

In Case You Missed It: Recent Changes in Guidelines, New Publications, and Updates From Recent Conferences



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Financial Relationships With Ineligible Companies (Formerly Described as Commercial Interests by the ACCME) Within the Last 2 Years

Dr Gulick reported no relevant financial relationships with ineligible companies. (Updated October 25, 2025)

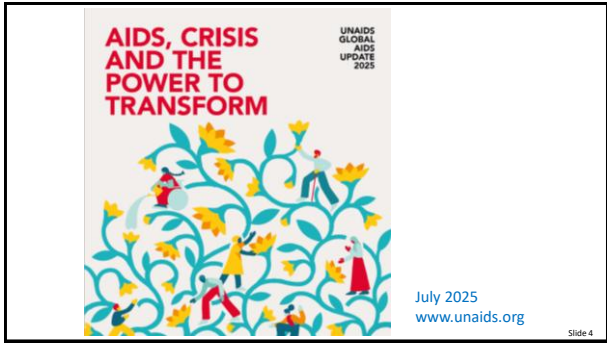
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Learning Objectives

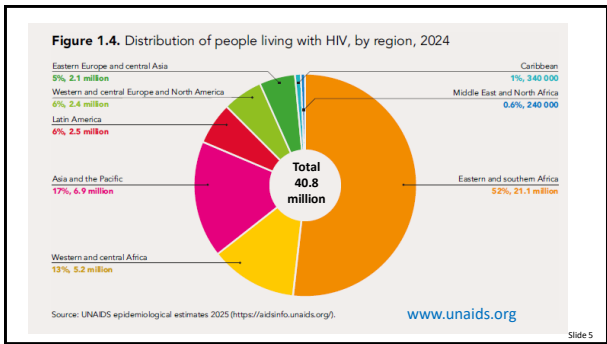
After attending this presentation, learners will be able to:

- Identify the latest worldwide trends in HIV epidemiology
- List recent changes to HIV treatment and prevention guidelines

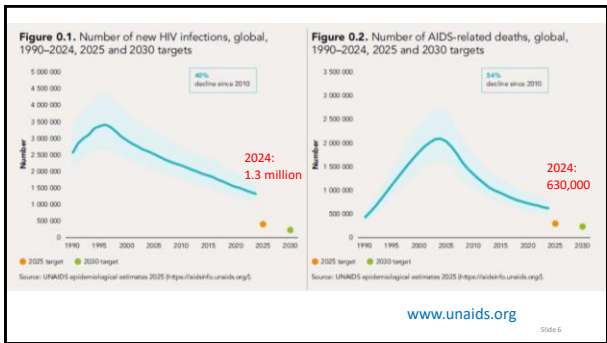
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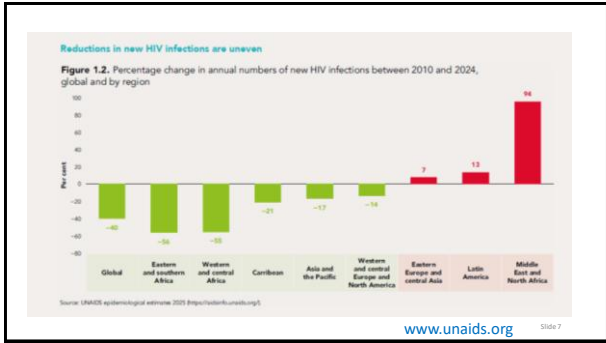
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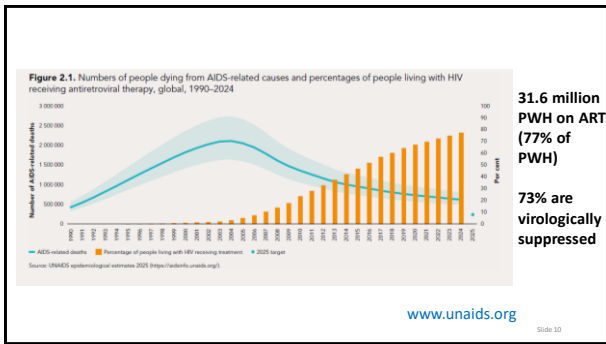
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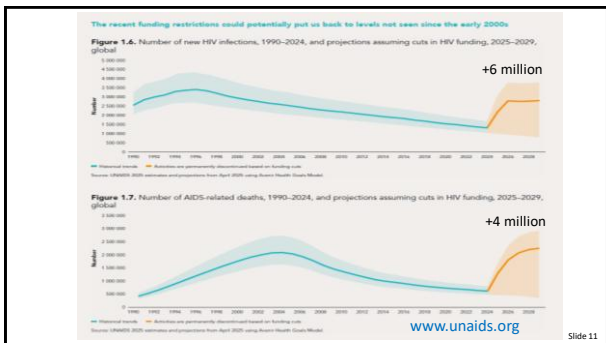
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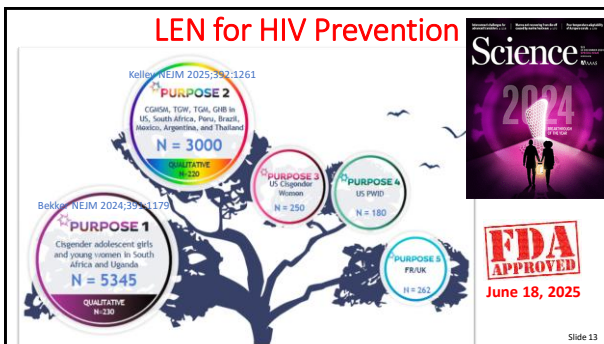
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WHO: LEN for Prep: July 2025

Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis

Table 1. Table of new and updated recommendations (2025)

HIV PrEP	Long-acting injectable lenacapavir <u>should be offered as an additional prevention choice</u> for people at risk of HIV as part of combination prevention approaches. (Strong recommendation, moderate- to high-certainty evidence)
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JAMA[®]

The Journal of the American Medical Association

August 19, 2025

COMMENT & RESPONSE

Preexposure Prophylaxis for HIV: Updated Recommendations From the 2024 International Antiviral Society–USA Panel

To the Editor Following the US Food and Drug Administration approval of lenacapavir for HIV preexposure prophylaxis (PrEP) on June 18, 2025, as well as new data on the use of tenofovir alafenamide/emtricitabine among cisgender women, the International Antiviral Society–USA (IAS–USA) panel provides a brief update of its 2024 recommendations for the prevention of HIV infection.¹

Lenacapavir is recommended for prevention of sexual acquisition of HIV for all individuals regardless of risk, including for people who inject drugs and have sexual exposures (AIII).

LEN for PrEP

- Initially
 - HIV Ag/Ab testing within 7 days
 - For likely HIV exposures within 21 days, HIV RNA testing
- Follow-up
 - HIV Ag/Ab testing every 3–6 months
 - HIV RNA testing **not** recommended
- No other safety labs needed (initial or f/up)
- TAF/FTC** recommended for PrEP for vaginal exposure (if TDF/FTC is “contraindicated or undesirable”)

Landovitz JAMA 2025;334:638–9

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U.S. Centers for Disease Control and Prevention

MMWR

Weekly / Vol. 74 / No. 35

Morbidity and Mortality Weekly Report

September 18, 2025

Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis — United States, 2025

Rago R, Patel, MD¹, Kato W, Hansen, MD², Alkhouli L, MD³, Jones Calabrese, PharmD⁴, Kattaria M, Rynd, MD⁵, Ashore F, Kwanza, MD, PhD⁶

- LEN **strongly recommended** as a PrEP option
- HIV Ag/Ab testing at initiation with HIV RNA, if available
- If switching from TDF/FTC or CAB, only HIV Ag/Ab testing needed
- If acute HIV suspected, check HIV RNA
- Follow-up at least every 6 months with HIV Ag/Ab testing
- For HIV seroconversion on LEN PrEP, use integrase inhibitor-based regimen

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CDC

Morbidity and Mortality Weekly Report (MMWR)

