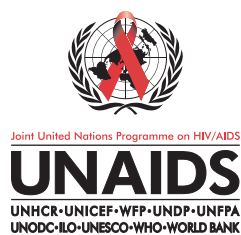


Financing the expanded response to AIDS:

HIV vaccine and microbicide research and development

Executive summary



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Introduction

In the 20 years since the identification of HIV as the cause of AIDS, the HIV pandemic has grown to be the greatest public health crisis facing the world since the 13th century. Over 65 million people have been infected with HIV to date, and each day another 14 000 people are infected. More needs to be done to expand access to prevention and treatment – but there is also an urgent need simultaneously to develop additional prevention methods. HIV vaccines and microbicides are two technologies currently under development that would provide people with new options for protecting themselves from HIV.

The 2001 United Nations Declaration of Commitment on HIV/AIDS called for mobilizing massive new resources to mount an effective, comprehensive response to the epidemic. In particular, it called for increased investment in research related to HIV and AIDS and, more specifically, for the development of sustainable and affordable prevention technologies, such as vaccines and microbicides.

There is increasing scientific confidence that it will be possible to develop a safe and effective preventive HIV vaccine and a safe and effective microbicide. However, there are many scientific challenges ahead and ensuring that both of these technologies are developed in a timely fashion will require increased global collaboration and coordination. It will also require the investment of significantly more resources. Given the many uncertainties in developing new technologies, it is impossible to say exactly how much money will be required to develop an effective HIV vaccine or an effective microbicide. The targeted investment of significantly more resources, however, should increase the likelihood of success and should be built into a balanced portfolio approach to AIDS that incorporates both increased access to currently available interventions and services and increased investment into new interventions.

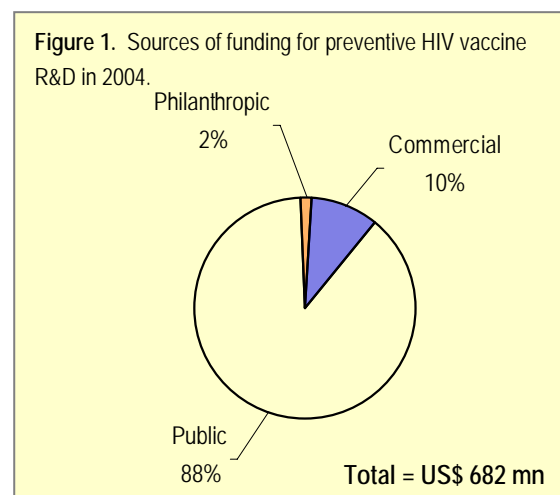
In recent years UNAIDS and its partners have significantly increased global capacity to monitor resource flows for AIDS. In 2004, UNAIDS, the Alliance for Microbicide Development (AMD), the AIDS Vaccine Advocacy Coalition (AVAC) and the International AIDS Vaccine Initiative (IAVI) established a collaborative project to track funding for preventive HIV vaccines and microbicide research and development (R&D). Two reports have been published by the HIV Vaccines and Microbicides Resource Tracking Working Group and a third report will be available early in July.¹

Resource flows for preventive HIV vaccine R&D

In 2004, the public, philanthropic, and commercial sectors invested² approximately US\$ 682 million in preventive HIV vaccine R&D (see Figure 1). The public sector dominated funding for HIV vaccine R&D and accounted for 88% of total investment in 2004. The commercial sector accounted for 10% and the philanthropic sector for 2%.

¹ A preliminary report was published in March 2005: “Public and Philanthropic Investments in Preventive HIV Vaccines and Microbicides: 2000 to 2004” and the final report on vaccines, “Tracking Funding for Preventive HIV Vaccine Research and Development: Estimates of annual investments and expenditures 2000-2005”, was published in June 2005. The report *Tracking Funding for Microbicide Research and Development: Estimates of Annual Investments 2000-2005* will be available in early July.

² The HIV Vaccine and Microbicide Resource Tracking Working Group collected information on both investments and expenditures. Investments were defined as annual disbursements by funders and expenditures as the level of funding directly spent on R&D activities in a particular year. The main reasons for differentiating between these two were: (1) some funders may forward fund (i.e., disburse funding in one year to be expended over multiple years), (2) research projects may be delayed, and (3) the rise in the importance of public-private partnerships (PPPs) who require sufficient funds either banked or committed to enter into credible multi-year contracts.



