FOIA Number: 2007-1550-F

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The World Bank
INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT
INTERNATIONAL DEVELOPMENT ASSOCIATION

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September 30, 1998

Mr. Todd Summers
Deputy Director
White House Office of National AIDS Policy
808 17th Street, NW, Suite 820
Washington, DC 20006

Dear Fellow FCAA Member,

It is now over 6 months since we all gathered at White Oak for an inspiring three day program. During that time, I promised to send to you, copies of recent works from the Africa Region in which I had been involved.

Enclosed please find three documents: *The Impact of World Bank Support to the HNP Sector in Zimbabwe*, the *Malawi AIDS Assessment Study* and *The Impact of AIDS on Capacity Building*.

The first study, *The Impact of World Bank Support to the HNP Sector in Zimbabwe* attempts to assess the relevance and impact of World Bank policy advice and project support to HNP in Zimbabwe over the past 15 years, including the influence of macroeconomic dialogue and policies on the health sector. In brief, the Study found that the Bank has "usually done the right things in the Zimbabwe health sector, but has not always done things right". This report was written by the Bank's Operations Evaluation Department.

The second study, the *Malawi AIDS Assessment Study* found the epidemic to have reached crisis proportions in Malawi and recommends several priority actions in policy (establishing a Cabinet AIDS Committee and reorganizing the NACP); strategy (refocus on high risk behaviors) and operations (establishment of an NGO grant facility). The Government has already carried out the first action on establishing the Cabinet AIDS Committee.

The third study, the *Impact of AIDS on Capacity Building* was written quickly as a background paper for the Bank's Capacity Building Group's annual meetings. I've included this document as an example of what a non-health sector can do to integrate AIDS-related issues into its development agenda.

Much talk during our weekend had centered around the development of information systems to aid in our coordination efforts. I've included the executive summary of *The National and International Financing of the National Response to HIV/AIDS* preliminary report developed by UNAIDS and Harvard School of Public Health. I regret the copy is not a good one. However, Sally Cowal advises me that the final report will be coming out shortly.

I hope you find these materials informative. All the best to each of you.

Sincerely,

Wendy Roseberry
Sr. Health Technical Specialist
Human Development Group 1
Africa Region

The National and International Financing of the National Response to HIV/AIDS

Preliminary Report

Daniel Tarantola*, Gunilla Ernberg**, Mary Pat Kieffer*,
Bernhard Schwartländer**, Mary Bachman*, Marjorie Opuni**, Arlyne Beeche*

Executive Summary

The monitoring of national and international financing of HIV/AIDS programs in the developing world is of critical importance to the development and implementation of the global response to HIV/AIDS. There are several reasons for this: (a) it provides information on overall funding trends as the pandemic and the prevention and care needs continue to grow; (b) it shows where the disparities between needs and financial commitments are the greatest; (c) it stimulates accountability by governments and donors on their respective financial support to HIV/AIDS programs in general, and reflects efforts made to reach specific populations and geographic areas; and (d) it generates data reflective of the extent to which global solidarity in responding to the global pandemic continues to be a reality.

A study carried out jointly by the François-Xavier Bagnoud Center for Health and Human Rights of the Harvard School of Public Health and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1998 examined the funding of HIV/AIDS prevention, care, support and research in selected developing countries during the years 1996 and 1997. The objectives were to estimate the amount of national resources budgeted and disbursed; to determine the amount of financial resources made available from Official Development Assistance (ODA) agencies; to track these resources from their sources (ODA agencies, national, and others) to their destinations (Government National AIDS Programs, Institutions, NGOs and others participating in the national response to HIV/AIDS); and to collect, analyze and present information obtained from donors on short-term future trends.

Data were collected from four types of sources: (a) a panel of 73 countries to which UNAIDS provided financial support in 1996-1997; (b) headquarters of 20 ODA agencies; (c) UNAIDS Cosponsors; and (d) published reports by international organizations providing lists of economic, social, epidemiological and other health indicators.

This study was able to estimate the amount of resources obligated in 1996 in a panel of 64 low/medium income countries accounting for 96 percent of overall international ODA, 69 percent of the world population, and 88 percent of the adults and children living with HIV/AIDS. Information for 1997 was not sufficiently complete to warrant analysis of financial reports for that year. The study did not succeed in ascertaining the gap between projected financial needs (resources budgeted) and resources obligated as information on budgeted figures was inconsistently provided by countries.

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Combined information from the responses of 64 countries, 15 ODA agencies, and from UNAIDS and its Cosponsors revealed the following:

- In 1996, about USD 559 million was estimated to have been obligated by countries in support of national responses to HIV/AIDS.
- For every US dollar spent by international agencies in support of national responses to HIV/AIDS in the countries surveyed, two to three US dollars were obligated from their own national resources.
- Countries reported a 31 percent increase between 1993 and 1996 in the amount of resources made available from national sources to support national responses to HIV/AIDS.
- Reported national per-capita funding for HIV/AIDS in 1996 ranged from less than USD 0.001 in China and Ethiopia to USD 1.23 in Brazil. Of the 64 countries included in this analysis, 56 reported obligations of less than USD 0.25 in that year.
- Two-thirds of the international resources obligated for HIV/AIDS in low/medium income countries in 1996 were obligated in support of national responses to HIV/AIDS in sub-Saharan Africa, one-third was obligated in Asia and a few percent in other regions.
- Countries reported that, in 1996, 74 percent of their international funding came from ODA agencies, 17 percent from UNAIDS, its Cosponsors and other UN agencies, and 9 percent from other sources.
- The major recipients of HIV/AIDS international funding were Uganda and Tanzania, who reported having received more than USD 10 million each in 1996 and who were among 11 countries who reported having obligated more than USD 5 million from international sources in that year.
- International resources obligated by countries from UNAIDS and its Cosponsors represented 17 percent of total international resources. For every US Dollar obligated from UNAIDS sources by the surveyed countries, USD 33 were obligated from other international sources and USD 63 from national sources (including World Bank loans).
- The USA was the single largest source of ODA in support of the national and global responses to HIV/AIDS in 1996, accounting for 37 percent of the USD 263.6 million made available internationally for this purpose.
- Of USD 263.6 million made available by ODA agencies in support of the global and national responses to HIV/AIDS in 1996, USD 70.9 million were allocated to governmental HIV/AIDS programs, USD 112.6 million to non-governmental programs and USD 8.8 million to other institutions or organizations.

- Previous studies suggested that the amount of resources made available internationally to support the global and national responses to HIV/AIDS increased steadily starting in 1986, reaching USD 257.3 million in 1993 (*AIDS in the World II, Oxford University Press, 1994*). The present study suggests that USD 263.6 million were obligated internationally in 1996.

- Comparing the 1993 and the 1996 figures, the increase of USD 6.3 million (2.4 percent) does not compensate for inflation during that three year interval. Although this trend may be affected by incomplete ODA data for 1996 (for example only USD 11 million of EU funding was included as the EU was unable to report for 1996), it was consistent with the trend of global ODA in recent years.

- UNAIDS reported to have obligated USD 17.8 million in support of national responses to HIV/AIDS in 1996-1997. Countries in Africa and Asia received 52 percent and 27 percent of this amount, respectively.

- There were considerable differences between amounts of resources reported by ODA agencies to have been obligated by them to countries, and amounts of ODA resources reported by countries to have been obligated from these funds. The strengthening of the capacity of countries to monitor the financing of their response to HIV/AIDS will require a more efficient and transparent exchange of information between ODA agencies and recipient countries.

PRELIMINARY IDEAS ON MECHANISMS TO ACCELERATE THE DEVELOPMENT OF AN HIV/AIDS VACCINE FOR DEVELOPING COUNTRIES[1]

April 6, 1999

I. INTRODUCTION

The World Bank is fully committed to combat the AIDS epidemic, and has been doing so since 1986 through four fronts: (a) its lending program; (b) its grants program; (c) policy dialogue; and (d) research. Through its lending program, the Bank has financed 74 AIDS projects and project components for a total of US$765 million. Most funding has been through IDA credits. Projects focus on targeted, cost-effective, and efficacious preventive activities, including: information, education and communication (IEC) for behavior change, condom promotion and distribution, sexually transmitted infection (STI) treatment, blood safety, and for the reduction of mother-to-child transmission. Although the focus has been on prevention of HIV infection, some projects also provide treatment for opportunistic infections, tuberculosis, and malaria.

Through its Development Grant Facility (DGF), the Bank has provided financing for the WHO Global Programme on AIDS (GPA, the predecessor of UNAIDS) and UNAIDS in the amount of US$18.0 million since FY1986. The DGF has also contributed to the International AIDS Vaccine Initiative (IAVI), a private, non-profit organization established in 1996 to ensure the development of safe, effective preventive HIV vaccines for use world-wide, contributing a total of US$1.74 million since its inception. The Bank provided an additional US$400,000 to IAVI through the Global Forum for Health. SIDALAC, a Latin American research initiative on HIV/AIDS, received a US$500,000 grant in 1995, and currently receives earmarked funds through UNAIDS of up to US$430,000 per year. And, through its small grants program, the Bank has financed AIDS-related activities in Africa and Asia for a total of US$56,000.

Policy dialogue is becoming an increasingly important part of the Bank's strategy to combat the spread of HIV/AIDS. In Africa, where the epidemic has had its most devastating effects, the Bank is actively mobilizing high level awareness of HIV/AIDS as a development issue. Policy dialogue is supported by research conducted on HIV/AIDS and its impact. The wide dissemination of analytical contributions, like "Confronting AIDS: Public Priorities in a Global Epidemic", an economic analysis of the AIDS epidemic in developing countries, published in 1997, strengthen the Bank's policy dialogue.

The World Bank's focus has been on prevention. However, it is evident that without a viable HIV/AIDS vaccine, current prevention efforts will be insufficient to contain the spread of HIV infection. The Bank has begun to focus on HIV vaccine development indirectly through its participation in IAVI. Evidence of market disincentives faced by the pharmaceutical industry to

[1] Prepared by Sandra Rosenhouse, LCSHD, World Bank. This paper is a technical background paper that was input into the issues paper, "Accelerating an HIV/AIDS vaccine for developing countries: Issues and options for the World Bank." The opinions expressed in this paper reflect the findings and deliberations of the World Bank AIDS Vaccine Task Force and do not necessarily reflect the views of the World Bank's Board of Directors or the governments they represent. Please address comments to: srosenhouse@worldbank.org.

invest in the development of an HIV/AIDS vaccine for strains of the virus and conditions in developing countries, led the Bank to take a further step and analyze the reasons for this market failure and identify possible courses of action that might be taken by the Bank and the development community. Initial discussions in mid-1997 centered around the feasibility of establishing an AIDS Vaccine Purchase Fund. As ideas developed, so did the need to establish a more systematic mechanism for exploring options for World Bank action. An institution-wide Task Force was established in April 1998 for this purpose. It was awarded $265,000 to collect background information on the problem and work on the options available to the Bank.

The Bank is not and will not be in the business of epidemiological and medical development in connection with AIDS. Hence, its participation as a partner in UNAIDS, relying on WHO and other relevant agencies with scientific and medical mandates and expertise to address these aspects. The Bank, however, clearly has a comparative advantage in its financial capacity as a lender to developing countries' HIV/AIDS programs, and in addressing economic issues related to market failure. The failure of the private sector to invest in the development of an HIV/AIDS vaccine is a common type of market failure encountered in other sectors. Because of the positive externalities of HIV/AIDS prevention, there is strong justification for government intervention to prevent HIV/AIDS. Further, the technology for a preventive vaccine for developing countries is a clear example of an international public good that is unlikely to be developed without the action of the international community. Approaches adopted in reducing market failure might be applicable for other international public goods facing similar constraints.

II. WHAT CAN THE WORLD BANK DO?

The World Bank Group, through its four main institutions[2], is dedicated to alleviate poverty and promote economic growth in developing countries. In order to fulfill its mandate, the Bank has a broad array of programs and instruments with which to assist developing countries. With the exception of IDA, each of these institutions provides funds at market costs and mobilizes the bulk of its funding from the private sector. IDA provides concessional funds[3] and relies primarily on donor funding. In FY1998 IDA extended approximately US$7.5 billion in credits out of which 14 percent where invested in health and education. In the same period, IBRD extended US$21.1 billion in loans and guarantees, with 4 percent going to health and education.

The Bank works closely with members of the development community. Its partnerships can be financial and/or intellectual, drawing upon other institutions' skills and experience, and, additional financial support. Financial partnerships, through trust fund activities or cofinancing arrangements, can generate joint solutions for global problems. Intellectual partnerships, through coordination of assistance programs, consultations, dissemination and training, and joint policy dialogue, can also result in effective solutions to current development problems[4]. The World Bank is prepared to deploy its capabilities as a financier as well as the synergies it can generate through its collaboration with other international partners to accelerate the development of an HIV/AIDS vaccine for developing countries.

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[2] The four institutions comprising the World Bank Group are: the International Bank for reconstruction and Development (IBRD), the International Development Association (IDA), the International Finance Corporation (IFC) and the Multilateral Investment Guarantee Agency (MIGA).

[3] Countries eligible to borrow IDA resources must have a 1997 GNP per capita below US$925. Countries must also lack creditworthiness to borrow on market terms, or a need for concessional resources to finance the country's development program. And finally, they must demonstrate good policy performance. At present 80 countries are eligible, out of which 17 also receive IBRD resources.

[4] An example of a successful partnership in the area of health is the African Program for Onchocerciasis Control.

The AIDS Vaccine Task Force, which includes staff of the World Bank Group and the president of IAVI, with inputs from technical experts from WHO/UNAIDS, NIAID/NIH, and the pharmaceutical industry, has examined a number of options where the Bank might mitigate market failure either through its financial capabilities or by bringing together other actors in areas where it does not have a comparative advantage vis-à-vis other players. The options considered have evolved over time as a result of internal discussions, consultations with experts and the results of two commissioned studies.[5]

The two major strategies for promoting an HIV vaccine can be classified as "push" activities that directly contribute to increasing R&D for an AIDS vaccine in the short run and "pull" activities that provide incentives for R&D by ensuring a future return on these investments. An example of "pull" activities are different types of "assurances" to pharmaceutical companies on the size and profitability of a future market for vaccines in developing countries, should a safe, effective, and low-cost vaccine be developed. It would also include demonstrating available effective mechanisms to ensure vaccines, once developed, would be distributed efficiently and cost-effectively to needed areas. An example of "push" activities includes the lowering of the actual costs and risks of private R&D either through direct subsidies or by lowering transaction costs. A successful World Bank strategy is likely to incorporate both "push" and "pull" interventions.

The findings of the Task Force indicate that the Bank might most effectively contribute to enhance "pull" factors specifically through three approaches:

- Demonstrating to industry that demand for existing vaccines can be increased in developing countries
- Providing better information on the potential developing country markets for an HIV vaccine
- Assuring industry a credibly large market for an HIV vaccine

The first two options could be implemented immediately, as the Bank's current instruments could be employed to finance existing vaccines (the Bank has already launched an initiative along these lines), and the collection and provision of information on developing country markets could be supported through existing lending and research activities. The third approach, however, would be a departure from existing Bank practices and involve the use of Bank instruments in different ways.

Promising areas identified on the "push" side include:

- Providing direct support for vaccine R&D through grants to non-profit organizations, and through its lending program, by financing partnerships in the development, product adaptation and testing of potential vaccine candidates
- Developing World Bank technical capacity to assist potential borrowers in participating in vaccine development and testing

[5] Batson, Amie, and Piers Whitehead. "HIV/AIDS vaccines: What motivates private investment in R&D?" Background paper for the AIDS Vaccine Task Force. World Bank, Washington, D.C., and Mercer Management. Draft: Bishai, David, Maria Lin, and C.W.B. Kiyonga (1999). "The global demand for an AIDS vaccine". Background paper for the AIDS Vaccine Task Force. Department of Economics, Johns Hopkins University, Baltimore, MD, USA. January 1999 Draft.

The Bank already provides grant support for vaccine R&D through its support to IAVI. Support for partnerships/joint ventures could be available from IFC in the case of private sector ventures, and IDA and IBRD in the case of the public sector. This could begin immediately. The development of World Bank technical capacity could be developed in line with demand for loans for HIV/AIDS vaccine development and testing.

Policy dialogue with borrowers and development partners can enhance both push and pull approaches. The Bank can play a crucial role in accelerating global HIV/AIDS vaccine development by encouraging developing country leaders to politically support HIV/AIDS vaccine research and development. It can raise awareness among key policy makers regarding the impact AIDS can have on government expenditures and labor productivity, available cost-effective preventive interventions, and issues regarding vaccine development, including the costs and risks that it may imply. It can make evident the high costs of inaction. The Bank's unique credibility and entrée to treasury and finance officials as well as development/health leaders ensures broad based support for this endeavor.

Policy dialogue can also foster the formation of international partnerships in the development, product adaptation and testing of potential vaccine candidates, reducing the costs and risks of vaccine trials to industry. Policy makers need to be aware of the risks (scientific, political, financial and medical) that HIV/AIDS vaccine development implies, and be informed as to the stages of vaccine development and the costs each implies. If political leaders appreciate the risks being taken by potential industry partners and by funding agencies, they will be more likely to enter into research partnerships. They should also comprehend that vaccine development is a protracted process, where multiple vaccine candidates will have to undergo multiple field efficacy trials in populations where the vaccine will be applied, before a viable vaccine is developed. Understanding the issues involved in vaccine development and the benefits of moving simultaneously on a number of fronts will encourage international collaboration in the development of an HIV/AIDS vaccine.

This background paper discusses in detail each of the options outlined above and the follow up actions that would be necessary if each were to be pursued. This list of mechanisms is not exhaustive, and it is anticipated that additional suggestions will arise in the process of consultation with the Bank's internal and external constituencies.

III. PULL MECHANISMS:

A. STIMULATING THE MARKET FOR EXISTING VACCINES

Long-term promises to guarantee a market for an HIV vaccine would have greater credibility to industry if the international community found a way to stimulate the market in developing countries for existing priority vaccines. World Bank lending for vaccines and immunization programs—including financing to strengthen delivery systems and to purchase vaccines—has historically been relatively small, amounting to less than $110 million since 1990. Until recently, funding by UNICEF and bilateral donors was deemed adequate to finance vaccine purchase and delivery needs of developing countries. However, with the introduction of new vaccines that are more expensive (more than $1 per dose), this will no longer be the case.

The World Bank's institutional commitment to finance existing vaccines and immunization programs is already on the rise. In March 1998, World Bank President James Wolfensohn met with heads of public agencies and the vaccine industry at a meeting on "Vaccine Development and Delivery: Leadership for the 21st Century". The World Bank has launched an

immunization demonstration project to explore how loans in 6-8 countries[6] could increase the support for immunization and new vaccines. WHO, UNICEF, and the U.S. Centers for Disease Control and Prevention (CDC) will provide technical expertise on setting the priorities for immunization, structuring the loan component, and monitoring results.

Building on the demonstration projects, the World Bank will identify a number of countries each year to target for heightened immunization support through IDA credits and IBRD loans. It has committed to work more closely with industry and with other immunization partners such as WHO and UNICEF.

