

TRACKING FUNDING FOR MICROBICIDE RESEARCH & DEVELOPMENT:

ESTIMATES OF ANNUAL INVESTMENTS 2000 TO 2005

AUGUST 2005

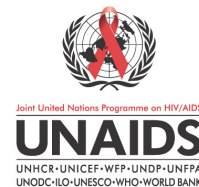
HIV Vaccines and Microbicides Resource Tracking Working Group

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



This report was prepared on behalf of the HIV Vaccines and Microbicides Resource Tracking Working Group by Polly Harrison (AMD), Gabrielle Lamourelle (IAVI), Jane Rowley (Consultant) and Mitchell Warren (AVAC).

ACKNOWLEDGEMENTS

In 2002, UNAIDS established a Global Resource Tracking Consortium for AIDS composed of international experts, and in October 2004, an HIV Vaccines and Microbicides Resource Tracking Working Group was formed. This working group was tasked with generating better information on investments in research and development for vaccines and microbicides.

The Working Group would like to thank the many individuals from the public, philanthropic and commercial sectors who provided us with information and whose participation was invaluable to the completion of this project. In particular, we would like to thank the Global Campaign for Microbicides for its assistance with collating information on investments in advocacy and policy development and the International Partnership for Microbicides for its help throughout the project.

Support for this project was provided by the Alliance for Microbicide Development (AMD), the AIDS Vaccine Advocacy Coalition (AVAC), the International AIDS Vaccine Initiative (IAVI) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

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1. 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.¹

Clearly more needs to be done to expand access to prevention and treatment – but there is also an urgent need to simultaneously develop new prevention methods. Microbicides and HIV vaccines are two technologies currently being developed that would provide people with new options for protecting themselves from HIV.

Accelerating the development and widespread use of microbicides and preventive HIV vaccines will require the active engagement of governments, international agencies, the private sector and community-based organizations. Whilst significant research progress has been made, it will still be a number of years before these two technologies are licensed and widely used. However, the time to their development, licensure and widespread use could be significantly reduced with increased and more efficient research and development (R&D) spending, accompanied by greater and sustained political commitment and action. This includes support for: conducting basic and applied research; designing and implementing clinical trials; developing and sustaining clinical trial infrastructure; strengthening the capacity of national regulatory agencies; assuring capacity for manufacturing pilot lots of product for trials; conducting process development to ensure that any licensed product can be manufactured at scale at a reasonable price; establishing large-scale manufacturing capacity; and undertaking policy and advocacy activities directed at accelerating microbicide development and use.

Over the past several years, a number of estimates have been made of global investments and expenditures on microbicide and HIV vaccine R&D,² but comparison of these estimates from year to year, from one technology to another, and across funders suffers from a lack of uniformity in how the estimates were generated.

In late 2004, the Joint United Nations Programme on HIV/AIDS (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 microbicides and HIV vaccines. Each of the organizations had been working separately to track funding levels but agreed that working together would improve the quality and comparability of the data gathered and its analysis.

The specific objectives of this collaboration were to:

1. Develop a common approach for estimating global investment and expenditures by the public, philanthropic and commercial sectors to generate comparative annual data.
2. Generate estimates of annual global investment levels for each technology from 2000 to 2004 and preliminary estimates for 2005, as well as annual global expenditures by stage of product development from 2000 to 2004.
3. Monitor progress in the implementation of the Declaration of Commitment on HIV/AIDS, adopted at the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in 2001. This declaration contains a number of global and national indicators that are being monitored on an annual basis by UNAIDS and others. The second of the global commitment and action indicators,

¹ UNAIDS/WHO (2004). *AIDS Epidemic Update 2004*. Geneva.

² Previous estimates include: a) IAVI (2004). *Global Investment and Expenditures on Preventive HIV Vaccines: Methods and Results for 2002*. New York; b) UNAIDS (2003). *Progress Report on the Global Response to the HIV/AIDS Epidemic, 2003: Follow-up to the 2001 United Nations General Assembly Special Session on HIV/AIDS*. Geneva; c) Alliance for Microbicide Development (2004). *Funding for Microbicides: An Overview Chart*. Silver Spring; and d) AVAC (2004). *AIDS Vaccine Advocacy Coalition Report 2004*. New York.

which is the specific focus of the work reported here, is the “Amount of public funds available for research and development of vaccines and microbicides.”³