Over the last five years there has been a marked increase in the level of investment in preventive HIV vaccines. Between 2000 and 2004 investments from non-commercial (public and philanthropic sectors) almost doubled from US\$ 327 million to US\$ 614 million and by April, 2005 disbursements and firm commitments from the same sources had already reached US\$ 627 million (see Table 1).³

Table 1. Annual investment in preventive HIV vaccine R&D by the public and philanthropic sectors between 2000 and 2005 (current US\$ million). The 2005 estimates represent actual disbursements and firm commitments made as of April 5, 2005.

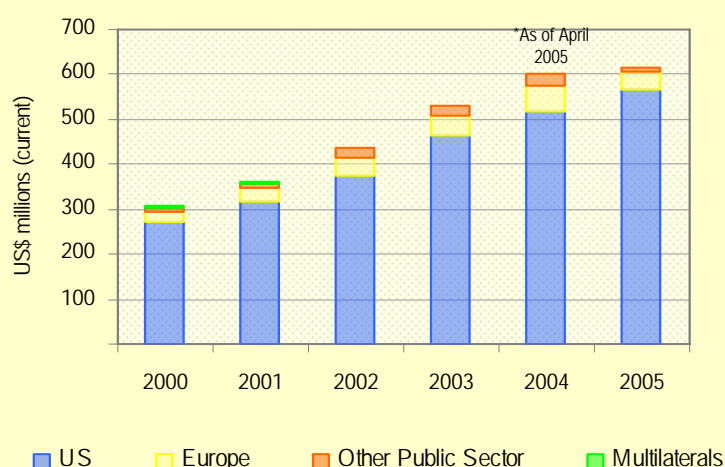
	2000	2001	2002	2003	2004	2005
Public Sector						
- US	272	314	376	463	516	568
- Europe ^A	23	32	39	44	57	39
- Other ^B	10	12	21	24	28	8
- Multilaterals	2	2	2	2	2	2
<i>Total public</i>	307	359	436	532	602	617
Philanthropic Sector						
<i>Total philanthropic</i>	20	7	112	15	12	10

^A This figure includes funding from the European Commission.
^B Other includes all national public sector funding apart from funding from the US and Europe.

The **public sector** is the main source of funding for preventive HIV vaccines and in 2004 the public sector invested US\$ 602 million, or 88% of the combined global funding in that year from the public, philanthropic and commercial sectors. The United States dominates public sector funding and in 2004, the US accounted for 86% of the total funds invested by the public sector. European national governments and the European Commission together accounted for just over 9%, while national governments from the rest of the world accounted for just under 5%, and the multilateral organizations (WHO, UNAIDS and the World Bank) for under 0.5% (see Table 1 and Figure 2).

³ The 2005 estimates do not include the Requests for Proposals announced by the Bill & Melinda Gates Foundation in February 2005, which committed the Foundation to provide up to US\$ 360 million over the next five years for HIV vaccine R&D. It is anticipated that the initial awards will not be announced until late 2005, with funds being disbursed starting in early 2006.

Figure 2. Annual public sector investment in preventive HIV vaccine R&D between 2000 and 2005 by region.



Thirteen countries were identified that invested more than US\$ 1 million of public sector funds in 2004 and only three countries that invested more than US\$ 10 million (Canada, the United Kingdom and the United States) (see Table 2). In addition, the European Commission (EC) invested approximately US\$ 12 million. Investment figures for individual years, however, do not necessarily reflect long-term donor commitment. In terms of total funds disbursed for HIV vaccine R&D between 2000 and 2004, the top five countries (excluding the EC) in descending order were: the United States, Canada, the United Kingdom, the Netherlands and France.

Table 2. National public sector investment in preventive HIV vaccine R&D by country in 2004. Note, only countries investing more than US\$ 50,000 are included.

