

# Board of Directors' Report

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## 30 Largest PATH Programs

January 1 through December 31, 2011 (projected)



No.	Program Name	Area	2011 Core Budget* (USD)	2011 Total Budget** (USD)	Percentage of PATH Total Budget
1	Malaria Vaccine Initiative	Malaria Vaccine Initiative	14,559,691	58,021,974	19.71
2	AIDSTAR Sector 1 ICQ	HIV/AIDS and TB	6,536,158	25,391,823	8.62
3	AIDS, Population, and Integrated Health Assistance (APHIAplus) Zone 1	Kenya Country Program	13,067,666	23,353,446	7.93
4	Malaria Control and Evaluation Partnership in Africa	Malaria Control Program	8,692,477	9,740,977	3.31
5	Pneumococcal Vaccine Project	Vaccine Development	3,283,034	9,357,034	3.18
6	Accelerated Vaccine Introduction Initiative Technical Assistance Consortium	Vaccine Access and Delivery	4,854,769	8,879,232	3.02
7	Meningitis Vaccine Project	Meningitis Vaccine Project	3,467,370	8,524,741	2.90
8	Enteric Vaccine Initiative	Vaccine Development	3,501,486	8,443,009	2.87
9	Safe Water Project	Technology Solutions	5,045,133	8,264,929	2.81
10	TB Task Order 2015	HIV/AIDS and TB	6,656,329	8,097,015	2.75
11	Advancing Rotavirus Vaccine Development Phase 3	Vaccine Development	2,552,256	7,593,912	2.58
12	Optimize: Immunization Systems and Technologies for Tomorrow	Technology Solutions	4,480,620	7,548,443	2.56
13	Infant and Young Child Nutrition Project	Maternal and Child Health and Nutrition	5,452,868	7,307,748	2.48
14	The Khusela Project	Maternal and Child Health and Nutrition	3,743,736	6,236,694	2.12
15	Influenza Vaccine Project	Vaccine Development	2,299,683	5,100,572	1.73
16	TASC 2 TB Task Order 2	HIV/AIDS and TB	3,889,778	4,446,091	1.51
17	HPV Vaccines: Evidence for Impact	Reproductive Health	3,872,724	4,419,219	1.50

No.	Program Name	Area	2011 Core Budget* (USD)	2011 Total Budget** (USD)	Percentage of PATH Total Budget
18	Technologies for Health (HealthTech IV)	Technology Solutions	3,391,306	4,071,666	1.38
19	Sure Start	India Country Program	1,895,019	3,810,019	1.29
20	Enhancing HIV Prevention Programs for At-Risk Populations	HIV/AIDS and TB	827,085	3,542,694	1.20
21	Disposable Syringe Jet Injector Project	Technology Solutions	1,367,099	3,093,099	1.05
22	Health Innovation Portfolio	Technology Solutions	2,638,749	2,908,149	0.99
23	The Oxytocin Initiative Project	Maternal and Child Health and Nutrition	1,691,162	2,652,489	0.90
24	Screening Technologies to Advance Rapid Testing for HPV for Cervical Cancer Prevention in Developing Countries (START-UP)	Reproductive Health	1,540,287	2,629,537	0.89
25	Reproductive Health Supplies Coalition Secretariat	Reproductive Health	1,993,276	2,451,276	0.83
26	TeenPATH Project	Thailand Country Program	1,466,530	2,257,030	0.77
27	Developing Stable Influenza Vaccines	Technology Solutions	960,662	2,060,662	0.70
28	Advancing Rotavirus Vaccine Development BRV Phase 3	Vaccine Development	1,524,120	2,009,120	0.68
29	Enhancing Influenza Vaccine Development in Vietnam	Vaccine Development and Vietnam Country Program	777,016	1,897,016	0.64
30	Advancing Rotavirus Vaccine Development	Vaccine Development	1,490,595	1,883,869	0.64
Thirty largest programs			117,518,686	245,993,483	83.55
Next 60 projects			28,311,091	39,920,126	13.56
Projects less than \$100,000			5,935,588	8,498,243	2.89
<b>Total 2011 budget</b>			<b>151,765,365</b>	<b>294,411,852</b>	<b>100.00</b>

\* Budget amounts are based on projected expenses sorted by award and may reflect projects from multiple programs that are funded under the same award. Data include overhead.

\*\* Data include project budget plus subordinate agreements and equipment.

## 1. Malaria Vaccine Initiative

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2011 core budget:	\$14,559,691
2011 total budget:	\$58,021,974
Percentage of PATH budget:	19.71

### Project description

The PATH Malaria Vaccine Initiative (MVI) is a focused vaccine development program funded primarily by the Bill & Melinda Gates Foundation. Its mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world.

Working with partners in private industry, government, and academia, by 2015, MVI aspires to develop a malaria vaccine that has at least 50 percent protective efficacy against severe disease and lasts longer than one year. By 2025, MVI aims to develop a vaccine with greater than 80 percent efficacy against clinical disease that lasts longer than four years. MVI works with international health and development partners to guarantee that the vaccines will be affordable and available where needed, and collaborates with malaria-endemic country experts and policymakers to ensure ownership and leadership. MVI-supported activities include:

- Development, manufacture, and production of malaria vaccine candidates.
- Development of clinical trial sites and malaria vaccine clinical trials.
- Development and refinement of vaccine evaluation tools.
- Advocacy and communications around the need for a malaria vaccine and for greater investment in malaria vaccine research and development.

### Project activities and impact

Following the 2009 initiation of the RTS,S phase 3 efficacy trial, in 2010, MVI and its partners completed enrollment of 5- to 17-month-olds mid-year and, as of January 31, 2011, completed enrollment of 6- to 12-week-olds, for a total enrollment of 15,460 in the trial. This remarkable milestone was reached through a partnership between MVI, GlaxoSmithKline Biologicals, and scientists in Africa, which has evolved into a model product development partnership.

As MVI implemented its new research and development strategy, which has a long-term goal of eradicating malaria, the project also initiated its first-in-man *Plasmodium vivax* vaccine challenge study. *P. vivax* is less deadly than *P. falciparum*, but is more prevalent and has a wider geographic range. The data yielded by this study will provide critical information to the malaria vaccine field, which, to date, has not been deeply focused on *P. vivax*.

MVI also began to accelerate the development of transmission-blocking vaccines (TBVs). MVI held a TBV workshop that focused on whether the development of a vaccine that targets only *P. falciparum* and/or *P. vivax* sexual-stage or mosquito antigens is biologically and technically feasible, and if such a vaccine could have a defined policy and regulatory pathway. The outcomes of that meeting included a statement by a US Food and Drug Administration (FDA) representative that a regulatory pathway for licensure of a TBV is feasible. As 2010 drew to a close, MVI considered several more projects focused on transmission-blocking approaches.

Finally, in 2010, MVI started to work on a protocol for a clinical trial of MVI's first "prime-boost" vaccine approach, which is being developed in collaboration with Crucell. The trial is expected to begin mid-2011.

## 2. AIDSTAR Sector 1 IQC

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2011 core budget:	\$6,536,158
2011 total budget:	\$25,391,823
Percentage of PATH budget:	8.62

### Project description

PATH is one of seven prime contractors under the United States Agency for International Development's (USAID) AIDS Support and Technical Resources (AIDSTAR) Sector I Indefinite Quantity Contract (IQC). This funding mechanism offers US government entities and the Global Fund faster access to HIV prevention, care, and treatment support in resource-constrained settings worldwide. As a holder of an AIDSTAR prime contract, PATH is among a preselected group that is eligible to compete on multiple projects (called task orders) under a \$750 million funding ceiling.

In this project, an exceptional team of 11 partners with extensive experience addressing global HIV/AIDS priorities joins PATH. The consortium has successfully secured several multimillion-dollar task orders under this IQC.

### Project activities and impact

Highlights of PATH's AIDSTAR task order projects include:

- Thogomelo Project (South Africa, \$10 million, October 2008–2013). In partnership with the South African Department of Social Development, PATH is building South Africa's capacity to care for community caregivers and protect children left vulnerable by the AIDS pandemic. ("Thogomelo" means "to care for" in the Venda language.) Project accomplishments include the development of resource guides, toolkits, and a training curriculum for community caregivers. PATH manages the project, while Health & Development Africa and the International HIV/AIDS Alliance are responsible for implementing key activities.
- Strengthening Communities' Responses to HIV/AIDS (Ethiopia, \$35 million, April 2009–2012). Joined by four AIDSTAR partners—the International HIV/AIDS Alliance, International Relief & Development, International Training & Education Center for Health, and Westat—PATH is strengthening the organizational development and human capacity of civil society organizations so they are better able to reach people across Ethiopia with high-quality interventions that reduce the impact of HIV/AIDS. By 2012, the project will reach 300 towns to provide assistance in community-based care and support (palliative care), HIV counseling and testing, economic strengthening, and human capacity development for HIV/AIDS community services.
- ProVIC (Democratic Republic of Congo, \$45 million, October 2009–2014). PATH's integrated HIV/AIDS project in the Democratic Republic of Congo aims to reduce the incidence and prevalence of HIV and mitigate its impact on people living with HIV/AIDS and their families in four geographic areas: Bukavu, Kinshasa, Lubumbashi, and Matadi. Chemonics International leads the consortium, which includes Catholic Relief Services, the Elizabeth Glaser Pediatric AIDS Foundation, and the International HIV/AIDS Alliance. Five-year goals include expanding and improving HIV counseling and testing

and prevention services; improving care, support, and treatment for people living with HIV/AIDS and orphans and vulnerable children; and strengthening health systems.

- Partnership for an HIV-Free Generation Project (Kenya, \$50 million, August 2010–July 2015). PATH and its partners—the Government of Kenya, the Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria, and the Partnership for an HIV-Free Generation in Kenya are working to revolutionize HIV prevention interventions by combining the core competencies of the private sector with technical expertise of government and development partners in the creation and expansion of innovative and effective HIV prevention programs targeting youth ages 10-24 years in Kenya. PATH will transfer skills to launch an independent local NGO to lead, build, and sustain a social movement to halt the HIV epidemic among Kenya’s youth through public-private partnerships.

