

Working with Botswana to Confront Its Devastating AIDS Crisis

President Festus Mogae told the U.N. General Assembly with brutal candor that his country was ‘threatened with extinction.’



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Program Area

Global Health

Our Goal

Through an innovative partnership between the government of Botswana, Merck, and the Bill & Melinda Gates Foundation, demonstrate for the first time in Africa a successful national effort to treat those living with HIV, slow the transmission of the virus, and minimize the impact of the epidemic.

Our Progress in Brief

Despite major challenges, the African Comprehensive HIV/AIDS Partnerships (ACHAP), which the government of Botswana, Merck & Co., Inc., The Merck Company Foundation, and the Bill & Melinda Gates Foundation launched in 2000, is making tremendous progress, particularly in expanding access to HIV treatment and care.

More than 50 percent of those who can benefit from antiretroviral (ARV) therapy—and 85 percent of those with advanced HIV infection—are now receiving these lifesaving drugs. These are the highest rates in Africa.

Botswana has made less-rapid progress in preventing the spread of HIV, although there are some signs that ACHAP’s investments are starting to have an impact (for example, a 45 percent reduction in the number of HIV-positive babies born to HIV-positive mothers).

Botswana’s progress in expanding HIV testing, treatment, and care has provided valuable lessons for other developing countries hit hard by HIV/AIDS. However, the model we have helped to build in Botswana requires significant medical infrastructure, which could make it difficult to adopt in countries with fewer resources.

The Challenge

Botswana is a Texas-sized country in southern Africa with a stable democracy, mineral wealth, and some of the most awe-inspiring game reserves in the world. It also has one of the world’s highest rates of HIV infection (33 percent among people aged 15 to 49). In 2001, when researchers estimated that half of all women in Botswana in their 20s would die of AIDS, President Festus Mogae told the U.N. General Assembly with brutal candor that his country was “threatened with extinction.”

AIDS Threatens Decades of Success

Botswana was one of the world’s poorest countries at the time of its independence from the United Kingdom, in 1966. But a year later, geologists from the De Beers company discovered diamonds in the northern part of the country. Botswana’s diamonds dramatically changed the

development trajectory of the country, bringing broad social and economic progress—without conflict. Botswana became one of the few economic success stories in Africa, growing 13 percent a year from 1970 to 1990.

AIDS threatens to undo all this progress. The disease is hitting every segment of the economy and society—from rural farmers to teachers and civic leaders. Employers are struggling to cope with frequent absenteeism, rising health-care costs, and the loss of skilled workers. Hospitals are operating at 200 percent capacity, with an estimated 80 percent of their patients being treated for HIV-related illness. Out of a population of 1.6 million people, approximately 120,000 children are now orphans because of AIDS.

Can ARVs Work in Africa?

Combination ARV therapy, which emerged in the mid-1990s, has brought about a dramatic decline in AIDS deaths in the industrialized world. But in 2000, when we began our work in Botswana, many believed it would be impossible to provide widespread access to ARVs in developing countries, owing to the high cost of the drugs, the lack of adequate personnel and health-care facilities, and the difficulty of ensuring adherence to complex treatment regimens.

The Response

The person most responsible for leading Botswana's response to AIDS is President Festus Mogae. At a time when other African leaders would not utter the word "HIV" in public, President Mogae issued a battle cry of "*Ntwa e bolotse*" ("The war has started") and committed Botswana to making lifesaving ARVs available to every citizen in need. To reduce the crippling stigma around AIDS in his country, he even had himself tested for HIV on national television.

Big Pharma Thinks Big

The seeds of the Botswana–Merck–Gates Foundation partnership were sown in the 1980s, when Merck launched a program to provide free supplies of its drug Mectizan to fight river blindness in Africa and elsewhere. The world-renowned epidemiologist Bill Foege, who at the time was the executive director of the Carter Center and later became a senior fellow at the Gates Foundation, came to know and respect Merck through his work with the firm on the anti-river blindness campaign.

In 1999, Merck executives shared with Dr. Foege and his Gates Foundation colleagues a plan they had developed with the support of Raymond Gilmartin, then Merck's CEO. The plan laid out a sophisticated blueprint for a project to demonstrate that a comprehensive, well-funded project in one African country could produce meaningful results in the fight against HIV/AIDS.

Dr. Foege was so impressed with the plan that, at the last minute, he invited two Merck executives to present it in Seattle at a previously scheduled meeting of large foundations and U.N. officials working to address HIV/AIDS. Some of the other meeting sponsors had such distrust of the pharmaceutical industry that they sought to rescind the invitations, even as the executives were in the air on their way to Seattle. In a tense, three-hour meeting, Dr. Foege convinced the dissenters to let the invitation stand.

The next day, the Merck plan was the surprise hit of the meeting. The presentation showed clearly that Merck was serious—and thinking big.

Merck, Gates, and Mogae Join Forces

A few months later, the Gates Foundation and Merck agreed to collaborate to launch the plan, and they set out to identify an African country that would give the project a good chance to succeed. Botswana was a natural choice. Not only did it have a very heavy HIV burden; it also had a straight-talking president who was personally committed to confronting the crisis and had invited outside support. Botswana also had a stable democracy and significant resources of its own to commit.

By July 2000, Merck and the Gates Foundation created the African Comprehensive HIV/AIDS Partnerships and formally joined forces with President Mogae to support the country's already ambitious efforts to combat the epidemic. The Merck Company Foundation and the Gates

Foundation each committed \$50 million over five years to help Botswana strengthen its health infrastructure, such as training new health workers and managers, and establishing new laboratories and mobile clinics. In addition, Merck committed free supplies of its two current AIDS drugs. Soon after, others signed up to provide technical expertise, including the Harvard School of Public Health.

ACHAP's first job was to work with the government to create a national HIV/AIDS strategy—that is, to turn a serious but fragmented response into a comprehensive and coordinated national campaign. Although the resulting framework had much technical merit and was backed by strong political leadership and financing, implementing it proved to be more difficult than anyone expected.

A Shortage of Health Workers, an Excess of Stigma

The most significant challenge was the dire shortage of health staff. Because Botswana does not have a medical school, the government has worked hard to recruit new health professionals from neighboring countries as well as from India and Cuba. But that has been a slow process.

Another major challenge was (and is) social stigma. As has been the case in almost every part of the world, members of Botswana's tightly knit society were reluctant to be seen entering clinics associated with AIDS, which meant that few people took advantage of voluntary HIV testing and counseling. Of the approximately



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260,000 adults in Botswana estimated to be HIV positive, only a small percentage had been tested and knew their status. Those who did show up at hospitals or clinics for testing were often very sick, and as a result, they required a great deal of doctor time and hospital resources. In the words of the treatment program's first director, "If you spend all your time and capacity on the very sick people, you can never get to those who are not sick, and unfortunately, that sets up a loop of perpetually insatiable demand."

As a result of these and other challenges, the early results were disappointing. President Mogae hoped to get 19,000 people on ARVs by the end of 2002, the program's first full year. The program managed to enroll only 3,200. Although the ARVs were undoubtedly saving lives, the small numbers stoked fears that Botswana's example would be held up for the world as proof that the hurdles to ARV treatment were just too great—that if it couldn't be done in a country with all of Botswana's advantages, it couldn't be done anywhere.

Treatment Takes Off, Prevention Lags

By 2004, the situation had improved and perceptions had begun to turn around. By the end of that year, nearly 40,000 people, roughly 36 percent of those who were believed to need it, were receiving ARVs. The Princess Marina Hospital in Gaborone had become the largest single provider

of ARV therapy in Africa, and 31 other sites in Botswana were offering free ARV therapy. Not only had the early investments in health infrastructure begun to kick in; President Mogae had decided to adopt a policy of routine, voluntary HIV testing for all people seeking medical care for any condition ("opt out" instead of "opt in"). This led to more people with HIV learning their status, which allowed them to seek treatment and take steps to protect their partners from infection. In 2005, after the new routine-testing policy went into effect, 177,831 people were offered the test and 157,894 accepted—an 89 percent acceptance rate.

