AETC AIDS Education & Training Center Program Northeast/Caribbean

HIV Antiretroviral Update 2026

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Disclosures

- I have no financial disclosures
- Co-chair of Immunization Subgroup for OI Guidelines

Learning objectives

By the end of the session, participants will be able to:

- Decide when to consider 2-drug regimens for switch therapy and treatment naïve patients.
- Approach treatment of multi-class resistance including when to use newly approved agents.
- Counsel patients on the indications and contraindications for long-acting injectable medications.
- Describe the highlights in the ART pipeline, and anticipate the future of ART.

Roadmap

- What to start?
- When is 2 drugs enough?
- Approach treatment of multi-class resistance. When do I need new agents?
- When should I consider LA-injectable ART?
- What is on the horizon?

Case 1 – “A missed dose of PrEP”

49-year-old man with a new diagnosis of HIV. He was previously on LA-CAB for PrEP, but missed his last injection due to travel. He does not like taking medication and would like to defer as long as possible. When do you recommend he initiate ART?

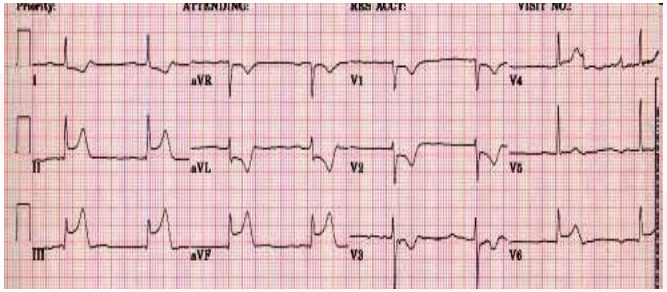
A. At today’s visit
B. When results of the labs come back in about 3-5 days
C. Wait until CD4 cell count falls below 350/μL, or symptoms develop, whichever comes first

Historical Reasons for Deferring Antiretroviral Therapy

Body shape changes

High pill burden

High cost



Metabolic abnormalities/↑CV risk

Resistance

Slide credit: Paul Sax

ART in 2026

HIV Treatment: what we know now

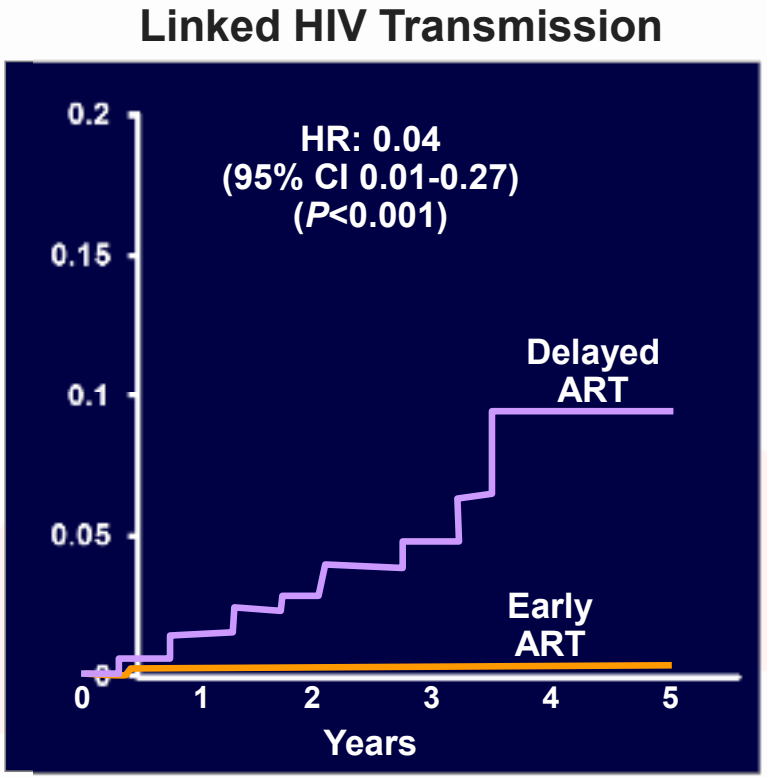
1. 
2. U=U (treatment as prevention)
3. Risk of uncontrolled viremia independent of CD4 count

HIV Treatment: what we know now

1. 
2. U=U (treatment as prevention)
3. Risk of uncontrolled viremia independent

HPTN 052: Treatment as Prevention

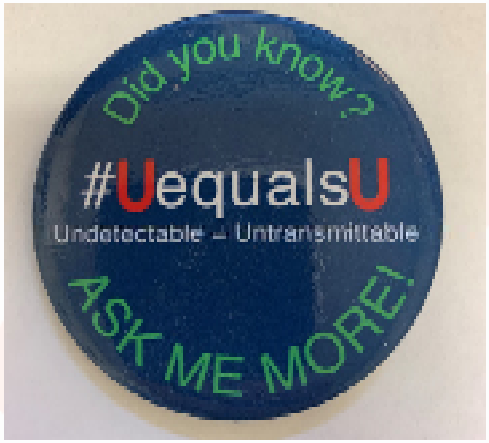
- 1763 serodiscordant couples
- Randomized study of early vs delayed ART
- Early ART led to a 96% reduction of linked HIV transmissions
- Study stopped early



Cohen MS, et al. *N Engl J Med.* 2011

PARTNERS2

Number of condomless sex acts	Number of HIV transmissions



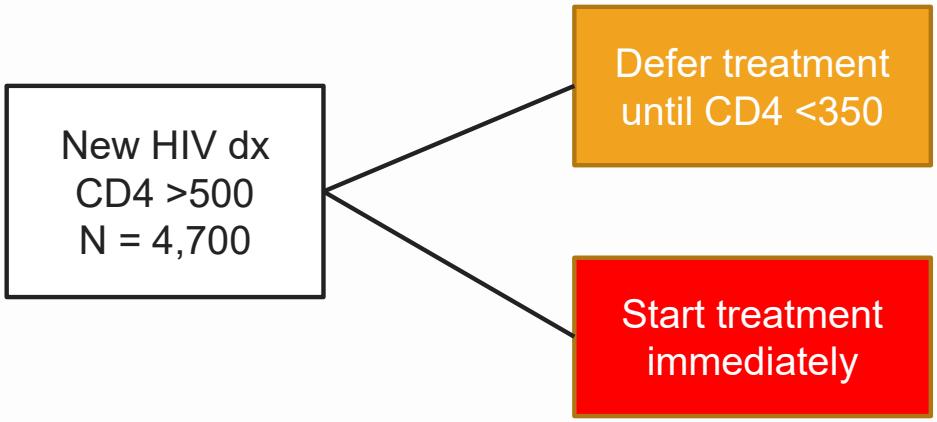
Roger AJ et al. *Lancet* 2019. Vol 393:10189 2428-2438

My patient’s viral load is 46, does U=U still apply?

