

## Webinar Summary: The Scientific Journey of Lenacapavir — and the Urgency to Defend HIV Prevention Science

June 2025

On June 11, AVAC hosted a conversation, <u>The Scientific Journey of Lenacapavir: From basic science to clinical development to impact</u>, to explore how US support from NIH for basic science and South Africa's clinical research infrastructure made possible the development of <u>lenacapavir for PrEP</u> (LEN), a discovery in HIV prevention that went on to be named <u>Science</u> magazine's 2024 <u>Breakthrough of the Year</u>.

As the field anticipates initial regulatory approval from the US FDA by June 19 and a WHO recommendation in July, Linda-Gail Bekker of the Desmond Tutu Health Foundation, Wes Sundquist of the University of Utah and Mitchell Warren of AVAC underscored how this moment of promise is threatened by sweeping attacks on science, research and the very systems that made the development of LEN possible.



"If we don't ensure that #HIVprevention R&D gets back on track, we run the risk of not having the next #lenacapavir, the next #cancer treatment, the next #Alzheimer's drug. Because #basicscience & int'l collaborations matter. And they've made lenacapavir possible." - Mitchell Warren

Sundquist described his research collaborations beginning in 1991 (at the time Magic Johnson shared his HIV status he noted) that led to understanding the structure, functions, and inhibition of the HIV capsid. He explained how sustained NIH support was essential to this breakthrough.

"LEN didn't emerge overnight. It's the result of patient, persistent basic science—of believing we could understand a virus deeply enough to target it effectively."

Wes Sundquist, University of Utah

Bekker noted that while Gilead Sciences funded the PURPOSE trials that demonstrated LEN's safety and efficacy last year, the infrastructure to answer the question "does LEN for PrEP work" so quickly was based on decades of NIH investments in research infrastructure around the world, and especially in South Africa. She emphasized how South Africa's 25 trial sites were instrumental in <a href="the PURPOSE studies">the PURPOSE studies</a> and represent the kind of partnerships and research collaboration that advance science and global health for all.

"The investment in infrastructure and the clinical trial infrastructure is not a handout to us. We are very much in partnership with NIH and collaborators in the North. And this incredible partnership has brought us to a point where I would say that we've got five years to deliver on the promise of bringing this epidemic under control. The light is at the end of the tunnel...I'm talking about bringing the epidemic under control. Every minute matters when it comes to preventing HIV."

Linda-Gail Bekker, Desmund Tutu Health Foundation

Bekker and Sundquist both warned of the devastating impact of current U.S. policy shifts:

"What history tells us is that basic science is a feedstock for new innovation. That makes it particularly challenging to think about the proposed NIH cuts. The proposal from the president's budget is a 40% cut in NIH...This would be crippling [to basic science]."

Wes Sundquist, University of Utah

"Unless a miracle happens, I'll have to retrench 130 of my 400 highly experienced staff across seven South African sites. We are losing expertise the world can't afford to lose. We have a contribution to make."

Linda-Gail Bekker, Desmund Tutu Health Foundation

Both speakers reminded the audience that the HIV epidemic can be brought under initial control by 2030—but only with continued investment in innovation, access, and infrastructure.

"We've come too far to let the rug be pulled out from under us. We must regroup, push through, and make sure we don't lose this moment."

Linda-Gail Bekker, Desmund Tutu Health Foundation

The discussion closed with a call to action. Since January 20, the US administration has taken aggressive steps to dismantle USAID, disrupt PEPFAR, shut down NIH-funded research, and propose draconian budget cuts. These include, most recently, ending HIV vaccine design and development consortia, blocking international collaborations, and recommending the removal of COVID-19 vaccines from the childhood immunization schedule.

"If we don't fight to restore HIV prevention R&D, we won't just lose the next LEN, we'll lose the next cancer therapy, the next Alzheimer's breakthrough. Because basic science matters.

Global partnerships matter. And they're all under attack."

Mitchell Warren, AVAC

Listen for the full discussion here
Check out the impacts of the US government cuts on R&D and PrEP here
Follow the progress of LEN for PrEP here
Advocate for NIH research here