This paper describes the methods developed to estimate annual public and philanthropic investments in microbicide R&D for the period 2000 to 2004 and commitments for 2005 (as of May 2005). In generating these estimates we used a broad definition of R&D and data were collated not only on product development efforts but also on support for clinical trial preparations; community education; and advocacy and policy efforts directed at accelerating microbicide development and use. We had planned to provide trend data on commercial sector investment levels and data on annual expenditures. Unfortunately, we were unable to do so given the time-scale of the project; we will, however, address this situation for the next set of estimates. A companion paper on preventive HIV vaccine funding was released in June 2005.⁴

Over the last five years, funding for microbicide R&D from the public and philanthropic sectors has more than doubled, rising from US\$ 65 mn in 2000 to US\$ 142 mn in 2004 and, based on current commitments and disbursements for 2005, at least US\$ 163 mn will be invested in 2005. In addition, in 2004 between US\$ 3 mn and 6 mn was invested by the commercial sector. This total level of investment, however, falls far short of the US\$ 280 mn per year that the International Partnership for Microbicides and the Alliance for Microbicide Development estimate will be required over the next five years to accelerate the search for a safe and effective microbicide.⁵

The figures presented in this report are a marked improvement on previous efforts to track R&D funding for microbicides and provide a useful baseline against which future investments and expenditures can be compared. Collecting comparable and reliable international funding data, however, is a challenge. The development of better systems for reporting and collecting this type of information at both the national and international levels, linked to efforts to estimate what level of funding is needed and can be absorbed, will help researchers and policy makers:

- Monitor current levels of effort;
- Identify trends in investment, spending and research focus;
- Identify areas where more resources and effort need to be focused; and
- Assess the impact of public policies aimed at increasing investment in microbicides.

³ UNAIDS (2003). *Progress Report on the Global Response to the HIV/AIDS Epidemic, 2003: Follow-up to the 2001 United Nations General Assembly Special Session on HIV/AIDS*. Geneva.

⁴ HIV Vaccines and Microbicides Resource Tracking Working Group (2005). *Tracking Funding for Preventive HIV Vaccine Research and Development: Estimates of Annual Investments and Expenditures 2000 to 2005*.

⁵ African Microbicides Advocacy Group, Alliance for Microbicide Development, Global Campaign for Microbicides, International Partnership for Microbicides (8 July 2005). *Global health leaders react to G8's first-ever call for more investment in microbicides to protect women from HIV*. Press release.

2. METHODS

2.1 ANNUAL INVESTMENT

Investment figures were based on estimates of the level of funds disbursed each year and generated from the perspective of the funder. In other words, funds were allocated to the year in which they were disbursed irrespective of whether the funds were expended by the recipient in that year or in future years.

In developing these estimates, we distinguished between primary funders and intermediary organizations. Intermediary organizations are those who receive resources from multiple funders and use these resources to fund their own work as well as others. For example, CONRAD, the International Partnership for Microbicides (IPM), the Microbicides Development Programme (MDP) and the Population Council were classified as intermediary organizations. In order to avoid double counting, intermediary organizations were classified as recipients rather than funders. All identified primary funders of microbicide R&D were allocated to one of three categories (see Table 1).

A broad definition of R&D was used and data were collated not only on product development efforts but also on support for clinical trial preparations; community education; and advocacy and policy efforts directed at accelerating microbicide development and use. We did not, however, include research that may have benefits or links (e.g., platform technologies) but that was not directed primarily at microbicides.

A four-step process was followed to estimate annual investment levels for both microbicide and preventive HIV vaccine R&D (see Box 1). All primary funders were asked to provide data on annual disbursements,⁶ as this gives a more accurate picture of annual investments than commitments or pledges made.⁷ However, not all organizations were able to provide disbursement data, and for these organizations commitment data were used instead.⁸

It should also be noted that many public sector and philanthropic agencies do not specifically track funding for microbicide R&D. In these situations, the information provided was generally from a key word search conducted by the agency of projects funded or was based on the knowledge of the informant contacted. The former can lead to the identification of a number of projects where only a portion of each grant is directly related to microbicides. In these cases, we reviewed the description of the project and estimated the percentage of the overall grant directly related to microbicides. In addition, not all organizations were able to provide annual breakdowns of their grants. For these organizations, we allocated the total funds disbursed or committed equally over the duration of the grant.