Today, the treatment program is enrolling patients at a rapid pace, averaging about 1,000 a month. AIDS mortality is falling, and those who doubted that a national ARV program could work in sub-Saharan Africa have changed their tune.

But many challenges remain. For example, roughly 50,000 people who could benefit from ARVs—especially those in remote districts—still have not been reached. Those who are already on ARVs will need a lifetime of treatment and monitoring, including access to new, more-expensive treatments if first-line drugs begin to fail. And HIV-prevention efforts are still fragmented and not highly visible, leading some visitors to comment that it is hard to realize that the country is at the epicenter of the global AIDS pandemic.

Results

- **Treatment:** ACHAP and its partners have established the first comprehensive, nationwide HIV treatment program in sub-Saharan Africa. Today, almost 64,000 people in Botswana are receiving ARVs. This represents well over half of those who could benefit from ARVs and more than 85 percent of those with advanced HIV infection.
- **Adherence:** 85 to 90 percent of all patients are adhering to their treatment regimens. In the United States, the average adherence rate is only 70 percent.
- **HIV Infections:** Between 2003 and 2005, the percentage of 15- to 19-year-olds who are HIV positive has declined by 22 percent and the percentage of HIV-positive infants born to HIV-positive mothers has declined by 45 percent—offering epidemiologists the first rays of hope that new infections are slowing.
- **Training:** With ACHAP's funding and technical assistance, Botswana has now trained more than 3,900 health professionals, significantly expanding the country's testing, counseling, treatment, and monitoring efforts.
- **Policy:** ACHAP and its partners have had a positive effect on national policy. For example, ACHAP played a key role in advocating for policies to expand access to HIV testing and to reduce the age of consent for HIV testing from 21 to 16, policies that were adopted by the national government.

- **Infrastructure:** ACHAP has built 24 treatment centers throughout the country and equipped 11 labs, greatly increasing access to care.

Key Lessons

- **Skeptics were wrong when they said that treatment programs would not work in Africa.** We now know that it is difficult but possible to “scale up” a national ARV program in Africa and save lives today. We also know that Botswana’s patients adhere to their drug regimens more faithfully than Americans do.
- **Bold political leadership is essential.** When we began our search for a country in which to work, we knew we were looking for countries with leaders who offered profiles in courage in fighting this disease. Our view that success rides on such top-level leadership has only increased over the past five years. We now see that it is an essential precondition for success. However, we also see that even the boldest political stance is not enough to erase the deeply rooted stigma associated with HIV/AIDS.
- **Working hand-in-hand with government was the right call in Botswana.** Working closely with a national government in any country can slow down a project—and that can be frustrating. But working directly with the government of Botswana has allowed us to help the nation build its own capacity to wage a successful war on HIV/AIDS.



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Having said this, it was unrealistic for us to expect that all the support ACHAP provided to government ministries would cascade down quickly to remote rural villages. As a result, ACHAP is now devoting more time and money to supporting work being conducted by the government and nongovernmental organizations at the grassroots level. So far, this effort seems to be succeeding at building greater community ownership and empowerment.

- **Prevention can get lost amid the effort to expand treatment.** Although all of the ACHAP partners recognized the importance of prevention, during ACHAP’s early years the immediate task of saving the lives of HIV-positive people often had higher priority than the task of helping to prevent new infections. The cost of lifelong treatment and care for all of those who are gaining access to ARVs remains very high. Sustaining that effort will depend on success in slowing dramatically the rate of new HIV infections.

- **“Absorptive capacity” is a real issue.** ACHAP and Botswana’s government have not been able to spend the funding they have available at the rate we anticipated. The original \$100 million in funding from the foundation and Merck was designed to last through 2005, but only \$55 million was actually spent over that period. Of course, spending money fast is not the objective. But the fact that the spending has been slower than we anticipated is an indicator that we underestimated just how hard it is to build up the systems necessary to confront HIV/AIDS across an entire country.
- **We believe Botswana will, over time, be able to sustain the costs of its treatment program.** Botswana has shown a tremendous willingness to direct its own resources to fighting this epidemic. For example, it already pays for more than 80 percent of all treatment costs. However, we have seen that long-term sustainability will require all the partners to reduce the costs per patient. The current model relies too heavily on frequent, expensive viral-load tests and on visits with doctors in hospitals (doctors are still in short supply, and there is as yet no medical school in the entire country).

Next Steps

Based on the progress to date of Botswana’s national efforts, Merck & Co., Inc./The Merck Company Foundation and the Gates Foundation last year committed an additional \$6.5 million each to fund ACHAP’s operating costs for five more years. Thanks to a major strategic review last year, all of the partners are confident that prevention and treatment are now gaining equal footing. It is clear to all that Botswana will not be able to make meaningful progress toward its goal of “an AIDS-free generation by 2016” without dramatically expanding its prevention efforts, including its efforts to bring HIV/AIDS education to every classroom, make free condoms more widely available, and further expand testing.

Web Sites

- African Comprehensive HIV/AIDS Partnerships:
www.achap.org
- Merck & Co.:
www.merck.com
- Government of Botswana:
<http://www.naca.gov.bw/>
- Harvard School of Public Health:
<http://www.hsph.harvard.edu/>

Helping High School Students Prepare for—and Afford—College

We combined reform and scholarships because we believed that a coordinated approach—making students aware of college, making sure they're prepared for it, and helping them pay for it—would have the best results.



Program Area

U.S. Programs: Education

Our Goal

Help students graduate from high school prepared for college and work by helping reform 16 Washington state high schools; award college scholarships to talented, low-income students who attend those schools.

Our Progress in Brief

Five years into the program, most of the high schools that received Washington State Achievers grants have changed significantly, with higher expectations and new ideas about how to reach them. Most important, more kids are taking tougher classes that will prepare them for college. Students in some schools have made impressive gains in graduation rates and standardized test scores, but on the whole we have yet to see dramatic improvements in these key

statistical indicators. However, the program is still relatively new, and we expect graduation rates and test scores to improve more quickly over the next several years as the work continues.

Meanwhile, the scholarship program has been a success. Washington State Achievers scholars are attending college and staying enrolled at much higher rates than their peers.

The Challenge

In today's economy, high school graduates who are applying for jobs need the same skills as their peers who are applying to college. Employers won't hire young people who don't know algebra or who can't write clearly.

Unfortunately, U.S. high schools simply don't prepare most of our young people for college and work. Only about 30 percent of ninth-graders will

graduate high school with the skills they need to take the next step in their lives. The statistics are even worse for students from low-income families.

Even when low-income students beat the odds and graduate prepared for college, they often can't afford it. Financial barriers prevent nearly half of all qualified low-income high school graduates from attending a four-year college.

Put the failure of our high schools and the extraordinary expense of college together, and it's understandable that just one in 10 low-income students will earn a bachelor's degree by age 26. These numbers aren't acceptable—not when a college graduate can expect to earn \$1 million more over a lifetime than a high school dropout. And yet our schools won't get better results unless they adopt a whole new approach to education.

The Response

When the foundation started giving grants to help schools change their approach to teaching and learning in the late 1990s, we noticed that while elementary and middle schools seemed eager to try to reform, high schools showed little interest. Then, in 2001, a new study revealed that the U.S. high school graduation rate was just 71 percent. The report confirmed our belief that high schools faced a unique set of challenges. In cities around the country, including New York and San Diego, we began to invest in a strategy to improve graduation rates by converting large high schools into a group of “small learning communities.”

The Washington State Achievers Program, launched in partnership with the Washington Education Foundation in 2001, is part of this strategy. The three-part Achievers program combines an initiative that helps middle school students think ahead about college, a high school redesign effort in 16 schools around the state, and a college scholarship and mentoring program. The Achievers program has received grants totaling \$134 million.

