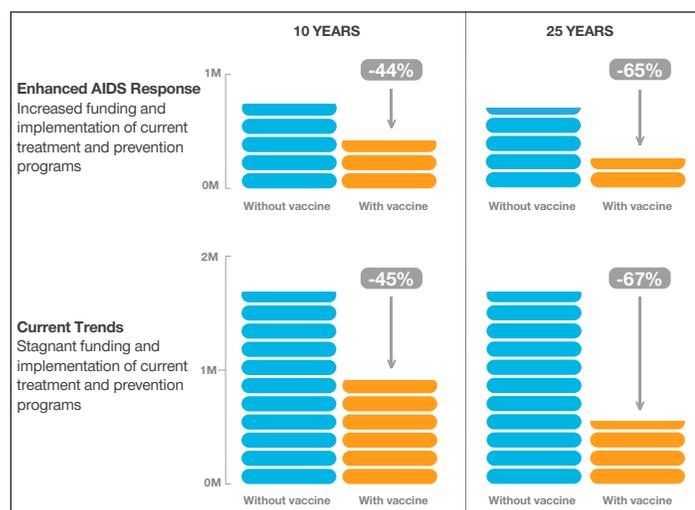


Insights

POLICY BRIEF | AUGUST 2016

The Potential Health Impact and Cost-Effectiveness of an AIDS Vaccine in Low- and Middle-Income Countries

Figure 1: Reductions of new annual HIV infections (millions) in low- and middle-income countries in years after vaccine introduction



AIDS is one of our greatest global health challenges

Since its discovery 35 years ago, HIV has infected 78 million people worldwide, of whom 35 million have died from AIDS. Despite remarkable advances in antiretroviral treatment (ART), 1.1-1.2 million people died of AIDS-related causes in 2015. Major investments in current treatment and prevention programs have not reduced new annual HIV infections over the past several years. In 2015 alone, 2.1-2.5 million became newly infected with HIV. Almost two-thirds of new infections were in Sub-Saharan Africa, where more people die of AIDS in one week than died in the entire 2014/15 Ebola epidemic.

Challenges remain in funding and effectively deploying available programs

Only 40% of people living with HIV globally have access to ART, with many of those facing challenges to sustaining adherence necessary to prevent transmission to others. This disparity currently exists in low- and middle-income countries (LMICs), where the great majority of people living with HIV are situated, as well as in high-income countries. Pre-exposure prophylaxis (PrEP) using ART, the development of longer-lasting ART regimens, and gels, films, or rings containing HIV-blocking agents (microbicides) have the potential to avert many

KEY FINDINGS

While critically important, existing tools alone are unlikely to end HIV/AIDS

Even with strongly increased funding and implementation of current treatment and prevention programs, hundreds of thousands of people will be newly infected with HIV annually in low- and middle-income countries, for decades to come.

A vaccine is essential to end AIDS

A 70% efficacious and well-adopted vaccine as part of a comprehensive HIV/AIDS response could prevent the majority of annual new HIV infections.

A vaccine's impact would be even stronger should the funding and implementation of existing prevention and treatment programs fail to increase to the aspired levels.

AIDS vaccine research and development is a smart public health investment

A well-adopted vaccine of at least 60% efficacy would be cost-effective in cost ranges comparable to other recent vaccines and could save money over time by reducing the number of people needing treatment.

POLICY RECOMMENDATIONS

- Invest in HIV vaccine and prevention research and development to conclusively end HIV/AIDS.
- Maximize access to and adoption of existing treatment and prevention programs to further reduce new HIV infections and AIDS-related deaths.
- Apply a comprehensive, evidence-based response combining medical tools, education and programs to eliminate gender inequality, stigma and discrimination for people at risk of contracting or already living with HIV.

new HIV infections and AIDS-related deaths in the near- to mid-term if quickly and effectively implemented. However, many of the people most in need are faced with circumstances that hinder delivery and regular use of these interventions.

Annual funding for HIV/AIDS programs in LMICs approached US\$22 billion in 2015, but funding for proposed expansions of programs would require an annual \$26-31 billion* by 2020 alongside strong efficiency gains, reduced program and commodities costs, and confronting structural and sociocultural barriers that prevent many at risk of HIV from accessing products or programs.

