

HEALTH IMPACT OF A POTENTIAL HIV VACCINE AMONG MEN WHO HAVE SEX WITH MEN IN THE US

Turgay Ayer¹, Selin Merdan², Valerie Oriol Mathieu³, Thierry Van Effelterre⁴, Ismail Fatih Yildirim², Frank Tomaka⁵, Maria Grazia Pau³, Jagpreet Chhatwal⁶, Antoine C. El Khoury⁷

¹Georgia Institute of Technology, Atlanta, Georgia & Emory Medical School, Atlanta, GA, ²Value Analytics Labs, Boston, Massachusetts, ³Janssen Vaccines & Prevention, Leiden, Netherlands, ⁴Janssen Pharmaceutica N.V., Beerse, Belgium, ⁵Janssen Research & Development US, Raritan, NJ, ⁶Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, ⁷Janssen Global Services, Raritan, NJ

OBJECTIVES

- Of the 34,800 new HIV infections in the United States (U.S.) in 2019, 70% occurred among men having sex with men (MSM).
- The objective of this study was to evaluate the long-term health outcomes of a hypothetical HIV vaccine in the MSM population under different scenarios of efficacy, durability, and coverage.

METHODS

- We developed an agent-based model that simulates the sexual transmission of HIV among the MSM population aged 13-65 years in the U.S.
- The HIV viral load is the primary driver of immune system deterioration, and thus the assigned viral load level determined the rate at which the patient's CD4 cell count declined in the absence of antiretroviral therapy (ART) in the model. With natural disease progression (i.e., in the absence of ARTs), each HIV-infected person transitioned through the following disease stages: acute infection, chronic infection, and AIDS
- Individuals became eligible to form relationships when they entered the model at sexual debut. Each relationship was defined by four attributes: the two specific individuals involved in this relationship, the type of the relationship (main or casual), the duration of the relationship, and the number of sex acts to be performed each month.
- The target population was offered a hypothetical HIV vaccine along with other preventative interventions, including condom use and pre-exposure prophylaxis (PrEP).
- We simulated long-term outcomes over a 50-year time horizon under the status quo (no HIV vaccine) and under multiple scenarios defined by different combinations of vaccine efficacy (30%, 50%, 70%, and 90%), coverage (30%, 45%, and 60%), durability (0 and 2 years), and booster frequency (every 3 and 5 years).
- We validated the modeled natural history of the HIV disease by comparing the historical model-estimated HIV prevalence and incidence to the published estimates.
- For each scenario, we calculated HIV prevalence, incidence, and the number of HIV infections and deaths averted, evaluated over the time horizon 2025-2075.

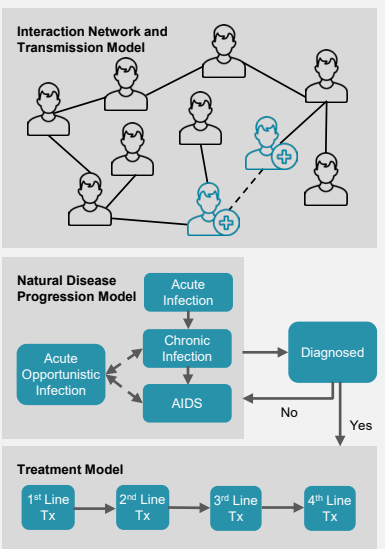
KEY FINDING

Remarkable reductions in HIV incidence can be achieved with lower efficacy and higher coverage vs. higher efficacy and lower coverage. Hence, even a partially efficacious HIV vaccine with modest efficacy could substantially reduce HIV incidence, especially when the uptake is high. Vaccine durability and booster frequency could also impact the overall HIV burden reduction.

RESULTS

- Table 1 presents the estimated HIV incidence and HIV-related mortality in MSM for each combination of the vaccine efficacy and coverage scenarios, as compared with no vaccination. Under the status quo (i.e., no vaccination), 5.9 new annual infections per 1,000 MSM are expected in 2075. Cumulatively, this translated into a total of over 1.3 million new HIV infections between 2025 and 2075.