B. PROVIDING BETTER INFORMATION ON DEVELOPING COUNTRY MARKETS

Private firms' decisions to invest in R&D for an HIV vaccine, as with other products, are highly dependent on their perception of some future lucrative market for sale of that product. A study of industry's perspective on the development of an AIDS vaccine for developing countries revealed that R&D investment decisions to date have been based almost exclusively on the potential market in OECD countries.[7] Potential markets in developing countries have not entered into their calculations because of the track record of the public sector in the purchase of other "new" priority vaccines and the small share of the global market for childhood vaccines represented by developing countries ($200 million out of a global market of $4 billion).

Better information about the potential public and private global demand for an HIV/AIDS vaccine and the characteristics of vaccines that are likely to be demanded in developing countries will alert firms to an important market segment they might otherwise ignore. The process of collecting this information would have the added benefit of raising awareness among developing country policymakers about the current state of vaccine research, the characteristics and price of an HIV vaccine, and issues related to improving the access to a vaccine once it is available.

Commissioning this work is within the mandate of the World Bank's AIDS Vaccine Task Force and, with sufficient resources, could be included in its work program. Related to this, the World Bank could work with the UNAIDS secretariat and representatives from industry and developing countries to develop a set of priorities and guidelines concerning the optimal characteristics of an HIV vaccine for use in developing countries. Meeting such criteria could be the "trigger" point for market guarantee mechanisms, below.

C. MARKET ASSURANCES

Increased knowledge of the potential developing country market for an appropriate HIV/AIDS vaccine and an improved track record in the distribution and utilization of existing vaccines may not be sufficient to change firms' R&D behavior if: (a) the potential market appears to be small; or (b) there is still too much uncertainty as to whether the potential market will materialize, given all of the political and economic shocks that can occur (or even development of a cure for AIDS) in the intervening decade before an HIV vaccine is introduced. Uncertainty about the future market for an HIV vaccine in developing countries can be substantially reduced through agreements that "guarantee" the purchase of a certain number of doses of an appropriate HIV/AIDS vaccine at an agreed-upon price at some future date, if such a vaccine is developed.

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[6] Included in the demonstration project are Bolivia, Uganda, Vietnam, Zimbabwe and Tanzania.

[7] Batson, and Whitehead (1988),op.cit.

There appears to be no precedent for this type of activity in the international community—creating or assuring a future market in order to foster private sector development of technology. Existing Bank Group guarantee instruments are designed to provide comfort against political and commercial risks. Specifically, such guarantees are issued on the basis of an expected income stream that would normally occur during the period covered by the guarantee to interested private companies or lenders[8]. The borrower/insured pays the standby and interest fees derived from the guarantee. In contrast, a market assurance mechanism, is not insurance against risk for a period of time, but rather a promise to deliver a market, and in this case, over an uncertain time frame. Moreover, the entity "receiving" the assurance of a market is not yet identified and is not expected to enter into a financial agreement with the Bank.

Our preliminary thinking points to two options that the Bank might pursue to assure a large enough market for an HIV/AIDS vaccine of pre-specified characteristics and price to industry: (a) the establishment of a Vaccine Purchase Fund; and (b) the further development of Contingent Loans and Credits for the purchase of vaccines and the improvement of vaccine delivery systems. In what follows, we identify the issues that need to be explored regarding these two ideas to be able to ascertain which and what aspects of each could be realistically pursued. We hope to enrich the analysis with the views expressed by the interested parties, including donors and borrowers.

Vaccine Purchase Fund:

A Vaccine Purchase Fund could be established to finance the purchase of HIV vaccines for the poorest countries or to provide matching funds to resources provided by developing countries themselves for the same purpose. The fund would be capitalized by contributions primarily from industrialized countries (Part I countries), although middle-income countries (MIC), particularly those with high prevalence of HIV, would also be invited to contribute. Part I country contributions would be used by IDA countries, and MIC contributions would be used by the contributor for its own markets. Non-contributing IBRD countries could receive matching grants for the purchase of vaccines. IDA countries could receive grants. The trust fund could be financed now, allowing the fund to accrue interest, or be financed in the future through government pledges or promissory notes. The funds would become available, and the promissory notes callable, only when a contingency clause (a vaccine of pre-determined characteristics) is satisfied. Clearly, many details would need to be worked out in this regard, including the specific criteria on price, effectiveness, and applicability for developing countries that a vaccine would have to meet. Furthermore, decisions regarding what the criteria should be and determinations of when they are being met, all of which would be politically sensitive, would need to be arrived at in a transparent manner, for example, by a panel of international experts from both Part I and Part II countries.

Such a fund could be managed by the World Bank in the same way it manages other multilateral trust funds, as an independent facility. The structure and function of the fund would be determined at its inception, as would the eligibility criteria for beneficiaries, donors and suppliers, and the rules to access the funds. Decision-making influence could be tied to amount of

[8] Typically, IBRD/IDA provide longer-term guarantees for private investments in infrastructure against political risks including government default or, alternatively, they provide short-term guarantees to banks, foreign trading companies and input supply companies that have provided credit or goods for the production of export goods and services against commercial and against political risk. MIGA provides long-term guarantees against political risks on equity and loans to private sector projects/companies. IFC periodically provides guarantees against commercial risk to private sector projects.

contribution. The timing of the contributions could be structured in a number of ways. One possibility would be for donors to provide promissory notes that would be drawn down only when a vaccine was deemed viable and could be purchased with the fund. Alternatively, relatively small cash contributions could be provided at inception—given that the funds would not be needed for some time. The Vaccine Purchase Fund would also outline the procedures for refunding contributions—cash or promissory notes—if the trigger event does not occur. Mechanisms for contributions and payments could be modeled on the Bank's existing modalities for multilateral funds such a as the Global Environmental Facility (GEF) or the Highly Indebted Poor Countries Initiative (HIPC) Trust Fund.

The Vaccine Purchase Fund would also specify how the resources would be managed. Funds could be employed to purchase an initial supply of vaccines for a country, enough to satisfy initial "catch up" demand, leaving maintenance demand to be met with other resources. What the initial supply would consist of would have to be determined. Resources could be used to purchase vaccines directly from providers or could be converted into vouchers to obtain a given value of "time-based protection units", such as "x number of people protected from contracting HIV in a given year." It would also specify the actions to be taken in case of delays in encashment schedule, and defaults. The Vaccine Purchase Fund would outline the procedures to be followed in the event that more than one eligible vaccine is developed and would define procedures for oversight for use of resources.

The World Bank has considerable experience in setting up and administering trust funds created for specific purposes and in dealing with donor pledges (they constitute the bulk of IDA's resources), giving it a comparative advantage in setting up and managing a fund of this nature. The advantage of employing a fund structure rather than loans or credits is that a trust fund could disburse more rapidly, and that it is a more concrete way of demonstrating to industry a prior commitment to purchase vaccines.

The main issues to be addressed are: (a) whether donors would be willing to commit resources to address this global issue; (b) whether they would be willing to do so with a 10-15 year lead time; and (c) whether this commitment is large enough and credible enough for industry to believe that these promises to assure a market will materialize. Trust funds designed to address issues of global and regional concern have been employed in the past. However, development assistance has been under pressure for some time now. Given the competing uses for scarce resources, and the uncertainty of the timing of the trigger criteria being met, donors may be reluctant to pledge a large amount of resources to this effort.

Even if the cause were deemed to be worthy, the Vaccine Purchase Fund would have to adapt to this long-term time frame. Donor promissory notes for GEF and IDA are drawn down over seven to nine years and draw downs begin within a year from when a pledge is made. Thus, it may well be that donors would require a review of the situation from time to time—perhaps after seven to nine years.

Finally, it needs to be determined whether the amount amassed to assure a market is sufficient and credible enough to move the industry to invest more in R&D. Moreover, given that the pharmaceutical industry is one of the most powerful and resource rich industries in the world, questions could be raised about whether or not a Vaccine Purchase Fund is a judicious and politically viable use of taxpayer resources. Should this initiative be deemed to be a worthy cause, questions regarding how an industry "pay back" would be structured once it breaks even would have to be addressed.

Contingent Loans and Credits:

A second option available to the World Bank to assure industry the existence of a "sizeable" market for an HIV/AIDS vaccine is to issue IBRD loans and/or IDA credits to developing countries to finance the strengthening of the borrower's vaccine delivery capacity in the present, and the purchase of HIV/AIDS vaccines when a suitable vaccine is developed. The loans or credits would be designed for use right now, for upgrading delivery systems and existing vaccines. Part of the loan might be contingent on the development of a viable HIV/AIDS vaccine—that is, one that meets the same criteria as might be established for the trust fund, discussed above. Loans or credits could be made fully contingent although they would be less credible to industry.

The World Bank has some experience in contingent lending, primarily in the trade and financial sectors. Contingent, or partially contingent loans have been made to back-up government facilities in South Africa, Moldova and Ukraine that provide guarantees against commercial and political risk to the private sector. In the case of South Africa, only part of the loan is contingent. These loans only disburse if claims are made.[9] They pay the usual commitment fee charged to all undisbursed loan proceeds (currently 75 with a 50 basis points waiver for IBRD). In the case of IDA, there are few incentives to request contingent credits as no interest is charged on the funds disbursed, and commitment fees are currently zero. Thus, IDA borrowers needing to provide guarantees to local lenders, producers and exporters, rely on a traditional IDA credit which disburses into an escrow account used initially to back up a guarantee facility, and employed for pre-identified uses when the project closes. IDA has now established a pilot program of direct guarantees (since 1998)[10].

Contingent loans have also been used in financial sectors to reduce the impact of liquidity shocks on the borrower's (Argentina) banking system in the event of severe capital flight. The loan is designed to disburse only if and when the repurchase facility established as part of a Special Structural Adjustment Loan is activated, and thus implies zero or full disbursement. Here again, commitment fees are charged for the undisbursed amount. Contingent loans, however, have not been issued for longer periods than five years, and have never been employed in the health sector.

The main constraint to the use of contingent loans or guarantees is that it is highly unlikely that Governments would be willing to pay commitment/standby fees for an uncertain length of time and for an uncertain outcome. Moreover, even if borrowers were willing to undertake these loans, there would be no assurance to pharmaceutical companies that when a viable vaccine were developed that borrowers would draw down these loans to procure the new vaccines. Given the uncertain time frame, the borrower's economic/political situation could be such at the time a viable vaccine is available, that it would find it untenable to draw down such loans or credits, sending the wrong signal to industry.

Long-term lending commitments (in the case of the contingent portion of the loan) would also reduce the ability of IBRD and IDA to lend for more pressing and currently addressable problems. And, in the case of IDA, expected repayments may not materialize in the amount and

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[9] The World Bank has made these types of loans when conditions do not permit the involvement of the Multilateral Investment Guarantee Agency (MIGA), which cannot cover short-term non-equity transactions, or IFC, which cannot lend to governments.

[10] One guarantee has been processed to date (a Power Project in Cote d'Ivoire), and another is being prepared (in Bangladesh).

timing expected, as some debt might be forgiven, and some debt might be restructured, adding a further disincentive to making such long-term commitments.

While there are disincentives for both Borrowers and the Bank to commit to future lending, the Bank has recently developed a new lending instrument that can accommodate the uncertainty the future holds. The Adaptable Program Loan is an instrument that is designed to fund a program of activities defined to achieve an agreed development purpose over a long-term horizon. The project is designed as a sequence of loans for phased support of the program, with agreed objectives, triggers, and indicators of outcomes/impacts for each phase of the program. The overall cost and implementation period of the program is approved during Board consideration of the first phase loan. Subsequent loans under the program are approved by the Regional Vice President (within the initial funding limit and time frame outlined for the program). In general, each phase of the program is expected to average US$50 million, and last for 3-5 years. Thus, a first phase of a program could consist of an analysis of vaccination capability and the upgrading of infrastructure and human resources. A second phase could focus on increasing coverage of currently existing vaccines. And, a third phase could include the introduction of an HIV/AIDS vaccine.

Thus, there are some alternatives already available to the Bank. It could signal its readiness to provide resources for these purposes through an active and aggressive program to support the deployment of existing vaccines. Loans and credits could be prepared and provided to improve vaccine delivery readiness, as well as to purchase vaccines, whether these are structured as traditional investment loans or as adaptable program loans. Vaccine readiness is needed for any vaccine and thus the investment would have a more generalized use. Finally, options could be explored to utilize the Bank's guarantee authority to help private lenders finance vaccine delivery, with the Bank's guarantee used to validate the borrowing government's resolve to make vaccines available as necessary.

IV. PUSH MECHANISMS:

A. PROVIDING DIRECT SUPPORT FOR VACCINE R&D

Grant Financing for Initiatives Designed to Accelerate HIV Vaccine Development

The World Bank is currently supporting HIV vaccine research indirectly through participation in IAVI, an international non-profit, non-governmental organization whose mission is to ensure the development of safe, effective, accessible preventive HIV vaccines for use throughout the world. Its objective is to stimulate investment and demand for HIV vaccines that will benefit the whole world, including developing countries. It pursues this objective through advocacy, targeted support to R&D for novel vaccine approaches, and measures that reduce obstacles to private investment. Other innovative initiatives to accelerate HIV vaccine development could be supported.

Lending for International Partnerships

Most HIV/AIDS vaccines in developing countries will probably be developed using vaccines that were at least initially designed and manufactured in developed nations. To ensure rapid product adaptation of available candidates, teams of scientists, manufacturers, epidemiologists, and clinical trial specialists from both developed and developing countries, could be brought together in "Vaccine Development Partnerships." North-to-south partnerships could be fostered early on in the process of development to build trust and commitment by both

parties, and promote knowledge transfer and capacity building. Partnerships could include reciprocal exchanges of personnel between North and South partners, giving counterparts an opportunity to work closely with others who are actively engaged in research on the specific vaccine project so as to create true partnerships. Bank loans could be sought to finance these partnerships.

The Bank could also be influential in encouraging specific types of partnerships, and in bringing together potential partners. Given that most scientists agree that the prospects for a successful demonstration of vaccine efficacy are increased if the vaccine is matched to the prevalent strain of the HIV virus circulating in the population, the Bank could encourage initiatives to field-test vaccines in the regions where they will be applied. Vaccines also need to be designed so as to be practical to use in developing country settings. Evidence suggests that efficacy study population sizes can be smaller and trials can be conducted in a shorter time in populations where incidence is highest. The Bank could foster dialogue between potential partners to encourage more cost-effective trials. Where effective joint ventures between the private sector in developing countries and an interested developed country firm might be established, IFC financing could be sought. Where the public sector takes the lead, IBRD and IDA loans and credits could be sought.

B. DEVELOPING WORLD BANK TECHNICAL CAPACITY

Effective policy dialogue and the partnerships that may develop could generate demand for investments designed to put these partnerships into action, including infrastructure for product testing and evaluation, and/or for product research and development. Although technical agencies can provide assistance in project preparation and execution, the Bank should have some in-house technical capability to manage and supervise these projects within the Bank. An analysis of the staff profiles this readiness would entail can be conducted with the help of experts in the field early in the process.

V. CONCLUSIONS

There are clearly many options for the World Bank, through its dialogue with policy makers, research and lending program, to encourage investment in R&D to develop an HIV/AIDS vaccine for developing country contexts. Several options are considered in this document. They vary in terms of potential impact, feasibility and political acceptability. They are work-in-progress and represent the most plausible of the options discussed in the Task Force. While the Bank may have a comparative advantage among the actors in the international community to pursue some of these approaches, an effective program should involve a concerted effort among the entire international community, including multilateral and bilateral donors, developing country policymakers, and industry. Moreover, it is likely that multiple approaches must be pursued to maximize impact. However, we would like to obtain donor's feedback as to which options would be the most viable, and any other options that would be worthwhile to pursue.

THE WORLD BANK GROUP

PRESS RELEASE

News Release No. 98/1513

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CONFRONTING THE SPREAD OF AIDS

World Bank urges greater efforts to prevent new infections in developing countries

GENEVA/WASHINGTON, November 3, 1997 — With approximately 90 percent of all HIV infections occurring in developing countries, more intensive government prevention efforts, especially among people who have many sex partners or inject drugs, could save millions of lives and reduce the severe economic and social costs of the epidemic, according to a World Bank report released today in Geneva and Washington.

The report-**Confronting AIDS: Public Priorities in a Global Epidemic**-says that 23 million people worldwide are now infected with HIV and that 8,500 people are newly infected each day. Two decades after the first appearance of the human immunodeficiency virus, 6 million people have died from AIDS, and new evidence suggests that while Sub-Saharan Africa has most people infected-14 million-the virus may be on the verge of exploding in other regions such as Central and Eastern Europe.

"*HIV is continuing to spread and is taking a terrible toll*," said **Mead Over, co-author of the report**. "*In many hard-hit countries, HIV has already reduced life expectancy by more than a decade.*"

The report identifies priorities for developing countries and the international community in responding to the epidemic, the first measure being to help people with the riskiest behavior protect themselves and others from HIV infection. Yet in many countries, government-backed prevention programs do not reach people with the riskiest behavior. Activities that greatly increase the risk of contracting HIV include unprotected sex with many partners and injecting drugs using unsterilized shared needles.

"It is a fundamental responsibility of government to ensure that HIV is prevented among people with the riskiest behavior," Mr. Over said. *"This will prevent the largest number of infections among all people--even among people who do not take risks."*

For example, in Nairobi, Kenya, treating sexually transmitted diseases among 500 prostitutes and increasing their condom use to 80 percent, prevented 10,000 infections per year among their clients, the clients' wives and other partners. A similar level of condom use among 500 men in the community would have prevented fewer than 100 infections.

"*HIV moves through populations in a series of overlapping epidemics*," **Martha Ainsworth, co-author of the report**, said in Washington. "*Once the virus has spread widely among people with very risky behavior, preventing its spread to others becomes increasingly difficult.*"

Programs that make it easier for injecting drug users to get sterile injecting equipment have also been highly effective. Several cities around the world which have needle exchange programs, such as Glasgow, Scotland and Sydney, Australia, have held HIV infection rates among injecting drug users to less than 5 percent; while in nearby cities without these programs, infection rates among injecting drug users have soared to more than 50 percent. Needle exchange programs have also been highly successful

in Toronto, Canada; Tacoma (Washington) U.S.A.; Lund, Sweden; and Katmandu, Nepal.

Other people besides sex workers, their clients, and injecting drug users also engage in high risk behavior. Studies have shown that soldiers, police officers, prisoners, long distance truck drivers, migrant workers, and homosexual and bisexual men, often have more sexual partners than others.

Governments need to find out which groups have the riskiest behavior and work with them to prevent the spread of HIV. However, governments are often unwilling to back prevention efforts with such groups because critics argue that these controversial programs will encourage people to have multiple sex partners or to inject drugs. Research has shown this not to be the case.

Non-governmental organizations (NGOs) can sometimes avoid this controversy and are often more effective than governments at working with people with very risky behavior. In Calcutta's Sonagachi red-light district, for example, the Indian government, donor countries, three local NGOs, and sex workers are working together in a prevention program that has held HIV among the sex workers in the area at low levels.

Governments need to act as early as possible. *"In every country that now has a serious epidemic, people said 'it can't happen here.' They were wrong,"* Ms. Ainsworth said. *"By the time that many AIDS cases are observed, it is too late to avert a serious epidemic; HIV will already have spread widely."* In Honduras, for example, where fewer than 8,000 AIDS cases have been reported, an estimated 50,000 adults are already infected with HIV.