Our goal for the redesign process was to help spur new ways of thinking about education that would ultimately help all students prepare for college and work. We gave the 16 Achievers schools a five-year grant to undergo a thorough redesign process that would change everything from the size and structure of the schools to the expectations teachers and principals set for themselves and their students.

We also funded 500 scholarships a year over 10 years to students at Achievers schools. These scholarships are awarded during students' junior year, and they provide not only tuition assistance but also mentoring and other kinds of support to help prepare young people, many of whom had never even thought about higher education before, for the opportunities and challenges of college.

We combined reform and scholarships because we believed that a coordinated approach—making students aware of college, making sure they're prepared for it, and helping them pay for it—would have the best results. Moreover, we assumed the scholarships would give high schools an incentive to undertake the difficult reform process.

A New Vision for High Schools

The redesign work has three main components:

College Awareness: To help seventh- and eighth-grade students believe that they can and should go to college, the program funds the CollegeEd college-awareness curriculum in 32 middle schools that feed the Achievers high schools.

Small Learning Communities: Based on experience and research showing that students do better in small schools where they can build important relationships with teachers, administrators, and each other, we emphasized structural reform. Twelve Achievers schools had been large, comprehensive high schools,

and the grant required them to break themselves into semi-autonomous small learning communities of no more than 400 students.

Instruction and Curriculum: Once a high school sets the goal of preparing all its students for college and work, its teachers must adopt a new set of approaches in the classroom. We laid out a list of school and classroom attributes—like high expectations, personalized learning environments, time to collaborate, and active inquiry, in-depth learning, and performance assessment—to help guide them. In addition, we brought in teaching coaches and encouraged faculty members to meet extensively with each other and share ideas about how to get the best results for their kids.

Another pillar of the Achievers program is scholarships. They are what are known as last-dollar scholarships, which means they cover all costs not defrayed by other financial aid. The scholarship program focuses on what we call “diamonds in the rough”—talented students who may not have considered college as a possibility. To help these students, the Achievers Scholars program offers more than just money. Students are awarded the scholarships in their junior years, and they are given mentors and additional support to help them succeed as they complete high school, navigate the application process, and manage the difficult transition to college.

Learning From a Slow Start

The school-redesign work has been the most challenging aspect of the Achievers program. The unintended consequence of our strategy to use the scholarship program to entice schools to reform themselves was that many schools that applied for grants were most interested in the scholarships, and it took longer than we had expected to build momentum for dramatic change at many Achievers schools.

In addition, we didn't want to tell schools precisely how to redesign themselves; and yet, as a result, we may not have provided enough guidance to principals and teachers who were responsible for making big changes. Moreover, it's virtually impossible to build consensus among students and their parents and school and school-district staffs. Some people involved in the redesign process didn't agree with its fundamental goals. Many others didn't agree on how to implement it. It took two or three years before the details of the structural reform were ironed out and teachers could turn their attention to classroom instruction. In general, it's extraordinarily difficult to change existing organizations, and the Achievers program has helped us understand more of the complexities involved.

Results

Scholarships

- The Achievers program has awarded scholarships to almost 2,500 low-income students.



- Almost two-thirds of Achievers scholars have enrolled in four-year colleges and universities, and these numbers have improved as the program has evolved. Seventy-three percent of the most recent class of Achievers enrolled directly in four-year colleges and universities.
- These students also stay enrolled at higher than average rates. One study found that 80 percent of Achievers who went directly to a four-year college were still enrolled three years later. Almost all these students were enrolled full time, at least in part because they don't have to work to pay tuition and other expenses.
- Forty-four percent of Achievers scholars graduate college in five years, compared to 15 percent of a national sample of student who come from similar backgrounds but don't have scholarships.

High School Redesign

- Most Achievers schools have made significant progress toward implementing structural reform and revamping school culture to emphasize college preparedness.
- All 12 comprehensive high schools have converted into small learning communities, and in the majority of these schools the commitment to seeing redesign through is strong. That commitment is weaker in three or four of those schools, and it's possible that some or all of them may revert to their old structures when they stop receiving funds from the program.

- Most schools have replaced remedial classes with a requirement that struggling students take additional classes in their area of need. The percentage of students taking college-preparatory courses has increased at almost all Achievers schools, and the majority of schools report an increase in the number of students enrolling in Advanced Placement or International Baccalaureate classes.
- Twelve Achievers schools have advisories, an innovative approach to fostering relationships at school. In advisories, the same group of students meets with the same teacher every day, which helps guarantee that no students fall through the cracks. Most small learning communities also have formal systems in place to help teachers share information about students who are struggling.
- The majority of small learning communities have scheduled time for teachers to work together on a range of issues, including assessing students' work and examining their own teaching practices. A few of the communities have implemented a program that lets teachers visit their colleagues' classes to get new ideas and give feedback.

However, some of the key statistical indicators have not improved as quickly as we would have liked. For example, the test scores at Achievers schools are up, but not appreciably more than

scores throughout the state. Graduation rates are down slightly. Nevertheless, more graduates from Achievers schools are attending college, and it is important to note that most of the small learning communities have existed for only a year or two, and the process of creating them was disruptive in many ways. Over the next several years, we expect to see improvements in test scores, graduation rates, and college attendance rates.

Key Lessons

- **It's critical to get the mission right.**
We need to be very specific about our goal—that high schools should prepare all students for college and work. We also need to ensure that students, parents, schools, and school districts are committed to that goal and know what reaching it entails. In the Achievers program, we didn't do enough to get key partners on board. For example, at first, many principals and teachers didn't know how much work the redesign process would require. In addition, as the small learning communities began to take shape at the Achievers schools, some parents resisted the changes for a variety of reasons, ranging from how they affect extracurricular activities to how they sometimes limit elective course options. Now we try to engage districts, school boards, and community organizations to conduct outreach and get input from all interested parties.

- **It's hard to strike the proper balance among the key elements of the high school redesign process.** We decided to start with structural reform—helping the comprehensive Achievers schools convert into small learning communities—but the controversy generated by these changes delayed other essential tasks such as revamping the curriculum and working with teachers to improve classroom instruction. However, it's not clear that the process would have gone more smoothly if we'd started with instruction and curriculum, because changing what happens in the classroom is also controversial. Also, it may be easier for teachers to make adjustments in the more nurturing environment of small learning communities. We learned from the Achievers grant not to overemphasize size to the exclusion of other improvements, but we're still working to determine how to coordinate all the moving parts of a successful high school redesign effort.
- **It's essential to work with school districts as well as individual high schools.** We didn't ask the Achievers schools to consult with their districts as they drew up their redesign plans, and ultimately this lack of communication became a major hurdle. Each Achievers school has a different relationship with its district, but many had problems getting districts to sign off on certain aspects of the redesign work. (Some of the major stumbling blocks involved changing the master schedules to accommodate longer class periods

and reserving extra time for teachers to attend to their professional development.) Districts don't merely need to be involved in redesign efforts. We've learned that they have the expertise and resources to drive broad, effective school reform. Our current grantmaking strategy emphasizes work at the district level.

- **Redesign work puts extraordinary demands on principals and teachers.** Since the Achievers program started five years ago, only two of the original 16 principals remain in their jobs (and they are leaving in 2006). Some Achievers schools have gone through three principals. Although this kind of turnover can interrupt the reform process, it can also rejuvenate school staffs. Redesigned schools attract particularly energetic leaders, and the redesign process itself has helped create a new cadre of teacher-leaders who are dynamic forces at their schools.
- **Mentoring and other kinds of support are necessary for both high school and college students.** Assigning mentors to Achievers scholars has been an important factor in the program's success; mentors serve as role models and provide practical advice about college that some students may not be able to get elsewhere. We have also found that scholars who initially enroll in community colleges more often make a successful transition to a four-year institution if they continue to receive academic support.



