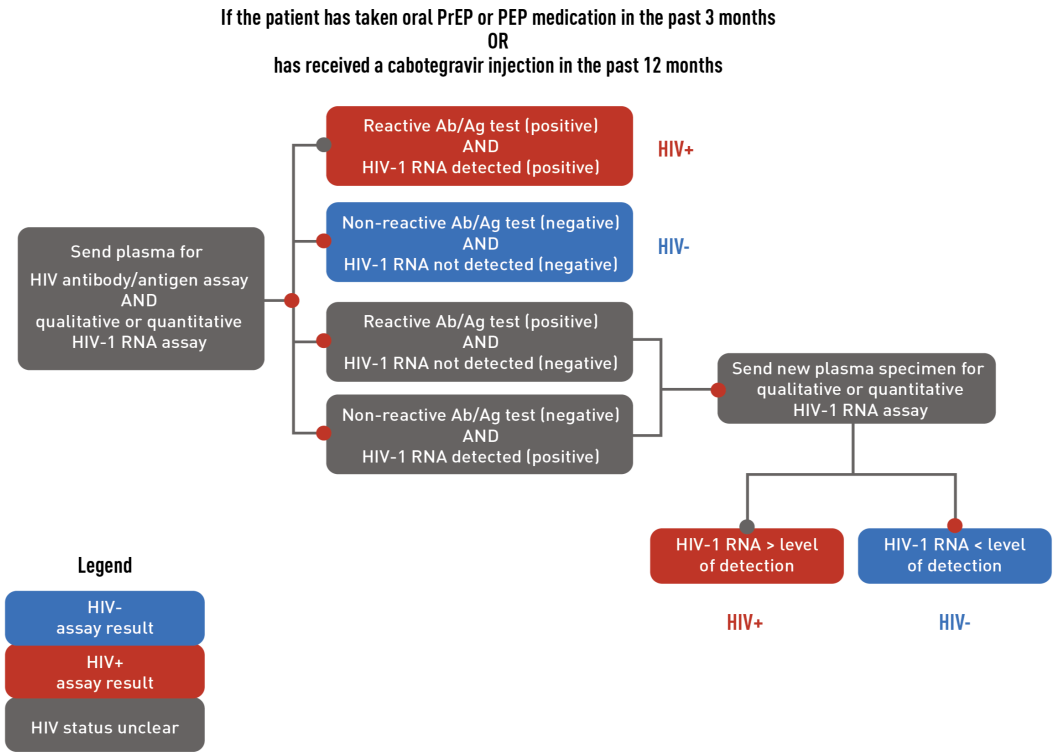
Baseline assessments needed before prescribing injectables to all population living with or at risk for HIV

- Perform the following baseline assessments for all injectable PrEP candidates:
  - HIV testing: Confirm that the patient does not have HIV before prescribing PrEP
  - Sexually transmitted infection (STI) testing: Screen injectable PrEP candidates who are sexually active for chlamydia, gonorrhea, and syphilis

FLOWCHART FOR INJECTABLE PrEP INITIATION

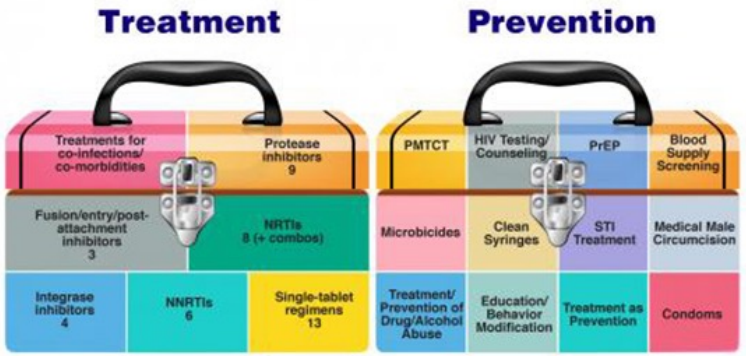


FLOWCHART FOR INJECTABLE PrEP INITIATION



LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

- What ongoing support and assessments are required for patients on injectable PrEP?
  - PrEP should be prescribed as part of a combination prevention plan
  - At minimum, while patients are on injectable PrEP, CDC recommends that health care provides perform routine follow-up with patients



LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

What ongoing support and assessments are required for patients on injectable PrEP?

