

IMAGINE A WORLD WITHOUT AIDS



THE INTERNATIONAL AIDS VACCINE INITIATIVE  
2006 ANNUAL PROGRESS REPORT



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The full text of this report is available online at <http://www.iavi.org/2006report>

## IAVI'S MISSION is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

This report is dedicated to the late Professor Job Joab Bwayo and Dr. Kenneth Anthony Kalanyi Kebba, who were IAVI friends and colleagues as well as devoted scientists and leaders in the AIDS vaccine development field. In their memory, and for the nearly 40 million people living with HIV, we remain committed to finding an effective AIDS vaccine, the world's best hope for ending the AIDS pandemic.

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# Contents

Acronyms .....	i
Message from The President .....	ii
Executive Summary .....	iv
<b>I.</b> Accelerate Research & Development of AIDS Vaccines .....	1
<b>II.</b> Mobilize Strong and Sustained Global Commitment .....	7
<b>III.</b> Advocate for Public Policies that Support Vaccine R&D and Future Access .....	17
<b>IV.</b> Partner with Countries where the Epidemic is, or is Likely to be, Most Severe .....	23
<b>V.</b> Operate an Optimally Efficient and Effective Organization to Advance the IAVI Mission .....	27
Conclusion .....	34

## ACRONYMS

AAV	Adeno-associated virus
AAVP	African AIDS Vaccine Program
ADARC	Aaron Diamond AIDS Research Center
AIDS	Acquired immunodeficiency syndrome
AMC	Advance market commitment
ART	Antiretroviral Therapy
AVAC	AIDS Vaccine Advocacy Coalition
AVC	AIDS Vaccine Consortium
BD	Becton, Dickinson & Company
CAB	Community Advisory Board
CAVD	Collaboration for AIDS Vaccine Discovery
CGI	Clinton Global Initiative
CSIS	Center for Strategic and International Studies
DBT	Department of Biotechnology
DFID	Department for International Development (U.K.)
EU	European Union
FDA	Food and Drug Administration (U.S.)
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IAVI	International AIDS Vaccine Initiative
IBSA	India-Brazil-South Africa
IPM	International Partnership for Microbicides
IPPF	International Planned Parenthood Federation
IUAC	International Union Against Cancer
KAVI	Kenya AIDS Vaccine Initiative
LAC	Live Attenuated Consortium
MRC	Medical Research Council
MVA	Modified Vaccinia Virus Ankara
NAC	Neutralizing Antibody Consortium
NARI	National AIDS Research Institute
NGO	Non-governmental organization
NIH	National Institutes of Health (U.S.)
NPT	New prevention technologies
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PBS	Public Broadcasting Service (U.S.)
PDP	Product development public-private partnership
PPP	Public-private partnership
R&D	Research and development
SAVVI	South African AIDS vaccine initiative
SIV	Simian immunodeficiency virus
STI	Sexually transmitted infection
STOC	Screening Test of Concept
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	UN General Assembly Special Session
USAID	U.S. Agency for International Development
UTAC	Until There's a Cure
WHO	World Health Organization

## MESSAGE FROM THE PRESIDENT

We are pleased to present the IAVI *2006 Annual Progress Report* to our global constituency of donors, partners, staff, and other supporters to highlight our activities undertaken in the search for an AIDS vaccine. As reflected in our report, 2006 was a particularly important and productive year. Guided by our three-year strategic plan, we made progress in speeding the pace of research, mobilizing stronger and more sustained political and financial commitment, and advocating for sound policies to strengthen research efforts and ensure future access. We are encouraged by the progress we have made, but are humbled by the recognition that we are still a long way from ending the AIDS crisis.

Looking forward, I see a changing environment with new challenges and opportunities for IAVI and its partners. On the positive side, there continues to be progress on a number of new prevention technologies. Recent data from the U.S. National Institutes of Health, confirming that circumcision can halve men's risk of becoming infected with HIV, offers positive news. IAVI supports the development of new prevention technologies, plays an active role in promoting them, evaluates their impact on vaccine research and development work, and ensures their availability through our networks in the developing world. We recognize that none of these interventions will be 100% effective alone. Together, they are complementary tools that should be used in combination as part of a comprehensive HIV prevention strategy.

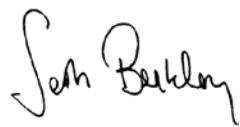
At the same time, we believe that our organization must maintain a laser-like focus on the search for and access to a preventive AIDS vaccine as the best "exit strategy" for ending the pandemic. In this regard, IAVI and the rest of the field is eagerly anticipating the results from trials on the most advanced vaccine candidates today — sanofi pasteur's Phase III trial in Thailand and Merck's Phase IIb test of its Adeno-5 vector candidate due in 2008-2010. Both of these candidates, the former attempting to induce cellular-helper and humoral immune responses, and the latter eliciting cellular-cytotoxic mediated immunity, will have a significant impact on the AIDS vaccine pipeline. IAVI and its scientific leaders and advisors are currently assessing the possible scenarios surrounding these pivotal trials and their implications for AIDS vaccine research and development.

Scientists believe that a T-cell vaccine could reduce viral load, slow HIV disease progression, and potentially lower HIV transmission rates, but is not likely to completely prevent persistent infection. Nevertheless, even limited success from the Merck and sanofi pasteur trials will likely provide important direction for research, including insights for future clinical trials on correlates of immunity and surrogate markers, as well as validation of our animal models. Whatever the outcome of these trials, IAVI has an important role to play in helping to communicate the results and sustaining commitment to the AIDS vaccine effort by donors, partners, and other stakeholders.

These dynamic times will test IAVI's guiding principles of flexibility, speed, and ability to take informed risk — especially in augmenting and strengthening our applied science program. In the absence of a fully preventive vaccine, IAVI is moving forward to develop vaccine candidates with greater potential efficacy — including subsequent generations based on different and complementary approaches. Our interim goal over the coming five years includes advancing vaccine candidates that elicit broadly neutralizing antibodies against HIV and/or approach the level of protection conferred by live-attenuated simian immunodeficiency virus in preclinical models. Through our vaccine consortia comprising leading research institutions worldwide, IAVI is tackling the key scientific questions and exploring novel alternatives to vaccine design and product development. To do so will require a redoubling of our efforts to find and stimulate scientific innovation in the field.

As we adapt to the changing AIDS vaccine scientific landscape over the coming years, we will also need to recalibrate and constantly improve our policy research and advocacy work so that it supports successful research and development innovation and product development. We will also need to sustain and build on our country-level programs across the world and engage new national partners, intensifying our ongoing efforts in India, Africa, and elsewhere. With increased national backing for HIV research and a network of top in-country scientists and other supportive stakeholders, China is also in a particularly strong position to more actively participate in the global search for new AIDS prevention technologies, and IAVI will explore collaborations in that country, too.

As one of the world's first biomedical product development public-private partnerships, we will continue to work with the field to find a vaccine to end one of the most destructive infectious disease pandemics in human history. However, this will only be possible with the generous support of a dedicated group of donors, partners, and staff. Together, we must continue to overcome scientific barriers, fuel creativity and innovation, drive policy change and effective advocacy, and engage developing country partners in our quest to find the tool to end the AIDS pandemic for the next generation.



Seth F. Berkley, M.D.  
President and CEO



## EXECUTIVE SUMMARY

IAVI, the *only global nonprofit exclusively dedicated to the quest for an AIDS vaccine*, aims to ensure the development of safe, effective, accessible preventive AIDS vaccines for use throughout the world. A decade after IAVI's founding, the organization's mission has never been more critical to the future health and well-being of our world.

Nearly 40 million people worldwide are living with HIV, including 4.3 million who became infected in 2006. Between 2001 and 2006, the annual number of AIDS deaths increased by one-third, with almost three million deaths occurring in 2006 alone. Women now represent 45% of all HIV infections globally, and young people (under age 25) accounted for 40% of new infections in people over age 15 in 2006. In its third decade, the pandemic continues to inflict the most significant reversal in human development in recorded history.

Recent years have witnessed an important quickening of the global response. Global spending on HIV-related activities in low- and middle-income countries increased more than six-fold between 2000 and 2006, and more than two million people worldwide are now receiving antiretroviral therapy (ART).

Yet only limited progress has been made in preventing new infections. Only 11% of pregnant HIV-infected women have access to basic services to prevent mother-to-child transmission, and targeted prevention services reach only 8% of injection drug users, 9% of men who have sex with men, and less than 30% of sex workers. With HIV prevention efforts faltering, global HIV incidence appears again to be on the rise, especially in Eastern Europe and Central Asia, where the number of new infections increased by 50% over the last two years alone. Without sharp reductions in the rate of new HIV infections, global treatment efforts will confront insurmountable financial and logistical obstacles, leaving many millions in the pandemic's path without hope of receiving life-preserving care.

A vaccine remains the world's best hope for reversing the AIDS pandemic. Just as vaccines have

revolutionized global efforts to control smallpox, polio, measles, and diarrheal diseases, such a tool is urgently needed to respond to the spread of HIV. Developing an AIDS vaccine is one of the world's most complicated and important scientific challenges, requiring years of learning about the virus, translating scientific findings into novel vaccine candidates, and testing the most promising candidates for safety and efficacy. The difficulty of the task at hand, however, cannot deter the world from the urgent imperative of accelerating development of one or more preventive vaccines, on which the lives and health of millions depend.

IAVI's efforts to advance its mission are currently guided by a three-year strategic framework for 2005 through 2007. The 2005-2007 strategic plan charts four principal strategic directions for IAVI:

- *Accelerate* research and development (R&D) on AIDS vaccines, by expanding IAVI's research program, improving the product development pipeline, and accelerating efforts to find answers to key scientific questions;
- *Mobilize* strong and sustained global political and financial commitment to vaccines, in part through cultivating and strengthening a broad array of influential constituencies in developed and developing countries that actively advocate for AIDS vaccine R&D and for future vaccine access;
- *Advocate* for public policies that strengthen AIDS vaccine R&D and increase the likelihood of timely, worldwide access to future vaccines;
- *Partner* effectively with the countries most affected by the epidemic, with particular emphasis on preparing countries and individual sites to support AIDS vaccine research.

The 2005-2007 strategic plan also calls for comprehensive efforts to *operate* IAVI with optimal efficiency, effectiveness, and professionalism.

In 2006, IAVI passed an important milestone, marking its first 10 years of existence. To commemorate its first decade and to plan for the future, IAVI partners and team members from around the world

convened in New York in September for a three-day, multi-disciplinary information-sharing and strategic planning meeting. Events also included a tenth anniversary special board and donor dinner in June. A year-long history project produced a variety of archival material, including a web-based multimedia presentation, timeline, and history brochure. One decade after the meeting at the Rockefeller Foundation Study and Conference Center in Bellagio, Italy that gave rise to IAVI in 1996, the organization convened another meeting at Bellagio of AIDS and vaccine experts to assess developments in the field and to advise IAVI on ways to maximize the organization's strategic impact over the next several years.

The 10-year anniversary provided an opportunity to assess IAVI's contributions to the field in its first decade of work. IAVI has expanded the product pipeline by developing and testing six candidate vaccines, mobilized hundreds of millions of new dollars for AIDS vaccine research, dramatically enhanced clinical trial capacity in developing countries, created new models of collaborative AIDS vaccine research, and helped place the search for an AIDS vaccine near the top of the global political agenda. At the dawn of its second decade, IAVI aims to retain optimal flexibility to respond rapidly to emerging challenges and opportunities, bringing unprecedented research focus to key scientific challenges in the field and pursuing innovative public policies to speed development and assessment of the most promising approaches.

This report summarizes key IAVI achievements and activities in 2006, the second year of the current strategic plan. Like the *2005 Annual Progress Report*, this one outlines progress under each of the five pillars of the 2005-2007 strategic plan, including:

### *I. Accelerate R&D:*

- Phase I safety and immunogenicity data were generated on four vaccine candidates at clinical trial sites in six countries worldwide. Additionally, IAVI successfully conducted clinical trials in two new countries, Rwanda and Zambia;
- IAVI expanded and strengthened its research consortia designed to obtain answers to key scientific questions, including the characteristics of broadly neutralizing antibodies;

- IAVI, as a partner in the Global HIV Vaccine Enterprise, published its biennial *AIDS Vaccine Blueprint 2006: Actions to Strengthen Global Research and Development*, which calls for a major increase in collaborative scientific empiricism to ensure that the most promising vaccine candidates are advanced through the R&D pipeline;
- IAVI's AIDS Vaccine Development Laboratory in Brooklyn became fully operational in 2006, undertaking a broad range of work in immunology, vector design, and reagent purification.

### *II. Mobilize Global Political Support and Leadership on AIDS Vaccines:*

- IAVI's advocacy efforts included favorable language on vaccines in the Political Declaration on HIV/AIDS that emerged from a five-year United Nations review of global AIDS progress, as well as in the final declaration of the India-Brazil-South Africa (IBSA) Summit, a meeting of heads of government of Brazil, India, and South Africa, held in Brasília, Brazil in September;
- IAVI strengthened partnerships with key civil society groups, including women's health advocates and other product development public-private partnerships (PDPs);
- In its ongoing efforts to position IAVI as the world's most trusted source of information on AIDS vaccines, the organization undertook a comprehensive branding analysis, launched a new publications unit, and significantly increased the distribution of key IAVI publications.

### *III. Advocate for Public Policies to Accelerate R&D and Ensure Future Access:*

- IAVI published widely cited analyses of current spending on AIDS vaccine R&D, the potential public health impact of a partially effective vaccine, and projected demand for a future vaccine;
- Advocacy by IAVI supported the strong endorsement by the Group of 8 (G8) industrialized countries of AIDS vaccine R&D and of advance market commitments (AMCs) as a strategy to ensure a viable market for future prevention technologies in developing countries;
- IAVI is working with the Program for Appropriate Technology in Health (PATH) to accelerate the introduction of human papillomavirus (HPV) vaccines in developing countries





*Jean-Marc Giboux/Getty Images*

*There are now more than 30 trials ongoing in 24 countries, and IAVI and its collaborators are currently conducting four ongoing trials in India, Kenya, Rwanda, Uganda, South Africa, and the United States*

and to ensure that lessons learned from HPV are applied to future efforts to introduce new AIDS vaccines.