Yet many countries still have an opportunity to prevent a widespread HIV epidemic. In 30 developing countries, and in large areas of China and India, HIV has infected less than 5 percent of people who engage in very high risk behavior. Bangladesh, Indonesia, the Philippines, most countries from the former Soviet Union, and much of Eastern Europe are at this early stage of the epidemic.

For the 2.3 billion people who live in these countries and parts of China and India with "nascent" epidemics, investing in effective prevention now can keep infection rates very low and at relatively low cost.

In other countries, HIV is already widespread among groups with the riskiest behavior but has yet to spread widely among other people. More than 40 developing countries have "concentrated" epidemics, including Pakistan, Ukraine, most of Latin America, parts of Western Africa, and most of Indochina. Parts of India and the southwestern regions of China bordering the "Golden Triangle" of the drug trade also have concentrated epidemics.

Preventing a widespread epidemic in these countries, home to 1.6 billion people, is still possible, but it becomes more difficult and costly than dealing with it at an earlier stage. In Thailand, which has a concentrated epidemic, an extensive campaign promoting universal condom use in brothels is slowing the epidemic. Infection rates among young army conscripts have declined.

Twenty-one countries have "generalized" epidemics in which 5 percent or more of women attending maternity clinics are infected. Most are low-income African countries where the resources needed to cope with the epidemic are most scarce. In these countries, home to 226 million people, it is still crucial to help people with the riskiest behavior protect themselves and others. In addition, prevention among people with fewer partners becomes increasingly important as the epidemic spreads.

Governments in countries with a generalized epidemic also face the problems of deciding how to cope with the increased demand for medical care, and how to respond to the effects of AIDS on poor households. The report recommends that governments in all countries, especially those in the worst-affected regions, ensure that low cost, effective treatments for illnesses that often strike people with HIV are available. For example, treating oral thrush, which makes swallowing extremely painful and affects many people in the early stages of AIDS, costs only about $2.00 per episode.

"Even some quite poor households would readily pay this cost provided that the medicine were

available," said Mr. Over. *"Sadly, these medicines are often not available."*

Tuberculosis, which also often strikes people with HIV, can be treated for as little as $36 per person. Since tuberculosis is highly infectious, governments have an obligation to fund such treatment in any patients who would otherwise go untreated, regardless of their HIV status, the report says. It also cautions that recent medical advances in the treatment of HIV/AIDS involving combinations of expensive drugs are too complex and costly for widespread use in developing countries.

"Antiretroviral therapy costs about $12,000 dollars a year and requires sophisticated clinical support that is rarely available to people in developing countries," Mr. Over said. *"To be fair, governments should subsidize expensive HIV treatments at the same rate that they subsidize other treatments that are equally expensive, complex and experimental."*

Even if the cost of new HIV/AIDS treatments declined substantially, governments would still need to consider carefully whether scarce government resources should be used for treatment or prevention.

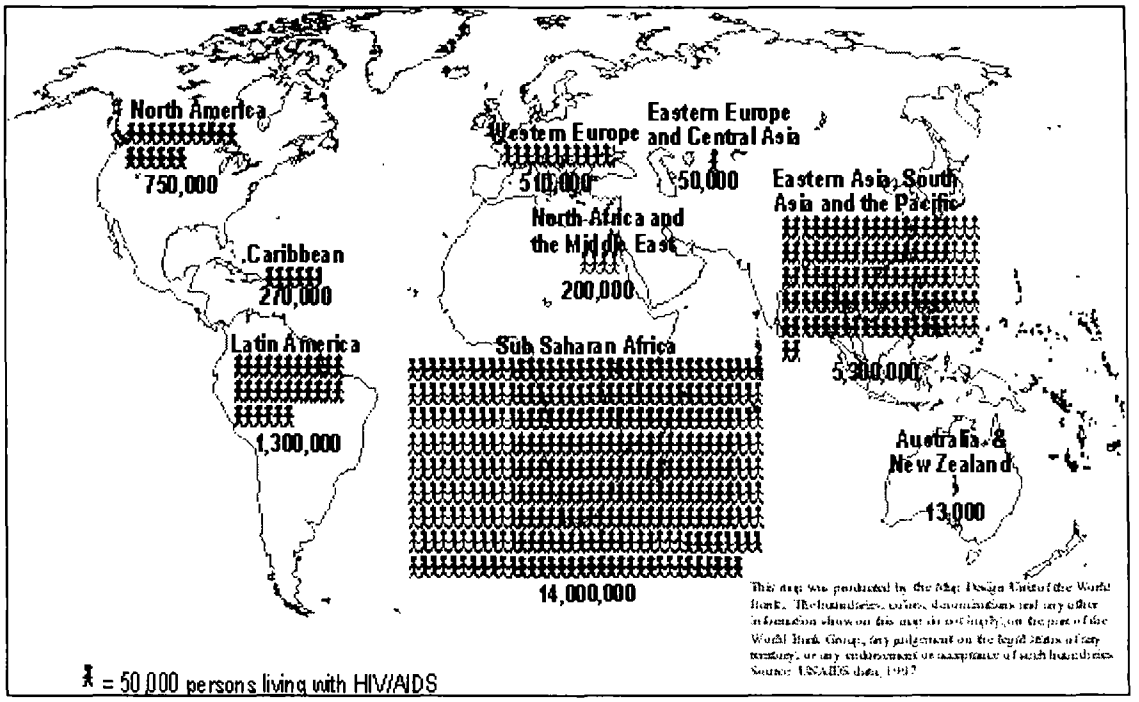
In hard-hit countries, AIDS has greatly increased the number of deaths of adults during their prime working years. Such deaths create particular hardships for the poorest families, who often reduce food consumption and withdraw their children from school to cope with the loss of income. The report suggests that governments can mitigate these impacts of the epidemic by ensuring that anti-poverty programs include poor families affected by HIV/AIDS.

"AIDS presents policymakers with extremely difficult choices in allocating public resources," **Joseph Stiglitz, Chief Economist and Senior Vice President of the World Bank** said in Washington. *"The study helps to identify policies that are fair and cost-effective,"* he added. The report differs from many other studies of HIV/AIDS by analyzing the epidemic from the perspective of public economics, which focuses on how to allocate government resources.

Speaking at a press briefing in Geneva, **Peter Piot, the Executive Director of UNAIDS**, said that the World Bank's research in the report is an example of the benefits of international AIDS cooperation. He urged all governments to put AIDS higher on their agendas. *"Governments must act now to confront this epidemic and must challenge all sectors of society to become involved,"* he added. Preparation of the report received extensive support from UNAIDS and the European Commission.

A joint forward to the book signed by Mr. Piot, World Bank President James Wolfensohn, and João de Deus Pinheiro, a member of the European Commission praised the report as *"a valuable contribution to the international debate on the role of government in addressing the AIDS epidemic in developing countries."*

The World Bank is one of the largest sources of finance of AIDS prevention measures in developing countries. At the end of 1996, the Bank had committed $632 million to 61 HIV/AIDS projects in 41 countries.



For on-line information about the economics of HIV/AIDS, visit
http://www.worldbank.org/aids-econ/

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The World Bank
Washington, DC 20433
U.S.A.

JAN PIERCY
U.S. Executive Director

March 30, 2000

The Honorable Richard A. Gephardt
United States House of Representatives
1226 Longworth
Washington, D.C. 20515

Dear Congressman Gephardt:

I want to thank you for addressing the International Center for Research on Women policy roundtable on HIV/AIDS 3/14. Your leadership in attracting U.S. attention to this devastating crisis is achieving important results.

Ministers attending WB/IMF Spring Meetings will discuss economic consequences and strategies to address HIV/AIDS in the Development Committee session, which Secretary Summers will attend as U.S. Governor for the World Bank. I'll take the liberty of sending you the background paper for this meeting when it is final. We just renewed it at the Board and it will be revised for the Ministers.

If my office can at any time assist you or your staff in your efforts on HIV/AIDS, please let me know.

With best regards,

Jan Piercy

cc: Sandra Thurman, Director of White House Office of National AIDS Policy

The World Bank
Washington, D.C. 20433
U.S.A.

JAMES D. WOLFENSOHN
President

May 27, 1999

His Excellency
Jacques Chirac
President of the Republic of France
Palais de l'Elysée
55, 57 rue du Faubourg-Saint Honore
75008 Paris
FRANCE

Dear Mr. President:

The AIDS epidemic is reversing decades of progress in improving the quality of life in developing countries. More than 33 million men, women, and children are infected with HIV worldwide, and more than 90 percent of those infected live in developing countries—two-thirds in Sub-Saharan Africa. In the hardest-hit African countries, life expectancy is now 10-20 years shorter than it would have been without AIDS. Meanwhile 16,000 more people worldwide become infected each day.

AIDS has therefore become a core development issue, and confronting the AIDS epidemic in developing countries has become critical to all our efforts for poverty reduction, growth, and improved quality of life. I welcome the strong concern G8 leaders have shown at past meetings, but I believe we now have to move together to a new level of action, on three fronts:

First, we must reinforce political commitment and active leadership in preventing HIV/AIDS. There is no cure for AIDS and no vaccine, but there *are* educational and behavioral interventions that work *now* to curb its spread. Half of the population of developing countries—3.5 billion people—live in countries or areas where there is still time to prevent an epidemic. Top-level, visible political leadership can make a critical difference in bringing AIDS to the top of the social and political agenda.

Second, we must urgently find low-cost, effective therapies that are within the reach of developing countries—for example to prevent mother-child transmission and to fight AIDS-related infections like TB—and strengthen health systems to deal with the increased demand for health care. This is particularly acute in Sub-Saharan Africa, where the largest number of AIDS patients live, health systems are weak, and the ability to pay is very low.

Third, we need to recognize that there is an emerging set of global health issues for which we need new approaches and instruments: accelerating the development of an HIV/AIDS vaccine that is affordable and effective in developing countries is a crucial instance. An AIDS vaccine for low-income countries is an *international public good* which is not likely to happen without innovative international public action. Private industry must play the critical role in developing and marketing a vaccine, but the private sector currently does not have the incentives to develop an AIDS vaccine for the strains of the virus and the health system capabilities of developing countries. There is growing consensus on the need for global partnership to ensure that AIDS vaccine development will move swiftly—but it will take a number of years, and much longer unless we act now.

The Bank is already hard at work on this through a special task force charged with developing new partnerships and financing instruments which bring the private and public sectors worldwide together to speed the advent of an AIDS vaccine. In this, we are working closely with UNAIDS, WHO, the International AIDS Vaccine Initiative, and other international partners. And we are starting a major program to push much greater deployment of existing vaccines, which will be good for poor people's health now, and will also encourage industry to bring new vaccines onstream.

The World Bank has lent more than US$765 million since 1986 to help developing countries deal with the AIDS epidemic, and in recent years has been lending about $1.6 billion annually for programs to strengthen health systems. But this is not enough. We are developing a new initiative of intensified action against AIDS in Africa, and I am determined that we will dramatically increase our response to this global epidemic. On all these fronts, we will work closely with our partner institutions of the UNAIDS coalition.

It is time to take collective action on the G8 communiqués from Denver and Birmingham to spur the development of an AIDS vaccine, and perhaps to link this effort to other global health challenges, such as the need for new therapies and a vaccine for malaria. The international community, including the developing countries, urgently needs to elaborate a global strategy for advancing this effort, an understanding of what different actors are already doing, and where there are gaps that need to be filled. The World Bank is ready to play its part in bringing it to fruition.

We will warmly welcome your support and ideas, and your commitment to urgent international action.

Sincerely yours,

James D. Wolfensohn

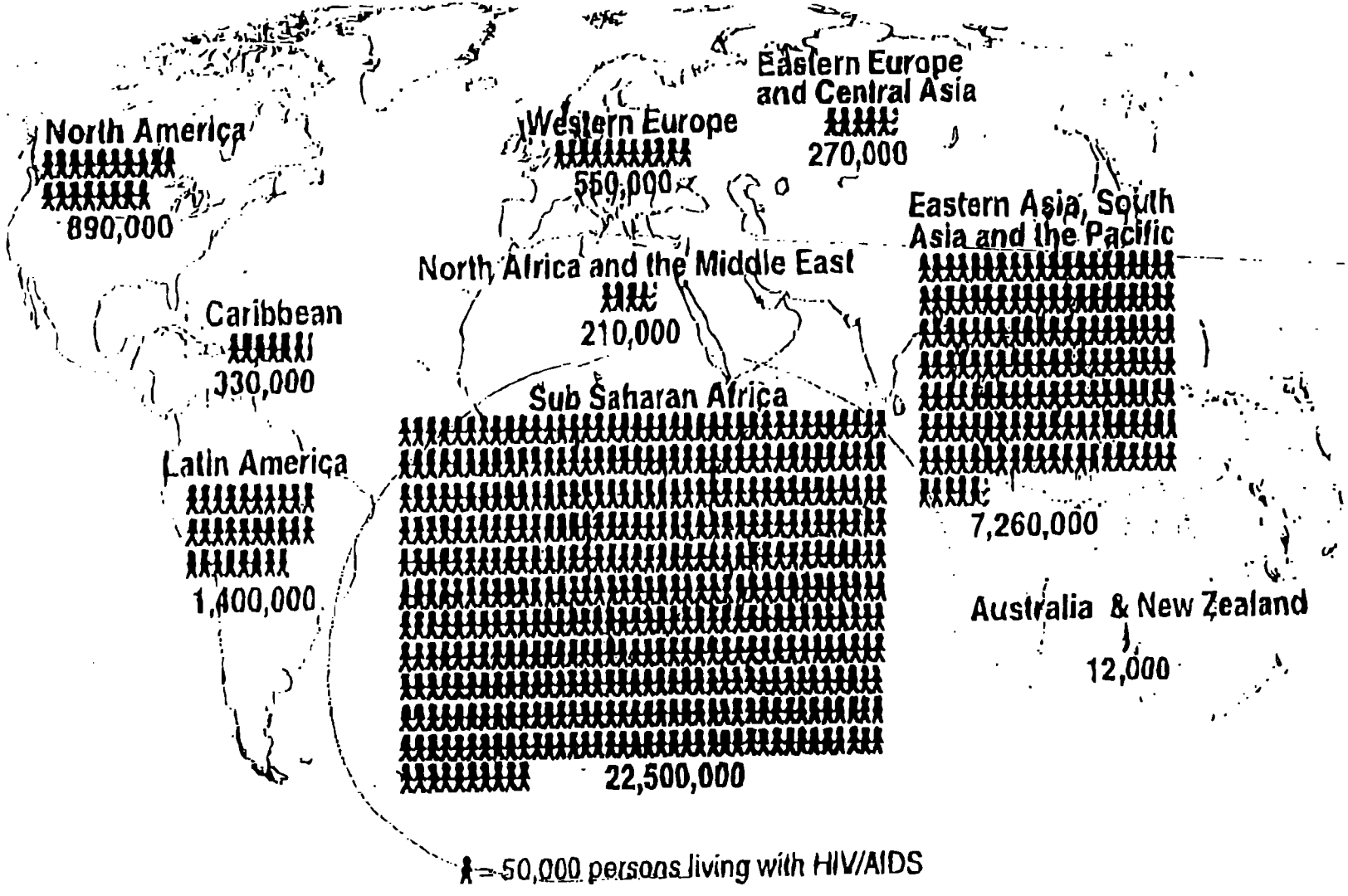
cc: Hon. Dominique Strauss-Kahn, Minister of Finance

Attachment

Global Overview of the HIV/AIDS Epidemic

- HIV/AIDS is now the number one overall cause of death in Africa, and has moved up to fourth place among all causes of death worldwide, according to the latest annual World Health Report.
- An estimated 33.4 million people are living with HIV/AIDS worldwide and almost 14 million people already have died of AIDS (1998).
- 16,000 individuals are newly infected with HIV each day.
- Greater than 8.2 million children have been orphaned by HIV/AIDS. This figure may increase to 40 million HIV/AIDS orphans by 2010.
- Of all global regions, **Sub-Saharan Africa** has been hardest hit by the epidemic. The 21 countries possessing the highest HIV/AIDS prevalence rates in the world are all in this region. Two-thirds (22.5 million) of all those living with HIV/AIDS globally are from Sub-Saharan Africa.
- The **Asian** HIV/AIDS epidemic is building momentum, with South and Southeast Asia experiencing the most dramatic increases in HIV infection. About 6.7 million people are presently living with HIV/AIDS in South and Southeast Asia.
- There is also a rapid rise in the epidemic in **Eastern Europe and Central Asia**. HIV/AIDS infection rates have increased six-fold between 1990-1997.
- Over 1.7 million people are living with HIV/AIDS in **Latin America and the Caribbean**.
- **North Africa and the Middle East** still possess relatively low epidemic levels, although much is still unknown about the status of the HIV/AIDS epidemic in this region.

Number of Adults and Children Living with HIV/AIDS, 1998



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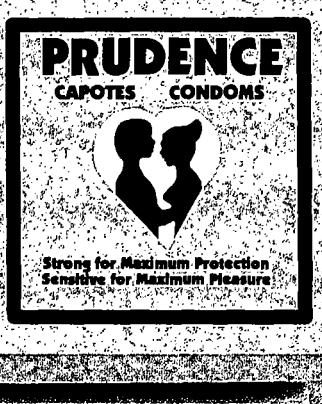
A WORLD BANK POLICY RESEARCH REPORT

CONFRONTING AIDS

PUBLIC PRIORITIES IN A GLOBAL EPIDEMIC

SUMMARY



DRAFT

World Bank Task Force on Accelerating the Development of an HIV/AIDS Vaccine for Developing Countries

HIV Vaccine Industry Study
October-December 1998

Study by Mercer Management Consulting

1. Introduction

The World Bank commissioned Mercer Management Consulting, a general management consulting firm, to perform a study of the biotechnology, vaccine and pharmaceutical industries' perspectives on R&D investment in an HIV vaccine for developing countries.* The study was conducted during the fall of 1998 and was co-funded by the International AIDS Vaccine Initiative (IAVI).

2. Objectives and methodology

The basic objective of the study was to determine whether and how the World Bank might stimulate the development and introduction of a preventive vaccine for HIV in the developing world via market-based mechanisms. The study had three main questions to start:

- What factors influence industry investment in HIV vaccine research and development?
- How might industry decisions be affected by mechanisms guaranteeing a market in less developed countries?
- What mechanisms would be most effective and acceptable in achieving desired industry behaviour?

The study was divided into two phases. The first phase was desk-based, and involved synthesising as much publicly available data as possible, under three headings: science, barriers and company profiles. The second phase was interview based. Mercer interviewed 15 companies and 7 experts. One company declined to participate, and it proved impossible to contact a further three (see annex 1 for the list of interviews).

The duration of each interview, and the number of people involved from each company, varied significantly, usually based on company preference. At every company, the interviews were at board/subsidiary board level with each interview following the same broad agenda. The agenda was as follows:

- A description of relevant current activity
- Perceptions of the potential market
- Attitude towards developing country markets
- Barriers to the development of an HIV vaccine
- Impact of a developing country market guarantee mechanism
- Reactions to/suggestions for different types of guarantee mechanism

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* Any comments should be addressed to Amie Batson at the World Bank. Address: G3-054, The World Bank, 1818 H Street NW, Washington DC 20043.
E-mail: abatson@worldbank.org.

