Policy Brief

Potential Global Demand and Revenue Projections for Preventive HIV Vaccines

A first-generation HIV vaccine could generate global sales revenues* of US$1.6 to $3.8 billion per year over a 30-year period, and up to US$2.5 to $5.5 billion in peak annual revenues less than ten years after launch.

The importance of HIV vaccine forecasting

At the end of 2005, approximately 40 million people worldwide were living with HIV/AIDS, most of them adults, 95% of them in developing countries.[i]

New technologies are required to augment existing prevention efforts. An HIV vaccine could help reverse the pandemic and save tens of millions of lives if made widely available and adopted and implemented quickly in the countries most affected.

The development of an HIV vaccine is likely to require a combination of public sector research and translational research and development (R&D) by private sector actors to transform innovative ideas into commercial products that can be marketed and licensed.

However, pharmaceutical and biotechnology companies face many reasons not to invest in prevention for diseases of the developing world including the significant scientific hurdles, potentially high legal liabilities, and uncertain prospective markets and commercial returns.

- Having created a modeling framework to estimate the potential demand for a first-generation HIV vaccine, IAVI can provide product developers and financiers with a means of defining more credible estimates of future market potential.
- This framework could be used to inform R&D portfolio management decisions, and capital investment decisions in new production facilities when rapid scale-up is required. Simply projecting health or product needs is insufficient to encourage this type of investment.

Modeling the global demand for an HIV vaccine

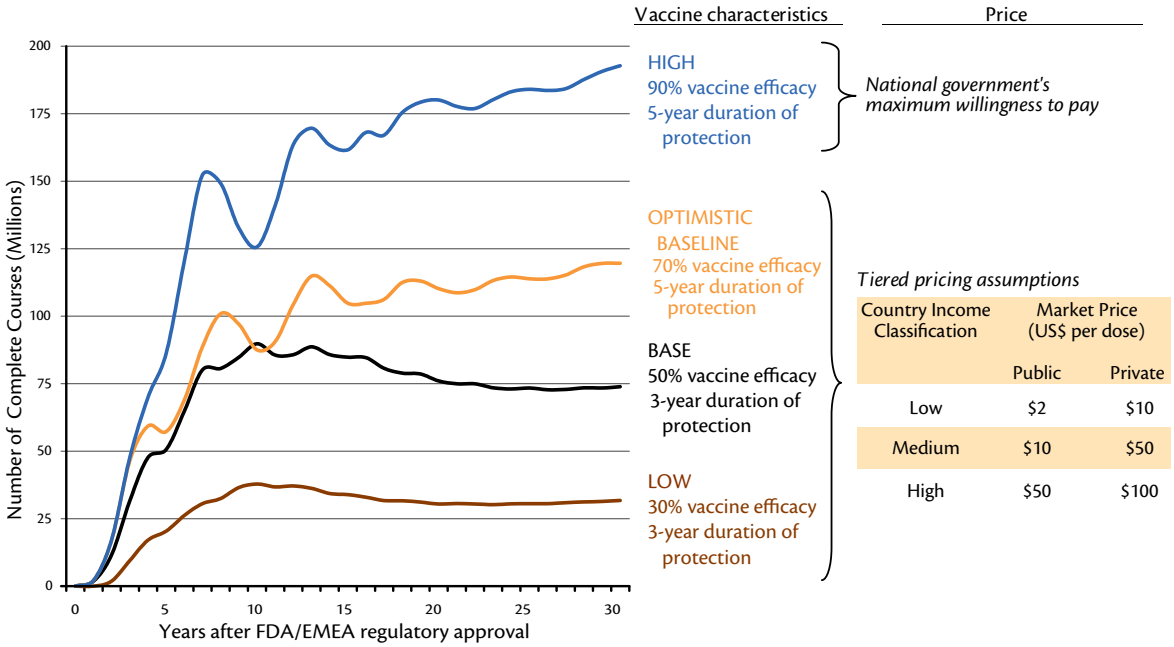
Previous academic and industrial approaches to forecasting were reviewed in order to identify the key drivers of demand. A forecasting framework for first-generation HIV vaccines was then designed to build upon previous work in this realm.[ii]

Eighty expert stakeholders worldwide, including government policymakers, NGO personnel, pharmaceutical executives, academics, and vaccine researchers, were interviewed to assess their perceptions with respect to:

- the range of acceptable characteristics of a first-generation HIV vaccine;
- vaccine adoption decisions and the vaccination strategies that might be employed; and
- the ability of these strategies to reach and cover target recipient populations given capacity and funding constraints.