### 3. AIDS, Population, and Health Integrated Assistance (APHIAplus) Zone 1

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2011 core budget:	\$13,067,666
2011 total budget:	\$23,353,446
Percentage of PATH budget:	7.93

#### Project description

APHIAplus Zone 1 is a \$143 million, five-year project in Kenya funded by USAID. The project is designed to work with existing structures and build capacity at the provincial, district, facility, and community levels to fully integrate health service delivery in Nyanza and Western provinces. The PATH-led project will maximize Kenyan ownership and align project goals with the strategies of key stakeholders, including the US government, the Government of Kenya, and private- and public-sector partners. Implementing partners are the Elizabeth Glaser Pediatric AIDS Foundation, Jhpiego, and World Vision.

#### Project activities and impact

**Integrated service delivery:** The project will integrate health services to increase availability and demand. Integration will include family planning, prevention of mother-to-child transmission, and pediatric and adult antiretroviral therapy with maternal and child health services; family planning with antenatal or postnatal care; and HIV with tuberculosis services.

**Social determinants of health:** APHIAplus will support strategies that address contextual factors affecting health, such as poverty, education, environment, and socio-cultural norms.

**Economic strengthening:** The project will link vulnerable families to supportive economic services that will help them to build assets and competitively engage in market activities.

**Food security:** APHIAplus will engage community groups to encourage the use of proven organic farming technologies for improved production of healthy foods.

**Education, life skills, and literacy:** The project will strengthen the Ministry of Education to improve literacy and numeracy rates for children.

**Safe water, sanitation, and improved hygiene:** To reduce the incidence of diarrhea, APHIAplus will increase access to improved water supplies and sanitation by focusing on hygienic practices and the sustainability of community water projects. The project will support the government's technical specialists, using innovations such as chlorine dispensers in schools, synergizing water interventions, and enhancing water ownership within communities.

**Protective services:** There are an estimated 500,000 orphans and vulnerable children (OVC) in Nyanza Province and 250,000 in Western Province. APHIAplus aims to reach 150,000 OVC and HIV/AIDS-affected households with care packages addressing needs related to health, education, nutrition, psychosocial factors, shelter, protection, and livelihood support. APHIAplus will engage community health workers to conduct household poverty/health assessments and to create linkages to assistance mechanisms.

**Social mobilization for health:** Behavior change communication interventions will address a range of health and development issues by strategically reaching locations with specified needs.

## 4. Malaria Control and Evaluation Partnership in Africa

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2011 core budget:	\$8,692,477
2011 total budget:	\$9,740,977
Percentage of PATH budget	3.31

### Project description

Established in 2004 through a nine-year grant from the Bill & Melinda Gates Foundation, the Malaria Control and Evaluation Partnership in Africa (MACEPA) aims to scale up malaria prevention and control efforts across Africa that rapidly reduce malaria incidence and ultimately eliminate malaria-related deaths. Originally funded to work only in Zambia, MACEPA's mandate has expanded to include additional countries and new investments in documenting and disseminating the evidence base. MACEPA has improved malaria control program delivery and advocacy efforts that support sustained political commitment and funding for malaria control.

MACEPA works with ministry, nongovernmental (NGO), and UN agency partners in sub-Saharan Africa to achieve and sustain high coverage of malaria control interventions. These interventions include insecticide-treated bednets, indoor residual spraying, prevention during pregnancy, access to diagnostics and medicine, and efforts to expand malaria control work to further reduce transmission.

MACEPA currently partners with Ethiopia, Malawi, Mozambique, Senegal, Tanzania, and Zambia and is an active member of each of the Roll Back Malaria Partnership's sub-regional networks. The partnership continues to demonstrate how targeted investments in planning, resourcing, implementing, performance monitoring, and impact evaluation can bring effective malaria control interventions to additional African countries.

### Project activities and impact

MACEPA helps countries meet their malaria control program goals through capacity-building activities. This includes support to develop and monitor strategic and action plans, improve planning for and delivery of interventions, and develop and strengthen surveillance and reporting systems. By strengthening countries' performance-monitoring and impact evaluation capacities, MACEPA helps to generate data to inform decision-making and strategic planning. MACEPA assists countries with documenting and disseminating lessons learned and tools regionally, and through documented reductions in malaria infection and death, helps to make the case for sustained malaria control funding.

In 2010, MACEPA staff supported national efforts in Malawi, Senegal, and Zambia to conduct rigorous malaria program reviews and supported Global Fund for AIDS, Tuberculosis, and Malaria funding applications in Ethiopia, Senegal, and Zambia. MACEPA assisted with national Malaria Indicator Surveys in Malawi and Zambia as well as technical reports and fact sheets that convey critical, real-time epidemiologic data. National strategic planning workshops led by MACEPA took place in 14 countries.

Through the publication of 17 articles by MACEPA staff and partners in peer-reviewed journals and 65 print media pieces that featured MACEPA's work, MACEPA grew the evidence base on topics including barriers to bednet ownership and predictors of malaria risk. The Roll Back Malaria Partnership's Progress and Impact Series also included the publication of five technical reports.

## 5. Pneumococcal Vaccine Project

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2011 core budget:	\$3,283,034
2011 total budget:	\$9,357,034
Percentage of PATH budget	3.18

### Project description

With funding from the Bill & Melinda Gates Foundation, PATH is advancing research and development for new pneumococcal vaccines to immunize infants and children in the developing world. The Pneumococcal Vaccine Project (PVP) aims to accelerate development of one or more vaccine candidates that are effective against pneumococcal disease and will improve the health and well-being of children in Africa and other developing regions.

### Project activities and impact

In 2010, project highlights included:

- Supporting the advancement of an inactivated whole cell vaccine (WCV) with Children’s Hospital Boston and the Butantan Institute in Brazil through a successful pre-investigational new drug meeting with the FDA. The WCV has shown considerable promise in preclinical testing and has the potential to offer broad serotype-independent protection in a cost-effective manner.
- Launching a two-stage phase 2 clinical trial of a vaccine against *Streptococcus pneumoniae*— a protein-plus-conjugate pneumococcal vaccine for infants and children— in Fajikunda, The Gambia. The trial began in early 2011 in partnership with GlaxoSmithKline Biologicals, Medical Research Council The Gambia, and London School of Hygiene and Tropical Medicine.
- Advancing our partnership with the Serum Institute of India Ltd. on the development of a low-cost, limited-valency pneumococcal conjugate vaccine.
- Completing the preclinical evaluation of pneumolysoid constructs and selecting a lead candidate to move to development in 2011.
- Completing a phase 1 clinical trial of a common protein pneumococcal vaccine through our partnership with Intercell AG.
- Co-sponsoring the 7th International Symposium on Pneumococci and Pneumococcal Diseases—wherein a presentation by PVP’s director and several partner presentations/posters highlighted the importance of developing affordable and accessible pneumococcal vaccines for the developing world.

In 2011, PATH expects to advance several of the investigational protein and conjugate pneumococcal vaccines supported under PVP into clinical trials.

## 6. Accelerated Vaccine Introduction Initiative Technical Assistance Consortium

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2011 core budget:	\$4,854,769
2011 total budget:	\$8,879,232
Percentage of PATH budget	3.02

### Project description

In 2009, the GAVI Alliance awarded PATH a grant to establish the Accelerated Vaccine Introduction Initiative Technical Assistance Consortium (AVITAC). AVITAC aims to introduce rotavirus vaccines in 42 GAVI-eligible countries and pneumococcal conjugate vaccines (PCVs) in 44 GAVI-eligible countries by 2015. Ultimately, the project seeks to develop a common platform for new vaccine introduction.

PATH joins the United Nations Children’s Fund (UNICEF), the World Health Organization (WHO), and a global consortium of academic and research institutions working to achieving this goal. AVITAC supports partners’ efforts by providing leadership in strategic vaccine supply, advocacy and communications, special studies, and large-country introduction.

### Project activities and impact

In 2010, AVITAC introduced PCVs in Nicaragua and rotavirus vaccines in Guyana. PCV introductions have continued in 2011 in Yemen and Kenya, with anticipated introduction in numerous other countries, including North Sudan in 2011. Coordinated efforts among all partners to establish strategies and milestones for each distinct work stream drove the following activities:

- The special studies and strategic vaccine supply teams continued work on a series of scientific and economic studies and supply and demand forecasts. Achievements included completion of a global review of rotavirus strains and progress on studies designed to provide evidence-based information to country decision-makers. Strategic vaccine demand and supply forecasts were updated to provide an accurate picture of pneumococcal and rotavirus vaccines available for introduction in GAVI-eligible countries.
- The large-country introduction team focused on activities in India and Nigeria. The team conducted social network mapping; message testing; stakeholder analyses; and knowledge, attitudes, and practices studies to identify barriers and solutions regarding introduction of rotavirus vaccines and PCVs.
- The advocacy and communications team played a growing role in supporting GAVI outreach efforts to inform and engage global donors. The team contributed to a media tour of Rwanda on the first anniversary of the introduction of a PCV, led numerous advocacy activities for World Pneumonia Day, and prepared for communications activities to promote publication of pivotal clinical trial results on rotavirus vaccines’ efficacy in the developing world.

## 7. Meningitis Vaccine Project

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2011 core budget:	\$3,467,370
2011 total budget:	\$8,524,741
Percentage of PATH budget	2.90

### Project description

The Meningitis Vaccine Project (MVP), a partnership between PATH and WHO, was created in 2001 with funding from the Bill & Melinda Gates Foundation. Its goal is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, and introduction of conjugate meningococcal vaccines.

