SUSTAINING THE HIV PREVENTION RESEARCH AGENDA: FUNDING FOR RESEARCH AND DEVELOPMENT OF HIV VACCINES, MICROBICIDES AND OTHER NEW PREVENTION OPTIONS 2000 TO 2007

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HIV Vaccines and Microbicides Resource Tracking Working Group
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AIDS Vaccine Advocacy Coalition **AVAC**
Alliance for Microbicide Development **AMD**
International AIDS Vaccine Initiative **IAVI**
Joint United Nations Programme on HIV/AIDS **UNAIDS**

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EXECUTIVE SUMMARY

In this report, the HIV Vaccines and Microbicides Resource Tracking Working Group (Working Group) documents spending on biomedical HIV prevention research and development (R&D) for the year 2007. The report has been published annually since 2004, tracking investment trends as far back as 2000.

Data show that financial allocations for vaccines and microbicides increased by only a small amount (2–3%) from 2006 to 2007. A wider lens reveals that since 2000 there have been significant funding increases across the board by virtually all donors involved in HIV prevention research, and a number of new funders have joined the effort.

Total global investment in 2007 for HIV vaccines, microbicides, and other prevention options amounted to $961 million, $226.5 million, and $59.4 million respectively. Investment levels are significantly higher now than in 2000, but the challenge going forward will be to sustain sufficient financial commitment to maintain the research effort.

FUNDING FOR HIV VACCINE R&D

- In 2007, total global investment in preventive HIV-vaccine R&D was an estimated US$961 million, a 3% increase over 2006 funding levels.
- Annual public and philanthropic R&D funding for HIV vaccines almost tripled from US$327 million in 2000 to US$877 million in 2007.
- In 2007, public-sector funders provided approximately 82% (US$789 million) of the funds allocated to preventive HIV-vaccine R&D. The philanthropic sector provided 9% (US$88 million) and the commercial sector accounted for the remaining 9% (US$84 million).
- In 2007 European funders invested US$79 million in HIV vaccine R&D, up from $23 million in 2000, but flat as compared to the previous year's contribution of US$82 million. Similarly, US funding was essentially flat between 2006 and 2007, showing only a marginal increase from US$654 million to US$659 million. Investments from non-US and non-European countries such as Brazil, India, South Africa and Thailand increased 29% to US$49 million.
- A breakdown of global funding allocations by type of activity was estimated from a subset of investments. Funds predominantly supported basic and pre-clinical research, which together accounted for approximately 66% of the funds spent. Support for clinical trials accounted for 20%, cohort and site development for 12% and advocacy and policy development for the remaining 2%.

FUNDING FOR MICROBICIDES R&D

- In 2007, total global investment in microbicide R&D was approximately US$226.5 million, a 2% increase over 2006 funding levels.

- Annual public and philanthropic R&D funding for microbicides more than tripled from US$65 million in 2000 to US$222 million in 2007.

- In 2007, the public sector provided 90% (US$203 million) of the funds allocated to microbicide R&D. The philanthropic sector provided 8% (US$19 million) and the commercial sector accounted for 2% (US$4.5 million) of investments made in 2007.

- During the last eight years, European funders increased their commitment to microbicide R&D from US$0.7 million to approximately US$59.4 million. In 2007, R&D activities outside of the US and Europe decreased to about US$3.4 million from US$10 million in 2005, but still significantly exceeded investment of each year prior to 2005.

- A breakdown of global funding allocations by type of activity was estimated from a subset of investments on microbicide R&D. Of this, 9% was devoted to basic mechanisms of mucosal transmission; 24% to pre-clinical research; 5% to product formulation; 46% to clinical trials; 7% to social science research; 6% to infrastructure; and 3% to advocacy.

R&D FUNDING FOR OTHER NEW PREVENTION OPTIONS

- In 2006, the Working Group chose to start monitoring four additional experimental HIV-prevention options: adult male circumcision, herpes simplex virus type 2 (HSV-2) suppression, cervical barriers and pre-exposure prophylaxis using antiretroviral drugs (PrEP). Investments to date have now resulted in the validation of at least one new prevention option—adult male circumcision in 2006.

- Between 2000 and 2007, six public-sector funders and two foundations supported approximately US$208 million in research and development activities directed towards one or more of these four HIV-prevention interventions. Public sector funders provided 47% (US$98 million) of the total funds for new prevention options, the philanthropic sector provided 50% (US$105 million), and the commercial sector consisted of a estimated US$5 million in-kind donation of antiretroviral drugs for PrEP research.

HIV Prevention R&D: Looking Ahead

Sustain momentum in HIV prevention R&D investment.

Increase accountability by efficiently linking research and funding to scientific priorities.

Support an expanded toolbox of new prevention options as part of a comprehensive response to the epidemic.

Develop and validate estimates of future HIV prevention R&D investment need.

Sustaining Investment Momentum

Investment levels have grown over recent years, but scientific challenges in developing new prevention options may affect future funding needs. In 2007, the HIV prevention field saw several trials result in findings of no or inconclusive efficacy. Sustained funding for HIV prevention R&D is needed to explore new approaches to vaccine and microbicide design, bring novel candidates to the pipeline and investigate other prevention options. The challenge going forward will be to sustain the research effort and to rapidly capitalize on what we have learned.

Increasing Accountability

Funding streams are limited and there are a number of other global health needs competing for funds. The HIV prevention community need to ensure that R&D activities are focused on key priorities and are not duplicative of other efforts so that the impact of this limited funding is maximized.

Supporting an Expanded Toolbox

A comprehensive plan to combat the epidemic requires investment in a wide range of more effective methods of prevention to complement expanding access to existing HIV treatment and prevention options and enhance the sustainability of commitments to universal access.

Assessing Investment Need

One key step in supporting sustained funding for prevention research is to project future investment needs for HIV vaccines, microbicides and other new prevention options. Estimates of resource needs prepared in 2004 for vaccines and microbicides no longer reflect current costs and research priorities. Funders, policy-makers, civil society and researchers should jointly develop an updated, data-driven, comprehensive assessment of investment needs. Projected funding requirements can be used as a tool to determine gaps when measured against real-world spending and support greater accountability by tying spending to investment needs.

While investment for HIV prevention R&D has significantly increased over time, it is critical to sustain financial commitment. Collection and dissemination of annual data on R&D investments in HIV vaccines have proven valuable to monitoring levels of effort and understanding the significance of investment trends, and in the future, this information may be used to assess the impact of public policies aimed at accelerating scientifc progress. Going forward, funding must be linked more effectively

and efficiently to scientific priorities, funding allocations must be diversified to support the full range prevention options under investigation, and resource needs for future HIV prevention R&D must be assessed systematically. Continued evaluation of investments and expenditures can help the HIV prevention community to acchieve, and track progress against these goals.

1. INTRODUCTION

More than 25 years into the HIV/AIDS epidemic, it is clear that greatly improved access is needed for HIV prevention and treatment interventions that currently exist. At the same time, there is also an urgent need to identify additional prevention strategies. In the biomedical arena, HIV vaccines and microbicides are two of the prevention options currently in development. If they show efficacy, these tools could provide people—especially women, who are disproportionately at risk of HIV infection —with new options for protection against HIV. Investment in HIV prevention research into vaccines and microbicides has been expanded over the past five years to also include a number of other experimental prevention tools, such as adult male circumcision and pre-exposure prophylaxis (PrEP).

Since 2004, the HIV Vaccines and Microbicides Resource Tracking Working Group (Working Group) has generated estimates of research and development (R&D) investment that can be compared year to year, from one technology to another, and across funders.[1] This effort was undertaken to respond to the 2001 United Nations General Assembly Special Session (UNGASS) Declaration of Commitment on HIV/AIDS which called for increased investment in research related to HIV and AIDS and, specifically, for the development of sustainable and affordable prevention technologies, such as vaccines and microbicides.[2] In April 2008, the Report of the Secretary General on global progress toward that commitment reaffirmed the need for investment in new prevention research, acknowledging that the road to successful development of these technologies may be lengthy.[3]

Over this eight-year period from 2000 to 2007, funding from the public and the philanthropic sectors for R&D efforts directed at developing HIV vaccines and microbicides has increased significantly. Subsequently, the past several years have brought the results of an unprecedented number of trials of biomedical HIV prevention methods. (*For details on Recent HIV Prevention Trial Results, see sidebar on page 11*). The investments in 2007 preceded the outcomes of the trials, which in some cases showed no or inconclusive effect. As the results from these trials unfold, they could impact future funding trends and priorities.

