

## From Research to Rollout: The impact of USG global health pullout



*In this special edition of Px Wire, AVAC is going beyond a quarterly update of biomedical HIV prevention. In this issue, we look at how the new US Administration’s attack on global health can be expected to devastate HIV prevention, including the capacity to deliver existing PrEP options, the scale up of new PrEP products, and the paralyzing impact on research and development.*

“People other than PBFW [pregnant and breast-feeding women] who may be at high risk of HIV infection or were previously initiated on a PrEP option cannot be offered PEPFAR-funded PrEP during this pause of U.S. Foreign Assistance or until further notice.”

*February 6, from the Global Health Security and Diplomacy memo, US Department of State*

The United States’ presidential regime has launched a sustained, multi-pronged attack against foreign assistance, scientific inquiry, due process and good governance. It threatens economies, human rights, international partnerships, global health at large, and the rule of law. For HIV prevention, a single sentence, issued in a February 6 advisory from the US Department of State, has derailed the entire field, potentially setting back the HIV response by years, if not decades.

Read on for resources to support your advocacy and fortify our solidarity at this critical time.

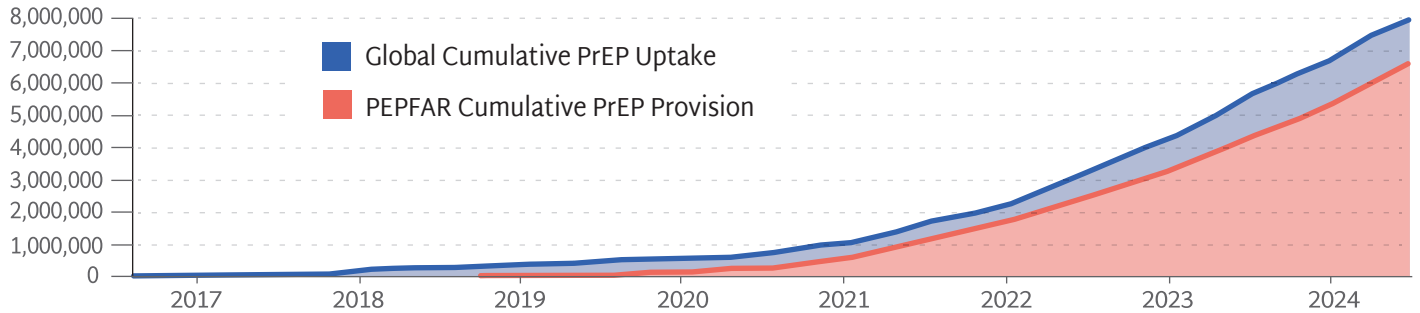


New Vision, Uganda, February 11, 2025

# Progress in PrEP Uptake: Threatened



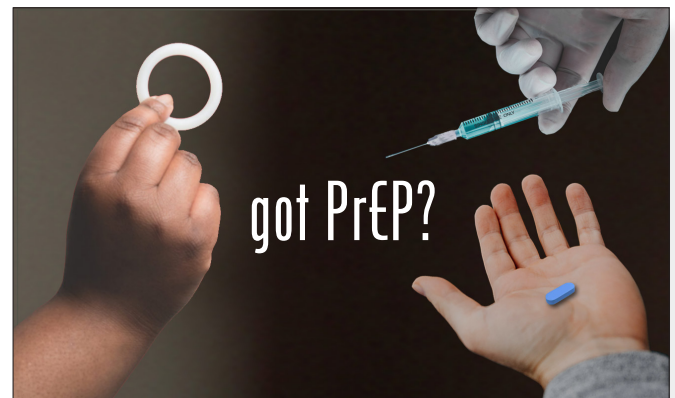
## Global PrEP Uptake and PEPFAR's Role, 2016-2024



PEPFAR has been pivotal to accelerating PrEP uptake, significantly expanding HIV prevention coverage. The freeze on foreign aid prohibits funding to PEPFAR's PrEP programs and poses a serious threat to global efforts to control the epidemic.

AVAC's [Global PrEP Tracker](#) has documented cumulative PrEP initiations on a quarterly basis for nearly a decade. This graph presents the final data collected while PEPFAR was fully operational—PEPFAR support was responsible for 79% of PrEP uptake globally in the last year and reached 83% by the end of September of 2024. Data on the fourth quarter of 2024 is inaccessible since PEPFAR was taken offline in late January.

At the time of the foreign aid freeze, PrEP uptake had reached 8 million initiations since 2016, an achievement that's taken almost 10 years to reach – too slow and too small to reach UNAIDS targets, but a robust foundation to finally accelerate PrEP uptake with next-generation PrEP. Current US policies, instead of expanding PrEP coverage, are leading to the closure of programs, and will reverse global progress against HIV.