In the case of commercial organizations, we contacted the main companies engaged in microbicide R&D as of mid-2005 and asked them to provide us with information on their levels of investment, excluding direct or indirect funding from the public sector and intermediary agencies, for the period 2000 to 2004, as well as their expected investment in 2005. However, we had to scale back our expectations as many of the companies contacted did not specifically track funding for microbicide R&D, and others were reluctant to share information on funding levels citing concerns about proprietary business issues.

⁶ Organizations were asked to provide data based on the calendar year if possible and, if not, by their fiscal year. For organizations for which the fiscal year and the calendar year did not match we treated the fiscal year as equivalent to the calendar year in which it predominantly occurs. For example, the fiscal year April 1, 2004 to March 31, 2005 was treated as 2004 and the fiscal year July 1, 2004 to June 30, 2005 was treated as 2005.

⁷ The Organization for Economic Cooperation and Development (OECD) makes a clear distinction between disbursements and commitments. Disbursements reflect the amount actually spent by a donor and record the actual release or transfer to a recipient of financial resources, goods or services valued at the cost to the donor. A commitment, on the other hand, is a firm obligation expressed in writing and backed by the necessary funds to provide a particular level of support.

⁸ For example, the US National Institutes of Health (NIH) and Agency for International Development (USAID) figures are based on commitments and are charged against the year in which the commitments were made.

All figures in the report are reported in current US dollars and have not been adjusted for inflation. Funding information provided in other currencies was converted into US dollars using the appropriate International Monetary Fund (IMF) annual average exchange rate,⁹ except for those funds where we had access to the actual rate received.

Table 1. Public, Philanthropic and Commercial Sector Primary Funders	
Public sector	<ul style="list-style-type: none"> • National governments (including government research bodies, international development assistance agencies and other government funding agencies) • European Commission • Multilateral agencies
Philanthropic sector	<ul style="list-style-type: none"> • Private, not-for-profit organizations (e.g., foundations, trusts and non-governmental organizations) • Charities • Corporate donations • Individual gifts and bequests
Commercial sector	<ul style="list-style-type: none"> • Biotechnology/biopharmaceutical companies

2.2 DATA LIMITATIONS

Every effort was made to obtain a comprehensive set of data that was comparable across organizations and countries. The data presented in this report, however, are subject to a number of caveats.

Missing or incomplete information:

Requests for information were directed to all public and philanthropic organizations that were identified as providing funding for microbicide R&D. However,

- We may have missed key funding organizations or developers.
- Public sector data collection efforts focused on national and international funding; information on state or provincial funding was not included in the estimates.
- Not all organizations provided financial information. For those that did not, annual investment estimates were extrapolated based on publicly available information and expert opinions.
- Many private sector companies do not specifically track spending on microbicides and hence do not have the relevant data readily available. In addition, some companies were reluctant to share financial information due to proprietary business concerns.

Differences in definitions:

In our data analysis we tried to make the data collated consistent across funders and over time so that accurate trends and comparisons could be drawn. However,

- Not all funders reported disbursement data on a calendar year but, instead, reported funding flows based on their own fiscal year and contracting mechanisms.
- Within a particular organization, changes may have occurred in how it classifies funds over the five-year period studied.

⁹ For investments made in 2005, the 2004 IMF annual average exchange rates were used (www.imfstatistics.org).

Sources of information and double counting:

Every attempt was made to reduce the potential for double counting and to distinguish between funders and recipients of funding. However,

- All financial information was “self reported” and not independently verified.
- The majority of the biotechnology/biopharmaceutical companies active in microbicide R&D receive either direct or indirect support from the public sector (e.g., the US National Institutes of Health [NIH] and the European Community [EC]) and/or intermediary organizations (e.g., CONRAD, the International Partnership for Microbicides [IPM] and the Microbicides Development Programme [MDP]) to finance their work. The data presented here reflect, to the best of our ability, only the direct expenditures by the companies of their own financial resources.

Box 1: The process followed to estimate annual investments for both HIV vaccines and microbicides**Step 1: Identifying key funding agencies**

A list of all organizations involved in funding preventive HIV vaccine and microbicide R&D was drawn up based on funders identified in previous resource tracking efforts and supplemented by discussions with key individuals working in the HIV vaccine and microbicide fields. As new funders were identified, they were added to the list.

Step 2: Collecting publicly available information

For each of the funders identified, the publicly available information was reviewed for data on annual investment levels. Information sources consulted included: government reports, annual reports, US Securities and Exchange Commission (SEC) filings, published studies and articles, 'grey' literature, scientific presentations and website postings.