Figure 1: Transmission, progression, and treatment modeling scheme.



Notes. The infected agents are shown in blue and uninfected agents are shown in black. The solid lines show relationships among agents with possible transmission of disease, the dashed lines show transmission. Each infected agent can progress to advanced stages of the HIV disease shown by a state-transition model in the middle pictogram. Tx: antiretroviral therapy.

- Under different combinations of vaccine efficacy and uptake, the estimated HIV incidence in 2075 ranged between 3.7-5.6 per 1,000 MSM. Of those 1.3 million expected new HIV infections, between 73,744 (5.43% reduction) and 495,480 (36.46% reduction) could be prevented under various vaccination scenarios (Table 1). For example, under a 50% modest vaccine efficacy with 45% uptake, the number of HIV infections prevented would be nearly 200,000 (14.17% reduction).
- We further found that similar reductions in HIV incidence rate could be achieved with lower vaccine efficacy and higher vaccine uptake, or with higher efficacy and lower uptake. For example, a 70% efficacious vaccine with 30% uptake, a 50% efficacious vaccine with 45% uptake, or a 30% efficacious vaccine with 60% uptake would reduce the HIV incidence rate by 12-14%.

Table 1: HIV incidence and mortality with and without an HIV vaccine under different vaccine efficacy and coverage scenarios.

Years Durability		HIV Incidence		HIV Mortality	
Booster at 3 Years		Rate per 1,000 MSM in 2075*	Total Number of New Infections from 2025–2075*	Death Rate per 1,000 MSM in 2075*	Total Number of HIV Deaths from 2025–2075*
No Vaccination		5.9	1,359,037	4.4	1,000,1527
30% efficacy	30% uptake	5.6 (5.08%)	1,285,293 (5.43%)	4.2 (4.55%)	973,152 (2.83%)
	45% uptake	5.4 (8.47%)	1,245,127 (8.38%)	4.1 (6.82%)	956,671 (4.48%)
	60% uptake	5.2 (11.86%)	1,196,032 (11.99%)	3.9 (11.36%)	936,029 (6.54%)
50% efficacy	30% uptake	5.4 (8.47%)	1,234,078 (9.19%)	4 (9.09%)	951,842 (4.96%)
	45% uptake	5.0 (15.25%)	1,166,513 (14.17%)	3.9 (11.36%)	924,206 (7.72%)
	60% uptake	4.7 (20.34%)	1,086,181 (20.08%)	3.6 (18.18%)	890,369 (11.1%)
70% efficacy	30% uptake	5.1 (13.56%)	1,179,650 (13.2%)	3.9 (11.36%)	930,056 (7.14%)
	45% uptake	4.7 (20.34%)	1,086,187 (20.08%)	3.7 (15.91%)	890,737 (11.06%)
	60% uptake	4.2 (28.81%)	977,237 (28.09%)	3.3 (25%)	844,513 (15.68%)
90% efficacy	30% uptake	4.9 (16.95%)	1,123,096 (17.36%)	3.8 (13.64%)	906,325 (9.51%)
	45% uptake	4.3 (27.12%)	1,001,466 (26.31%)	3.5 (20.45%)	855,817 (14.55%)
	60% uptake	3.7 (37.29%)	863,557 (36.46%)	3 (31.82%)	795,328 (20.59%)
* % reduction compared with no vaccine scenario					

* % reduction compared with no vaccine scenario

- Table 2 presents the results for each combination of the vaccine durability and booster frequency scenarios at fixed 70% efficacy and 45% uptake rate. Under a vaccination program with no durability (i.e., waning starts immediately upon prime vaccine administration) and a booster vaccine every 5 years, the cumulative number of new HIV infections would be reduced by 90,129 (6.63% reduction). On the other hand, if the vaccine has 2 years of durability and a booster vaccine is given every 3 years, then the new HIV infections would be reduced by 272,850 (20.08% reduction).

Figure 2: Total number of HIV new infections and deaths without and with a 70% efficacious HIV vaccine with 45% coverage under different durability and booster administration scenarios from 2025-2075.