US\$ 50k to 500k	US\$ 500k to 1 mn	US\$ 1 mn to 5 mn	US\$ 5 mn to 10 mn	US\$ 10 mn to 25 mn	Over US\$ 25 mn
-Australia	-Brazil	-Denmark	-Ireland	-Canada	-United States
-China	-Finland	-France	-Italy	-United Kingdom	
-Cuba	-Russia	-Germany	-South Africa		
-India		-Japan			
-Thailand		-Netherlands			
		-Norway			
		-Sweden			

The **philanthropic sector** accounted for US\$ 12 million or 2% of the total funds disbursed in 2004. Levels of philanthropic funding have varied considerably between 2001 and 2002 from a low of US\$ 7 million to a high of US\$ 112 million (see Table 1). The peak in 2002 reflects the multi-year US\$ 100 million challenge grant awarded by the Bill & Melinda Gates Foundation to IAVI and disbursed in full to IAVI in 2002. Funding from the philanthropic sector, however, is projected to increase substantially in the next few years as a result of the Requests for Proposals (RFPs) announced by the Bill & Melinda Gates Foundation in February 2005. These RFPs pledge up to US\$ 360 million over the next five years to support HIV vaccine R&D as part of the Global HIV/AIDS Vaccine Enterprise.

Total **commercial sector** investment in 2004, excluding funding from external sources, was estimated to be US\$ 68 million (range US\$ 54 million to US\$ 82 million) with most of this funding (87%) coming from large pharmaceutical companies (see Table 3). Total expenditures by the commercial sector, however, are considerably greater than this as many of the companies active in HIV vaccine R&D receive programme funding from external sources such as public sector agencies (e.g., National Institutes of Health [US] and Agence

Nationale de Recherches sur le Sida [France]) or Public Private Partnerships (e.g., IAVI and the South African AIDS Vaccine Initiative).

Table 3. Annual investment in preventive HIV vaccines by the commercial sector in 2004 (current US).

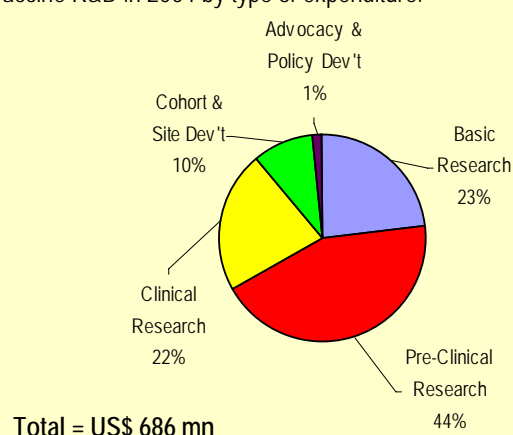
Pharmaceutical Companies	US\$ 59 mn (87%) (range 47 to 71)
Biotechnology Companies	US\$ 9 mn (13%) (range 7 to 11)
Total	US\$ 68 mn (range 54 to 82)

The Resource Tracking Working Group had hoped to generate longitudinal data on commercial sector investment, however, given the time available for this study, expectations had to be scaled back as many of the companies contacted did not specifically track funding for HIV vaccine R&D and others were reluctant to share information on funding citing concerns about proprietary business issues. As a result, the industry estimates are for one year only (2004) and presented as a range.

Total expenditures by the public, philanthropic and commercial sectors on HIV vaccine R&D in 2004 were estimated to be US\$ 686 million. Over the five year period 2000 to 2004 total expenditures have almost doubled and for the first time annual expenditures were estimated to be greater than annual investments by a total of US\$ 4 million.

In 2004 basic research and pre-clinical research together were estimated to account for 67% of the funds spent. In comparison, support for clinical trials accounted for 22%, cohort and site development for 10%, and advocacy and policy development for 1% (see Figure 3).

Figure 3. Breakdown of total expenditures on preventive HIV vaccine R&D in 2004 by type of expenditure.



Resource flows for microbicide R&D

In 2004 public and philanthropic investment in microbicide R&D reached US\$ 142 million. This represents a marked increase in the level of investment by the public and philanthropic sectors over the last 5 years. Between 2000 and 2004 investments from the public and philanthropic sectors more than doubled, from US\$ 65 million to US\$ 142 million, and by April 2005 disbursements and firm commitments from the same sources for 2005 had already reached US\$ 163 million (see Table 4).