Projecting future HIV/AIDS programming

Modeling of increased funding and improved implementation of global HIV/AIDS programs within an enhanced investment framework proposed by the Joint United Nations Programme on HIV/AIDS (UNAIDS IFE) reinforced the positive impact from such an expansion, while also highlighting potential contributions by other emerging prevention technologies, including PrEP, treatment as prevention (TasP), and a potential AIDS vaccine, to reduce new HIV infections and AIDS-related deaths [Stover et al. 2014]. In 2014, UNAIDS’ proposed a ‘Fast Track’ approach to end the AIDS epidemic as a public health threat by 2030, mainly through strongly enhanced funding and use of ART.

This analysis explores in more detail the potential health impact and cost-effectiveness of future AIDS vaccination in LMICs as part of a comprehensive HIV/AIDS response depending on the level

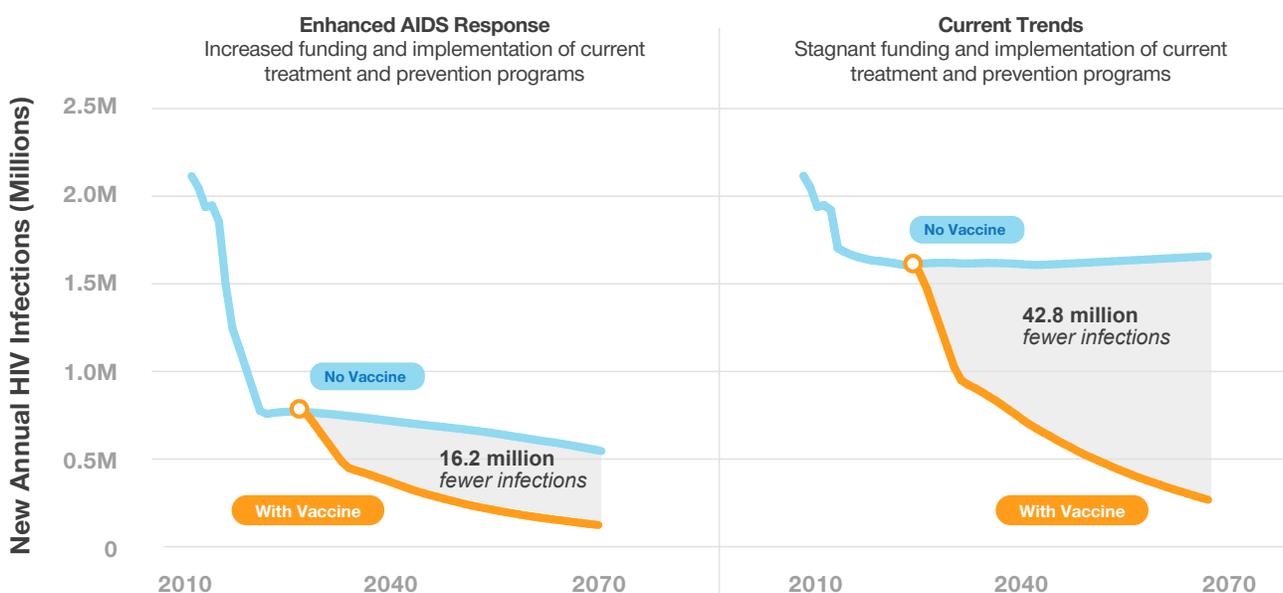
of expansion current treatment and prevention programs within the UNAIDS IFE.† The analysis also assesses the relative impact of individual vaccine characteristics, such as vaccine efficacy and duration of protection, as well as of adoption of and adherence to vaccination by target populations. Underlying assumptions draw on advice from experts in the fields of research, vaccination and public health, in addition to experience from existing HIV/AIDS interventions and vaccination programs in LMICs.

An AIDS vaccine could more than halve the number of new HIV infections in LMICs

The number of new HIV infections averted by a vaccine will depend on how successfully other HIV prevention, treatment and care programs are funded and implemented prior to vaccine introduction and in combination with a vaccine after introduction. This analysis utilizes the Full Scale-up of UNAIDS IFE – a fully funded and implemented program of current treatment and prevention programs – as the primary background scenario (“Enhanced Response”). Given that the availability of existing treatment and prevention programs in reality has regularly fallen short of aspirational targets we consider this a conservative approach with regard to the potential impact of AIDS vaccination. In contrast, a Current Trends scenario shows flatlined progress in preventing new infections with existing interventions (Figure 1).

