

HIV Vaccines—Key Messages

HIV Vaccine Awareness Day

May 2020

For more on the state of HIV vaccine research and advocacy, please visit: www.avac.org/hvad

On HIV Vaccine Awareness Day this May 18, 2020, it's time to call attention to the continuing urgent need for an HIV vaccine and take stock of the progress. It's a day to recognize the enormous contributions of vaccine trial participants and researchers. Finally, HVAD provides an opportunity to frame the HIV vaccine movement's transformational impact on the global capacity to respond to other epidemics, such as COVID-19.

- There is a clear, urgent and ongoing need for a safe and effective HIV vaccine. New HIV infections continue unabated in many parts of the world and populations.
 - Among adolescent girls and young women in sub-Saharan Africa, new infection rates often reach a staggering 4 percent per year or higher.¹
 - o In many parts of the world, the estimated prevalence of HIV infection among people who inject drugs exceeds 40 percent.²
 - Nearly 1 in 5 new HIV infections in the US occur among young men ages 13-24 who have sex with men, the majority of whom are Black or Latino.³
 - o In all, even with highly effective treatment, and proven prevention methods such as PrEP, most recent data show an estimated 1.7 million people around the world still became newly infected with HIV in 2018.
- A vaccine is needed for a durable and sustainable end of the HIV epidemic.
- As the search for an HIV vaccine continues, the knowledge gained from HIV vaccine research, along with the field's history of innovative collaboration, and community engagement efforts, are speeding the search for vaccines and treatments for another pandemic COVID-19.

HIV vaccine research is more productive than ever, with multiple large-scale vaccine trials underway and dozens of promising vaccine approaches in development.

- "Mosaic-based" vaccine regimens designed to protect against a wide variety of HIV sub-types are being tested in two efficacy trials: the *Imbokodo trial (HPX2008/HVTN 705)* in five countries in sub-Saharan Africa and the *Mosaico trial (HPX3002/HVTN 706)* in eight countries across the Americas and Europe.
 - Due to the COVID-19 pandemic, Mosaico has temporarily delayed new enrollments until June 1, at which time the situation will be reassessed; Imbokodo was fully enrolled in May 2019 and is expected to complete its vaccinations in the near future.
- The innovative PrEPVacc study has yet to begin but will be conducted in four African countries, testing two vaccine regimens and comparing two daily oral pre-exposure prophylaxis (PrEP) options, F/TDF (Truvada) and F/TAF (Descovy).

³ https://www.cdc.gov/hiv/group/age/youth/index.html



 $^{^1\,}https://www.the lancet.com/journals/lancet/article/PIISO140-6736(19)31288-7/full text$

² Mathers BM, Degenhardt L, Phillips B, et al. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. Lancet. 2008;372:1733–1745.

- Two antibody-mediated prevention (AMP) proof of concept studies will report later this year whether infusions of a broadly neutralizing antibody (bNAb) against HIV can offer protection against infection.
- Dozens of other vaccine approaches are being studied in pre-clinical and early clinical studies. These include more than 40 vaccine candidates in development designed to elicit broadly neutralizing antibodies, non-neutralizing antibodies, T-cell responses against HIV, or some combination.
- The field did experience a significant disappointment this year with an early stop to vaccinations in the HVTN 702 vaccine study.
 - Researchers had hoped that the vaccine in this study would improve on the modest efficacy seen in 2009 from the RV144 vaccine study in Thailand. While that did not occur, what is learned from HVTN 702 can help make future HIV vaccine research efforts smarter and stronger.

The scientific and funding collaborations, community engagement models and research knowledge gained over decades of HIV vaccine development and investment is catalyzing the development of COVID-19 vaccines and treatments.

Research

- HIV research has generated more scientific knowledge about immune function and responses than ever existed, greatly advancing understanding of COVID-19.
 - The rapid development of many COVID-19 vaccine candidates is built on techniques and platforms developed through HIV vaccine research to map virus structure and build robust immune responses.
 - Nucleic-acid based vaccines, such as RNA & DNA vaccines and viral vectors, were pioneered largely through HIV vaccine development.
 - Monoclonal antibody approaches for COVID-19 treatment and prevention are derived directly from work on broadly neutralizing antibodies in HIV.
- HIV research also pioneered the field of antiretroviral treatments, in parallel with vaccine research. This same dual approach is happening now, including the evaluation of some HIV treatments for possible use against COVID-19.

Research Infrastructure and Collaboration

- Research and funding collaboratives developed to advance vaccine research on HIV and emerging
 pathogens created models for increased global cooperation and collaboration. Those models are now
 being applied in the response to COVID-19. A few examples:
 - The NIH-led <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership</u> is leveraging infrastructure and expertise from collaborative HIV and other research efforts to speed the development of COVID-19 vaccines and treatments.
 - The Access to COVID-19 Tools (ACT) Accelerator is a global collaboration established by the Bill & Melinda Gates Foundation, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust and WHO to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines.
 - The Coalition for Epidemic Preparedness Innovations (<u>CEPI</u>), established in 2017, is spearheading data sharing, pooling resources, coordinating vaccine development and prioritizing global access for products that lack a commercial market.
 - Based on recent HIV vaccine experience, collaboratives such as these can fundamentally change research and development and speed the production and delivery of urgently needed interventions in response to COVID-19. To do so, they must harmonize the development process, establish shared criteria to evaluate and compare studies, commit to transparency and data sharing, and mobilize



resources from private, public and philanthropic sectors to scale up manufacturing and distribution for COVID-19 vaccines.

HIV research networks and extensive research sites have been established all over the world, including in resource limited settings. This vital global resource, which has successfully tested countless HIV treatment and prevention candidates, is now being deployed to test interventions against COVID-19.

Community Engagement

- Investments to strengthen community engagement in HIV research and treatment efforts, especially in resource-limited settings, have laid the foundation for effective local and global responses to COVID-19.
- Good Participatory Practice (GPP) Guidelines, developed by AVAC and UNAIDS to strengthen community involvement in HIV research, has been adapted for emerging pathogens. GPP helps trial funders, sponsors, implementers and community stakeholders partner effectively in the design and conduct of ethical, inclusive biomedical research.
- HIV advocates helped build the systems now being used to ensure that research planning for COVID-19 include commitments to ensure equitable, affordable and sustainable global access to the vaccines and treatments they develop.
- Community-led health education models pioneered in HIV are working today to counter stigma and misinformation around COVID-19.
- HIV advocates are also playing a vital role in holding political leaders accountable and supporting adequate funding for the global COVID-19 response.

About AVAC | AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic.

www.avac.org