MVP has developed a group A meningococcal conjugate vaccine, MenAfriVac™, for mass vaccination of people aged 1 to 29 years in the WHO Expanded Program on Immunization (EPI) African “meningitis belt” countries. MVP has worked with a consortium of international partners to ensure an affordable, high-quality vaccine that can be sustainably delivered in Africa. MVP also supports enhanced surveillance in meningitis belt countries and promotes vaccine introduction through a variety of interventions, including advocacy and communication.

### Project activities and impact

2010 was a year of significant progress and achievement for MVP.

Following licensure of MenAfriVac™ in late 2009, WHO prequalified the vaccine on June 23, 2010. Prequalification triggered a cascade of activities leading to vaccine introduction in Burkina Faso, Mali, and Niger. A phased approach to introduction was agreed upon and campaigns to immunize more than 1 million individuals in selected districts of Burkina Faso, Mali, and Niger occurred in September 2010. The official launch of MenAfriVac™ followed in Burkina Faso in December 2010 and 11.4 million Burkinabe were subsequently vaccinated across the country. Mali and Niger also launched campaigns in select districts in December, with 4 million vaccinated in Mali and 3 million in Niger. The remainder of the target populations in Mali and Niger will be vaccinated during the fourth quarter of 2011.

MVP clinical activities focused on preparing, managing, and monitoring concurrent clinical studies in Africa and India: a phase 2 study to research and document an indication for MenAfriVac™ use in infants; a phase 3 lot consistency study to confirm equivalence of immune response of consecutive vaccine lots produced at commercial scale; and a phase 3 safety study, looking at potential rare adverse reactions following vaccine administration. Study results have confirmed vaccine consistency and safety. Pharmacovigilance activities conducted during and following the first round of vaccination campaigns in Burkina Faso, Mali, and Niger continue to indicate that MenAfriVac™ is a safe vaccine.

MVP advocacy included distributing community outreach materials in meningitis belt countries and increasing awareness of MenAfriVac™ in the lead-up to introduction. Major news agencies covered the vaccine launch in more than eight languages. MenAfriVac™ introduction has been praised as one of the most exciting public health achievements in 2010, and the United Nations News and Commentary Forum ranked the MenAfriVac™ introduction among “The Five Biggest Global Health Stories of 2010.”

## 8. Enteric Vaccine Initiative

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2011 core budget:	\$3,501,486
2011 total budget:	\$8,443,009
Percentage of PATH budget	2.87

### Project description

With funding from the Bill & Melinda Gates Foundation and the United Kingdom's Department for International Development, the Enteric Vaccine Initiative (EVI) works through partnerships with public- and private-sector organizations to advance research and development efforts for vaccines against the two leading bacterial causes of diarrheal disease: enterotoxigenic *Escherichia coli* (ETEC) and *Shigella*. Efforts are aimed at people in developing countries, particularly children. EVI's work also includes an advocacy and policy strategy that integrates information about enteric diseases within the broader public health priority of diarrheal disease control. The goal of the project is to advance at least one ETEC and one *Shigella* vaccine through phase 2 studies in a developing country by the end of 2012.

### Project activities and impact

In 2010, EVI signed new partnership agreements with:

- The International Vaccine Initiative to develop a prototype vaccine against *Shigella* based on a novel antigen.
- Oklahoma State University to research a vaccine against *Shigella* comprising conserved proteins as an innovative means of inducing broad immune coverage.
- The US Naval Medical Research Center to conduct laboratory toxicology testing of a new adhesin-based vaccine candidate against ETEC.
- Mucosis B.V. to explore the use of their Mimopath™ technology in oral vaccines against *Shigella* and ETEC.

Additional 2010 milestones for EVI include:

- Completing a phase 2b challenge study of an oral, ETEC multicomponent attenuated vaccine candidate with TD Vaccines. The results indicate that it had an overall positive impact on the reduction of disease incidence and severity as well as shedding of the challenge organism.
- Helping to support the launch of a phase 1 trial of a novel oral, inactivated whole cell ETEC vaccine with the University of Gothenburg and a phase 1 trial of the double mutant heat-labile toxin (dmLT) adjuvant/vaccine with the US National Institute of Allergy and Infectious Diseases.
- Co-funding a workshop at Old Herborn University to examine the mechanisms that may contribute to the poor response of infants in developing countries to oral vaccines, the discussions from which were published in the *Old Herborn University Seminar Monograph*.
- Hosting a regional workshop for policymakers and health officials in partnership with the Vietnam Ministry of Health and the National Pediatric Hospital of Vietnam to highlight solutions for defeating diarrheal disease, including the role of vaccines.

## 9. Safe Water Project

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2011 core budget:	\$5,045,133
2011 total budget:	\$8,264,929
Percentage of PATH budget	2.81

### Project description

Funded by the Bill & Melinda Gates Foundation, the Safe Water Project tests the viability and sustainability of commercial market and targeted product development approaches for providing household water treatment and safe storage (HWTS) solutions to low-income people. PATH and our collaborators have developed and are testing the effectiveness of various commercial strategies and product improvements in developing countries among people who lack access to safe water. The project is helping to determine to what extent these efforts can help fulfill the essential, universal, and ongoing need for safe water around the world.

### Project activities and impact

In 2010, the Safe Water Project:

- Collected promising results from three pilots and launched a fourth pilot where large HWTS manufacturers are partnering with microfinance institutions in India.
- Tested direct and retail sales channels in Cambodia, featuring the sale of a new ceramic water purifier design.
- Designed, developed, and tested a HWTS device designed for and with users.
- Developed partnerships with three Chinese manufacturing partners and one US-based partner to develop and produce new HWTS products and filters that follow PATH-developed design guidelines for low-income users.
- Concluded a pilot to distribute Aquatabs through bicycle entrepreneurs in Uttar Pradesh, India.
- Partnered with the Safe Water and AIDS Project and Chujio Ceramics to offer a ceramic water purifier to the group's community of Kenyan households.
- Launched a pilot in Vietnam to distribute Aquatabs at local health stations.
- Analyzed and communicated an assessment of the HWTS market and gaps in the HWTS value chain in India, Cambodia, Vietnam, and Kenya.
- Continued to monitor the results of our commercial pilot efforts and evaluate the effectiveness of distribution channels to reach target populations.

## 10. TB Task Order 2015

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2011 core budget:	\$6,656,329
2011 total budget:	\$8,097,015
Percentage of PATH budget	2.75

### Project description

USAID awarded PATH Tuberculosis (TB) Task Order 2015 on September 29, 2009, with a scheduled end date of September 28, 2014. The Task Order ceiling is \$58 million and USAID has obligated \$22,396,249 to date.

PATH is implementing activities requested by USAID Washington and the following USAID Missions: Democratic Republic of Congo, India, Mexico, Tanzania, Ukraine, Vietnam, Eastern Europe, Central Asia, and Regional Development Mission Asia. We work with international and country partners, including the Stop TB Partnership; WHO; the American Society for Microbiology; the Foundation for Innovative New Diagnostics; Initiatives Inc.; Management Sciences for Health; Partners in Health; and the University of California, San Francisco.

PATH provides technical assistance to countries with high TB burdens, implementing interventions under the Stop TB Strategy, as recommended by WHO and divided by Task Areas:

- Task Area 1 (mostly Mission-funded): Short-term technical assistance for up to ten countries and long-term technical assistance for up to six countries.
- Task Area 2 (mostly core-funded): Support of advocacy, communication, and social mobilization (ACSM); control of multidrug-resistant TB (MDR-TB); introduction of new tools; and technical assistance to prepare Global Fund to Fight AIDS, Tuberculosis and Malaria applications.

### Project activities and impact

Core-funded activities have included developing a generic ACSM curriculum, which was piloted in Tanzania and adapted for trainings in India, Sri Lanka, Tajikistan, Tanzania, and Ukraine. Other activities included two regional workshops, drafting the *Guide to Monitoring and Evaluating ACSM Intervention*, and participation in Stop TB Partnership ACSM core group.

The project has standardized MDR-TB assessment and planning approaches by developing the *MDR-TB Assessment and Monitoring Tool* with global experts and the Green Light Committee Secretariat. The tool, which has improved MDR-TB control, was used for national assessments in Mexico and Moldova and statewide assessments in India. More than 200 individuals have been trained to use the tool and more than 300 CD versions were distributed. The tool is freely available on the Internet and has been translated into Spanish and Russian.

In India, PATH continues to support the country's Revised National Tuberculosis Control Program in laboratory strengthening, infection control, ACSM, public-private mix, and MDR-TB control.

In Eastern Europe and Central Asia, following initial assessment interviews, we completed country selection in consultation with USAID. Eight countries were included in the phase

assessment: Armenia, Azerbaijan, Belarus, Georgia, Moldova, Kazakhstan, Kyrgyzstan, and Tajikistan. An in-country report guide was developed and is being translated into Russian. In-country consultants have been identified, and contracting is in process. Two sub-regional workshops were held in Kyiv (September 2010) and Dushanbe (January 2011) with 54 participants from 11 countries. ACSM curriculum and resource materials have been distributed. Technical assistance requests have come from 7 countries.

In Tanzania, we work with the Ministry of Health and Social Welfare, the National TB and Leprosy Program, and the Zanzibar TB and Leprosy Program to support implementation and scale-up of the Stop TB Strategy and Tanzania's MDR-/extensively drug-resistant (XDR) TB Response Plan. The program focuses on human resource capacity development, laboratory strengthening to improve TB diagnosis, support for TB surveillance, targeted active case finding, and strengthening infection control in health care settings. For the first time, patients have received treatment for MDR- and XDR-TB in Tanzania.

In Vietnam, PATH has collaborated with the National TB Program and the Hai Phong Provincial Health Department since 2008 to implement a public-private mix model in four districts in Hai Phong province. This project gives pharmacists and private providers the skills they need to refer those suspected of having TB to public TB services. PATH helps the national program to facilitate and scale up public-private mix activities within Hai Phong, Ho Chi Minh, Nghe An, and Can Tho provinces, covering 19 districts.

