

The HIV/AIDS Pandemic: Where are we now?

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Disclosures

U.S. National Institutes of Health (NIAID, NIDA, NIMH) Hock Professorship, Duke University School of Medicine Co-I HPTN 103/PURPOSE 4, supported in part by Gilead Sciences

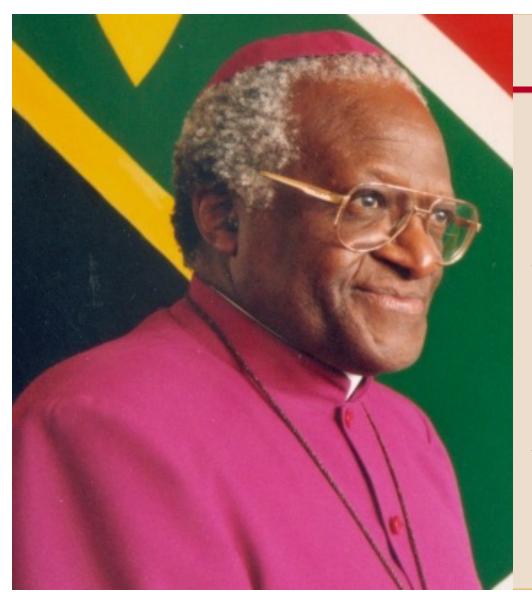
Member, PEPFAR Scientific Advisory Board Member, WHO Scientific and Technical Advisory Committee on HIV/AIDS

Member, Advisory Board, Fogarty International Center, NIH



A Few Words About Our Global HIV Community

- Diversity
- Equity
- Inclusion



Inclusion

"...for the LGBT youth out there who are struggling, who are made to feel inferior, let me say this: God loves you as you are. Never let anyone make you feel inferior for being who you are. When you live the life you were meant to live, in freedom and dignity, you put a smile on God's face."

The Lancet, 2012



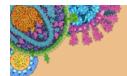


Outline

- I. The Pandemic in 2025
- II. Interrogating Incidence
- III. Challenges for Primary Prevention
- II. Changing US Policies and Priorities

 Modeling impacts
- IV. Moving Forward





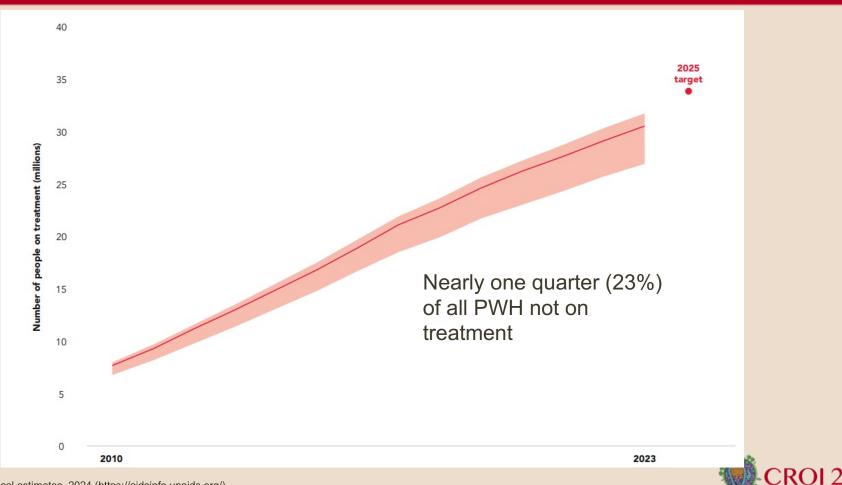
The State of the Pandemic

2025 Targets We Didn't Meet





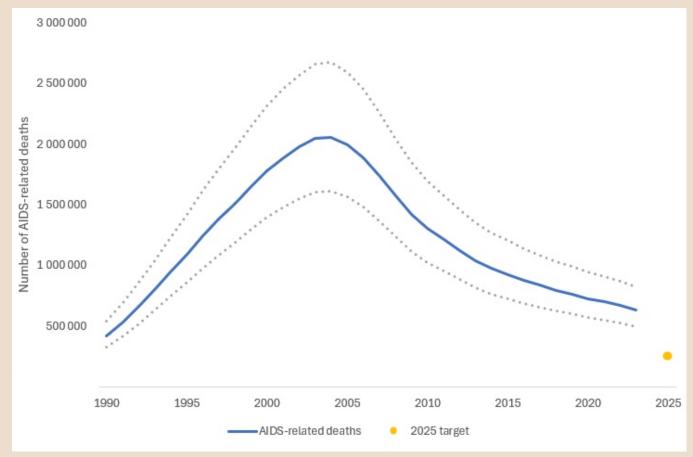
Access to HIV Treatment Must Continue



UNAIDS epidemiological estimates, 2024 (https://aidsinfo.unaids.org/).