Adding an AIDS vaccine of 70% efficacy with strong uptake‡ to Enhanced Response would reduce annual new HIV infections

Figure 2: Reduction of new annual HIV infections with and without an AIDS vaccine under different scenarios for funding and implementation of current treatment and prevention programs between 2010 and 2070

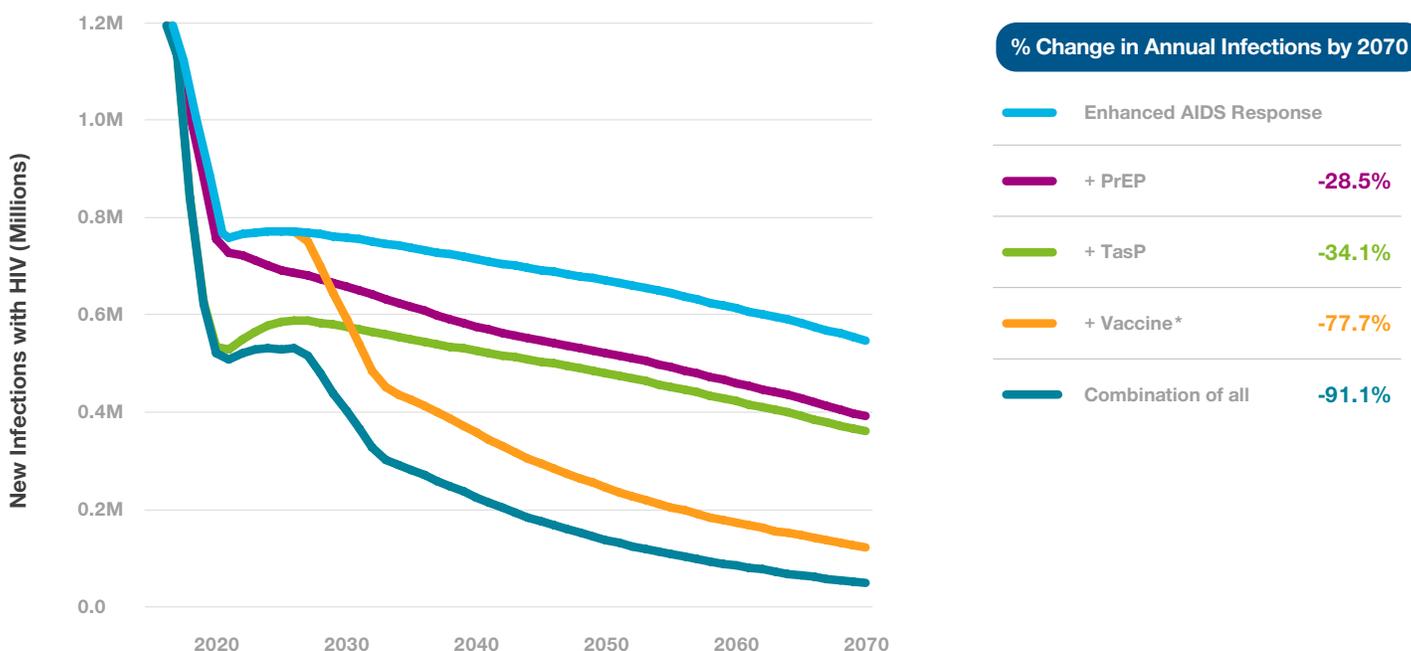


* Based on two scenarios of scaling up “Fast Track” goals as articulated by UNAIDS, dependent on assumed reductions in annual ART costs in different regions.

† As defined in UNAIDS Investment Framework Enhanced, proposing increases in funding for programs specific to HIV/AIDS epidemic types in LMICs. See Stover et al 2014 in PLoS ONE.

‡ Base characteristics of AIDS vaccine in this model, not based on any candidate in current clinical pipeline: introduction in 2027, an efficacy of 70%, three doses for primary vaccination, a booster vaccination after five years (returning the individual to full modeled efficacy for life), and a pre-defined target coverage (generalized epidemics: routine 10 year olds, 70%; catch-up 11–14 year olds, 60%; catch-up 15–17 year olds, 55%; catch 18–49 year olds, 50%; high-risk populations, 50%) within 6 years. Additional background on these assumptions and other technical inputs are available in Harmon et al 2016.