- **Scholarships not only help students from low-income families attend college but also improve their chances of graduating and doing well.** By removing both real and perceived financial barriers to college, financial aid dramatically increases the likelihood that students with limited means will enroll in college. We have also learned that scholarships reduce students' need to work a job, which often means they can be more involved with campus activities and build stronger relationships with faculty members. Students who work less are also more likely to earn their degrees.

Next Steps

In May 2006, we celebrated the fifth anniversary of the Achievers program, and we committed an additional \$4.3 million over two years to assist the Achievers high schools as they continue their redesign work. Specifically, these grants will help create school cultures in which college is a priority, provide struggling students with the support they need to stay in school, and implement an effective framework for classroom instruction. The scholarship program will continue until 2011.

Making Sure All Americans Benefit From Computers and the Internet

It is increasingly difficult to operate in today's world without access to computers and the Internet. And for tens of millions of people who don't have home computers, public libraries are the places to go for these tools.



Program Area

U.S. Programs: U.S. Libraries

Our Goal

Ensure that any person who can get to a library anywhere in the United States can access the Internet for free.

Our Progress in Brief

We met our original goal. A study released in 2005 showed that 99.6 percent of public libraries in the United States offer public access computing. However, additional data shows that many libraries, especially in rural areas, are having difficulty sustaining their programs. Furthermore, many library programs are at risk of becoming obsolete because their hardware is old or their connection speeds are too slow.

The Challenge

In 1997, the six public libraries in Terrebonne Parish, La., home to more than 100,000 people, provided patrons with just two computers connected to the Internet. The next year, with help from the foundation, they added 28 more. A branch library in Terrebonne Parish was selected to be one of Louisiana's five regional computer-training centers, and the librarians there have conducted more than 100 classes a year since then, teaching people from miles around basic computer literacy. And that's in addition to thousands of informal training sessions that help patrons use computers and the Internet to write résumés and research papers, apply for jobs and college admission, start their own businesses, or find information about government services.

By August 2005, after an impressive local fundraising effort, Terrebonne Parish's libraries had a second computer-training center and a total of 88 public access computers.

A Lifeline After Hurricane Katrina

People needed those computers, because when Hurricane Katrina hit nearby New Orleans in September 2005, more than 1,000 refugees moved into an emergency shelter across the street from the main branch of the library. Suddenly, the library's computers were occupied morning, noon, and night.

Many people in the shelter had never used a computer before, but phone lines were down and they needed to find out if their friends and family were safe and if their houses were under water. Then they had to apply for help from the Federal Emergency Management Agency. According to Wanda Bruchis,

who runs the public access computing program in the parish's libraries, "They wanted information, and we were it."

Library employees worked overtime to meet the demand, and they met every morning to prepare for the rush. Their biggest concern was for patrons who couldn't locate their family members. "We became social workers," Bruchis said. "We became ministers."

Three weeks after Katrina, Hurricane Rita hit Terrebonne Parish especially hard. One-third of library employees lost their homes, and two branch libraries were destroyed. But the staff buckled down again, this time to help their neighbors get the information they needed to communicate with friends and family and get back on their feet.

Information Have-Nots

In this crisis, libraries and their public access computers became a lifeline for thousands of people. But even under less trying circumstances, public access computing is absolutely essential. It is increasingly difficult to operate in today's world without access to computers and the Internet. And for tens of millions of people who don't have home computers, public libraries are the places to go for these tools.

And yet, in the mid-1990s, public access computers were hard to find. In 1995, the *New York Times* editorialized, "The most basic promise of the information age—that books, facts and figures will be widely and cheaply disseminated over telephone lines—will come to nothing unless public access to computers and telecommunications

technology is broadly expanded." Most libraries simply didn't offer public access—in 1997, only 28 percent of libraries in the United States included computers and the Internet among their services.

Around the same time, the Department of Commerce released data showing that a significant percentage of Americans—most of them low-income minorities—didn't have access to computers at all.

With so many information have-nots and so little public access, millions of people were on the wrong side of the so-called digital divide. And American life was growing increasingly reliant on information technology. The digital divide threatened to further isolate communities already marginalized by a host of economic and educational inequities.

The Response

In 1997, Bill and Melinda Gates created the Gates Library Foundation, with the goal of making sure that all people have access to computers and the Internet through public libraries. (In 2000, the Library Foundation merged with the William H. Gates Foundation to become the Bill & Melinda Gates Foundation.)

The Library Foundation grew out of Libraries Online, an 18-month pilot project operated by Microsoft in partnership with the American Library Association. Libraries Online helped about 200 libraries in low-income areas across the country launch public access computing programs. The results were

so encouraging that Bill and Melinda decided to expand the project and make it a focus of their philanthropy. "We realized we could do this with thousands and thousands of libraries and ensure that children and adults have an access point to technology whether they have a computer or not," said foundation chairwoman and president, Patty Stonesifer (now CEO of the Bill & Melinda Gates Foundation).

Installation, Training, and Technical Support

Unlike our other programs, the U.S. Libraries program started as an operational effort, which means we ran the program ourselves and implemented it on the ground, with a lot of help from state agencies and other partners. We drew up state-by-state plans to work with all libraries in areas where the poverty rate was 10 percent or higher, which turned out to amount to almost 11,000 libraries. Then we solicited proposals from eligible library systems and used the information we gathered to tailor our plans to each library's needs.

We provided three primary services:

1. **Installation:** Our teams traveled from library to library installing computers that we designed especially for the program. Gateway provided the hardware, Microsoft provided the software, and we developed a standard configuration appropriate for heavy use in a public setting. This package reduced computer-security and maintenance concerns for libraries and made it possible to offer training and technical support

to all program participants. Libraries that didn't want the standard package could opt for cash grants to buy their own hardware and software.

2. Training: Between 10 and 50 trainers were in the field at any given time, helping librarians learn how to use computers and the Internet and how to help their patrons do the same. Librarians from larger systems also attended joint trainings at our offices in Seattle to learn how to maintain public access computing labs and develop their own staff- and patron-training programs.

3. Technical Support: We operated a call center in Seattle that handled technical-support requests from participating libraries. In the program's early phases, we offered this service to each library for three years; in the later phases, we offered one year of technical support as we looked for more sustainable methods of providing the service.

Learning From a Slow Start

We began the program in Alabama in December 1997, and it took much longer than we'd expected to install computers and train staff in about 250 libraries there. In fact, Bill and Melinda traveled to Alabama to celebrate the program in February 1998, when the work was scheduled to be done, but their visit was premature: We didn't finish until June.

The biggest problem was that we didn't understand how important it would be to prepare libraries for installation. We instructed librarians to have their



Internet connections and computer networks ready on a certain day, but we didn't give them the support they needed to get it done. As a result, in future states, we focused more on consulting and communicating with librarians and state library agencies beforehand, and the work went more smoothly.

Because we had trainers in the field getting constant feedback from librarians, we were able to make a number of improvements during the course of the program. For example, many larger, urban library systems were already running their own public access computing programs, and our prepackaged library computer didn't always fit their specifications. Consequently, we began giving these

systems cash grants to help them improve preexisting public access programs.

We also learned that our original training manuals were too dense for patrons to use easily. As a result, we rewrote them and produced a series of "Quick Guides" to accommodate those with different skill levels.

The Challenge of Sustaining Progress

By 2002, when the program was nearing completion, we understood the pressing need to give libraries access to training and technical support after the program ended. We knew we could no longer offer these services, but we understood they would be absolutely critical to the long-term success of the program. As a result, we gave a grant

to the Online Computer Learning Center to build WebJunction, an online community where librarians can share knowledge and get technical support. WebJunction has since become an integral part of our strategy to help libraries sustain their public access computing programs.

When the program finished in 2003, we had granted more than 47,000 computers to about 11,000 libraries—more than two-thirds of the libraries in the United States—in low-income areas. We then shifted our focus to helping these libraries sustain public access computing. Achieving this goal has been a much bigger challenge than we expected, especially in the thousands of rural libraries that operate on tiny budgets and often serve the disadvantaged populations that need public access the most.