As expected, each company's responses were individual, and influenced by their particular circumstances such as their size, current activity level and participation in the market for existing vaccines. However, on certain issues, the interviewees responses were highly consistent.

3. Interview findings

Activity levels

Having conducted interviews that covered a wide range of companies with varying levels of activity, Mercer formed two overall conclusions.

First, given development and trials timelines, the only vaccine that will be available over the next seven years will almost certainly be based on the GP120 or pox vector candidates currently in Phase II/Phase III trials. Mercer noted that outside the companies directly involved in developing and testing these candidates, there was considerable scepticism as to their likely efficacy: however, as noted below, such scepticism can only reflect probabilities of success rather than certainty of failure.

Some of the smaller companies have novel constructs or approaches, about which they were optimistic, and which conceivably could be available in less than seven years. Mercer is not a science based firm and as such had neither the scientific basis nor the mandate to judge the real potential of different approaches. However, the study found that given the current funding environment for biotech HIV vaccine work, the likelihood of these candidates rapidly moving through the development stages is low.

Mercer's second observation was that, while all the interviewees recognised the seriousness of the HIV epidemic, the actual level of effort across the industry is not commensurate with the health threat. With the exception of a few small companies, HIV vaccine development is not the primary focus of vaccine development efforts. Mercer estimated that fewer than 200 scientists in the private sector are dedicated to HIV vaccine related work, and judged that this number probably exaggerated the resources devoted by the private sector, since some of these scientists were grant-supported by the public sector. Total private sector funded R&D on HIV vaccines is estimated to be less than $50m per annum. However, it was noted that this position appears to represent a significant improvement as compared to three or four years ago.

Mercer concluded that the mismatch between the magnitude of the threat and the lack of urgency or priority given to HIV vaccine development across the private sector in general could only be explained by company's inability to see a realistic commercial return on the required investment.

Perceptions of potential market

It was striking that, with only one exception, companies were unable to give a detailed description of their views on the potential market for an HIV preventive vaccine.

Even views on the likely OECD market were divided. One view was that a substantial developed world market would exist for a safe and efficacious HIV vaccine, and that its order of magnitude and development path would likely be similar to hepatitis B vaccine.

A second view, however, held that the OECD market would be both small initially, and slow to develop. This view reflects both the current disease pattern in OECD countries (stable and limited infectivity) and the success of combination therapies in reducing mortality. Some manufacturers believe it will take years before an HIV vaccine is universally recommended in the OECD, if it ever is. These firms noted that the minimum performance characteristics of an "acceptable" vaccine is significantly higher today than it was ten years ago.

Not surprisingly, companies expecting a substantial OECD market are devoting greater resources to their development efforts than those expecting a small market.

Perceptions of the developing country market

Again views on the potential of these markets were divided. One group of companies, primarily smaller concerns with limited experience supplying today's vaccines, took for granted the existence of a substantial market and necessary funding. Others, and in particular the larger companies, attached little or no commercial value to developing country markets. Across both spectrums of opinion, there were very few, if any, projects motivated primarily by the needs of developing countries.

There is nonetheless widespread acceptance of the importance of being able to meet developing country demand. Further, all companies have in general accepted the need for prices to be tiered, although the lowest price tiers would need to be significantly above those now prevailing for mature vaccines.

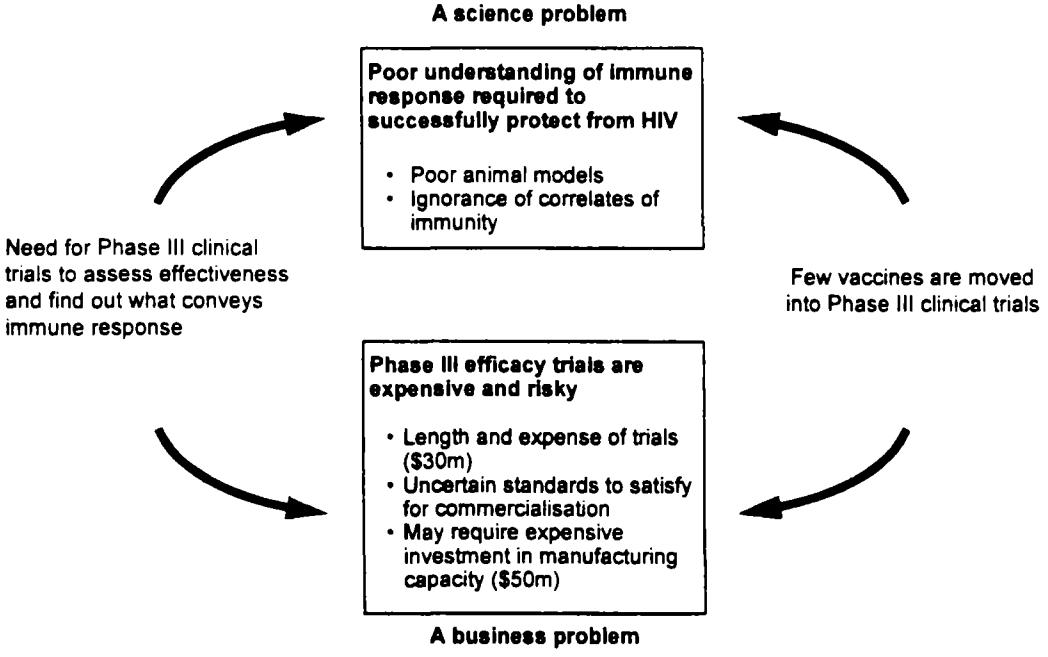
Barriers to development

It is evident that industry is not working urgently in an effort to be first on the market with an HIV vaccine. Mercer has suggested that this can only be explained by the inability of companies to see a realistic commercial return. However, only one company specifically cited concerns about the existence of a commercially attractive market as a primary disincentive to their R&D effort. This omission on the part of the companies is all the more striking when taken in tandem with the fact that the World Bank had made it clear that its primary interest was in exploring market guarantee mechanism.

Most companies cited the scientific barrier as the most critical. In the absence of a truly compelling and urgent OECD demand, the low probability of success of any given candidate and high profile of some failures has had a significant impact on corporate thinking. The absence of a scientific consensus is evident from the number of approaches still being considered, more than a decade after the effort started.

The reality of this scientific barrier can be appreciated when one considers that the HIV has to date defeated all three of the current human vaccine approaches, two of them without human trials. Safety issues around a retrovirus with 97% mortality have prevented the testing of live attenuated or whole killed candidates. Whole killed candidates have also been hampered by manufacturing difficulties. The failure to neutralise primary isolate has prevented first generation recombinant candidates entering efficacy trials, although an improved recombinant product recently started such trials. The bulk of vaccine efforts today are focused on approaches which have few or no current vaccine analogues.

This scientific uncertainty is compounded by the fact that there is currently limited understanding of the virus, a lack of correlates of immunity and no available animal models. This has resulted in a much higher degree of uncertainty as to potential efficacy of a vaccine candidate then is typical when considering investing in expensive Phase III trials ($30m was a frequently quoted figure). Low infectivity in developing countries makes for highly expensive trials of uncertain statistical outcome. In developing countries, where infectivity is often much higher, there are both political and infrastructure barriers. Efficacy trials often also involve investment in process development and manufacturing capacity, also costing tens of millions of dollars. All or most of this investment is lost if a commercial product does not result from efficacy trials.



This creates a vicious circle, since Phase III efficacy trials are an effective way of advancing knowledge to identify and develop an efficacious product. However, very few companies have sufficient confidence in their current candidates to risk the required amounts of money in the near future.

Nearly all the smaller companies interviewed cited difficulty in raising capital as a major barrier. Indeed, most of the smaller companies either limited their activity in HIV vaccines to what activities covered by public sector grants, or relied on other activities to attract investment and pursued HIV vaccine research in a low-profile fashion. The difficulties faced by the small companies in raising finance are, in all probability, symptomatic of the lack of confidence of the larger companies. This is because large companies are a major source of investment in smaller companies, and arguably give a lead to the venture capital markets.

Impact of a developing country market guarantee mechanism

Given the level of concern over scientific rather than market barriers, Mercer found it unsurprising that most companies were cautious about the value of a developing country market guarantee mechanism. Only one company took the view that the existence of such a mechanism would permit a significant increase in development expenditure. The remainder felt that such a mechanism would be welcome, would generate positive publicity and might have a small incremental impact on activity levels.

The emphasis of industry's comments was heavily biased towards reducing the levels of risk involved in HIV vaccine development rather than increasing the potential reward.

Mercer noted three possible reasons why increasing the reward might not increase the investment (i.e. the risk) companies are willing to take.

- Some companies currently perceive the absolute probability of successful development of a vaccine as too low, making the size of the reward irrelevant.
- For most companies, the perceived timeline to commercial revenue is so long that the reward is heavily discounted and ultimately not the primary driver of decision-making.
- Companies supplying current vaccines to the developing country market regard that market, and the public sector role in it, as lacking commercial credibility. Companies may therefore discount promises over a hypothetical future product which are at variance with their current experience.

A number of companies suggested that it would be useful for the public sector to generate a minimum set of criteria which a vaccine should meet. Further, it was suggested that the public sector should create scenarios as to efficacy, demand, capacity and cost to begin to form the basis for a dialogue on mechanism details. This would provide industry with a better definition of the performance characteristics of an acceptable vaccine.

Whilst most companies indicated understanding of, and support for, tiered or differential pricing, it was emphasized that the lowest price would likely be dollars rather than cents per dose. Some companies also expressed the concern that any subsidy or purchase mechanism not cannibalize more wealthy market segments and therefore segmentation would need to be applied.

Finally, some of the companies involved in the existing market felt that the best way to attract investment for future product development for developing countries was to establish a commercially attractive market for today's products. In effect, this suggestion would create a situation analogous to OECD markets, where the development of future products is funded from the revenue of today's products.

4. Interpretation and recommendations

A composite problem

There are four components to the problem of accelerating the development and introduction of an HIV vaccine for the developing world. The fact that this is a composite problem strongly suggests that it will not be susceptible to a single "silver bullet" solution, market based or otherwise.

The four components are:

Candidates, that is to say screening possible approaches for promise and then ultimately selecting certain one's for development. The study found that relatively few companies are pursuing multiple approaches; there seem to be a number of approaches which have been shelved prior to determining their potential value; and there is relatively limited big company interest in novel ideas originating in the biotech sector.

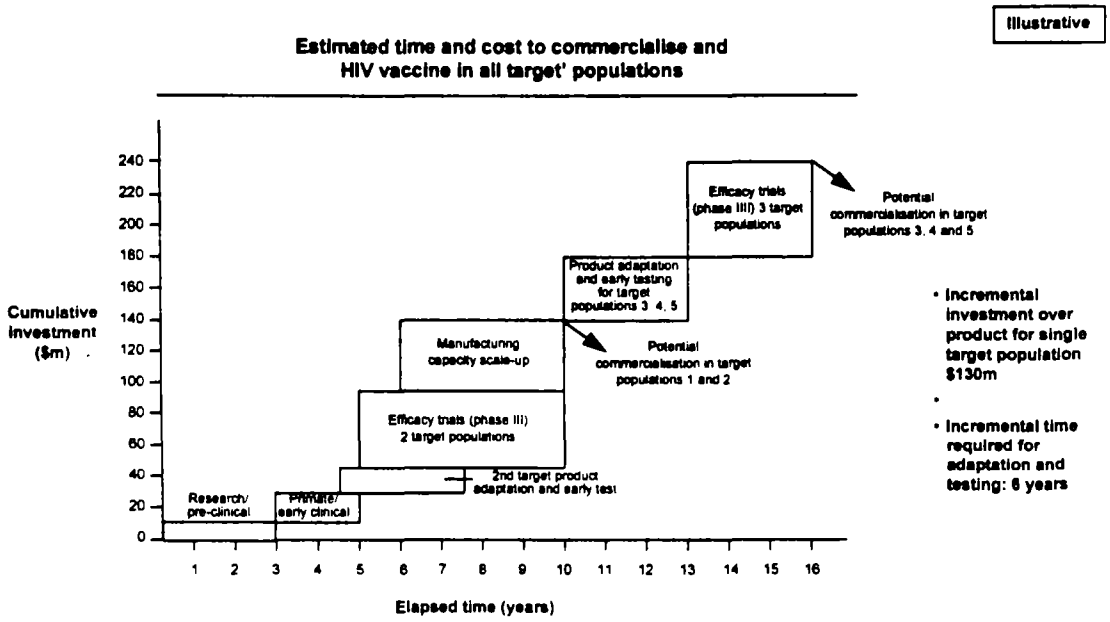
The paucity of active candidates appears to be primarily due to barriers at the development component, defined as taking a candidate through testing and manufacturing scale-up to commercialisation in a single target population. The barrier at this stage is the low expectation of success coupled with the high costs of trials and bad publicity of failure.

Success in the candidate and development components would lead to the introduction of an HIV vaccine, most probably for the OECD markets. Meeting the World Bank's objectives would require that two other components are satisfied.

The first is relevance, defined as adapting and testing a vaccine to ensure safety and efficacy in all target populations. Depending on the approach taken, and its cross-reactivity, it is probable that a vaccine will need to be adapted to different target groups. Given the variability in human genetics and epidemiological conditions in the different target populations, it is certain that safety and efficacy testing will be required in each target population. The costs of such adaptation and testing are significant, but there are currently very few incentives to motivate a firm to undertake them.

In addition, the risk of investing in adaptation and additional testing can be reduced if the firm waits until the efficacy trials on the core product are complete. However, such a sequential approach will delay availability of tailored products by several years.

The following graphic illustrates the costs and number of years needed to identify a candidate, develop and test it for one target market and then the additional costs and time required to adapt and test the product for developing country markets. Mercer estimated that if approached sequentially the incremental cost of adapting and testing the product for 3 additional target populations would be roughly $130 million and take an additional 6 years.



Source. Mercer analysis

'Assumes 5 target population/clade tests required

The last component is access, defined as ensuring that manufacturing capacity and funding/pricing structures are sufficient to enable broad and early developing country access. Mercer estimated the additional capacity needed to serve the global demand would necessitate a large incremental investment on the order of $100-150 million. The critical point here is that rapid access to a new vaccine for developing country requires a new paradigm in public sector supply policies.

Currently, existing vaccines only reach "affordable" prices once the market matures, creating competition and overcapacity and thus a willingness to sell at marginal prices. Little or no investment is made in R&D or capacity to serve developing countries. The penalty paid to reach these low prices with the current system is delays to broad availability of a decade or more.

A decision that a new vaccine should be made broadly available at the earliest possible technical and regulatory opportunity requires that the manufacturers make development and capital investments explicitly to support supply to the developing world markets. Industry will only do this if they are confident that a reasonable return on these

investments will be forthcoming. This, in turn requires that the public sector have in place commercially credible funding, pricing and supply policies.

5. Ideas to stimulate development and introduction

The fact that companies were primarily focused on "push" (risk and cost) barriers rather than "pull" (reward) barriers resulted in a series of very broad discussions on mechanisms and incentives.

"Pull" recommendations : ways to provide market rewards

- **Market guarantee mechanisms**. A future market could be guaranteed through a financing mechanism such as contingent loans or a contingent purchase fund. These mechanisms would ensure funds were available to purchase an appropriate vaccine or provide a per dose subsidy. This would generate positive publicity and have some impact on development activities. These mechanisms would however, greatly increase industry motivation to ensure that a product is adapted, scaled-up and made accessible to developing countries.

- **Prize**: Manufacturers expressed very little interest in the idea of a prize awarded for the development of an HIV/AIDS vaccine meeting certain criteria.

- **Indirect pull incentive such as patent extensions linked to existing products in OECD markets**. Patent extensions in the G8 or several OECD markets might stimulate greater interest from large pharmaceutical companies in the field, in turn providing a stimulus to candidate and development efforts, especially in the biotech sector. In addition a patent extension has the advantage that, whilst worth several hundred million dollars to any major pharmaceutical company, its cost is hidden. The cost to G8 healthcare systems could nonetheless be justified by the future healthcare savings which would be generated by success development of a vaccine. This option would require extensive legal and political groundwork.

- **Demonstrating the commercial credibility of any proposed guarantee mechanism by supporting the rapid introduction of an existing new vaccine.** Improving the commercial credibility of the existing developing country vaccine market will significantly enhance relevance and access for all future vaccine products. It would also provide immediate benefits for health. World Bank support of vaccines has been ad hoc but could be systematically targeted to support immunization and accelerate the introduction of existing new vaccine.

"Push" recommendations

"Push" mechanisms are fundamentally less attractive than "pull" mechanisms because they, by definition, require the selection of a specific approach or company for support. While more money spent on a very difficult problem might result in a solution, it is also

possible that such money will be misdirected. The only way to mitigate this risk is to support multiple approaches. There is also a risk of duplication of the work of other agencies. The World Bank does not have the expertise to select specific scientific approaches however, through Bank projects and support of other agencies its involvement would serve two objectives:

- Sharing the cost and therefore risk of late stage development
- Reducing the cost and accelerating product adaptation for developing countries where required.

Possible "push" options include:

- **Projects to build national capacity and infrastructure to perform clinical trials**. The World Bank can work with government partners to include support for building of national capacity and infrastructure to perform clinical trials in upcoming projects.

- **Projects which include components to fund efficacy trials for vaccine candidates where justified by scientific review**. Funding these trials will help in the discovery of a successful HIV/AIDS vaccine and, if the vaccine fails, will increase the understanding of the virus and vaccine approaches. Other agencies which are better positioned to review the science would need to take a more proactive role in brokering contacts between industrial country companies with R&D candidates and appropriate potential developing country trial sites.

- **Explore mechanisms to support the investment in product adaptation for developing countries in advance of efficacy trials**. As noted earlier, it is probable that vaccine candidates designed for an industrial country market will need to be adapted for different developing country markets. Given the objective to accelerate the development of an HIV/AIDS vaccine, it will be important that product adaptation occurs as early as possible.

- **Manufacturing capacity**: Mercer advised against the Bank funding manufacturing capacity, either directly or through technology transfer. They noted that capacity would be adequate if effective "pull" mechanisms are in place. They also noted that capacity investments must often be made prior to the results of the clinical trial and so have a risk of being "wasted" if the vaccine fails. This is in contrast to trials funding, which may be expected to advance understanding of the virus, even if no product results.

6. Conclusions

The single most important reason why there is not an HIV vaccine today is scientific, compounded by the high costs and risk of definitive efficacy testing. This means that, on their own, market guarantee mechanisms will do little to accelerate development.

Such mechanisms will however be critical in ensuring access and to some extent relevance, once a product is in late stage development. Further, overcoming the problems inherent in the existing paradigm of vaccine supply to developing countries has a significant global health value beyond HIV alone.

The various "push" and "pull" options outlined below will not guarantee the development of an HIV vaccine within any given timeframe. However they will have three valuable effects. First, these mechanisms will increase private sector interest and effort in the development of an HIV/AIDS vaccine. Second, some of the pull mechanisms will vastly enhance the access to a vaccine once it is developed. Finally, these new approaches to correct market failures affecting R&D intensive products with high public, but limited market value will be beneficial for numerous other priority areas.

