Policy Brief

International AIDS Vaccine Initiative

Assessing the Demand for an HIV Vaccine

A preventive vaccine is the best hope for ending the AIDS epidemic. But unless the vaccine is widely available and used by those at risk of HIV, this goal will not be realized. To what extent will governments, especially in developing countries, be willing and able to purchase or subsidize the vaccine and deliver it in their countries? Who should receive the vaccine and what is their willingness to be vaccinated? Are some individuals ready to pay for a vaccine, at least partially?

Answering these questions is essential to ensuring swift and sufficient global supply, financing, and delivery of an HIV vaccine. This policy brief highlights key issues in assessing the demand for an HIV vaccine, summarizes what we have learned so far from policy research, and outlines what steps must be taken to improve upon previous efforts to generate such estimates.

I. The Importance of Understanding Demand

Good demand forecasting is an essential building block for stimulating faster research and development (R&D) and ensuring swift global access to an HIV vaccine. Demand forecasts can positively impact four critical areas:

- **R&D Investment:** The willingness of both industry and government to invest in HIV vaccine R&D is predicated in part upon their assessment of the expected uptake and impact of the vaccine. Will industry be able to sell enough vaccine to recover their costs? Will the health and economic benefits of a vaccine be large enough to justify government and donor spending on R&D? To answer these questions, industry and government need credible estimates of demand for such a vaccine.

- **Manufacturing:** Building industrial capacity for vaccine production typically requires a 5 year lead time, at a cost of hundreds of millions of dollars. Manufacturers need to know in advance the actual number of doses demanded so they can build vaccine plants with the optimal capacity.[i]

- **Financing Supply:** Due to the lack of a robust market in poor countries and delays in mobilizing international donor support to help compensate for these weak markets, there has historically been a lag of ten or more years before new vaccines such as Hepatitis B become widely available in developing country markets.[ii] Credible demand forecasting can be used to help build global support for early commitments to finance manufacturing capacity and/or vaccine purchase in these markets, for example through an advance purchase mechanism.

- **Delivery:** Use of cost-effectiveness analysis based on demand models can help guide policy decisions on which population groups to target for immunization. The process of demand forecasting helps to highlight the need to strengthen vaccination infrastructure in low-income countries and to reach out to target groups with information, counseling, and other promotional activities to stimulate demand for an HIV vaccine.

II. Key Factors Influencing Demand for an HIV Vaccine

One might assume that determining demand for an HIV vaccine would be as simple as adding up the number of people who could benefit from the vaccine, based on disease burden and the size of the at-risk population, or "need." However, actual demand – how much vaccine governments and individual will want to use – is likely to be lower than need. This is because demand takes into account factors including the cost of the vaccine, characteristics of the vaccine such as efficacy and possible side effects, individual attitudes and perceptions and their impact on willingness to be vaccinated, and public policies related to which

groups will be targeted for vaccination and how this will be financed. All of these factors tend to reduce demand to a level that is less than the number of persons who might obtain some benefit from using the vaccine. Nevertheless, for a highly effective and inexpensive HIV vaccine, this level of demand might still be very large -- hundreds of millions of doses.

Demand forecasting involves identifying potential vaccination scenarios and influencing factors under various assumptions, and estimating the number of vaccine doses (or courses, where several doses need to be given to each person in order to obtain the maximum protective benefit). Demand forecasts must take into consideration a number of complex and interconnected factors including:

- **Efficacy, cost, and other vaccine characteristics:** How effective will the vaccine be – will it protect 90% of those vaccinated or only 50%? Will there be side effects? Will it be effective across different HIV subtypes? Will it be approved for use in children and adolescents? How much will it cost to manufacture and deliver the vaccine?

The more efficacious the vaccine is in preventing infection, the higher demand will be. Higher efficacy vaccines could be used in large segments of the population, for example all young people.[iii] However, a vaccine with a low to moderate efficacy level could still be a powerful prevention tool, particularly if used in countries with high prevalence rates or in high risk populations.[iv] Decisions on how to use a low to moderately efficacious vaccine may depend on local circumstances. Targeting high risk groups such as men who have sex with men, commercial sex workers and intravenous drug users could contain the spread of HIV in a country with an early epidemic. But in a mature epidemic country where many high risk individuals may already be infected by the time immunization is available, a universal campaign could potentially be more effective.[v]

- **Political commitment**: Because the vast majority of those most likely to benefit from an HIV vaccine live in low income countries, a vaccine that is expensive to produce would impose a heavy financial burden on most households. In these circumstances, HIV vaccines will need to be purchased, or heavily subsidized, by governments with help from donors. Experience by the Global Alliance for Vaccines and Immunizations (GAVI) in expanding access to Hib and Hepatitis B vaccine in developing countries has shown that the relatively high cost of these new vaccines and a lack of understanding by national policymakers about disease burden in their countries and the potential health impact of such vaccines has reduced the level of demand.[vi]

In the case of an HIV vaccine, awareness by government decision makers and the public is relatively high, so demand for an HIV vaccine may be stronger. Nevertheless, it will be important for these public officials to assess which groups to target, what delivery mechanisms to use, and how much to budget for vaccine purchase. All of these considerations will affect demand.