- At visit 1 month after initial injection (month 1, second injection
  - Test for HIV antigen/antibody and HIV-1 RNA assays and assess for signs or symptoms of acute injection
  - Administer CAB injection
  - Respond to new questions
  - Provide medication adherence and behavioral risk-reduction support

LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

What ongoing support and assessments are required for patients on injectable PrEP?

- At each bimonthly visit (beginning with the third injection in months 3)
  - Test for HIV with antigen/antibody and HIV-1 RNA assays and assess for signs or symptoms of acute injection.
  - Administer CAB injection
  - Respond to new questions and provide any new information about CAB for PrEP
  - Discuss the benefits of persistent CAB for PrEP use and adherence to schedule injection visits.

LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

What ongoing support and assessments are required for patients on injectable PrEP?

- At least every 4 months (every other injection visit, beginning with the third injection in month 3)
  - Conduct bacterial STI screening for gay, bisexual, and other men who have sex with men and transgender women who have sex with men (oral, rectal urine, blood)

LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

What ongoing support and assessments are required for patients on injectable PrEP?

- At least every 6 months (beginning with the fifth injection in month 7)
  - Screen all heterosexually active people for bacterial STIs (vaginal, rectal, urine, as indicted; blood).

LONG-ACTING HIV INJECTABLES – HIV PREVENTION (PrEP)

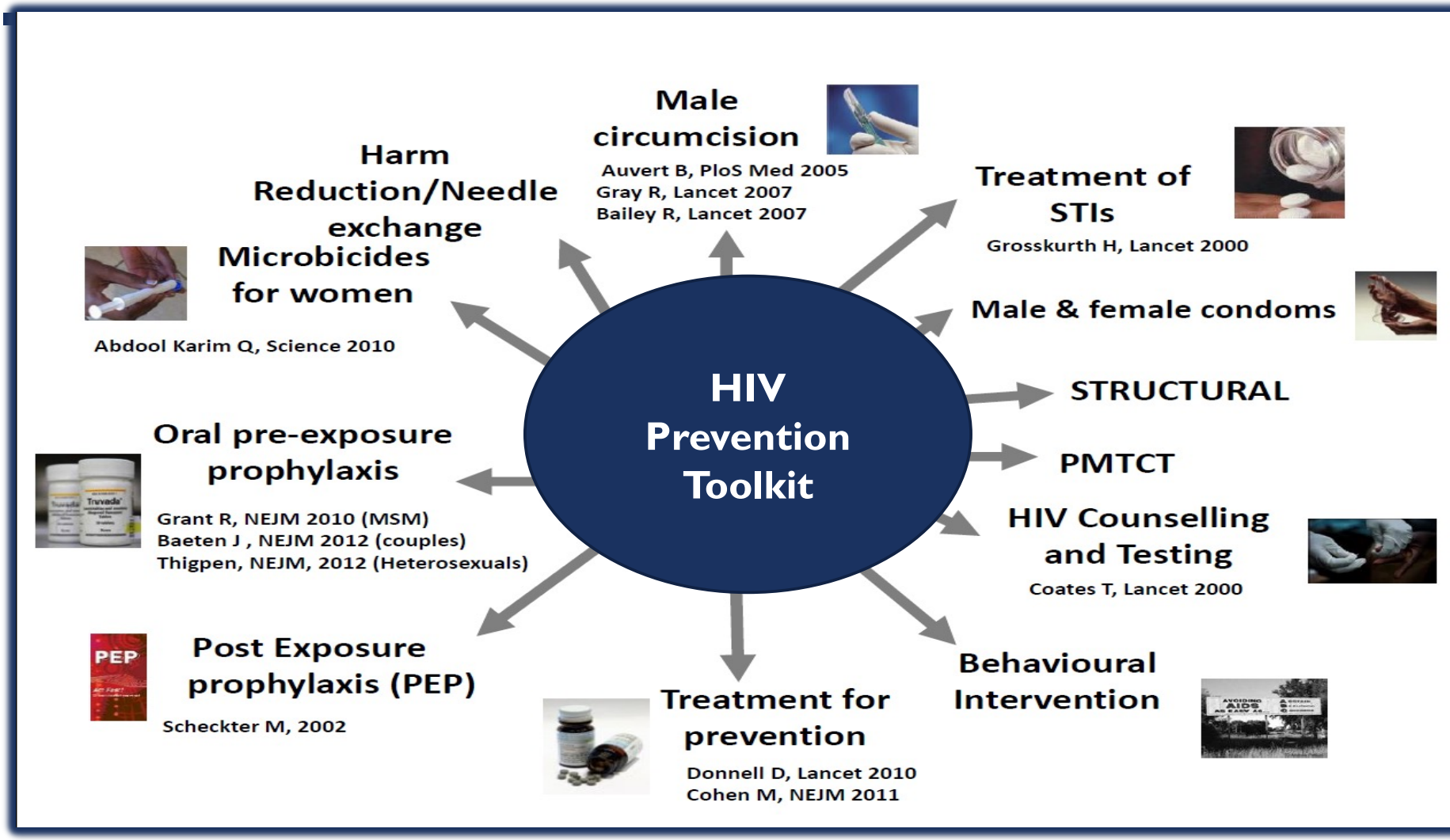
What ongoing support and assessments are required for patients on injectable PrEP?