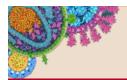


Number of AIDS-related Deaths, Global, 1990–2023, and 2025 Target

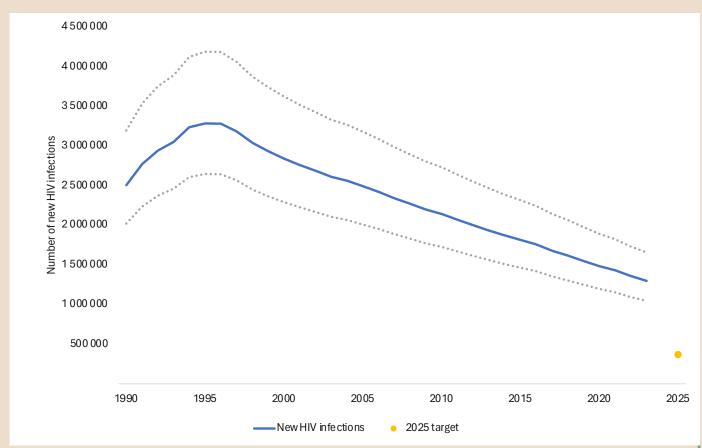




Source: UNAIDS 2024 epidemiological estimates

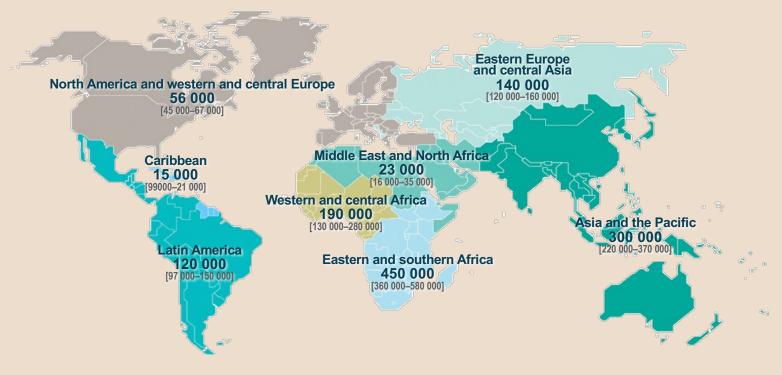


Number of New HIV Infections, Global, 1990–2023, and 2025 Target



CROI 2025

Estimated Number of Adults and Children Newly Infected with HIV (2023)



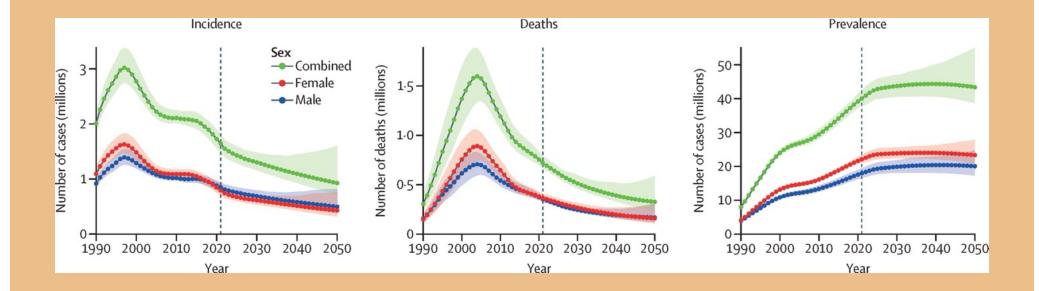
Total: 1.3 million [1.0 million–1.7 million*]

*Data from the Russian Federation are likely too low by 50-100%





Temporal Trends of HIV Incidence, Mortality, and Prevalence Counts for 1990–2050





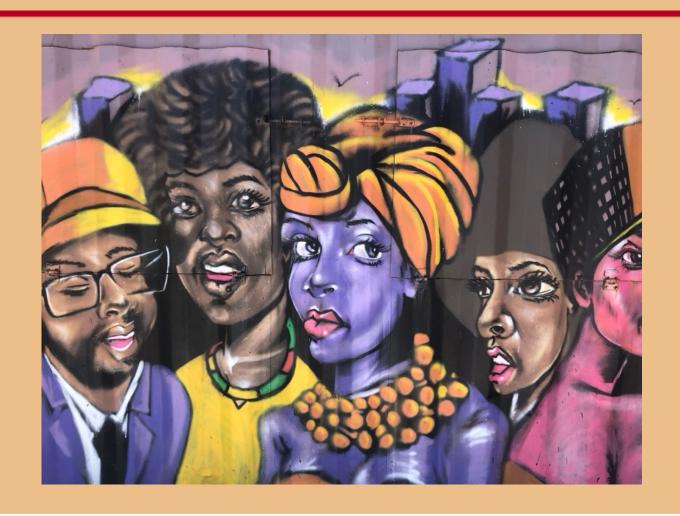


Key Messages Epidemiology

- We did not meet the UNAIDS 2025 targets on HIV incidence or mortality—both are in decline, but too slowly
- HIV incidence remained too high to achieve pandemic control before Jan. 20th, 2025
- 3 regions (E. Europe & Central Asia; Latin America, Middle East and North Africa) are in epidemic expansion in 2025



Measured incidence: Placebo Arms of HIV Prevention Trials







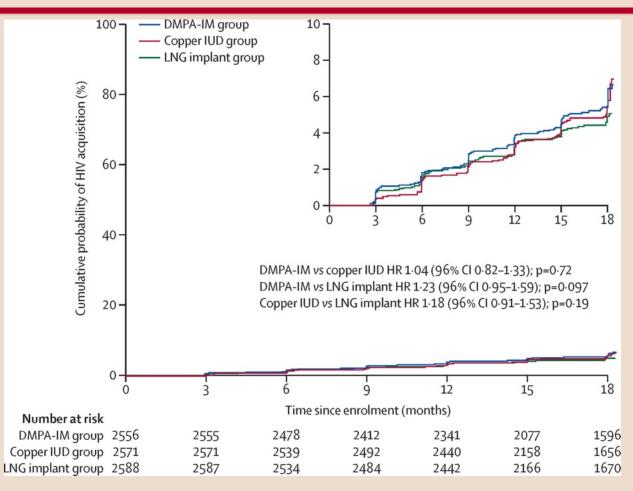
ECHO Contraceptive Trial HIV Results

345 incident HIV infections in 7647 woman-years of follow-up.