#### *IV. Partner with Developing Countries:*

- IAVI undertook substantial efforts to build the capacity of all its sites, including staff training, support for learning opportunities, and provision of technical assistance in such areas as gender, informed consent, counseling, HIV education, and quality assurance;
- IAVI launched its Southern Africa office and undertook Zambia's first-ever AIDS vaccine trial;
- In Southern Africa, IAVI established a partnership with Aurum Health Research to assess trial preparedness in the mining district of Rustenberg, including an analysis of risk behaviors, community health, and health service access;
- IAVI undertook a comprehensive mapping exercise to assess the strengths and weaknesses in its community engagement efforts at all sites.

#### *V. Operate an Optimally Efficient and Effective Organization:*

- IAVI enhanced information technology capacity at field sites and began a mapping exercise to

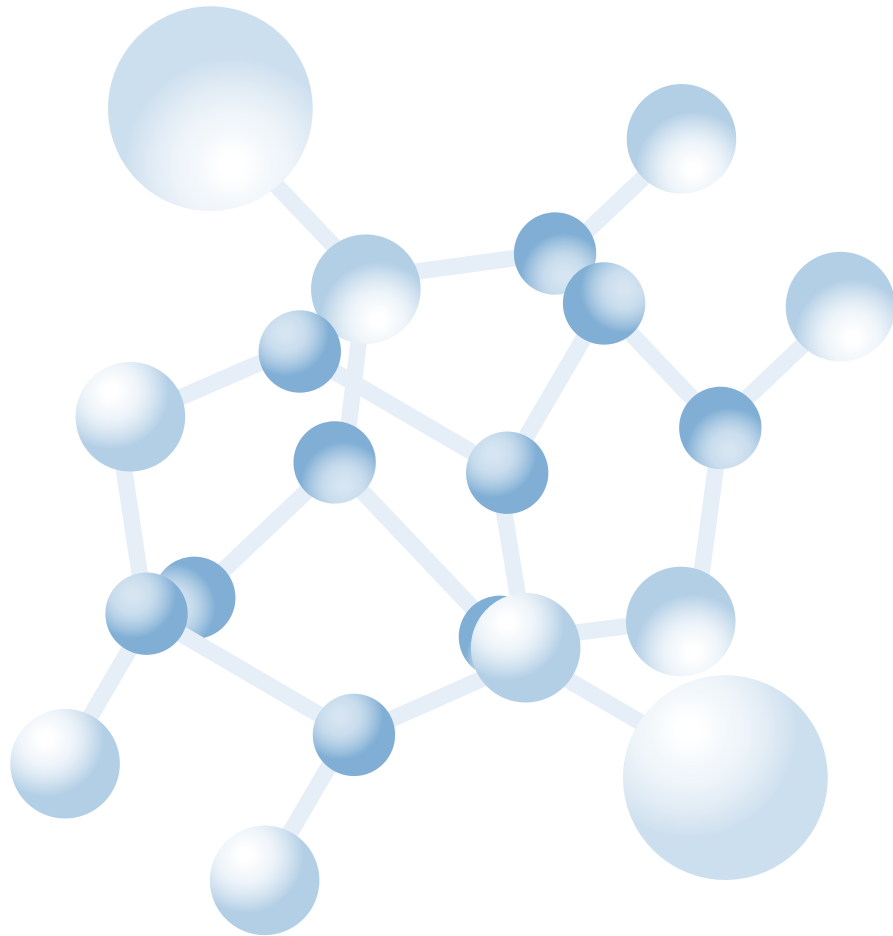
document its country programs;

- IAVI established a new unit — a portfolio and project management office — to focus and strengthen internal efficiency and effectiveness of the organization's scientific work;
- IAVI made significant strides in 2006 to strengthen performance-based management of the organization. A new workplan tool has provided the organization with expanded global capacity in the planning and implementation of its activities to assess the financial impact of particular initiatives and to monitor progress in meeting desired outcomes;
- Work also began on a comprehensive monitoring and evaluation system, which should be operational by mid-2007. The monitoring and evaluation framework will support IAVI's board of directors, senior management, and donors in assessing the organization's efforts toward its mission;
- Government commitments to IAVI increased substantially in 2006. In addition, IAVI received a projected US\$33 million from the Bill & Melinda Gates Foundation for targeted vaccine research, corporations provided more than US\$650,000 in financial and in-kind support, several private foundations increased their giving to IAVI, and individual gifts increased by more than 20%.



# Accelerate Research and Development of AIDS Vaccines

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## I. ACCELERATE RESEARCH & DEVELOPMENT OF AIDS VACCINES

The centerpiece of IAVI's strategic plan for 2005-2007 is a major expansion of the organization's research and development (R&D) program. With the goal of complementing efforts by other stakeholders and partners, IAVI's R&D program focuses on three major initiatives:

- Developing new products and streamlining clinical trials to accelerate the most promising candidates;
- Solving the key scientific questions that have impeded swifter progress in the field;
- Improving the scale, integration, and industrialization of the AIDS vaccine research effort, while enhancing the capacity for informed scientific risk-taking and technological innovation.

In addition, IAVI's research and capacity-building activities in developing countries have expanded the world's knowledge base on epidemiology, early transmission events, and genomic sequencing, helping speed and inform rational vaccine design and clinical testing.

*Objective: Significantly improve the product development pipeline with candidates that have greater potential for success*

When IAVI was established in 1996, the global AIDS vaccine effort was largely moribund. Today, IAVI is playing a leading role in the robust and growing global AIDS vaccine effort. In its first 10 years, IAVI substantially strengthened the product pipeline by developing and testing six new candidate vaccines. Because the field does not currently know the correlates of protection, no clinical or preclinical markers for efficacy currently exist, underscoring the need to test promising candidates in clinical efficacy trials.

IAVI's development and testing of new vaccine candidates are undertaken in collaboration with leading government research agencies, pharmaceutical and biotech companies, and academic

researchers. In recent years, the number and depth of IAVI's scientific partnerships have significantly grown. Currently, IAVI is testing five different candidates in clinical trials, and its targeted research consortia and new Brooklyn laboratory, described in greater depth in later sections, will inform and accelerate design of promising new candidates in the future. IAVI-supported candidates represent one in six of all AIDS vaccine candidates in clinical trials worldwide.

- *Ad5.* At present, the leading candidate in clinical trials is Merck's adenovirus vector vaccine (Ad5), which is currently in trials that will likely yield efficacy data in late 2008 or early 2009. Because exposure to Ad5 is widespread, potentially limiting the effectiveness of the approach in the developing world, IAVI is prioritizing work on candidates that may overcome the potential anti-vector immunity challenges of Ad5.

- *DNA+Ad5.* IAVI was asked to participate in clinical trials of the DNA prime plus Ad5 boost vaccine candidate of the Vaccine Research Center at the National Institutes of Health (NIH), which has demonstrated better protection in preclinical studies than Ad5 alone. A trial of the candidate has begun at IAVI's sites in Kenya and Rwanda, and IAVI's Core Laboratory at the Imperial College in the U.K. was the first laboratory in the multi-site trial to generate data demonstrating DNA+Ad5's safety and immunogenicity. IAVI and the NIH are now planning an additional 500-person trial in a high-risk population in Africa. IAVI has also proposed enrolling approximately 600 of the 8,500 participants who will be needed for a Phase IIb efficacy trial.

- *AAV.* In collaboration with Targeted Genetics and the Children's Hospital of Philadelphia, IAVI completed A001, a Phase I trial in Belgium, Germany, and India that demonstrated the safety and immunogenicity of AAV-2, a candidate with an adeno-associated virus (AAV) as vector that

protects against simian immunodeficiency virus (SIV) in preclinical studies. AAV is an especially attractive vector for a candidate vaccine because it does not cause disease, has an excellent safety profile, and persistently produces target immunogens. In addition to the Phase I trial, IAVI initiated a Phase II trial at a higher dose in South Africa, Uganda, and Zambia, which is to be completed in 2007.

- **MVA.** Immunization regimens incorporating priming with a DNA vaccine and boosting with recombinant modified vaccinia virus Ankara (MVA), a poxvirus, have been found to provide some degree of protection in non-human primates following viral challenge. Experts on poxvectors are advising IAVI on selection of the most promising poxvector candidate, with IAVI aiming to initiate preliminary trials with higher-risk volunteers in early 2008.

IAVI completed Phase I trials for two different MVA candidates in 2006 separately developed in collaboration with Therion and the Aaron Diamond AIDS Research Center (ADARC). The Phase I trial of the Therion candidate began in Chennai, India, in January 2006, with the high-dose group fully enrolled in the first week. IAVI is analyzing data from the trial generated by IAVI's Core Laboratory in London. In addition, a Phase I trial of the ADARC MVA candidate demonstrated that 62% of subjects developed a positive immune response in validated assays for cell-mediated immune responses.

- **Low Seroprevalent Adenovirus Candidates.** Because more than 80% of people living in developing countries have pre-existing immunity against Ad5, there are concerns that Merck's promising Ad5 vaccine might have limited effectiveness. In anticipation of this potential problem, IAVI has initiated preclinical development of low-seroprevalent adenovirus candidates, including the simian adenovirus vector (in collaboration with GlaxoSmithKline) and the human adenovirus (in collaboration with Crucell). Phase I clinical trials of these candidates are planned for early 2008; regulatory meetings have already been held in Europe and the U.S. to prepare for applications to conduct clinical testing.

To develop and manufacture adenoviruses for clinical trials, IAVI licensed the HER cell line

(AdVac® technology) from Crucell. In 2006, IAVI completed characterization of this cell line and received favorable regulatory feedback from the U.S. Food and Drug Administration (FDA). As a major part of its efforts to assist the entire vaccine field, IAVI has provided a non-exclusive license to the Beth Israel Deaconess Medical Center, a major teaching hospital of Harvard Medical School, to manufacture adenovirus vector candidates for clinical trials.

*Objective: Address the major scientific obstacles that impede global efforts to develop superior product candidates*

Nearly all AIDS vaccine candidates in the development pipeline focus on a single hypothesis: that generating a strong cellular response will confer immunity against HIV-related disease. It is hoped that vaccines based on cell-mediated immunity will reduce viral load, slow HIV disease progression, and reduce HIV transmission rates, although such products may not prevent persistent infection. Based on current scientific knowledge, IAVI assumes that a vaccine that can prevent HIV infection will likely need to elicit broadly neutralizing antibodies, have cellular-mediated response capable of targeting mucosal sites where HIV replicates early after infection, and approach the level of protection conferred by live-attenuated SIV in preclinical models. No candidates in the pipeline currently achieve these criteria, and efforts to design such a product have been impeded by the many scientific obstacles presented by HIV. IAVI has developed an integrated program to address key scientific challenges, with the aim of contributing to the development of superior candidates.

- IAVI established its AIDS Vaccine Development Laboratory in Brooklyn in 2005 to rapidly and cost-effectively improve the pipeline. This is being accomplished with the development of a series of new and improved vaccine candidates, particularly novel high-risk candidates currently not under development by our industrial partners. IAVI had previously done much of its vaccine design and development work through contractors but realized that this was both more costly and less effective than building its own internal capability. The most recent addition to IAVI's R&D program, the lab is the world's first industrial-style discovery and development research laboratory operating within a non-governmental organization (NGO).

It is also the first focused exclusively on accelerating the development of an AIDS vaccine. The Brooklyn lab is now fully operational, having made important achievements in 2006 to enhance the strategic focus of IAVI's scientific program on key challenges, and is fully functional with respect to equipment, personnel training, and regulatory approval for upcoming studies. The lab works on assay development on viral vectors, protein design and purification, and immunology and vaccine design.

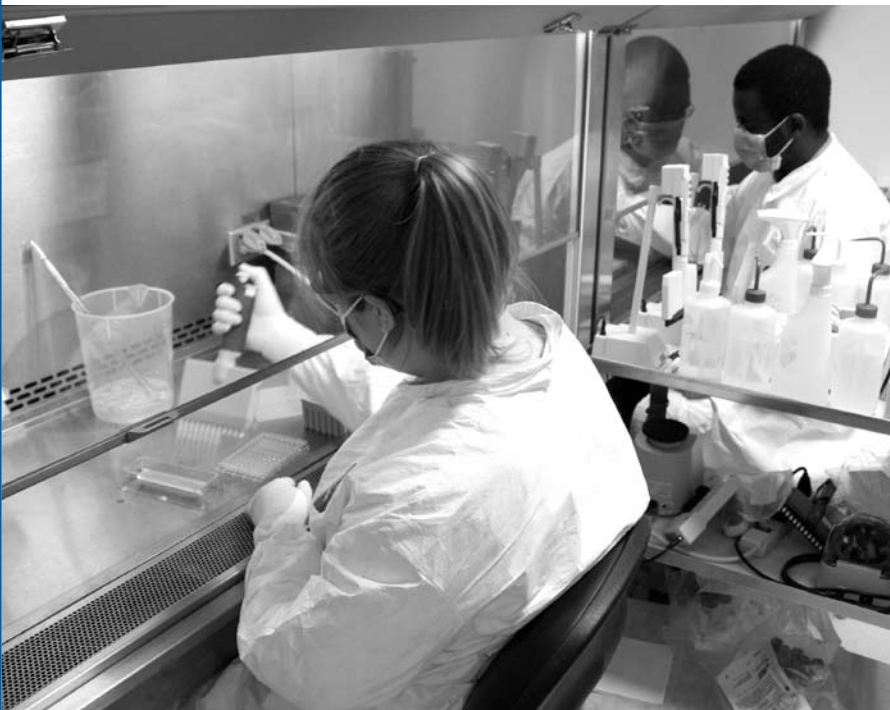
The Brooklyn laboratory is organized into three key groups: immunology, vector, and protein. Among the lab's many accomplishments in 2006, the Immunology Group has established and standardized assays for collaborators in the Collaboration for AIDS Vaccine Discovery (CAVD). The Vector Group is currently producing the first set of adenovirus vectors for immunogenicity and challenge studies in non-human primates. The Protein Group has begun purifying reagents to support the organization's scientific program. Negotiations for a permanent laboratory location, as well as financing for this future lab, were undertaken in 2006, with an expected completion date in early 2008.