- At least every 12 months (after the first injection)
  - Assess desire to continue PrEP injections
  - Screen all sexually active people for STI, even if asymptomatic.

RISK REDUCTION COUNSELING FOR PREVENTION OF HIV

AIDS FREE GENERATION




HIV Prevention Toolkit
Male circumcision
Auvert B, PloS Med 2005
Gray R, Lancet 2007
Bailey R, Lancet 2007
Treatment of STIs
Grosskurth H, Lancet 2000
Male & female condoms
STRUCTURAL
PMTCT
HIV Counselling and Testing
Coates T, Lancet 2000
Behavioural Intervention
Treatment for prevention
Donnell D, Lancet 2010
Cohen M, NEJM 2011
Post Exposure prophylaxis (PEP)
Scheckter M, 2002
PEP
Oral pre-exposure prophylaxis
Grant R, NEJM 2010 (MSM)
Baeten J , NEJM 2012 (couples)
Thigpen, NEJM, 2012 (Heterosexuals)
Truvada
Harm Reduction/Needle exchange
Microbicides for women
Abdool Karim Q, Science 2010

BIOMEDICAL ADVANCES- POTENTIAL FOR ENGAGING IN RISKY BEHAVIORS WHILE ON PrEP?

- **Thoughts on Risk Compensation**
  - Risk compensation is the idea that as a person feels greater protection from potentially contracting HIV - they may compensate by taking greater risk
    - They may engage in more unprotected sex with more people
  - None of the studies mentioned above supported the argument of sexual risk compensation by people taking PrEP
  - Risk reduction counseling should still be offered as a part of a **comprehensive prevention strategy**

CDC, 2013; Cassell, Halperin, Shelton, and Stanton, 2006)

BIOMEDICAL ADVANCES- COMPREHENSIVE PREVENTION PLAN

- PrEP should be a component of a comprehensive strategy for the prevention of and should include counseling about the following:
  - *Consistent and correct use of condoms to avoid STIs
  - Safer sex practices and risk-reduction options
  - Mutual monogamy
  - Knowledge of their HIV status and that of their partner(s)
  - Routine screenings for other sexually transmitted diseases
  - Mental health and substance use screening, when indicated
- It is important to instruct clients that having an STI can increase a person's chance of becoming infected with HIV if they are exposed to it. It is recommended that we should educate our patients on the signs and symptoms of STIs and the importance of treatment.