Table 4. Annual investments in microbicide R&D between 2000 and 2005 (current US\$ million). The 2005 estimates represent actual disbursements and firm commitments made as of April 5, 2005.

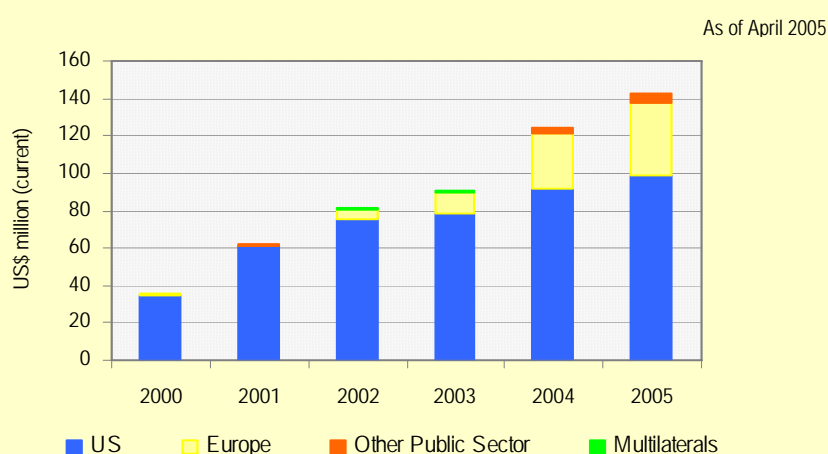
	2000	2001	2002	2003	2004	2005
Public Sector						
- US	34.6	61.3	75.3	78.8	92.0	99.3
- Europe ^A	0.7	0.4	5.1	10.6	29.9	37.8
- Other ^B	0.3	< 0.1	0.2	0.9	2.0	5.0
- Multilaterals	< 0.1	0.3	0.4	< 0.1	0.2	0.2
Total public	35.7	62.0	81.0	90.2	124.2	142.3
Philanthropic Sector						
Total philanthropic	29.4	3.4	24.8	16.9	18.1	21.1

^A This figure includes funding from the European Commission.

^B Other includes all national public sector funding apart from funding from the US and Europe.

The **public sector** is the main source of funding for microbicides and in 2004 the public sector was estimated to have invested US\$ 124 million, or 87% of the combined global funding in that year from the public and philanthropic sectors. The United States dominates public sector funding and, in 2004, the US accounted for 74% of the total funds invested by the public sector. European national governments and the European Commission together accounted for just over 24%, while national governments from the rest of the world and the multilateral organizations (WHO, UNAIDS and the World Bank) together accounted for 2% (see Table 4 and Figure 4).

Figure 4. Annual public sector investment in microbicide R&D between 2000 and 2005 by region.



Seven countries were identified that invested more than US\$ 1 million of public sector funds in 2004 and only three countries that invested more than US\$ 5 million (the Netherlands, the United Kingdom and the United States) (see Table 5). In addition, the European Commission (EC)

invested approximately US\$ 6 million. Investment figures for individual years, however, do not necessarily reflect long-term donor commitment. In terms of total funds disbursed for HIV vaccine R&D between 2000 and 2004, the top five countries (excluding the EC) in descending order were: the United States, the United Kingdom, the Netherlands, Ireland and Norway.

Table 5. National public sector investment in microbicide R&D by country in 2004. Note, only countries investing more than US\$ 50,000 are included.

US\$ 50k to 500k	US\$ 500k to 1 mn	US\$ 1 mn to 5 mn	US\$ 5 mn to 10 mn	US\$ 10 mn to 25 mn	Over US\$ 25 mn
-Australia -Belgium -China -Germany -India -Italy	-Denmark -France -South Africa	-Canada -Ireland -Norway -South Africa -Sweden	-Netherlands	-United Kingdom	-United States

In 2004, funding from the **philanthropic sector** totalled US\$ 21 million or 13% of the total funds disbursed. Levels of philanthropic funding have varied considerably over the period studied – from a low of US\$ 3 million in 2001 to a high of US\$ 29 million in 2000. The peaks in 2000 and 2002 reflect multi-year awards by the Bill & Melinda Gates Foundation to CONRAD (US\$ 26 million) and the Population Council (US\$ 20 million) that were disbursed in full the year in which they were awarded.