Step 3: Contacting the funding agencies identifiedPublic sector:

Letters were written to all of the public sector funders identified asking them for information on funds disbursed since 2000 and future commitments in their local currency. Information requested included:

- Description of the projects or programs funded;
- Duration of grants/ contracts/ awards;
- Total funding committed;
- Funding disbursement by year since 2000; and
- Projected disbursement or future funding commitments by year.

Agencies contacted included national research funding agencies [e.g., Agence Nationale de Recherches sur le Sida (ANRS) in France and the Canadian Institutes of Health Research (CIHR)], overseas development agencies [e.g., the Department for International Development (DFID) in the UK and the Agency for International Development (USAID) in the US] and multilateral organizations (e.g., UNAIDS, the World Bank and the World Health Organization). Each national agency was also asked to suggest other national agencies that should be contacted.

Philanthropic sector:

Letters were written to all of the identified philanthropic funders known to have awarded more than US\$ 100,000 to either technology between 2000 and 2004. The letters were similar to those sent to public sector funders and asked for the same information. For smaller funders, disbursement estimates were based on information collated from intermediaries and internet searches and, where no information was readily available, the organizations were contacted directly.

In the case of corporate donations, data were only collected on cash donations. No attempt was made to include in-kind support such as goods, services and donated staff time owing to the difficulties in valuing these contributions.

Commercial sector:

Each of the main companies identified was contacted in writing, in person, or by phone and asked to provide information on its own internal funding (i.e., they were asked not to include funds received from external sources such as research agencies or intermediary organizations).

Step 4: Reviewing, checking and analysing the information collated

The financial information received from each funder was reviewed against the project inclusion criteria and cross-checked. Any issues or questions were followed up with the funder. In the case of US agencies that track microbicide funding explicitly, we have made use of their self-reported figures rather than examining each grant individually.

For those organizations that did not respond even after repeated follow-ups, annual disbursements were estimated based on publicly available information, supplemented by discussions with experts working in the field.

The estimates for each sector were then reviewed for consistency to ensure that similar definitions were used and to eliminate double counting.

3. RESULTS

3.1 TOTAL INVESTMENT

- In 2004, public and philanthropic investment in microbicide R&D reached US\$142 million. The public sector was the main source of these funds accounting for US\$ 124 mn (87%) of the funds invested. In addition, the commercial sector invested between US\$ 3 mn and 6 mn of its own funds in microbicide R&D.

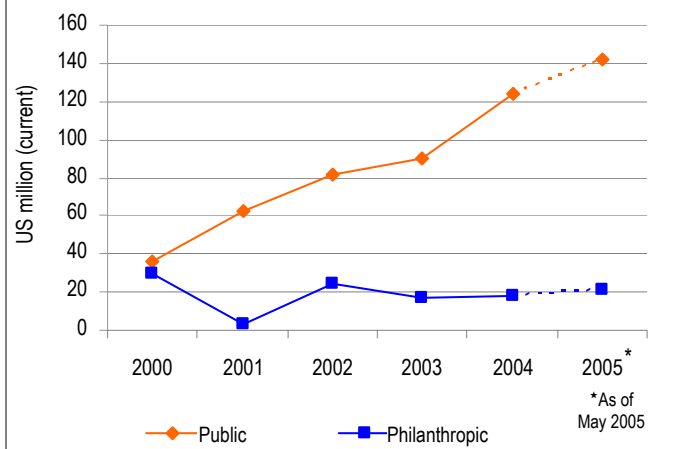
Table 2. Annual investments in microbicide R&D by the public and philanthropic sectors between 2000 and 2005 (current US\$ million). The 2005 estimates represent actual disbursements and firm commitments made as of May 2005.

	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
Non-Commercial (Public & Philanthropic)						
Total non-commercial	65.1	65.4	105.8	107.1	142.3	163.4

^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.