Annex 1: List of interviews

Large therapy	Large vaccine	Biotech	Experts	Declined
• Hoffmann LaRoche	• Merck	• Cel-Sci	• Prof. Barry Bloom (Harvard School of Public Health)	• Vical Inc
• Glaxo Wellcome	• Chiron	• Vaxgen	• Dr. Seth Berkley (IAVI)	[• Auragen]
	• Wyeth Lederle/Apollon	• Immuno Science	• Dr. John Moore (Aaron Diamond)	[• Immune Response]
	• Pasteur-Merieux Connaught	• Protein Sciences	• Dr Anthony Fauci, Dr John LaMontagne (NIH)	[• Acrogen]
	• Smith-Kline Beecham	• Therion Biologics	• Jonathon Cohen (Science Magazine)	
	• Immuno AG	• United Biomedical	• Richard van de Broek (Hambrecht and Quist)	
		• Virus Research Institute (VRII)		
		•		

Industry overview: Overall level of corporate HIV/ AIDS research effort

Relatively few companies have shown sustained commitment to HIV vaccine research.

Apparent level of commitment \ Importance for company	Sole activity	Major activity	Component of research/ drug portfolio	Minor activity	No evidence of current effort
Serious (evidence of sustained commitment over time)	• **VaxGen**	• **Apollon** • **ImmunoAG** • **Pasteur-Merieux Conn.** •	• **Cel-Sci** • **Chiron** • **Glaxo Wellcome** • **Merck**	• **Genentech**	
Moderate	• **Immune Response Corp** • **MicroGeneSys**	• Acrogen • Agouron Pharmaceuticals • Auragen/ Agracetus • AVR Corp • Cell GeneSys • Gilead Sciences • **Immuno Science Inc.** • Vertex Pharmaceuticals • **Virus Research Institute**	• Abbott Laboratories • Boehringer Ingelheim • **Bristol-Myers Squibb** • **British Biotech** • DuPont Pharmaceuticals • **Hoffmann LaRoche** • Immunex Corp • **Therion Biologics** • **Wyeth Lederle**		• Bayer AG • Hoechst AG
Sporadic (one or occasional mentions)		• IDT Inc. • US Bioscience	• Immunol Inc. • **MedImmune Inc.** • **Progenics Pharmaceuticals** • **Sequus Pharmaceuticals** • **Sharman Pharmaceuticals** • **Theratechnologies Inc.** • **United Biomedical**	• Pharmacia & Upjohn • **SmithKline Beecham** • **Steroidogenesis Inhibitors Int'l** • Vical	

Bold = vaccine developers

Source: Mercer research

Accelerating an AIDS Vaccine for Developing Countries: Issues and Options for the World Bank*

April 1, 1999

Comments welcome. Not for citation.

Contents

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The opinions expressed in this discussion paper are those of the authors and reflect the findings and deliberations of the AIDS Vaccine Task Force. The judgments expressed in this paper do not necessarily reflect the views of the World Bank's Board of Directors or the governments they represent. Please address comments to: mainsworth@worldbank.org and abatson@worldbank.org.

Accelerating an AIDS vaccine for developing countries: Issues and options for the World Bank

I. Introduction

The worldwide AIDS epidemic is a human tragedy that is reversing the gains in life expectancy of the last 30 years and exacerbating poverty in developing countries (see Box 1). Worldwide, 33.4 million people are infected with HIV and 13.9 million have already died of AIDS. More than nine out of every ten HIV infections are in developing countries, and two-thirds are in Sub-Saharan Africa. Every day, 16,000 people become infected. AIDS is a fatal infectious disease for which there is no cure and no vaccine. Antiretroviral therapies that have extended the lives of patients in industrialized countries are out of reach in the poorest developing countries because they are too expensive and difficult to administer effectively in these settings. Since 1986, the World Bank has lent $765 million for HIV/AIDS prevention and care in 74 projects in 49 countries, primarily for information campaigns, behavioral change (like raising condom use), and treatment of sexually transmitted diseases.[1]

At present, the best hope for reducing the spread of HIV and its human and economic impacts is through behavioral change—reducing the number of sexual partners among people with many, raising condom use, and enabling safer injecting behavior. Governments like those in Australia and Thailand have shown that these measures *can* have an impact in reducing the spread of HIV on a national scale. Too few countries have shown the level of political commitment necessary for an effective response. The World Bank and its development partners, including the Joint United Nations Program on HIV/AIDS (UNAIDS), are continuing their efforts to raise the level of policy dialogue on AIDS as a development issue, to obtain greater political commitment and more effective programs.

Substantial benefits could be gained in terms of slowing the epidemic through concerted public action on prevention, and this strategy must be vigorously pursued. In addition, countries where HIV is already widespread in the general population urgently need an HIV vaccine to add to their arsenal in the struggle to control the epidemic. A vaccine that is effective and affordable in developing countries would greatly improve the prospects for dramatically reducing the scope of the epidemic, not just in developing countries but the world over. HIV does not respect geographic boundaries and spares no racial, ethnic, or religious group. No country or population is exempt.

[1] In addition, the World Bank has contributed $18 million over the past 13 years to the Global Programme on AIDS and its successor, the Joint United Nations Programme on HIV/AIDS (UNAIDS).

BOX 1: The impact of AIDS on development

The AIDS epidemic has managed to wipe out nearly all of the progress of the last three decades in raising life expectancy in Sub-Saharan Africa. In the hardest-hit countries the lifetime risk of dying of AIDS is 40-50% and life expectancy is 10-20 years less than it would have been in the absence of AIDS.

The demand for AIDS-related health care is overwhelming fragile heath systems. AIDS is exacerbating poverty in the poorest countries. In hospitals in major African cities, half or more of hospital beds are occupied by AIDS patients, displacing patients with conditions that might be cured. Access to the most basic palliative care and treatment of opportunistic infections is severely limited. It is killing prime-age adults—the breadwinners of households who leave behind young orphaned children in the care of relatives or the state. In Northwestern Tanzania, families are coping with the economic impact of AIDS deaths by consuming less, selling assets, drawing on contributions from the extended family, and removing older children from school to work in the home. In coping with this short term shock, the poorest families are sacrificing investments in human capital that are important to the welfare of the next generation.

Source: World Bank (1997), Stover and Way (1998).

Scientists now believe that an effective preventive HIV vaccine is feasible (see Box 2), but this does not make its development a foregone conclusion. Although the public sector often has financed or subsidized basic research for vaccines, it has limited expertise in transforming these discoveries into marketable products. The development of vaccine products and the technology for their manufacture is usually undertaken by the private sector, which can do this more efficiently. In the case of an HIV/AIDS vaccine, both public and private investment is currently small and oriented toward the needs of the richest countries. There are at least two reasons why private investment in an HIV vaccine is likely to be less than the socially optimum amount:

The technology for an HIV vaccine is an *international public good.* Regardless of which firm or country develops it, the benefits of an HIV vaccine technology will be global. Even those who do not invest in the research and development (R&D) will benefit. Those who invest in the technology will not be able to recoup revenue from many who will benefit. The private sector is unlikely to invest adequately in products tailored to the needs of developing countries or populations in which ability to pay is low.

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At the current pace it is likely to be several decades before an effective vaccine becomes available in OECD countries, let alone in developing countries. An HIV/AIDS vaccine that is effective and affordable in developing countries is even less likely to become a reality if private actors are left to respond to existing incentives.

In April 1998, the World Bank set up an institution-wide Task Force to examine ways in which it could help accelerate the development of an AIDS vaccine for developing countries, as one element of its broader program to combat AIDS. The AIDS Vaccine Task Force has consulted with numerous experts and sponsored studies of both the pharmaceutical industry and the potential demand for an AIDS vaccine. It has also examined and discussed a range of possible Bank responses, including financial instruments that could be used to assure future markets for an HIV vaccine in developing countries. This work is ongoing, and country-specific case studies will shortly be launched.

BOX 2: The scientific challenges of an HIV/AIDS vaccine

The development of a safe and effective AIDS vaccine poses several scientific challenges. A successful vaccine must elicit immune responses capable of blocking infection by sexual, intravenous, and mother-to-child transmission. It must be capable of stimulating immune responses like antibodies, which may be effective at neutralizing free virus particles, as well as cellular immune responses, which destroy incoming virus-infected cells. In addition, the tremendous geographic diversity of the subtypes of HIV worldwide suggest that mixtures or "cocktails" of vaccines may be required for universal protective immunity. Finally, there is a lack of understanding of which anti-HIV immune responses are required for generating protective immunity against HIV and therefore which components of HIV are necessary for an effective AIDS vaccine.

Despite these challenges, there is now broad agreement within the scientific community that an effective AIDS vaccine is possible. First of all, a small but growing number of people who have been repeatedly exposed to HIV have remained uninfected and have elicited anti-HIV immune responses that could explain their resistance to infection. Second, there are now several candidate vaccines that have protected monkeys from infection and/or disease caused by the simian immunodeficiency virus (SIV), which is very similar to HIV. Third, some candidate vaccines already in clinical trials have induced strong anti-HIV immune responses in human volunteers. Finally, vaccines have successfully been developed against several other viruses—measles, mumps, rubella, polio, hepatitis B, and rotavirus, for example—with much less knowledge of their fundamental biology and pathogenesis than HIV.

This paper reviews what the AIDS Vaccine Task Force has learned to date about the nature of the problem of under-investment in an HIV/AIDS vaccine for developing countries, and summarizes some of the approaches under consideration. Its objective is to launch a discussion within the World Bank, and – critically – with its bilateral and multilateral partners, on the best course of action for the institution, given its mandate, its comparative advantages in relation to the other agencies involved in the international effort, and the likely effectiveness of alternative measures for accelerating the development of an HIV/AIDS vaccine for developing countries.

II. Worldwide investment in an HIV/AIDS vaccine

Total global research and development (R&D) for preventive HIV vaccines in both the public and private sectors in 1998 was on the order of only US$300 million.[2] Most of this is public expenditure and is focused on basic research, as opposed to applied research and vaccine

[2] Estimate by International AIDS Vaccine Initiative (IAVI). The United States National Institutes of Health budgeted $180 million for HIV/AIDS vaccine research in fiscal year 1999 (OAR 1998).

development. Privately funded R&D on HIV vaccines was probably less than $50 million per year and fewer than 200 scientists in the private sector worldwide are dedicated to AIDS vaccine-related work, some of it subsidized by the public sector (Batson and Whitehead 1999). Progress has been slow. While more than 25 candidate vaccines have been developed and tested for safety and immune response in small groups of volunteers, only one firm has embarked on Phase III clinical trials of an HIV vaccine—the stage at which a vaccine is tested for efficacy in a large human population.[3]

There are 10 or more subtypes of HIV in the world. Research to date has focused on a vaccine for HIV subtype (or clade) B, which is the predominant strain in North America, Europe, Australia, and Japan. However, the predominant subtypes in Subsaharan Africa and Asia—where the epidemic has hit hardest—are subtypes A, C, D, and E. There is no guarantee that a vaccine based on subtype B will be effective against these other subtypes. Further, cellular immunity—which is thought to be important for protection against HIV—is influenced by the genetic makeup of the individual. Even if a vaccine is not specific to a subtype of the virus, the effectiveness could vary across populations. An HIV/AIDS vaccine for use in developing countries should also be inexpensive and easily administered (preferably oral). Other important characteristics include: a minimum number of doses, preferably one; long-term immunity; heat tolerance; and long shelf life. The vaccine should be as efficacious as possible.[4] In addition, since it would be costly to test every potential recipient for HIV before being vaccinated, the preventive vaccine should not be harmful to people who are already infected.

According to the International AIDS Vaccine Initiative (IAVI), less than $5 million per year is being spent on AIDS vaccines that are specifically designed for use in developing countries. One efficacy trial for a clade B/E vaccine is underway in Thailand; the only other ongoing efficacy trial is in the United States.[5] In it's 1998 "Scientific Blueprint", IAVI laid out a research plan that was most likely to result in an AIDS vaccine for world use by 2007. The plan was costed at $350-$500 million over this period (IAVI 1998).

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[3] Many of these candidates, while safe, have a low probability of being effective because of poor immunogenicity. Nevertheless, it is difficult to know whether laboratory assays will predict the effectiveness in human beings. There are at least a half dozen of these that warrant additional clinical study and efficacy trials (Peggy Johnston, IAVI, personal communication).

[4] Vaccine efficacy is defined as one minus the ratio of the incidence of infection in vaccinated and unvaccinated groups of people. However, efficacy as measured in vaccine trials is not the only factor affecting the impact of a vaccine on community levels of infection (McLean and Blower 1995). The duration of immunity, the level of infectiousness and incubation period of HIV among vaccinees are also key variables. "...in areas of moderate to high transmission, low-efficacy vaccines administered at high coverage levels could act to significantly reduce the endemic prevalence of HIV-1"(Anderson and Garnett 1996). Haber, Watelet and Halloran (1995), point out that a vaccine that is not efficacious at an individual level but that reduces the infectiousness of HIV (the probability of transmission) among those vaccinated could have an important effect in reducing infection in the population. Anderson, Swinton, and Garnett (1995) find even that a low-efficacy vaccine that protects for only a few years "...can save many lives if significant coverage is maintained over many years."

[5] VaxGen is supporting a trial of a bivalent B/E gp120 envelope vaccine in Thailand and is also conducting a US trial on a subtype of the B vaccine.

In contrast to the limited funds spent on AIDS vaccine development, an estimated $2 billion annually is being spent worldwide on research for AIDS treatment, much of it in the private sector.[6] There is far more certainty for the private sector about the profitability of this research. There are more than 33 million people infected worldwide, almost all of them adults who would be willing to pay some amount for treatment when they fall ill. Three million of those infected live in industrialized countries where purchasing power is high. The global market for drugs for AIDS and related infections in 1995, before the widespread introduction of combination therapies that include protease inhibitors, was estimated at $1.3 billion annually. In 1996, it was estimated that protease inhibitors alone might bring in $755 million per year in revenue by 2000, but this is surely an underestimate.[7] Middle-income countries are also becoming important purchasers of expensive antiretrovirals, which must be taken continuously for the rest of the patient's life at a cost of $7,000-$12,000/year. In 1998, Brazil spent $400 million on antiretroviral drugs for treating AIDS patients.[8]

III. The potential market for an AIDS vaccine in developing countries

There are 2.5 billion adults of reproductive age in developing countries who are not infected with HIV, including 260 million in the hardest-hit region, Sub-Saharan Africa. This is the number of people who might benefit today from an AIDS vaccine. However, this is not the same as the "demand" for the vaccine, which is the number of doses that would be purchased by government and private individuals. The demand for an AIDS vaccine in developing countries will depend, among other things, on:

the characteristics of the vaccine, in terms of its efficacy for relevant strains of the virus, its safety, the number of doses to infer immunity, and its ease of administration in the conditions in developing countries;
the price of the vaccine;
levels of income in developing countries and the willingness of international donors to purchase the vaccine for the poorest countries or the poorest people;
the perceived vulnerability of different populations to becoming infected, their potential for spreading the virus, and their political clout;[9] and
the costs and capacity of the public and private sectors to administer the vaccine.

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[6] The US National Institutes of Health budgeted $482 million for research on therapeutics and $526 million for research on etiology and pathogenesis of HIV/AIDS in FY 1999, out of a total AIDS research budget of $1.73 billion.

[7] Business Week (1996)

[8] Preliminary 1998 figures (423.3 million reais) (Brazil AIDS control program website).

[9] The political climate is a key factor affecting demand. Political pressure could force the hand of government—even if the vaccine is very expensive—to guarantee access to an HIV vaccine to everyone. For example, some Latin American governments must provide expensive triple-drug antiretroviral therapy to all AIDS patients who ask for it, irrespective of the cost. On the other hand, if the vaccine is perceived to be less than 100% safe, people who are at relatively low risk of contracting HIV may refuse to be vaccinated, lowering demand. These reactions are difficult to anticipate.

The relation between the price of an HIV vaccine and the number of doses purchased is not known. Childhood vaccines are provided at very low prices to the public sector in developing countries and free to the population. The price of all four basic childhood vaccines[10] combined is less than US$1 per child. Nevertheless, even at these low prices, coverage is far from universal—about 70-80 percent of children under one year of age. The initial price of an HIV/AIDS vaccine is likely to be much higher, measured in dollars or tens of dollars, not cents. Delivery costs—estimated at about $14 per child in the poorest developing countries for the childhood vaccines[11]—could also be higher for HIV, since delivery systems for immunization of other groups in the population, like young adults, may have to be set up. Thus, only a share of all who could benefit from an HIV vaccine will ever be vaccinated.

Global spending on childhood vaccines is estimated at $4 billion annually, of which spending in low- and middle-income countries accounts for about $200 million, most of it financed by the public sector. But this may not be a good guide to potential spending for an HIV/AIDS vaccine. First, the current market for childhood vaccines in developing countries represents a "maintenance" phase, as older children were immunized in previous years. When an HIV/AIDS vaccine becomes available, there will be initial large "catch up" demand, since none of the population will have been previously immunized. Second, AIDS is almost always fatal and it primarily affects prime-age adults. While most childhood vaccines are purchased by or for government programs, adults (even poor adults) may be more willing to pay for an HIV vaccine than for childhood immunizations. No study has attempted to measure the public or private demand response to hypothetical HIV vaccines of different prices or characteristics in a developing country setting.

Historically, vaccines become available and affordable for developing countries after the market in OECD countries has matured. Only after substantial saturation of the OECD market do competition and over-capacity generate the willingness among firms to sell their product at marginal prices that are affordable in developing countries. For example, the hepatitis B vaccine appeared in 1982 but did not effectively become available in developing countries for 10-15 years, when its price had dropped from $150 to about $2-4 for the 3-dose vaccine series. Thus, even when a new product becomes available in OECD countries, it often takes many years for the product to become available and affordable in developing countries.

IV. Why isn't industry investing?

A study commissioned by the World Bank AIDS Vaccine Task Force of industry's perspective on HIV/AIDS vaccine R&D concluded that companies do not believe there will be a realistic commercial return on the required investment for an HIV vaccine in developing countries (see Box 3). There are two important contributing factors.

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[10] BCG, oral polio vaccine (OPV, 4 doses), diptheria-pertussis-tetanus (DPT, 3 doses), and measles.

[11] UNICEF/WHO (1996).

BOX 3: Industry's perspective on HIV vaccines

The World Bank and the International AIDS Vaccine Initiative (IAVI) recently commissioned a study of the factors affecting private sector research and development of an AIDS vaccine. The study team interviewed 15 companies and seven international experts on AIDS vaccine development. Of the firms interviewed, two were large firms involved in AIDS therapy, six were large vaccine manufacturers, and seven were smaller biotechnology firms that specialize in early stage research. Biotechnology firms eventually sell their technological discoveries to larger pharmaceutical companies that have the infrastructure, resources, and technical know-how to conduct clinical trials and large-scale production. Only one of the interviewed firms was involved in Phase III efficacy trials for an HIV vaccine, four were involved in Phase I and II early clinical trials, and seven were in pre-clinical stages of an AIDS vaccine. Two firms were very large and not involved in HIV vaccine work, and a third had discontinued work on an HIV vaccine. In each firm, senior managers and/or CEOs were interviewed.