## 11. Advancing Rotavirus Vaccine Development Phase 3

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2011 core budget:	\$2,552,256
2011 total budget:	\$7,593,912
Percentage of PATH budget	2.58

### Project description

The Bill & Melinda Gates Foundation awarded the Advancing Rotavirus Vaccine Development Phase 3 project to PATH in November 2009 to support the late-stage development of the 116E rotavirus vaccine candidate produced by Bharat Biotech International Ltd. (BBIL). The Department of Biotechnology in India (DBT) and the Research Council of Norway through the Norwegian Institute of Public Health are also funding the trial. The phase 3 efficacy clinical trial will be conducted at three sites in India, beginning in March 2011. The sites have varying socioeconomic conditions and population groups, and we anticipate they will have different rotavirus strains circulating. The project is scheduled to end in September 2013.

### Project activities and impact

The objectives of the project are to:

- Complete a phase 3 study to evaluate EPI noninterference and lot-to-lot consistency with the BBIL 116E rotavirus vaccine.
- Complete a phase 3 efficacy study with the 116E vaccine.
- Prepare and submit the regulatory file for licensure of 116E in India and file for WHO prequalification.

The clinical trials of the 116E rotavirus vaccine will be conducted under International Conference on Harmonization/Good Clinical Practices standards. They will follow Drug Controller General of India (DCGI) and WHO international standards and requirements.

PATH will also assist BBIL with preparing the regulatory file for licensure of the vaccine in India and for WHO prequalification. Specifically, PATH will support BBIL in its preparation of the market authorization file by enlisting international regulatory experts to review the file before submission to DCGI. The experts will also review the BBIL's regulatory file before it is considered for WHO prequalification.

Key accomplishments in 2010 include the following:

- Established a Project Management Committee to oversee the management of the trials, a Clinical Operations Management unit to coordinate the trial operations and report to the Project Management Committee, and a Data Safety Monitoring Board.
- Produced and released clinical lots of vaccine for the trials, composed of three consistency lots of vaccine and the placebo.
- Completed a disease burden study, conducted by the Society for Applied Studies (SAS) and funded by DBT. Data confirmed that cases of severe diarrhea due to rotavirus can be identified and scored appropriately, and completion of this study allowed SAS to set up operations, training, and procedures in preparation for the phase 3 studies.

- Prepared two additional sites for the phase 3 efficacy trial: King Edward Memorial Hospital in Pune and Christian Medical College in Vellore.
- Made improvements toward validation of DBT's Translational Health Science and Technology Institute to serve as the central laboratory for the studies.

## 12. Optimize: Immunization Systems and Technologies for Tomorrow

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2011 core budget:	\$4,480,620
2011 total budget:	\$7,548,443
Percentage of PATH budget	2.56

### Project description

Optimize is a collaboration between WHO and PATH that is funded by the Bill & Melinda Gates Foundation. The project focuses on designing future vaccine supply chains and technologies that are flexible and robust enough to handle an increasingly large and costly portfolio of vaccines. Optimize ultimately aims to create synergies with the delivery of other health commodities.

By 2012, the project seeks to have stakeholders sharing an informed vision of optimal health logistics and technologies for the future. Optimize activities are organized under the following three strategic objectives:

- Innovate: Put in place mechanisms and policies that drive innovation.
- Demonstrate: Establish a strong evidence base for optimal combinations of systems, technologies, and practices.
- Facilitate: Obtain a global-level commitment to the advancement and adoption of optimal health logistics and technologies.

### Project activities and impact

In 2010, Optimize focused on strengthening existing groups and involving new ones, particularly for the development of a long-term vision for immunization supply and logistics systems. This long-term plan, which would end in 2020, includes landscape analyses and recommendations.

Optimize improved mechanisms to help ensure that low- and middle-income countries' needs are considered in new guidelines and policies. Examples include increased flexibility in the WHO system for approving equipment; engaging industry partners to develop a generic Preferred Product Profile for new vaccines; and advancing a strategy for using vaccines in a controlled environment at temperatures higher than the 2°C to 8°C range.

The project supported the advancement of 13 novel cold-chain products through laboratory testing and field testing, and advancing innovative ways to access peripheral data and to use these data to drive vaccine supply chains.

After completing two years of development, field testing, and extensive global training, Optimize handed over the Effective Vaccine Management (EVM) assessment tool to WHO and UNICEF, which will support at least ten EVM assessments in 2011.

Demonstrations and operational research implemented in 2010 include:

- Albania: Developed an information system with computerized individual immunization records/registry for vaccine management.

- Guatemala: Supported the definition of an integrated health information platform.
- Senegal: Integrated supply chains for vaccines and pharmaceuticals, including the use of an insulated truck to deliver vaccines at lower levels and the use of solar refrigerators.
- Tunisia: Implemented a “net-zero energy” supply chain using innovative solar technologies.
- Vietnam: Applied commune-level passive cooling technologies, electronic vaccine tracking, web-based immunization reporting, mobile technology, and digital immunization registry.
- South Africa and Thailand: Conducted two studies on outsourcing to the private sector.

Optimize also completed a baseline vaccine supply chain and logistics model. The model will be used to strengthen the evidence base through a cost-benefit analysis of different solutions for optimization

## 13. Infant and Young Child Nutrition Project

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2011 core budget:	\$5,452,868
2011 total budget:	\$7,307,748
Percentage of PATH budget	2.48

### Project description

The Infant and Young Child Nutrition (IYCN) Project, led by PATH, is a five-year cooperative agreement with USAID. Since 2006, the project has focused on proven interventions to improve nutrition during the first 1,000 days of life, from pregnancy through 23 months of age. The project team includes CARE; The Manoff Group; and University Research Co., LLC.

IYCN aims to improve the nutritional status and promote HIV-free survival of infants and young children. The project also promotes good nutrition among mothers. To achieve these goals, IYCN assists countries with developing tailored, effective nutrition interventions and provides global leadership to identify and share practices that strengthen nutrition programs.

To date, IYCN has worked in 15 countries: Bangladesh, Côte d'Ivoire, Ethiopia, Ghana, Haiti, Kenya, Lesotho, Madagascar, Malawi, Mozambique, Nigeria, Peru, Sierra Leone, South Africa, and Zambia.

### Project activities and impact

Last year, IYCN strengthened nutrition programs in Côte d'Ivoire, Haiti, and Zambia, and launched new programs in Ethiopia, Ghana, Malawi, and Mozambique. The project focused on the following areas of work:

**Training for feeding and nutrition:** Trained more than 1,300 health workers and community-based workers in six countries on infant and young child feeding or maternal nutrition.

**Formative research for behavior change impact:** Completed 13 formative research studies in seven countries to illuminate current maternal, infant, and young child feeding practices; identify barriers to changing behaviors; and assess nutrition counseling and support services. The research will help to strengthen existing programs and design new evidence-based behavior change activities.

**Strengthening health systems:** Conducted more than 1,000 exit interviews with mothers in Côte d'Ivoire and Zambia to monitor the quality of individual counseling and group health talks in facilities.

**Integrating agriculture and nutrition:** Led dialogue with global health and agriculture stakeholders on the intersection between agriculture and nutrition, built critical links between agriculture and nutrition programs in three countries, and developed a new tool for assessing the potential nutritional impact of agricultural interventions on vulnerable groups.

**Addressing community-based nutrition:** Developed innovative tools to assess and promote complementary feeding practices and evaluate the role of household members, such as fathers and grandmothers, to positively influence and support maternal, infant, and young child nutrition.

**Encouraging the adoption of international guidelines:** In Nigeria, where early consensus had favored rejecting new WHO guidelines on HIV and infant feeding, IYCN summarized evidence supporting the new recommendations and collaborated with partners to build consensus among national leadership to adopt the new guidelines and to promote breastfeeding as a national strategy to maximize HIV-free survival.

**Broadening our reach through mass media:** Created and launched a series of 13 radio programs in Zambia with evidence-based behavior change messages that address identified feeding problems and encourage mothers to prevent malnutrition in their children.

**Emergency response in Haiti:** Conducted infant and young child feeding training workshops for more than 300 emergency health workers following the January 2010 earthquake in Haiti. We offered support in baby tents, where embattled mothers sustained adequate feeding practices despite stressful conditions. We also trained more than 320 trainers and health workers on nutrition counseling after early infant diagnosis of HIV and created a nationally validated set of infant and young child feeding counseling cards for facility and community health workers.

**Expanding nutrition support for orphans and vulnerable children:** Collaborated with the National Program for Orphans and Vulnerable Children in Côte d'Ivoire to develop pre- and in-service curricula for social workers who support families at social centers. We also supplied more than 20 social centers with equipment necessary to promote optimal feeding practices, identify growth faltering and malnutrition, and refer children for health services.

**Improving access to research, tools, and innovations:** Distributed more than 13,000 tools and resources to help global health colleagues strengthen nutrition programs through the IYCN website, e-newsletter, and international conference appearances. Thousands of users from 125 countries visited the project's website to access critical research, training materials, and information about innovative programs in the field.

## 14. The Khusela Project

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2011 core budget:	\$3,743,736
2011 total budget:	\$6,236,694
Percentage of PATH budget	2.12

### Project description

The Khusela Project is a five-year cooperative agreement with the US Centers for Disease Control and Prevention (CDC) to increase use of high-quality, comprehensive prevention of mother-to-child transmission (PMTCT) of HIV services in South Africa's Eastern Cape Province. Since 2007, PATH has worked in partnership with the Eastern Cape Department of Health (ECDOH), the Health Information Systems Program, and other South African partners to support 80 facilities in two districts.

The Eastern Cape Province has one of the country's highest HIV prevalence rate among adults, and only about half of pregnant women living in the province are tested for HIV. The infection rate among newborns continues to be very high despite the existence of a national PMTCT program.

The Khusela Project aims to:

- Improve availability and quality of counseling and testing services during antenatal care.
- Increase access to and provision of antiretroviral prophylaxis for PMTCT.
- Improve counseling and support for safe infant feeding practices.
- Improve quality of family planning counseling, particularly during the postpartum period.
- Increase awareness of and demand for services in communities.