Figure 3: Reduction of new annual HIV infections with PrEP, TasP and vaccination added individually and in combination to enhanced funding and implementation of current treatment and prevention programs (Enhanced HIV/AIDS Response) between 2015 and 2070

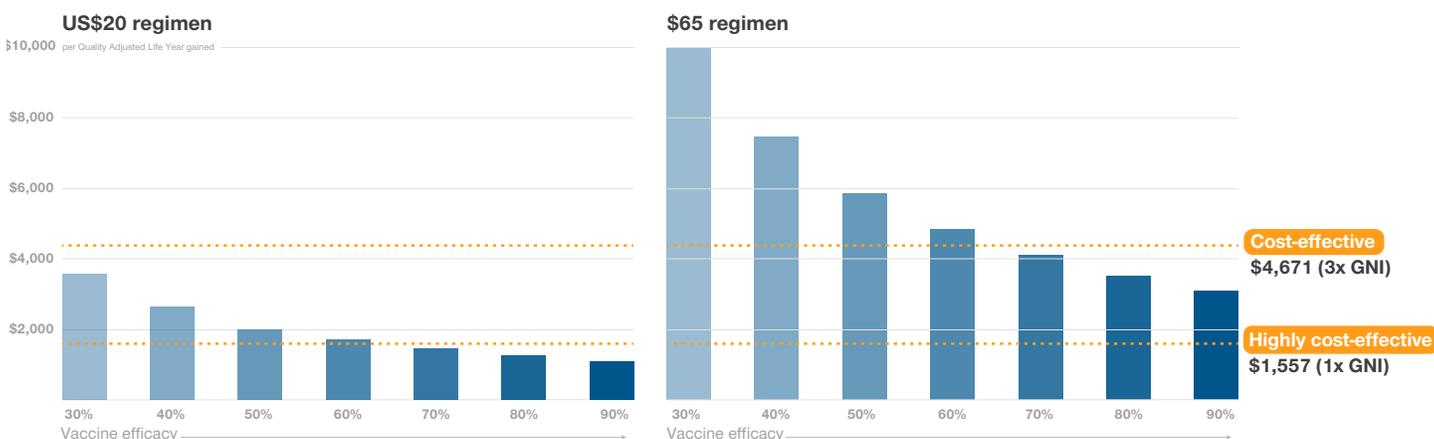


by about 45% to 412,000 in the first decade and by about 66% to 236,000 after 25 years. Cumulative reductions over time would result in 2.1-4.7 million fewer infections in the first decade depending on background scale-up, and 7.9-12.0 million fewer infections in the first 25 years. The relative reduction would be comparable if funding and implementation of current treatment and prevention programs continued at current trends, but cumulative reductions through vaccination would be much higher as existing treatment and prevention programs would have averted fewer HIV infections before a vaccine became available (Figure 1).

An integrated prevention response has the biggest impact, with a vaccine providing the strongest individual contribution

The addition of PrEP, TasP and vaccination individually to an Enhanced Response would reduce the number of annual new HIV infections in 2050 by 22%, 28% and 64% respectively, with vaccination providing the strongest single benefit even if introduced at a later stage. The combination of PrEP, TasP and vaccination could reduce the number of annual infections with HIV to 137,000 (-80%) by 2050, underscoring the importance of a comprehensive prevention response (Figure 2).

Figure 4: Cost per Quality-Adjusted Life Year gained in low-income countries through AIDS vaccination, by efficacy, when added to improved and more fully resourced HIV/AIDS programs†



† Cumulative 2027-2070, discounted at 3% per year

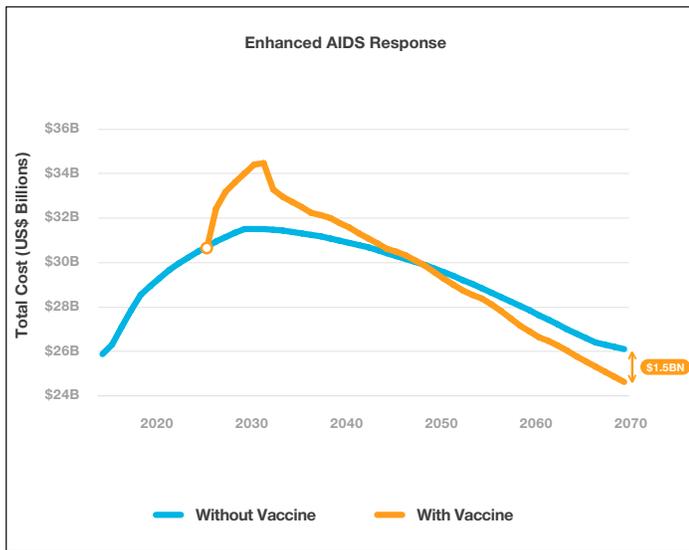
A vaccine’s value will hinge on its key characteristics