CDC, 2013; NYS Task Force to End AIDS, 2015

CASE STUDY #2

CASE #2: THE SERO-DISCORDANT COUPLE

"Marcus Jackson," a 22-year-old male, comes to see you in your primary clinic today for a follow-up visit and HIV testing. His partner of four weeks disclosed his HIV status to Marcus by revealing that he was seen three months ago in the Emergency Department (ED) and was diagnosed with acute HIV infection.

Your medical records for Marcus noted that his last HIV test was three months ago, and the result was negative. He likes this person and would like to continue seeing them. Although they are not currently sexually active, Marcus revealed to you that he does not use condoms consistently as he finds them to be uncomfortable. He is in your office today to discuss possible options that may prevent him from acquiring HIV while in a relationship with his partner. What are his options?

WHAT ELSE DO WE NEED TO KNOW ABOUT PREP? LOTS!

- Community input on how PrEP should be delivered
- Provider input and barriers to prescribing PrEP
- Contraindications (creatinine clearance, liver function, HBV)
- Counseling messages (e.g., continue condom use)
- Risk compensation (individuals, society)
- Risk compensation (individuals, society)
- HIV testing frequency (e.g., quarterly for study, then?)
- STI screening and treatment
- Side effects (neuro, GI)
- ART resistance
- Cost, cost-effectiveness
- Delivery system, sustainability

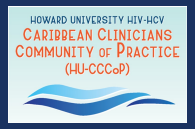
SUMMARY

- Long-acting injectable HIV medication was approved in the United States was approved by the FDA for treatment and prevention of HIV infection
- The evidence to date supports the application of injectables as an effective treatment and prevention strategy for those non-adherent to daily oral pills
- Injectables used for PrEP should be used as a component of a larger prevention plan to reduce incidence of new HIV infections

SUMMARY

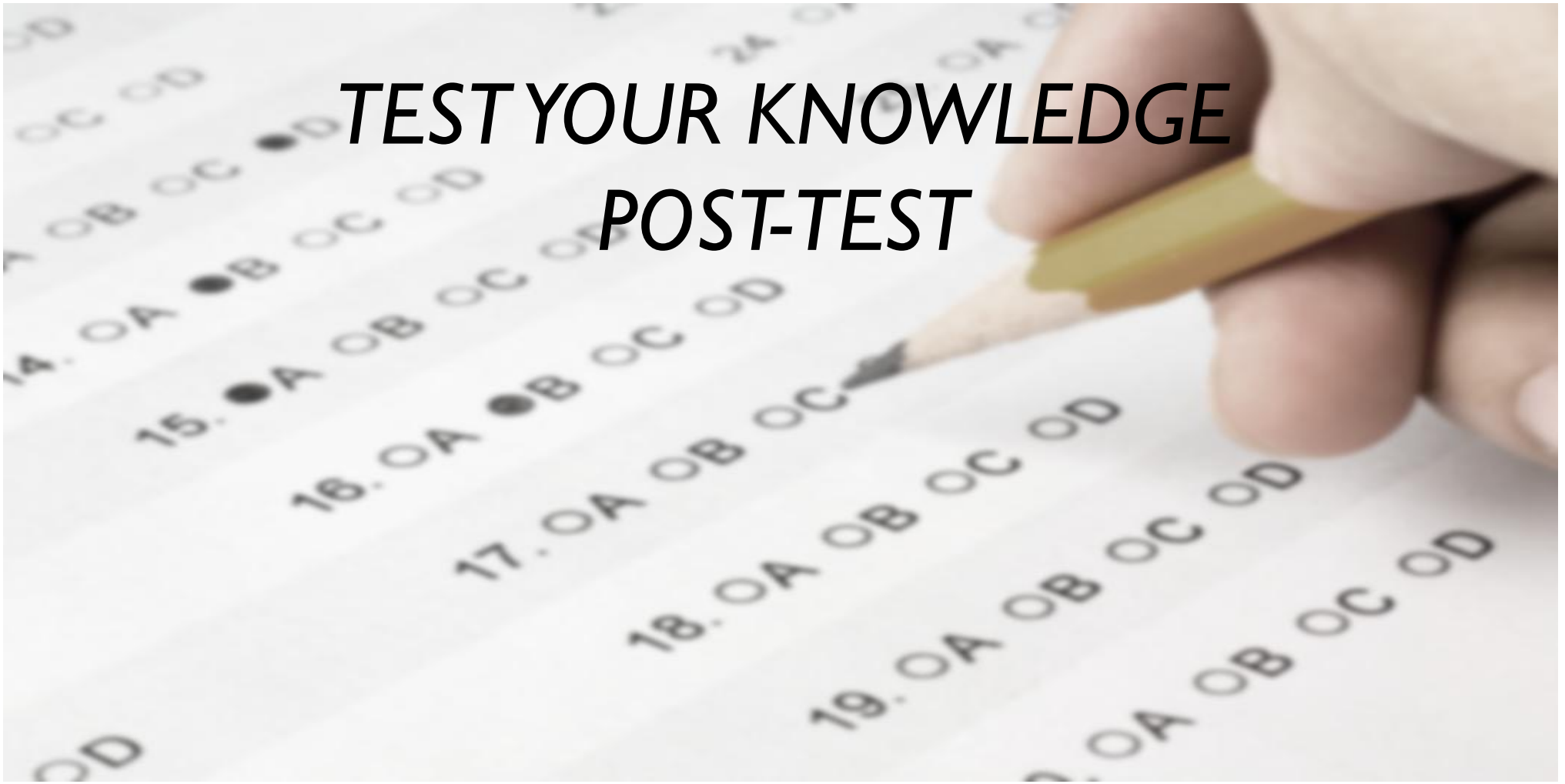
- Cost and storage requirements pay present a challenge for clinics without adequate resources
- Special considerations should made for populations that are severely at risk for HIV infection or who have experienced treatment failure as a result of nonadherence
- Cultural humility is a key component for maximizing uptake of injectables for HIV treatment and PrEP
- Work together with other members of the health care team to provide behavioral counseling, condoms, screening for STIs, and testing for clients interested in PrEP