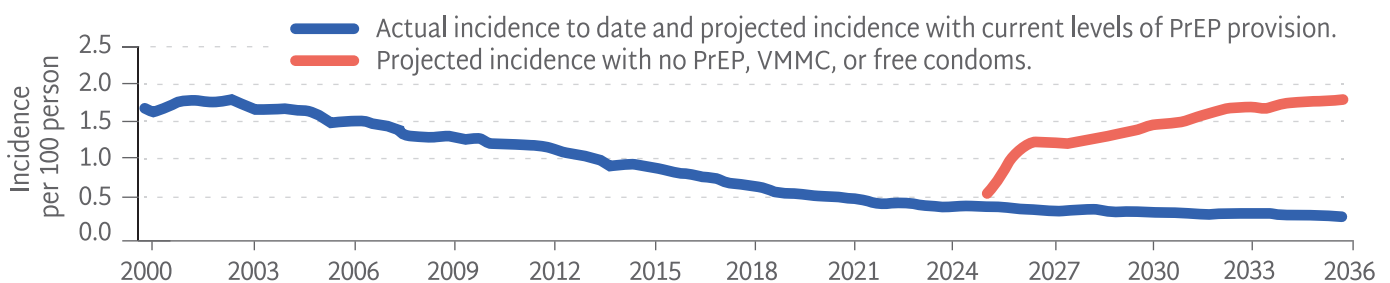


For the last 8 years, AVAC has proudly worked with PEPFAR to document PrEP uptake and its impact around the world. That stopped in January with a stop work order from the US government. But protecting access to PrEP is vital. Are you leading a PrEP program? Whether supported by PEPFAR or not, we invite you to work with us to ensure global data on PrEP is not lost.

Find us at [PrEPWatch@AVAC.org](mailto:PrEPWatch@AVAC.org)



## HIV incidence, age 15-49



Without primary prevention, the HIV epidemic is poised to rage on, with incidence among adults on track to triple over the next ten years. This [HIV Synthesis model](#), developed by the HIV Modelling Consortium, estimates

the impact of stopping all HIV prevention services across Africa from now through 2036—including PrEP, voluntary medical male circumcision (VMMC), and free condom distribution.

