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The HIV Vaccine Funding Landscape in 2010

The past thirty years have seen the rise of HIV and AIDS as a massive global health and development issue, followed by a recent period of unprecedented resource and political mobilization that has slowed but not reversed the tide of new infections. In 2009, an additional 2.6 million people were infected with HIV globally, and 1.8 million people died from causes related to AIDS, the great majority of these occurring in low- and middle-income countries (UNAIDS 2010). The intractability of the HIV pandemic has convinced donors, policymakers and advocates to support the research and development (R&D) of new HIV-prevention tools, such as preventive vaccines, to bolster existing strategies for HIV prevention and, ultimately, end the pandemic.

The HIV Vaccines and Microbicides Resource Tracking Working Group was founded in 2004 to collect data on the resources dedicated to the development of new biomedical tools for HIV prevention in order to provide a better understanding of the trends in such funding. The Working Group is a collaboration between AVAC: Global Advocacy for HIV Prevention, the International AIDS Vaccine Initiative (IAVI), the International Partnership for Microbicides (IPM), and the Joint United Nations Programme on HIV/AIDS (UNAIDS). Funding data assembled by the Working Group dating back to 2000 has enabled a systematic monitoring of investment in new HIV-prevention strategies and the identification of new trends in that area.

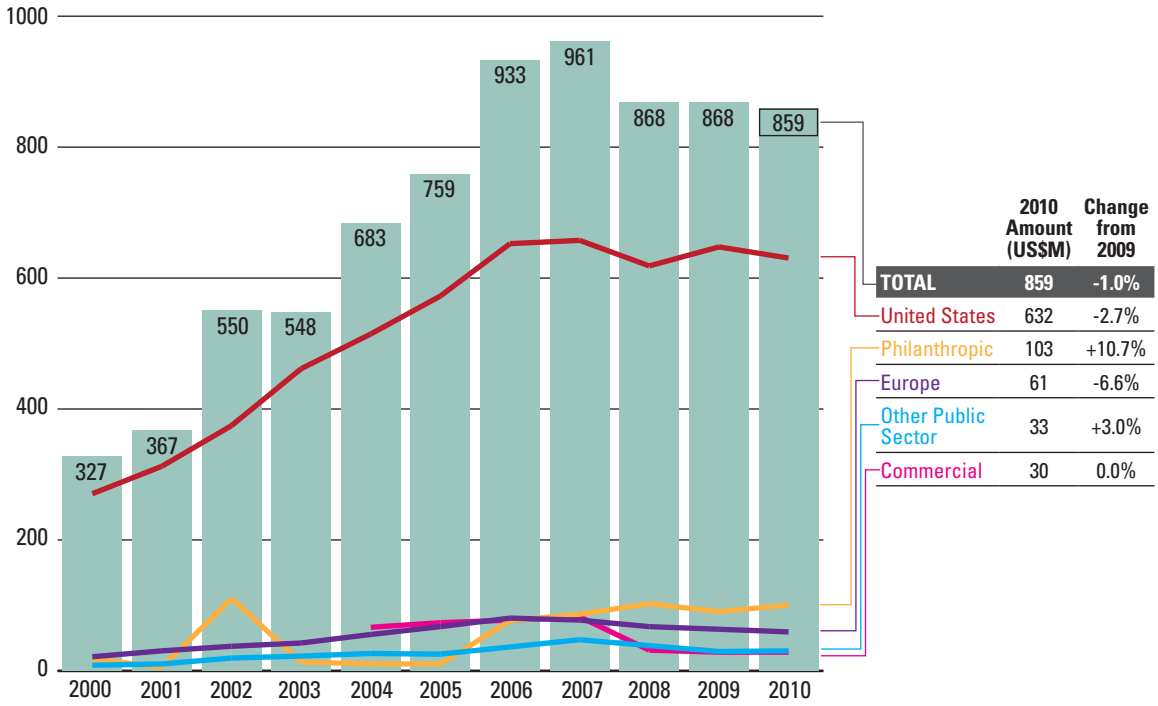
This Policy Brief focuses on 2010 HIV vaccine R&D funding data, recently published in the Working Group's latest report, *Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010*. Funding for preventive HIV vaccine R&D nearly tripled from US$ 327 million in 2000 to $961 in 2007, but subsequently dropped about 10% due to the termination of the Phase III STEP HIV vaccine trial in 2007. HIV vaccine funding has since stabilized during a period of exciting research breakthroughs. But a closer look at the composition of that funding reveals vulnerabilities to the resource base, which in turn threaten the scientific momentum of this effort.