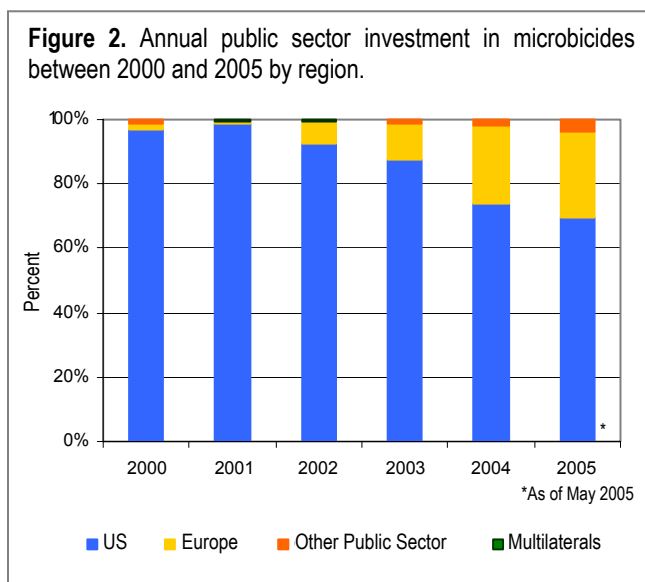
Figure 1. Annual investment in microbicide R&D between 2000 and 2005 by the public and philanthropic sectors. 2005 estimates are based on actual disbursements and firm commitments made as of May 2005.



- By May 2005, estimated disbursements and firm commitments from public and philanthropic sources for 2005 had already reached US\$ 163 mn.
- Funding for microbicides has increased significantly over the last five years. Investments from the public and philanthropic sectors more than doubled between 2000 and 2004, from US\$ 65 mn to US\$ 142 mn.

3.2 PUBLIC SECTOR INVESTMENT

- In 2004, the public sector invested US\$ 124 mn in microbicide R&D, and by May 2005 US\$ 142 mn had already been disbursed or committed for 2005.
- Public sector investment in the five years between 2000 and 2004 increased almost 3.5 times from US\$ 36 mn to US\$ 124 mn.
- The United States dominates public sector funding and in 2004 committed about 74% (92 mn) of the total funds invested by the public sector. European national governments and the European Commission together accounted for just over 24%, whilst national governments from the rest of the world and multilateral agencies (UNAIDS, UNFPA and the World Bank) together accounted for under 2%.



- Within the United States the main source of funding is the National Institutes of Health (NIH). The NIH accounted for 72% (about US\$ 66.2 mn) of US public sector funding in 2004, or 53% of total global public sector investment.
- The last five years have seen an increase in the proportion of public sector funding coming from outside the United States. In 2000, the US accounted for 97% of public sector funding; by 2004, its share had fallen to 74%.
- Seven countries were identified that invested more than US\$ 1 mn of public sector funds in 2004 and only three countries that invested more than US\$ 5 mn (the Netherlands, the United Kingdom and the United States). In addition, the European Commission¹⁰ invested approximately US\$ 6 mn in 2004. In comparison, in 2000 only one country, the United States, invested more than US\$ 1 mn.

Table 3. National public sector investment in microbicide R&D by country in 2004. Note, only countries investing more than US\$ 50,000 are included. Countries are listed alphabetically within each category.

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 -South Africa	-Denmark -France	-Canada -Ireland -Norway -Sweden	-Netherlands	-United Kingdom	-United States

- Investment figures for any individual year, however, do not necessarily reflect long-term commitments made by donors. In terms of aggregate funds invested in microbicide 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.

¹⁰ This figure includes funding provided from the Directorate General for Research, the Directorate General for Development and the European and Developing Countries Clinical Trials Partnership (EDCTP).

Table 4. Per capita public sector investment in microbicide R&D by country in 2004.^A Countries are listed alphabetically within each category.

Less than US\$ 0.01	US\$ 0.01 to 0.10	US\$ 0.10 to 0.25	US\$ 0.25 to 0.50	US\$ 0.50 to 1.00
-Australia -Belgium -China -France -Germany -India -Italy -South Africa	-Canada	-Denmark -Sweden -United Kingdom	-Netherlands -Norway -United States	-Ireland

^A Population size estimates are for the year 2003. Source: 2005 World Development Indicators. The World Bank. Washington, DC.

Table 5. Public sector investment in microbicide R&D in 2004 by country as a percentage of GDP.^B Countries are listed alphabetically within each category.

Less than 0.00001	0.00001 to 0.0001	0.0001 to 0.001	0.001 to 0.0025
-China -Germany -India	-Australia -Belgium -France -Italy	-Canada -Denmark -Norway -Sweden -South Africa -United Kingdom -United States	-Ireland -Netherlands

^B GDP estimates are for the year 2003. Source: 2005 World Development Indicators. The World Bank. Washington, DC. Note: no GDP data were available for Cuba for 2003.