Vaccine impact at the population level correlates heavily to the vaccine’s efficacy, but even a vaccine of relatively low efficacy could reduce new HIV infections significantly if uptake was strong. Vaccine impact varies significantly based on how effectively vaccine programs reach their target populations, but even with lower uptake HIV infections would decrease significantly. Vaccines that help protect over a longer timeframe would greatly reduce the cost of vaccination and are likely to increase uptake.

An AIDS vaccine could be cost-effective in low-income countries (LICs) and could reduce total costs over time

A Quality Adjusted Life Year (QALY) is a well-accepted measure of the capacity of a health tool to reduce disease burden. A health tool is considered cost-effective by thresholds adopted by the World Health Organization (WHO) if the cost per QALY does not exceed the per-person income of a country (Gross National Income, or GNI).

Figure 5: Total cost for Enhanced AIDS Response without/with a vaccine



High disease burden, high effectiveness of the tool in reducing it, and low cost for the tool can all contribute to lowering the cost per QALY. Also, the lower the GNI of a country, the less the tool needs to cost to remain cost-effective in that context.

Using World Health Organization standards of cost-effectiveness, our analysis shows an AIDS vaccine of at least 60% efficacy would be highly cost-effective across a broad range of implementation scenarios at per regimen costs of \$20-30 (Figure 4), comparable to costs observed for other recently introduced vaccinations. Gavi, the Vaccine Alliance, the multilateral organization driving uptake of established and new vaccines in LMICs, uses the same threshold to consider supporting vaccination programs. The vaccine would still be cost-effective at per-regimen costs over three times higher, and cost-effectiveness would be even higher should the funding and implementation of existing prevention and treatment programs fail to reach aspired levels.

A vaccine could reduce total costs over time

The Enhanced Response scenario projects a strong increase in the number of new people accessing ART, but that number begins to fall as HIV-positive individuals live out natural lifespans. A vaccine could significantly decrease the number of people who will need to initiate ART and the associated related cost by diminishing the number of new infections. Adding a vaccine could eventually reduce the total overall cost of the AIDS response in LMICs (Figure 5).

Methodology

Our model combined AIDS epidemiological information, the effectiveness of existing and new interventions, and associated costs of the response to explore the potential impact of AIDS vaccination in LMICs in combination with other interventions through 2070. Assumptions were based on perspectives from research, vaccination and public health experts, as well as observations from other HIV/AIDS interventions and vaccination programs. Sensitivity analyses also varied vaccine efficacy, duration of protection, coverage and cost.

For additional information on the methods of this analysis, assumptions and a more comprehensive discussion of modeling results see the PLoS ONE publication, “Exploring the Potential Health Impact and Cost-Effectiveness of AIDS Vaccine Within a Comprehensive HIV/AIDS Response in Low- and Middle-Income Countries.”

References

Harmon TM, et al. (2016) Exploring the Potential Health Impact and Cost-Effectiveness of AIDS Vaccine within a Comprehensive HIV/AIDS Response in Low- and Middle-Income Countries. PLoS ONE 11(1): e0146387. doi:10.1371/journal.pone.0146387.

Stover J, et al. How can we get close to zero? The potential contribution of biomedical prevention and the investment framework towards an effective response to HIV. PLoS One 9(11), e111956, L2014. doi: 10.1371/journal.pone.0111956 PMID: 25372770.

UNAIDS. (2016) *Global AIDS Update 2016*. <http://www.unaids.org/en/resources/documents/2016/Global-AIDS-update-2016>. June 1, 2016.

IHME 2016 - Estimates of global, regional, and national incidence, prevalence, and mortality of HIV, 1980–2015: the Global Burden of Disease Study 2015 GBD 2015 HIV Collaborators. The Lancet HIV xxxxxxxxxxxxxxxx.

UNAIDS. (2016). *Fast-Track Update on Investments Needed in the AIDS Response* (Reference). http://www.unaids.org/en/resources/documents/2016/unaids_fast-track_update_investments_needed. Accessed April 7, 2016.



iAVI gratefully acknowledges the generous support provided by the following major donors