The willingness of international donors to subsidize vaccination programs in low and middle income countries will also be a particularly powerful determinant of demand for an HIV vaccine. At present, donors account for a large share of the cost of the childhood immunization activities in Africa and South Asia, and in some poor countries of Latin America, and they would be expected to shoulder a significant proportion of the cost of an HIV vaccine.

- **Target populations**: Decisions about which groups to target for vaccination will vary from country to country, depending on the size of the epidemic and the distribution of infections, assumptions about the accessibility of particular groups, and political circumstances. The capacity of existing health and immunization systems to reach various groups, particularly given the stigma often associated with HIV, also will be a consideration. The likelihood that HIV vaccines will be targeted to adults and adolescents, rather than children, who are the targets of current immunizations, means that new thinking will be required – in advance – on how to increase the capacity to reach these groups through innovative, non-traditional means such as school health programs, youth groups, etc.

- **Acceptability and accessibility:** Successful vaccination will require not only demand from policymakers but from individuals themselves. Studies have found high demand for an HIV vaccine among potential target groups, particularly in countries and populations where awareness of HIV is high. In Uganda, for example, analysis of a sample of households' representative of the general

population found that 94% said they would be willing to be vaccinated.[vii] A similar study found that 70% of Kenyans aged 18-55 years would be willing to be vaccinated.[viii] An HIV vaccine is so highly sought in these environments that even poor people are willing to pay out of their pockets for a vaccine: three quarters of those surveyed in the Uganda study would purchase a vaccine at US$ 3 per dose, and in Thailand roughly 40% of those surveyed would purchase an effective vaccine at a price of US$ 25.[ix] Not surprisingly, vaccine efficacy and perception of individual risk of infection were significant factors in people's willingness to be vaccinated. The study in Thailand found that 97% of commercial sex workers and 95% of intravenous drug users were willing to be vaccinated, compared to 78% of the general population.

III. Estimates of Global Demand for an HIV Vaccine

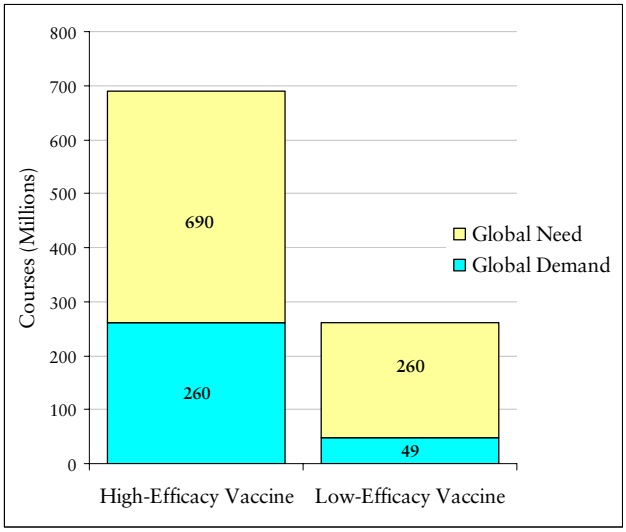
There have been three projects so far to forecast global demand for an HIV vaccine. Although the methodologies used were different, all three studies suggested that when taking a public health approach (i.e., delivering the vaccine to those who might benefit, but giving relative priority to those at higher risk of HIV infection and of onward transmission to others), the estimated "demand" for the developing world would amount to several hundred million courses in the early catch-up years of implementation.[x]

A study by the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)[xi] produced a figure of 326 million vaccine courses, another by Bishai et al estimated 235 million courses, [xii] and the third, by WHO, UNAIDS, and IAVI projected a need and demand for 260 and 49 million courses, respectively, for a low to moderate efficacy vaccine.[xiii] For a high efficacy vaccine, the latter study raised its need and uptake estimates to 690 and 260 million courses respectively. Because of other constraints such as stigma and vaccine delivery system weaknesses, the WHO/UNAIDS/IAVI study predicted that effective uptake of an HIV vaccine would only be a fraction of the public health need – less than 20% for a low to moderate efficacy vaccine and around 40% for a high efficacy vaccine (see Figure 1).

All three studies identified regions or coverage areas and target populations. The WHO-IFPMA study focused on the level of accessibility of the target populations and prioritized countries for vaccination according to current and projected future risk of HIV infection. The WHO/UNAIDS/IAVI study, on the other hand, covered the widest range of potential population groups and analyzed the accessibility and acceptability of each target group in estimating the level of vaccine uptake. Although accessibility was implicitly linked to delivery cost, no information was presented on vaccine delivery strategies and related cost. Only the study by Bishai et al considered vaccine price as a factor in determining the global demand.

Each of these studies has limitations in methods and data that point to the need for further refinement in the demand forecasting for an HIV vaccine. Nevertheless, they suggest that if donors and governments were willing to commit to pay a manufacturer a modest price per person vaccinated in order to cover the manufacturer's R&D investment costs, this could effectively create a multi-billion dollar market in the developing world, generating important incentives for industry to work on HIV vaccines.