Incidence =

4.51 per 100 woman-years (95%CI 4.05-5.01).

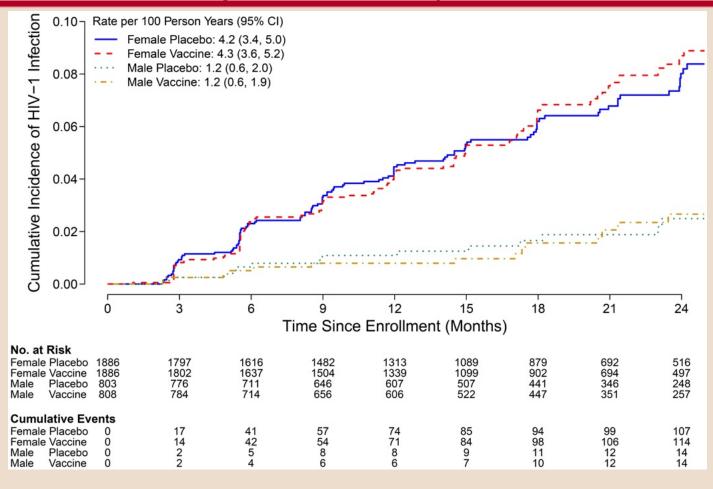
Palanee-Phillips T, et al. PLoS One. 2022.



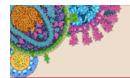




HVTN 702 cumulative HIV-1 incidence, Months 0-24 by Sex at Birth: (5,407 South Africans)









The Lancet HIV

Volume 11, Issue 7, July 2024, Pages e489-e494



Viewpoint

Is HIV epidemic control by 2030 realistic?

Prof Chris Beyrer MD ^{a b} A M, Prof Georgia D Tomaras PhD ^{b c}, Huub C Gelderblom MD ^d,

Prof Glenda E Gray MBBCH ^h, Prof Holly E Janes PhD ^d, Prof Linda-Gail Bekker MD ^e,

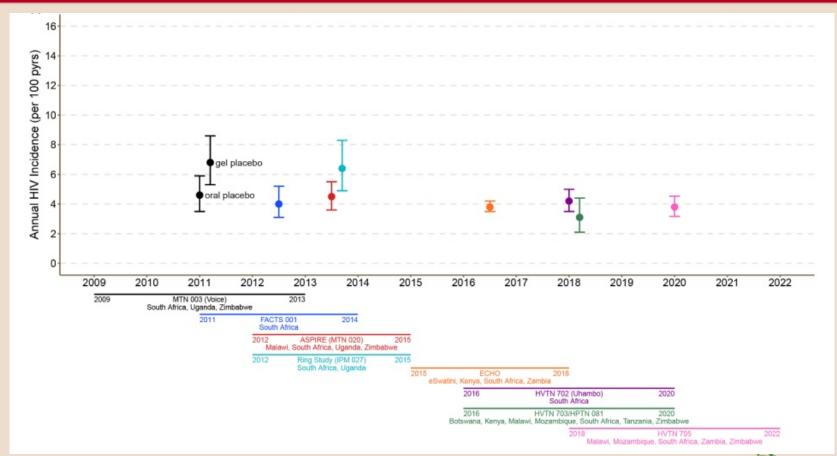
Gregorio Millett MPH ^f, Prof Giuseppe Pantaleo MD ^g, Prof Susan Buchbinder MD ⁱ,

Prof Lawrence Corey MD ^d

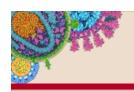




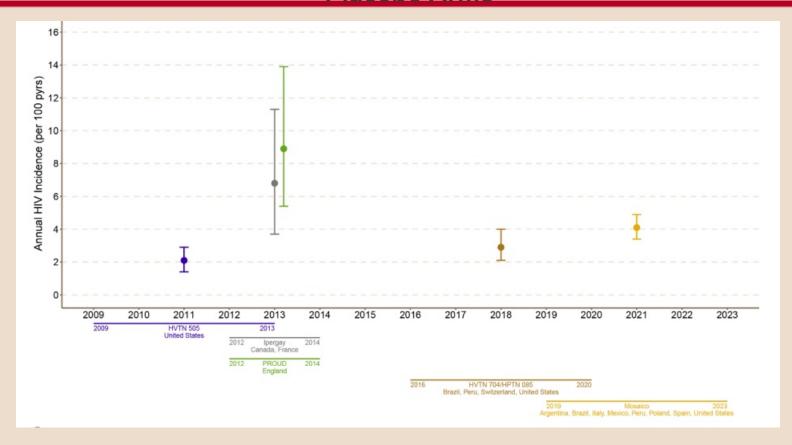
HIV-1 Incidence Estimates Among Female Placebo Recipients in Recent HIV Prevention Efficacy Trials in sub-Saharan Africa