- In terms of funding disbursed per capita in 2004, Ireland, the Netherlands, Norway and the United States were the four largest public sector investors.

- As a percentage of Gross Domestic Product (GDP) invested in 2004, Ireland and the Netherlands were the two largest public sector investors.

- The source of public sector funding for microbicide R&D varies widely from country to country. For example, in some countries all of the funding comes from health and research agencies, whilst in others it is all from international development agencies. The United States is unusual in having significant funding from both types of agencies; in 2004 the NIH and the Centers for Disease Control and Prevention, both primarily health and research funding agencies, accounted for 76% of US public sector funding, whilst USAID, an international development funding agency, accounted for 24%.

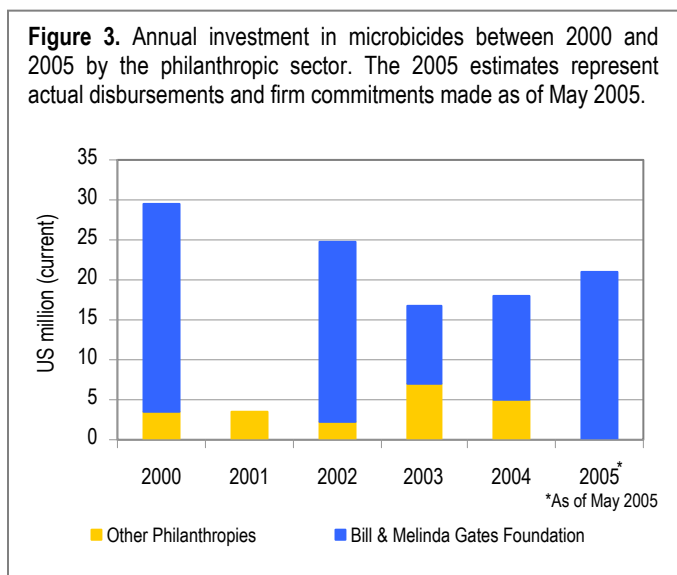
Table 6. Countries where clinical trials for microbicides are on-going or where trial sites are actively being developed.

Trials ongoing in 2004 or the first half of 2005	Trials not yet underway but where trial sites are actively being developed and trials are planned to start soon
-Belgium -Ghana -India -Malawi -Nigeria -South Africa -Tanzania -Thailand -United Kingdom -United States -Zambia -Zimbabwe	-Benin -Botswana -Burkina Faso -Cameroon -Kenya -Rwanda -Uganda

- Funding for R&D is only one component of the significant contribution that the public sector makes to microbicide R&D. The public sector, particularly in the developing world, also provides significant non-financial support. For example, in countries where trials are planned or ongoing, government salaried collaborators and government - sponsored hospitals and clinics play a crucial role in the conduct of safe and ethical clinical trials, as do national regulatory authorities and ethics committees.

3.3 PHILANTHROPIC SECTOR INVESTMENT

- In 2004, philanthropic funding totaled US\$ 21 mn or around 13% of the total funds invested by the public and philanthropic sectors.
- Levels of philanthropic funding have varied considerably over the period studied – from a low of US\$ 3 mn in 2001 to a high of US\$ 29 mn in 2000.
- The relatively high levels of investment in 2000 and 2002 reflect multi-year awards by the Bill & Melinda Gates Foundation to CONRAD and the Population Council that were disbursed in full in the years in which they were awarded. The expenditures of these funds, however, were spread over several subsequent years.



- In 2004, two philanthropic organizations (the Bill & Melinda Gates Foundation and the Rockefeller Foundation) were identified who provided funding of more than US\$ 100,000 for microbicide R&D.
- The largest philanthropic funder of microbicide R&D is the Bill & Melinda Gates Foundation. Of the total cumulative funds disbursed by philanthropic organizations between 2000 and 2004, the Bill & Melinda Gates Foundation accounted for 77% or US\$ 71 mn of the US\$ 92 mn disbursed. In addition, the Bill & Melinda Gates Foundation has already awarded grants committing it to investing an additional US\$ 54.9 mn between 2005 and 2007.

Table 7. Philanthropic investment in microbicide R&D by organization in 2004. Organizations are listed alphabetically within each category.