1. The categories used to define research and development (R&D) can be found in the Appendix. R&D also includes policy and advocacy work in support of R&D efforts.
2. These data are used to monitor the implementation of the UNGASS Global Commitment and Action Indicator 2–the amount of public funds available for HIV vaccine and microbicide research and development.
3. Declaration of Commitment on HIV/AIDS and Political Declaration on HIV/AIDS: Midway to the Millennium Development Goals (April 1, 2008).

HIV Prevention Trial Results 2007–2008

The HIV prevention field has been able to successfully test several promising HIV prevention methods. However most candidates to date have not proven effective, which is consistent with the way in which biomedical researched is conducted and new products are developed. This global effort, therefore, continues in the face of findings of no or inconclusive effect in several HIV prevention trials. In the HIV vaccine field, the STEP and Phambili trials of the promising Merck adenovirus HIV vaccine were halted in 2007 —except for follow-up—when an interim analysis of the study data found that the candidate could not show efficacy. The preliminary results from the STEP trials also suggested that the vaccine being tested might have increased susceptibility to HIV infection in those with prior exposure to adenovirus. Researchers are now examining the STEP results to see what can be learned for future vaccine development.

There have been other recent HIV prevention trials that have not shown effect. A study testing HIV prevention through the addition of the diaphragm found no evidence of added efficacy in July 2007. Two different studies of treatment with the drug acyclovir to suppress HSV-2 disease to prevent HIV infection found no effect in 2007 and 2008. Finally, studies of two different microbicides saw no effect on HIV acquisition according to results released in 2007 and 2008.

Trials of any biomedical intervention face challenges. Vaccines and microbicides face obstacles due to the need for large trial size and regulatory and manufacturing complications. Very few vaccines for other diseases have been developed in less than 25 years—the time elapsed since HIV was identified. Developing a microbicide that blocks infection by HIV—or any other pathogen—through topical application poses an unprecedented scientific and practical challenges. Compounding these difficulties is the unique genetic diversity of HIV, and its ability to attack the very immune cells that should help protect against infection.

But these research results and scientific challenges do not change the fundamental rationale for continued research and development of additional prevention options. Still there remain the same scientific reasons to believe these challenges can be overcome, and that safe and effective HIV vaccines, microbicides and other prevention options can be developed.

2. RESULTS

2.1 GLOBAL INVESTMENTS IN HIV VACCINE R&D

In 2007, total global investment in HIV vaccine R&D was approximately US$961 million, a 3% increase over 2006. Public sector funders provided 82% (US$789million) of those investments, the philanthropic sector 9% (US$88 million) and the commercial sector 9% (US$84 million).

TABLE 1. ANNUAL INVESTMENTS IN HIV VACCINE R&D 2000–2007 (US$MN)

	2000	2001	2002	2003	2004	2005	2006	2007
Public sector								
US	272	314	376	463	516	574	654	659
Europe[A]	23	32	39	44	57	69	82	79
Other[B]	10	12	21	24	28	27	38	49
Multilaterals	2	2	2	2	2	2	2	2
Total public	307	359	436	532	602	672	776	789
Philanthropic sector								
Total philanthropic	20	7	112	15	12	12	78	88
Total non-commercial investment	327	366	548	547	614	684	854	877
Commercial sector								
Pharmaceutical companies	-	-	-	-	59 (range 47 to 71)	64 (range 52 to 76)	70 (range 52 to 89)	75 (range 52 to 89)
Biotechnology companies	-	-	-	-	9 (range 7 to 11)	9 (range 9 to 13)	9 (range 9 to 13)	9 (range 9 to 13)
Total commercial	-	-	-	-	68 (range 54 to 82)	75 (range 61 to 89)	79 (range 65 to 93)	84 (range 61 to 102)
Total global investment	327	366	548	547	682	759	933	961

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

TABLE 2. FIFTEEN HIGHEST HIV VACCINE FUNDERS: 2006–2007 (US$MN)[A]			
	2006	2007	% Change 2007 to 2006
NIH	593.7	596.8	+0.5
BMGF	74.6	80.9	+8
Merck & Co.	40-50 (est)	45-55 (est)	+11
Walter Reed	27.5	31.3	+14
USAID	29.0	29.0	0
EC	21.1	23.1	+9
Russian Federation	0.8	16.6	+1975
UK MRC	3.0	12.2	+316
UK DFID	20.2	12.0	-40
CIDA	13.2	9.3	-30
ANRS	3.8	9.1	+140
DCI	6.3	6.6	+0.5
CIHR	5.9	5.9	0
MRC	8.3	5.6	-32
Wellcome Trust	1.0	4.9	+390

A. A glossary of funders can be found in the Appendix.

2.1.1 PUBLIC INVESTMENTS IN HIV VACCINE R&D

Public agencies and institutions continued to dominate funding for HIV vaccine R&D. Four countries (Canada, the Russian Federation, the United Kingdom, and the United States) invested more than US$10 million each of public sector funds in 2007 and seventeen countries invested more than US$1 million each. In addition, the European Commission (EC) invested US$23 million.

FIGURE 1. ANNUAL INVESTMENTS IN HIV VACCINE R&D BY SECTOR

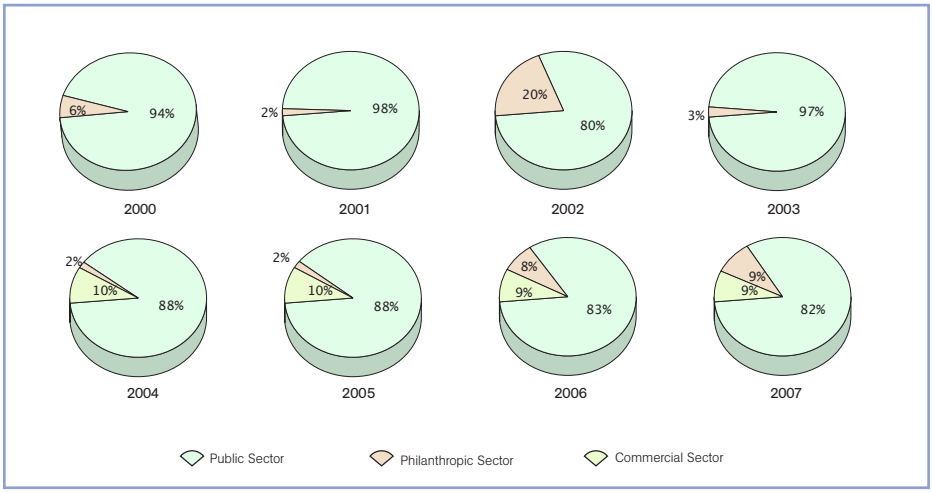
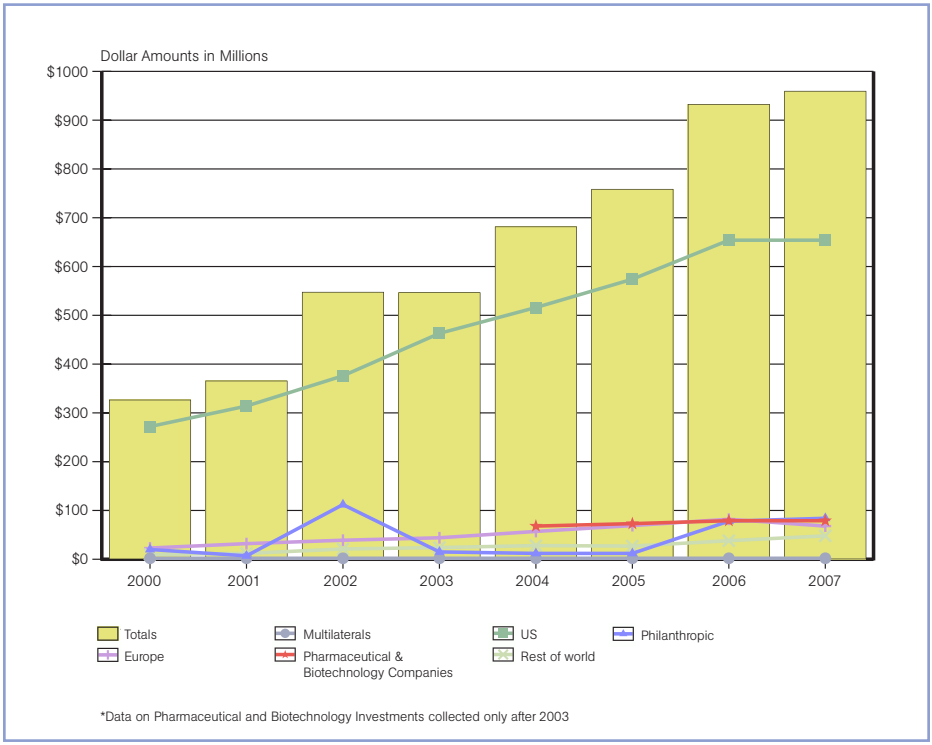