Search

Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025

Recommendations and Reports / May 6, 2025 / 74(20):1–10

- Emphasis on starting within the first 24 hours, no later than 72 hours
 - Consideration for source with undetectable VL or exposed person on PrEP
- New PEP regimens (within 72 hours of exposure; 4-week duration)
 - Preferred: **BIC/TAF/FTC** or **DTG + TDF/XTC**
 - Alternative: **DRV/b + TDF/XTC**
 - Suggested regimens for children, pregnancy, renal or hepatic dysfunction
- Follow-up testing
 - HIV Ag/Ab** and **HIV RNA** testing at 4–6 weeks post-exposure **may be deferred** for people who started PEP <24 hours after exposure with no missed PEP doses
 - Final **HIV Ag/Ab** and **HIV RNA** testing at 12 weeks
 - No f/up safety labs unless baseline tests abnormal or clinical indications
- PEP to PrEP transition plan

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Infectious Diseases & Hospital Epidemiology (IDHE), 1-12
 1001-1010 (2024) 1001-1010

SHEA
 July 2025

Review

2025 US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post-exposure Prophylaxis in Healthcare Settings

Aaron D. Rodman MD¹, Kimberly A. Struble PharmD^{2*}, Waldi Henslein PhD³, Britt Gayle MD⁴,
 Marie A. de Perio MD⁵, Devon L. Okusako-Schmuckler MD⁶, Christine N. So MD^{7*},
 Laura L. Anderson MD^{8*}, Eric C. Stone MPH, MD⁹, David R. Henderson MD¹⁰, and David T. Kuhar MD¹¹

- New PEP regimens (within 72 hours of exposure; 4-week duration)
 - Preferred: **BIC/TAF/FTC** or **DTG + TXV/XTC**
 - Alternative: **DRV/b + TXF/XTC**
- Post-Exposure Testing
 - **HIV Ag/Ab** and **HIV RNA** testing at 4-6 weeks post-exposure ONLY for people who started PEP more than 24 hours after exposure or who missed PEP doses
 - Final **HIV Ag/Ab** and **HIV RNA** testing at 12 weeks
 - No f/up safety labs unless baseline tests abnormal or clinical indications

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ART: What to Start?

Guideline	3-drug regimens	2-drug regimens
U.S. DHHS 2025 https://clinicalinfo.hiv.gov/en/guidelines	BIC/TAF/FTC DTG + TXF/XTC	DTC/3TC
IAS-USA 2024 Gandhi JAMA 2025;333:609-628	BIC/TAF/FTC DTG + TXF/XTC	DTC/3TC
BHIVA 2025 https://bhiva.org/clinical-guidelines/	BIC/TAF/FTC DTG + TXF/XTC	DTC/3TC
EACS 2025 https://www.easociety.org/guidelines/	BIC/TAF/FTC DTG + [TAF/FTC or TDF/XTC] DOR + [TAF/FTC or TDF/XTC] or DOR/TDF/3TC	DTC/3TC or DTG + XTC
WHO 2025 https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/guidelines/hiv-guidelines	DTG/TXF/FTC	none

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ART in Pregnancy: Preferred Drugs

- NRTI:
 - **tenofovir (TAF or TDF)**/(emtricitabine or lamivudine)
- PI:
 - **darunavir/ritonavir** (if previously on cabotegravir PrEP; need to use bid)
- INSTI:
 - **bictegravir**
 - **dolutegravir** (neural tube defects NOT significantly ↑ vs. other ART)
- **IV zidovudine** recommended close to delivery if VL >1000

DHHS Perinatal Guidelines 6/12/25 <www.clinicalinfo.hiv.gov>

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ART in Pregnancy: Alternative and Other Drugs

- **NRTI:** abacavir, zidovudine
- **NNRTI:** efavirenz, rilpivirine
- **PI:** atazanavir/ritonavir, darunavir/ritonavir
- **INSTI:** raltegravir
- Insufficient data: doravirine
- Only recommended for treatment-experienced:
 - etravirine, fostemsavir, ibalizumab, lenacapavir, maraviroc
- **Not recommended:** cobicistat (↓ drug concentrations);
2-drug regimens (could continue if already taking)