### Project activities and impact

The project uses three strategies to achieve its goals and objectives, each working at a different level of the health service delivery system:

- Support ECDOH systems that strengthen the delivery of high-quality, comprehensive PMTCT services.
- Build the capacity of health facilities and staff to provide high-quality, comprehensive PMTCT services.
- Increase community engagement and leadership in promoting, supporting, and utilizing PMTCT services.

The project also leads two additional efforts: facilitation of the Midwives AIDS Alliance, a platform where midwives can increase their representation in advocacy for PMTCT, and strengthening of TB infection control interventions in Swaziland.

The past year has been one of expansion, intense training and capacity-building, and mentoring good clinical and management practices. Health care facilities engaged with the project grew from 40 to 80, with new sites receiving the most focused support. Within ECDOH-supported facilities, the Khusela Project exceeded its annual target for women tested for HIV by 25 percent. Of women who tested positive for HIV, 22 percent completed a course of antiretroviral prophylaxis.

Although the percentage of infants exposed to HIV who receive polymerase chain reaction based testing at the clinics could still improve, there continue to be fewer infants who test positive for HIV. Project trainers and mentors continue to work on tools and approaches to strengthen nurses' counseling skills so that they can allay mothers' fears about having their babies tested for HIV. Community activities, for which demand continues to grow, reinforce acceptance of HIV-positive mothers and babies.

## 15. Influenza Vaccine Project

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2011 core budget:	\$2,299,683
2011 total budget:	\$5,100,572
Percentage of PATH budget	1.73

### Project description

PATH launched the Influenza Vaccine Project (IVP) in December 2007 with funding from the Bill & Melinda Gates Foundation. The goal of the project is to advance the development of promising new influenza vaccines, focusing on novel technologies that are accessible, affordable, and available to people in low-resource countries during influenza outbreaks.

### Project activities and impact

In 2010, project highlights included:

- Making significant progress in advancing the preclinical development of several avian live attenuated influenza vaccine (LAIV) candidates in partnership with the Institute of Experimental Medicine in Russia.
- Preparing a landscape analysis of intranasal delivery devices for use with LAIVs in collaboration with PATH's Technology Solutions group.
- Entering into new partnerships with Medicago, Inc., a Canadian biotechnology company, and the University of Pittsburgh to initiate research on influenza vaccines that can elicit broad coverage across influenza strains.
- Signing a research agreement with the Infectious Disease Research Institute of Seattle, Washington, to advance research on adjuvants—additives that can enhance a vaccine's immune response—for influenza vaccine candidates.
- Validating, through preclinical studies, the potential of an influenza vaccine candidate using recombinant technologies in partnership with Lentigen.
- Co-sponsoring Options for the Control of Influenza VII, an international conference in Hong Kong which included supporting travel grants for researchers from underserved research communities, participating in several presentations, and hosting a booth in the exhibition hall.
- Contributing to the scientific literature through various peer-reviewed journal articles by IVP team members on issues related to influenza vaccines.

The IVP team will work with partners in 2011 to prepare for several influenza vaccine clinical trials, including for selected LAIV candidates in the IVP portfolio.

## 16. TASC2 TB Task Order 2

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2011 core budget:	\$3,889,778
2011 total budget:	\$4,446,091
Percentage of PATH budget	1.51

### Project description

In September 2004, USAID awarded PATH the first TB Country Support Task Order. In 2007, PATH won two additional task orders under USAID's Technical Assistance Support Contract (TASC2) TB—one with a ceiling of \$15 million for global support and a second with a ceiling of \$9.6 million for support to Ukraine. Obligations to date total \$14,936,345. Under these two projects, PATH provides short- and long-term technical assistance to countries with high TB burdens and implements the full complement of interventions under the Stop TB Strategy, as recommended by WHO. These interventions include:

- Strengthening the quality of basic national TB control programs.
- Addressing the challenge of TB-HIV co-infection.
- Controlling multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB).
- Implementing effective TB infection control.
- Assisting countries in developing proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria, and providing assistance with project implementation.
- Enhancing advocacy, communication, and social mobilization (ACSM) interventions for effective TB control.
- Contributing to the development of global guidance and tools for TB control.

PATH works with international and country partners, including the Stop TB Partnership, WHO, the CDC, the American Society for Microbiology, Health Strategies International, Initiatives Inc., and national TB control programs.

### Project activities and impact

In Ukraine, PATH has implemented directly observed treatment, short-course (DOTS) expansion activities since 2001. These activities include: revising national policy to follow international standards, developing an electronic surveillance system, training clinicians in modern approaches to TB treatment, establishing a quality assurance program for TB laboratories, developing a model for continuity of care for prisoners, and encouraging collaboration between TB and HIV programs to produce better outcomes for co-infected patients. Control of MDR-TB has also become a priority for Ukraine.

In Tanzania, where TB-HIV co-infection is very high, PATH implements TB-HIV service integration projects and related TB control activities. PATH scaled up collaborative TB-HIV services to an additional 136 public- and private-sector service delivery outlets last year, bringing the total to 457 in all 26 PATH-supported districts since the project started in 2005. In project-supported sites, 93 percent (17,420) of newly registered TB patients gave their consent for HIV testing, were tested, and received test results by the end of September 2009.

Among those tested, 5,497 patients, or nearly 32 percent, were HIV positive. After diagnosis, these patients gained access to HIV care and treatment services.

In Cambodia, PATH joins the public and private sectors to increase TB case detection by identifying TB suspects at pharmacies, a key first point of contact within the health system. Initial data show that engaging pharmacies can greatly enhance TB case detection. In some PATH-supported districts, up to 25 percent of suspected cases referred to public health centers for evaluation are diagnosed as active TB cases. PATH supports activities in 11 pharmacies as well as the second phase of the national public-private strategy, which includes outreach to private providers for TB-HIV services. Now in the final year of a three-year project, we will concentrate on smoothly transitioning the work to in-country organizations under the direction of the National TB Control Program.

In India, PATH supports national TB control efforts, including laboratory accreditation for solid culture and drug susceptibility testing, which helps to accelerate India's response to MDR- and XDR-TB. We are piloting national infection control guidelines at the state level in Andhra Pradesh and are rolling out our ACSM model, which addresses local TB control challenges.

## 17. HPV Vaccines: Evidence for Impact

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2011 core budget:	\$3,872,724
2011 total budget:	\$4,419,219
Percentage of PATH budget	1.50

### Project description

Funded by the Bill & Melinda Gates Foundation, the HPV Vaccine Project uses operational research methods to assess the feasibility, impact, and costs of various strategies for reaching young adolescent girls with human papillomavirus (HPV) vaccine. The project includes components related to relevant global policies and national decision-making about comprehensive cervical cancer prevention, including screening adult women.

Project partners include ministries of health, NGOs, and vaccine manufacturers. PATH also works closely with WHO, Institut Català d'Oncologia, International Agency for Research on Cancer, and Harvard University, all of which have received funding from the Bill & Melinda Gates Foundation for complementary cervical cancer prevention projects.

### Project activities and impact

Demonstration projects have been completed or nearly completed in India, Peru, Uganda, and Vietnam, where we are assessing:

- Vaccine coverage associated with various vaccine delivery strategies.
- Acceptability of the vaccine.
- Feasibility of incorporating vaccination into existing health systems.
- Cost associated with providing HPV vaccine to young adolescent girls.

PATH has already begun disseminating results from the demonstration projects, and a number of papers will appear in peer-reviewed journals and other publications in 2011. Results will inform future HPV vaccine policy, program, and funding decisions, not only in the project countries, but also in other countries and for regional and global agencies.

The project also made small grants to support the generation of key missing data in countries where commitment to implement evidence-based cervical cancer prevention programs is strong. Grants were issued to groups in eight countries, primarily focusing on knowledge, attitudes, and practices related to cervical cancer prevention and use of HPV vaccine.

Assisting countries with the evidence generated by the project will remain an important activity in 2011 and 2012. This will be particularly important to decision-making related to comprehensive cervical cancer programming that offers vaccination for girls and screening and treatment for adult women. A new interactive tool, the Cervical Cancer Prevention Action Planner, is available online at [www.rho.org/actionplanner](http://www.rho.org/actionplanner).

## 18. Technologies for Health (HealthTech IV)

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2011 core budget:	\$3,391,306
2011 total budget:	\$4,071,666
Percentage of PATH budget	1.38

### Project description

Technologies for Health (HealthTech IV) builds on previous HealthTech programs, which were first initiated in 1987 and are supported by USAID. The program identifies health needs that can be met with technology solutions and adapts, designs, develops, and advances appropriate health, family planning, and nutrition technologies. HealthTech projects have led to major, single-topic research and development projects supported by other funders, demonstrating HealthTech's role as a catalyst for advancing innovative technology solutions.

### Project activities and impact

HealthTech plays a key coordination role in the development and implementation of USAID's effort to rollout the depo-subQ provera 104™ injectable contraceptive in the Uniject™ prefilled injection system (depo-subQ in Uniject). We communicate closely with Pfizer, the product manufacturer, to document and communicate up-to-date registration timelines. Pfizer expects to receive approval soon for depo-subQ in Uniject from the Medicines and Health Care products Regulatory Agency in the United Kingdom, and registration filings in USAID priority countries will follow. A pharmacokinetics study for subcutaneous administration in the upper arm is currently under way, and acceptability studies in Senegal and Uganda will begin in 2011. Significant project emphasis is being placed on:

1. Supporting a clear, comprehensive research agenda that will drive future decision-making and planning around procurement, in-country planning, and implementation.
2. Developing an adaptable set of training materials for depo-subQ in Uniject for use by health workers in facility and non-clinical settings for acceptability studies.
3. Defining potential product configuration (secondary packaging, inserts, possible bundled disposal boxes, etc.).
4. Maintaining clear communications and coordination among key stakeholders involved with planning the product's introduction.