- HIV vaccine R&D totaled $859 million in 2010, down 1% from $868 million in 2009. By sector, 2010 funding broke down as follows:
  - Public sector - $726 million (84.6%)
  - Philanthropic sector - $103 million (11.9%)
  - Commercial sector - $30 million (3.5%)
- The United States government remained the largest donor even after a small decrease, but budget cuts and the end of stimulus funding could lead to further reductions.
- European public-sector funding saw a significant drop.
- The HIV vaccine field has produced a flood of promising data in recent years, but the long-term nature of HIV vaccine development will require sustained, flexible investments.

Trends in funding for HIV vaccine R&D

Between 2009 and 2010, overall investment in HIV vaccine R&D dropped 1% from $868 million to $859 million. Public-sector funding accounted for 84.6% of the total in 2010. The philanthropic sector provided 11.9% and the commercial sector accounted for the remaining 3.5% of 2010 investments.

Figure 1: Investment in preventive HIV vaccine R&D, 2000-2010 (US$ millions)



Public-sector funding

In 2010, the United States provided the vast majority of all funding for HIV vaccine R&D at $632 million, 73.6% of the total, despite a 2.6% ($16.6 million) decline from 2009 to 2010. This funding flowed through four government agencies: the National Institutes of Health (NIH), the U.S. Agency for International Development (USAID), the U.S. Military HIV Research Program (USMHRP), and the Centers for Disease Control and Prevention (CDC). U.S. government support would have been significantly lower without an additional $26.7 million of stimulus funds provided to the NIH through the American Recovery and Reinvestment Act, which expires in 2011.

Contributions from European public-sector agencies and the European Commission (EC) dropped 6%, from $65 million in 2009 to $61 million in 2010. Two funders, the United Kingdom ($16.6 million) and the European Commission ($18.4 million), accounted for almost two-thirds of all European funding for HIV vaccine R&D.

Of non-U.S. and non-European funders, the Chinese government provided the largest amount in 2010, at an estimated $18.3 million. Other countries providing support included Canada, Australia, South Africa, India, and Thailand. Funding data for the Russian Federation, a major funder that provided about $10 million in 2009, were unavailable. But regional researchers indicated that HIV vaccine programs appear to have been heavily deprioritized by the government.

Figure 2: Top HIV Vaccine Funders, 2010 (US$ millions)

Rank	Funder	Amount
1	U.S. National Institutes of Health	561.6
2	Bill & Melinda Gates Foundation	81.0
3	U.S. Military HIV Research Program	41.6
4	U.S. Agency for International Development	28.7
5	European Commission	18.4
6	Government of China (est.)	18.3
7	UK Department for International Development	16.6
8	Ragon Foundation	10.0
9	French Nat'l Agency for Research on AIDS and Viral Hepatitis	6.6
10	Wellcome Trust	5.1
11	UK Medical Research Council	5.1
12	Dutch Ministry of Foreign Affairs	4.8
13	Canadian International Development Agency	3.8
14	Government of Spain	3.3
15	Norwegian Agency for International Development	2.5