DHHS Perinatal Guidelines 6/12/25 <www.clinicalinfo.hiv.gov>

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Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV

WHAT'S NEW IN THE GUIDELINES

Updated: September 25, 2025
Reviewed: September 25, 2025

- **New section: Cardiovascular (CV) and Metabolic Complications in PWH**
 - **Immune activation and inflammation**
 - Switching/adding ART, immunomodulatory or anti-inflammatory treatment, routine monitoring (e.g. CRP or IL6) **not** recommended
 - **CV complications**
 - Recs for calculating ASCVD risk score, checking lipids
 - **Statins**
 - For age 40-75, moderate-intensity statin [pitavastatin 4mg, atorvastatin 20mg, rosuvastatin 10mg daily] recommended for 5-~20% risk and favored for <5%
 - **Weight gain**
 - ART should not be delayed, interrupted, or discontinued for weight gain
 - Specific ART should not be selected to prevent or reduce weight gain

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Liraglutide (GLP-1 receptor agonist) for Obesity

- Open-label study in South Africa
- Inclusion criteria
 - ≥ 18 years old
 - On 1st-line ART ≥ 6 months
 - Suppressed viral load
 - BMI ≥ 30 kg/m²
 - No history of diabetes
 - No use of other weight-loss drugs
- 40 Individuals enrolled (mean age 38, 97% women, median BMI 39)
- Liraglutide for 12 weeks with dose escalation, plus lifestyle counseling

	On-treatment change (W0-W12)	Off-treatment change (W12-W24)
Weight, kg	-3.1 (-4.1, -2.1)**	1.0 (0.2, 1.8)
Body mass index, Kg/m ²	-1.2 (-1.8, -0.7)**	0.5 (0.1, 0.9)
Waist circumference, cm	-5.6 (-8.2, -2.9)**	2.5 (0.5, 4.6)
Systolic blood pressure, mmHg	-1.6 (-6.7, 3.5)	-1.0 (-5.8, 3.8)
Diastolic blood pressure, mmHg	-1.6 (-4.6, 1.5)	0.4 (-3.0, 3.7)
LDL, mmol/L	0.1 (0.04, 0.2)	-0.1 (-0.2, 0.1)
HDL, mmol/L	-0.04 (-0.03, 0.1)	0.02 (-0.1, 0.1)
HbA1c, %	-0.3 (-0.4, -0.2)**	0.1 (0.02, 0.2)
Depressive symptoms (PHQ-9)	-0.4 (-0.6, -0.2)*	-0.1 (-0.3, 0.2)
Sleep Quality (PSQI)	-1.6 (-1.8, -1.0)**	0.2 (-0.4, 0.9)

**p-value <0.01, *p-value < 0.05, (95% CI)

Conclusion:

Significant improvement at 12 weeks, not sustained

Behuhuma IAS 2025 #LB11

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U.S. Department of
Health and Human
Services

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV

Updated: September 25, 2025
Reviewed: September 25, 2025

WHAT'S NEW IN THE GUIDELINES

- Laboratory testing**
 - CD4: 3 months after starting ART, every 3 months (if <300), every 6 months (if ≥300 with VS for 1-2 years), optional (if ≥300 with VS after 1-2 years)
 - If ART is deferred: VL and CD4 every 3-6 months
- Starting ART**
 - Hospitalized people (whenever possible)
 - Elite controllers
 - Strong recommendation: HIV complications/comorbidities/pregnancy, ↓CD4, intermittent detectable VL
 - Recommend: all others
- Suboptimal CD4 recovery**
 - Adding/switching ART, IL2, and other interventions are not recommended
 - Optimize OI prophylaxis

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WHO: Revised ART Recommendations: July 2025