Results

The Public Access Computing Project at the University of Washington conducted an ongoing evaluation of the U.S. Libraries program. We have also made grants to Florida State University's Information Use Management and Policy Institute to study public access computing in all U.S. public libraries, and we hired Peter D. Hart Research Associates to do a survey of public access computer users. Through these studies, we learned that:

- In 1996, the year before the program started, less than 30 percent of public libraries were online. By 2005, that number was 99.6 percent.

- Public access computing at libraries helps those who otherwise have little or no access: 71 percent of library computer users say library computers are their primary form of access.
- Public access computing has helped reinvigorate libraries: Libraries that participated in our program reported a 36 percent increase in library traffic and a 9 percent increase in book circulation.

However, additional data also show that many libraries are having tremendous difficulty sustaining adequate public access computing programs.

- 63 percent of the libraries that participated in the original program are now at risk of having their programs become obsolete, because either their hardware or connection speeds don't meet current standards.
- 85 percent of libraries don't have enough computers for all the patrons who want to use them.
- 39 percent of libraries don't have high-speed access, which means their patrons can't use many of the most current applications. The vast majority of these are rural libraries, which are falling behind their urban and suburban counterparts.

Key Lessons

- **We need to do a better job communicating why public access computing is so important.** We assumed that the value of public-access computing would be obvious, and therefore we didn't put enough time and effort into making the case

for computers and Internet access at libraries, or into helping libraries develop the skills to make the case themselves. Now many libraries are in the position of explaining why their extremely popular computing programs deserve to be funded. One important strategy—to dispel the myth that public access is about idle Web surfing—is to emphasize the impact of computers and the Internet on community and economic development and patrons' quality of life.

- **We need to help state library agencies build administrative capability.** Thus far, we've worked primarily with the state library agencies as intermediaries, but they have a broad arena of responsibility (and rightly are focused on more than public access computing) and we may have overburdened them. Especially since public access computing is so new, there simply aren't enough intermediaries in the field who can help provide expertise to libraries and librarians. In our most recent round of grants, we provided some funds for administrative support in an effort to help these agencies more effectively implement new programs, and the initial results of this approach were promising.
- **We need to help librarians with technology planning and securing local funding.** Librarians need help with technology planning and with raising money for public access computing, since they must juggle these new programs with the rest of their library's services. This is

especially true in rural areas where budgets are extremely tight. Some librarians have been particularly effective in developing their public access computing programs, but we need to help all librarians build expertise in this area. About 65 percent of libraries are operating with technology budgets that remain flat or decline from year to year. We believe we can help libraries reverse this trend through strategic advocacy efforts.

- **We need to enforce the local matching requirements of our grants.** Our intent was to require financial commitments from local governments. The idea was to make sure other funders were invested in the project and would help maintain public access computing programs after the initial phase of our program was completed. However, we didn't follow through in practice, and as a result the government funding we assumed would follow our investment didn't always materialize, given the competition for limited local funding. By requiring matching funds in the future, we can guarantee that other funders commit themselves to public access computing.



- **Shifting from an operating foundation to a grantmaking foundation has presented both challenges and opportunities.** Ultimately, we decided that we could have more impact by making grants and helping build expertise and capacity in the fields where we worked, instead of developing many different kinds of expertise within our organization. This shift has posed challenges but also has provided an opportunity to create new and lasting capacity in the library community. Nevertheless, during the original phase of the U.S. Libraries program, we created strong relationships with libraries and librarians because we worked with them directly. With the loss of daily contact, we have recognized a need for greater outreach to the library community, our grantees, and advisers to make sure our programs stay on track.

Next Steps

The next phase of our U.S. Libraries program will focus on helping libraries sustain public access computing. Our grants will be designed to help libraries and librarians secure the public funding necessary over the long term to upgrade their hardware and connection speeds to provide high-quality access. They will also provide more support to existing intermediaries and work to identify new partners who can help administer future programs. Finally, they will fund more impact research to document the importance of public access computing.

We will focus on the 63 percent of libraries that are at risk of having their public access programs become obsolete, and so we will emphasize strategies that are especially appropriate for rural libraries and librarians.

Assisting Homeless Families in Transition

It is easy to see homelessness when it involves single men, often mentally ill or drug-addicted, who live on the streets. But homelessness is also thousands and thousands of parents with children who don't have a safe place to sleep at night.



Program Area

U.S. Programs: Pacific Northwest

Our Goal

Triple the Puget Sound region's supply of service-enriched housing, an innovative approach to homelessness that combines affordable housing and social services, to help homeless families move toward self-sufficiency and decrease their chances of returning to homelessness.

Our Progress in Brief

Sound Families has served more than 2,500 adults and children, and the majority of families that participated in a Sound Families program have been able to obtain permanent housing and make other life improvements.

While these results are encouraging, we are studying ways in which graduating families remain vulnerable. For example, program graduates increase their incomes, but most still don't make a wage that allows them to support a family. In addition, most families continue to need rental subsidies, and those that lose this assistance are at risk of returning to homelessness.

The Challenge

Not all types of homelessness are equally visible. It is easy to see homelessness when it involves single men, often mentally ill or drug-addicted, who live on the streets. But homelessness is also thousands and thousands of parents with children who don't have a safe place to sleep at night. This family homelessness is often hidden from view.

Consider Candice and Ryan, who met in a program for homeless teenagers, and their young son, Nathaniel. Candice's parents kicked her out of the house because she was fighting with her sister. Ryan's father told him to leave when he stopped going to school and started doing drugs. When they found out Candice was pregnant, they had no money, no prospects, and nowhere to go.

In 2004, they were accepted into a transitional-housing program where they were given a stable home and a case manager, Jen, who helped them devise a plan for the future. With extensive interview training, Ryan, who had stopped doing drugs, got a job at a grocery store. He earned three raises in just over a year. Candice stays at home with 1-year-old Nathaniel. With Jen's help, she found several organizations that counsel new parents, and she says they have "helped me be the mom I always wanted to be."

In 2006, Candice and Ryan graduated from the program and moved into their own two-bedroom apartment. Now their family has a permanent home, a steady income, and a bright future. “This is a great place to start over,” Candice said as she packed boxes for the move. “We’ve done it.”

On any given night in Washington state, more than 25,000 people are homeless, and 40 percent of them are like Candice, Ryan, and Nathaniel—families with children. Homeless families face a special set of challenges. For example, almost half of homeless children don’t attend school regularly, and they are four times more likely than other kids to be developmentally delayed.

The Response

In 1999, Melinda Gates asked Bill Gates Sr. what the foundation could do to help homeless families. Bill Sr. and others at the foundation worked with the University of Washington School of Social Work to survey experts in the community, and they all came back with the same recommendation.

The first priority, they said, is making sure families have a safe place to live. Without a roof over their heads, they cannot hope to address the underlying problems that led to their homelessness in the first place. But housing by itself is not enough; homeless families usually need additional help, whether it’s domestic-abuse counseling, alcohol and drug treatment, a GED program, job training, or child care.

In 2000, together with many partners in local and state government, we launched the Sound Families Initiative, a \$40 million effort to build 1,500 units of service-enriched housing in the three counties that make up the Puget Sound region of Washington state (King, Pierce, and Snohomish Counties). Service-enriched housing, sometimes referred to as transitional housing, provides homeless families with a combination of a home for up to two years and social services to help them prepare for a stable and self-sufficient future. Families are assigned a case manager who can help them access a wide range of services that target their specific needs.

A Partnership Comes Together

Sound Families necessarily began with a partnership, because it takes multiple organizations and funding sources to make service-enriched housing work. Sound Families is a joint effort involving dozens of housing and service providers, property managers, and a handful of government agencies at various levels, and it relies on state tax credits, federal housing subsidies, and a patchwork of local, state, and federal funding. Consequently, no single foundation could provide the necessary expertise and resources.