A national dissemination meeting was conducted in Bangladesh for chlorhexidine, a product for cleansing umbilical cords, and a regional dissemination meeting on the final chlorhexidine main trial results is planned for 2011. The team has also identified and conducted initial diligence with a possible Indian chlorhexidine product manufacturer, Bharat Immunologicals and Biologicals Corporation Limited.

HealthTech works to improve and ease adoption of active management of the third stage of labor and thereby reduce postpartum hemorrhage by facilitating a competitive commercial supply of and public-sector demand for oxytocin in the Uniject™ prefilled injection system. A HealthTech team presented the results of a pilot introduction study of oxytocin in Uniject at the facility level in Guatemala. The results were presented at the 1st Latin American and Caribbean Conference on Global Health. The team is implementing a facility- and community-level study in Honduras.

HealthTech also raises awareness and builds support for the Initiative for Multipurpose Prevention Technologies, which outlines how multipurpose prevention technologies can better address couples' reproductive health needs in developed and developing countries by preventing pregnancy, sexually transmitted infections, and other common reproductive tract infections. We have developed an advocacy brief and an accompanying brochure that makes the case for future development of and support for these technologies, and we contribute to outreach in a variety of forums.

## 19. Sure Start

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2011 core budget:	\$1,895,019
2011 total budget:	\$3,810,019
Percentage of PATH budget	1.29

### Project description

Led by PATH with financial support from the Bill & Melinda Gates Foundation, the Sure Start project complements and supports the Government of India's commitment to improving maternal and newborn health. Sure Start works in selected rural districts of Uttar Pradesh state and in urban slums in seven cities in Maharashtra state. The project partners with a multitude of organizations to effect sustainable change in a population of 24.5 million people.

Sure Start aims to sustainably improve maternal and newborn health by working toward the following objectives:

- Increasing individual, household, and community actions that directly and indirectly improve maternal and newborn health.
- Enhancing systems and institutional capabilities for sustained improvement in maternal and newborn care and health status.

### Project activities and impact

In Uttar Pradesh, the project reaches out to more than 23 million people through a consortium of five lead partner NGOs and 55 sub-partner NGOs. Sure Start works with 2,811 local self-governance bodies called Village Health and Sanitation Committees (VHSCs) and 7,540 community-based volunteers called Accredited Social Health Activists (ASHAs).

In Maharashtra, Sure Start has piloted finance, public-private partnership, and service-delivery models. Sure Start's methods include an emergency health fund, community-based health insurance, a prepaid health care card system, specialized clinics for prenatal and postnatal care, an "adopt-a-mother" model, self-help groups, and volunteer networks.

As a result of building the capacity of VHSCs in Uttar Pradesh, the committees are conducting meetings regularly, and members are becoming aware of their roles and responsibilities. Increased involvement by VHSCs has been instrumental in ensuring the success of large-scale communications campaigns and monitoring and support for frontline service providers. Currently, 98 percent of VHSCs register births, and 78 percent register deaths. In addition, 67 percent of pregnant women use four-wheelers to reach a health institution for their deliveries.

The role of ASHAs has also been strengthened. They now conduct mothers' group meetings with minimal support from Sure Start staff, and 82 percent of ASHAs attend monthly meetings at Sure Start sites. More than 76 percent of ASHAs mobilize communities for village health and nutrition days.

To spur behavior change and community action, Sure Start staff in Uttar Pradesh facilitate monthly meetings for 6,871 mothers' groups, composed of pregnant women, their mothers-in-law, and frontline health care providers. As a result of these meetings, knowledge of danger signs among pregnant women has increased from 58 to 80 percent; the percentage of women

who initiated breastfeeding within one hour postpartum rose from 31 to 89 percent; and the number of pregnant women attending mothers' groups meeting grew from 6 to 52 percent.

This past year, the project reached more than 22,000 mothers in Maharashtra, where a strengthened surveillance system has resulted in more women opting for pregnancy registration within 12 weeks—from 43 percent of women in 2007 to 82 percent in 2010.

## 20. Enhancing HIV Prevention Programs for At-Risk Populations

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2011 core budget:	\$827,085
2011 total budget:	\$3,542,694
Percentage of PATH budget	1.20

### Project description

In 2009, the Canadian International Development Agency awarded PATH a \$17 million grant to provide technical and financial support to a series of HIV prevention projects. In consultation with a technical advisory committee, PATH selected six projects in five countries working to avert new infections among most-at-risk populations. All of these projects are designed to address the needs of these vulnerable groups through innovative and cost-effective strategies. Numerous international and local partners work with the project, which will end in 2013.

The project goal is to reach nearly 100,000 people and to help avert new HIV infections among thousands in sub-Saharan Africa and India. The planned interventions aim to provide services to those who need them and to better understand the most cost-effective HIV prevention approaches through monitoring and evaluation strategies established by PATH.

### Project activities and impact

This past year, activities included applying for and responding to questions of local, national, and institutional research ethics committees to secure approvals for project research and laying the ground work for starting the anticipated research once the needed approvals are received. The six projects are listed below.

#### 1. Men who have sex with men (MSM): India

Goal: To decrease HIV risk behaviors among MSM in four Indian states through increased access to comprehensive, community-based HIV prevention services and capacity-building for community-based organizations and voluntary counseling and testing centers. Main partners: Naz Foundation International and Academy for Educational Development.

#### 2. Injecting drug users (IDUs): India

Goal: To avert HIV infections among IDUs and their sexual partners in New Delhi by expanding HIV prevention services and reducing risky injection and sexual behaviors. Main partners: The Population Council and Sahara Centre for Residential Care and Rehabilitation.

#### 3. Female sex workers (FSWs): Senegal

Goal: To reduce the spread of HIV and other sexually transmitted infections within the context of sex work in the Dakar region through behavior change and other strategies with FSWs and their partners, and by promoting risk reductions in sex work establishments. Main partners: Université Cheikh Anta Diop and Westat, Inc.

#### **4. HIV-positive women: Uganda**

Goal: To address unmet need for contraception among HIV-positive women in the Northern and Eastern regions, averting new HIV infections through increased dual-method use (e.g., condoms and other methods). Main partner: Pathfinder International.

#### **5. Couples: Zambia**

Goal: To prevent HIV infections among couples in the Copper-belt mining region by expanding HIV counseling and testing for couples (CVCT), encouraging risk reduction, referring HIV-positive clients to antiretroviral clinics, and promoting CVCT at government and community levels. Main partners: Rwanda Zambia HIV Research Group and Zambia-Emory HIV Research Project, Emory University.

#### **6. Pregnant women and their babies: Zimbabwe**

Goal: To reduce mother-to-child transmission of HIV among women seeking antenatal care in seven districts in Mashonaland Central Province. Main partners: The Population Council, the Zimbabwe AIDS Prevention Project, and the Clinton Health Access Initiative.

## 21. Disposable Syringe Jet Injector Project

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2011 core budget:	\$1,367,099
2011 total budget:	\$3,093,099
Percentage of PATH budget	1.05

### Project description

The disposable syringe jet injector (DSJI) project, which began in 2007, is funded by the Bill & Melinda Gates Foundation. DSJIs generate a high-pressure liquid stream that penetrates the skin and delivers injections without the use of a needle, reducing the amount of vaccine required by up to 80 percent. All devices use disposable syringes filled with a single dose of vaccine, preventing cross-contamination from one person to the next and eliminating needle-stick injuries and needle reuse. They also significantly reduce costs associated with complicated sharps waste disposal systems. DSJIs are uniquely positioned to extend the reach of vaccines in short supply.

### Project activities and impact

Since 2005, PATH has been assessing the appropriateness of DSJIs for use in developing countries. In collaboration with WHO and the CDC, as well as with vaccine manufacturers and device developers, PATH is evaluating the applicability of DSJIs in clinical trials with a number of vaccines. PATH has also been gathering evidence to clarify the DSJI value proposition for suppliers and purchasers and continues to advise developers as they apply for international regulatory approval and work toward potential inclusion of DSJIs in global immunization programs.

During the third year of the project, PATH:

- Agreed to collaborate with the WHO Global Polio Eradication Initiative and with DSJI manufacturer Bioject to explore intradermal delivery of inactivated poliovirus vaccine using DSJIs.
- Assisted DSJI manufacturer PharmaJet through a regulatory process with the FDA for clearance of an intradermal injector. This recent 510(k) clearance is in addition to previous clearance granted by the FDA, Brazil's National Health Vigilance Agency, and European Union for subcutaneous and intramuscular injectors.
- Helped formalize a WHO Performance, Quality, and Safety (PQS) specification and verification pathway for DSJI technology. PharmaJet has submitted a device for PQS prequalification.
- Completed enrollment for a non-inferiority based clinical trial of the measles, mumps, and rubella vaccine. The trial will compare delivery of the vaccine with DSJIs to that with traditional needle and syringe. The trial was conducted in Brazil in collaboration with the Brazilian vaccine manufacturer Bio-Manguinhos.
- Published a paper on the value proposition of the potential future use of inactivated poliovirus vaccine in low- and middle-income countries.
- Published a paper co-written with the London School of Tropical Medicine and Hygiene in Vaccine. The paper compared costs of introducing DSJIs for delivery of routine childhood vaccinations to traditional needle and syringe in Brazil, India, and South Africa.

- Published a paper in the Bulletin of the World Health Organization, which outlines potential benefits and current challenges of intradermal delivery methods.

## 22. Health Innovation Portfolio

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2011 core budget:	\$2,638,749
2011 total budget:	\$2,908,149
Percentage of PATH budget	0.99

### Project description

For nearly 30 years, PATH has built a comprehensive, hands-on capacity to design, develop, and introduce a portfolio of technologies that addresses high-priority health problems in low- resource settings. Now with three sources of support—from the Bill & Melinda Gates Foundation, individual donors to the Fund for Health Technologies, and a portion of HealthTech IV program funds—we have a corpus of funds to significantly scale up our work and address health problems proactively. The program also has multiple public- and private-sector partners.