<https://www.who.int/publications/i/item/B09471>

Treatment	New recommendations	Previous recommendations
Preferred PI options	CRT/r	ATV/r and LPV/r
Alternative PI options	ATV/r and LPV/r	DRV/r
Preferred NRTI options	Adults, adolescents and children > 30 kg: TDF or TAF Children < 30 kg: ABC	TDF for ART initiation in adults and adolescents ABC for ART initiation in children
Alternative NRTI options	No alternative	AZT or TAF
NRTI in subsequent regimens	Adults, adolescents and children > 30 kg: TDF or TAF (even if ABC or AZT previously used) Children < 30 kg: ABC or TAF (even if ABC or AZT previously used)	AZT if TDF or ABC used in initial regimen (and vice versa)
Dual ARV oral regimens	QTG+3TC as ART simplification strategy in adults and adolescents with undetectable HIV viral load (no active HBV infection)	---
LA injectable regimens	CAB + RPV as alternative ART switching option in adolescents and adolescents with undetectable HIV viral load (no active HBV infection)	---

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Intermittent ART in Adolescents: BREATH-ER Plus

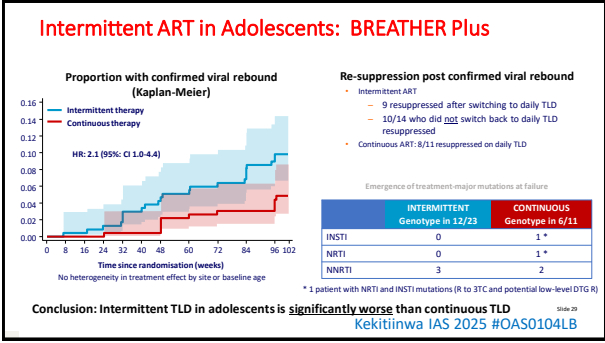
Short cycle ART in teens with weekends off: 96-week results

- Open-label, non-inferiority, RCT: short cycle (5 days on, 2 days off) vs continuous ART (TLD)
- Kenya, Uganda, South Africa, Zimbabwe
- Adolescents 12-19 y, on ART ≥ 1 year, on TLD ≥ 1 month, no history of treatment failure, HIV RNA < 50 c/mL > 12 months
- Primary endpoint: confirmed HIV RNA ≥ 50 c/mL
- N= 470; 56% female
- Median age: 16.5 years; 97% vertical transmission
- Median time on TLD: 2.5 years
- MEMS cap-measured adherence to schedule in both arms: 92%

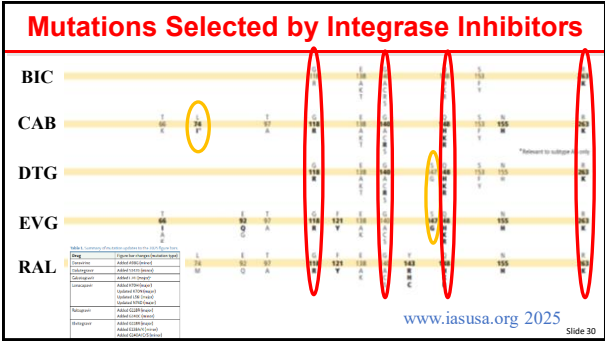
Kekitiinwa IAS 2025 #OAS010448

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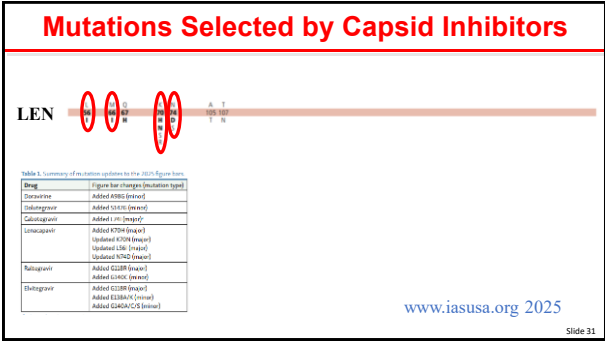
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- Cornell HIV Clinical Trials Unit (CCTU)
 - Division of Infectious Diseases
 - Weill Cornell Medicine
 - AIDS Clinical Trials Group (ACTG)
 - Division of AIDS/NIAID/NIH
 - The patient volunteers!
 - Marina Klein for slides
- rgulick@med.cornell.edu



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Q and A Session

IAS-USA
International AIDS Society - USA

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