*** All revenues presented in this paper are undiscounted**

Figure 1: Total annual global demand forecasts for a first-generation HIV vaccine



Tiered pricing assumptions

Country Income Classification	Market Price (US$ per dose)	
	Public	Private
Low	$2	$10
Medium	$10	$50
High	$50	$100

Additional Assumptions:
- Dosing schedule (for a full vaccination course) is assumed to be a 2-dose prime-boost combination.
- The vaccine efficacy is assumed not to be clade-specific; i.e. the vaccine is effective against all strains/subtypes.

The most important findings pertaining to countries' public sector adoption and implementation behavior are that:

- HIV vaccines may need to be at least 50% effective before governments will initiate vaccination in the general population in countries with widespread ("generalized") epidemics, while efficacy may need to reach at least 70% to persuade officials to vaccinate the general adult population in countries where the epidemic is still focused in small pockets ("concentrated") epidemics.
- For use in populations at higher risk, such as sex workers and their regular partners and injecting drug users, 30% may be an acceptable efficacy threshold for countries with generalized AIDS epidemics to endorse vaccine use, while 30% to 50% efficacy may be sufficient to convince officials to organize targeted vaccination campaigns in countries with concentrated epidemics.

These interview findings were combined with large secondary datasets from published sources to create a mathematical forecasting model capable of assessing demand and revenues at global and national levels, for public and private markets, and within a variety of the most likely target populations for an HIV vaccine.

Global demand and revenue forecasting scenarios

Modeling suggested that average global annual demand for a first-generation preventive HIV vaccine could range between 28 and 142 million courses over a 30-year period, and demand might peak at between 38 and 152 million courses some seven to ten years after vaccine launch (Figure 1). [NB: One course is assumed to equal two doses in a prime-boost dosing regimen. Key vaccine characteristics were varied: efficacy between 30% and 90%; and duration of protection from three to five years.]

Assuming tiered pricing between public and private markets and across developed and developing countries, (US$2 to $100 per dose), the above levels of demand could result in sales revenues of US$1.6 to $3.8 billion a year over a 30-year period, and up to US$2.5 to $5.5 billion in peak annual revenues (Figure 2). These projections suggest that at its peak, an HIV vaccine could represent 5% to 13% of the total global vaccine market.[iii, iv]

To contextualize these estimates:

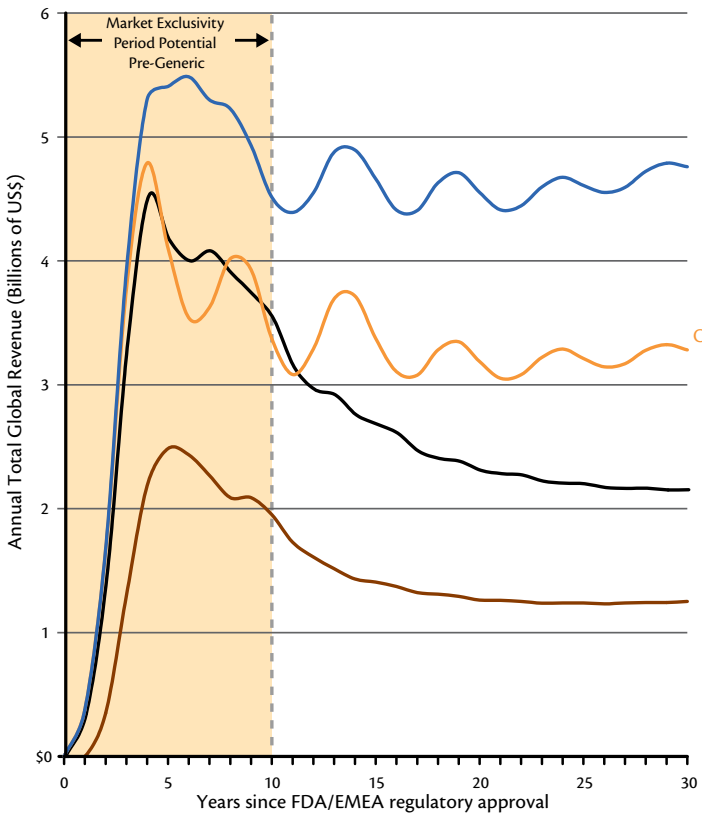
- In the year 2000, more than 50% of the global vaccine market revenues came from four vaccines: hepatitis B (20%), MMR (12%), flu (12%), and hepatitis A (10%).[v]
- Annual revenue projections for a newer, more expensive vaccine – Merck's HPV vaccine (Gardasil ©) – were US$1.4 billion for its first full year of sales (2007).[vi]

The 47 poorest (GAVI-eligible) countries might account for between 19% and 42% of total global demand by volume but only 4% to 9% of revenues; while the 47 wealthiest high-income (OECD) countries could absorb between 20% and 28% of total global demand but generate 64% to 72% of revenues.