HIV-1 Incidence Estimates among MSM/Transgender Persons Placebo Arms





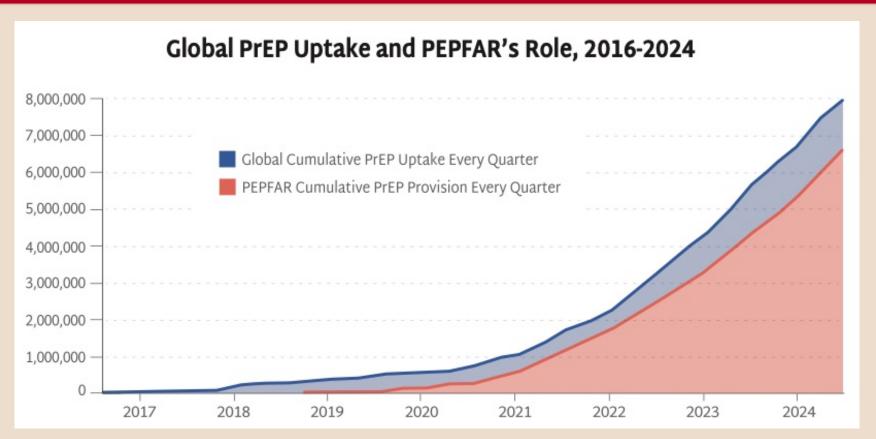


Challenges of Primary Prevention





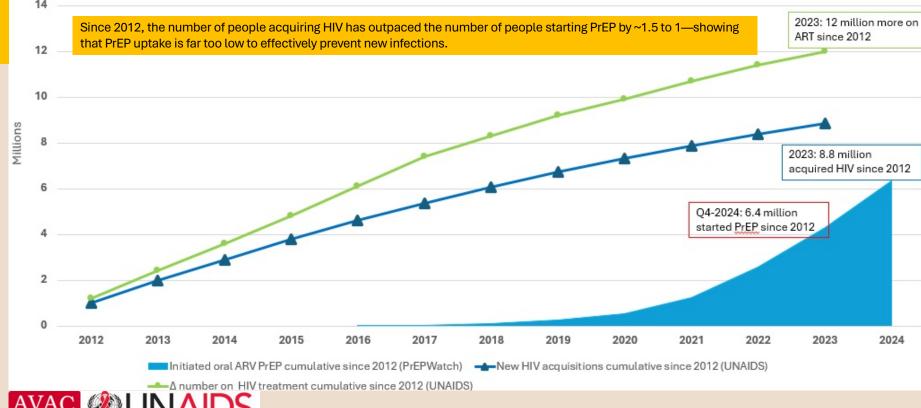
Cumulative PrEP Initiations to 2024





HIV, ART & PrEP 2012-2024 – Eastern and Southern Africa

HIV: PrEP ~1.5:1



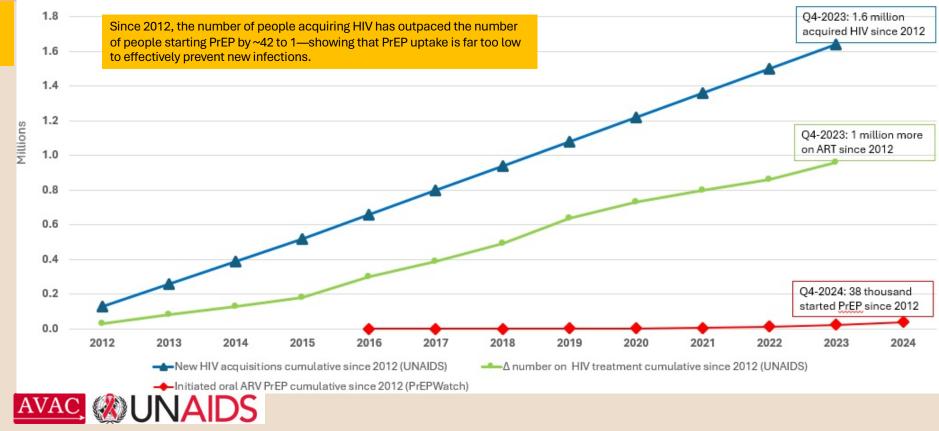




HIV, ART & PrEP 2012-2024 – Eastern Europe & Central Asia

HIV: PrEP

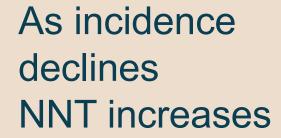
42:1

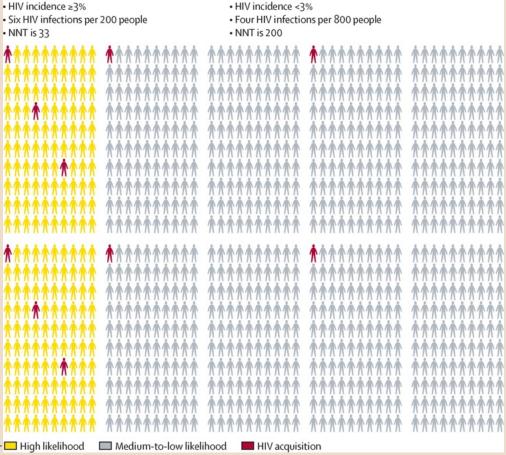






Likelihood of HIV Acquisition and Number Needed to Treat (NNT) with Oral PrEP





Medium-to-low likelihood

Beyrer C, Tomaras GD, Gelderblom HC, Gray GE, Janes HE, Bekker High likelihood Medium-to-low likelihood HIV acquisit LG, Millett G, Pantaleo G, Buchbinder S, Corey L.