*Scale up the Neutralizing Antibody Consortium (NAC) and establish the Live Attenuated Consortium (LAC) to form the AIDS Vaccine Consortium (AVC)*

Twenty-six years into the pandemic, it is still not clear how to generate immunity against HIV. Recognizing that rational vaccine design requires answers to key scientific questions, IAVI has recruited some of the world's leading scientific experts in research consortia to undertake targeted investigations. Specifically, IAVI has formed three scientific consortia — the Neutralizing Antibody Consortium (NAC), the Live Attenuated Consortium (LAC), and the Vectors Consortium (VEC) to address major obstacles in AIDS vaccine development.

- The NAC was expanded to 15 members in 2006. Achievements by the NAC's principal investigators include initiating a protocol to identify broadly neutralizing sera, characterizing broadly neutralizing sera, intensifying the focus on the CD4 binding site, and producing and screening first-generation carbohydrate and scaffold immunogens. IAVI established a Cooperative Research and Development Agreement with the Vaccine Research Center at the NIH to accelerate the design of immunogens to elicit broadly neutralizing antibodies. IAVI and Scripps Research Institute launched their own fully integrated and automated crystallography platform, CrystalMation by RoboDesign, in June 2006. NAC researchers have exclusive access to this crystallization robot — a first for an academic research consortium — which will accelerate scientific investigation by enabling rapid and consistent protein crystallization.

- IAVI established the LAC to determine the protection mechanism conferred by live-attenuated SIV. The program has been streamlined to answer four key questions, with studies initiated and efforts to standardize assays ongoing.



*Ernest Cumi/SUNY Downstate Medical Center*

*The most recent addition to IAVI's R&D program, the AIDS Vaccine Development Laboratory in Brooklyn, New York, is the world's first industrial-style discovery and development research laboratory operating within an NGO*



- The VEC was initiated in 2006 (as a member of the Collaboration for AIDS Vaccine Discovery, or CAVD) to systematically prioritize vector-based vaccines that target persistent and mucosal immune responses. Efforts are under way to design the first three vectors with common transgenes for comparative assessment.

*Forge a new R&D paradigm that significantly enhances and improves efforts to solve key scientific challenges*

Since its inception, IAVI has advocated for an approach to AIDS vaccine development that is innovative and flexible, can adapt to new scientific learning, and recognizes that time is of the essence to halt the pandemic. In 2006, taking into account the latest developments in the field, IAVI updated its vision for vaccine R&D with the publication of a new scientific blueprint.

- IAVI, as a partner of the Global HIV Vaccine Enterprise, published the *AIDS Vaccine Blueprint 2006: Actions to Strengthen Global Research and Development*, describing a new paradigm to enhance efforts to solve key scientific challenges. Launched at the International AIDS Conference in Toronto and disseminated at the AIDS Vaccine Conference in Amsterdam, the *Blueprint* includes key recommendations for accelerating progress in the field. Specifically, the *Blueprint* includes guidelines for solving major scientific challenges and translating solutions into improved vaccine design, for enhancing collaborative scientific empiricism to identify and advance the most promising candidates, for using earlier efficacy data to help set priorities for resources, and for establishing networks of excellence in AIDS vaccine R&D to prepare for future challenges.
- In keeping with the program proposed in the *AIDS Vaccine Blueprint*, IAVI has expanded the NAC and LAC to address key scientific challenges in the search for a vaccine. The organization has established the Brooklyn lab to translate information generated by these consortia into novel vaccine candidates. To enhance the effectiveness of scientific empiricism, the Brooklyn lab has established a process for systematically setting priorities for novel vector-based vaccines.

- IAVI is piloting a model to accelerate efficacy data on vaccine candidates to facilitate optimally efficient use of resources and prioritization of competing candidates. The Screening Test of Concept (STOC) trials aim to elicit early indications on the promise of new vaccine candidates, collecting limited efficacy data from trials of small numbers (360 to 600) of high-risk individuals.
- In his keynote address to the Vaccine Technology Conference in June 2006, Dr. Seth Berkley, IAVI president and chief executive officer, emphasized the need for a more strategic approach to vaccine research. Although more than 30 vaccine candidates are in clinical trials, Dr. Berkley noted that the pipeline is duplicative and oriented to testing a single approach — cellular immunity — to vaccination. He emphasized the need for renewed and creative approaches to vaccine development that solve the most important remaining scientific questions and that promote strong global partnerships between developed and developing countries.

*Enhance global surveillance efforts to produce new and better concepts in vaccine design*

IAVI has continued to enhance and expand its efforts to gain access to novel technologies for advancing AIDS vaccine development and tracking progress in the field. These include global surveillance of biotech companies focused on human and veterinary vaccines and new technologies designed to enhance immune responses to AIDS vaccines.

- In 2006, IAVI integrated several new technologies into the preclinical and clinical pipeline through its global surveillance efforts. With respect to the preclinical phase, the surveillance efforts identified several promising molecular adjuvants (molecules that may increase immune response to a vaccine candidate), including cytokines, apoptosis inducers, bacterial toxins, and toll-like receptor agonists. IAVI and collaborators are evaluating the effect of these adjuvants on immune responses to AAV-vectored HIV vaccines. In addition, IAVI has invested in the preclinical development of novel chimeric viruses (candidate vaccines aimed at mimicking the efficacy of live-attenuated vaccines that also demonstrate a safety profile acceptable for human use) with Global Vaccines, Inc., a not-for-profit vaccine research company.

- Global surveillance has also augmented IAVI's clinical development pipeline. IAVI evaluated and will be clinically testing novel vaccine delivery systems that have the potential to significantly improve the immune response of a vaccine. In addition, IAVI is advancing into Phase I clinical trials of novel prime-boost vaccine combinations to evaluate immune responses, set to begin in 2007.

**Objective:** *Strengthen infrastructure to expedite clinical testing of the most promising candidates in the developing world*

Testing of promising vaccine candidates in developing countries is essential, because 95% of new HIV infections occur in low- and middle-income countries. Conducting trials where the epidemic is most severe enables IAVI to gather information on the circulating virus, test candidates for efficacy in the populations that need them the most, and increase political support for the rapid introduction of future vaccines once they are available. Because biomedical research infrastructure is weak in developing countries, IAVI devotes considerable organizational resources to partnering with developing countries to establish and sustain the clinical trial capacity to test future vaccine candidates. IAVI has proven that high-quality clinical trials can be conducted in resource-limited settings. An independent five-year review of all IAVI field sites and laboratories yielded positive feedback.

- IAVI conducted Zambia's first vaccine trial in 2006, in partnership with the Zambia Emory HIV Research Project and Targeted Genetics Corporation. Meeting with Dr. Berkley in November 2006, Dr. B.U. Chirwa, director general of the National HIV/AIDS/STI/TB Council in Zambia, pledged to support efforts to strengthen and sustain political commitment on AIDS, including vaccine research.
- In addition to the clinical trials described above, IAVI is also conducting a series of clinical research studies to gather information relevant to rational vaccine design. IAVI has enrolled approximately 4,800 volunteers at five sites in Kenya, Uganda, and South Africa to assess HIV incidence and volunteer retention. More than 150 volunteers have been enrolled in a multi-center study of early and acute HIV infection. Researchers in high-income countries have long used readings on standardized laboratory assays as normal inclusion criteria for trial participation, but limited information exists on the normal ranges in individuals outside

the industrialized world. To ensure that Western laboratory reference ranges do not inadvertently exclude suitable trial participants in Africa, IAVI has enrolled 2,400 volunteers at seven sites in Africa to determine appropriate inclusion reference ranges for target populations in the region. Results will be released to the field in 2007, and it is hoped that their incorporation into international standards will impact reference ranges for clinical trials conducted in developing countries, across all diseases.

To identify individuals with broadly neutralizing antibodies for participation in future NAC investigations, IAVI is screening HIV-infected volunteers who remain healthy after at least three years of infection. In 2006, IAVI identified 10 broadly neutralizing antibody sera for monoclonal antibody studies.

- IAVI's clinical research is supported by a network of field laboratories, coordinated through IAVI's Human Core Laboratory at Imperial College in London, which also trains field lab staff. The Core Laboratory completed Good Clinical Laboratory Practices training for all 18 laboratories in its clinical laboratory network. In addition, the Core Laboratory was selected as the central laboratory for assay validation, standardization, and laboratory certification for the Gates-sponsored CAVD.



*Jean-Marc Giboux/Getty Images*

*Earlier this year South Africa began its first large-scale trial – Africa's first AIDS vaccine efficacy study – which will enroll 3,000 volunteers*



# Mobilize

Strong and  
Sustained Global  
Commitment

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## II. MOBILIZE STRONG AND SUSTAINED GLOBAL COMMITMENT

The strategic plan for 2005-2007 recognizes that the search for an AIDS vaccine will need to be sustained over many years, underscoring the importance of securing long-term, high-level political and financial support for AIDS vaccine R&D. The strategic plan calls for IAVI to implement a global advocacy initiative — an alliance of countries in the South — that will strengthen, expand, and maintain strong political commitment to AIDS vaccines. To uphold IAVI's leadership role within the field, the strategic plan calls for the organization to establish itself as the leading international organization for AIDS vaccine science, policy, and advocacy.

*Objective: Enhance global public and political commitment to accelerating the development of a safe and effective AIDS vaccine and ensure that it is available, acceptable, affordable, and effectively used, particularly in developing countries*

Sustaining the high-level support that will be needed over many years in the global search for an AIDS vaccine requires the active involvement of a wide range of constituencies: political leaders, private industry, opinion leaders, and civil society groups that influence official thinking and decision-making in both developed and developing countries.

*Expand political commitment and leadership by building on existing relationships and forging new relationships at national and international levels*

In 2006, IAVI worked with a wide range of political stakeholders to further political commitment and leadership for AIDS vaccines.

- *South-South Collaboration on Vaccines.* IAVI provided technical input and participated in the first India-Brazil-South Africa (IBSA) Heads of

Government Summit, held in Brasília, Brazil in September 2006. The IAVI India country director, Jayanthi Natarajan, attended as an official member of the Indian national delegation and also spoke at a seminar that influenced the meeting's outcome document. IAVI staff were also participants in the official meeting agenda. The three heads of government — Indian Prime Minister Manmohan Singh, Brazilian President Luiz Inácio da Silva, and South African President Thabo Mbeki — agreed to enhance trilateral cooperation to battle neglected diseases. The leaders specifically pledged to support collaborative action to accelerate R&D for new diagnostic tools, drugs, and vaccines, including a vaccine against HIV.

- *United Nations High-Level Meeting on AIDS.* IAVI advocacy efforts helped influence the outcome of the High-Level Meeting on AIDS at the UN General Assembly in June 2006, which attracted more than a dozen heads of state and more than 100 government ministers. A five-year review of commitments made by political leaders at the first-ever UN General Assembly Special Session (UNGASS) on HIV/AIDS in 2001, the High-Level Meeting resulted in a separate political declaration that recognized AIDS vaccines and other new prevention technologies (NPTs) as critical components of a comprehensive response to the pandemic (see Figure II-A). In collaboration with civil society partners, IAVI participated in the civil society hearings at the High-Level Meeting and secured statements supporting vaccines from high-level officials who spoke in roundtable and panel sessions.

The outcome document for the High-Level Meeting, the *Political Declaration on HIV/AIDS*, called for urgent development of vaccines and other new tools to fight the pandemic. The *Political Declaration* further endorsed greater

investment in vaccine research and exploration of AMC's and other mechanisms to promote development and uptake of NPTs. The declaration also expressed support for public-private partnerships as a tool to support R&Ds.

During the High-Level Meeting, IAVI organized a briefing for 25 UN missions and agencies hosted by the ambassador of Thailand, Lazanachantorn Laohaphan. With the leadership of IAVI Board member Hilde Frafjord Johnson, IAVI organized a private session for 45 influential leaders, including ministers from Germany, India, Kenya, South Africa, Sweden, and Zambia.

Figure II-A

UNGASS + 5 Support of AIDS Vaccines
<p><b><i>Preventive Vaccines and Microbicides Included as Part of a Comprehensive Response to HIV/AIDS</i></b></p> <p><i>“We, heads of State and Government and representatives of States and Governments participating in the comprehensive review of the progress achieved in realizing the targets set out in the Declaration of Commitment on HIV/AIDS on 31 May and 1 June 2006 and the High-Level Meeting on 2 June 2006;</i></p> <ul style="list-style-type: none"> <li>• Recognize also that to mount a comprehensive response, we must...do everything necessary to ensure access to life-saving drugs and prevention tools; and develop just as urgently better tools—drugs, diagnostics and prevention technologies, including vaccines and microbicides—for the future;</li> <li>• Commit to intensify investment in and efforts towards the research and development of new, safe and affordable HIV/AIDS-related medicines, products and technologies, such as vaccines, female-controlled methods and microbicides, pediatric antiretroviral formulations, including through such mechanisms as Advance Market Commitments, as well as encourage increased investment in HIV/AIDS-related research and development in traditional medicine;</li> <li>• Encourage pharmaceutical companies, donors, multilateral organizations, and other partners to develop public-private partnerships in support of research and development and technology transfer, and in the comprehensive HIV/AIDS response.”</li> </ul> <p><i>IAVI and its partners urged leaders to recognize the importance of investing in and intensifying support for new technologies — notably vaccines and microbicides — as a critical element of a comprehensive response to the AIDS pandemic</i></p>

Support for vaccines was also incorporated into other key 2006 global documents, including the *WHO/UNAIDS Report on the global AIDS epidemic; the UNAIDS Prevention Strategy; Africa's Common Position Paper to UNGASS* from the African Union Assembly in Abuja, a resolution signed by 14 African health ministers from East, Central, and Southern African countries; and the Civil Society Recommendations for the Political Declaration. Vaccines were also recognized as an important future option for women in the document, *With Women Worldwide — A Compact to End HIV/AIDS*, which was endorsed by hundreds of women's and youth organizations, and in the Resolution on the Women and the Girl Child and HIV/AIDS at the Commission on the Status of Women.