The resource tracking working group had hoped to collate data on annual expenditures and their breakdown by expenditure category for microbicides. However, we were not able to access this information within the time frame of the project for the US government funding agencies who accounted in 2004 for 65% of the funds invested.

Discussion

The HIV vaccines and microbicides resource tracking collaboration has generated a great deal of information on funding flows for HIV vaccine and for microbicide R&D⁴ that can be used to monitor levels of effort and to identify trends in investment, spending, and research focus. The data were generated primarily through direct contact with funding agencies and intermediary organizations. This approach, while time-consuming, provides the necessary detail to ensure data comparability across funders and over time. Nevertheless there are gaps, reflecting both missing and incomplete information, and we hope to improve the comprehensiveness of the data in future years.

Data for the public and philanthropic sectors are more comprehensive than the data for the commercial sector. This reflects both how companies track their own funding and corporate concerns about divulging proprietary information. Future estimates would benefit from a stronger collaboration with industry to find creative solutions approaches for tracking commercial sector investments and for tracking the level of funding the commercial sector receives directly from public and philanthropic sources and from intermediary agencies. This sort of information is essential if these figures are to be used for assessing the impact of public policies on private sector investment.

Future work in this area would also benefit from additional effort being directed at collating more detailed information on the breakdown of expenditures and sub-dividing some of the expenditure categories, such as pre-clinical research, that cover a wide range of topics.

⁴ The vaccine report was released in June 2005.

Collection of this type of information, combined with estimates of funding needs and absorptive capacity, should help identify areas where more resources and effort need to be focused.

The data collected show that over the last five years there has been a substantial increase in funding from the public sector for preventive HIV vaccine and microbicide R&D, and current commitment and disbursement figures suggest that funding levels in 2005 will be higher than in 2004. This increase in funding reflects both increased contributions from existing donors and a growth in the number and geographical distribution of funders as new donors are engaged in supporting this important work.

Current funding levels, however, are significantly less than what will be required to mount an accelerated search for either of these technologies. A recent study by the Coordinating Committee of the Global HIV/AIDS Vaccine Enterprise estimated that an accelerated search for an HIV vaccine will require annual expenditures on the order of US\$ 1.2 billion a year⁵ while a recent analysis by the International Partnership for Microbicides (in draft) suggests that annual funding for microbicide R&D needs to increase to US\$ 280 million a year over the next five years.

The significant increase in funding for both microbicides and preventive HIV vaccines over the last five years has coincided with a dramatic increase in the overall financial commitment to the HIV/AIDS field in general. While the HIV Vaccines and Microbicides Resource Tracking Working Group has not collected data on overall financial commitments to HIV/AIDS, anecdotal evidence suggests that funders have increased funding for the development of microbicides and preventive HIV vaccines in addition to – not at the expense of – their commitments to expanding access to the prevention and treatment tools already available.

⁵ Coordinating Committee of the Global HIV/AIDS Vaccine Enterprise. (2005). *The Global HIV/AIDS Vaccine Enterprise: Scientific Strategic Plan*. PLoS Med 2: e25.

Notes

The Joint United Nations Programme on HIV/AIDS (UNAIDS) brings together ten UN agencies in a common effort to fight the epidemic: the Office of the United Nations High Commissioner for Refugees (UNHCR), the United Nations Children's Fund (UNICEF), the World Food Programme (WFP), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations Office on Drugs and Crime (UNODC), the International Labour Organization (ILO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO), and the World Bank.

UNAIDS, as a cosponsored programme, unites the responses to the epidemic of its ten cosponsoring organizations and supplements these efforts with special initiatives. Its purpose is to lead and assist an expansion of the international response to HIV/AIDS on all fronts. UNAIDS works with a broad range of partners – governmental and nongovernmental, business, scientific and lay – to share knowledge, skills and best practices across boundaries.

HIV Vaccines and Microbicides Resource Tracking Working Group

AIDS Vaccine Advocacy Coalition (AVAC) www.avac.org

Alliance for Microbicide Development (AMD) www.microbicide.org

International AIDS Vaccine Initiative (IAVI) www.iavi.org

Joint United Nations Programme on HIV/AIDS (UNAIDS) www.unaids.org