High likelihood

Is HIV epidemic control by 2030 realistic? Lancet HIV. 2024 Jul;11(7)



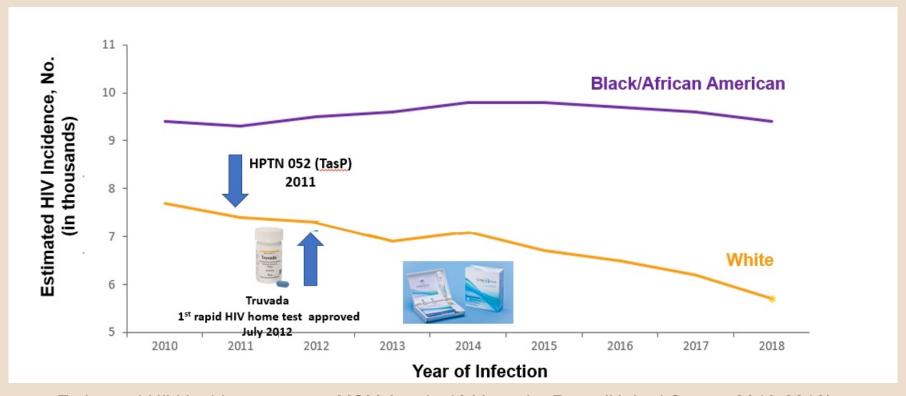
A STATE OF THE STA

Policy Tradeoffs between PrEP Reach and Efficiency: 118 Million Women 15-49, 15 countries

Cases averted N (%)	20,000 (5%)	130,000 (33%)	260,000 (67%)	369,000 (95%)	
Reach: N (%) on PrEP	0.8 million (1%)	7.9 million (7%)	25.1 million (21%)	78.6 million (66%)	
NNT:	39	61	96	213	
N on PrEP to avert 1 case	Nigeria Ethiopia Uganda Rwanda DEE Kenya	Nigeria Ethiopia Uganda Rwanda	Nigeria Ethiopia Cameroon Rwanda	Nigeria Ethiopia Uganda Kenya	
Women at highest risk	Namibia Namibia Tanzania Zimbabwe Eswatini Lesotho South Africa	Namibia Zambia Majtawi Zimbabwe Eswatini Lesotho South Africa	Namibia Zambia Malawi Zimbabwe Eswatini Lesotho South Africa	Rwanda A Tanzania Zambia Malawi Zimbabwe Eswatini Lesotho South Africa	
No women Women with partners outside the home All women Rosenberg, Shook-Sa, et al, CID, 2024					

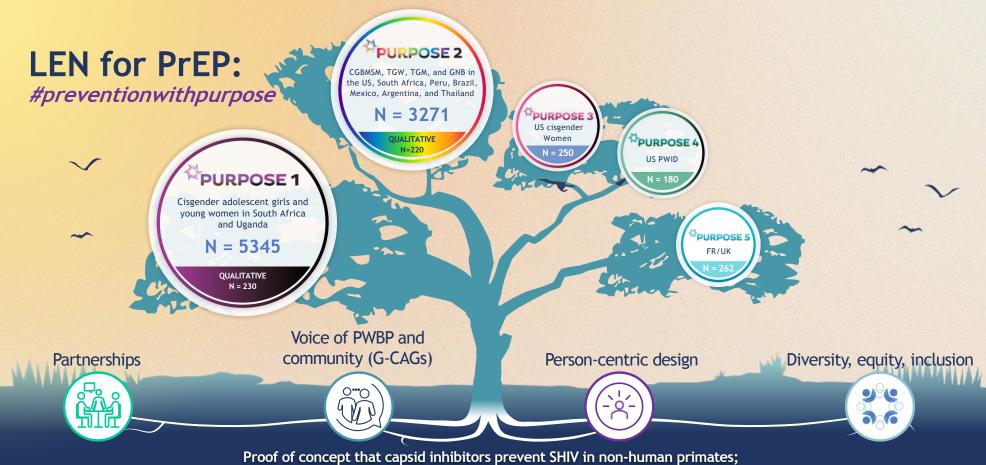


HIV Incidence Among Black MSM Has Remained Stubbornly High Despite Prevention Advances: HPTN 096



Estimated HIV Incidence among MSM Aged ≥13 Years by Race (United States, 2010-2018)





Proof of concept that capsid inhibitors prevent SHIV in non-human primates; Robust pharmacokinetic and safety database in persons with and without HIV;



PURPOSE 1 NCT identifier: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342. PURPOSE studies available at: https://www.purposestudies.com (accessed October 4, 2024).