US\$ 100k to 250k	US\$ 250k to 500k	US\$ 500k to 1mn	Over US\$ 1 mn
-American Foundation for AIDS Research (amfAR) -Ford Foundation	(none)	(none)	-Bill & Melinda Gates Foundation -Rockefeller Foundation

3.4 COMMERCIAL SECTOR INVESTMENT

Table 8. Commercial sector organizations engaged in microbicide research and development.

Companies conducting microbicide R&D in 2004 and/or 2005

- Biofem, Inc.
- Biosyn, Inc.
- Dow Pharmaceutical Sciences
- Gilead Sciences, Inc.
- Idenix Pharmaceuticals, Inc.
- Imutex Pharmaceuticals
- ImQuest BioSciences, Inc.
- Indevus Pharmaceuticals, Inc.
- Mapp Biopharmaceutical Inc.
- Novaflex Technologies
- Osel, Inc.
- Polydex Pharmaceuticals Ltd.
- ReProtect LLC
- Starpharma Ltd.
- Tibotec Pharmaceuticals Ltd.

- Preliminary data on annual investments by the commercial sector suggest that between US\$ 3 mn and US\$ 6 mn was invested in 2004.
 - 15 companies were identified that were actively engaged in microbicide R&D in 2004 and/or 2005.
 - Commercial sector investment has played an important role in the development of a number of microbicide candidates.
 - Virtually all of the companies engaged in microbicide R&D are funded from external sources, predominantly public sector agencies (e.g., DFID, NIH) and/or intermediary organizations (e.g., CONRAD, IPM). Funding from a philanthropic organization directly to a private company has been limited to a single case to date.
- Investments from companies' own financial resources are generally small and supplementary to any external funding they receive.

4. DISCUSSION

This paper presents information on annual public and philanthropic investment in microbicide R&D for the period 2000 to 2004 and preliminary investment estimates for 2005 generated through a collaborative project involving AMD, AVAC, IAVI and UNAIDS. This project has produced a considerable body of information on funding flows for microbicide and for HIV vaccine R&D¹¹ that can be used to monitor levels of effort and trends in investment, spending and research focus. In generating these estimates we used a broad definition of R&D and data were collated not only on product development efforts but also on support for clinical trial preparations; community education; and advocacy and policy efforts directed at accelerating microbicide development and use.

Over the last five years, funding for microbicide R&D from the public and philanthropic sectors has more than doubled from US\$ 65 mn in 2000 to US\$ 142 mn in 2004, and current commitment and disbursement figures suggest that investment levels in 2005 will be over US\$ 163 mn. This increase in funding represents both greater contributions from existing public and philanthropic donors as well as a growth in the number and geographical distribution of funders as new donors have started supporting microbicide R&D. In addition, based on the data the Working Group has collected to date, we estimate that funding from the commercial sector in 2004 was between US\$ 3 mn and US\$ 6 mn. This amount includes funds from companies' own resources but does not include funds received by these companies from public, philanthropic or intermediary agencies.

The growing funding for microbicide R&D reflects a number of factors including: increased scientific confidence that it will be possible to develop a safe and effective microbicide;¹² increased recognition of the potential role of a microbicide in controlling the spread of HIV;¹³ and the entry of five products into late-stage clinical trials.

There are, nonetheless, a number of scientific challenges ahead. Ensuring that a microbicide is developed in a timely fashion requires increased global collaboration and coordination, as well as political support.¹⁴ 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 produce an effective microbicide. However, a recent analysis supported by the International Partnership for Microbicides and the Alliance for Microbicide Development suggests that annual funding for microbicide R&D needs to double yet again, reaching US\$ 280 million a year over the next five years, to ensure that key developmental tasks are carried out.¹⁵ These tasks include: accelerating basic, applied and clinical science; moving new and existing candidate products into clinical trials; preparing sites and expanding trial capacity in host countries; implementing large-scale clinical trials necessary for regulatory approvals; manufacturing both pilot and bulk lots of product; and undertaking policy and advocacy activities directed at accelerating microbicide development and use.

The data presented in this paper were generated primarily through direct contact with funding agencies and intermediary organizations. Each organization was asked to provide information on the funds it disbursed over the last five years and to provide details of the specific projects funded. This approach, whilst time-consuming, provides the detail necessary for ensuring data comparability across funders and

¹¹ The vaccine report was released in June 2005.

¹² PF Harrison, TL Lamphear (2005). "Microbicides". In *The AIDS Pandemic: Impact on Science and Society*. KH Mayer, HF Pizer, eds. Elsevier Academic Press. San Diego.