HIV Treatment: what we know now

1. 
2. U=U (treatment as prevention)
3. Risk of uncontrolled viremia independent of CD4 count

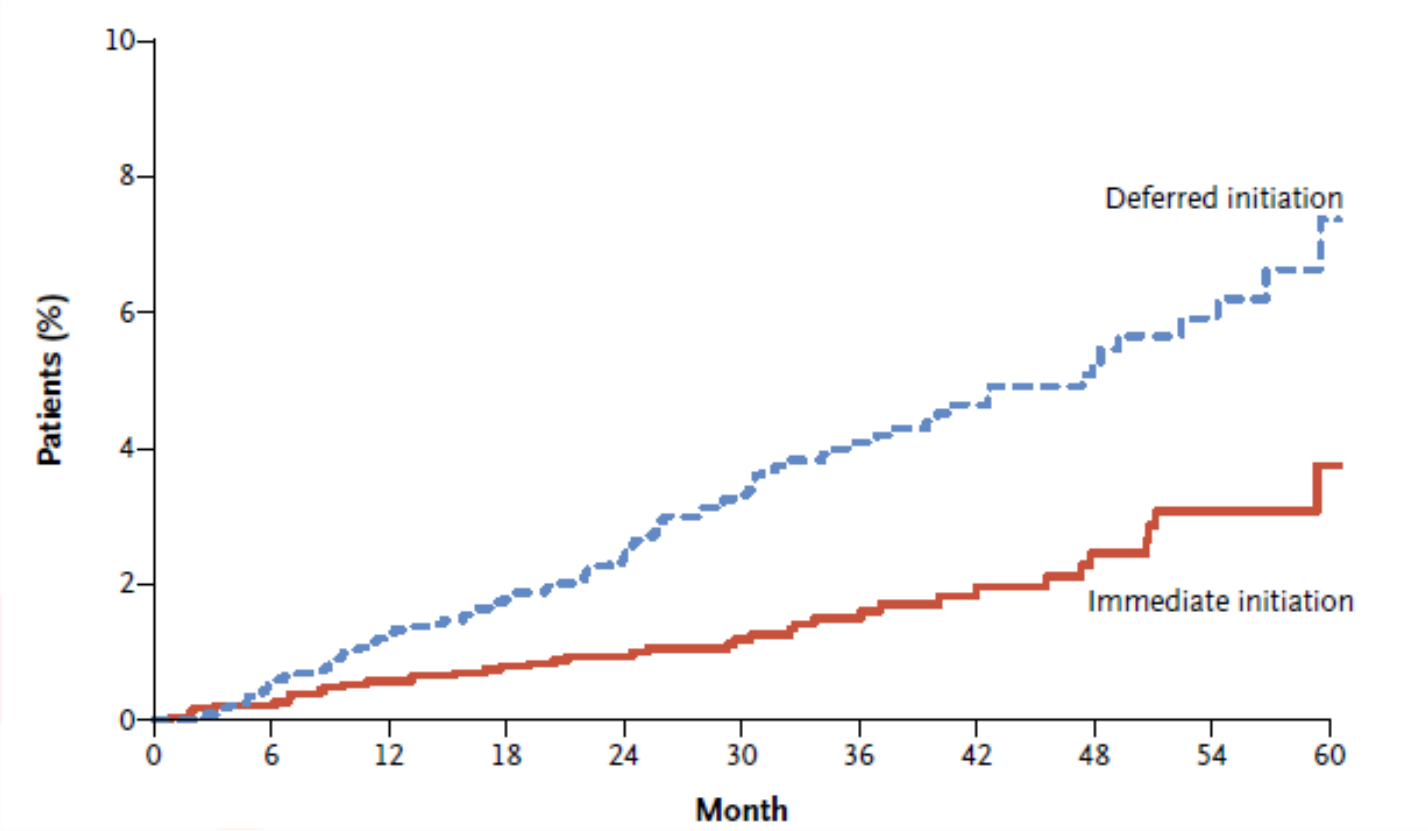
INSIGHT START trial



Composite primary endpoint

N Engl J Med. 2015:373:795-807.

Time to first event



N Engl J Med. 2015:373:795-807.

HIV Treatment: what we know now

1. 
2. U=U (treatment as prevention)
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Schema: When to start ART

Case 1 – “A missed dose of PrEP”

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Case 1 – “A missed dose of PrEP”

He hears you out and wants to start treatment right away. He would prefer as few pills as possible. Which of the following single tablet oral regimens is a recommended first line treatment while awaiting labs?

A. BIC/TAF/FTC (Biktarvy)
B. RPV/TAF/FTC (Odefsey)
C. DRV/c/TAF/FTC (Symtuza)
D. ELV/c/TAF/FTC (Stribild)

What to start?

(When is the answer *not* BIC/TAF/FTC?)

Approved HIV Medications (6/2026)

Nucleoside RT inhibitors
- Abacavir (ABC)
- Didanosine (ddI)
- Emtricitabine (FTC)
- Lamivudine (3TC)
- Stavudine (d4T)
- Tenofovir (TAF or TDF)
- Zidovudine (AZT or ZDV)

Non-nucleoside RT inhibitors
- Delavirdine (DLV)
- Efavirenz (EFV)
- Etravirine (ETR)
- Nevirapine (NVP)
- Rilpivirine (RPV)
- Doravirine (DOR)

Nucleoside RTT inhibitor
- Islatravir (ISL)

Protease inhibitors (PIs)
- Atazanavir (ATV)
- Darunavir (DRV)
- Fosamprenavir (FPV)
- Indinavir (IDV)
- Lopinavir (LPV)
- Nelfinavir (NFV)
- Ritonavir (RTV)
- Saquinavir (SQV)
- Tipranavir (TPV)

Integrase Inhibitors
- Raltegravir (RAL)
- Elvitegravir (EVG)
- Dolutegravir (DTG)
- Bictegravir (BIC)
- Cabotegravir (CAB)

Approved April, 2026

Fusion Inhibitor
- Enfuvirtide (ENF, T-20)

CCR5 Inhibitor
- Maraviroc (MVC)

Post-attachment inhibitor
- Ibalizumab (IBA)

Attachment inhibitor
- Fostemsavir (FTR)

Capsid inhibitor
- Lenacapavir (LEN)

PK Enhancer
- Ritonavir (RTV)
- Cobicistat (COBI)

CCR5 = C-C chemokine receptor type 5; PK = pharmacokinetic

Preferred initial regimen

Regimens approved for first line

TAF FTC BIC

Biktarvy

“A rose without a thorn”

Jed Pilkington,
BWH HIV fellow 2018-2019

TAF FTC

Descovy

+

DTG

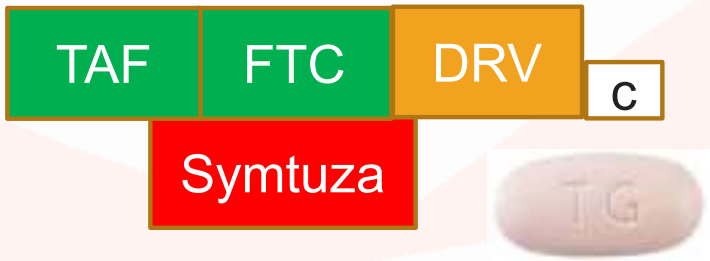
Tivicay

CLINICAL INFO HIVgov

https://clinicalinfo.hiv.gov/en
Accessed May 12, 2026

What about people on LA-CAB?