Access statements: https://www.gilead.com/company/company-statements/2024/updated-statement-on-access-planning-in-high-incidence-resource-limited-countries-for-lenacapavir-for-hiv-prevention (accessed October 4, 2024); https://www.gilead.com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries (accessed October 4, 2024).

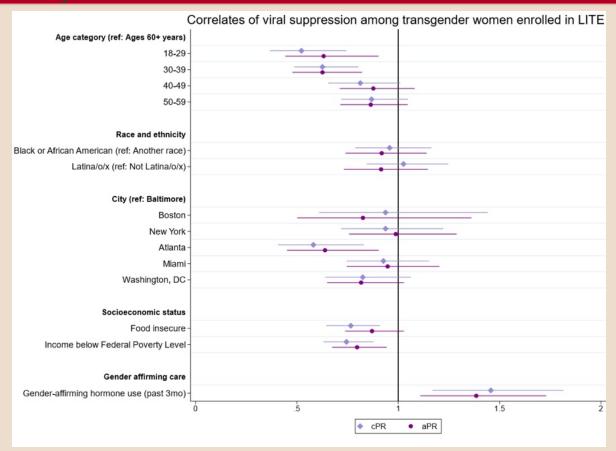
CGBMSM, cisgender gay and bisexual men who have sex with men; FR, France; G-CAG, Global Community Advisory Group; GNB, gender nonbinary individuals; LEN, lenacapavir; MDR, multi-drug resistant; NCT, National Clinical Trial; PrEP, pre-exposure prophylaxis; PWBP, people who may benefit from PrEP; PWID, people who inject drugs; SHIV, simian-human immunodeficiency virus; TGM, transgender women; Tx, treatment; UK, United Kingdom; US, United States.





Correlates of Viral Suppression (n=280 Transgender Women) The LITE Cohort

	Total		Suppressed	
	(N=230)	d (n=75)	(n=155)	p-value
Age group				
18-29	17.4%	28.0%	12.3%	
30-39	28.3%	37.3%	23.9%	
40-49	20.0%	16.0%	21.9%	
50-59	24.8%	16.0%	29.0%	
60-69	9.6%	2.7%	12.9%	
Black or Afric	0.67			
Yes	72.5%	74.3%	71.6%	
Latina/Hispai	3.0			
Yes	28.5%	27.4%	29.0%	
City	0.017			
Baltimore	17.6%	11.1%	20.6%	
Boston	3.5%	2.8%	3.9%	
New York	12.3%	9.7%	13.5%	
Atlanta	18.9%	31.9%	12.9%	
Miami	25.6%	20.8%	27.7%	
Washington,				
DC	22.0%	23.6%	21.3%	
Food insecur	0.004			
Yes	60.7%	74.3%	54.2%	
Income belov	0.003			
Yes	74.5%		68.5%	
Gender-affirn	<0.001			
Yes	63.4%			







Key Messages Prevention

- Significant increases in primary prevention programs, will be required to achieve epidemic control—
- But aside from PMTCT...PEPFAR prevention is on pause
- Advances in primary prevention, including LA injectables, could markedly reduce HIV incidence but only if taken to scale for both high incidence density populations (MSM, SW, TGW, AWYG in high burden settings) AND lower incidence ones
- >40 million people need to be on PrEP to reach epidemic control





Changing US Policies and Priorities

"It is chaos."

--PEPFAR supported African Investigator

Callaway E.

Nature Comms
Feb. 13th, 2025



"The way things are going, I feel like I have worked so much for nothing."

--Perinatally infected adult outreach worker.





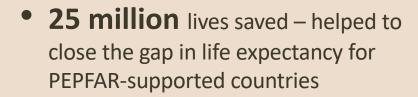
Before PEPFAR...

...Since PEPFAR

In high-burden HIV countries in Africa...

- Average life expectancy was declining by 10-30 years
- GDP was declining by2.6% annually
- 29 million people infected with HIV had no access to treatment

...20+ years and \$110 billion invested



- 20.5 million people on treatment
- **5.5M babies** born HIV-free
- GDP / capita is 2.1% higher







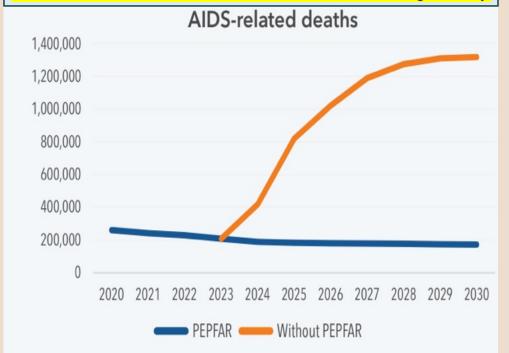




Expected Impact of PEPFAR: 2024-2030

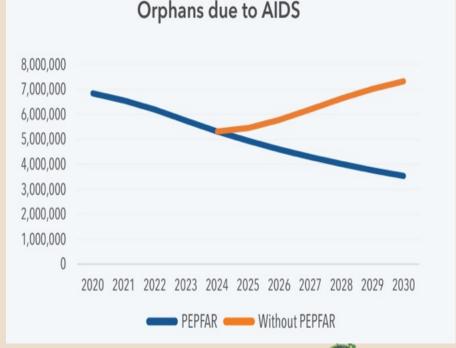
5.2 million AIDS-related deaths averted in 12 PEPFARsupported high disease burden countries from 2024-2030