45% Uptake		Total Number of New Infections from 2025 – 2075 (% reduction compared with no vaccine scenario)	Total Number of HIV Deaths from 2025 – 2075 (% reduction compared with no vaccine scenario)
70% Efficacy			
No Vaccination		1,359,037	1,001,527
No Durability	Booster at 5 years	1,268,908 (6.63%)	964,172 (3.73%)
	Booster at 3 years	1,237,670 (8.93%)	952,399 (4.91%)
2 Years Durability	Booster at 5 years	1,147,571 (15.56%)	914,539 (8.69%)
	Booster at 3 years	1,086,187 (20.08%)	890,737 (11.06%)

REFERENCES

[1] "CDC's HIV Work Saves Lives and Money Infographics | CDC," Dec. 28, 2021. <https://www.cdc.gov/nchhstpbudget/infographics/hiv.html> (accessed Apr. 05, 2022).

[2] "HIV Vaccines," IAVI. <https://www.iavi.org/our-science/hiv-vaccines> (accessed Apr. 05, 2022).

[3] S. Rerks-Ngarm et al., "Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand," N. Engl. J. Med., vol. 361, no. 23, pp. 2209–2220, Dec. 2009, doi: 10.1056/NEJMoa0908492.

[4] "NIH-sponsored HIV vaccine trial launches in South Africa," National Institutes of Health (NIH), Jul. 03, 2015. <https://www.nih.gov/news-events/news-releases/nih-sponsored-hiv-vaccine-trial-launches-south-africa> (accessed Apr. 05, 2022).

[5] B. M. Branson et al., "Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings," Morb. Mortal. Wkly. Rep. Recomm. Rep., vol. 55, no. 14, pp. 1–CE, 2006.

[6] A. D. Paltiel, G. R. S. III, and K. A. Freedberg, "Expanded Screening for HIV in the United States — An Analysis of Cost-Effectiveness," N. Engl. J. Med., p. 10, 2005.

[7] E. L. Ross et al., "The Clinical Role and Cost-Effectiveness of Long-Acting Antiretroviral Therapy," Clin. Infect. Dis., vol. 60, no. 7, pp. 1102–1110, Apr. 2015, doi: 10.1093/cid/ciu1159.

[8] R. P. Walensky et al., "Economic Savings Versus Health Losses: The Cost-Effectiveness of Generic Antiretroviral Therapy in the United States," Ann. Intern. Med., vol. 158, no. 2, p. 84, Jan. 2013, doi: 10.7326/0003-4819-158-2-201301150-00002.

[9] "About HIV/AIDS | HIV Basics | HIV/AIDS | CDC," Mar. 23, 2022. <https://www.cdc.gov/hiv/basics/whatisshiv.html> (accessed Apr. 06, 2022).

[10] L. Sagona-Teyssier et al., "Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPRGAY trial," p. 9.

[11] D. S. P. Buchbinder, "HIV pre-exposure prophylaxis in men who have sex with men and transgender women: a secondary analysis of a phase 3 randomised controlled efficacy trial," vol. 14, p. 8, 2014.

[12] K. R. Amico et al., "Study Product Adherence Measurement in the iPrEx Placebo-Controlled Trial: Concordance With Drug Detection," J. Acquir. Immune Defic. Syndr., vol. 66, no. 5, p. 8, 2014.

[13] J.-M. Molina et al., "On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection," N. Engl. J. Med., vol. 373, no. 23, pp. 2237–2246, Dec. 2015, doi: 10.1056/NEJMoa1506273.

[14] A. Liu et al., "Patterns and Correlates of PrEP Drug Detection Among MSM and Transgender Women in the Global iPrEx Study," J. Acquir. Immune Defic. Syndr., vol. 67, no. 5, p. 10, 2014.

[15] R. A. Elion et al., "Estimated Impact of Targeted Pre-Exposure Prophylaxis: Strategies for Men Who Have Sex with Men in the United States," Int. J. Environ. Res. Public Health, vol. 16, no. 9, p. 1592, May 2019, doi: 10.3390/ijerph16091592.

CONTACT Turgay Ayer, PhD | ayer@isye.gatech.edu