In the planning phase of Sound Families, we asked the Seattle Office of Housing to administer the program because it could provide experience and leadership we simply didn’t have. Shortly after the initiative was launched, our regional housing authorities joined

the partnership. Representatives from these bodies and the rest of our partners serve on the Sound Families Steering Committee that helps set policy and make funding decisions.

The money we put up for Sound Families did not stand alone. It augmented and helped coordinate the substantial public resources that are needed for housing and services. Sound Families typically pays no more than 20 percent of the capital budget of any transitional-housing unit, and it covers about a third of each family’s services budget (for the first five years of each program). As a result, for every dollar the foundation has spent on Sound Families, our public-sector partners have spent a total of more than \$7.

The Northwest Institute for Children and Families, which is affiliated with the University of Washington School of Social Work, has been evaluating Sound Families since its inception. By 2004, it was clear from the evaluation data that Sound Families was helping homeless families, but we were also beginning to realize that sustaining service-enriched housing beyond the life of the initiative would pose a challenge. Though government regulations require that subsidized housing remain affordable for at least 50 years, there was no steady funding available for the services component of the programs. (Due to this uncertainty, many organizations were hesitant to apply for Sound Families grants because they were wary of the commitment to provide services after the five years of funding were over.)

A Statewide Services Fund

The Sound Families Steering Committee began researching solutions to the problem and came up with the idea of a reserve fund that would support service-enriched housing efforts across the entire state and over the long term. Working with the state legislature and new partners in the public and private sectors, we helped devise a jointly funded program that would eventually become the Washington Families Fund.

In 2004, the state legislature appropriated \$2 million for the fund, and since then 13 private funders have contributed an additional combined \$3 million. In 2005, the Washington Families Fund made its first round of grants. It received 50 proposals and awarded 10 grants, totaling \$2.64 million. These grants could help as many as 500 homeless families get the services they need over the next decade. Based on its early success, in 2006 the legislature appropriated another \$4 million, bringing the total to \$9 million.

Results

After six years, the Northwest Institute for Children and Families' evaluation is one of the most comprehensive qualitative longitudinal studies of family homelessness in Washington state. In short, it shows that housing-plus-services works:

- As of April 2006, the Sound Families Initiative had funded more than 1,100 units of service-enriched housing that have served more than 2,500 adults and children.



- More than 80 percent of the families participating in the evaluation remained in the program until graduation.
- 86 percent of those families secured permanent housing.
- 49 percent of families increased their incomes during the program.
- Children in the program changed schools less often than they had previously: The percentage of children attending more than two schools in a year declined from 53 percent at intake to 5 percent at exit.
- Through the initiative, local housing providers, service providers, and property managers have formed more than 30 new partnerships, which will help improve the lives of homeless families over the long term. Tripling the number of service-enriched housing units in the region meant engaging new partners. Using a variety of techniques, from simple recruitment to advance funding commitments, Sound Families secured the participation of many nonprofit housing organizations that had not previously served homeless families, or that had done so only on a small scale.

Sound Families has also spurred systemic improvements in the provision of housing and social services.

- The Sound Families governance model has helped engage regional leaders. The diverse Steering Committee has provided guidance for six years as the initiative has evolved and expanded its focus beyond the original housing-production goals to grapple with how best to help homeless families obtain permanent housing and improve their lives by other measures.
- The adoption of a very ambitious goal—tripling the amount of service-enriched housing for families in the region—required innovation. For example, Sound Families Steering Committee members helped change the state tax-credit allocation rules to allow developers to include homeless units in conventional housing complexes and to prioritize these mixed developments. The housing authorities also helped secure a federal government waiver that allowed the flexible use of Section 8 project-based vouchers, which have been essential to the initiative.

Key Lessons

- **The foundation's resources and credibility can help bring together public agencies and private organizations to focus on critical issues.** By helping to convene the housing and service communities, we not only tapped into existing infrastructure and resources but actually helped strengthen these communities by encouraging collaboration and relationship-building. Sound Families has been a catalyst for better regional planning about housing and services and has initiated broad discussions on how to end family homelessness in our region.
- **Successful families need ongoing housing assistance.** The majority of Sound Families graduates are able to sustain permanent housing, but many could not do so without rental assistance. Although the incomes of working caregivers in the program increased (from \$8.40/hour at intake to \$11.50/hour one year after exit), most don't earn enough to afford an unsubsidized two-bedroom apartment in Seattle-King County.
- **Not all families need the same level of services.** There is no one-size-fits-all solution to family homelessness. For example, some homeless families, particularly those that struggle with substance abuse and mental illness, have been unable to complete the Sound Families program. These families may need more intensive and coordinated services.
- **Memoranda of Understanding (MOUs) help build and sustain collaborations with public partners.** At the launch of Sound Families, the foundation signed key MOUs with local and state government agencies and housing authorities. The goal of the original MOU wasn't so much to assign specific responsibilities as to document the partners' shared commitment. This has been especially helpful in weathering periods of political turnover and ensuring political support.
- **MOUs are also critical at the grantee level.** Many of the Sound Families-funded programs have been dependent on partnerships between the grantee and another organization, such as a service provider or housing owner. With so many partners, it's not always obvious which duties, including additional fundraising, belong to which partner. As Sound Families has progressed, we have found that increasingly specific MOUs help providers work together more effectively.
- **Government policies affect the foundation's initiatives.** Sound Families relies on government resources—most significantly, on federal Section 8 vouchers. Project-based vouchers help our grantees cover their operating costs. Tenant-based vouchers help graduates afford permanent housing. However, fewer and fewer vouchers are available, which makes it more difficult to build new service-enriched housing units and to ensure that graduates will maintain permanent housing.
- **Public-private partnerships can help drive new public-policy priorities and generate new funding.** These partnerships can build momentum behind new ideas and spur greater investment in them. Historically, public and private funders have not been enthusiastic about pooling resources. The Washington Families Fund selected an organization called AIDS Housing of Washington, which has the expertise to do the nitty-gritty work of underwriting and careful

monitoring, to administer the fund. This arrangement has proved very attractive to both public and private funders.

- **Good evaluation data helps us advocate for issues we believe in, because we can demonstrate results.** Without convincing proof that housing-plus-services works, the state legislature would not have taken an interest in the approach and agreed to help form the Washington Families Fund, and 13 different private funders wouldn't have been eager to contribute. With intense competition for limited resources, reliable data is essential to making a convincing case for support.
- **Evaluation helps our grantees provide better service.** Many of our grantees have used the evaluation data to improve their programs. For example, one grantee in rural Pierce County noted in the evaluation data that its graduates were not increasing their incomes enough to become truly self-sufficient. As a result, this grantee refocused its program; it now trains residents to pursue careers with growth potential, such as health care and trucking. It also learned through the evaluation that, given its rural location, transportation was a major obstacle for its residents, and it has addressed the problem by helping them get access to cars.



Next Steps

With Sound Families wrapping up as scheduled and a growing Washington Families Fund supporting service-enriched housing efforts throughout the state, we are continuing to explore solutions to the problem of family homelessness in Washington state.

Despite the success of our investments, families in our state and across the country continue slipping into homelessness, and the trend shows no signs of slowing. We hope to build on Sound Families by learning more about how the needs of families on the brink of homelessness could be met, finding ways to quickly house families that do become homeless, and continuing to strengthen the connection between housing and other kinds of support.

Developing a Safe, Inexpensive Cure for 'Black Fever'

If paromomycin is approved by the Indian drug authorities, it will be the first drug the foundation has played an important role in bringing all the way to regulatory approval.



PHOTO COURTESY OF INSTITUTE FOR ONEWORLD HEALTH.
JONATHAN TOROGOVNIK, PHOTOGRAPHER

Program Area

Global Health

Our Goal

Help the Institute for OneWorld Health (iOWH), a nonprofit pharmaceutical firm, bring an old antibiotic called paromomycin to market for a new use: curing visceral leishmaniasis.