- For people who have a history of CAB-LA as PrEP, INSTI genotype resistance testing should be performed before starting ART.
- If ART is started before results are available, a PI-based regimen is recommended such as:



https://clinicalinfo.hiv.gov/en
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Case 2a - “It takes two to tango”

52-year-old man with HIV on BIC/TAF/FTC for 3 years. HIV VL is <20, CD4 620. HBsAg negative. Baseline GT shows no resistance. At a routine visit you find that his creatinine is 1.6 with eGFR of 39. Which of the following oral regimens is a reasonable option?

A. DTG/3TC (Dovato)
B. DTG/RPV (Juluca)
C. DOR/ISL (Idvynso)

Two-drug therapy for ART switch

SWORD-1 & 2

DTG / RPV

Juluca

INSTI + NNRTI · NRTI-sparing

TANGO

DTG / 3TC

Dovato

INSTI + NRTI · Tenofovir-free

MK-8591A-052

DOR / ISL

Idvynso

NNRTI + NRTTI · INSTI-free & TDF-free

1. Llibre JM et al. SWORD-1 & 2. Lancet. 2018;391:839–849. 2. Aboud M et al. SWORD-1 & 2 Wk 100. Lancet HIV. 2019;6:e576.

3. van Wyk J et al. SWORD-1 & 2 Wk 148. JAIDS. 2020;85:325–330. 4. Osiyemi O et al. TANGO Wk 144. Clin Infect Dis. 2022;75:975–986.

5. Osiyemi O et al. TANGO Wk 196. JAIDS. 2024;86:S51. 6. Colson AE et al. MK-8591A-052 (NCT05630755) Wk 48. Lancet HIV. 2024;11:e812.

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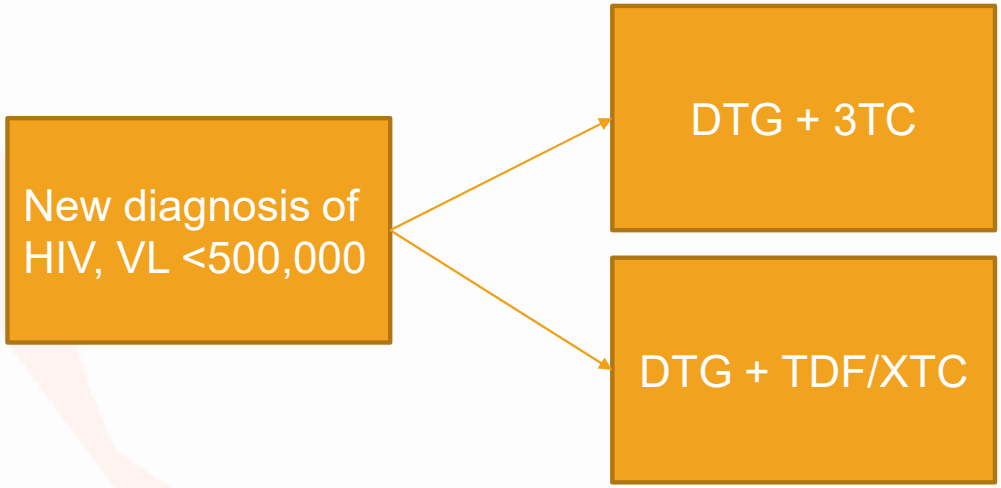
Case 2b – “Sweet Twins”

52-year-old man with **new diagnosis of HIV**. HIV VL is 200,000, CD4 420. HBsAg negative. Baseline GT shows no resistance. Baseline labs show creatinine is 1.6 with eGFR of 39. Which of the following oral regimens is a reasonable option **for initial therapy**?

A. DTG/3TC (Dovato)
B. DTG/RPV (Juluca)
C. DOR/ISL (Idvynso)

GEMINI-1,2



- Week 144: 2 drugs non-inferior, fewer adverse events
- No treatment related mutations

DTG + 3TC approved for first line Tx*

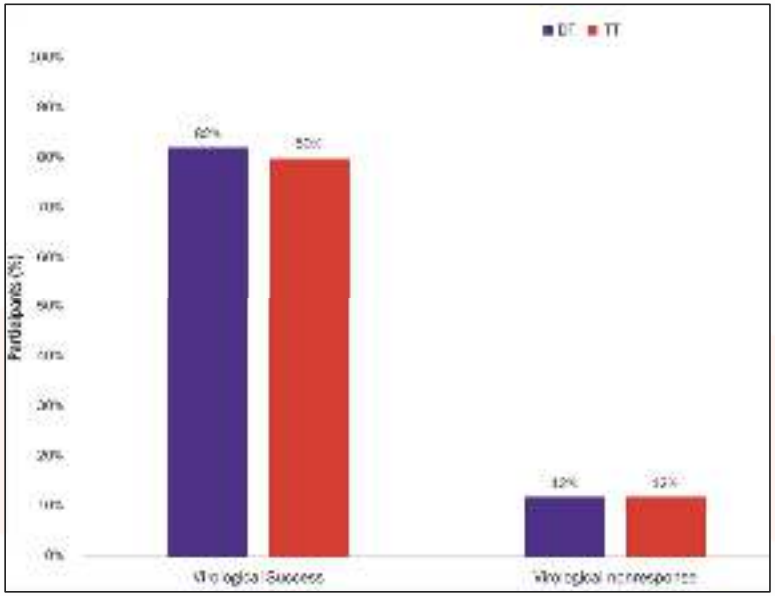
*Not recommended for:
- HIV VL >500,000
- HBV Co-infection

Cahn P et al. *Lancet* 2019

DOLCE

New diagnosis of HIV, CD4 ≤200

- DTG /3TC
- DTG + TDF/XTC



Metanalysis shows remains effective at high viral loads

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C. DOR/ISL (Idvynso)

Key Principles for 2-drug therapy

- Strategy to decrease cumulative drug exposure – most important for patients with renal disease
- Must be HBV negative
- Must have no resistance to either component of regimen
- Several 2-drug options for switch therapy
- DTG/3TC is the only 2-drug regimen preferred in treatment naïve patients
- Currently approved for HIV VL <500,000, but likely active at all viral loads

Two-drug therapy for ART switch

SWORD-1 & 2

DTG / RPV

Juluca

INSTI + NNRTI · NRTI-sparing

TANGO

DTG / 3TC

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Case 3 – “Phone a friend!”

64-year-old man with HIV diagnosed in 1988. He is heavily treatment experienced with periods of variable adherence. His last regimen was TAF/FTC + DRV/c. He returns to care after being off ART for about 1 year. HIV VL is 10,000 and cumulative genotype shows:

NRTI - M41L, D67N, M184V, L210W, T215Y
NNRTI - K103N, Y181C, E138K)
PI - L10I, K20R, M36I, I54V, A71V, V82T, I84V

Protease Inhibitors

atazanavir/r (ATV/r)	High-Level Resistance
darunavir/r (DRV/r)	Low-Level Resistance
lopinavir/r (LPV/r)	High-Level Resistance

Nucleoside Reverse Transcriptase Inhibitors

abacavir (ABC)	High-Level Resistance
zidovudine (AZT)	High-Level Resistance
emtricitabine (FTC)	High-Level Resistance
lamivudine (3TC)	High-Level Resistance
tenofovir (TDF)	Intermediate Resistance

Non-nucleoside Reverse Transcriptase Inhibitors

efavirenz (EFV)	Intermediate Resistance
etravirine (ETR)	High-Level Resistance
nevirapine (NVP)	High-Level Resistance
rilpivirine (RPV)	High-Level Resistance