# PrEParing for New Products: Is rollout still possible?



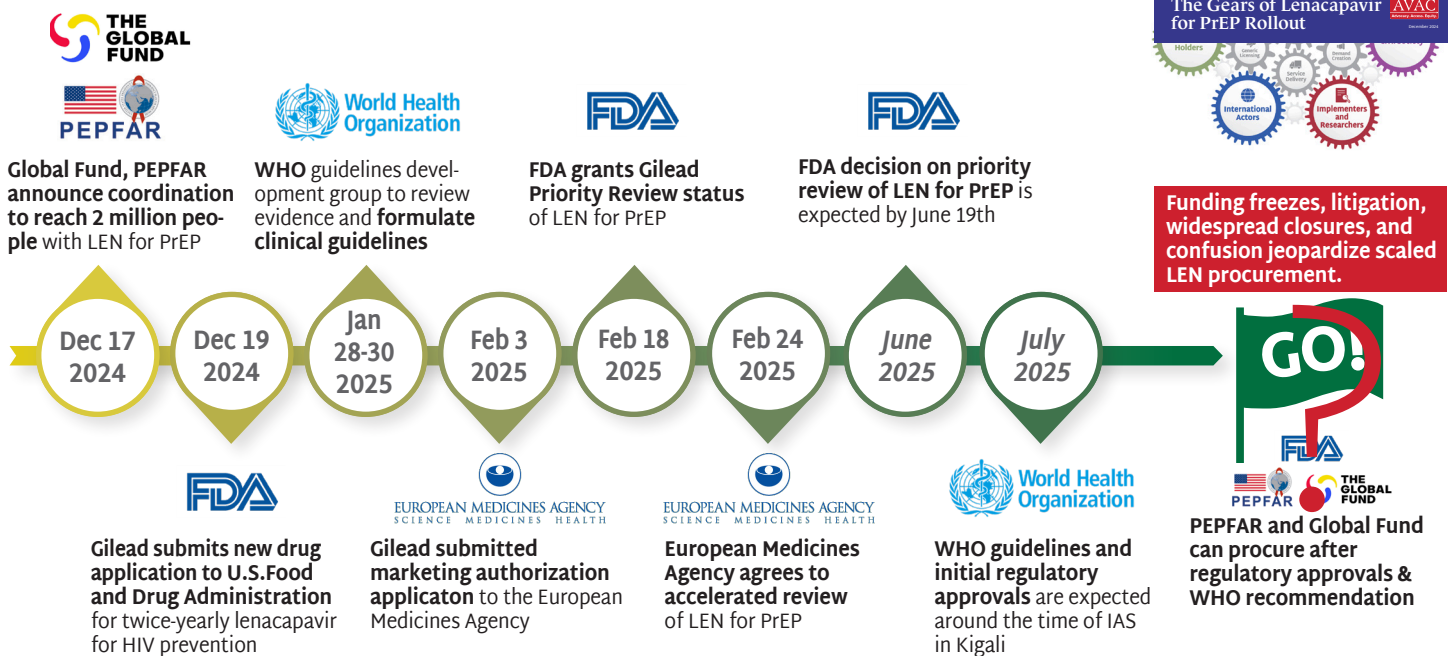
DAVID COX SCIENCE FEB 21, 2025 2:26 PM

## This New Drug Could Help End the HIV Epidemic—but US Funding Cuts Are Killing Its Rollout

Lenacapavir, a twice yearly injection that prevents HIV transmission, was named the breakthrough medicine of 2024. But without US foreign aid dollars, its delivery to millions worldwide is under threat.

Wired, February 21, 2025

### Where We Are Now with LEN for PrEP



The chaos in foreign assistance programs (including discontinuation of major PrEP programs), cuts in staffing and new demands on donor commitments will make decisions on the procurement of LEN for PrEP more complex and uncertain. In December 2024, the Global Fund and PEPFAR announced a plan to reach 2 million people with LEN for PrEP over three years. Exactly how funding to support this unprecedented introduction program will move forward, in the absence of significant US investment, is far from certain. The other stakeholders, including Global Fund, Gilead, CIFF and the Gates Foundation expressed commitments to the deal, but major questions remain. In the meantime:

- ➔ Gilead’s production of LEN for PrEP is continuing, as is the technology transfer to generic license holders.
- ➔ The FDA granted Gilead priority review status for LEN for PrEP, with a decision due by June 19, 2025.
- ➔ The EMA has agreed to an accelerated review of LEN for PrEP for both European access and as part of the EU-M4all program, reducing the review from seven months to five months.
- ➔ The WHO’s Guideline Development Group (GDG) met in January, and WHO is expected to issue guidelines by July 2025.

# The Latest R&D in the Prevention Pipeline: Supported or undermined?



GLOBAL HEALTH

## Abandoned in the Middle of Clinical Trials, Because of a Trump Order

The stop-work order on U.S.A.I.D.-funded research has left thousands of people with experimental drugs and devices in their bodies, with no access to monitoring or care.

*New York Times, February 6, 2025*






















*Science Magazine, February 5, 2025*

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## 'It's tectonic': U.S. foreign aid freeze deals a blow to research around the globe

Dismantling of USAID could disrupt clinical trials and wipe away U.S. "soft power" in developing countries, scientists warn

## Trials & Projects Halted by USAID Funding Suspension

Project	Product(s)	Type	Country(ries)	# of participants
	 TAF/EVG Fast-dissolving insert	MATRIX-001 Phase 1 safety and acceptability	Kenya, South Africa, USA	60
	 One month dapivirine vaginal film	MATRIX-002 Safety, acceptability, usability of placebo	Kenya, South Africa, USA, Zimbabwe	100
	 Non-ARV nonhormonal contraceptive multipurpose vaginal ring	MATRIX-003 Safety, acceptability, usability of placebo	South Africa, USA, Zimbabwe	100
	 Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	Cohort study of safety in mothers and babies exposed to ARV-based prevention	Kenya, Lesotho, Zimbabwe	500-800
	 One-month dapivirine vaginal film plus levonorgestrel (LNG)	Preclinical study	USA	Preclinical
	 BG505 GT1.1 and 426c.Mod. Core-C4b	B-001 Phase 1 clinical trial	Kenya, South Africa, Uganda	48
	 Polyvalent HIV-SET saMRNA vaccine clinical program	Pre-clinical and clinical trials	Multiple African countries	Exploratory
	 CAP 256 based mRNA vaccine candidates incl Africa-based mRNA manufacturing	Development program	Multiple African countries	Exploratory
	 Multiple founder virus-based vaccines	Exploratory program	Multiple African countries	Exploratory
	 Tech-transfer activities in Uganda with SOSIP trimers	Technology transfer	Uganda	Exploratory
	 Mosaic Trimers: MOS1SIP, MOS2SIP, M3SIP8 and MPLA	Vaccine	Rwanda, Zambia	40
	 Multisite Adolescent Girls and Young Women study	MAGY Epidemiological study	Uganda, Zambia, Kenya, South Africa	1,210
	 Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	CATALYST Implementation Science Study	Kenya, Lesotho, South Africa, Uganda, Zimbabwe	7,500
	 Injectable CAB, Dapivirine Vaginal Ring	Policy and programmatic support, including user-centered research and technical assistance	Bostwana, Eswatini, Kenya, Lesotho, Namibia, South Africa, Uganda, Zambia, Zimbabwe	Community-based
	 Dapivirine Vaginal Ring, Oral TDF/FTC	Increasing PrEP Options for Women in Eswatini	Eswatini	400
	 PrEP, vaccines and multipurpose technologies	Research translation and preparedness, policy support and advocacy to support prevention research	Kenya, Lesotho, Malawi, Nigeria, South Africa, Uganda, Zambia, Zimbabwe	Community-based