FIGURE 2. ANNUAL INVESTMENTS IN HIV VACCINE R&D



*Data on Pharmaceutical and Biotechnology Investments collected only after 2003

2.1.2 PHILANTHROPIC INVESTMENTS IN HIV VACCINE R&D

The philanthropic sector accounted for US$88 million or about 9% of the total funds disbursed for HIV vaccine R&D in 2007.

TABLE 3. PHILANTHROPIC INVESTMENT IN VACCINE R&D BY ORGANIZATION IN 2007
Organizations are listed alphabetically within each category

Over US$80 million	• Bill & Melinda Gates Foundation
US$1mn to 5 million	• Wellcome Trust
US$500k to 1million	• Elizabeth Glazer Pediatric AIDS Foundation
US$100k to 250K	• Becton Dickenson & Co. • Broadway Cares /Equity Fights AIDS • Ford Foundation • NY Community Trust • James B. Pendleton Trust • Pfizer Inc. • Rockefeller Foundation • Until There's a Cure

European & Developing Countries Clinical Trials Partnership (EDCTP)

The EDCTP was founded to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, malaria and tuberculosis. Its focus is on Phase II and III clinical trials in sub-Saharan Africa.

Founded by the European Commission in 2003, the EDCTP is jointly owned by participating EU member states and developing countries, allowing for the pooling of resources and collaborative projects. Member states are to match contributions of the European Commission. The EDCTP has budgeted approximately €6 million for microbicides and €7 million for HIV vaccines in 2007 to 2010. Thus far, funding for HIV prevention has primarily gone to networking, capacity development and strengthening in preparation for conducting high-quality and ethically sound clinical trials, not clinical trials per se. EDCTP funding for trials directed at HIV treatment, vaccines and microbicides is expected to be approved in the second half of 2008.

2.1.3 COMMERCIAL INVESTMENTS IN HIV VACCINE R&D

Total investment by the commercial sector (pharmaceutical and biotechnology companies) in HIV vaccine development in 2007 was estimated to be US$84 million (range US$60 million to US$100 million). The majority of this funding—almost 90%—comes from large pharmaceutical companies. An estimated 11% comes from the biotech industry. The amounts described here are estimated commercial investments of companies' own funding and do not include the financial support that many of these companies receive from the public sector and through public-private partnerships.

Investments in 2007 do not reflect any retrenchment in commercial sector involvement in HIV vaccines that may occur post STEP and Phambili trials. (*For details on Recent HIV Prevention Trial Results, see sidebar on page 11*). The STEP trial results came in September 2007 at a time when most companies had already made 2007 funding decisions.

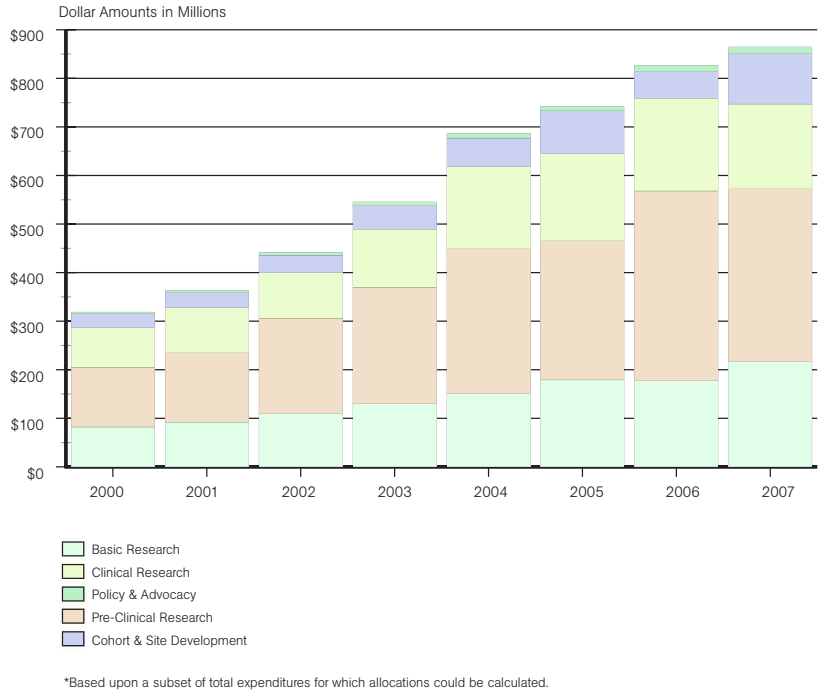
TABLE 4. COMMERCIAL ENGAGEMENT IN HIV VACCINE R&D BY COMPANY IN 2007

Over US$10 million	• Merck & Co, Inc.	
US$5 million to US$10 million	• GlaxoSmithKline • Novartis International AG • Sanofi Pasteur	
US$1 million to 5 million	• GeoVax, Inc. • Wyeth-Ayerst Lederle, Inc.	
US$100k to 1 million	• Advanced BioScience Laboratories • AlphaVax Human Vaccines Inc. • Bavarian Nordic • Crucell N.V. • Epimmune Inc. • FIT Biotech PLC • EpiVax • GenVec, Inc.	• Impfstoffwerk Desau Tornau GmbH • Juvartis BioTherapeudics • Maxygen, Inc. • Progenics Pharmaceuticals, Inc. • Targeted Genetics Corporation • Transgene • Vical Inc.

2.1.4 FUNDING ALLOCATIONS FOR HIV VACCINE R&D

In 2007, spending by the public and philanthropic sectors on HIV vaccine R&D predominately supported basic and pre-clinical research activities. Of the five categories across which funding was allocated, basic research and pre-clinical research accounted for 25% and 41% of funds, respectively. In comparison, support for clinical trials accounted for 20%, cohort and site development for 12% and policy and advocacy 2%. Since not all funder budgets or awards permit disaggregation according to these categories, these percentages were estimated from an $871 million subset that did permit such allocations.

FIGURE 3. VACCINE EXPENDITURES*



*Based upon a subset of total expenditures for which allocations could be calculated.

2.2 GLOBAL INVESTMENTS IN MICROBICIDE R&D

In 2007, total global investment in microbicide R&D was approximately US$226.5 million, a 2% increase over 2006 funding levels. Public sector funders provided 89% (US$203 million) of the funds, the philanthropic sector provided 8% (US$19 million) and the commercial sector accounted for about 2% (US$4.5 million) (range US$3 million to US$6 million).