The study recommended that the World Bank pursue activities to guarantee a profitable developing country market for an AIDS vaccine, which could be influential to private R&D in the long run. The World Bank should also consider making short-run investments that will speed the access of developing countries to an AIDS vaccine when it becomes available. Enhanced lending for existing vaccines in developing countries and investments in infrastructure necessary to implement them quickly will help to demonstrate that viable LDC markets exist. The study also recommended that the World Bank consider activities in the short term that will accelerate the pace and relevance of HIV vaccine clinical trials in developing countries.

Source: Batson and Whitehead (1999, forthcoming).

The potential market is perceived to be small

Private investment in research on an HIV/AIDS vaccine is based mainly on firms' assessment of the potential market in high-income, OECD countries. There are two points of view. Some firms believe that there will be substantial demand for a safe and efficacious HIV vaccine of the order of magnitude of that for the hepatitis B vaccine. Other firms believe that because HIV is spreading slowly in the developed world and therapies have been successful in extending the life of patients, the OECD market will be small at the outset and slow to develop. Firms that believe there is a potential OECD market are investing in HIV vaccine R&D.

With only one exception, the Task Force's study of industry found that the potential market for an AIDS vaccine in developing countries was not cited as a factor in R&D investment decisions, nor is it a factor in decisions on investing in most products. The more involved a firm already was in developing country markets, the lower was its estimate of the potential sales of an HIV/AIDS vaccine in those markets. Even firms that anticipated some developing country demand expected that their R&D costs will be recouped in the OECD market. Acceptance of market segmentation for the purpose of pricing—price "tiering", enabling firms to maintain high prices in OECD markets while charging marginal costs in developing countries—will be critical if firms are to introduce an HIV vaccine in developing country markets for a price that these

countries could reasonably afford. Based on their experience to date, the firms cited lower-than-expected uptake of new vaccines developed since the 1970s, like hepatitis B, yellow fever, and Hib[12], as evidence that work on future "high-priority" vaccines may not necessarily be rewarded by adequate sales.

The late-stage development costs of an HIV vaccine are high and the probability of success uncertain

There are many steps in bringing new vaccines to the market, which under normal circumstances can take a decade or more (see Box 4). The normally very long time horizon for developing a commercial product—from 10 to 30 years—means that the commercial benefits of developing an AIDS vaccine are far in the future and thus highly discounted in making investment decisions. In the case of an HIV/AIDS vaccine, there has been no good animal model and the correlates of immune protection remain unknown. As a result, the science has been challenging and the level of industrial investment low. More than a decade after the effort to develop an HIV vaccine was launched, there is only limited clinical testing underway and no scientific consensus on the best approach. Safety issues have prevented the testing of live attenuated or whole killed vaccine candidates in humans. While there are a few novel approaches in the early phase of testing, only one recombinant vaccine candidate globally has entered an efficacy trial.

A large-scale trial is needed to show the efficacy of any given vaccine candidate, but because of the huge expense of such trials ($10-30 million) industry is unwilling to pay for them unless there is a high degree of certainty that the vaccine will be efficacious. The main approaches for an HIV/AIDS vaccine at present have few or no current vaccine analogues, which means there is still a large degree of uncertainty about their efficacy in a large trial, even after safety and immunogenicity are demonstrated. HIV vaccine efficacy trials in industrialized countries are particularly expensive because the incidence of HIV is low and the sample size would have to be very large. Trials in developing countries with higher HIV incidence could be smaller, but there are hidden costs such as political barriers and inadequate infrastructure. Since levels of protection against different strains of HIV cannot be assumed, it is highly likely that vaccines based on different strains will have to be tested in areas where those strains are prevalent. The additional costs of expanding the trial of a single vaccine candidate beyond one OECD country to include a vaccine for multiple strains of HIV in additional sites has been estimated at $100 million. Further, efficacy trials usually involve some limited investment in manufacturing process and plant, investment that is lost if an efficacy trial does not result in a commercial product.

[12] Haemophilus influenzae type B.

BOX 4: Vaccine clinical trials

Once a vaccine has been shown effective in animal models, it must be tested in people. These studies, called clinical trials, determine the safety, immunogencity, and efficacy of candidate vaccines. They provide the data necessary for regulatory agencies to decide whether or not a product should be licensed for use in their market. Before a vaccine will be recommended globally, efficacy studies are also required in different epidemiological sites (Asia, Africa, Europe, North America, Latin America). Often, governments will also require efficacy studies be repeated in their own country before agreeing to license a product. There are three types of human clinical trials that must be conducted without exception before a vaccine will be considered for licensure.

Phase I: Safety Phase I trials determine the safety and preliminary dosing studies of a vaccine candidate in a small sample of 10-30 people. They are generally conducted in healthy adults at low risk of HIV infection, take six months to one year, and cost about $1-3 million.

Phase II: Immunogenicity. Phase II trials measure the safety and immune response in a larger sample of several hundred volunteers. They measure whether the vaccine candidate is stimulating the immune function or some other marker that may be indicative of protection. These studies are usually conducted in persons at high risk of HIV infection, typically take 6-24 months, and cost roughly $2-4 million.

Phase III: Efficacy. In the third and final phase before licensure, the efficacy of the vaccine candidate in protecting against disease is tested in a large population (5,000 to over 50,000 people). Efficacy is measured as the difference between rate of disease in people who receive the vaccine and in others who receive a placebo. The lower is the incidence of the disease in the population or the smaller is the anticipated impact of the candidate vaccine, the larger must be the sample of people who participate to demonstrate an effect. These studies take 2-4 years and can cost $10-30 million, depending on the size of the study.

A high level of efficacy does not guarantee an equivalent level of effectiveness when a vaccine is offered in the field. Efficacy trials typically select healthy volunteers and administer the vaccine or placebo under very carefully controlled conditions. Neither of these are assured in field conditions in developing countries. In a number of instances, so-called "Phase IV" "effectiveness" trials have been conducted to demonstrate the true costs and effectiveness of vaccines in typical field conditions.

V. What can the World Bank do?

The mission of the World Bank is to alleviate poverty and to promote economic growth. It pursues these objectives through three traditional channels—lending to developing country governments, engaging in policy dialogue, and conducting economic research.[13] In the case of an HIV vaccine, the World Bank objective is not only to ensure that a vaccine is developed, but also to guarantee the broad and early access of developing countries to a vaccine adapted to their needs. The World Bank does not lend money to the private sector of any country. However, the International Finance Corporation (IFC)—the World Bank group's investment bank for developing countries—can lend directly for private sector projects in developing countries. International Development Association (IDA) credits are available to the poorest countries on

[13] In fiscal year 1997, total World Bank commitments to developing countries amounted to $14.5 billion in IBRD lending and $4.6 billion in IDA credits. Since 1970, total World Bank lending for health, nutrition, and population (HNP) amounted to $14.7 billion. Over the years 1995-98, average annual lending for HNP was $1.6 billion.

highly concessionary terms. With the exception of a small amount of money provided through the Development Grant Facility (about $130 million per year), the World Bank does not make grants to developing countries or institutions.

Given its institutional mandate, what can the World Bank do to accelerate the development and availability of an HIV vaccine for developing countries? There is a range of possibilities that warrant consideration. First and foremost, the Bank can engage governments in policy dialogue, pointing out the economic impact of AIDS, the need for prevention, the issues surrounding development of an HIV/AIDS vaccine in developing countries, and actions that will promote the process. Such a dialogue will condition the effectiveness of any other instruments or mechanisms that the Bank might propose to accelerate an AIDS vaccine, and can also help to broaden and reinforce the commitment within governments and thereby buttress the work of agencies with a more specialized health focus. Beyond this, the Bank can seek to influence the private R&D investment for an AIDS vaccine through existing and future financial mechanisms or instruments. There are two strategies for this: "push" activities directly contribute to increasing R&D for an AIDS vaccine in the short run, and "pull" activities that provide incentives for private R&D by raising the expectation of a future return on these investments. An example of "pull" activities are different types of "assurances" on the size and profitability of a future market for vaccines in developing countries should a safe, effective, and low-cost vaccine be developed. A successful strategy is likely to incorporate intense policy dialogue accompanied by both "push" and "pull" interventions.[14]

Policy dialogue

The World Bank can play a crucial role in accelerating global HIV/AIDS vaccine development by elevating the seriousness of the AIDS epidemic in the dialogue with developing country policymakers, raising the level of political commitment to support HIV/AIDS vaccine research and development, and helping to forge partnerships between developing countries, industry, and international donors. The Bank's credibility and access to treasury and finance officials, as well as development/health leaders, puts it in a strong position to engage all actors in the policy dialogue, and reinforce the efforts of specialized agencies.

To raise the support for AIDS vaccine development, policymakers must first be convinced that AIDS is a serious development issue that will set back investments in all sectors of the economy if not addressed as early as possible with effective prevention efforts.[15] Since there is no HIV/AIDS vaccine and no cure for AIDS, the highest priority must be to prevent HIV in the most cost-effective manner, using existing proven interventions to change behavior. Policymakers also need to understand that an AIDS vaccine will be a useful, even critical,

[14] For a more detailed discussion of the specific "push" and "pull" instruments and issues of implementation, see the Background paper by Rosenhouse (1999).

[15] The Bank is in fact already engaged in this dialogue through current lending operations and analytic contributions, such as *Confronting AIDS* (World Bank 1997). These efforts could be reinforced.

prevention tool, but its availability at an affordable price and in a form that can be effective in developing countries cannot be assumed. Without the proactive involvement of developing countries themselves, it could easily be 20-30 years before an affordable vaccine becomes available for their needs. Partnerships between governments, industry, and civil society can pave the way for ensuring broad access to an effective and affordable vaccine by fostering political support and greater research and development for AIDS vaccines in developing countries with appropriate and transparent locally-determined safeguards. Vaccine development is a protracted process in which multiple candidates will have to undergo multiple efficacy trials in populations where the vaccine will be applied. While there are always risks involved in such endeavors, the developing countries bear very high risks of inaction.

"Push" interventions

Both basic research and clinical testing are essential in developing a new vaccine. In the case of HIV/AIDS, the basic research strategy is well funded by national research institutions in industrialized countries. Clinical testing and development of a marketable vaccine product has always involved the private sector. Push interventions lower the costs and risks of private R&D for an HIV/AIDS vaccine, either through direct subsidies or by lowering transactions costs.

1. Direct support for vaccine research

The most direct way of accelerating R&D for an HIV/AIDS vaccine in developing countries is to directly subsidize the relevant scientific research. However, as previously noted, the World Bank has very limited ability to confer grants and the grants that are awarded are small. Further, the World Bank does not have the capacity to evaluate the merits of alternative scientific approaches for developing an AIDS vaccine.

Nevertheless, the World Bank has supported HIV vaccine research indirectly through participation in the International AIDS Vaccine Initiative (IAVI), an international non-profit, non-governmental organization set up by the Rockefeller Foundation in 1996. IAVI's mission is to ensure the development of safe, effective, accessible preventive HIV vaccines for use throughout the world. Its objective is to stimulate investment and demand for HIV vaccines that will benefit the whole world, including developing countries. IAVI works with both the public and private sectors, pursuing this objective through advocacy, targeted support to R&D for novel vaccine approaches, and measures that reduce obstacles to private investment. Last year, it launched two vaccine development partnerships in sub-Saharan Africa. The World Bank contribution to IAVI has grown from $200,000 in 1997 to roughly $1 million annually in 1998 and 1999.[16] The World Bank is represented on IAVI's Board of Directors. Given the limited availability of grants from the World Bank (about $20 million in grants is available annually for the health sector), it is unlikely that its own financial contribution could be increased

[16] 1998: $1 million ($400,000 from the Global Forum for Health; $600,000 from the DGF); 1999: $940,000 from the DGF.

substantially under the existing structure.[17] Irrespective of whether additional grant funds could be found, the World Bank could play a role in leveraging contributions to IAVI from international organizations and bilateral donors to accelerate the vaccine product development and testing effort.

2. Reducing the costs or risks of vaccine clinical trials in developing countries

This strategy will accelerate the development of vaccines for developing countries, ensure that whatever product is developed will address the infrastructure and delivery constraints, and encourage investments by industry and donors in the infrastructure that would make immunization possible. Investments and improved collaboration will enhance the capacity of developing country researchers to engage in this type of research and the prospects for eventual local production of vaccines or important components of them.

This would be a new activity for the World Bank, but there are several ways that it might participate using its traditional instruments. This might include: elevating HIV/AIDS vaccines in the policy dialogue with developing country governments and smoothing the way for collaboration with industry for conducting clinical trials (discussed above); lending to developing countries for infrastructure and capacity building that are necessary to conduct vaccine trials; and lending for the finance of vaccine trials themselves in countries where partnerships have been established. In this activity, the Bank would presumably focus on elements that add to what is already being done through its financial contributions to IAVI.

"Pull" interventions

Pull interventions create incentives for increasing private R&D for an HIV vaccine for developing countries by demonstrating or guaranteeing a substantial market in developing countries or other form of financial return on investment.

1. Expanded lending for existing vaccines

Long-term promises to guarantee a market for an HIV vaccine would have greater credibility to industry if the international community found a way to stimulate the market in developing countries for priority vaccines that already exist. World Bank lending for vaccines and immunization programs historically has been relatively small—less than $20 million annually. Until recently, funding by UNICEF and bilateral donors was deemed adequate to finance vaccine purchase and delivery needs of developing countries. However, with the introduction of new vaccines that are more expensive (>$1/dose), this will no longer be the case.

[17] Larger contributions could be sought from the Bank's net income (after any necessary increases in reserves). However, this would require the approval of the entire membership of the World Bank, which would have to weigh the use of net income for funding HIV vaccines against other alternative uses—notably additional resources for IDA, which serves the poorest countries, or the Highly Indebted Poor Countries Initiative (HIPC). Furthermore, as net income is expected to experience a downturn in the next few years, the share for reserves is likely to increase.

The World Bank's institutional commitment to finance existing vaccines and immunization programs is already on the rise. In March 1998, World Bank President James Wolfensohn met with heads of public agencies and the vaccine industry at a meeting on "Vaccine Development and Delivery: Leadership for the 21st Century". The World Bank has launched an immunization demonstration project to explore how loans in 6-8 countries could increase the support for immunization and new vaccines. WHO, UNICEF, and the U.S. Centers for Disease Control and Prevention (CDC) will provide technical expertise on setting the priorities for immunization, structuring the loan component, and monitoring results. Building on the demonstration projects, the World Bank will identify a number of countries each year to target for heightened immunization support. It has committed to work more closely with industry and with other immunization partners such as WHO and UNICEF. The World Bank will also explore ways to increase vaccine financing through new financial instruments.

2. Providing better information on developing country markets

Private firms' decisions to invest in R&D for an HIV vaccine, as with other products, are highly dependent on their perception of some future lucrative market for sale of that product. The study of industry revealed that the investment decisions to date have been based almost exclusively on the potential market in OECD countries. Potential markets in developing countries have not entered their calculations. The level of private demand for the purchase of an HIV vaccine is unknown, and public sector purchase of other "new" priority vaccines in developing countries has been limited. Better information on the characteristics of vaccines that are likely to be demanded in developing countries and on the responsiveness of both public and private purchasers of an HIV/AIDS vaccine may alert firms to an important market segment they might otherwise ignore.

A desk study commissioned by the AIDS Vaccine Task Force reviewed the available information on the potential global demand for an HIV/AIDS vaccine estimated the public sector demand for AIDS vaccines under two different sets of decision rules (Bishai and others 1999). However, the validity of these decision rules is not known and to date there has been no basic research on the public or private willingness to pay for hypothetical HIV vaccines with different characteristics and prices. The process of collecting this information would have the added benefit of raising awareness among developing country policymakers about the current state of vaccine research, the characteristics and price of an HIV vaccine, and issues related to improving the access to a vaccine once it is available. Commissioning this work is within the mandate of the World Bank's AIDS Vaccine Task Force, and with sufficient resources could be included in its work program. Related to this, the World Bank could work with the UNAIDS secretariat and representatives from industry and developing countries to develop a set of priorities and guidelines concerning the optimal characteristics of an HIV vaccine for use in developing countries. Meeting such criteria could be the "trigger" point for market guarantee mechanisms, below.

3. Market assurances[18]

Increased knowledge of the potential developing country market for an appropriate HIV/AIDS vaccine alone is unlikely to be sufficient to change firms' R&D behavior because: (a) the potential commercially viable market may be small; and (b) there is still great uncertainty as to whether the potential market will materialize, given all of the political and economic shocks that can occur (or even development of a cure for AIDS) in the intervening time before an HIV vaccine is introduced. Uncertainty about the future market for an HIV vaccine in developing countries can be substantially reduced through agreements that "guarantee" purchase of a certain number of doses of an appropriate HIV/AIDS vaccine at an agreed-upon price at some future date, if such a vaccine is developed.

There appears to be no precedent for this type of activity in the international community—creating or assuring a future market so that the private sector will develop a technology. The World Bank has some experience with financial guarantees in its operations, but on a shorter time frame than would be necessary for development of an HIV/AIDS vaccine (Rosenhouse 1999). New financial instruments could be developed to meet the need for longer-term market assurances, taking into account different contingencies. Such instruments could be important new mechanisms for generating private investment in other high-priority public goods. In the course of deliberations, the World Bank AIDS Vaccine Task Force identified three main types of market guarantee activity that might be pursued.

(a) Vaccine purchase fund. A fund could be established for the purchase of HIV vaccines for the poorest countries or to provide matching funds provided developing countries themselves. The fund would be capitalized by contributions primarily from industrialized countries, although middle-income countries would also be invited to contribute. The trust fund could be financed now, allowing the fund to accrue interest, or financed in the future through government pledges or promissory notes. The trust fund monies would become available only if and when a vaccine was developed that meets very specific criteria, in terms of its price, effectiveness, and applicability for developing countries. This fund could be managed by the World Bank through an independent facility, according to agreed-upon access rules and a "trigger" mechanism or "contingency clause" that defines when the criteria for a vaccine have been met.

The World Bank has ample experience in setting up and administering trust funds created for specific purposes. The Global Environmental Facility (GEF) and the Heavily Indebted Poor Countries Initiative (HIPC) are two examples. It is also quite experienced in dealing with donor pledges, as they constitute the bulk of IDA's resources. However, the trust funds administered by the World Bank generally disburse soon after they are replenished, and the government promissory notes that finance IDA are valid over a 3-year time frame. An HIV/AIDS vaccine for developing countries could take 10-15 years to develop. The main issue to be addressed is

[18] For a detailed description of existing types of World Bank guarantees, contingent-type loans, and options for market assurances, see Rosenhouse (1999).

whether donors would be willing to commit funds with a 10-15 year lead time, and whether industry believes that these promises will materialize.

(b) Contingent loans and credits. The World Bank could issue IBRD loans[19] and/or IDA credits to developing countries to finance the strengthening the borrower's vaccine delivery capacity and the purchase of HIV/AIDS vaccines when a suitable vaccine is developed. The loans or credits would be agreed to in the present; part or all of the disbursements would be contingent on the development of a viable vaccine—that is, one that meets the same criteria as might be established for the trust fund, discussed above.