- *Political Leadership in Developing Countries: India.* Senior IAVI leadership met with Indian President Dr. APJ Abdul Kalam to update him on the latest developments in the AIDS vaccine field with particular attention to developments in India. High-level meetings were also held with leading officials of research and scientific agencies. IAVI met with senior officials of heavily affected Indian states, apprising them of the status of ongoing vaccine trials at the National AIDS Research Institute (NARI) in Pune. IAVI developed a draft framework for a National AIDS Vaccine Development Plan for India, presenting it for consideration to its National Advisory Board members. IAVI has forged a successful, interactive relationship with the office of Indian President Dr. APJ Abdul Kalam, providing input numerous times on the president's speeches on AIDS and vaccines.
- *Political Leadership in Developing Countries: Africa.* In March 2006, Dr. Berkley met with Rwandan President Paul Kagame, who expressed his strong support for AIDS vaccine development efforts in his country. Senior IAVI leadership also met with Rwanda's Minister of HIV/AIDS, Dr. Innocent Nyaruhirira. In collaboration with the African AIDS Vaccine Program (AAVP) and Projet San Francisco, IAVI supported an update of the National AIDS Vaccine Plan in Rwanda to reflect the country's current research environment.



*Photo courtesy of the President of India's Office*

*IAVI works to promote awareness with political and scientific leaders, such as the President of India, Dr. APJ Abdul Kalam, about the urgent need for a vaccine*

IAVI supported the development and launch of the Uganda AIDS Commission's National Guidelines for HIV Vaccine Research. Uganda's parliamentary subcommittee included a new chapter on AIDS vaccines in its HIV/AIDS toolkit, with technical support from IAVI. IAVI also contributed to the development of a new HIV/AIDS and sexually transmitted infection (STI) strategic plan for South Africa for 2007-2011.

In Kenya, Dr. Berkley worked with Minister of Health Charity Kaluki Ngilu and Minister of Foreign Affairs Raphael Tuju and supported the Vaccine Subcommittee of the Ministry of Health in implementing national guidelines for AIDS vaccine R&D. IAVI also disseminated findings of a World Health Organization (WHO) study on the cost-effectiveness and delivery of AIDS vaccines in two Kenyan provinces. In collaboration with AAVP, IAVI co-convoked consultations on vaccines for the Common Market for Eastern and Southern Africa and for the African Union.

Former President Joaquim Chissano of Mozambique agreed to include AIDS vaccines in the agenda of the Former African Presidents Forum in November 2006. President Chissano also pledged to convene a meeting of political advocates from the North and South in early 2007 to advocate for

increased commitment and resources for AIDS vaccine R&D.

- *Political Leadership in Developing Countries: China.* AIDS vaccine research funding from the Chinese government has increased by more than 20% in recent years, with expectations that such spending will jump 20-fold over the next 15 years. To capitalize on this momentum and catalyze additional action, Dr. Berkley and other senior IAVI officials held a series of meetings in China in December 2006, including a meeting in Beijing with influential policymakers.

This meeting promoted strategic investment in AIDS vaccine development in China and introduced the strategic directions set forth in the *AIDS Vaccine Blueprint 2006*, which was translated into Chinese and provided to stakeholders. Attendees included senior officials from the State Food and Drug Administration, the Ministry of Science and Technology, the Ministry of Health, the National Center for AIDS Prevention and Control, and the Chinese Academy of Medical Sciences. The policymaker briefing, plus individual meetings with national and regional government officials and researchers, identified a number of possible areas where IAVI might assist national efforts to strengthen AIDS vaccine research.

- *Political Leadership in Industrialized Countries.* IAVI engaged with focal points for the G8 industrialized countries before their July summit meeting in St. Petersburg. IAVI made a formal presentation at the G8 parliamentary conference organized by the Russian State Duma Interfactional Deputies' Working Group on HIV/AIDS, the U.K. All-Party Parliamentary Group on AIDS, and Transatlantic Partners Against AIDS. These efforts helped influence the summit communiqué, which supported increased outlays for developing an AIDS vaccine and AMCs for new prevention products. IAVI also briefed parliamentarians and policymakers in more than

SHORT EXCERPT FROM THE HOUSE OF REPRESENTATIVES RESOLUTION  
May 25, 2006

R109TH CONGRESS

2D SESSION **H. RES. 844**

*Congratulating*

the International AIDS Vaccine Initiative on ten years of significant achievement in the search for an HIV/AIDS vaccine, and for other purposes.

*Now, therefore, be it Resolved, that the House of Representatives*

- (1) congratulates the International AIDS Vaccine Initiative on ten years of significant achievement in the search for an HIV/AIDS vaccine;*
- (2) recognizes the role of the International AIDS Vaccine Initiative in raising awareness and increasing financial and political support for this important cause;*
- (3) admires the commitment of the International AIDS Vaccine Initiative to collaborating with developing country researchers, governments, and civil society in the common goal of finding a vaccine;*
- (4) expresses support for the continued success of the International AIDS Vaccine Initiative; and*
- (5) directs the Clerk of the House of Representatives to transmit an enrolled copy of this resolution to the International AIDS Vaccine Initiative.*

10 European countries on IAVI's work and helped ensure inclusion of vaccines in major European Union (EU) statements and policy frameworks, including the EU's new research policy agenda. IAVI also continued its advocacy with the U.S. and Canadian governments and welcomed passage of a resolution in the U.S. House of Representatives honoring IAVI's tenth anniversary (see Figure II-B).

*Build a strong set of influential constituencies (e.g., civil society, media, science, private sector) that actively advocate for AIDS vaccine R&D and future access*

**Building Strong Public Support.** In addition to its advocacy targeting opinion leaders and policymakers, IAVI also invested substantial organizational effort in creating strong, sustainable public support at the national and global levels for AIDS vaccine R&D.

- IAVI sponsored or participated in a variety of activities to commemorate World AIDS Day in December 2006. Among the many global activities that took place, IAVI unveiled a new European brochure for European parliamentarians about

vaccine R&D and the role of Europe. IAVI staff participated as speakers in a road show throughout several cities in Spain to build support for renewed 2007 AIDS vaccine funding, and the PBS documentary "Ending AIDS" that featured IAVI, aired on VRT, a Belgian TV station.

In India, an article focused on IAVI and other AIDS vaccine organizations appeared in *The Hindu*, one of India's leading daily papers, featuring quotes from IAVI leadership. IAVI pamphlets and t-shirts were disseminated at a World AIDS Day youth walk organized by the U.S. Agency for International Development (USAID). The India office also provided the president of India with vaccine messages for a speech he made to both houses of Parliament on World AIDS Day.

- IAVI India entered into an agreement with ANI News agency to make a 45-second film on IAVI's work in the country. This film, which focused on the AIDS vaccine trials being conducted in Chennai, received extensive television coverage from PBS (U.S.); CFMT-TV (Canada); and Zee News, Prime Time National TV (NDTV), Doordarshan News, Shara Samay, Janmat,



CNN-IBN, and a host of regional channels in India. The leading news channel in India, NDTV also interviewed IAVI's country director Jayanthi Natarajan on the need for an AIDS vaccine.

- A co-sponsored satellite meeting organized by IAVI, *Partnership for the Future: AIDS Vaccine Research in the Developing World*, at the International AIDS Conference in Toronto brought together more than 130 people from 32 countries. The meeting highlighted the growing contributions of developing countries to the search for an AIDS vaccine, identified opportunities to build and sustain research capacity in developing countries, and provided participants in the field the opportunity to discuss key issues in the global AIDS vaccine effort.
- At a briefing for Congressional staffers sponsored by the Global Health Council on Capitol Hill in September 2006 IAVI staff presented the state of the AIDS vaccine field as part of a discussion on the improvements made in HIV/AIDS treatment and prevention.
- In order to accelerate progress and fully engage country partnerships, IAVI sought input on its in-country programming activities and strategic direction from high-level country stakeholders, including government officials, parliamentarians, and individuals representing NGOs and the media. A 2006 meeting included stakeholders from nine developing countries. Annual meetings with rotating participants are envisioned for the future.

*Civil Society Partnerships.* Civil society organizations are vital partners in IAVI's work, helping to educate and mobilize communities about AIDS vaccines, advocating with country governments for policies that support vaccines, and helping IAVI forge strong relations with key opinion leaders and decision-makers. Possessing an unparalleled understanding of the needs of communities affected by the epidemic, civil society groups also help inform IAVI's strategic and programmatic decisions.

- IAVI's civil society partners met in Amsterdam in March 2006, bringing together for the first time the full spectrum of key IAVI partners in both developed and developing countries. Partners explored various opportunities for joint advocacy and agreed to collaborate on advocacy targeting the United Nations High-Level Meeting on AIDS and the G8 summit.

- In collaboration with the AIDS Vaccine Advocacy Coalition (AVAC), IAVI partnered with Health and Development Networks, a Thailand-based NGO, to disseminate vaccine preparedness information via accessible electronic forums.
- In India, IAVI briefed 30 NGOs from Assam, Manipur, and Nagaland, three states in Northeastern India, on progress in AIDS vaccine R&D. Consultative meetings were also held with NGOs in Tamil Nadu and Maharashtra. IAVI also began work with partners to establish a Vaccine Literacy Center in Chennai (Tamil Nadu) to disseminate information on AIDS vaccines and clinical trials.
- IAVI continues to support three Brazilian NGOs — Grupo de Incentivo à Vida (GIV) in São Paulo, Grupo de Apoio a Prevenção da AIDS (GAPA/RS) in Porto Alegre, and Grupo Pela Vida in Rio de Janeiro — that disseminate AIDS vaccine information throughout the country.
- In Europe, IAVI undertook outreach to civil society in 10 countries — Austria, Belgium, Denmark, Germany, Finland, The Netherlands, Norway, Spain, Sweden, and the U.K. — as well as at the EU level to increase understanding of AIDS vaccines and of IAVI's work, and to plan joint advocacy initiatives, such as media outreach and parliamentary meetings.

*Vaccines as a Women's Issue.* IAVI enhanced its work in 2006 to position vaccines as a key women's issue and to build support for vaccines among women's organizations.

- At the invitation of Stephen Lewis, then Special UN Ambassador on AIDS in sub-Saharan Africa, IAVI published an opinion editorial commentary on women and AIDS vaccines in the *Ottawa Citizen* during the International AIDS Conference in Toronto.
- In collaboration with the Global Campaign for Microbicides, IBIS Reproductive Health, and the Center for Health and Gender Equity, IAVI co-organized "Choices for Women: Promoting Investment in Multiple Female-initiated or -controlled HIV Prevention Methods," a session at the International AIDS Conference. IAVI then convened a follow-up gender consultation in New York in December



Jean-Marc Giboux/Getty Images

*Enlisting the support of political leadership, non-governmental organizations, community groups, and a range of strategic coalitions is essential for amplifying and reinforcing support for AIDS vaccines*

2006 to develop joint advocacy for a range of female-initiated or -controlled HIV prevention methods.

- Dr. Berkley participated with Dr. Zeda Rosenberg, president of the International Partnership for Microbicides (IPM), in a panel discussion on vaccines and microbicides at the Center for Strategic and International Studies (CSIS) in Washington in October 2006. The panel was intended to assist CSIS's HIV/AIDS Task Force in its efforts to improve the effectiveness and sustainability of the U.S. global AIDS response and to increase attention to HIV prevention.

*Product Development Public-Private Partnerships.* PDPs aim to transcend the limitations of the public and private sectors by adopting innovative new development approaches for affordable drugs, vaccines, and diagnostics needed in developing countries. IAVI was one of the first PDPs, incubated within the Rockefeller Foundation in the mid-1990s, and continues to serve as a model for the field. In 2006, IAVI intensified its collaborative advocacy work with other PDPs.

- IAVI successfully worked with other PPPs to encourage key EU officials to include a strong emphasis on neglected diseases in the EU's new research policy agenda.
- In November, Dr. Berkley delivered a plenary address on PDPs at the conference of the Global Forum for Health Research in Cairo, Egypt.
- *UNAIDS Programme Coordinating Board.* UNAIDS is the leading global body setting policy on HIV. IAVI worked in 2006 to strengthen its collaborative work with UNAIDS, including advising the Programme Coordinating Board, UNAIDS' governing body, on HIV prevention policy.

IAVI successfully advocated for the inclusion of AIDS vaccines and microbicides in the *UNAIDS HIV Prevention Policy Position Paper*, which articulated essential components for a comprehensive and effective response to the pandemic. This policy position paper was endorsed by the Programme Coordinating Board in 2006.

With the IPM, IAVI hosted a briefing for UNAIDS Programme Coordinating Board members in June 2006 on recent developments in the search for vaccines and other NPTs.

- IAVI was designated renewed status as a UNAIDS Collaborating Center and was approved as a PAHO/WHO Collaborating Center on HIV/AIDS Vaccine R&D.

*Engaging the Business Community.* With HIV causing growing economic and social harm in many countries, the pandemic has become a major issue for business and industry, which serve as influential partners in efforts to increase awareness of and commitment to AIDS vaccine R&D.

- A delegation from the Global Business Coalition on HIV/AIDS visited the Kangemi site of the Kenya AIDS Vaccine Initiative (KAVI) in November 2006. During the visit, IAVI and KAVI addressed a World AIDS Day symposium attended by Kenyan Vice President Moody Awori and Health Minister Charity Kaluki Ngilu.
- IAVI partnered with the Africa-Japan Forum and the AIDS Vaccine Development Association to sponsor the International Symposium on New Prevention Technologies in Tokyo, which focused on the need for a comprehensive AIDS response, including development of NPTs such as vaccines and microbicides. The audience included Japanese policymakers, industry representatives, and members of civil society.
- Dr. Berkley attended the World Economic Forum's Annual Meeting in Davos. The theme of the 2006 meeting was "The Creating Imperative," encouraging leaders from business, government and international organizations to apply fresh thinking to pressing global challenges, including financing for development and PPPs. Dr. Berkley spoke on a panel "AIDS Funding: Making the Money Work" and participated in the Global Health Initiative's Meeting on "Healthier Partnerships for HIV/AIDS, TB and Malaria."

*Implement a global policy advocacy campaign to build support for AIDS vaccine R&D and future access*

The strategic plan for 2005-2007 calls for an intensified global effort to build strong and durable support for AIDS vaccines.