¹³ C Watts, A Foss, P Vickerman, L Kumaranayake (2004). *Microbicide Awareness, Investment and Demand – Advocacy and Networking to Accelerate Microbicide Development and Availability: Emerging Issues from Epidemiological and Economic Analysis* London School of Hygiene and Tropical Medicine, Health Policy Unit, Department of Public Health and Policy. London.

¹⁴ At their recent summit in Gleneagles (UK) the Group of Eight (G8) expressed support for "increasing direct investment and taking forward work on market incentives, as a complement to basic research, through such mechanisms as Public Private Partnerships and Advance Purchase Commitments to encourage the development of vaccines, microbicides and drugs for AIDS...". See <http://www.g8.gov.uk> for the full G8 summit communiqué.

¹⁵ African Microbicides Advocacy Group, Alliance for Microbicide Development, Global Campaign for Microbicides, International Partnership for Microbicides. (8 July 2005). "Global Health Leaders React to G8's First-Ever Call for More Investment in Microbicides to Protect Women from HIV". Press release.

over time. Nevertheless there are gaps, reflecting both missing and incomplete information, and we plan to improve the comprehensiveness of the data in future years.

The quality of commercial sector data in future estimates would benefit from a stronger collaboration with industry to find creative solutions to track funding from their own resources; funding they receive from public, philanthropic and intermediary agencies; and the flow of non-financial goods between the different agencies (e.g. transfer of intellectual property rights). 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 resource tracking efforts would also benefit from directing a concerted effort at collating detailed information on the breakdown of R&D expenditures by stage of product development. 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 significant increase in funding for 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.

APPENDIX 1: COUNTRIES AND ORGANIZATIONS REVIEWED TO GENERATE THE MICROBICIDE ESTIMATES

Public sector – Countries

- | | | |
|-----------------------|-------------------|------------------|
| ▪ Australia | ▪ Finland * | ▪ Norway |
| ▪ Belgium | ▪ France | ▪ Russia * |
| ▪ Brazil * | ▪ Germany | ▪ South Africa |
| ▪ Canada | ▪ India | ▪ Sweden |
| ▪ China | ▪ Ireland | ▪ Thailand * |
| ▪ Cuba * | ▪ Italy | ▪ United Kingdom |
| ▪ Denmark | ▪ Japan * | ▪ United States |
| ▪ European Commission | ▪ The Netherlands | |

Public sector - Multilaterals

- | | | |
|---|------------------|-----------------------------|
| ▪ Joint United Nations Programme on HIV/AIDS (UNAIDS) | ▪ The World Bank | ▪ World Health Organization |
| ▪ United Nations Population Fund (UNFPA) | | |

Philanthropic sector – Foundations, Trusts and NGOs

- | | | |
|--|--|--------------------------|
| ▪ American Foundation for AIDS Research | ▪ John & Marcia Goldman Foundation | ▪ Moriah Fund |
| ▪ Ford Foundation | ▪ Richard & Rhoda Goldman Fund | ▪ Parthenon Trust |
| ▪ Bill & Melinda Gates Foundation | ▪ Linda & John Gruber Foundation | ▪ Rockefeller Foundation |
| ▪ Elizabeth Glaser Pediatric AIDS Foundation * | ▪ William and Flora Hewlett Foundation | ▪ Stichting Aids Fonds |
| | ▪ John M. Lloyd Foundation | ▪ Turner Foundation |
| | | ▪ Wellcome Trust |

Intermediary Organizations

- | | | |
|--|--|---|
| ▪ Alliance for Microbicide Development | ▪ Global Campaign for Microbicides | ▪ Microbicides Development Programme |
| ▪ CONRAD | ▪ International Partnership for Microbicides | ▪ Population Council |
| ▪ Family Health International | | ▪ PATH (Program for Appropriate Technology in Health) |

*Countries and organizations were contacted, but no specific funding for microbicide R&D was identified for the period 2000 to 2004.

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

For more information on HIV vaccines, please contact the AIDS Vaccine Advocacy Coalition (avac@avac.org) or the International AIDS Vaccine Initiative (publicpolicy@iavi.org).

For more information on microbicides, please contact the Alliance for Microbicide Development (info@microbicide.org).

For more information on UNAIDS resource tracking activities, please contact the UNAIDS Resource Tracking Unit (rtpdata@unaids.org).