Philanthropic funding

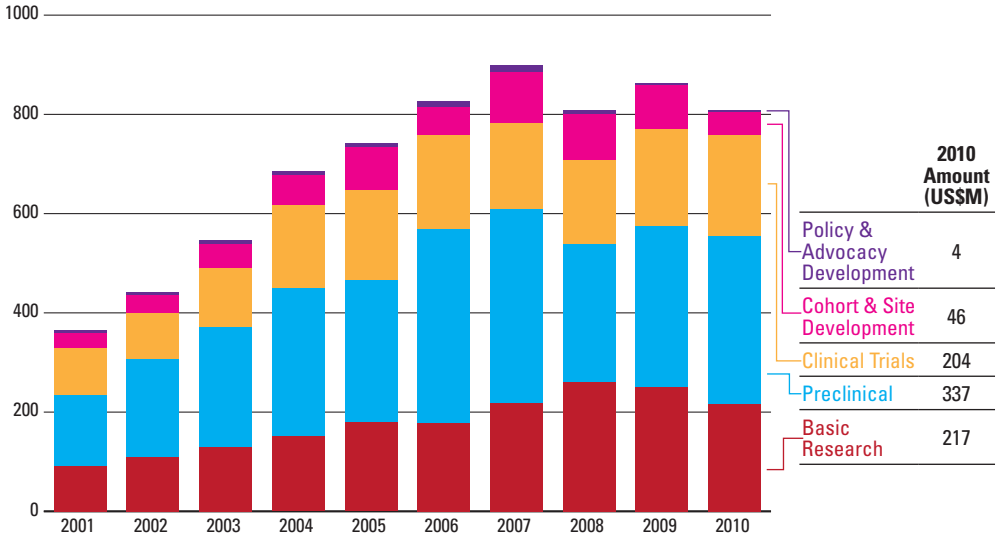
Philanthropic funding for the HIV vaccine field saw the greatest gain by percentage between 2009 and 2010, rising 11.5% from $92.0 million to $102.6 million. Three private foundations accounted for most of the philanthropic total (94%): the Bill & Melinda Gates Foundation (BMGF), the Phillip T. and Susan M. Ragon Institute Foundation, and the Wellcome Trust. The BMGF provided $80.9 million, most of it toward the Collaboration for AIDS Vaccine Discovery (CAVD), an international network of research consortia focused on vaccine design and improving candidate evaluation. The Ragon Foundation provided $10.0 million as part of a 10-year, $100 million grant to the Phillip and Susan Ragon Institute based at the Massachusetts General Hospital, Massachusetts Institute of Technology and Harvard University. The Wellcome Trust provided support to HIV vaccine research in a number of academic settings in the United Kingdom, including the University of Oxford and Imperial College London.

Commercial funding

Estimates of commercial investment in HIV vaccine R&D remained level in 2010, at $30 million, though an increase in activity in the biotechnology sector reflected renewed industry interest in HIV vaccines. Four of the ten largest pharmaceutical companies by 2009 revenues (Merck, GlaxoSmithKline, Novartis, and Sanofi) funded internal HIV vaccine programs in 2010, but at low levels (ContractPharma 2010). A number of biotechnology companies advanced their own early-stage candidates in 2010, including GeoVax and Inovio Pharmaceuticals.

However, funding for HIV vaccine R&D efforts by biopharmaceutical firms remained low in 2010. The sector's contributions to HIV vaccine development continued to be channeled primarily through partnerships partially or fully funded by the public and philanthropic sectors, such as two separate programs at the NIH's Vaccine Research Center (VRC) utilizing vectors originally developed by GenVec and Crucell.

Figure 3: Expenditure distribution for public and philanthropic funding for HIV Vaccine R&D 2010



Funding in context – where is the money going?

Funding for HIV vaccine R&D currently supports a diverse set of priorities and partnerships. This includes follow-up studies to better understand and improve upon the results of a vaccine trial conducted in Thailand that, in 2009, provided the first evidence that a vaccine can prevent HIV infection. It also includes successful efforts to elicit and study broadly neutralizing antibodies against HIV, further research into replicating viral vectors to improve the cell-mediated response to candidate HIV vaccines, and ongoing clinical trials such as the HVTN 505 Phase II trial expected to provide efficacy results in 2013.