- IAVI was one of four organizations on the global health track recognized in September 2006 on the opening day of the Clinton Global Initiative (CGI) meeting in New York. Former U.S. Health and Human Services Secretary Donna Shalala highlighted IAVI's CGI commitment to mobilize greater support to accelerate the development and eventual delivery of AIDS vaccines. IAVI's CGI work builds on the model of the organization's successful efforts in India to increase public awareness of and support for AIDS vaccine research.
- IAVI organized a series of events in Spain (Barcelona, Bilbao, and Madrid), including high-level meetings and extensive media coverage. With the support of Basque International Cooperation and a Basque NGO, IAVI initiated a vaccine awareness campaign in the Basque region. IAVI's partner organization, Grupo de Trabajo sobre Tratamientos del VIH, implemented an awareness campaign in Catalan, with the support of the Catalan International Development Agency.
- In the U.K., IAVI provided input to three important policy papers that will guide the government's priorities and policy actions in the coming years. With support from IAVI, the White Paper on International Development and the new health strategy of the Department for International Development (DFID) now include language supporting science, research development, and PDPs. IAVI also helped ensure that DFID's gender strategy recognizes AIDS vaccines as a critical technology for women.

*Objective: Enhance global financial commitment to AIDS vaccine R&D and ensure that any future vaccine is available, acceptable, affordable, and effectively used, particularly in developing countries*

To expedite progress toward an AIDS vaccine, and to sustain financial commitment for vaccine development, IAVI supported resource mobilization efforts by tracking current spending levels on vaccine R&D. Resource tracking by IAVI and its



partners indicated that spending on AIDS vaccine R&D doubled between 2000 and 2005. IAVI also devoted greater attention to strengthening advocacy for increased resources for vaccine research.

- In St. Petersburg, Russia, leading up to the G8 summit meeting in 2006, IAVI advocated for elevating the level of global financing for vaccine R&D.
- IAVI also played an influential advocacy role in successfully encouraging leading donor countries to establish a pilot advanced market commitment (AMC) for pneumococcal vaccines, an approach that creates incentives for private industry and accelerates uptake of future vaccines, including an AIDS vaccine.
- IAVI collaborated with Spanish researchers to gain new funding from the Spanish government for AIDS vaccine research efforts in Spain.

*Objective: Establish IAVI as the leading international organization for AIDS vaccine science, policy, and advocacy*

IAVI seeks to become the global brain trust on AIDS vaccines. In addition to collecting and analyzing the best available data on vaccine science, policy, and advocacy, IAVI uses state-of-the-art communications strategies to disseminate such

information in ways that are optimally compelling and accessible.

*Communications.* IAVI continued a year-long study to assess the organization's branding position and value in the eyes of key stakeholders in light of the evolution of the AIDS vaccine field. Findings from this study helped IAVI develop an organizational repositioning strategy aligned with the strategic planning process for 2008-2010.

- In 2006, IAVI developed a new global communications plan, with goals based on recommendations from the organizational repositioning project. Components of the new communications plan include refinement of key messages, improved outreach strategies in different regions, enhanced materials development, and greater cultivation of external IAVI champions.
- Press activities throughout the year centered on a number of key achievements and events. IAVI publicized the launch of vaccine trials in India, Kenya, Uganda, and Zambia. IAVI secured high-profile press coverage during the World Economic Forum in Davos, including a Reuters interview and a commentary ("We're Running Out of Time") by Dr. Berkley in *Newsweek International*. IAVI conducted a Webcast for European reporters on IAVI's *AIDS Vaccine Blueprint 2006* as a prelude to the AIDS Vaccine 2006 conference in Amsterdam, resulting in coverage in numerous publications, including *Red Herring* and Switzerland's *Le Temps*. In connection with World AIDS Day 2006, IAVI obtained coverage in *El Correo* (Spain), *Financial Times*, CNN, *The Hindu* (India), *The Independent* (U.K.), and other European outlets. The PBS documentary, *Ending AIDS*, was broadcast on Belgian television prior to World AIDS Day. The opening of IAVI's Southern Africa office in November 2006 gained significant media attention in key South African media outlets, including *Business Day*, which published an opinion editorial commentary by Dr. Berkley. IAVI spokespersons appeared on numerous television and radio shows in 2006, including National Public Radio's *Science Friday* and PBS's *Charlie Rose Show*, as well as in leading print outlets, such as the *San Diego Tribune*, *San Francisco Chronicle*, *Seattle Post-Intelligencer*, and *Washington Post*.



Jean-Marc Giboux/Getty Images



*In 2006, IAVI staff, Board members, and partners returned to IAVI's birthplace, the Rockefeller Foundation's center in Bellagio, Italy, to assess ways to maximize IAVI's strategic impact in the upcoming years, and commemorate its tenth anniversary*

**Publications.** IAVI augmented its publications capacity in 2006, with the goal of improving the comprehensiveness and strategic effectiveness of its scientific, policy, and advocacy publications for the field.

- IAVI produced an array of materials, including the *AIDS Vaccine Blueprint 2006: Actions to Strengthen Global Research and Development*, an AIDS vaccine information kit, a tenth anniversary organizational brochure, and an anthology of *IAVI Report* and *VAX* articles, as well as the publication of six editions of *IAVI Report* and 12 editions of *VAX*, including two special issues.
- Regional publications included a brochure for European policymakers; *Sankalp*, IAVI's India newsletter, which published six issues in 2006, including a commemorative addition celebrating the organization's tenth anniversary; and in East Africa, vaccine literacy materials translated into French for use in Rwanda. IAVI also provided technical and financial support for the development of various educational and communications materials at IAVI-sponsored sites in Africa.
- IAVI resources reached readers in over 3,600 organizations in 143 countries. Bulk distribution of *IAVI Report* increased 98% in 2006, and distribution of *VAX* increased by 24%. In addition, *Sankalp* now reaches 6,500 readers in India, and IAVI's India Web site is available in four languages: English, Tamil, Marathi, and Hindi.

IAVI will continue to further its readership and outreach by bolstering its international distribution and by expanding the translation of various resources into Chinese, French, German, Portuguese, and Russian to promote better understanding and commitment for AIDS vaccines.

**Clinical Trials Ethics.** IAVI adheres to recognized international ethical standards when it conducts clinical trials. Within the AIDS vaccine field, IAVI increasingly serves as a resource on trial ethics.

- In collaboration with the Center for Bioethics of Peking Union Medical College and the Chinese Medical Association, IAVI co-sponsored a full-day meeting in August 2006 on ethical issues in AIDS vaccine clinical research in Beijing. The meeting occurred as a satellite session at the 8th World Congress on Bioethics, bringing together Chinese investigators and stakeholders with international experts on ethics and research.

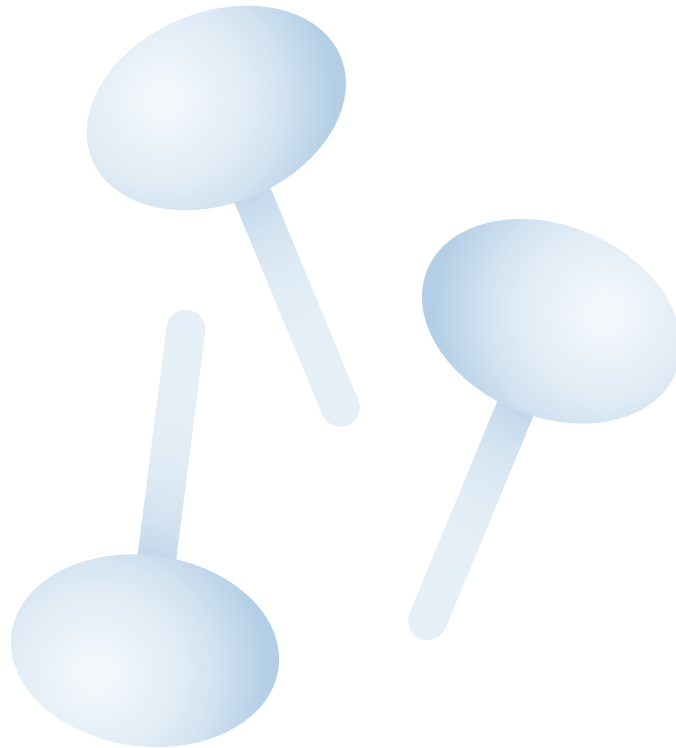
**XVI International AIDS Conference.** IAVI played a visible leadership role at the XVI International AIDS Conference in Toronto in August 2006, which focused on the promises and progress made to scale up treatment, care, and prevention.

- IAVI organized a well-attended satellite meeting on vaccine research in developing countries, which provided attendees with extensive materials about IAVI and the field. IAVI also held a press conference to launch the *AIDS Vaccine Blueprint 2006*, with speakers including Dr. Berkley; Stephen Lewis, IAVI Board member and then United Nations Special AIDS Envoy in Africa; and Pontiano Kaleebu, assistant director of the Uganda Virus Research Institute.
- The launch of the *AIDS Vaccine Blueprint 2006* and other IAVI activities at the conference resulted in substantial media coverage in the *Los Angeles Times*, *Toronto Star*, *Globe and Mail*, *El Pais*, Agence-France Presse, Canadian Broadcasting Corporation, Deutsche Presse Agentur, Reuters, and other high-profile outlets.

# Advocate

for Public Policies that  
Support Vaccine R&D  
and Future Access

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### III. ADVOCATE FOR PUBLIC POLICIES THAT SUPPORT VACCINE R&D AND FUTURE ACCESS

The strategic plan recognizes that financing alone will not ensure that a safe and effective AIDS vaccine will be developed and appropriately used. To accelerate AIDS vaccine R&D and promote early uptake of future vaccines, a range of public policies are needed to complement global political and financial commitment. To enable IAVI to lead global efforts to implement sound policies to support vaccines, the strategic plan provides for IAVI to develop a strong evidence base for its advocacy positions, the highest-quality policy analyses, and strong advocacy partnerships.

**Objective:** *Make the case for increased and improved public sector investment in an AIDS vaccine*

While IAVI continues to engage the private sector in the search for an AIDS vaccine, the public sector currently accounts for 90% of global investment in AIDS vaccine R&D and is likely to remain the

Figure III-A

Annual Average Public Sector Investments in Preventive AIDS Vaccine R&D by Country Relative to National Wealth (2003–2005)

Country	% of GDP ( $\times 10^3$ )
United States	4.0–5.0
Ireland	2.0–3.0
Canada, Netherlands, South Africa	1.0–2.0
Denmark, Norway, Sweden, United Kingdom	0.5–2.0
Australia, Brazil, China, Finland, France, Germany, India, Italy, Japan, Russia, Thailand	<0.5

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primary funder for such efforts. The strategic plan calls for IAVI to make the best evidence-based case possible for why public sector investments in AIDS vaccine R&D represent sound public policy.

#### *Effectively advocate for an appropriate level of financing to drive an accelerated R&D program*

**Resource Tracking.** IAVI is a founding member of the HIV Vaccines and Microbicides Resource Tracking Working Group, which also includes the AVAC, the Alliance for Microbicide Development, and UNAIDS.

- In August 2006, the Working Group published updated estimates of public, philanthropic, and commercial funding for HIV vaccine and microbicide R&D. In 2005, funding for HIV vaccine R&D was estimated at US\$759 million, with the public sector accounting for nearly 90% of global investment. The 2005 estimates were widely cited in, among other sources, the annual *WHO/UNAIDS Report on the global AIDS epidemic*, the *Journal of the American Medical Association*, and such leading media outlets as Bloomberg, Fox News, and *Fortune* magazine.
- IAVI published a Research Working Paper in November 2006 that documents and analyzes the European Commission's support for R&D on AIDS, tuberculosis, and malaria.

**Modeling Vaccines.** In collaboration with the Bill & Melinda Gates Foundation, IAVI analyzed how improvements to the vaccine development pipeline could potentially shorten the time frame for developing an effective vaccine. The project assessed the investments that such improvements would require.

- Findings from the analysis show that such key actions as targeting critical bottlenecks for

investment and improving the organization and management of vaccine R&D could potentially accelerate the development of a vaccine by three to 22 years. Even at the conservative end of that range, having a vaccine five years sooner would translate into 10 to 15 million infections averted.

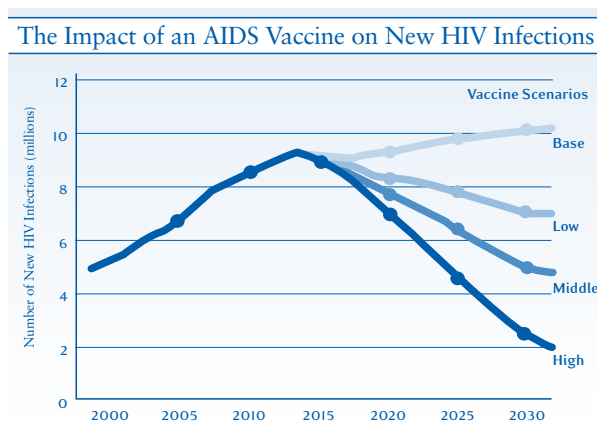
- IAVI also initiated a project to identify and review key features of available vaccine R&D models, based on experience with vaccines licensed over the last 60 years. The project found that, over the last several decades, public and private sectors have played widely varying roles in the development of new vaccines. As part of the project, IAVI also reviewed the Manhattan Project, the War on Cancer, and other large R&D initiatives characterized by centralized decision-making and narrow focus; an important conclusion was that the efficiency of a centralized effort must be balanced against the risk of suppressing innovation. Preliminary results of the project were presented at the Amsterdam AIDS Vaccine Conference in 2006, with publication anticipated in 2007.

*Convince key decision-makers of the favorable cost-benefit rationale for investing in AIDS vaccine R&D and future access*

*Assessing the Impact of an AIDS Vaccine.* IAVI and the Futures Institute developed a new estimate of the number of infections that could be averted by a partially effective AIDS vaccine. Using selected countries to develop regional estimates, the analysis indicated that even a modestly effective vaccine, which provides limited protection from infection and lowers the probability of transmission by vaccinated individuals who subsequently become infected, could avert more than one million new infections annually. It is estimated that introduction of one or more AIDS vaccines would avert between 5.5 million and 28 million infections between 2015 and 2030 and save up to US\$132 billion in HIV-related treatment costs.

- Estimates of the potential global impact of an AIDS vaccine were presented at the Amsterdam AIDS Vaccine Conference and at a meeting of the WHO-UNAIDS Collaborative Study on the Cost-Effectiveness of AIDS Vaccines in Beijing.
- IAVI plans to collaborate with local partners in several countries to develop country-specific impact assessments.