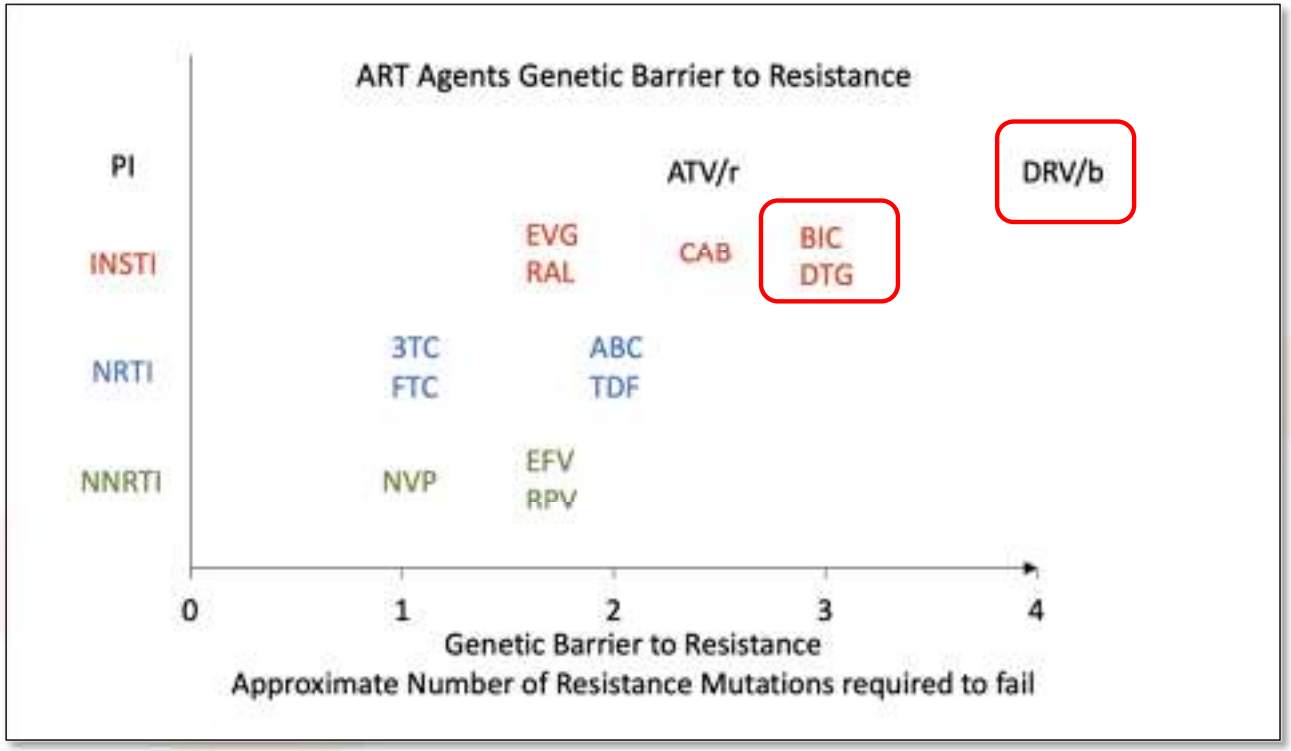
Integrase Inhibitors

Raltegravir (RAL)	Susceptible
Elvitegravir (ELV)	Susceptible
Dolutegravir (DTG)	Susceptible
Bictegravir (BIC)	Susceptible

Approach to multiclass resistance

- Which classes remain available?
- Which drugs are worth continuing even if there is predicted resistance?
- What new drugs are available?

Genetic barrier to resistance



Clutter DS et al. Infection, Genetics and Evolution 2016

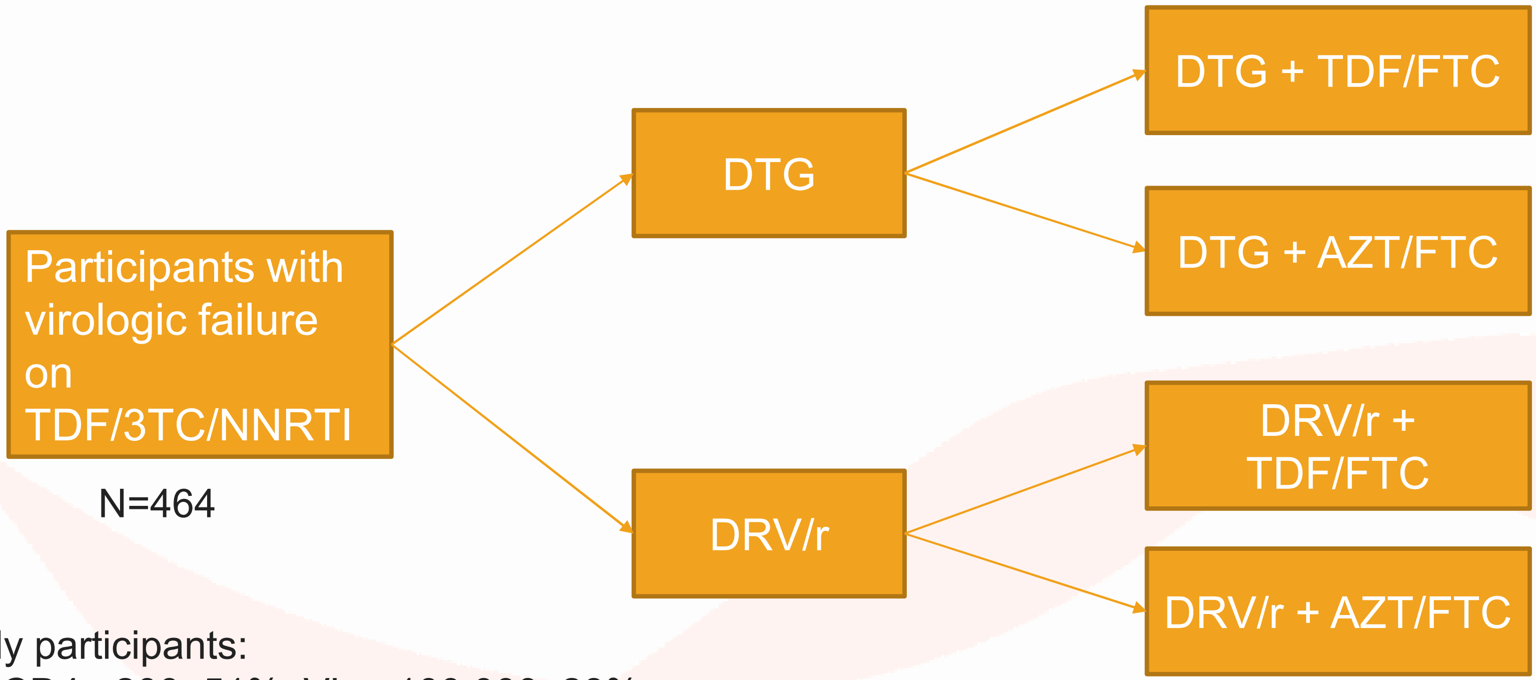
ORIGINAL ARTICLE

Dolutegravir or Darunavir in Combination with Zidovudine or Tenofovir to Treat HIV