FIGURE 4. ANNUAL INVESTMENTS IN HIV MICROBICIDE R&D BY SECTOR

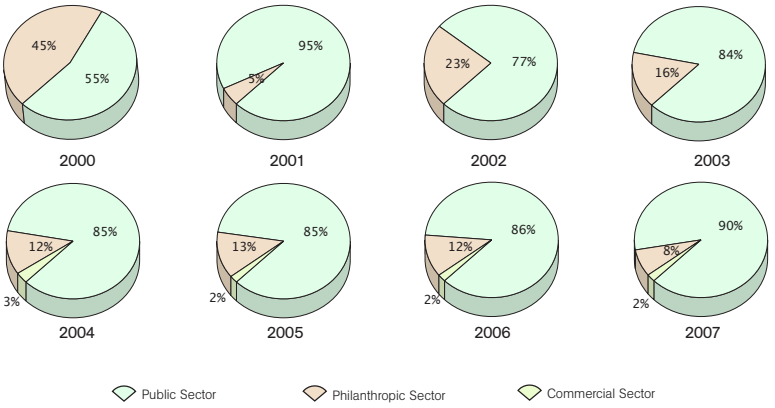
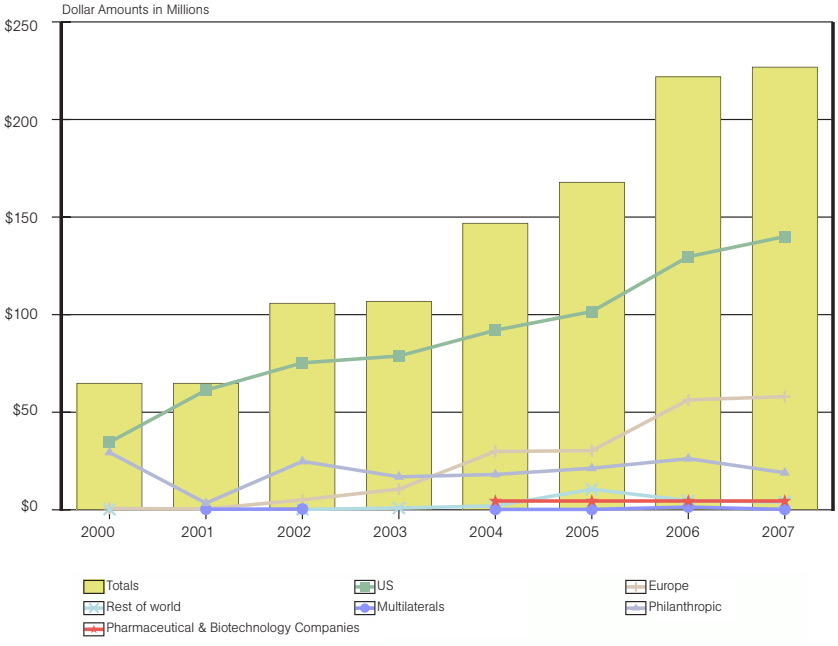


FIGURE 5. ANNUAL INVESTMENTS IN HIV MICROBICIDE R&D BY SECTOR*



*Data on Pharmaceutical and Biotechnology Investments collected only after 2003

2.2.1 PUBLIC INVESTMENTS IN MICROBICIDE R&D

In 2007, public sector investment in microbicide R&D accounted for 90% of the combined global funding for microbicide research, development and advocacy. The United States continues to maintain the largest presence in public sector funding for microbicides, providing 62% (US$139.8 million). European national governments and the European Commission together accounted for 26% (US$59.6 million).

TABLE 5. ANNUAL INVESTMENTS IN MICROBICIDE R&D 2000–2007 (US$MN)

	2000	2001	2002	2003	2004	2005	2006	2007
Public sector								
US	34.6	61.3	75.3	78.8	92	101.6	129.7	139.8
Europe[A]	0.7	0.4	5.1	10.6	29.9	30.3	56.3	59.6
Other[B]	0.3	<0.1	0.2	0.9	2.0	10.5	4.7	3.4
Multilaterals	<0.1	0.3	0.4	<0.1	0.2	0.2	1.4	0.2
Total public	35.7	62.0	81.0	90.2	124.2	142.6	191.2	203
Philanthropic sector								
Total philanthropic	29.4	3.4	24.8	16.9	18.1	21.3	26.2	19
Total non-commercial investment	65.1	65.4	105.8	107.1	142.3	163.9	217.4	221
Commercial sector								
Pharmaceutical companies								
Biotechnology companies					4.5 (range 3 to 6)	4.5 (range 3 to 6)	4.5 (range 3 to 6)	4.5 (range 3 to 6)
Total commercial					4.5 (range 3 to 6)	4.5 (range 3 to 6)	4.5 (range 3 to 6)	4.5 (range 3 to 6)
Total global investment	65.1	65.4	105.8	107.1	146.8	168.4	221.9	226.5

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

TABLE 6. TEN HIGHEST MICROBICIDE FUNDERS: 2006–2007 (US$MN)[5]			
	2006	2007	Percentage Change 2006 to 2007
NIH	88.3	98.7	+12
USAID	39.6	39.6	0
DFID	18.7	21.1	+18
BMGF	20.9	14.9	-28
EC	12.8	11.5	-10
UK MRC	2.9	7.5	+158
DCI	6.5	6.7	+3
MoFA	6.8	6.3	-7
RMFA	3.9	4.3	+10
CIDA	2.5	2.7	+8

5. A glossary of funders can be found in the Appendix.

2.2.2 PHILANTHROPIC INVESTMENTS IN MICROBICIDE R&D

In 2007, the philanthropic sector provided US$19 million, or 8%, of the total funds disbursed for microbicide development, which amount represents a decrease from 2006. This may reflect the cyclical funding practices of the philanthropic field, which can involve strategic one-time funding of specific projects, as well as forward funding of multiple-year grants (i.e., disbursing funding in one year to be expended by recipients over multiple years).

TABLE 7. PHILANTHROPIC INVESTMENT IN MICROBICIDE R&D BY ORGANIZATION IN 2007 Organizations are listed alphabetically within each category	
Over US$10 million	• Bill & Melinda Gates Foundation
US$100k to 500K	• Wellcome Trust
US$100k to 500K	• amfAR, the Foundation for AIDS Research • Ford Foundation

2.2.3 COMMERCIAL INVESTMENTS IN MICROBICIDE R&D

Total commercial sector microbicide investment in 2007, which excludes funding from government and philanthropic sources, was estimated to be US$4.5 million (in the range US$3 million to US$6 million), the same as in past years. The number of active biotechnology firms in microbicide research has remained fairly stable over the past few years. Virtually all of these companies received support for their microbicide R&D through public sector granting mechanisms, predominantly from the NIH, and/or through intermediary organizations such as CONRAD and IPM.

Rectal Microbicide Research Moves Forward

The Working Group does not track vaginal and rectal microbicide separately, as very few donors differentiate their funding in this regard. Basic and pre-clinical research can potentially benefit both possible applications, while clinical trials are mostly exploring vaginal microbicides.

The year 2007, however, brought the launch of the first rectal microbicide safety trial—a Phase I randomized, blinded, placebo-controlled safety and acceptability study of the UC-781 microbicide gel formulation applied rectally in HIV-1 sero-negative adults. Looking ahead, two more Phase I trials are poised to begin testing the rectal safety of tenofovir gel and the gel PRO 2000 in 2008. Other completed or ongoing research includes development of the product pipeline, behavioral studies examining anal sexual practices, development of rectal applicators, establishment of colorectal baseline measurements, and the safety profile for sexual lubricants.