Figure III-B



*Documenting the Benefits of Trials.* While the primary goal of clinical trials is to produce clear, reliable findings on candidate vaccines, trials can also benefit local communities, helping build research capacity and catalyzing improvement in local HIV services.

- IAVI published a feature article, “AIDS Vaccine Research — Partnering with the Developing World,” in *Global HealthLink*, the news magazine of the Global Health Council. IAVI subsequently initiated a project to review experiences of ongoing or completed trials to identify intermediate benefits to participants, communities, researchers, and health systems. Publication of a full report on the project will occur in 2007.

Figure III-C

**Benefits of AIDS Vaccine Trials for Local Communities**

Preliminary findings suggest that key benefits of trials for local communities include:

- Human capacity building in research and trial management;
- Expanded awareness and knowledge of HIV and vaccines;
- Improved access to medical care and voluntary HIV counseling and testing; and
- Strengthened regulatory approval mechanisms.

**Objective:** *Pursue initiatives to increase and accelerate R&D by the private sector or by PPPs*

IAVI’s strategic plan for 2005-2007 recognizes that existing market incentives are unlikely to generate



the level of private sector engagement needed to ensure a robust global AIDS vaccine effort. To create the reliable market needed in developing countries to entice companies to invest greater resources in AIDS vaccine R&D, a range of innovative mechanisms is required to correct existing market shortcomings.

*Facilitate implementation of needed “push” and “pull” mechanisms to increase private sector engagement in AIDS vaccine R&D*

*Advance Market Commitments (AMCs).* IAVI released a proposal in 2006 for an AMC for AIDS vaccines. An AMC is a legally binding contract offered by a government or other financial entity to guarantee a viable market for future health products for neglected diseases. This “pull” mechanism aims to create a market comparable in size and certainty to the market for medicines in rich countries, thereby increasing incentives for biotech and pharmaceutical companies to invest in the development of new vaccines to tackle the world’s most important diseases.

- IAVI’s analysis indicates that an AMC for AIDS vaccines would be technically feasible, financially credible, and attractive to industry, sponsors, and developing countries. An expert committee commissioned by the Group of 7 finance ministers selected pneumococcal vaccines as the focus of an AMC pilot vaccine.

*Incentives in Developing Countries.* Working with International Market Assessment, IAVI completed a policy research study, “Accelerating AIDS Vaccine R&D in India: Assessing Policy Obstacles and

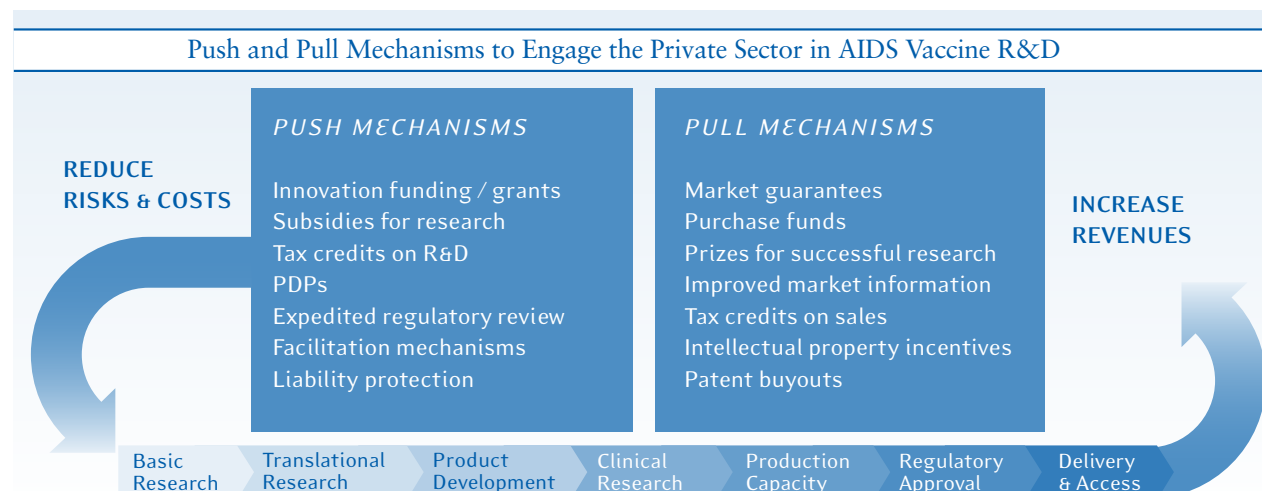
Opportunities.” The report identified various policies to encourage greater involvement by the private sector in AIDS vaccine R&D. One policy option identified by the study is establishing a vaccine R&D support fund to provide sustainable financing for companies engaged in novel vaccines.

*Collaborate with key stakeholders, most notably IAVI’s partners in the Global HIV Vaccine Enterprise, to clarify and expedite regulatory approval processes for clinical trials and product licensure in both developed and developing countries*

Because national regulatory systems for medicines and vaccines are weak in many developing countries, delays can often occur in national approval of clinical trials or in licensure of new products that have proven to be safe and effective. With 11,000 or more HIV infections occurring daily, removing such delays is an urgent global necessity.

- As part of its ongoing efforts to document best practices in developing countries, IAVI presented an analysis of ethical and regulatory aspects of AIDS vaccines at a workshop organized by Brazil’s National AIDS Program in October 2006. Attendees, who included the country’s leading AIDS vaccine research centers, government officials from the regulatory realm, and civil society representatives, made commitments to implement several strategies to enhance the quality and speed of clinical trial reviews.
- At the XVI International AIDS Conference in Toronto, IAVI presented a poster that compared ethical and regulatory systems in five countries,

Figure III-D



with plans to expand the analysis to additional countries.

- IAVI continued its close collaboration with its partners in the Global HIV Vaccine Enterprise. Dr. Berkley also serves on the steering committee of the Enterprise.

**Objective:** *Ensure that manufacturing capacity and regulatory processes facilitate R&D and rapid access to an AIDS vaccine*

Traditionally, drugs and vaccines have been introduced in developing countries many years after they were first developed for Western countries. IAVI and its partners, along with other PPPs, are creating an entirely new paradigm: specifically designing new health tools for use in developing countries. Because there is little experience in rapidly scaling up manufacture, licensure, and introduction of new products in developing country markets, delays are likely unless steps are taken in advance to plan for a sufficient global supply of new vaccines and for regulatory processes that expeditiously evaluate and approve new health products.

- In partnership with the Brazilian Ministry of Health and WHO, IAVI sponsored a workshop in Brazil on regulatory and ethical review for vaccine trials. More than 100 experts and stakeholders from around the country attended and discussed both regulatory bottlenecks and strategies for overcoming them. Regulatory and ethics experts from India and South Africa presented their experiences at the meeting.

**Objective:** *Build the knowledge base to better understand the need and demand for AIDS vaccines, and advocate for policy initiatives to ensure adequate global supply and the rapid adoption of AIDS vaccines by countries and individuals*

*Increase understanding of the potential impact of an AIDS vaccine with different characteristics in different epidemiologic settings*

As IAVI and the Futures Institute found (see p. 19), even a modestly effective vaccine would prevent one million new infections. Over a 15-year window, an AIDS vaccine could avert up to 28 million infections, equivalent to 72% of all current HIV infections.

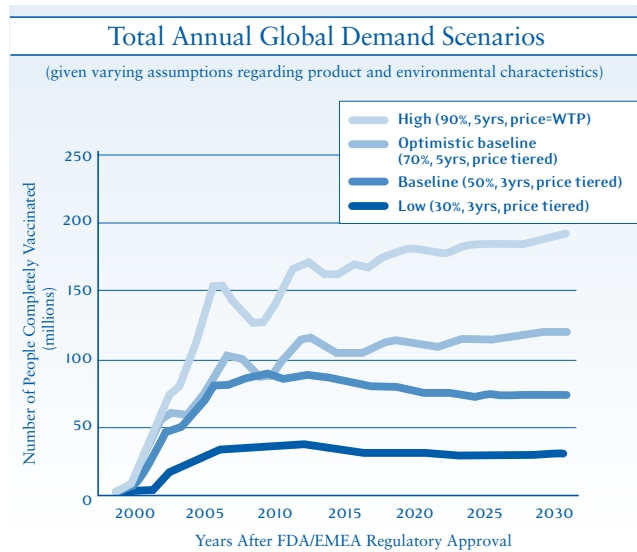
*Identify and increase understanding of the factors that will affect AIDS vaccine acceptability, public and private demand, and uptake*

To have an impact on the pandemic, a new vaccine must be widely embraced by people at risk of infection. IAVI sponsors research to assess the acceptability of candidate vaccines and to project the global supply that will be needed to meet the likely demand for a new vaccine.

- IAVI and the Boston Consulting Group initiated research to develop a long-term demand forecasting framework for AIDS vaccines. Informed by more than 70 interviews with policymakers and experts from the AIDS, vaccine, and health policy fields in developed and developing countries, the project characterized and quantified key drivers for demand.
- An IAVI article, “Estimating the Demand for a Preventive HIV Vaccine: Why We Need to Do Better,” appeared in the September 2006 online journal *Public Library of Science (PLoS) Medicine*. The article discusses why improved estimates of demand for future vaccines are needed to inform private sector decisions on R&D investments and manufacturing capacity.
- IAVI generated a study that examined future demand for an AIDS vaccine based on variable vaccine profiles. The study suggested “block-buster” potential for a first-generation vaccine, especially if the product could provide efficacy of 50 to 70%, protect for a duration of three to five years, and benefit from tiered pricing.

According to IAVI’s analyses, the annual global demand for such a product could range from 68 million to 92 million complete courses, with a complete course equaling two doses (prime-boost). This translates into 2.1 billion to 2.8 billion complete courses over a 30-year time-frame. The number of courses could, however, rise higher, due to additional actions to address regulatory issues, infrastructure limitations, and political constraints on access. Preliminary results of IAVI’s analyses were presented at the Amsterdam AIDS Vaccines conference in 2006, with final results to be published in 2007.

Figure III-E

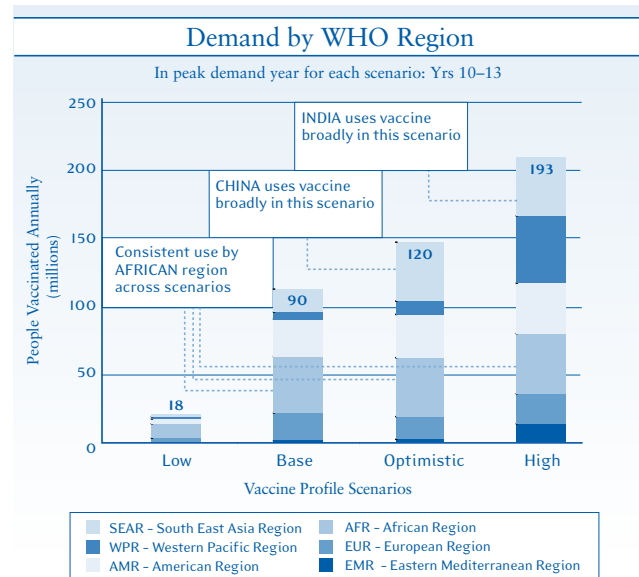


*Work with other stakeholders and advocacy partners to help prepare the delivery systems needed to distribute future vaccines*

With initial support from the Hewlett Foundation, IAVI is using its expertise in community preparedness, global advocacy, and policy research and analysis to promote the introduction of HPV vaccines. A key aim of the project is to ensure that the AIDS vaccine field benefits from lessons learned from the introduction of HPV vaccines. IAVI's work on HPV vaccines builds on a strategic partnership with the Program for Appropriate Technology in Health (PATH) to conduct operational research while piloting introduction of the HPV vaccine in four countries.

- IAVI will work with PATH on HPV vaccine introduction in India and Uganda, as well as on global policy development and advocacy efforts. IAVI is also part of a broader coalition of organizations focused on HPV introduction, through which IAVI seeks to identify partnerships and opportunities to support HPV introduction in other countries where IAVI has a presence. In September 2006, IAVI and PATH co-sponsored a two-day workshop to introduce NPTs in India, attracting more than 70 experts from both the public and private sectors.
- IAVI is also collaborating with a broad range of other global partners on HPV vaccine introduc-

Figure III-F



tion. In December 2006, IAVI co-convened a London meeting on global action on HPV vaccines, collaborating with AVAC, the International Planned Parenthood Federation (IPPF), the International Union Against Cancer (IUAC), PATH, the Rockefeller Foundation, and others. The London meeting defined key advocacy and programmatic actions required to overcome potential barriers to HPV vaccine access. In 2007, IAVI and its partners plan to explore actions to create an ongoing HPV vaccine coalition to support early access for girls and women in developing countries.

**Objective:** *Lead targeted policy advocacy efforts to support IAVI-wide initiatives to enhance global public, political, and financial commitment to an AIDS vaccine*

IAVI worked successfully with advocacy partners to include language supporting new vaccines and AMCs in the communiqué of the annual summit of the G8 industrialized countries (see p. 10).



# Partner

with Countries where  
the Epidemic is,  
or is Likely to be,  
Most Severe

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## IV. PARTNER WITH COUNTRIES WHERE THE EPIDEMIC IS, OR IS LIKELY TO BE, MOST SEVERE

Since its inception, IAVI as a global organization has pursued its work with active partners in both developed and developing countries. IAVI's country programs educate communities, engage political leaders, and raise public awareness of vaccine-related issues. IAVI strives for consistency and coherence across country programs, harmonization of country-based efforts with IAVI goals, representation of field interests and perspectives in organizational operations and decision-making, and management of relationships with developing country stakeholders and with networks of organizations that focus on developing countries.

The strategic plan for 2005-2007 stipulates that IAVI will build on these achievements to enhance the capacity of developing countries to serve as full partners in the global search for a safe and effective vaccine. In particular, IAVI aims to contribute to a substantial expansion of global clinical trial capacity and to help countries prepare for eventual introduction of future vaccines. In 2006, IAVI further augmented its presence in heavily affected countries by opening an office in South Africa, the country with the second greatest number of HIV infections worldwide.

**Objective:** *Ensure national and site preparedness to accelerate all stages of AIDS vaccine trials, especially in countries where the epidemic is most severe and incidence is high*

**Building Country-Level Support.** IAVI devoted substantial effort to strengthening country-level support for vaccine research, especially where trials are taking place.