Authors: Nicholas I. Paton, M.D., Joseph Musaazi, M.Sc., Cissy Kityo, Ph.D., Stephen Walimbwa, M.D., Anne Hoppe, Ph.D., Apolo Balyegisawa, M.D., Arvind Kaimal, M.D., ..., for the NADIA Trial Team* Author Info & Affiliations

Published July 21, 2021 | N Engl J Med 2021;385:330-341 | DOI: 10.1056/NEJMoa2108609 | VOL. 385 NO. 4

NADIA

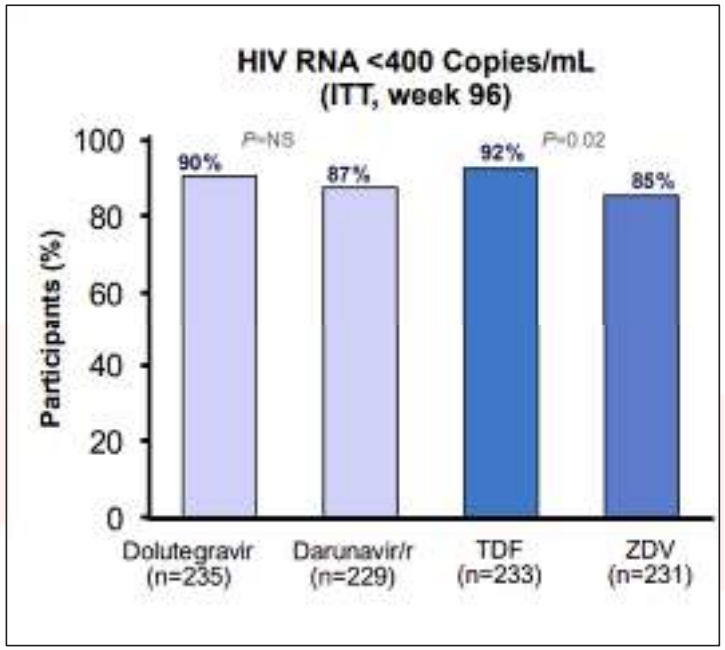


Study participants:
- CD4 ≤200: 51%, VL ≥ 100,000: 28%
- Resistance K65R/N: 50%; M184V:86%

Paton NI et al. New Engl J Med 2021

NADIA:
Integrase + recycled NRTIs was highly effective

- TDF > AZT
- High rates of suppression even when no NRTIs predicted to be active
- 4% developed resistance in DTG group
- Results replicated in other trials (ARTIST, VISEND)



Paton N et al. Lancet 2022

Key Concept:
Residual NRTI activity even with extensive resistance

- Selective drug class interruption in PWH with multiclass resistance
- Discontinuation of NRTIs but not PIs or NNRTIs led to HIV RNA increase
- Results help partially explain success of integrase inhibitors plus NRTIs even with NRTI resistance.

Deeks SG, et al. JID 2005

What if there is resistance to integrase inhibitors?

Lenacapavir

Fostemsavir

Lenacapavir (Sunleca)

- First in class capsid inhibitor
- No cross-resistance with existing drug class
- Dosing: oral load day 1, 2 → SC injection q6 months

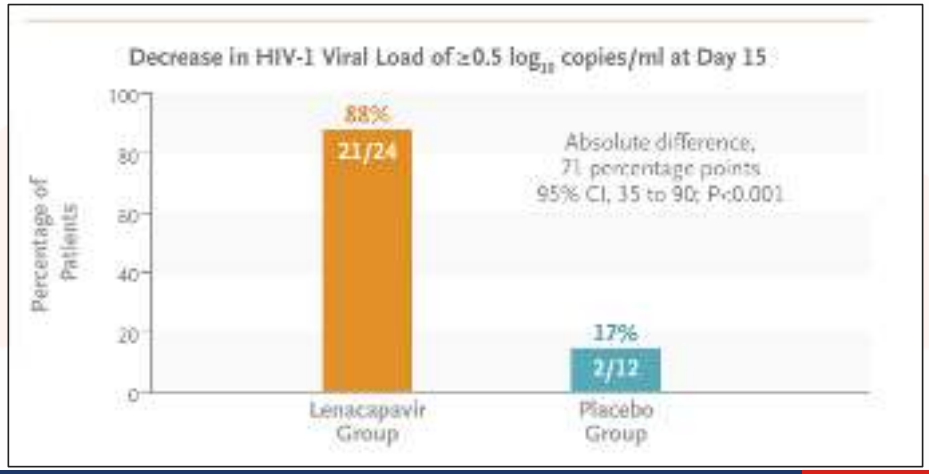
CAPELLA trial

Participants with virologic failure

N=36

→ Background ART + LEN

→ Background ART + placebo



Segal-Maurer S et al. New Engl J Med 2022

Fostemsavir (Rukobia)

- Attachment inhibitor, novel site of action
- No cross-resistance with existing drugs
- Dosing: oral, BID

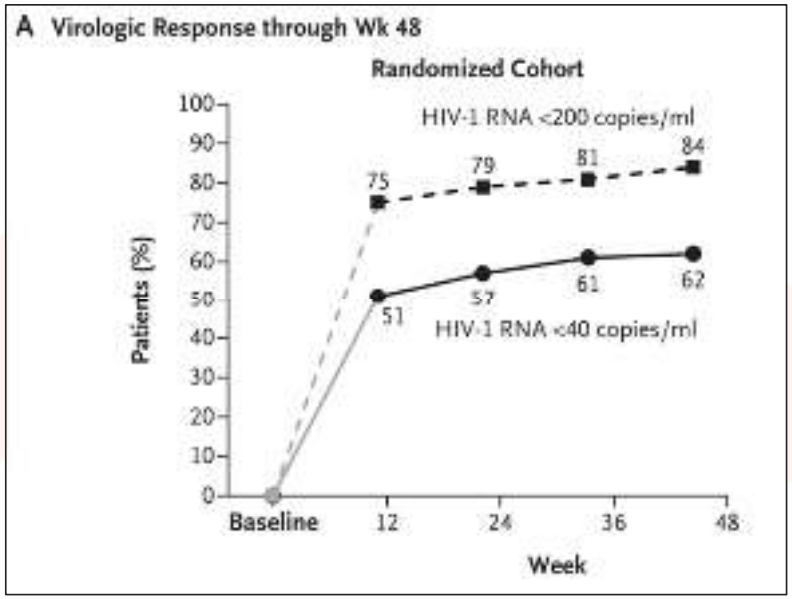
BRIGHTE trial

Participants with virologic failure, only 1 or 2 remaining options

N=272

Background ART + FOS

Background ART + placebo



Kozal M et al. New Engl J Med 2020

Key updates for multiclass resistance

- You do not need to memorize resistance mutations
- Protease inhibitors and 2nd generation Integrase inhibitors have highest barrier to resistance
- Some NRTI mutations confer a fitness cost to the virus
- Integrase inhibitor + NRTI backbone is effective, even if extensive NRTI resistance
- For patients with integrase resistance, consider new agents with novel mechanisms of action
  - Lenacapavir
  - Fostemsaivr

Case 4a – “Daily pills are a drag”

36-year-old man with HIV, currently on BIC/TAF/FTC for the past 18 months. HIV viral load is undetectable, CD4 780. No prior treatment failure. HBsAg negative. Baseline genotype with no resistance.