Our Progress in Brief

Thanks to the hard work of our grantee, we are likely to achieve this goal in 2006 (one year later than originally planned). This is a significant milestone for the foundation. If, as expected, paromomycin is approved by the Indian drug authorities, it will be the first drug the foundation has played an important role in bringing all the way to regulatory approval.

The goals for this work have now expanded. Once it became clear that iOWH was likely to succeed in bringing the drug to market, both the foundation and iOWH recognized that for real impact they needed to extend this work beyond regulatory approval to distribution. We are now supporting iOWH's work to ensure that the drug will reach those who need it most—all the way to the village level. We are in the early stages of addressing this new goal.

The Challenge

Visceral leishmaniasis (VL), also known as kala-azar (Hindi for "black fever"), is a deadly parasitic disease that has plagued human beings for at least a thousand years. VL, which is transmitted by the bite of female sand flies, kills as many as 200,000 people every year—more than any parasitic disease other than malaria. The disease is almost always fatal if not treated.

Ninety percent of all VL cases occur in five countries: India, Bangladesh, Brazil, Nepal, and Sudan. About half of all the world's cases occur in one state in India—Bihar, just south of Nepal.

The impact of VL is greatest in poor Bihari villages like Harpur Hardi, where village women work in 110° heat harvesting rice and wheat for about a dollar a day. Here, everyone knows someone who has died of the disease.

Sitting on a straw mat, a weary but self-possessed woman who looks 60 but is probably much younger recently related a story that is all too familiar in her village. Her only daughter took ill at age 10 with an unrelenting fever, lost her appetite, and became very weak. Although the family did not have the benefit of a formal education, they recognized the signs of kala-azar and were terrified. The family did not even have enough rupees for bus fare to the city hospital—much less the money

for a full course of drugs (about \$75–\$100). Without treatment, the daughter soon died.

Doctors currently use a number of drugs to combat VL. But even the least-expensive of these treatments are still too expensive for the poorest of the poor. To make matters worse, several of the drugs are highly toxic, and some have become ineffective as drug-resistant strains of the parasite have emerged. There are a small number of effective drugs with minimal side effects, but they are far beyond the reach of the vast majority of those who are afflicted with VL. For example, the drug liposomal amphotericin B costs more than \$5,000 for a full course of treatment.

Because VL almost always strikes those with the least financial resources, large pharmaceutical companies have had little market incentive to develop new drugs that are safe, effective, and inexpensive. This market problem is by no means unique to VL treatment. Over the past 30 years, 1,556 new drugs were brought to market; only 21 of these drugs target diseases that disproportionately affect the developing world.

The Response

In 2001, Dr. Victoria Hale approached the foundation seeking support for a risky new venture she had started the year before, shortly after leaving the successful biotechnology company Genentech. Dr. Hale's venture, named the Institute for OneWorld Health, was a first in the United States—a nonprofit pharmaceutical firm. Dr. Hale explained that iOWH would focus exclusively on developing new medicines for “diseases of poverty” and would be driven by “global need rather than financial opportunity.”

When Dr. Hale approached us, she had just found her first drug candidate: an antibiotic called paromomycin that she believed could be repurposed as a cure for VL. Equally important, she had found that the government of India was eager to partner with her.

Paromomycin had been patented about 50 years before by an Italian pharmaceutical firm for treating infections unrelated to VL, but the drug had fallen into disuse when new products came to market. Only one small facility in Malta was still producing it and was thinking about closing down production.

In the late 1980s, Kenyan physician Dr. Charles Chungu was able to obtain a modest quantity of the drug and, with the support of the World Health Organization (WHO), tested it as a potential cure for VL. His study found that paromomycin was effective in curing all 53 patients who received it.

Additional small studies in India produced similarly positive results. The WHO reviewed the results of these studies but was not able to secure the funding to follow them up.

That is where Dr. Hale picked up the challenge. In order to bring paromomycin to market for this new use, her firm would have to 1) work with the WHO, the government of India, and private researchers to organize and carry out a large and expensive clinical-trial program and 2) navigate India's challenging regulatory-approval process.

In May 2002, the foundation approved the first of three grants to finance this effort. iOWH then initiated the largest-ever clinical trial for VL with the help of Indian doctors who had been treating this disease for decades.

The clinical trial proved more difficult and time-consuming than we anticipated. As newcomers to the global-health field, the foundation and iOWH both had short track records and were met with hesitation by people on the ground in India as well as by international health organizations. For example, local political figures were not eager to have outsiders shine a spotlight on problems in their communities—even in the context of an offer to help address those problems. More surprising was the fact that an international agency was reluctant to share important data from previous paromomycin trials. (For more on these challenges, see “Key Lessons,” below.)

But when iOWH completed the trial and the results came in, they confirmed iOWH's greatest hopes for the drug: Paromomycin cured 95 percent of the 667 patients in the trial, without causing significant side effects.

Dr. Hale and her team are now working to secure regulatory approval for the drug in India. This month (June 2006), iOWH will hand-deliver a final "dossier" of more than 7,000 pages to the office of the Drug Controller General of India. They hope to receive approval by this fall. If all goes well, they may present a similar dossier to the U.S. Food and Drug Administration (FDA). An endorsement from the FDA would carry weight with health authorities in all the countries where VL exists.

Results

- iOWH's large-scale clinical trial has proved that paromomycin is a safe and effective cure for VL and has significant advantages over the existing treatments. (Its one disadvantage is that it must be injected; there is one treatment that can be administered orally, but it is more expensive and cannot be given to women of childbearing age.)
- With iOWH's help, an Indian pharmaceutical firm has developed a safe and efficient process to produce paromomycin at a price of about \$10 for a full course of treatment, significantly less than any other available treatment.



PHOTO COURTESY OF INSTITUTE FOR ONEWORLD HEALTH, JONATHAN TORGOVNIK, PHOTOGRAPHER

- iOWH's work on paromomycin has proved to us and to others that a nonprofit organization can help correct the "market failure" that results when there are inadequate incentives for private industry to address neglected diseases. Paromomycin would have languished in obscurity if not for iOWH's efforts.
- Even prior to formal approval of the drug, the Indian government, with support from the World Bank, is already looking at ways it can incorporate paromomycin into its countrywide disease-control strategies.

Key Lessons

- **Developing a new drug is important, but it is not a final outcome.** The foundation must not view drug development as an end in itself; it is just one step in a long road toward saving lives. For all of paromomycin's cost and safety advantages, it is conceivable that governments, NGOs, and clinicians will not choose to buy it. (As mentioned earlier, one drawback is the fact that it must be delivered through injections rather than orally.) Like commercial pharmaceutical companies, nonprofits must use every tool at their disposal to understand the market for a new treatment, the attitudes and practices of those who

need treatment, and the smartest ways of building demand. Without these comprehensive efforts, the expense of drug development—and the opportunity to help save thousands of lives—could be lost.

- **We underestimated the funding that would be necessary to bring this product to market.** iOWH has been frugal with its resources and has brought in significant volunteer and in-kind support. But even with careful stewardship, when it comes to neglected diseases, the final stages of drug development are extremely expensive—and not easy to predict with certainty ahead of time. We ask grantees for highly detailed cost projections, but we are learning that we need to allow for uncertainty and flexibility.
- **It is essential for grantees to have a strong, local project manager.** When iOWH initiated its clinical trial, the organization tried to navigate complex local issues from a distance; they didn't have a local project manager with access and credibility on the ground. Fortunately, they were able to rectify this by hiring an outstanding on-site project manager, who worked very effectively with local leaders and scientists. (iOWH is now planning to open two local offices in India, staffed by Indians.) This project taught us that we need to ensure that our grantees have high-caliber local project managers in place at the outset of such efforts—and that we need to be willing to pay for this.
- **The foundation must be willing to step in to mediate disputes (but pick its battles carefully).** At one point, the foundation stepped in to ask an international agency to expedite the release of critical data our grantee needed in order to carry out its trial. That agency felt that we were heavy-handed. We do not take that criticism lightly; we recognize that we need to be very careful if we are to avoid being “a bull in a china shop.” But in this case, we feel that it was an appropriate use of our voice. If a similar scenario presented itself in the future, we would step in sooner.
- **Without our funding, the Institute for OneWorld Health's current funding model would need to change.** iOWH has proven that a nonprofit pharmaceutical firm can develop new medicines for diseases of poverty. However, we must acknowledge that its ability to meet this goal rests heavily on a single source of financial support. The foundation has committed nearly \$180 million to iOWH for a host of different projects, approximately 96 percent of its funding. To ensure that iOWH succeeds over the long term and that other nonprofit organizations join the field, we need to find ways of helping iOWH expand its funding base.
- **Visiting local project sites is essential for the foundation's program officers.** If we had not conducted site visits or had not been granted the ability to speak directly with the local iOWH project manager on a regular basis, we would not have had a full understanding of the nature of the delays in the clinical trial, and we might have pulled back our support prematurely.