400 % increase in AIDS related deaths from 2023 if PEPFAR goes away



4 million fewer AIDS orphans in 12 PEPFAR0supported high disease burden countries from 2024-2030

Doubling AIDS orphans from 2023 if PEPFAR goes away









Projected Human Toll: 100,000 Lives Lost in One Year

Tram KH et al. Journal of the International AIDS Society 2025, 28:e26431 http://onlinelibrary.wiley.com/doi/10.1002/jia2.26431/full | https://doi.org/10.1002/jia2.26431



VIEWPOINT

By executive order: The likely deadly consequences associated with a 90-day pause in PEPFAR funding

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Global Health Security and Diplomacy US Department of State Feb. 6, 2025 Waiver for PEPFAR

PEPFAR-supported life-saving HIV Care & Treatment and Prevention of Mother to Child Transmission (PMTCT) services should be resumed as soon as possible...

HIV Pre-exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) should be offered only to pregnant and breastfeeding women (PBFW; see section above) during this pause of U.S. Foreign Assistance. PBFW may receive either oral or long-acting PrEP.

 Note: People other than PBFW who may be at high risk of HIV infection or were previously initiated on a PrEP option can not be offered PEPFARfunded PrEP during this pause of U.S. Foreign Assistance or until further notice.



HIV Care & Treatment and Prevention of Mother to Child Transmission Activities Approved Under PEPFAR Limited Waiver

February 6, 2025

PEPFAR-supported life-saving HIV Care & Treatment and Prevention of Mother to Child Transmission (PMTCT) services should be resumed as soon as possible. PEPFAR implementing agencies should take necessary actions to expedite resumption of these services.

This document is intended to provide additional clarification of activities approved under the PEPFAR 90-Day Limited Waiver. Activities not specifically listed should not be resumed. If further clarification is needed, send an email to ghad_eg@state_gov. Resumption of activities approved under the PEPFAR 90-day waiver is limited to activities provided to the provided of the performance of the performance

"For purposes of this limited waiver, life-saving humanitarian assistance applies only to: Delivery of life-saving HTV care and resterance services through support for health workers (doctors, nurses, and other clinical and community health workers, etc.) delivering or monitoring HTV care and treatment or le source continuity of service provision. These workers deliver care at hospitals, primary healthcare clinics, faith-based clinics, and community settinus."

Salaries for health workers, laboratory, and supply chain staff necessary to carry out the specific activities described in this document are included in this waiver.

HIV Testing Services for All Populations [For HIV Case Finding, Re-entry in Care, and

- "Provision of HIV testing in community and facility settings" To identify people
- Referral and navigation to confirmatory HIV testing (including for those who
- screen positive with an HIV self-test)
 Referral and navigation to antiretroviral treatment (ART) for those with a
- Referral and navigation as appropriate to PMTCT services
- HIV screening for people diagnosed with TB: All individuals who are either diagnosed with or presenting with pulmonary or extrapulmonary symptoms of tuberculosis should be tested for HIV
- All PMTCT and HIV exposed infant (HEI)-related testing, inclusive or



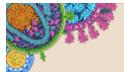


Disaggregates

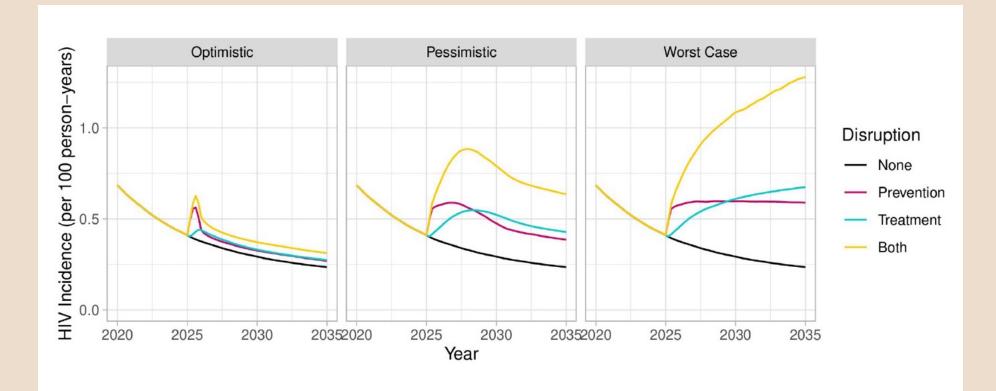
The KP [Key Population] disaggregates are removed from the indicators covered under the indicator.

They are also removed from the MER [Monitoring and Evaluation Reporting] guidance, data entry streams, and from the data model.