This activity is due in part to funding from the National Institute of Allergy and Infectious Diseases and amfAR, and to the formation of the International Rectal Microbicide Advocates (IRMA). In 2004, NIAID allocated its first five-year rectal microbicide grant, totaling $17.6 million and averaging $3.5 million a year in allocations. The monies were distributed to researchers by way of the U-19 Microbicide Development Program. The program focuses primarily on translational work to advance research into clinical trials, and is headed by the University of California, Los Angeles (UCLA). Other funders of rectal microbicide research include: amfAR, the Foundation for AIDS Research, the US Centers for Disease Control, the UK's Medical Research Council, the National Institute of Child Health and Human Development, the NIH Sexually Transmitted Infections Clinical Trial Group, and the Population Council. For more information about recent trends and needs in rectal microbicide research, see IRMA's recent report *Less Silence, More Science.*

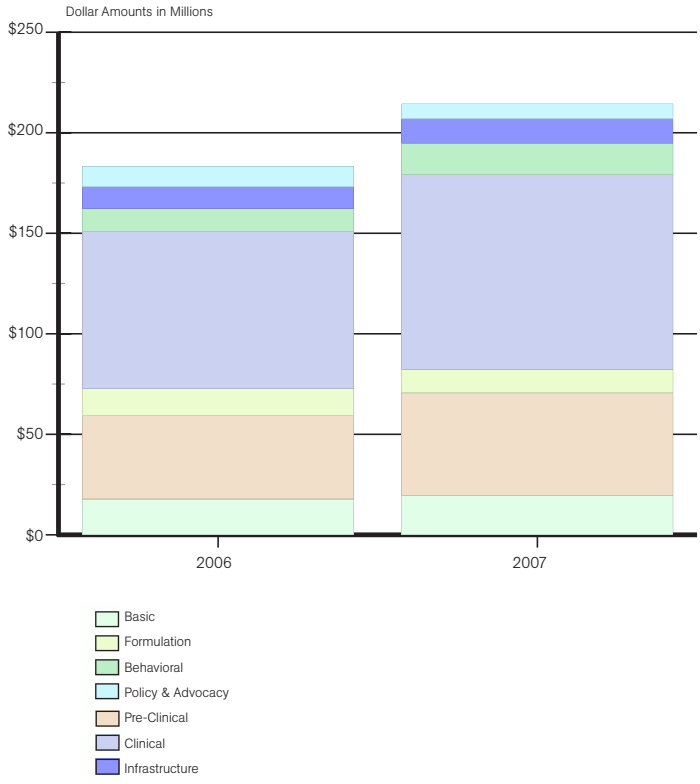
TABLE 8. COMMERCIAL ENGAGEMENT IN MICROBICIDE R&D BY COMPANY IN 2007

- Ablynx
- Advanced BioSciences Labs
- Agennix
- BioStat Solutions, Inc.
- Carbohydrate Synthesis Ltd.
- DakoCytomation
- EMD Biosciences
- Farmovs-Parexel
- Fisher BioServices Corporation
- Gilead Sciences, Inc.
- Glycores 2000
- HLSP
- HTI Plastics
- Idenix Pharmaceuticals
- ImQuest BioSciences
- Indevus Pharmaceuticals, Inc.
- Instead, Inc.
- I.T.I., Inc.
- Lekoko PMC
- LIFElab
- Lionex Diagnostics & Therapeutics
- Mapp Biopharmaceutical
- MatTek Corporation
- Medivir
- MDG Pharma
- Novaflux Technologies
- Novartis (Siena)
- Osel, Inc.
- Paradigm Pharmaceuticals
- Pepscan Systems
- Progenics
- Renaissance Scientific, LLC
- Replicor
- ReProtect, Inc.
- Restrizymes
- RNA-TEC
- SGS Biopharma
- Social & Scientific Systems, Inc.
- Starpharma Holdings Ltd.
- Tibotec BVBA
- Vision7 GmbH
- VivoMetrics
- Voxiva
- Zhejiang CONBA

2.2.4 FUNDING ALLOCATIONS FOR MICROBICIDE R&D

In 2007, expenditures on microbicide R&D were allocated across seven NIH-defined categories: Basic Mechanisms of Mucosal Transmission (9%): Discovery, Development and Pre-clinical Testing (24%); Formulations and Modes of Delivery (5%); Clinical Trials (46%); Microbicide Behavioral and Social Science Research (7%); Microbicide Research Infrastructure (6%) and Policy and Advocacy (3%). Since not all funder budgets or awards permit disaggregation according to these categories, these percentages were estimated from a $206 million subset that did permit such allocations.

FIGURE 6. MICROBICIDE EXPENDITURES 2006–2007*



*Based upon a subset of total expenditures for which allocations could be calculated.

In-Kind Contributions from Commercial Sources

The commercial sector contributes to the development of HIV prevention research in a number of ways. Some companies invest their own resources; under the Working Group's methodology these funds were accounted for in the commercial sector investments estimate (with the exception of corporate donations, which were included as philanthropic funding).

A number of companies have been particularly active in recent years in providing ARV compounds for development as potential microbicides, and for use in PrEP trials, which have been essential to creating a pipeline of new generation candidates. Gilead Sciences, Inc. has donated several million dollars worth of its compounds for use in the PrEP trials.

Between 2004 to 2007, the major contributions from industry were made to the International Partnership for Microbicides (IPM), which obtained non-exclusive royalty-free licenses to develop the following compounds as microbicides: Dapivirine (TMC120), a nonnucleoside reverse transcriptase inhibitor (NNRTI) from Tibotec in 2004; Merck L-860, 167, a CCR5 inhibitor (and two related backups) in 2005 and L'644, a gp41 fusion inhibitor in early 2008 from Merck, Inc.; BMS-599793, a gp120 binder from Bristol-Myers Squibb in 2005; Tenofovir, a nucleoside reverse transcriptase inhibitor (NRTI) from Gilead Sciences, Inc. in 2006 (a license is also held by CONRAD). In 2007, IPM signed Material Transfer Agreements with the following pharmaceutical companies: Pfizer for its new FDA approved therapeutic drug Maraviroc (leading to full royalty-free license in early 2008); and Schering Plough for three different CCR5 blockers for early-stage evaluation.

2.3 GLOBAL INVESTMENTS IN R&D FOR OTHER PREVENTION OPTIONS

A number of other experimental biomedical interventions received funding in 2007. These include: use of the drug acyclovir to reduce HIV transmission to HSV-2 infected individuals, use of diaphragms as a cervical barrier to prevent HIV infections, and the use of antiretroviral drugs as a prophylactic measure to prevent HIV infection, known as PrEP (pre-exposure prophylaxis). Additional research also continued on male circumcision, a proven method of reducing men's risk of acquiring HIV during vaginal sex.

From 2000 to 2007, six public sector funders and two foundations funded approximately US$208 million in R&D activities in support of these four HIV prevention interventions–adult male circumcision, HSV-2 suppression, cervical barriers and PrEP. Public sector funders provided 47% (US$98 million) of the 2007 funds allocated to new prevention options R&D. The philanthropic sector provided 50% (US$105 million). Commercial involvement consisted of US$5 million donation of antiretroviral drugs by Gilead Sciences Inc. for use in the PrEP trials over five years.

2.3.1 INVESTMENTS IN HIV PREVENTION R&D RELATED TO ADULT MALE CIRCUMCISION

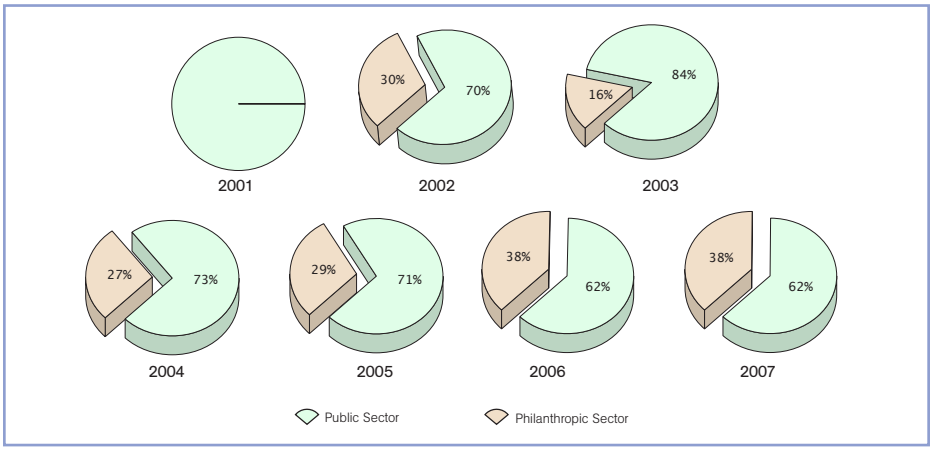
Global public sector and philanthropic investment in adult male circumcision totaled US$41 million over the last seven years. Investment in circumcision research slowed in 2007 after the completion of the NIH funded trial in Rakai, Uganda in 2006. The studies that have been completed to date provide conclusive evidence of the safety and protective effect of circumcision in HIV seronegative men. In addition, studies are needed to establish the protective effect, if any, in MSM, and in female partners of circumcised men. In addition, operations research is needed to determine how best circumcision can be implemented.