He travels a lot for work and sometimes forgets to bring his ART. Moreover, he does not like keeping ARVs in his medicine cabinet at home. “Is there something I don't have to take every day?"

Why long-acting injectables?

Travel

Forgetting pills across time zones or trips

Variable Schedule

Shift work & irregular routines disrupt daily dosing

Privacy

No pill bottle at home; discreet from partners or family

Pill Aversion

Difficulty swallowing or strong aversion to daily pills

Stigma

Daily pill is a constant reminder of HIV status

Housing Instability

Secure storage & reliable daily access not guaranteed

Cognitive Burden

Memory impairment or mental health disrupts adherence

LA-ART:
How did we get here?

ATLAS

ORIGINAL ARTICLE

Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression

Authors: Susan Swindells, M.B., B.S., Jaime Federico Andrade Villanueva, M.D., Gary J. Richmond, M.D., Giuliano Rizzardini, M.D., Axel Baumgarten, M.D., Mar Masiá, M.D., Gulam Latiff, M.D., , and William R. Spreen, Pharm.D. Author Info & Affiliations

Published March 4, 2020 | N Engl J Med 2020;382:1112-1123 | DOI: 10.1056/NEJMoa1904398 | VOL. 382 NO. 12

Suppressed on oral ART

N=616

Switch to CAB + RPV

N=308

Continue Oral ART

N=308

HIV VL ≥ 50 at 48 weeks

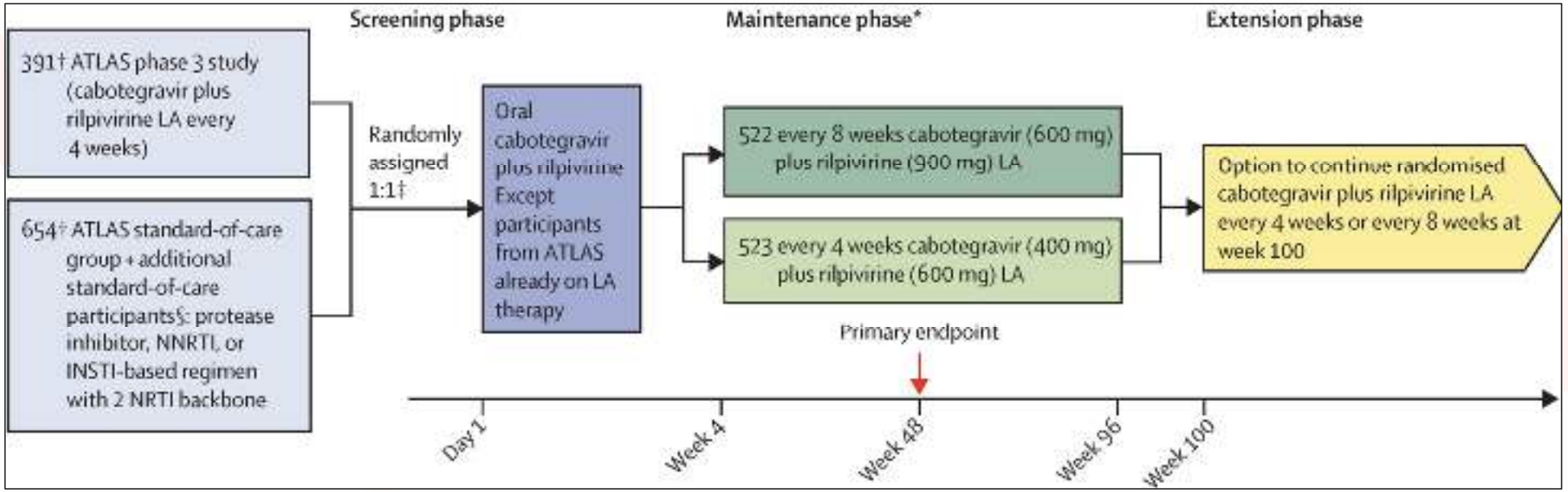
Swindells S et al. New Engl J Med 2020

ATLAS-2M

ARTICLES Volume 396, Issue 10267, P1994-2005, December 19, 2020 Download Full Issue

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

Edgar T Overton, MD · Gary Richmond, MD · Prof Giuliano Rizzardini, MD · Hans Jaeger, MD · Catherine Orrell, MBChB · Firaya Nagimova, MD · et al. Show more



HIV-1 RNA ≥50 copies/mL (Primary endpoint)[1,3]

Noninferiority: lower bound of 95% CI for treatment difference <4%

CVF* reported through Week 152[3]:

(12/522 patients) every-2-month CABENUVA†	2.3%
VS	
(2/523 patients) once-monthly CABENUVA	0.4%

Resistance-associated mutations in patients who meet protocol-defined CVF[1,3-4]

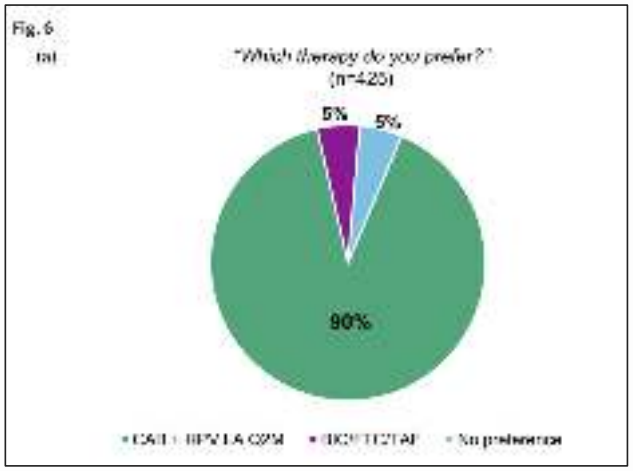
	EVERY-2-MONTH CABENUVA (n=522)	ONCE-MONTHLY CABENUVA (n=523)
Patients with CVF, n (%)	12 (2)*	2 (<1)
INSTI resistance-associated mutations‡	N155N/H+Q148Q/R (n=2), T97A+N155H, N155H, Q148R (n=3)	N155N/H and Q148+E138E/K
NNRTI resistance-associated mutations‡	K103N, K101E, Y188L, Y188L+P225H, K101E+E138A, E138A+K103N, E138E/K, K101E+M230L, K103N+Y181C, E138K, E138A+M230M/L, E138A+Y181Y/C	K101E+M230L