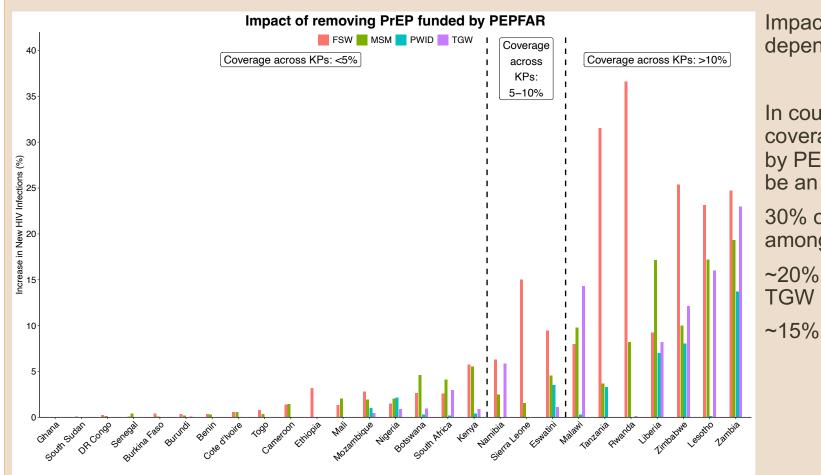
Pausing Prevention for FSW has a large projected Impact on HIV Incidence 2025 – 2035



* median of 1000 model fits, Eswatini



Relative Increase in New HIV Infections due to Removing PEPFAR Funded PrEP for KPs in SSA



Impact of removing PrEP depends on coverage

In countries with higher coverages of PrEP funded by PEPFAR, there could be an increase of over:

30% of new infections among FSW

~20% among MSM and TGW

~15% among PWID







US: Lifesaving Programs Remain Suspended Despite Waivers

Millions at Risk as Vital Programs Shut Down February 10, 2025 2:00PM EST

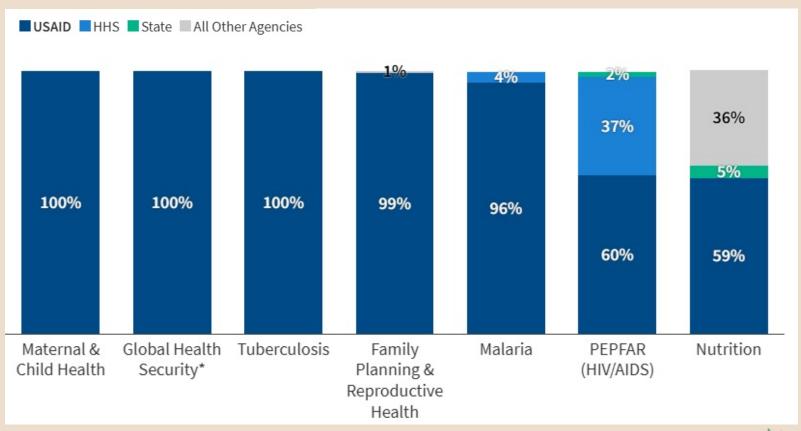


US Secretary of State Marco Rubio speaks after being sworn in by Vice President JD Vance near the White House in Washington, DC, January 21, 2025. © 2025 AP Photo/Evan Vucci





USAID Obligated/Implemented Most U.S. Bilateral Funding Across Global Health Sectors





RFK Jr. Targets Transgender Protections in One of First Moves at HHS 02/20/25

"This administration is bringing back common sense and restoring biological truth to the federal government...The prior administration's policy of trying to engineer gender ideology into every aspect of public life is over."

Robert F. Kennedy Jr. Secy DHHS



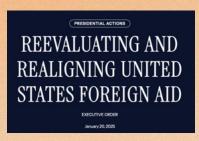
"It's deeply concerning that ... HHS is instead focusing its time and taxpayer dollars on anti-science, anti-health PR campaigns...This approach is not only ignorant; it's deliberately harmful."

Matthew Rose Human Rights Campaign



AVAC v. US Department of State; GHC v. Trump

How It Started



New lawsuit challenges US foreign aid funding freeze

Judge orders Trump administration to restore funds for foreign aid programs

Then...

USAID contracts and grants still being terminated despite court order

Constitutional Crisis...

Nearly 10,000 awards cut from USAID, State Department Judge Gives Trump Administration
Deadline to Release Foreign Aid

Chief Justice Allows U.S. to Continue Freeze on Foreign Aid Payments

U.S.A.I.D. Memos Detail Human Costs of Cuts to Foreign Aid

"Lift the Freeze": HIV/AIDS Advocates Win Supreme Court Victory in Fight over Trump Foreign Aid Cuts

Trump administration ordered to pay select USAID partners by Monday

Full timeline & links to documents at https://avac.org/avac-vs-dept-of-state/

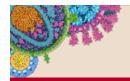




Key Messages Current Policies

- The abrupt pause of PEPFAR, USAID, PMI, has led to widespread service disruptions, and increased HIV incidence, morbidity and mortality
- The limited PEPFAR waiver led to some return of access, but 2/3 of PEPFAR is/was implemented through USAID
- PEPFAR Authorization expires on March 25, 2025--in 15 days. We need a full reauthorization
- Most affected will be those living in countries with the weakest health services and already marginalized communities
- A new coalition will likely be needed to close new gaps: governments, the private sector, foundations, and communities will be called on to do more





So...

- Restore PEPFAR and its prevention program
- Support KP clinics and community partners
- Support 8th Global Fund Replenishment
- Uphold Human Rights





Mr. Bush announced his trip to Africa in conjunction with World AIDS Day in November [2008], quoting from Deuteronomy:

"I have set before you life and death ...

Therefore, choose life."





Acknowledgements

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