The Health Innovation Portfolio (HIP) supports the stages of discovery and proof of principle for meaningful technology solutions to global health problems. HIP allows us to continually explore and test new ideas and ultimately add new products to the portfolio. Activities focus on the exploration, prioritization, and evaluation of new ideas—from discovery through proof of concept. Once funded, individual project teams simultaneously investigate technical feasibility, acceptability, and marketability of their concepts. Evidence they gather eventually leads to proposals to donors for full product development and introduction.

### Project activities and impact

During the third year of the program, we screened multiple unmet health needs across five categories of health. We then reviewed and approved the most promising projects that focus on proof of principle of new and innovative technology solutions. Since its inception, HIP has supported critical exploration of more than 70 innovative technologies, progressively passing each project through a rigorous risk management system to ensure that project funds are directed only to the most promising technologies.

Including continuing projects from last year, HIP supported 46 projects in the reporting period: 15 projects at the first risk management stage (RMS-1), 18 at RMS-2, and 13 at RMS-3. The breakdown by cluster is as follows: sexual and reproductive health, 1; vaccines and pharmaceuticals, 13; diagnostic technologies, 15; maternal and neonatal health technologies, 11; and community and systems technologies, 6. Sixteen projects were completed during the year, several of which were declined for advancement to the next RMS; five new proposals were also declined.

The third year of HIP marked the first time that we “graduated” several projects from RMS-3 and have final results to report. Especially significant are the global access strategies and value propositions completed for several projects. Five projects garnered external funding, either as co-funding during the course of the HIP project or as significant follow-on funding to take the projects to the next stage; others have proposals to donors pending. The Analytical Resource Group, which provides support to all HIP teams, developed a substantial electronic database and resource center called the Analytical Resource Library—a collection of dozens of major documents produced by the teams.

During the year, we requested and were granted a two-year, no-cost extension of the program by the Bill & Melinda Gates Foundation, which allows us to support this early-stage discovery work for a longer period of time—until October 2014.

## 23. Oxytocin Initiative Project

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2011 core budget:	\$1,691,162
2011 total budget:	\$2,652,489
Percentage of PATH budget	0.90

### Project description

The Oxytocin Initiative project has been funded by the Bill & Melinda Gates Foundation since November 2008. The project aims to improve maternal health and survival in resource-poor settings in Ghana and India through the safe use of oxytocin. PATH chose to work in these two countries because both have large populations and high rates of postpartum hemorrhage (PPH) and maternal mortality. PATH also has experience working in both countries, making the project sites cost-effective choices.

PATH works with local and international partners to meet following project objectives:

- Increase evidence needed to maximize safe use of oxytocin and other uterotonics in two countries.
- Improve the knowledge base and define factors leading to misuse of oxytocin and other uterotonics in two countries.
- Improve available evidence on how to maximize safe use and minimize misuse of oxytocin.

### Project activities and impact

PATH has formalized agreements with the Department of Population, Family and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health and RTI International to oversee studies in the two countries:

- A landscape analysis exploring the use of oxytocin in and around birth in two states in India and three regions in Ghana.
- A trial conducted in four districts in Ghana to determine if intramuscular administration of 10 IU of oxytocin in the Uniject™ injection system during the third stage of labor by a community health officer in Ghana will reduce the risk of PPH.

In India, the Social and Rural Research Institute will conduct the landscape review. In Ghana, the Kintampo Health Research Center will carry out the trial and the Regional Institute for Population Studies will conduct the landscape review. PATH will work with its partners to oversee the research and data management, and to provide technical, quality assurance, supervision, and administrative oversight. PATH anticipates that the project's research results will inform health policy and practice related to uterotonic use for PPH prevention in Ghana, India, and internationally.

Results and impact to date:

- Required research ethics committees approved the Ghana trial, and the preparatory phase started in March 2011.
- Data collection for the Ghana landscape review was completed in October 2010, and data analysis and dissemination activities are under way. Preliminary results show poor quality of available uterotonics, and issues with knowledge and use of both pharmaceutical and

traditional uterotonics. Because of these results, multiple countries and the Maternal and Child Health Integrated Program (MCHIP) are interested in moving forward with uterotonic quality testing. The project is also pursuing additional follow-up work in Ghana and India. Research documents and consent forms for the India landscape review are being finalized and translated and will be submitted for final approval. It is hoped that field work and data collection can begin in May 2011.

- Oxytocin in Uniject™ was registered in India and Gland Pharma produced its first batch in late 2010. Instituto Biologico Argentino entered into an agreement with Vicdoris Pharmaceuticals Ltd. and the registration process in Ghana will begin in early 2011.
- The project co-organized the Africa Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care with MCHIP. This meeting focused on PPH and pre-eclampsia/eclampsia and was held in Addis Ababa, Ethiopia, in February 2011. This meeting was well received by both donors and participants and attracted more than 300 participants from 22 African countries. A similar meeting is planned for Asia in early 2012.

## 24. Screening Technologies to Advance Rapid Testing for HPV for Cervical Cancer Prevention in Developing Countries (START-UP)

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2011 core budget:	\$1,540,287
2011 total budget:	\$2,629,537
Percentage of PATH budget	0.89

### Project description

Cervical cancer is a preventable disease affecting nearly 500,000 women each year and leading to more than 250,000 deaths, nearly 85 percent of which are in low-income countries where conventional screening by Pap smear is not sustainable. In partnership with Qiagen Inc. and Arbor Vita Corporation, PATH developed tests that give women more accurate alternatives to Pap smears and can provide same-day test results. Under START-UP, PATH is addressing barriers to the adoption of Qiagen's HPV DNA rapid-batch test (*careHPV*™) and is advancing Arbor Vita's rapid-strip test (AVC AVantage HPV E6 Test™). PATH is also working to identify sustainable service-delivery platforms upon which the new tests can be incorporated.

### Project activities and impact

**Activity 1:** PATH is demonstrating the feasibility, effectiveness, and acceptability of the *careHPV*™ test in comparison to other screening strategies. By the end of 2010, four clinical studies were underway in India, Nicaragua, and Uganda. Data received to date continue to be encouraging. Of special interest is the ready acceptance of client self-sampling (as opposed to health care professionals taking cervical samples). This could help remove many barriers to screening, including reducing wait times and eliminating client refusal to screen due to sensitivities about pelvic exams. Cost studies are under way as well.

**Activity 2:** PATH is performing market assessments to understand factors that hinder or facilitate the introduction and uptake of HPV tests, particularly the *careHPV*™ test. The assessments will help develop the optimal product introduction strategy.

**Activity 3:** By broadly sharing data from the demonstration studies, PATH is advocating for and helping to guide national cervical cancer prevention programs.

**Activity 4:** In collaboration with the Cancer Institute, Chinese Academy of Medical Sciences, in late 2010, PATH began to assess the clinical utility of the AVantage HPV E6 test for predicting risk of progression to precancer. Study results will further inform the development of the test.

**Activity 5:** PATH is promoting a sustainable service-delivery platform for cervical cancer screening and treatment upon which new screening tests may be introduced. The service-delivery platform is being modeled by a regional Training Excellence Center (TEC) for Latin America, established in collaboration with the National Cancer Institute of Peru and Jhpiego. In 2010, the TEC expanded its work in Peru to Colombia, and is poised to expand to Nicaragua in 2011 with START-UP funding and to Bolivia with separate financing from the Pan American Health Organization (PAHO) and the CDC.

**Activity 6:** PATH is working closely with a variety of regional and global health organizations to educate staff and members about screening and treatment and to promote newly harmonized practice standards, to translate and disseminate scientific information, to develop updated toolkits for program planning and implementation, and to encourage incorporation of alternatives to Pap smear into organizational guidelines.

## 25. Reproductive Health Supplies Coalition Secretariat

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2011 core budget:	\$1,993,276
2011 total budget:	\$2,451,276
Percentage of PATH budget	0.83

### Project description

PATH serves as the secretariat of the Reproductive Health Supplies Coalition, a global partnership of public, private, and nongovernmental organizations dedicated to ensuring that all people in low- and middle-income countries can access and use affordable, high-quality supplies to ensure their reproductive health (RH). Since 2004, the coalition has been at the forefront of international efforts to secure RH supplies by increasing resources, strengthening systems, and building effective partnerships.

Coalition goals include:

- Increasing the availability, predictability, and sustainability of financing for RH supplies.
- Strengthening the capacity of health systems to deliver RH supplies in a sustainable manner.
- Ensuring the added value of the coalition as a productive and sustainable global partnership through support for efficiency, advocacy, and innovation.

PATH manages the secretariat, based in Brussels, Belgium, with funding from the Bill & Melinda Gates Foundation, UK Department for International Development (DFID), USAID, and the United Nations Population Fund (UNFPA).

Coalition members include DFID, the West African Health Organization, the World Bank, the European Parliamentary Forum on Population and Development, UNFPA, USAID, the Bill & Melinda Gates Foundation, ICON, PAHO, International Planned Parenthood Federation, and more than 100 other multilateral organizations, bilateral and private foundations, low- and middle-income country governments, civil society organizations, inter-governmental organizations, NGOs, and the private sector.

### Project activities and impact

In 2010, the coalition:

- Hosted an annual membership meeting in Kampala, Uganda—the first annual meeting to take place in a developing country. Media coverage of the event spurred significant momentum toward reproductive health commodity security in Uganda, including increased funding for commodities and greater access to public-sector supplies by NGOs.
- Launched the HANDtoHAND Campaign, a successful advocacy effort aimed at rallying the support of the family planning community behind the United Nations Secretary-General's Global Strategy for Women's and Children's Health. The campaign unveiled a dramatic but achievable goal: 100 million new family planning users by 2015. The goal has been adopted as the cornerstone of the new USAID/DFID/AusAID/Gates Foundation Alliance.