TABLE 9. ANNUAL INVESTMENTS IN ADULT MALE CIRCUMCISION 2001–2007 (US$)[4]

	2001	2002	2003	2004	2005	2006	2007	2001–2007
Public sector								
ANRS	0	446,349	541,297	0	268,963	1,000,000	1,000,000	3,256,600
CIHR	472,850	516,890	578,606	622,757	414,695	0	0	2,605,800
NIH/USAID	0	1,205,721	3,806,768	3,654,655	4,118,300	5,984,441	3,817,337	22,587,222
Total public	472,850	2,168,960	4,926,671	4,277,412	4,801,958	6,984,441	4,817,337	28,449,600
Philanthropic sector								
BMGF	0	949,307	949,307	1,596,810	1,988,814	4,246,979	2,905,668	12,636,900
Total philanthropic	0	949,307	949,307	1,596,810	1,988,814	4,246,979	2,905,668	12,636,900
Total	472,900	3,118,300	5,875,978	5,874,200	6,791,800	11,231,400	7,723,000	41,086,514

4. The quality of the data collected on R&D investment in adult male circumcision, cervical barriers, HSV-2 suppression, and PrEP is sufficiently accurate that it can be reported in the greater detail included in Tables 9-11.

FIGURE 7. ANNUAL INVESTMENTS IN ADULT MALE CIRCUMCISION 2001–2007



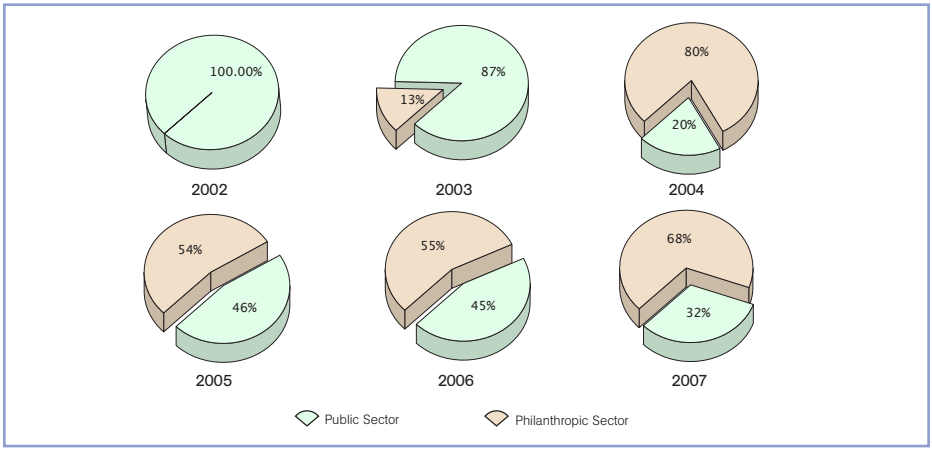
2.3.2 INVESTMENTS IN HIV PREVENTION R&D RELATED TO HERPES SUPPRESSION

Global public sector and philanthropic investment in herpes simplex virus-2 (HSV-2) suppression totaled US$46.6 million over the last six years. Investment in this research declined after the completion of two trials. An NIH study conducted in nine countries provided acyclovir treatment to HIV-negative participants with HSV-2 infection. Half of the participants were heterosexual women from African countries such as South Africa, Zambia, and Zimbabwe and the other half were MSM from the United States and Peru. Researchers announced in 2008 that they found no reduction in HIV infection as a result of HSV-2 suppression through acyclovir treatment. Another study of HSV-2 suppression conducted in Tanzania and funded by the Wellcome Trust found no protective effect in results announced in 2007. A third study of HSV-2 suppression in sero-discordant couples in Botswana, Kenya and Tanzania funded by the Bill & Melinda Gates Foundation is expected to announce results in 2009.

TABLE 10. ANNUAL INVESTMENTS IN HERPES SUPPRESSION 2002–2007 (US$)

	2002	2003	2004	2005	2006	2007	2002–2007
Public sector							
DFID	60,514	60,515	0	0	0	0	121,000
MRC UK	0	0	0	302,400	306,300	242,144	850,800
NIH	2,571,932	2,481,754	1,625,723	5,208,813	4,838,673	2,909,511	19,636,400
Total public	2,632,446	2,542,269	1,625,723	5,511,213	5,144,973	3,151,655	20,608,300
Philanthropic sector							
BMGF	0	0	6,000,000	6,000,000	6,000,000	6,000,000	24,000,000
Wellcome Trust	0	377,674	377,674	377,674	377,674	517,674	2,028,400
Total philanthropic	0	377,674	6,377,674	6,377,674	6,377,674	6,517,674	26,028,400
Total	2,632,400	2,919,900	8,003,400	11,888,900	11,522,600	9,633,300	46,636,600

FIGURE 8. ANNUAL INVESTMENTS IN HERPES SUPPRESSION 2002–2007



2.3.3 INVESTMENTS IN HIV PREVENTION R&D RELATED TO CERVICAL BARRIERS

Global public sector and philanthropic investment in cervical barriers totaled US$43.9 million over the last six years. In 2007, the MIRA trial of HIV prevention through use of a latex diaphragm in 4,500 at-risk HIV-uninfected women in South Africa and Zimbabwe was completed. The scientific basis for the trial was using the diaphragm to physically block HIV access to the cervix and so potentially reduce the risk of HIV transmission. The results of this trial did not show that use of a diaphragm prevented HIV acquisition among women.

TABLE 11. ANNUAL INVESTMENTS IN CERVICAL BARRIERS 2002–2007 (US$)

	2002	2003	2004	2005	2006	2007	2002–2007
Public sector							
USAID	0	0	0	0	525,000	528,625	1,053,625
Total public	0	0	0	0	525,000	528,625	1,053,625
Philanthropic sector							
BMGF	7,000,000	7,000,000	7,000,000	7,000,000	7,441,596	7,441,596	42,883,200
Total philanthropic	7,000,000	7,000,000	7,000,000	7,000,000	7,441,596	7,441,596	42,883,200
Total	7,000,000	7,000,000	7,000,000	7,000,000	7,966,600	7,970,221	43,936,800

2.3.4 INVESTMENTS IN HIV PREVENTION R&D RELATED TO PRE-EXPOSURE PROPHYLAXIS

Global public sector and philanthropic investment in pre-exposure prophlaxis (PrEP) totaled US$76.6 million over the last six years. The scientific rationale behind these studies is that antiretrovirals may prevent HIV infection in HIV-uninfected individuals by disabling or interfering with HIV during the initial period after an individual is exposed. There are currently five PrEP trials involving use of one of two antiretroviral drugs as PrEP against HIV infection, tenofovir-disoproxil fumarate (TDF) and TDF combined with emtricitabine (TDF/FTC):

- A safety study is testing TDF in 400 HIV-uninfected MSM in the United States, funded by CDC.
- Daily dosage of TDF to prevent HIV infection in injection drug users in Bangkok, Thailand, funded by CDC.
- A daily regime of TDF/FTC for prevention of HIV infection in heterosexually active adults in Botswana, funded by CDC.
- A safety and effectiveness trial called iPrEx of daily TDF/FTC in preventing HIV transmission in HIV-1 uninfected MSM in Ecuador, Peru and the United States, with sites in additional countries being added, funded by NIH and the Gates Foundation.
- The Partners PrEP Study, a trial comparing TDF and TDF/FTC among sero-discordant heterosexual couples in Kenya and Uganda, funded by the Gates Foundation.