- In India, for example, IAVI updated National Advisory Board members through biannual meetings, regular reports, and quarterly extranet

updates. At the Second International Inter-Faith Conference on Prevention and Control of HIV/AIDS, IAVI updated religious leaders on progress in the search for a vaccine.

- IAVI co-sponsored media workshops to educate journalists about AIDS vaccine activities in Brazil, India, and Uganda.



*Jean-Marc Giboux/Getty Images*

*IAVI is studying how a vaccine can be effective in populations where most new HIV infections are occurring*

- In China, IAVI introduced a vaccine preparedness program in Kunming. In February 2006, in collaboration with the Chinese Academy of Medical Sciences in Beijing, IAVI convened all major organizations involved in vaccine research in the country to promote information exchange and coordination. The meeting resulted in a consensus document outlining key programmatic activities for vaccine preparedness in China. (See p. 10 for a discussion of IAVI meetings with leading policymakers in China in December 2006.)

- In Africa, IAVI updated parliamentarians on AIDS vaccine issues, developed and promoted vaccine literacy materials and workshops, and supported the Kenyan NGO Vaccine Support Network. In South Africa, IAVI worked with trial sites and the South Africa AIDS Vaccine Initiative (SAAVI) to adapt and harmonize materials among all sites and partners.

*Cohort Development and Site Preparedness.* IAVI worked in 2006 to strengthen services that are needed for trials, including treatment and care referrals for trial volunteers and for individuals who are screened out as HIV-positive.

- IAVI supported training on HIV counseling at multiple sites in East Africa. IAVI joined with the Medical Research Council (MRC) to construct clinics in Entebbe, Uganda, for voluntary counseling and testing and other medical services. In addition, IAVI provided home-based voluntary counseling and testing to 5,000 individuals near Entebbe. IAVI also worked closely with Projet San Francisco to support two health centers and two testing sites in Rwanda.
- In Southern Africa, IAVI established a partnership with Aurum Health Research to begin an assessment of trial preparedness in the mining district of Rustenberg, including an analysis of risk behaviors, a community health profile, and health service access. IAVI is also supporting cohort development and community mobilization activities in Soweto, South Africa.
- IAVI initiated a study in three states in India to identify possible barriers and opportunities for community involvement in large-scale clinical trials, focusing on men who have sex with men and transgendered communities. In addition to informing efforts to increase the participation of these populations in future trials, IAVI expects the research project to provide useful information for the design and implementation of broader service strategies for these vulnerable groups. A proposal was submitted for ethical and regulatory review, and initial consultations were held with research institutions, NGOs in the three states, and representatives of the target populations.

- In East Africa, IAVI initiated a social science project in collaboration with the International Center for Research on Women (ICRW) and the University of Nairobi, Department of Community Health. The project will study gender issues with respect to recruitment and retention of study participants and analyze the social effects of participation in vaccine trials and feasibility studies.

*Site Capacity Building.* In 2006, IAVI undertook substantial efforts to evaluate the level of program support at all IAVI sites, including staff training, support for learning opportunities, and provision of technical assistance in such areas as gender, informed consent, counseling, HIV education, and quality assurance.

- In East Africa, for example, IAVI examined all components of the informed consent process and identified lessons learned to date from Phase I and II vaccine trials. IAVI initiated counseling supervision programs at sites in the region, completed development of a new informed consent video, and implemented a new program to promote cross-site learning on voluntary counseling and testing for couples.
- In Southern Africa, IAVI provided media training to trial staff in Lusaka, Zambia, and initiated quality assurance activities about voluntary counseling and testing at the trial site in Cape Town, South Africa. Vaccine literacy materials were pre-tested at a regional meeting in October 2006, which provided an opportunity to assess capacity building needs throughout the different sites in the region.
- IAVI developed a comprehensive gender strategy, which addresses the role of gender in IAVI's policies and programs, and articulated an advocacy plan to position a vaccine as an ultimate solution to women's HIV-related vulnerability. IAVI conducted gender sensitivity trainings among staff in India, Kenya, and Uganda, using a questionnaire to assess the effectiveness of the training. The organization collaborated with the Uganda Women's Network to provide support on gender issues related to clinical trials and to explore joint advocacy on vaccines as a women's issue.

*Community Engagement.* IAVI undertook a comprehensive mapping exercise to assess strengths and weaknesses in its community engagement efforts at all sites. Community mobilization activities were documented using a set of standardized tools. IAVI is also part of a core group convened by UNAIDS to develop international guidelines for community involvement in HIV prevention research.

- In India, a community awareness and outreach initiative was launched to ensure speedy trial recruitment at the second research site in Chennai. Strong support from influential religious groups, media, and other community partners facilitated speedy recruitment for a second Phase I trial site. IAVI's India staff also met with representatives of men who have sex with men and transgendered populations to understand their perspectives about participating in vaccine studies.

*Community Advisory Boards (CABs).* IAVI commissioned a global assessment of the CABs of all IAVI partners to identify lessons learned, best practices, and mechanisms to facilitate information exchange

and cross learning. In June 2006, IAVI brought together CAB representatives from IAVI programs worldwide to share information and perspectives.

Other CAB activities included support for:

- A vaccine literacy training for CAB members in Rwanda;
- A public speaking workshop for CAB members in Lusaka;
- A needs assessment for CAB development at a potential new site in South Africa.

*Objective: Prepare for accelerated access and use of a vaccine in trial countries and in other countries where the epidemic is severe and incidence is high*

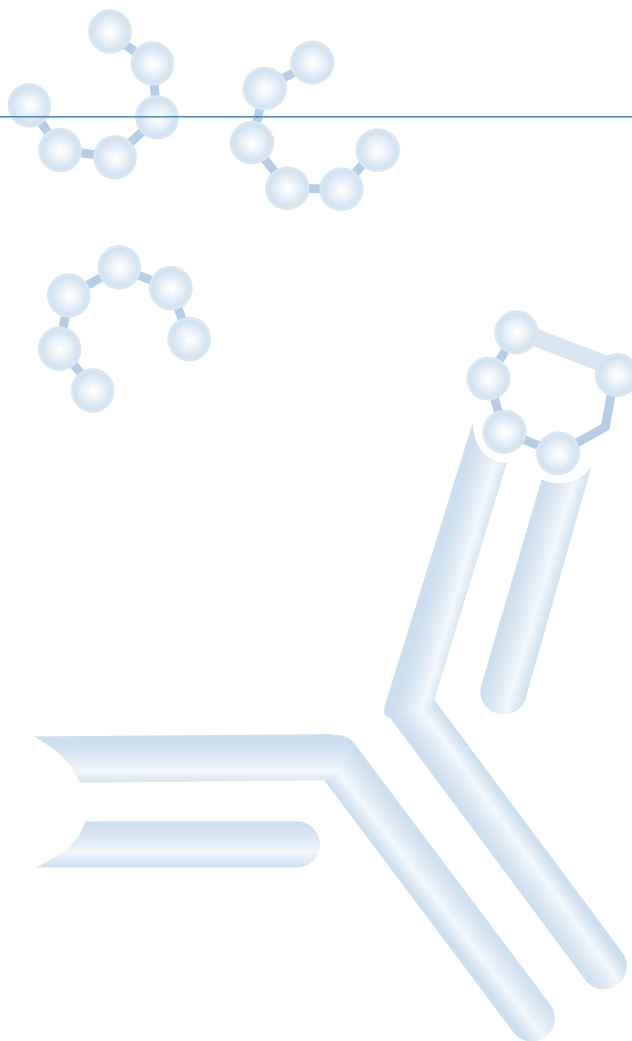
IAVI is working with PATH to learn from the introduction of HPV vaccination, with the aim of using lessons learned to inform the introduction of future AIDS vaccines. In particular, IAVI will work with PATH on community preparedness, global advocacy, and policy research and analysis in promoting introduction of HPV vaccines.



Jean-Marc Giboux/Getty Images

*In areas where vaccine trials are taking place, IAVI facilitates the creation of Community Advisory Boards (CABs) that liaise between researchers and the community and monitor the conduct of IAVI-sponsored trials*

# Operate an Optimally Efficient and Effective Organization to Advance the IAVI Mission







## V. OPERATE AN OPTIMALLY EFFICIENT AND EFFECTIVE ORGANIZATION TO ADVANCE THE IAVI MISSION

To further its ambitious agenda of speed and innovation in the global search for an AIDS vaccine, IAVI requires internal operations that adhere to the most demanding professional standards. The strategic plan for 2005-2007 provides for ongoing assessment and improvement of IAVI's internal policies and practices, including human resources, information technology, and internal communications.

### *Organizational structure and management*

As IAVI has adapted to new challenges and opportunities — creating an in-house vaccine development laboratory, opening a new Southern Africa office, forging additional research linkages in a growing number of developing countries, and overseeing cutting-edge scientific research projects — it has increased organizational investments in strategies to improve performance-based management, ensure financial accountability, and meet the reporting requirements of diverse donors.

- IAVI made significant strides in 2006 to strengthen performance-based management of the organization. A new workplan tool was implemented, enabling the organization to gain a global view of ongoing and planned activities, to assess the financial impact of particular initiatives, and to monitor progress in meeting desired outcomes. Work began on a comprehensive monitoring and evaluation system which should be operational by mid-2007.
- Ernst & Young LLP completed their fifth audit of IAVI in April 2006. The clean audit opinion stated that IAVI's financial statements fairly and accurately communicate the organization's financial position; no material adjustments to IAVI's financial statements were needed. To comply with laws applicable to organizations that receive U.S. government funding, Ernst & Young

also completed their fourth A-133 audit, which focuses on financial controls for such funding; the audit yielded a clean opinion.

- Two USAID audits, undertaken in April 2006 in anticipation of a cooperative agreement with IAVI, yielded positive results. IAVI also received its second clean audit opinion from the EU in connection with the EU's three-year grant to IAVI to support activities in East Africa.
- The organization established the financial and operational infrastructure of its South Africa field office in 2006. IAVI also conducted its second annual finance skills and compliance workshop in South Africa for all IAVI-funded sites, including headquarters and the core laboratory. The workshop educated IAVI stakeholders on standardized reporting, IAVI finance policy, and donor compliance requirements.

### *Best operational practices*

IAVI aims to adhere to state-of-the-art organizational practices to maximize productivity, enhance accountability, and ensure optimal value for IAVI's stakeholders.

- IAVI has initiated an effort to document and evaluate its country programs, using a standardized assessment tool to document IAVI's country-level activities. The organization intends to use results from this project to develop criteria for future organizational decisions on investing in new countries.
- A new Advocacy Coordination Group has strengthened internal processes for key advocacy-related activities, including event planning and coordination, relationship management, and development and dissemination of advocacy messages. The Advocacy Coordination Group

coordinated the development of an organization-wide advocacy strategy for 2007, drawing on the combined expertise of numerous IAVI departments. Key goals for the advocacy strategy include advancing the policy agenda to accelerate R&D and future access, promoting the priorities of the *AIDS Vaccine Blueprint 2006*, and increasing political and financial support for AIDS vaccine R&D.

- IAVI launched a crisis management initiative to prepare for serious events that might threaten the reputation and operations of the organization. A crisis team has finalized a protocol that delineates staff responsibilities in the event of a crisis and is in the process of developing a crisis manual for use by IAVI offices worldwide.

### *Business model and intellectual property*

With the aim of drawing the best from both the public and private sectors, IAVI aims to operate like a first-class business to create essential new international public goods that are affordable and accessible in developing countries.

- In keeping with IAVI's increased emphasis on improving internal monitoring and evaluation, a Project Management Office was established in 2006 to oversee its various scientific projects.
- To support IAVI research projects, collaboration agreements were executed with the Bill & Melinda Gates Foundation's CAVD, India Department's of Biotechnology (DBT), the ADARC, and Danish and U.S. biotech companies.
- IAVI entered a new collaboration agreement with Targeted Genetics, Children's Research Institute (U.S.), and the Children's Hospital of Philadelphia to support ongoing research on the AAV vaccine candidate.
- In 2006, IAVI filed provisional U.S. patents for the administration of heterologous vaccines and the use of antibody-antigen complexes as HIV vaccines.

### *Human resources*

IAVI's goals cannot be met without a staff that is highly qualified in relevant disciplines, well managed, and motivated. IAVI will continue to build the capacity of its staff and invest in the foundation and infrastructure of the organization.

- A key focus of IAVI's human resource initiatives in 2006 was strengthening early assistance to new staff. The organization revitalized its early orientation efforts, developing and delivering three new "on-boarding" programs to enhance staff retention.
- As part of its first leadership development program (IAVI University), the organization surveyed staff to inform design, delivery, and evaluation of program contents. A mid-year performance management process in 2006 helped establish the foundation for more formal career development initiatives planned for 2007. Performance management was strengthened by incorporating cross-functional goal assessments and implementing systematic training and formal evaluation techniques.
- After a comprehensive review of its staff benefits, IAVI improved the breadth of its benefits while reducing overall costs to the organization by more than \$50,000. The organization aims to review its global benefits policies at least once every two years. IAVI also implemented a benefits plan for its field offices. The organization hired a new benefits broker and established a new benefits portal for U.S.-based staff to improve benefits management and access.

### *Information technology*

With offices in six countries and a research presence in a growing number of developing countries, the challenge of ensuring the ability of IAVI staff and partners to share information and communicate in real time can be daunting. By rapidly incorporating advances in communications technology, IAVI aims to work as a single organization, coordinating targeted efforts in different parts of the world to achieve the organization's mission.

- IAVI enhanced information technology capacity in field sites, improving connectivity, data sharing,



Jean-Marc Giboux/Getty Images

*IAVI's efficient and cost-effective information technology infrastructure allows for swift data processing and ensures that valuable and accurate information is accessible to scientists*

- and efficiency. The organization also implemented new security measures to protect against viruses, spam, and other online threats.
- Establishment of the Johannesburg office included implementing an information technology system for the new site. Similarly, the Brooklyn lab required sophisticated data management systems, as well as adequate back-up and security.
  - IAVI's information technology expertise was highlighted in a poster presentation at the XVI International AIDS Conference in Toronto, "A Participatory Approach to Information and Communications Technology (ICT) Transfer for Clinical Trials in Resource-Constrained Settings." The presentation focused on IAVI's initiatives to increase local capacity in information technology at all IAVI sites. IAVI's information technology work in Kenya was nominated in the health category for The Tech Museum Awards, which honor organizations and individuals that apply technology for the benefit of humanity.