Figure 1 WHO-UNAIDS-IAVI Study



IV. Estimates of Country Demand for an HIV Vaccine

Studies to assess public sector demand at the country level demonstrate the importance of differences in individual country circumstances and policy choices.

Four studies conducted by independent researchers in Brazil,[xiv] Thailand,[xv] Southern Africa,[xvi] and Southern India[xvii] identified likely populations to target for vaccination, based on local political and epidemiological factors. They also made different assumptions about the rate at which individuals would be vaccinated and the share of each population group that would ultimately be reached.

Three of four studies calculated the cost-effectiveness of reaching each group (that is, the cost per HIV infection averted) in an effort to help government decision-makers set priorities in the event that financial and capacity constraints forced them to choose a targeted immunization approach. In Brazil, however, the researchers concluded that the prevailing political philosophy of broad equity would compel the government to offer vaccination to everyone, and that such a broad approach would also encourage wider acceptability of HIV vaccination among the population.

Results from these studies, shown in **Figure 2**, indicate that demand for a 100% effective HIV vaccine in the catch-up phase would be quite large if all groups were covered: 121 million courses in Brazil and a maximum of 195 million in Southern India. Under a targeted approach, the number of courses would be lower: for example, 9.1 million HIV vaccine courses would be needed in Brazil for those at greatest risk, and 9.6 million courses in Southern India if high risk individuals and women receiving antenatal care services were targeted.

V. Building on What's Been Learned

Credible estimates of the public health need and demand for an HIV vaccine are vital to ensure early and accurate planning for investment, financing and delivery of a future HIV vaccine. To obtain improved estimates, additional research will have to be undertaken to address the following issues:

- The potential public health and economic impact of hypothetical HIV vaccines with various characteristics, and the consequence of targeting different population groups

Figure 2. Public Sector Demand in Four Countries

Thailand [15]

Doses required based on estimated vaccine coverage and size of each non-infected population group:

Group	Catch-up	Maintenance
Priority recipients	0.67	0.07
Other potential recipients	5.2	1.23
Total	5.9	1.3

Note: Priority recipients include direct CSW, IDU in treatment, IDU out of treatment, male with STI, transport workers, indirect CSW, conscripts, and prisoners; potential groups are MSM, police/military, pregnant women, civil servants, health workers, university and high school students.*

Brazil [14]

Assuming 100% coverage and one dose vaccine, the number of doses required is:

Group	Catch-up	Maintenance
I	9.1	4.0
II	19.9	12.1
III	92.5	3.5

Note: Group I included CSW, IDU, prisoners, MSM, males with STI, transport workers; Group II included females with STI, military, police, health workers, pregnant women, high school & university students, conscripts; Group III included men and women 15–49 years of age*.

Southern Africa[16]

If the policy was to vaccinate all 15-year-old school students, the number of doses required for seven countries is 1.3 million.

Country	Catch-up
Botswana	29,500
Lesotho	17,000
Namibia	26,000
South Africa	986,000
Swaziland	14,500
Zambia	65,000
Zimbabwe	187,500

Southern India[17]

Assuming vaccine was introduced in 2002, the number of doses required for 100% coverage for some population groups:

Group	Catch- up
High risk CSW, STI patients, truck drivers	2.6
Adults 15-49 years	141
Children <6 years	45
ANC women	7

* Note: ANC: Antenatal care; CSW: Commercial sex worker; IDU: Intravenous drug user; MSM: Men who have sex with men; STI: Sexually transmitted infection

- The willingness of developing country governments to purchase and adopt HIV vaccines, and the factors that influence those decisions (price, level of expected cost-effectiveness, political leadership and community support, stigma, etc)
- The capacity of developing countries to deliver an HIV vaccine to target populations through public and private channels, and the likely coverage rates that can be achieved.
- The willingness of international donors to finance HIV vaccine purchase and delivery and the factors that drive their decisions.

Improving demand forecasting is an important part of IAVI's work to accelerate access to an HIV vaccine. IAVI is developing a model to estimate global demand that will build on earlier studies while using a more up to date and detailed profile of what a future vaccine may look like. IAVI is also planning to design and roll out an interactive tool to estimate HIV vaccine need and demand at country level, using data and interviews with key decision makers. Results from this demand analysis will be fed into other studies on R&D investment requirements for HIV vaccines, innovative financing mechanisms, and the expected benefits and costs of a vaccine, and will be used to strengthen advocacy and policy discussions with industry and governments.

Notes and References

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About IAVI: IAVI (www.iavi.org) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI's financial and in-kind supporters include the Bill & Melinda Gates, Rockefeller, Alfred P. Sloan and Starr foundations; the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the United Kingdom and the United States; multilateral organizations including the European Union and the World Bank; corporations such as BD (Becton, Dickinson & Co.), Continental Airlines and DHL; leading AIDS charities such as Crusaid, Deutsche AIDS Stiftung and the Until There's A Cure Foundation; and other private donors such as the Phoebe W. Haas Charitable Trust B.

Policy Brief

IAVI's Policy Brief series outlines key public policy issues in the research, development and eventual distribution of HIV vaccines.

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