QUESTION & ANSWER SESSION



Thank You

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CARIBBEAN CLINICIANS
COMMUNITY OF PRACTICE
(HU-CCCoP)


TEST YOUR KNOWLEDGE
POST-TEST

Test Your Knowledge
Question #5

Which of the following is NOT a component of a comprehensive HIV prevention plan to reduce HIV infection?

A. Consistent and correct use of condoms to avoid STIs

B. Risk reduction behavioral counseling

C. Biomedical interventions (i.e., PrEP, microbicides, and vaccines)

D. Testing once yearly for HIV and other STIs

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Test Your Knowledge
Question #6

Which of the following medication is NOT approved for HIV prevention?

A. Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)

B. Cabotegravir (200mg/ml)

C. Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose vial

D. All of the above

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Test Your Knowledge
Question #7

Which of the following injectable medications require a lead-in period prior to the first injection?

A. Cabotegravir (200mg/ml)/rilpivirine (300mg/ml)

B. Cabotegravir (200mg/ml)

C. Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose vial

D. All of the above

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Test Your Knowledge
Question #8

Cabotegravir (200mg/mL)/rilpivirine (300mg/mL) or Lenacapavir 463.5mg/1.5mL (309mg/mL) single-dose can be used for the prevention of HIV?

A. True

B. False

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REFERENCES

- Overton ET, Richmond G, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. *Lancet*. 2021;396(10267):1994-2005. doi:10.1016/S0140-6736(20)32666-0
- https://pancap.org/pancap-releases/millions-of-lives-at-risk-as-progress-against-hiv-and-aids-falters/
- https://docs.bvsalud.org/biblioref/2022/10/1398127/9789240054097-eng.pdf
- https://www3.paho.org/hq/index.php?option=com_content&view=article&id=10459:2015-new-who-policy-injection-safety-seeks-reduce-spread-disease-through-unsafe-practices&Itemid=0&lang=fr#gsc.tab=0
- Centers for Disease Control and Prevention. US drug overdose deaths continue to rise; increase fueled by synthetic opioids.

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