### *Internal communications*

IAVI launched a new internal communications unit within the Communications Department that aims to improve the understanding of IAVI initiatives among staff in all IAVI offices, facilitate internal information flow, and foster a sense of community within the organization.

- As part of IAVI's efforts to improve its internal communications, the *IAVI Connection*, an internal newsletter, was launched, and the intranet was improved.

### *Resource mobilization*

The strategic plan for 2005-2007 provides for expanding and diversifying IAVI's funding base, with the aim of ensuring that adequate resources are available to support the organization's strategic and operational objectives. In 2006, IAVI created and filled the new position of senior vice president for External Strategy Development, which includes a specific focus on mobilizing private industry to accelerate the search for an AIDS vaccine. Key activities by sector include:

**Public Sector.** Public sector support accounted for more than 90% of IAVI's 2006 revenue. The total number of governments providing financial support to IAVI reached 10 in 2006.

- In Europe, IAVI obtained increased financial support from Ireland, The Netherlands, Norway, and Sweden and finalized a new multi-year contribution from Denmark. Altogether, European donors contributed US\$25 million to IAVI's 2006 budget, with amounts secured for 2006-2009 exceeding US\$80 million. IAVI completed all narrative and financial reporting for its European grants and submitted new funding proposals to three different European governments.
- In North America, IAVI received more than US\$28 million in 2006 from USAID, with which it also entered into a five-year, US\$155 million cooperative agreement. The Canadian government also approved an unrestricted CAD\$12 million (US\$10 million) grant to IAVI, as well as a new, two-year unrestricted award of CAD\$20 million for 2007-2008. The World Bank also renewed its support for IAVI, awarding a grant of US\$1 million for 2006-2007.

**Private Sector.** As part of IAVI's tenth anniversary, a dinner was held in June 2006 to honor past and current board members and donors. New York City Mayor Michael Bloomberg delivered the keynote address, and remarks were also made by Peter Piot, executive director of UNAIDS; Geeta Rao Gupta, executive director of the International Center for Research on Women; Kapil Sibal, minister of science and technology for India; and Geoffrey Lamb, IAVI Board chair.

- Three donors — the Alfred P. Sloan Foundation, Merck & Co., Inc., and Pfizer Inc — provided



underwriting toward IAVI's multi-faceted tenth anniversary history project, which summarized IAVI's history in print and film and made special note of the accomplishments and assistance of IAVI's many partners. The history project distilled lessons learned from the first 10 years of the world's first PDP.

- For the fifth consecutive year, Charity Navigator, a leading independent charity evaluator, awarded IAVI its highest rating of four stars. This rating, based upon IAVI's strong commitment to programmatic work, places the organization among the top 1% of the 5,000 charities evaluated nationwide by Charity Navigator. This rating continues to play a key role in expanding IAVI's donor base.



*Alex Oliveira/Startraks Photo*

*New York City Mayor Michael Bloomberg delivered the keynote address at a special dinner honoring IAVI's donors and Board members to commemorate IAVI's tenth anniversary*

**Foundations.** Until There's A Cure Foundation (UTAC), one of IAVI's founding donors and supporter of IAVI's R&D program, increased its award to US\$100,000, bringing UTAC's total giving to US\$1.1 million. The New York Community Trust awarded US\$575,000 to IAVI for 2006-2007 to support IAVI's AIDS Vaccine Development Laboratory, IAVI's first scientific venture in New York City and its first in-house research facility. The James P. Pendleton Charitable Trust, which originally supported IAVI's launch of its NAC in 2002, pledged support for equipment purchases for the new lab.

- In July 2006, the Bill & Melinda Gates Foundation announced that IAVI would receive US\$23.7 million to pursue novel viral vectors through its T-Cell Vaccine Research and Development Consortium. The grant was among 16 announced by the Gates Foundation to establish an international network of HIV vaccine consortia called the CAVD. Through a US\$9.46 million sub-grant from the Foundation for the National Institute of Health, IAVI will also collaborate on another Gates Foundation grant establishing central facilities to assist with research standardization and benchmarking.
- During IAVI's first decade, the Gates Foundation has been one of the organization's most important supporters. In May 2006, IAVI recognized the foundation's extraordinary support by co-sponsoring a reception in honor of Melinda Gates at the Senate Foreign Relations Committee. More than 100 people attended, including members of Congress, the executive branch, embassies, international organizations, and non-governmental organizations. During her remarks at the reception, Ms. Gates emphasized that the search for a vaccine and other HIV prevention technologies remains one of the foundation's central priorities.
- Providing invaluable general operating support, The Haas Trusts doubled their award to US\$100,000 for 2006. Broadway Cares/Equity Fights AIDS increased its support from US\$100,000 to US\$150,000. The Rockefeller Foundation supplemented its US\$500,000 award for 2005-2006 with a special one-time grant of US\$200,000 for general support in 2006.

- In anticipation of a successful AIDS vaccine, support from the William and Flora Hewlett Foundation helped launch an innovative new project focusing on contributing to and learning lessons from the introduction of HPV vaccines in developing countries.

**Corporate.** Previous and new corporate donors provided substantial support to IAVI in 2006, with total corporate financial and in-kind contributions exceeding US\$650,000.

- In 2006, Pfizer sent three global health fellows to work with IAVI in South Africa and Uganda, which, along with the company's support for

IAVI's History Project, brought the monetary equivalent of Pfizer's cumulative contributions to IAVI to US\$585,000.

- Merck & Co., Inc.'s award supporting IAVI's History Project represents the company's first grant to IAVI.
- Continental Airlines renewed its support with a two-year (2006-2007) in-kind contribution of domestic and international travel vouchers.
- Two law firms, Shearman & Sterling and White & Case, provided IAVI with pro bono legal services.
- A five-year, US\$1 million grant from Becton, Dickinson & Company (BD) is entering its final year, with discussions under way to finalize a multi-year renewal of the relationship, which includes a clinical collaboration with IAVI's Core Laboratory. In addition to financial support, BD provided ongoing product and service discounts with an estimated value of US\$120,000 in 2006.
- *Marie Claire*, a leading women's magazine with international distribution, cited IAVI as one of the "10 Best Charities" in its June 2006 issue, prompting a congratulatory letter to the editor from U.S. Rep. Eliot Engel (D-NY), the lead sponsor of a congressional resolution honoring IAVI for its first 10 years of work.
- IAVI also continued its strong relationship with the Global Business Coalition on HIV/AIDS. John McGoldrick, IAVI senior vice president, External Strategy Development, participated in a delegation of the Global Business Coalition that reviewed progress in Kenya, including a tour of IAVI facilities on World AIDS Day 2006. McGoldrick is one of three independent members of the Global Business Coalition's 2007 strategy review to chart future directions for the coalition.

*Major Gifts.* In its first year with staff resources dedicated to building a major gifts program, IAVI received five major gifts totaling US\$400,000. Two board members pledged major gifts to IAVI in 2006: John Evans, through the John D. Evans Foundation, and Paul Klingenstein, together with wife Kathy Bole. These board gifts enhance IAVI's ability to secure future large contributions from other major donors.

*Individual Giving.* In 2006, IAVI's small gifts program surpassed US\$100,000 for the first time, reaching total revenues of US\$125,000, a nearly 35% increase over 2005. An additional US\$12,500 in small gifts from family foundations also came to IAVI through its individual giving program.

- The quarterly e-newsletter produced by IAVI's New York-based private sector team, now in its second year, increased its circulation more than ten-fold in 2006, with each issue now reaching more than 600 individual and institutional donors.
- Several factors account for these impressive increases in individual giving. In 2006, Google announced that IAVI's *AdWords* grant will be renewed indefinitely. This program, which features IAVI's ad and web site when one of nearly 400 keywords are entered into the Google search engine, accounts for roughly one in four visitors to IAVI's web site. In 2006, Google users clicked IAVI's ad more than 40,000 times, for an in-kind contribution exceeding US\$26,000.
- A recent phenomenon is the surge in extemporaneous grassroots fundraising events hosted by volunteers. In 2006, more than a dozen grassroots sponsors organized fundraisers for IAVI, including a raffle, charity ball, theater production, photo exhibit, wedding registry, and a holiday CD and live performance.

*Donor Briefing at the XVI International AIDS Conference.* IAVI capitalized on the biennial conference to brief donors on recent progress. Florence Manguyu, IAVI's senior advisor in Kenya; Anjali Gopalan, executive director of the Naz Foundation (India) Trust; and Dr. Kavitesi Kayitenkore, clinical coordinator of Projet San Francisco in Kigali, Rwanda, briefed donors on vaccine research efforts in Kenya, India, and Rwanda, respectively. Presentations emphasized how IAVI is working with governments to increase their commitment to vaccines, streamline regulatory processes, and enhance interaction between key stakeholders.

## FINANCIAL ABSTRACT

A 2006 review of IAVI's financial position showed an organization that rests on a firm financial foundation, with US\$81,220,000 in revenue and US\$76,993,000 in expenditures. IAVI's financial strength is driven by four key elements: a well-diversified and growing donor base, a strong balance sheet, management prioritization of key programs, and effective management of financial resources. In 2006, a significant number of renewals and new grants established a new baseline of support for the organization.

In 2006, public sector grants — largely through Official Development Assistance — contributed 88% of IAVI's revenue (Figure V-A). The level of government support reflects the widespread recognition that an AIDS vaccine can help blunt and ultimately end the pandemic and is essential to achieving international development goals to lower poverty rates, ensure that all children complete primary education, reduce child mortality, improve maternal health, and curb the global tuberculosis epidemic in countries where the AIDS epidemic has taken a terrible toll.

Consistent with the urgency to accelerate AIDS vaccine development, R&D activities accounted for 68% of expenditures (Figure V-B), similar to earlier IAVI trends, with the balance going to collateral programs, including vaccine education and advocacy, and public policy research and analysis. IAVI has also consistently kept administrative costs to no more than 15%, which has helped it win acclaim from Charity Navigator as a four-star charity. Looking forward, IAVI projects expenses of US\$89.4 million in 2008, rising to an estimated US\$95.2 million in 2011 to meet strategic objectives. Based on revenue forecasts for the period 2007-2011, IAVI expects a funding gap of approximately US\$230 million by 2011 in the absence of new and renewal income to meet projected programmatic spending.

Figure V-A

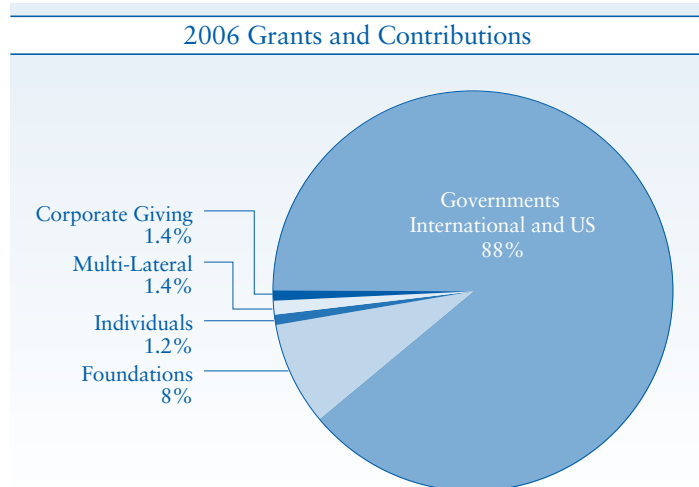
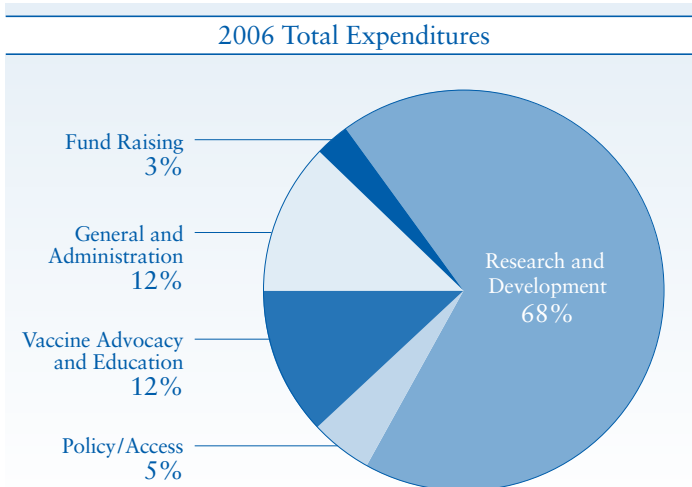


Figure V-B



## *CONCLUSION*

IAVI and its partners helped lay the groundwork for future progress in the vaccine field, undertaking targeted research on key scientific questions, building clinical trial capacity in developing countries that will be needed to test promising candidates, and successfully encouraging the adoption of policies to accelerate vaccine development and provide sustainable financing for future vaccine access. In 2007, IAVI will continue to be guided by the three-year strategic plan that governed its work in 2006.

IAVI is currently developing a new strategic plan for 2008-2010. Like the current plan, the 2008-2010 strategy will seek to maximize the speed, flexibility, innovation, and excellence of IAVI's work.

With the continued support of its generous donors and the pioneering efforts of its many partners in all parts of the world, IAVI believes that the challenges and opportunities of the next several years can be effectively translated into concrete progress toward a preventive vaccine. As it has since its creation in 1996, IAVI continues to believe in the possibility of a world without AIDS and will remain steadfastly focused on creating the tools necessary to get us there.

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\* As of 11/06

And many other generous individuals from around the world.



*Immagina un  
mondo senza AIDS*

*Forestil dig en  
verden uden AIDS*

*Stellen Sie sich eine  
Welt ohne AIDS vor*

*Fikiria huwaje maisha  
duniaini pasipo na Ukimwi*

تخیل عالمًا بدون آیدز

Представьте себе мир без СПИДа

*Stel je een wereld  
voor zonder AIDS*

## IMAGINE A WORLD WITHOUT AIDS

*Imagina un  
mundo sin SIDA*

让我们想象一个没有艾滋病的世界

सोचो एक दुनिया एड्स के विना

*Imaginez un  
monde sans SIDA*

*Föreställ dig en  
värld utan AIDS*

*Imagine um  
mundo sem AIDS*

“目指そう！ エイズのない世界”