The World Bank has some experience in contingent lending. It has made loans to back up government facilities that provide guarantees against commercial and political risk to the private sector. These loans only disburse if claims are made.[20] Contingent loans have also been used to reduce the impact of liquidity shocks on the borrower's banking system in the event of severe capital flight. However, the period over which risk is covered in both cases has never exceeded five years. Given the unknown demand for funds for alternative uses in the distant future by both the World Bank and client countries, the main issues for contingent loans for an HIV/AIDS vaccine are, first, whether the IBRD and IDA would be willing to commit resources with such a long time horizon, and second, whether developing countries would be willing to borrow on a contingent basis so far out into the future.[21] A related issue is whether such "promises to borrow" are viewed as credible promises by firms responsible for investing in R&D for an HIV/AIDS vaccine.

(c) High-profile international public signing of intent. Public visibility can be a powerful incentive for public action and strengthen the commitment of the international community to eventually purchase an HIV/AIDS vaccine for developing countries. The World Bank would coordinate public pledges to purchase an HIV/AIDS vaccine by donors and client countries, in international forums with wide press coverage and attendance of heads of state or other high officials. This would give greater prominence to the problem of generating adequate R&D on technology that is an international public good, in general, and specifically for an AIDS vaccine. It would give greater visibility to governments who commit themselves by providing resources now or in the future.

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[19] International Bank for Reconstruction and Development, the arm of the World Bank that lends primarily to middle-income developing countries at market rates.

[20] The World Bank has made these types of loans when conditions do not permit the involvement of the Multilateral Investment Guarantee Agency (MIGA), which cannot cover short-term non-equity transactions, or IFC, which cannot lend to governments.

[21] While there are disincentives for both borrowers and the Bank, under the existing framework, to commit to future lending, the Bank has recently developed a new lending instrument—the Adaptable Program Loan—that is designed to fund a program of activities to achieve an agreed upon development objective over a long-term horizon. The project is designed as a sequence of loans for phased support of the program, with agreed objectives, triggers, and indicators of outcomes/impacts for each phase of the program. For additional discussion on how the APL might be adapted to the issue of AIDS vaccines, see Rosenhouse (1999).

VI. Issues

As an international institution committed to economic growth and poverty alleviation, the World Bank has a vital interest in the development of a preventive HIV/AIDS vaccine that will stop the spread of a virus that is already having such a huge impact on the poorest countries. Scientists believe that an AIDS vaccine is possible. This note has provided an analysis of the problem of underinvestment in R&D for an HIV/AIDS vaccine, a discussion of the main reasons from the perspective of firms, and a summary of the main mechanisms by which the World Bank might accelerate the development and availability of an AIDS vaccine for developing countries.

The AIDS Vaccine Task Force must now develop proposals to World Bank management and the Board of Directors for the most effective way forward to accelerate an AIDS vaccine for developing countries as part of the Bank's broad strategy to combat AIDS. Such proposals might draw on existing World Bank instruments or propose the development of new ones; it will certainly incorporate a combination of policy dialogue and both "push" and "pull" activities. However, the success of the strategy and any new instruments will depend centrally on the extent to which they are seen as relevant and practical by the World Bank's members, by task managers within the institution, and by industry. New financial instruments can be effective only if there is some demand for them by developing country borrowers and by those who might contribute.

At this stage, therefore, the AIDS Vaccine Task Force is requesting feedback from the development community particularly on the following issues:

1) What are the views of industrialized countries, developing countries, and international institutions on the feasibility, desirability, and potential support for different World Bank options such as those set out in this paper?

2) Are there other ideas or activities that would accelerate development of an HIV vaccine for developing countries in which the World Bank could play a particularly useful role?

3) Are there complementarities between these options and current or planned activities on vaccines by bilateral and multilateral partners – and can these be developed and exploited?

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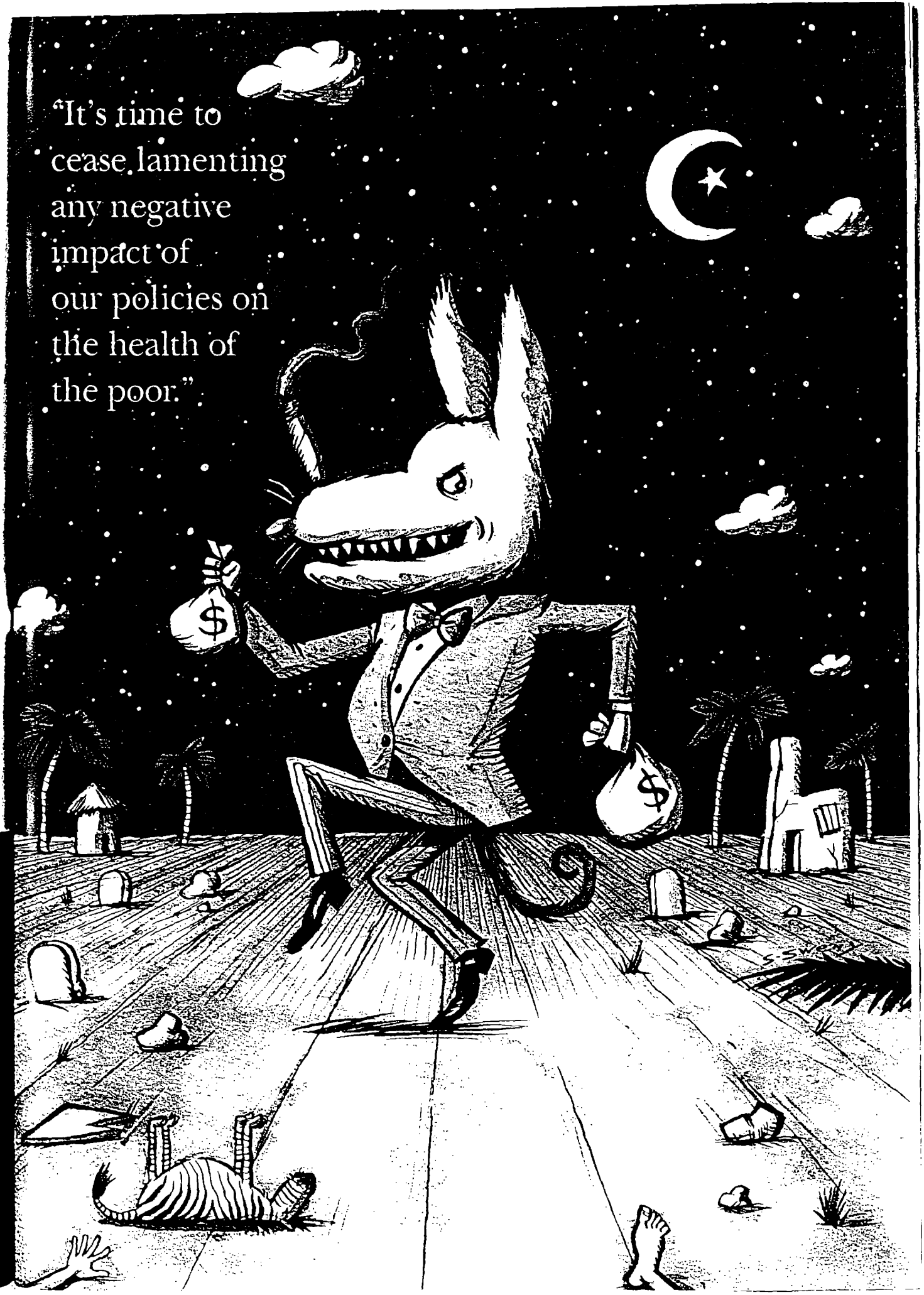
African nations are slashing budgets and shrinking health care. The World Bank and the IMF call it streamlining. Critics say it's killing PWAs

Banking on Disaster

Aseffa Okoso was a strong, imposing man with a hearty laugh and a gentleness that defied his stature. He lived in a small city in Ghana, a West African country hard-hit by AIDS. Okoso had a wife, five children and many friends with whom he shared his repertoire of jokes and songs. ■ For eight years, Okoso worked in an American-owned gold mine. But in 1996, at age 43, he began to waste and was diagnosed with AIDS. At first, he was able to pay for antidiarrhea medicines, but after his illness forced him to leave his job, medical expenses were beyond his means. When Okoso's family had trouble handling the financial burdens of his illness, his friends helped him pay for care. But knowing that they were poor as well, Okoso eventually stopped accepting their assistance. ■ Three months after leaving the mines, Okoso—suffering from both chronic diarrhea and tuberculosis—gave up on health care altogether. ■ Though a

BY JOYCE MILLEN AND BOB LEDERER

ART BY STEPHEN SWENY FOR *POZ*


"It's time to cease lamenting any negative impact of our policies on the health of the poor."

clinic was just a few miles away, he chose to stay home. As Okoso said at the time: "We live day to day on what my wife makes selling vegetables in the market or what my sons bring home from selling things on the streets. If I went to the clinic, they would make me pay a new fee, which my family cannot afford." And any prescription he received for meds would be out of his reach as well. Ultimately, Okoso died of TB—an easily treatable illness—just seven months after being diagnosed with AIDS.

Okoso's story is typical of the 90 percent of people with HIV worldwide who live in poor countries—approximately 28 million, the UN estimates. According to Paul Farmer, MD, an author and infectious disease specialist who divides his doctoring between Harvard Medical School and rural Haiti, "In much of Africa, Asia and Latin America, PWAs die far more quickly than do their counterparts in Western Europe and North America, largely because they lack access to effective care." He notes, for example, that most PWAs in poor countries are, like Okoso, killed by TB, a disease that can be treated for as little as $36 per person. Other common killers, such as diarrhea and fungal or parasitic infections, can be treated for just pennies a day.

But for cash-starved governments with rising AIDS caseloads, those pennies add up fast. That's a particular crisis for sub-Saharan Africa, where the UN estimates that 21 million have HIV, about 17 percent of the sexually active population. As Farmer says, "Most PWAs in Africa can't afford an aspirin—let alone $12,000-a-year protease cocktails." World Bank figures show that the average amount spent by African countries on health care is less than $14 per person per year—compared to $2,763 in the United States.

Yet spending was not always so low. After independence in the 1950s and 1960s, many new African governments set out to redress the inequities created by European colonial rule by providing expanded and free—or at least low-cost—health care to their populations. By the 1970s, according to the United Nations, such health indicators as life expectancy and infant mortality had begun to improve significantly in those countries.

But by the 1980s, even before the AIDS crisis established a stranglehold on the continent, much of Africa—including Okoso's Ghana—plunged into a severe and still-ongoing economic crisis. Country after country saw worsening rates of poverty, hunger and disease, including HIV infection. Average incomes fell to that of 1960s levels—a decline of as much as 50 percent in some cities. But rather than expanding health services to meet growing needs, governments began slashing—in some cases dismantling—their health care programs.

Budget cuts slashed the number of doctors in Ghana by half.

Many analysts charge that not only these massive health care cuts, but also the escalating poverty, are largely the result of harsh economic austerity measures. Called "structural adjustment programs" (SAPs), they have been imposed on more than 70 developing nations (40 of them African) since the early 1980s by two powerful international financial institutions: The World Bank (WB) and International Monetary Fund (IMF).

The problem dates back to the 1970s, when commercial banks, heady with deposited oil profits, extended substantial loans throughout the developing world. Within a few short years, as interest rates skyrocketed and commodity export prices collapsed, many countries were about to default. So international lending institutions moved in to protect the commercial banks.

The IMF and WB, largely controlled and funded by governments of the United States, Japan and the wealthiest Western European nations, made SAPs the precondition for new loans to poor countries seeking to escape from their crushing debts. SAPs, which parallel the United States' "government downsizing" policies of recent years, are characterized by lifting worker protections and environmental regulations, devaluing currencies, granting foreign investors tax breaks, ending food subsidies and slashing public spending through layoffs, pay cuts and privatization. Any indebted government refusing to adopt SAP conditions is threatened with being blacklisted for loans by most Western banks and cut off from U.S. foreign aid.

A 1994 WB report explained the rationale: "SAPs are designed to pave the way for long-term development and prosperity by fundamentally restructuring African economies." The theory holds that by promoting exports (made cheaper by currency devaluation) and reducing "inefficient" government spending, SAPs will help poor countries earn enough foreign exchange to pay back their debts. This economic growth, the argument goes, will eventually trickle down to reduce poverty and improve public services such as health care.

But by all accounts, the human costs of SAPs—still in effect in almost every nation where the poorest PWAs live—have been devastating. Reports from government health ministries, private aid organizations, independent academics, the UN and even the WB itself have found that every country adopting SAPs has suffered significant backslides in health and welfare.

In Africa, SAPs have been particularly disastrous for PWAs: Medicines have become prohibitively expensive; basic drugs and equipment are unavailable to most health facilities; hundreds of clinics are closed or grossly understaffed; malnutrition has increased, contributing to rising disease rates; and water-filtration and sanitation budgets have been slashed, prompting a resurgence of such communicable diseases as cholera, hepatitis and typhoid.

The *British Medical Journal* has reported that in the early years of SAPs, Ghana—widely touted by the WB as a "success story"—had to reduce its health budget by 47 percent (the average cut for sub-Saharan Africa

from 1980 to 1985 was 26 percent). SAP-inspired civil service layoffs and salary cuts forced many doctors and nurses to moonlight or even emigrate. According to the WB, the number of doctors in Ghana decreased by almost half between 1985 and 1991. Similar medical brain drains continent-wide have crippled patient care.

Those who have stayed behind are crushed in overwork. The story of Demba Djemay, a highly trained nurse in Senegal—another WB-touted model—is typical. Although he works in a small hospital near his hometown, he is largely unable to use his skills to care for patients—many of them PWAs. His hospital lacks the most basic equipment and medicines. Besides Djemay, only one other nurse and a part-time physician serve a region of more than 250,000 people; Djemay sees up to 70 patients a day. "My work is one frustration after another," he laments. "Under these conditions, I simply can't provide my patients the kind of care they urgently need." Many of them must wait for hours, even days, to see him. And once they do, most cannot afford the few available meds.

Besides such direct reductions in health spending, the SAP measure most often blamed for the breakdown in medical systems is the imposition by some 30 African governments of "user fees." One WB report argued that the pre-'80s policy of many African states "to treat [health care] as a right of citizenry and to attempt to provide free services to everyone...prevents the government health system from collecting revenues that many patients are both able and willing to pay." Another report added, "When a service costs money, people will think twice about demanding it." Aseffa Okoso, the PWA from Ghana, was living proof of that—until he died. And in country after country, according to Oxfam, a nonprofit development aid organization, user fees led to a 40 to 65 percent decline in attendance at health facilities, including STD clinics.

"The combination of user fees and highly inflationary currency devaluation has meant that people can no longer get the medicines they need," says Mary C. Smith Fawzi, a Harvard epidemiologist conducting AIDS research in Tanzania. "For PWAs, that often means no antifungals or antibacterials, essential for treating opportunistic infections."

Another SAP measure—privatization of governmental functions—is further jeopardizing access to medications. The WB has strongly urged governments to dismantle such programs as centralized purchasing of pharmaceuticals (which allows for bulk discounts) and drug price controls.

Meanwhile, some researchers maintain that SAPs help increase HIV *transmission*. In 1995, Peter Lurie, MD, a research scientist who spent years studying AIDS in developing countries and is now at the University of Michigan, reported (along with two colleagues) in the journal *AIDS* that SAPs, besides reducing medical care, "may have created conditions favoring the spread of HIV infection" by increasing levels of poverty, driving subsistence farmers off their land, and promoting mass migration to urban centers where HIV is widespread. In a letter to *AIDS*, the WB unsuccessfully attempted to dissuade the editor from publishing the paper, which it labeled "nonsense."

Indeed, the WB—which has taken the lead in defending SAPs—has often accused critics of falsely connecting its policies with Africa's recent medical crises. In a 1995 publication, WB officials wrote, "It is time to cease lamenting any possible negative impact of SAPs on the health of the poor in Africa." And A. Edward Elmendorf, the WB's health specialist for Africa, argues, "During the adjusting years, health sector spending was reduced in some countries in Africa, but this decrease was due to economic decline, not SAPs." The WB blames that decline on a range of factors, including government mismanagement, corruption, overpopulation, droughts and even the AIDS epidemic itself. Officials insist that the WB never specifically required cuts in medical spending. And WB research associate Martha Ainsworth says her agency has even taken steps to protect local populations: "As part of its adjustment lending, the Bank has often included programs of social assistance for people who otherwise might be hurt in the short run."

In fact, the WB says it helps fight AIDS in Africa, citing $800 million in easy-repayment loans granted since 1986 to 27 sub-Saharan African nations for AIDS-related projects. But the majority of this funding has gone into prevention efforts or research programs. Only recently has the WB begun to address the problem of *treating* AIDS, granting African countries several small interest-free loans to purchase drugs for STDs and TB. Last December, the WB, a key participant in the UN's AIDS program, helped launch a pilot project offering loans to four poor nations, two of them African, for the purchase of antiretroviral drugs at greatly reduced prices.

"They give with one hand while taking with another," says the University of Michigan's Lurie. "SAPs and growing external debt undermine governments' capacity to care for PWAs, so the World Bank comes back with nominal efforts to prevent the worst effects. It's too little, way too late."

Silvia Federici, an associate professor of political philosophy at Hofstra University, has researched the IMF and WB extensively and challenges the agencies' assertion that they don't exercise power over national health policies. She says, "IMF reps sit on its central bank board, no major economic project can be launched without their approval, and every few months the government must plead with foreign agencies for debt rescheduling or new loans."

The ultimate defense offered by WB officials is that, as one report put it, SAPs "may take five or more years to bear fruit." But the Bank's chief economist for Africa admitted in 1991, "We did not think that the human costs of these programs could be so great, and the economic gains so slow in coming."

Neither did many elected officials in some lender nations, until recent years. In a 1995 open letter to the WB and IMF, 130 U.S. representatives, 30 U.S. senators and 1,200 parliamentarians from Western countries wrote that SAPs "have too often been associated with lower incomes for the poor and reductions in basic education and health." The letter called for reforms of SAPs—including protecting health spending and avoiding medical user fees—as well as increased loans for health and education.

The WB responded by promising to pressure indebted governments to spend more on social programs and to make more loans to support such efforts. Yet WB figures show that a year later, its lending for health and education programs actually *declined* from $4 billion to $2.25 billion.

The core of the problem remains the crushing debt burden, which, ironically, has *increased* in most of these countries, despite SAPs. The WB says that between 1980 and 1995,

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sub-Saharan Africa's external debt rose from 92 percent to 242 percent of its annual exports. The Africa Policy Information Center recently reported, "Africa now spends four times as much on debt repayment as on health care." No wonder that when President Clinton toured the continent in April, *The New York Times* reported, "The subject of debt relief had been raised by every African leader he had met."

Lurie and his colleagues wrote in their 1995 *AIDS* article, "The charters of the IMF and the World Bank must be altered to permit the cancellation or rescheduling of debt." They also called for the relaxation of strict SAPs. Such sentiments have echoes around the world, most prominently in the form of three grassroots pressure campaigns.