- Established the first regional forum on commodity security. The Latin America/Caribbean Forum on Reproductive Health Commodity Security comprises 13 member organizations that meet regularly.
- Through the Secretariat, developed and launched ten new web-based profiles that consolidate country-specific information on RH supplies in the coalition's focus countries.
- Grew its membership to 129 institutions. More than half of the new members are from the Global South.
- For the fourth year in a row, increased donor support for coalition-related programs (excluding Secretariat operations and the Innovation Fund) from approximately \$1.3 million in 2007 to \$10.66 million. In addition to this amount, coalition-related programs were directly responsible for the procurement of \$8.7 million in RH commodities needed to confront potential supply crises.

## 26. TeenPATH Project

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2011 core budget:	\$1,466,530
2011 total budget:	\$2,257,030
Percentage of PATH budget	0.77

### Project description

The TeenPATH Project is an HIV/AIDS prevention program for in- and out-of-school youth. Over the past five years, the project has developed a comprehensive sex education (CSE) program, relevant for Thai youth at various stages of development. The CSE content promotes AIDS awareness, tolerance of different sexual lifestyles, and responsible sexual behavior. The project has helped teachers to have a fuller understanding of diverse sex lifestyles, positive youth development, and use of a student-centered approach to learning.

### Project activities and impact

The project has modified the approach to school-based sex education in important ways:

- Established model schools to serve as demonstration centers of systematic CSE at all levels as an integral part of the fixed curriculum.
- Established a network of teachers who understand the process of establishing CSE and positive youth development.
- Created a team of sex educators in the project's area of implementation.
- Created a model curriculum and principles for youth sex education at the primary, secondary, vocational, non-formal, and undergraduate levels.
- Helped to develop youth groups to promote AIDS awareness and sex education in schools and communities. Youth peers assumed leadership roles and were accepted by project partners.
- Gained acceptance for CSE among policymakers in the Ministry of Education. Key agencies in the national education policymaking process (Bureau of the Commission on Basic Education, Bureau of the Commission on Vocational Education, Bureau for Non-formal Education), along with institutions of higher learning, showed support for the establishment of a formal curriculum on sex education for all levels.
- Mobilized local resources to promote sex education activities.
- Increased coverage of sex education and references to TeenPATH partners in the media.

The project has implemented activities in 763 educational institutions in 76 provinces: 459 in general education schools (in 33 provinces); 242 in vocational schools; 12 in colleges/universities; 48 in non-formal education institutions; and 2 in child/youth training centers.

More than 8,000 persons received training in the CSE curriculum and more than 900,000 school students were exposed to the curriculum during the first five years of implementation.

## 27. Developing Stable Influenza Vaccines

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2011 core budget:	\$960,662
2011 total budget:	\$2,060,662
Percentage of PATH budget	0.70

### Project description

This project began in August 2010 with funding from the US Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA). Using multiple advanced vaccine formulation design and stabilization technologies, PATH and our partners aim to create influenza vaccine formulations with extended product shelf life. Meeting this goal would help to stockpile vaccines and rapidly distribute fully potent vaccines independent of the vaccine cold chain. The project also aims to investigate the manufacturability of selected stable vaccine formulations as well as the regulatory pathways and economic benefits of improved formulations when adopted and used at large scale.

### Project activities and impact

Influenza occurs in seasonal patterns worldwide, causing 250,000 to 500,000 deaths and up to 5 million cases of severe illness each year. If a highly virulent pandemic strain were to emerge in today's interconnected world, it could potentially kill millions of people. PATH anticipates that stable influenza vaccines with extended shelf life will improve global pandemic preparedness by expanding the availability and distribution of vaccine in low-resource settings as well as in developed countries like the United States—ultimately helping to contain the virus at an outbreak's point of origin, wherever it might be.

Under the BARDA contract, project activities will include evaluating liquid formulation and spray-drying technologies for subunit influenza vaccines, and liquid formulation, spray drying, and modified freeze drying (foam drying) technologies for live attenuated influenza vaccines. The stability of candidate formulations will be assessed after storage at various temperatures and tested for immunogenicity.

Following an 18-month base period of project work, options exist for PATH to receive additional funding from BARDA over a subsequent 18-month period to further evaluate and scale up promising stabilization approaches for influenza vaccines. Thus far, the project has:

- Secured supplies of bulk subunit influenza vaccine and live-attenuated influenza vaccine for use in the project.
- Executed a subcontract agreement with Aridis Pharmaceuticals, a privately held biotechnology company in San Jose, California, with proprietary formulation and drying technologies.
- Executed a subcontract agreement with Arecor Limited, a technology company based in Cambridge, England, that develops formulation solutions for recombinant proteins and vaccines.
- Established enhanced analytical capabilities in PATH's laboratories, as well as those of Aridis and Arecor, for use in evaluating candidate formulations of influenza vaccines.

- Developed relationships with leading academic laboratories to provide structural analyses to support the project's stabilization work.

## 28. Advancing Rotavirus Vaccine Development BRV Phase 3

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2011 core budget:	\$1,524,120
2011 total budget:	\$2,009,120
Percentage of PATH budget	0.68

### Project description

Since 2006, through a grant from the Bill & Melinda Gates Foundation, PATH's Advancing Rotavirus Vaccine Development (ARVAC) project has supported the development of the US National Institutes of Health (NIH) bovine-human reassortant rotavirus vaccine (BRV) candidate in partnership with select emerging-country manufacturers. In 2010, ARVAC conducted a due diligence analysis of the most advanced rotavirus vaccine candidates under development to identify those to be considered for phase 3 evaluation. The BRV candidate from the Serum Institute of India Ltd. (SIIL) emerged as the most worthwhile. Consequently, PATH received funding from the Bill & Melinda Gates Foundation in November 2010 to support phase 3 evaluation of SIIL's BRV candidate.

The ARVAC BRV phase 3 project has the following objectives:

- Prepare for a phase 3 efficacy trial.
- Conduct a pivotal phase 3 trial to evaluate vaccine efficacy, safety, and reactogenicity.
- Conduct a phase 3 immunogenicity study to compare SIIL vs. RotaTeq® (Merck), investigate non-interference with EPI vaccines, and evaluate lot-to-lot consistency.
- Prepare and submit the regulatory file for licensure of SIIL's BRV in India and file for WHO prequalification.

The clinical trials of SIIL's BRV candidate will be conducted under International Conference on Harmonization/Good Clinical Practices standards and will follow Drug Controller General of India and WHO international standards and requirements.

## 29. Enhancing Influenza Vaccine Development in Vietnam

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2011 core budget:	\$777,016
2011 total budget:	\$1,897,016
Percentage of PATH budget	0.64

### Project description

PATH launched the Enhancing Influenza Vaccine Development in Vietnam project in December 2009 with funding from the US Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA). The goal of the project is to advance work already being conducted by WHO and BARDA to build regionally based, independent, and sustainable influenza vaccine production capacity in Vietnam. By helping Vietnam to strengthen its production capacity, this project is an important step toward increasing local and regional vaccine supplies and improving real-time response in an influenza pandemic. It may serve as a model for building local production of influenza vaccines in developing countries.

### Project activities and impact

In 2010, the project:

- Entered into a collaborative agreement with the Institute of Vaccines and Medical Biologicals (IVAC) of Vietnam to prepare IVAC's vaccine production facility for the manufacture of influenza vaccines that meet international quality standards.
- Completed technical assessments of IVAC's manufacturing facility and quality systems to identify gaps and develop work plans.
- Conducted regulatory and clinical infrastructure assessments for influenza vaccines in Vietnam, which will inform decisions for IVAC's preclinical and clinical development planning.
- Strengthened its relationship with Vietnam's Ministry of Health, which included welcoming a delegation from the Ministry of Health to PATH's Washington, DC, office, for meetings to foster communication on influenza vaccine development and other health strategies in Vietnam.

PATH will continue to work with IVAC and the Ministry of Health in 2011 to advance an influenza vaccine candidate to clinical evaluation.

## 30. Advancing Rotavirus Vaccine Development

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2011 core budget:	\$1,490,595
2011 total budget:	\$1,883,869
Percentage of PATH budget	0.64

### Project description

With funding from the Bill & Melinda Gates Foundation, PATH's Advancing Rotavirus Vaccine Development (ARVAC) project aims to accelerate the introduction of safe, affordable, and effective rotavirus vaccines in the developing world by providing technical and financial support to emerging-country manufacturers. New vaccines produced by emerging-country manufacturers will help secure global supply, particularly for low-income countries. The new vaccines will also help drive down price and ensure locally manufactured products for public-sector use in countries with the highest burden of disease. PATH is working closely with our partners to optimize product-development timelines and provide support for clinical development, formulation, manufacturing, and compliance with national regulatory authorities and WHO.

### Project activities and impact

Primary activities of the ARVAC core grant aim to (1) support the development of the NIH BRV candidate at selected manufacturers; (2) establish and distribute a shared platform of technologies to inform development of BRV among the manufacturers' network; and (3) address key technical development aspects of the BRV with other manufacturers from emerging countries.

ARVAC provides a shared technology platform to manufacturers that have licensed the BRV candidate, which is composed of a host of technologies, training, and common technical support. In addition to minimizing cost and accelerating development, this platform is designed to avoid intellectual property issues that arise from single-company solutions and to meet common needs among emerging-country vaccine manufacturers.

In 2010, the project:

- Hosted the fourth annual meeting of the BRV shared platform network, which brought together partners, experts, and manufacturers for technical discussions and presentations in Kuala Lumpur, Malaysia.
- Advanced development of the BRV candidate, including quality control training of Wuhan Institute of Biological Products staff, progress toward finalizing the product development process and final formulation, and advisement on clinical trial design.
- Collaborated with PATH's Technology Solutions group to improve the blending procedure for BRV candidates and prepare relevant training for BRV manufacturers.
- Received a new grant from the Bill & Melinda Gates Foundation for phase 3 clinical study of the BRV candidate manufactured by the Serum Institute of India Ltd.