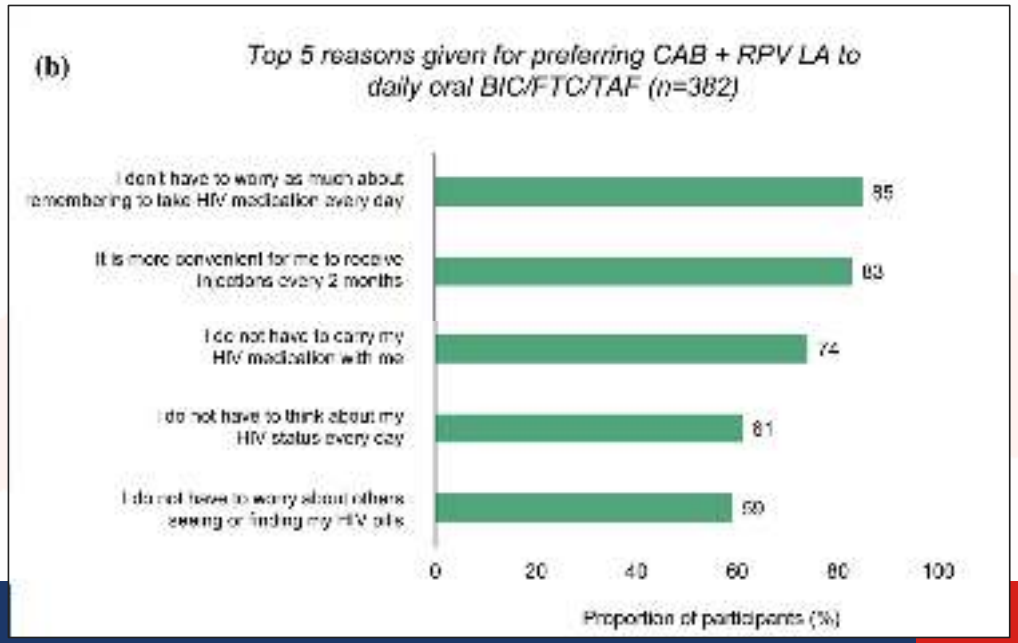
SOLAR Study

Suppressed on BIC/TAF/FTC

N=670

- Switch to CAB + RPV
- Continue BIC/TAF/FTC





Mussini C et al. AIDS and Behavior 2025

Presence of ≥2 baseline factors associated with virologic failure

- Baseline rilpivirine resistance
- A6/A1 HIV subtype
- BMI ≥30

Orkin C et al. Clinical Infectious Diseases 2023

CAB/RPV-LA (Cabenuva) — Patient Selection

Case 4b – “daily pills are not feasible”

44-year-old woman with HIV, substance use disorder, and intermittent homelessness. She is intermittently engaged in care and despite outreach efforts he has never been able to achieve virologic suppression. She cites housing insecurity, inconsistent access to pills as the greatest barriers. Most recent labs notable for HIV viral load of 8,000, CD4 210. Genotype shows no NNRTI or INSTI resistance.

Is CAB/RPV an option for her?

A. No
B. Yes
C. Yes, but only if she can achieve viral suppression with an oral lead in first

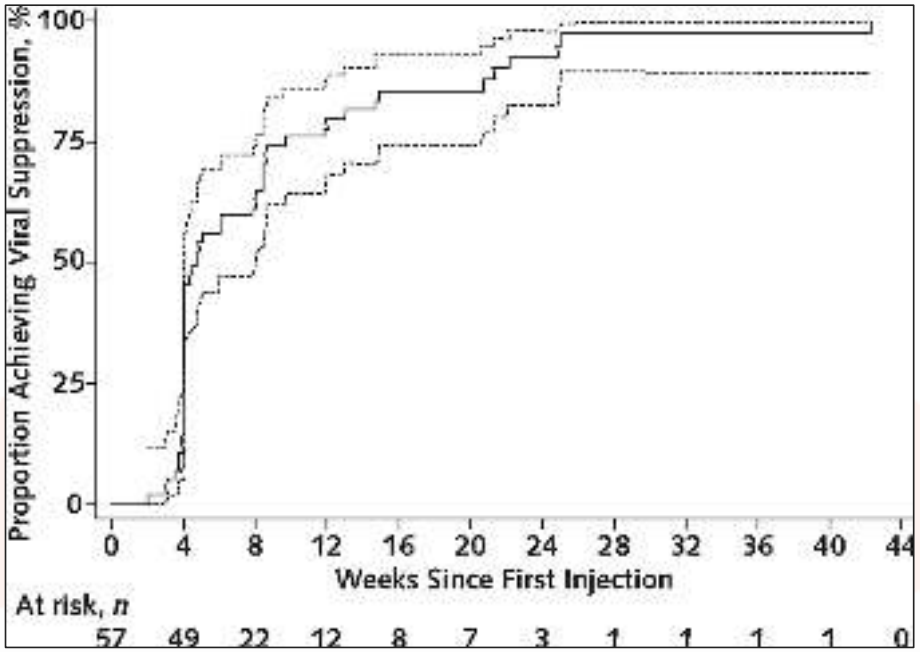
Long-Acting ART in patients with viremia

- 133 PWH started on LA-ART
  - 76 virologic suppression
  - 57 with viremia
  - 56 experiencing unstable housing or homelessness
  - 45 had active substance use
- SPLASH (Special Program of Long-Acting Antivirals to Stop HIV)
  - Clinic leadership, pharmacy, researchers, clinicians
  - Intensive management – biweekly meetings
  - Mobile outreach

Gandhi M et al. Ann Intern Med 2024

Among PWH with viremia

- 54 of 57 had viral suppression
  - 1 showed 2 log reduction in HIV RNA
  - 2 had early virologic failure
- 97.5% with virologic suppression by 33 weeks
- Virologic failure rate of 1.5% similar to other clinical trials



Gandhi M et al. Ann Intern Med 2024


Cabotegravir plus Rilpivirine for Persons with HIV and Adherence Challenges

LATITUDE

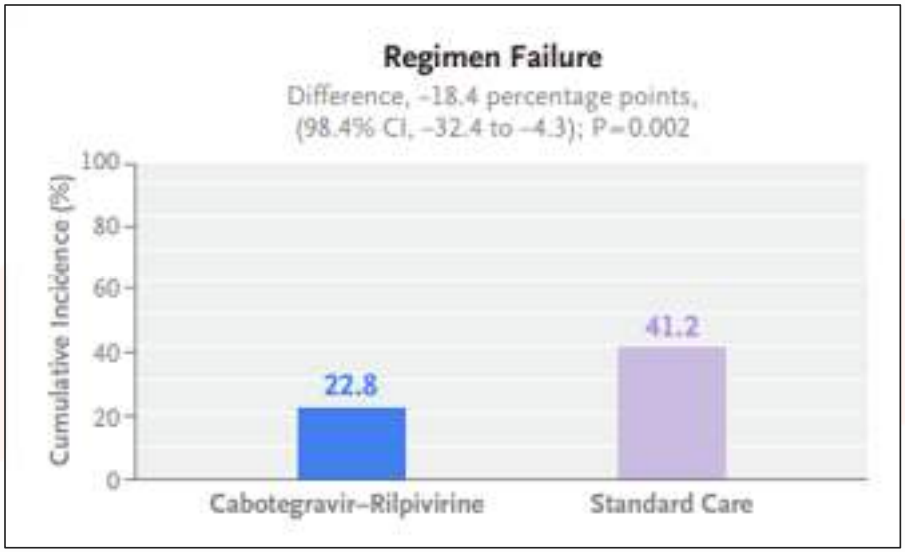
- Patients with viremia due to challenges with adherence
- Phase 1: adherence support, conditional economic incentives to achieve viral suppression

Phase 2

Suppressed on oral ART

Switch to CAB + RPV

Continue oral ART



Long-acting ART for patients with viremia in urban South

Characteristics of cohort (N=81)

- 93% Black, 40% cis/transwomen, median age 38yrs
- HIV diagnosed median 15.5yrs ago, 46% had prior OIs
- Median CD4 186 cell/mm^3 and VL 4.0 log10
- 56 CAB/RPV; 22 CAB±RPV+LEN; 3 CAB±RPV+LEN+IBA

Colasanti JA et al. Clin Infect Dis 2025

Update to IAS-USA guidelines

"When supported by intensive follow-up and case management, injectable CAB-RPV may be considered for people with viremia who meet the criteria below when no other treatment options are effective due to a patient's persistent inability to take oral ART"

Unable to take oral ART consistently despite extensive efforts and clinical support

High risk of HIV disease progression (CD4 cell count <200 or history of AIDS-defining complications)

Virus susceptible to both CAB and RPV

Sax PE et al. JAMA 2024

Case 4b – “daily pills are not feasible”

44-year-old woman with HIV, substance use disorder, and intermittent homelessness. She is intermittently engaged in care and despite outreach efforts he has never been able to achieve virologic suppression. She cites housing insecurity, inconsistent access to pills as the greatest barriers. Most recent labs notable for HIV viral load of 8,000, CD4 210. Genotype shows no NNRTI or INSTI resistance.