Two additional trials are currently being designed and will launch soon, one called VOICE funded by NIH that will test oral TDF, oral TDF/FTC and vaginal TDF gel in several countries, and another called FEMPrEP funded by USAID and the Gates Foundation testing TDF and TDF/FTC in a number of African countries.[6]

Both TDF and TDF/FTC are made by Gilead Sciences, Inc., and Gilead has provided study drug and placebo for these trials. It is estimated that this contribution amounts to about $5 million over the past four years.

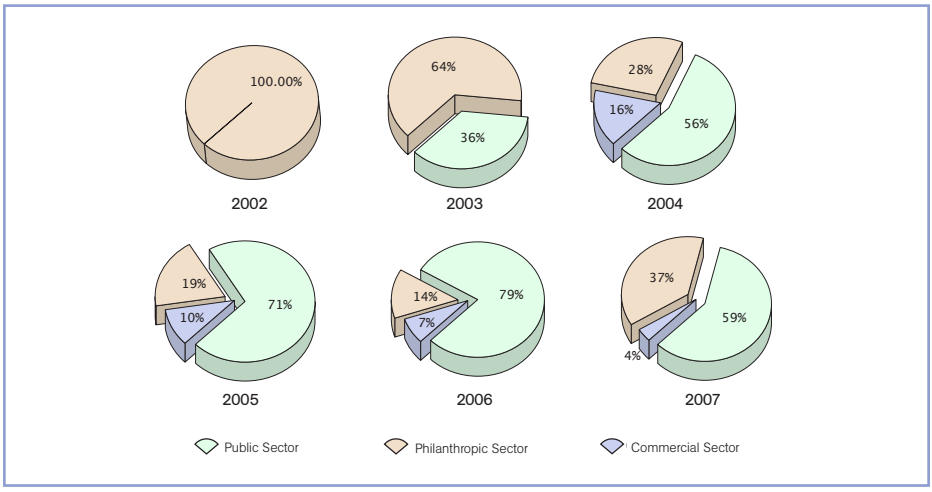
If these trials establish that PrEP is an effective HIV prevention strategy, further operations research will be needed to determine how this strategy can be implemented and its implications for therapy.

6. Some microbicide researchers have been funded to research the vaginal use of antiretroviral based microbicides which funding we allocate to microbicide investment. In this report, we have allocated the FEMPreP trial, funded by USAID, to microbicide funding not PrEP funding.

TABLE 12. ANNUAL INVESTMENTS IN PRE-EXPOSURE PROPHYLAXIS 2002–2007 US$[7]							
	2002	2003	2004	2005	2006	2007	2002–2007
Public sector							
CDC	0	798,013	3,104,000	6,339,851	9,700,275	15610000	35,552,100
NIH	0	424,308	1,372,528	2,513,398	3,772,807	4,100,900	12,183,900
Total public	0	798,013	3,555,212	8,853,249	13,473,532	19,710,900	47,736,100
Philanthropic sector							
BMGF	2,185,465	2,185,465	2,185,465	2,357,861	2,357,861	12,561,739	23,833,856
Total philanthropic	2,185,465	2,185,465	2,185,465	2,357,861	2,357,861	12,561,739	23,833,856
Commercial sector							
Gilead	0	0	1,250,000	1,250,000	1,250,000	1,250,000	5,000,000
Total commercial	0	0	1,250,000	1,250,000	1,250,000	1,250,000	5,000,000
Total	2,185,465	3,407,800	7,912,00	12,461,100	17,018,000	33,522,600	76,569,936

7. These figures do not include USAID funding for the FEMPrEP trial.

FIGURE 9. ANNUAL INVESTMENTS IN PRE-EXPOSURE PROPHYLAXIS 2002–2007



3. DISCUSSION

As part of its data collection process, the Working Group surveyed funders across technologies to ask what they thought would lead to accelerated, sustained HIV prevention research and development. The responses stressed the need for high-level political commitment, a clear achievable scientific agenda and international cooperation among researchers. To these funders, the development, licensure and widespread adoption of new HIV prevention options can only be achieved by sustained and effective R&D supported by political commitment and action.

It will be many years before vaccines and microbicides are licensed and widely utilized. Some experimental prevention options, such as PrEP, may become available more quickly, while others like adult male circumcision are now available. Ultimately, a comprehensive response to the epidemic will require the availability of a variety of options, in addition to expanding access to already proven prevention and treatment options. This will require basic research, clinical research, product development and eventually operational research to support delivery and access. The key to achieving these goals will be to: 1) sustain the momentum in R&D funding that has occurred; 2) increase transparency and accountability among researchers and funders; and 3) integrate prevention research into the larger comprehensive response to the epidemic.

One potential way to achieve these goals is to develop new investment needs estimates for the HIV prevention field to use as a way to measure progress. Calculating long-term needs could encourage more long-term and sustainable investment, enable greater accountability by tying spending to resource needs, and more generally help accelerate the development of a wide range of HIV prevention options.

TABLE 13. GLOBAL, PUBLIC AND PHILANTHROPIC R&D INCREASES OVER PRIOR YEAR

Funding Year	Microbicides	HIV Vaccines
2001	0%	12%
2002	62%	50%
2003	1%	0%
2004	33%	12%
2005	15%	11%
2006	33%	25%
2007	2%	3%

Sustaining Momentum

The increases in funding for HIV prevention R&D since 2000 have been significant. Yet as promising as the resulting investment levels were these levels are unlikely to continue to rise at the same pace.

Both the vaccine and microbicide fields saw only modest increases in 2007 compared to increases in most previous years as shown in Table 13. While those increases could reflect variations in donor funding cycles or disbursement schedules, they may also reflect larger trends. Total appropriations to the US National Institutes of Health, the largest funder of prevention R&D, have flattened. In 2007, HIV vaccine funding saw a less than 1% increase in NIH over the previous year. Philanthropic funding for vaccine research continued to be robust largely due to one specific donor—the Bill & Melinda Gates Foundation. Maintaining a sustained funding stream in the face of these challenges will be critical to ensuring that progress is made toward the goals of developing new prevention options.

Increasing Transparency and Accountability

As noted earlier, the challenges of preventing HIV infection are unique. In both the vaccine and microbicide fields, researchers are working without valid animal models, known correlates of protection, or a complete understanding of the immune system and its defenses against HIV. The pathways to either an effective vaccine or microbicide may involve testing many approaches, yet the resources to identify, develop and test a range of strategies for vaccines, microbicides and other new prevention options are limited. Ensuring that key scientific goals for the field are being explored by researchers and funded by donors will require collaboration and coordination.

Comprehensive Response

The financial resources required for vaccines, microbicides and prevention technology R&D are not only likely to be large but will need to be sustained for a long and undefined term. Still, the potential benefits of effective and accessible HIV prevention products make these investments worthwhile, since they could avert millions of new HIV infections in years to come. Clearly, no single new or existing prevention tool will end the pandemic, so that only by developing a variety of prevention tools, supported by robust funding, will it be possible to make a truly comprehensive effort. Abroad research effort will require a significant level of collaboration and coordination needed to meet scientific goals and the demands of full transparency and accountability.