The stop-work orders have disrupted USAID-supported HIV prevention research, halting critical investigations in vaccine and next-generation PrEP strategies.

- ➔ The **BRILLIANT** and **ADVANCE** projects' clinical, preclinical, and experimental trials testing HIV vaccine candidates have been suspended.
- ➔ The **MATRIX** projects', driving innovation with next-generation PrEP and MPT products, fast-dissolving inserts and vaginal films and rings, have been forced to stop their clinical trials.
- ➔ The **MOSAIC** projects' have suspended all implementation science activities, including the **CATALYST** study, investigating choice among oral PrEP, injectable cabotegravir and the dapivirine vaginal ring. Other implementation studies are continuing, but access to the commodities, much of which was procured by PEPFAR is questionable. See AVAC's *Integrated Study Dashboard* for details.
- ➔ The Coalition to Accelerate and Support Prevention Research (**CASPR**) has also been paused. Led by AVAC in partnership with a number of leading African civil

society organizations, CASPR focuses on building an enabling environment for HIV prevention R&D. (Note: In early February, AVAC led a lawsuit against the State Department seeking emergency relief from the freeze on foreign assistance, including funding for CASPR. The case, **AVAC v. United States Department of State**, is pending.)

These disruptions delay the development of urgently needed HIV interventions and threaten the sustainability of research infrastructure all over the world, with particularly egregious impacts on the research capacity of regions most impacted by the epidemic.

The abrupt suspension of these trials also raises serious ethical concerns. Stopping trials mid-course undermines trust in research, jeopardizes community engagement, and abandons participants who volunteer their bodies for scientific discovery. It will take years to build back this critical infrastructure — for HIV research and beyond — as well as the community partnership and trust needed to ensure smooth and ethical research.

## Prevention Playlist

AVAC develops a wide range of resources to inform decision making and action. Check out the latest:

### JOIN

- ➔ **Subscribe to Global Health Watch**  
AVAC's weekly newsletter dedicated to breaking down critical developments in US policies and their impact on global health. [avac.org/signup](http://avac.org/signup)
- ➔ **Seeking Visuals and Videos**  
Leading groups in Washington, DC, are urgently trying to collect videos and photos documenting the impact of the US government's foreign aid freeze, such as clinic closures despite the waiver. Non-professional phone videos and photos are welcome. Send to [media@avac.org](mailto:media@avac.org) for more details.
- ➔ **CHANGE**  
In response to the unfolding crisis, more than 1,300 people from civil society organizations around the world have launched CHANGE - Community Health & HIV Advocate Navigating Global Emergencies - a coalition formed to support urgent action. [contact.change.2025@gmail.com](mailto:contact.change.2025@gmail.com)

### USE

- ➔ *Graphic of studies of injectable cabotegravir and the dapivirine vaginal ring in eastern and southern Africa*, AVAC
- ➔ *Most Lifesaving Services Remain Paused: A Rapid Assessment of the PEPFAR StopWork Order*, amfAR, CHANGE, Data ETC

- ➔ *What Effect are HIV Programmes Having in Africa*, The HIV Modelling Consortium
- ➔ *PEPFAR & Global Fund Support for HIV Programs*, amfAR & Data ETC

### WATCH/LISTEN

- ➔ *[LISTEN] Would PEPFAR Survive Trump—and what would it look like?*
- ➔ *The Impact and Implications of Recent US Government Federal Funding Reductions on Health Programmes*, The Steve Biko Centre for Bioethics at The University of the Witwatersrand event recording

### READ

- ➔ *AVAC v United States Department of State*, AVAC. On February 10, 2025, AVAC and another nonprofit organization sued the new US Administration, seeking emergency relief from an Executive Order that inhumanely froze all funding for foreign assistance.

## About AVAC



AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Bluesky [@HIVpxresearch](https://bsky.app/profile/@HIVpxresearch); find more at [www.avac.org](http://www.avac.org), [www.prepwatch.org](http://www.prepwatch.org) and [www.stiwatch.org](http://www.stiwatch.org).