Conclusions

The demand and revenue forecasts presented here are sensitive to an HIV vaccine's profile. Yet for any of the specified profiles, the potential for a "blockbuster" market exists. While the wealthiest countries might account for a small proportion of global demand by volume, these forecasts suggest that they would account for a much more significant proportion of global revenues.

Figure 2: Total annual global revenue projections for a range of first-generation HIV vaccine profiles



Scenario	Peak Global Revenue	Average Annual Undiscounted Sales Revenue (over years 0-10)	Average Annual Undiscounted Sales Revenue (over years 0-30)	Cumulative Undiscounted Sales Revenue over 30-yr period
HIGH	5.49	3.83	4.34	134.37
OPTIMISTIC BASELINE	4.79	3.02	3.17	98.39
BASELINE	4.52	3.01	2.64	81.71
LOW	2.48	1.56	1.41	43.83

This model is limited by imperfect information and the inherent uncertainty of the future. Nonetheless, this research creates a framework for a longer-term dynamic forecasting process. Forecasts can be updated and strengthened as better data become available through lessons learned from the introduction of other vaccines (e.g., HPV vaccines) and other new prevention options (e.g., male circumcision) as well as other new initiatives to address informational constraints. To this end, IAVI supports the Center for Global Development's new recommendations for demand forecasting which include plans for an "Infomediary."[vii] This initiative has the potential to address many of the current informational constraints and improve future demand forecasts for medicines in the developing world.

This summary is drawn from IAVI Policy Research Working Paper #15, *Forecasting the Global Demand for Preventive HIV Vaccines.* This and other IAVI policy research publications are accessible online at www.iavi.org.

[i] UNAIDS and WHO. 2006. "AIDS Epidemic Update: Special Report on HIV Prevention." Geneva: UNAIDS, 90.

[ii] IAVI. 2005. "Demand for a preventive HIV vaccine: a review of the literature." Policy Research Working Paper #3. New York: IAVI. Available at: http://www.iavi.org/viewfile.cfm?fid=10825.

[iii] Kalorama Information. 2007. Vaccines: The World Market. Available online at: http://www.kaloramainformation.com/Vaccines-1351010/

[iv] Healthservicetalk. 2007. "World Vaccine market to exceed $15 billion in 2012". Accessed 1 May 2007 from: http://www.healthservicetalk.com/news/kal/kal133.html.

[v] Gréco M. "The future of vaccines: an industrial perspective". Vaccine 20 (2002) S101–S103.

[vi] Mantone J. "Products & Profits: Merck's Gardasil". Wall Street Journal Online. Posted 23 July 2007. Available at: http://online.wsj.com/public/resources/documents/info-pp-070723-garda.html

[vii] Center for Global Development Global Health Forecasting Working Group. 2007. "A Risky Business: Saving Money and Improving Global Health through Better Demand Forecasts". Washington: CGD. Available at: http://www.cgdev.org/content/publications/detail/13784/

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IAVI gratefully acknowledges the generous support provided by the following major donors.*

Alfred P.Sloan Foundation
Basque Autonomous Government
Becton,Dickinson and Company (BD)
Bill & Melinda Gates Foundation
Broadway Cares/Equity Fights AIDS
Canadian International Development Agency
Continental Airlines
Crusaid
Deutsche AIDS-Stiftung
European Union
Google Inc.
The Haas Trusts
Irish Aid
The John D. Evans Foundation
Kathy Bole & Paul Klingenstein
Merck & Co., Inc.
The Netherlands Ministry of Foreign Affairs
The New York Community Trust
Norwegian Royal Ministry of Foreign Affairs
Pfizer Inc.
The Rockefeller Foundation
Royal Danish Ministry of Foreign Affairs
The Starr Foundation
Swedish International Development Agency
Swedish Ministry of Foreign Affairs
U.K.Department for International Development
Until There's a Cure Foundation
The U.S.President's Emergency Plan for AIDS Relief through the U.S. Agency for International Development
The World Bank/Global Forum for Health Research

And many other generous individuals from around the world.

* As of 11/06