Developing and Validating Estimates of Investment Need

One step toward achieving sustainable HIV prevention R&D would be to establish current, data-driven estimates of resources needed to achieve an agreed scientific plan. The HIV prevention field would greatly benefit from new projections of investment requirements to help measure gaps and goals in funding for vaccines and microbicides and other experimental HIV prevention tools. In 2004, the Global HIV Vaccine Enterprise estimated that up to US$1.2 billion was needed annually to speed the search for a safe, effective HIV vaccine.[8] In the same year, the Alliance for Microbicide Development and the International Partnership for Microbicides estimated that US$280 million per year would be required over the next five years to accelerate development of a safe and effective microbicide. These

8. Adjusting for inflation, the US$1.2 billion estimated to be needed in 2004 actually represents $1.35 billion in 2007 dollars as adjusted by the Biomedical Research and Development Price Index used by the US government to estimate changes in cost of biomedical research. (See BDRI Distribution Table of Annual Values at http://officeofbudget.od.nih.gov/UI/GeneralBudgetInfo.htm).

estimates were prepared before recent experience with large vaccine and microbicide efficacy trials, recent scientific discoveries in the area of HIV transmission and human immunology, the course correction in HIV vaccine research after the STEP results and the onset of today's flat commercial investment environment. These investment markers no longer reflect current realities, and may need to be adjusted in accord with recent events. The time has come for the HIV prevention field, as represented by funders, civil society and researchers, to convene and develop a comprehensive assessment of investment needs for vaccines, microbicides and other new prevention options.

The rise in HIV infections in the face of current prevention efforts in the Global North and South has highlighted the need for expanding existing prevention efforts as well as developing new prevention options. An effective strategy to reduce HIV infections must be truly comprehensive, affording individuals and communities a range of options to use either alone or in combination. Achieving that goal will require **political commitment and sustained funding** to deliver the options available today to all who need them and simultaneously to develop new HIV prevention options in the years to come.

Collection and dissemination of annual data on R&D investments in HIV vaccines have proven critical to monitoring levels of effort and understanding the significance of investment trends, and in the future, this information may be used to assess the impact of public policies aimed at accelerating scientific progress. Going forward, funding must be linked more effectively and efficiently to scientific priorities, funding allocations must be diversified to support the full range prevention options under investigation, and resource needs for future HIV prevention R&D must be assessed systematically. Continued evaluation of investments and expenditures can help the HIV prevention community to achieve, and track progress against these goals.

4. APPENDIX

METHODOLOGY

This report was prepared by Cindra Feuer (AVAC), Betsy Finley (AMD), Kevin Fisher (AVAC), Gian Gandhi (IAVI), Polly Harrison (AMD), José-Antonio Izazola (UNAIDS), Shilpa Vuthoori (IAVI) and Mitchell Warren (AVAC) of the HIV Vaccines and Microbicides Resource Tracking Working Group.

The Working Group developed a systematic approach to data collection and collation which it has utilized since 2004. These methods were employed to generate the estimates of funding for R&D presented in this report. A detailed explanation of the methodology can be found in the 2006 report of the Working Group entitled *Building a Comprehensive Response: Funding for HIV Vaccine, Microbicide and New Prevention Options Research and Development 2000 to 2006* (2007).

The categories used to describe different R&D activities were derived from those developed by the US National Institutes of Health and are shown in Tables 14 and 15 for HIV vaccines and microbicides, respectively.

TABLE 14. CATEGORIES USED TO CLASSIFY HIV VACCINE R&D FUNDING

Category	Definition
Basic Research	Studies to increase scientific knowledge through research on protective immune responses and host defenses against HIV.
Pre-clinical Research	R&D efforts directed at improving HIV vaccine design. This includes vaccine design, development and animal testing.
Clinical Trials	Support for Phase I, II and III trials testing the safety, immunogenicity and efficacy of suitable HIV vaccine candidates or concepts in domestic and international settings (including the costs of producing candidate product lots for clinical trials).
Cohort & Site Development	Support to develop the strategies, infrastructure and collaborations with researchers, communities, government agencies, regulatory agencies, NGOs and industry necessary to identify trial sites, build capacity, ensure adequate performance of trials and address the prevention needs of at-risk populations in trial communities.
Policy & Advocacy	Efforts directed at educating and mobilizing public and political support for HIV vaccines and at addressing potential regulatory, financial, infrastructure and/or political barriers to their rapid development and use.

TABLE 15. CATEGORIES USED TO CLASSIFY MICROBICIDE R&D FUNDING

Category	Definition
Basic Mechanisms of Mucosal Transmission	Elucidate basic mechanisms of HIV transmission at mucosal/ epithelial surfaces that are important for microbicide research and development in diverse populations.
Discovery, Development, and Pre-clinical Testing	R&D efforts directed at the discovery, development, and pre-clinical evaluation of topical microbicides alone and/or in combination.
Formulations and Modes of Delivery	Develop and assess acceptable formulations and modes of delivery for microbicides, bridging knowledge and applications from the chemical, pharmaceutical, physical, bioengineering, and social sciences.
Clinical Trials	Conduct clinical studies of candidate microbicides to assess safety, acceptability, and effectiveness in reducing sexual transmission of HIV in diverse populations in domestic and international settings.
Microbicide Behavioral and Social Science Research	Conduct basic and applied behavioral and social science research to inform and optimize microbicide development, testing, acceptability, and use domestically and internationally.
Microbicide Research Infrastructure	Establish and maintain the appropriate infrastructure (including training) needed to conduct microbicide research domestically and internationally.
Policy & Advocacy	Efforts directed at educating and mobilizing public and political support for microbicides and at addressing potential regulatory, financial, infrastructure and/or political barriers to their rapid development and use.

GLOSSARY OF FUNDERS REFERENCED IN THE REPORT

Public sector–Countries

- Australia; National Health and Medical Research Council (NHRRC)
- Canada; Canadian International Development Agency (CIDA), Canadian Institute of Health Research (CIHR)
- European Commission (EC)
- France; Agence Nationale de Recherches sur le Sida et les Hépatites Virales (ANRS)
- India; Indian Council of Medical Research (ICMR)
- Ireland; Development Cooperation Ireland (DCI)
- Netherlands; Ministry of Foreign Affairs (MoFA)
- Norway; Royal Ministry of Foreign Affairs (RMFA)
- Russia Federation
- South Africa; Department of Science and Technology (DST), Medical Research Council (RSA MRC)
- Sweden; Swedish International Development Agency (SIDA)
- United Kingdom; Medical Research Council (UK MRC), Department for International Development (DFID)
- United States; National Institute of Health (NIH), Centers for Disease Control (CDC), US Agency for International Development (USAID), Walter Reed Army Institute of Research (Walter Reed)

Public sector–Multilaterals

- Joint United Nations Programme on HIV/AIDS (UNAIDS)

Philanthropic sector–Foundations, Trusts and NGOs

- American Foundation for AIDS Research (amFAR)
- Broadway Cares/Equity Fights AIDS
- Ford Foundation
- Bill & Melinda Gates Foundation (BMGF)
- Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
- NY Community Trust
- James B. Pendleton Trust
- Rockefeller Foundation
- Until There's A Cure Foundation
- Wellcome Trust (Wellcome)

Philanthropic sector–Corporate donors

- Becton, Dickinson and Co.
- Gilead Sciences, Inc. (Gilead)

Commercial sector–Pharmaceutical companies

- GlaxoSmithKline plc
- Novartis International AG
- Merck & Co. Inc. (Merck)
- Sanofi Pasteur
- Wyeth-Ayerst Lederle Inc.

Intermediary agencies

- Alliance for Microbicide Development (AMD)
- CONRAD
- International AIDS Vaccine Initiative (IAVI)
- International Partnership for Microbicides (IPM)
- Population Council

ACKNOWLEDGMENTS

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The full text of this report is available online at the
HIV Vaccines and MIcrobicides Resource Tracking Working Group's
website: www.hivresourcetracking.org

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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

More on the Working Group's activities and reports available at:
www.hivresourcetracking.org

For more information on HIV vaccines,
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For more information on microbicides,
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For more information on UNAIDS resource tracking activities,
please contact the UNAIDS Resource Tracking Unit: **rtdata@unaids.org**

AVAC AIDS Vaccine Advocacy Coalition

iavi International AIDS Vaccine Initiative

ALLIANCE FOR MICROBICIDE DEVELOPMENT

UNAIDS JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
UNHCR UNICEF WFP UNDP UNFPA UNODC ILO UNESCO WHO WORLD BANK