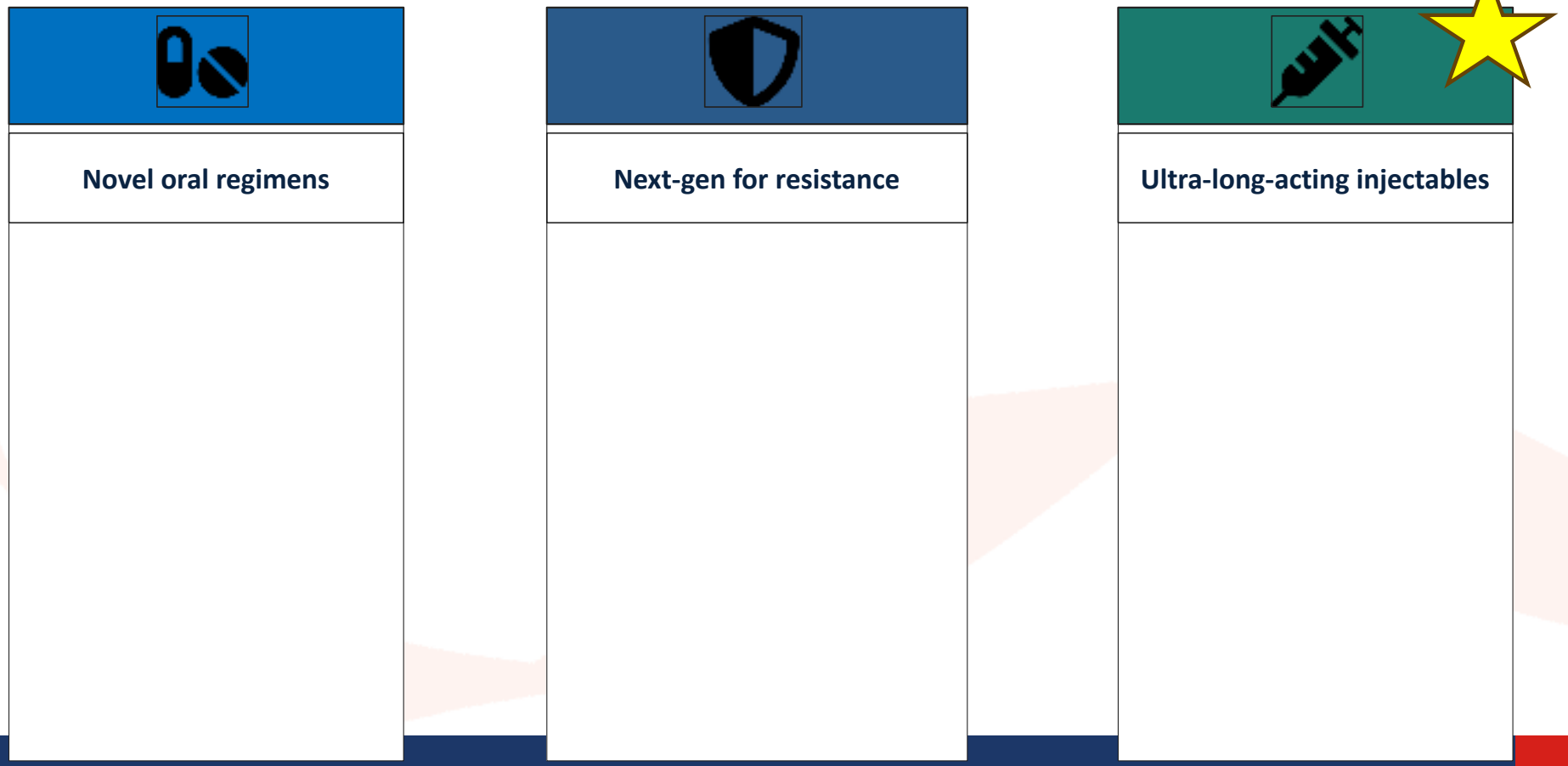
Is CAB/RPV an option for her?

A. No
B. Yes
C. Yes, but only if she can achieve viral suppression with an oral lead in first

Case 4c – “The future is long-acting”

Your final patient of the day has well controlled HIV on CAB/RPV q2m for the past 3 years. He is doing great with no injection side effects, but he finds the frequency of clinic visits to be burdensome. He says: "My friend told me there's a shot you take twice a year. Is that true? Can I get it?"

The HIV Pipeline — Organizing the Landscape



The HIV Pipeline — Organizing the Landscape

Novel oral regimens

- Once-weekly ISL + LEN (Phase 3)
- Weekly GS-1720 + LEN prodrug (Phase 2)

Does a once weekly regimen move the needle?

Next-gen for resistance

Ultra-long-acting injectables

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Next-gen for resistance

- VH-184: 3rd-gen INSTI vs DTG/BIC resistance (Phase 1)
- LEN + CAB combo for MDR (case series)
- BIC/LEN single tablet for complex regimens (Phase 3)

Ultra-long-acting injectables

Remember Lenacapavir?

- Capsid inhibitor
- Dosing: oral load day 1, 2 → SC injection q6 months
- Needs a dance partner!

The HIV Pipeline — Organizing the Landscape

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Ultra-long-acting injectables

- Twice-yearly LEN + bnAbs (Phase 2)
- GS-3242 INSTI Q4M+ (Phase 1)
- VH-499 capsid Q6M (Phase 1)

A note on the research agenda

- Patients with Viremia vs Suppressed Switch are different populations
- Lots of options for people who can take their meds well, but fewer choices for people who struggle with oral ART
- Tiers of drug development pathway:
  - Suppressed switch
  - Treatment naïve
  - Fewer studies of people who are treatment experienced but not suppressed

Roadmap

- What to start?
- When is 2 drugs enough?
- Approach treatment of multi-class resistance. When do I need new agents?
- When should I consider LA-injectable ART?
- What is on the horizon?

Learning objectives

By the end of the session, participants will be able to:

- Decide when to consider 2-drug regimens for switch therapy and treatment naïve patients.
- Approach treatment of multi-class resistance including when to use newly approved agents.
- Counsel patients on the indications and contraindications for long-acting injectable medications.
- Describe the highlights in the ART pipeline, and anticipate the future of ART.

Discussion, questions, comments

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