One is coordinated by the African Women's Economic Policy Network, a coalition of women's organizations working "to halt SAPs in Africa," while educating women to demand more equitable economic policies from both their national governments and the IMF and WB.

The second campaign, based in Washington, was launched in 1994 on the half-century anniversary of the two institutions' founding. The 50 Years Is Enough Network, composed of more than 300 religious, social-justice and development organizations worldwide, seeks, as its position paper states, to "reorient [the IMF and WB] to sustainable and participatory practices that alleviate poverty rather than exacerbating it" and to cancel 100 percent of the debt owed those institutions by the most severely indebted poor countries.

A third international coalition, Jubilee 2000, led by hundreds of religious organizations, calls for "cancelling unpayable debts of the world's poorest countries by the year 2000."

Where would the money for this come from? Advocates argue that the banks themselves could certainly afford those write-offs, since most indebted countries have long since repaid their loan principal.

Lobbying, letter-writing and demonstrations by these advocates and others have finally prompted the WB and IMF to respond. In a plan labeled "good news for the world's poor" by the WB's president, the two agencies have proposed to cancel between 67 percent and 80 percent of a country's debt—but only if its government is deemed in full compliance with SAPs and other harsh economic directives. Few nations have so far met that test. Even when they do, the plan will take several years to go into effect.

While words like "structural adjustment programs" and "debt relief" are increasingly being heard at AIDS conferences in developing nations, Western AIDS advocates have been slower to catch on. But the issue of inequitable treatment access for the poor reached center stage in several speeches at the 1996 International AIDS Conference in Vancouver. The official slogan of "One World, One Hope" was mocked by a group of angry African delegates who unfurled a banner that read, "What World? What Hope?" At the World AIDS Conference in Geneva this July, the theme is "Bridging the Gap," implying a readiness to confront the crisis in developing-world AIDS care.

But turning the rhetoric into reality will require tackling the deeper roots of those inequities. Peter Lurie believes that action is needed. "Until steps are taken to alleviate the crushing burden of African debt, lifesaving and life-extending AIDS therapies will remain out of reach for those who need them most." ■

World Bank HIV/AIDS Interventions: Ex-ante and Ex-post Evaluation

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World Bank Discussion Paper No. 389

The World Bank
June 1, 1998

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Foreword

The AIDS epidemic is one of the greatest development challenges of the 20th century. Since 1986 the World Bank has supported member country efforts to fight the epidemic in many ways, including lending, economic and sector analysis, grant support, technical assistance, and policy advice. This paper is the first comprehensive desk study of all World Bank HIV/AIDS-related activities from the perspective of public economics. It was prepared as a background paper for the recent World Bank Policy Research Report, *Confronting AIDS: Public Priorities in a Global Epidemic*. The paper is intended primarily for the use of World Bank staff, but we hope that it will also provide guidance to governments, other international agencies, and non-governmental agencies in the design and implementation of HIV prevention and mitigation programs. Learning from World Bank experience can help the Bank, together with its member countries, to confront the AIDS epidemic more effectively.

Abstract

This paper evaluates World Bank activities to prevent and mitigate the effects of AIDS in all regions of the developing world during fiscal years 1986 to 1996. It first prioritizes HIV-prevention and treatment interventions using the principles of public economics. Based on this framework, it assesses the appropriateness of Bank lending and grants, Bank Country Assistance Strategies, and country economic and sector work. While the Bank provided extensive assistance for efforts to collect information (surveillance and behavioral studies), support was less extensive for interventions that focus on reducing risky behaviors of those at highest risk for contracting and transmitting HIV. Few of the projects reviewed in the paper relied on strong economic analysis in ex-ante or ex-post evaluation. These findings suggest two primary challenges for the World Bank: (i) to focus its support for HIV prevention interventions that reach groups at highest risk to contract and spread HIV; and (ii) to improve the economic analysis used in preparing Bank HIV-related projects and in evaluating their effectiveness.

I. Introduction

Between 1986 and 1996, the World Bank committed over US $ 550 million to HIV/AIDS prevention and mitigation efforts. This paper assesses the appropriateness of Bank interventions from the perspective of public economics and reviews the economic evaluation and implementation of projects. It focuses on 27 countries, selected either because AIDS is a particularly severe problem or because the Bank is especially active in the country (Table 1).[1]

This study follows three previous reports on HIV/AIDS interventions supported by the World Bank. The first set out an agenda for World Bank action in Africa (World Bank, 1988). The second and third reports also focused on Africa and updated the Bank strategy (Lamboray and Elmendorf 1992 and World Bank 1996). Lamboray and Elmendorf (1992), building on the 1988 strategy, concluded that additional World Bank efforts should focus on promoting behavioral change among core groups, treating other sexually transmitted diseases, and on convincing central financial and planning agencies in African governments to focus on AIDS and its implications for development. The third report, *AIDS Prevention and Mitigation in Sub-Saharan Africa: A Strategy for Africa* (World Bank 1996), identified five new tasks for the Bank: (i) help to generate political commitment to OAU declarations on AIDS; (ii) work more vigorously to change behavior; (iii) intensify national programs according to a typology of countries based on severity of prevalence levels; (iv) increase the analysis of AIDS and its impact on development goals in economic and sector work; and (v) improve the design and implementation of cost-effective approaches to mitigate the consequences of AIDS.

Whereas past reviews have taken primarily a public health perspective, this paper evaluates the Bank's role from the perspective of public economics. It also reviews, for the first time, World Bank AIDS activities in all regions of the world. The paper focuses on World Bank lending, although reviews of HIV/AIDS coverage in Country Assistance Strategies and country economic and sector work are included in Appendices A and B, respectively. Section II discusses the public economics rationale for AIDS interventions. Section III reviews Bank lending for HIV/AIDS prevention and mitigation interventions. Section IV evaluates ex-ante and ex-post project evaluation. The final section draws conclusions.

[1] This paper reviews the same 12 African countries reviewed in World Bank (1996).

Table 1: Stages of the Epidemic for 27 Developing Countries

Nascent *Less than 5 percent of high risk groups infected*	Concentrated *More than 5 percent of high risk groups infected, less than 5 percent of women in urban antenatal clinics infected*	Generalized *5 percent or more of women in urban antenatal clinics infected*
Indonesia	Brazil	Botswana
Morocco	China	Burkina Faso
Philippines	Honduras	Burundi
Yemen	India	Central African Republic
	Mexico	Congo
	Thailand	Côte d'Ivoire
	Vietnam	Haiti
		Kenya
		Malawi
		Rwanda
Stage of Epidemic Unknown:		Tanzania
Kyrgyz Republic		Uganda
Romania		Zambia
		Zimbabwe

Source: Statistical appendix, Table 2, *Confronting AIDS: Public Priorities in a Global Epidemic*

II. Public economics and priorities for HIV prevention and treatment[2]

The principles of public economics provide a framework for making decisions about which activities merit government action and, among these, which should be priorities. From this perspective, there are two main reasons for government intervention: to maximize total social well-being – usually correcting a market failure and thereby enhancing efficiency – and to promote a more equitable distribution of well-being among social groups. Based on these principles, the recent World Bank Policy Research Report *Confronting AIDS: Public Priorities in a Global Epidemic* identified three activities in which governments have an indispensable role in ensuring the efficiency and equity of HIV prevention programs.

First, governments have a role in providing public goods related to prevention, such as the collection and dissemination of information about the epidemic. Information about the HIV/AIDS epidemic and how to avoid infection is a true public good. This means that those who gain access to new information subtract none of its value from others. Although in some case it is possible to restrict access to information by, for example, selling it, the information is often passed on to people who did not purchase it. Because of this, private firms, on their own,

[2] This section is based on *Confronting AIDS: Public Priorities in a Global Epidemic*, World Bank, 1996.

are likely to produce less information than is socially optimal and so there is reason for the public sector to subsidize or provide public goods. This is particularly true of epidemiological surveillance of infection rates, for which the value lies in making the results well-known. But the public role for producing information also includes country-specific information on how to identify and reach people at the highest risk of becoming infected with HIV and spreading it to others. In addition, research that will improve the effectiveness of prevention interventions is also a public good.

Second, governments need to support programs that reduce the negative externalities of risky behavior among people most likely to contract and spread HIV. An *externality* occurs when a transaction between two parties creates an unpriced effect on another party. In the context of HIV in developing countries, the largest externalities arise in the context of consensual sexual relations. Although the individuals involved can weigh their own individual risks, their activities still have consequences for their other (current and future) sexual partners. Ideally, those involved would consider these effects and decide to engage in safer sex. But the problem is that behavior -- safe or risky -- is difficult to prove. This means that individuals are likely to under-invest in activities that reduce the risk of infecting future partners, such as using condoms and treating other STDs. Because of the enormous positive externalities (of lowering HIV transmission) associated with these two activities, there is a clear role for governments to invest in them. Since HIV is transmitted sexually, the positive externalities of using condoms and being free of STDs are greatest for those individuals who have many sexual partners or needle-sharing partners. The more focused prevention interventions are on these groups, the more effective they will be in reducing HIV transmission.

Another example of an externality is mother-to-child transmission. Although this is a clear example of an externality in that the infant cannot control his or her exposure to HIV, the role for developing governments in directly preventing mother-to-child transmission may be limited in the context of scarce resources. This is because the externalities created by mother-to-child transmission are not very large as compared with externalities created others (e.g. those with many sexual or needle-sharing partners). Although mother-to-child is a horrible tragedy, it does not result in many secondary infections. Preventing the mother from becoming infected by HIV in the first instance may be the best strategy for developing countries, and this can be done

most effectively with HIV prevention programs for those who have the largest number of partners.

Third, the government has a role in promoting equity by ensuring that the most destitute are not denied access to the means to protect themselves from HIV. The government may want to subsidize clean blood for the poor, who cannot afford to purchase it. Safety net programs that help to reduce the vulnerability of poor households are especially important for those households that experience the death of a prime-age adult from AIDS. When women have low status, they are in a weak position for bargaining safer sexual relations. Thus, governments should also work to improve the status of women by expanding educational and employment opportunities and providing more legal protection. These policies merit support for economic and social reasons beyond the context of the AIDS epidemic, but the presence of the epidemic exacerbates the need for them.

Prioritizing among HIV/AIDS interventions

Using these principles of public economics and some general intuition about cost-effectiveness, it is possible to prioritize among types of interventions (Box 1). The exact mix of interventions will necessarily vary by country, depending on: (i) the stage and characteristics of the AIDS epidemic, which vary dramatically from country to country; (ii) the cost-effectiveness of particular interventions in that country; (iii) the level of resources available to confront HIV/AIDS, which usually depends on the level of economic development of the country; and (iv) the political support and implementation capacity in the country.[3]

Three prevention priorities are particularly efficient and potentially very cost-effective: (i) condom promotion/subsidy for high risk groups; (ii) STD treatment for high risk groups; and (iii) financing operational research and surveillance. There are other important policies that should be supported for reasons other than AIDS. These include improving the status of women, enforcing laws against rape and exploitation of minors, and supporting anti-poverty programs that help reduce the vulnerability of poor household. Finally, broad-based mass-media information campaigns, subsidized HIV testing and financing clean blood are not generally not as efficient or cost-effective.

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[3] Political support and implementation capacity in the country will not be discussed in this paper.

Box 1: Prioritizing Government HIV/AIDS Interventions Based on Public Economics

PRIORITY INTERVENTIONS:

- Finance operational research and disease surveillance
- Treatment STDs, particularly for high risk groups
- Promote/subsidize condoms for high risk groups
- Improve status of women by expanding educational and employment opportunities and more legal protection[1]
- Enforce laws against rape and exploitation of minors[1]
- Support anti-poverty programs that help reduce the vulnerability of poor household to the loss of a prime age adult[1]

OTHER (NON-PRIORITY) INTERVENTIONS

- Broad-based mass-media information campaign
- Subsidy for HIV testing for individuals
- Provision of safe blood

[1] There are other social reasons for supporting these policies, but the AIDS epidemic increases their importance.

III. World Bank projects that support HIV/AIDS interventions[4]

Between 1986,when it started lending for HIV/AIDS interventions, and 1996, the World Bank financed 60 projects in 41 countries, for a total commitment of US$ 552 million. This included nine free-standing AIDS projects and 52 projects with an AIDS component. Eight of the projects have been completed and about a dozen projects with an AIDS component were under of preparation as of June 1996. Since then, another freestanding AIDS project, the Argentina AIDS and STD Control Project (US$ 15 million) has been approved and at least two more are planned (for India and Guinea Bissau). All except one of the existing project are in the health or human resources sector and the implementing agency is almost always the Ministry of Health. The exceptions is the Uganda Transport Rehabilitation Project, which supports an AIDS awareness campaign in Districts that participate in the rural feeder roads campaign. The Bank also provides support for HIV prevention and mitigation through various grant programs (Box 2).

[4] This review is based on the project descriptions in the Staff Appraisal Reports (SAR). Any additions and/or changes made to the project since then have not yet reflected in this discussion.

Box 2: World Bank Grant Support for HIV/AIDS Prevention and Mitigation

The Bank finances grants for HIV prevention and mitigation and it also administers grant programs for other organizations. Most grant support is provided through four umbrella programs: the Special Grants Program, the Japanese Program for Human Resources Development, the NIARSH East Africa Initiative and the World Bank Small Grants Program.

The Special Grants Program recently funded a $9 million dollar, three-year program to support UNAIDS and several regional HIV prevention initiatives. The main purpose of the grant is to support the global effort to prevent the transmission of HIV/AIDS. UNAIDS, which has been established to inspire, focus and strengthen this effort, is the executor of this 'bundle' grant to support four activities:

- ***UNAIDS.*** The grant provides US $ 1 million to support efforts to coordinate HIV/AIDS policies, programs and funding. UNAIDS helps to establish a stronger link between AIDS and broader social, developmental and humans rights issues, in addition to providing policy, strategic and technical guidance.
- ***The Western Africa HIV/AIDS Prevention Projec***t. The project facilitates a coordinated response to the epidemic in three ways: (i) advocacy -- mobilizing political and opinion leaders throughout West Africa to address HIV/AIDS issues; (ii) pilot interventions - testing innovative ideas, particularly those relating to cross-border issues and commercial sex work; (iii) capacity strengthening-- enhancing capacity to identify, design, implement and monitor/evaluate inter-country and multi-sector projects.
- ***The Latin American and Caribbean Regional Initiative for AIDS/STD Control***. The overall objective of the grant is to mobilize and unify national and international efforts against HIV and other STDs. The project will be implemented over a period of three years and will finance (i) a series of regional studies on the epidemiology of HIV/AIDS, the impact of the epidemic on health service utilization and costs, and cost-effectiveness of alternatives, among other topics; (ii) a series of regional seminars and (iii) one regional conference.
- ***The South-East Asia HIV/AIDS Project***. The project serves Cambodia, Laos, Malaysia, Myanmar, Philippines, Thailand, Viet Nam, and the Yunnan Province in China by assisting them to strengthen national and regional responses to HIV/AIDS. This includes promoting and facilitating analytical work, policy tools and intervention options, consensus building and institutional development.

The Japanese Program for Human Resources Development (PHRD) sponsored a range of small research projects, mostly on the impact of AIDS, that help to guide the design of forthcoming Bank projects. The NIARSH Eastern Africa Initiative, financed by a group of donors, provides 1.3 million in funding for a range of prevention activities in Eastern Africa.

The World Bank Small Grants Program has made five grants in support of AIDS related activities, for a total of US $ 56,000.[1] In four of the five grants, the funding helped to support an NGO or a network of NGOs to host a conference or workshop. These have included a workshop sponsored by Education International, an NGO based in Togo, on 'School Health and HIV/AIDS prevention' and another workshop organized by HelpAge Zimbabwe on the impact of AIDS on older people. A grant to an Indonesia NGO Yayansan Kusuma Buana (YKB) supported the publication and dissemination of IEC materials for distribution at STD service outlets, public health facilities, and by other NGOs.

[1] The five grants were: US$ 10,000 to HelpAge Zimbabwe for a workshop; US$ 6,000 to Swaziland Network of AIDS Service Organizations for a workshop; US $15,000 to Education International (Togolese NGO) for a workshop; US$ 14,000 to YayasanKusuma Buana (Indonesian NGO) for IEC materials; and US$ 11,000 to the Asia Center in Thailand for an AIDS prevention seminar in Bangkok.

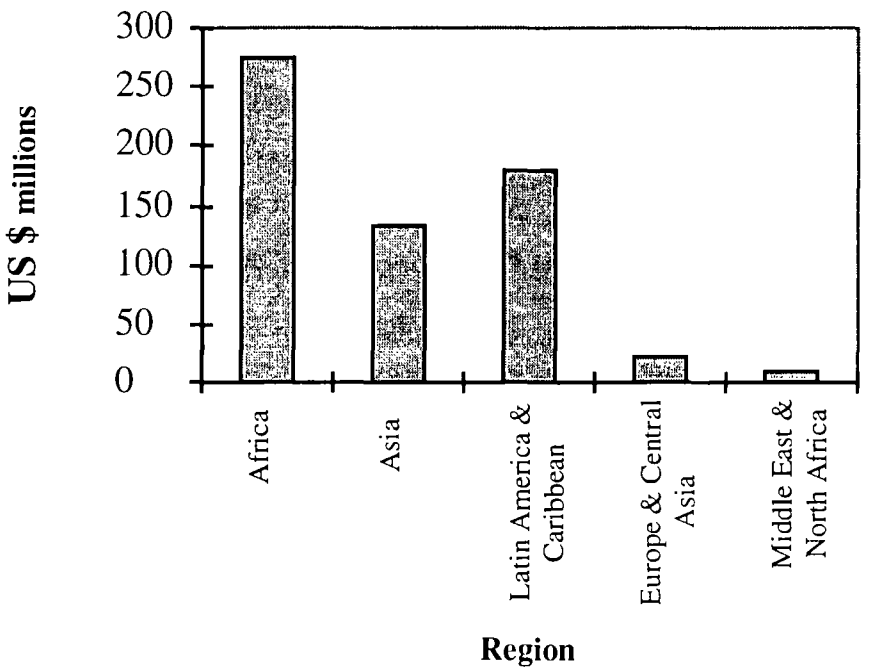
Source: Internal Bank grant proposal documents

A regional breakdown of this lending shows that almost half of the lending, US$ 274 million was directed towards 42 projects in the Sub-Saharan Africa region (Figure 1). Lending for four projects in Latin America amounted to US$ 173 million, much of which was allocated for the large loan for Brazil. The Bank has supported seven loans, equivalent to US$ 131 million, for HIV/AIDS interventions in South and East Asia, including two free-standing loans

for national AIDS prevention programs in India and Indonesia. Bank financing of AIDS prevention and mitigation activities in other regions of the world was more limited. Three projects in each the Eastern and Central Europe and the Middle East and North Africa regions have supported AIDS interventions.

Overall, most Bank lending for AIDS interventions took place between 1992 and 1994, when the Bank financed many of its large, free-standing AIDS projects, such as those for India (US$ 84 million) and Brazil (US $ 160 million) (Figure 2). Lending in the 1980s was disbursed in smaller amounts, usually as components of larger loans to countries in Africa.

Figure 1: World Bank Lending for HIV/AIDS Interventions, by Region, 1986-96



Source: Author's calculations