The Working Group allocated 2010 expenditure data to five HIV vaccine research categories used by the NIH. Analysis of these data was limited to funds contributed by public-sector and philanthropic parties, due to the difficulty in procuring granular funding data from the commercial sector. The largest change in funding allocation took place in the category of Cohort and Site Development, dropping from 10.3% of total funding to 5.7%.The percentage of total funds expended on preclinical research in 2010 grew from 37.5% to 41.7%, and the funds expended on clinical trials rose from 22.7% to 25.2%. The percentage of total funds expended on basic research declined from 29.1% to 26.9%. Some of these changes may reflect funding cycles and not policy shifts.

Discussion

Investments in the development of an HIV vaccine have resulted in an increasing number of scientific breakthroughs, with promising data being released and new avenues of research opening up at a higher rate in the past two years than in any previous period (Maurice, 2010). A slight 1% drop in funding from 2009 to 2010 attests to the commitment of funders in a time of hard choices and their understanding that vaccines and other new prevention tools will enable more effective management and the eventual end of the HIV pandemic. However, funding for the HIV vaccine field will face a number of challenges and concerns in the coming years:

- Stability for HIV vaccine R&D funding stems primarily from the large proportion of funding provided by a handful of major donors, especially the United States government and the Bill & Melinda Gates Foundation. This heavy concentration from a few funding sources creates the risk that small funding adjustments by major donors could have magnified impacts. For example, most of the 1% drop in total funding in 2010 could be accounted for by a 2.6% funding decrease by the United States government. A more diversified funding base, perhaps strengthened by new support from emerging economies, a new generation of philanthropic supporters, and long-term, sustainable and flexible R&D financing mechanisms could bolster the long-term resource stability needed by the HIV vaccine R&D field.

- Capitalizing on scientific breakthroughs will require prioritized programmatic support. One good example of this is the Pox-Protein Public Private Partnership (P5), a cross-sectoral collaboration between Sanofi Pasteur, Novartis, the NIH, the Bill & Melinda Gates Foundation, the USMHRP and the HIV Vaccine Trials Network organized to improve the efficacy of the RV144 candidate. Funding mechanisms need to be flexible enough to adapt to changing circumstances and, if needed, expand quickly. Resources have to be made available when they are required, especially as breakthroughs are translated into candidates that will ultimately be evaluated in complicated and expensive late-stage efficacy trials. Researchers should not have to wait for existing programs to come to an end before resources are made available to them.

- The health of the HIV vaccine pipeline will also require continued support for basic and discovery research. Recent advances in HIV vaccine R&D did not emerge from a vacuum, but from efforts to answer difficult scientific questions at academic and government labs, which would bear the largest brunt of budget cuts to public-sector research agencies such as the NIH and the United Kingdom's Medical Research Council.

- While investment by the commercial sector remains low, finding new ways to tap its innovation, existing technologies and development capabilities for HIV vaccine R&D could help transform the field. Most HIV vaccine development programs have entailed some level of collaboration with the biopharmaceutical sector, and efforts such as the NIH's Small Business Innovation Research program and IAVI's Innovation Fund, which is co-funded by the Bill & Melinda Gates Foundation, have brought new ideas and energy to the field. As vaccine candidates move into large, late-stage trials, the manufacturing expertise of the commercial sector in the United States, Europe, and companies based in emerging economies such as China and India will likely play a significant role.

The success seen in recent clinical trials evaluating pre-exposure prophylaxis, a candidate microbicide, treatment-as-prevention and, not least, the RV144 vaccine regimen have energized the HIV-prevention field. A comprehensive biomedical HIV prevention toolkit for those at risk has never been closer to realization. The crucial addition of a preventive HIV vaccine to that toolkit will not only depend on the sustained commitment of current donors. It will also depend on the support of a diversified field of new champions willing to fund the research required to capitalize on new discoveries in the HIV vaccine field.

Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010 can be found at www.hivresourcetracking.org.

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

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