Next Steps

In order to help the world combat VL, we need to ensure that paromomycin is put into use as one important component of a broad package of diagnosis, treatment, and prevention efforts targeting every aspect of the disease.

In 2005, we provided significant additional funding to iOWH to launch a pilot program in India that will help identify how to deliver paromomycin in the world's poorest rural settings. As part of this pilot program, some patients will receive paromomycin in government-run district hospitals and clinics. But, in a break from established tradition in India, many others will receive it through nongovernmental organizations, such as the Bihar-based Janani network.

The Janani network was started in 1996 as a set of franchisees selling condoms and oral contraceptives in small shops in Bihar and Jharkhand—two of India's poorest states. Today, thanks in great measure to outside support from the David and Lucille Packard Foundation, Janani franchisees are building more than 40,000 shops and 57,000 rural health centers—nearly one per village. We believe that making VL diagnosis and treatment available through Janani and other nongovernmental clinics will be an effective way to expand access in a setting where public-health services are extremely weak.

We are also working with other grantees to help develop the next generation of VL drugs. Paromomycin is highly effective today, but it is not a silver bullet. There is a small but real chance that the parasite will develop resistance to the drug. Therefore, the wisest public-health strategy is to combine paromomycin with other new drugs—just as doctors do with drugs for malaria, TB, and HIV/AIDS. We have already made one grant, to the University of North Carolina, to work on a new oral drug for VL. A vaccine for VL that would provide a lifetime of immunity would be an even more powerful weapon, and we have made a grant for this purpose to the Infectious Disease Research Institute.



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Web Sites

- Institute for OneWorld Health:
www.oneworldhealth.org
- Government of India:
<http://namp.gov.in/>
- World Health Organization:
www.who.org
- Janani:
<http://www.janani.org/>
- The World Bank Group:
www.worldbank.org

Ensuring the World's Poorest Children Benefit from Lifesaving Vaccines

“Supporting children’s immunization is undoubtedly the best investment we’ve ever made.” — Bill and Melinda Gates



Program Area

Global Health

Our Goal

Prevent needless deaths in the world’s poorest countries by increasing access to basic vaccines and speeding the introduction of new vaccines.

Our Progress in Brief

The Global Alliance for Vaccines and Immunization (GAVI), which the foundation helped to launch in 1999, has made significant progress. Children’s immunization is no longer a neglected area, and immunization rates are once again on the rise after a decade of stagnation. One of the best indicators of immunization coverage is the percentage of the world’s children who receive DTP (diphtheria, tetanus,

pertussis) vaccine. When GAVI was launched, 71 percent of the world’s children were receiving DTP vaccine. By 2004, the rate had increased to 78 percent.

GAVI has concentrated the greatest percentage of its resources on speeding the introduction of newer, more expensive vaccines, including those for hepatitis B, *Haemophilus influenzae* B (Hib), and yellow fever. The vaccine for hepatitis B, for example, had been widely used in rich countries for 20 years but was severely underutilized in the developing world because of a lack of political will and the vaccine’s relatively high cost. Today, 90 million children in the developing world have received the vaccine because of the alliance’s efforts. The progress on Hib and yellow fever has been slower—an additional 14 million children have received Hib and yellow fever vaccines.

The Challenge

Most people in rich nations do not realize how difficult it is simply to survive early childhood in many parts of the world. Every year, more than 10 million children are buried before they reach their fifth birthday. Of these, about 1.4 million die from diseases that existing vaccines can prevent—including measles, pertussis, and tetanus. Another 1.1 million die from diseases for which we will soon have vaccines. Because childhood death is so frequent, parents in some countries in Africa and Asia don’t even name their babies until they reach several months of age.

A Father’s Grief

Neonosa Muhani is a manioc farmer and community leader in the southern African nation of Mozambique, one of the most beautiful countries on Earth. He lives in a thatched-roof, mud-walled house in the rural village of Metoro, near the country’s border with Tanzania.

Three years ago, health workers affiliated with the innovative nonprofit VillageReach brought polio, BCG, measles, and DTP vaccines to Metoro for the first time.

But that was too late for two of Mr. Muhani's children. In 2000, his 2-year-old son, Maulana, took ill with fever, skin eruptions, red eyes, and diarrhea. Within weeks, he was dead from measles. Two years later, another measles outbreak swept the village and took with it Neonosa's 4-year-old daughter, Marina. Neonosa's grief and suffering are incalculable. The price of the vaccine that could have saved his children is not: The measles vaccine costs pennies a dose. It has been in existence since 1963.

Vaccine Progress Stalls

In the 1970s and 1980s, the world made dramatic progress in expanding access to basic vaccines, thanks in great measure to the leadership of the World Health Organization and UNICEF. Sadly, the progress ground to a halt in the 1990s.

Child immunization had dropped on the priority list of the world's major donors, and developing countries were left struggling to maintain access for their children. HIV/AIDS was beginning to devastate the world's poorest countries and absorb a large share of health-care dollars. Bureaucratic struggles between international agencies had set in. Wars, civil unrest, and famine in poor countries took their toll on vaccination campaigns. Pharmaceutical companies did not have consistent market incentives that would enable them

to invest more heavily in supplying vaccines to the developing world.

These problems undermined efforts even to provide established, basic vaccines to the world's children. Newer, more expensive, vaccines routinely given to infants in the rich world—such as those for *Haemophilus influenzae* B (Hib) and hepatitis B—were reaching almost no children in the poorest countries.

The Response

In November 1998, shortly after making their first large financial commitment to children's vaccines, Bill and Melinda Gates hosted a dinner at their home for a dozen leading scientists. Around a single table, they spent two-and-a-half hours discussing immunology and what could be done to overcome the barriers that were preventing nearly 30 million children from receiving basic vaccines every year. Bill and Melinda challenged their guests to come back with proposals for "breakthrough solutions." As the dinner was winding down, Bill said, "Don't be afraid to think big."

A Timely Hint

By all accounts, Bill and Melinda's challenge came at the right moment. It gave pharmaceutical companies, health ministers, international agencies, and nongovernmental organizations (NGOs) new incentive to restart failed discussions on how these entities could join together in an international alliance to strengthen the system for getting vaccines to where they are needed most.

In July 1999, key players from all these sectors came together for two days at the Port of Seattle and left with a blueprint for the Global Alliance for Vaccines and Immunization (GAVI) and the seeds of an idea for a sister entity that would raise money to support GAVI's work (now known as the GAVI Fund). The goal was to radically improve access to established and underused vaccines and to accelerate the development and introduction of new ones.

One Excuse Gone

By the end of the year, the foundation pledged \$750 million over five years to fund these efforts. In the words of the GAVI Fund's president, "Lack of money could no longer be the excuse for not getting children vaccinated."

The blueprint for GAVI called not for a large new international bureaucracy but rather for a lean secretariat housed within UNICEF's offices in Geneva, administered by widely respected Norwegian immunologist Tore Godal, and governed by a 12-member board. These 12 members represented all the major partners in the alliance, including developing-world governments, the World Health Organization, UNICEF, the World Bank, pharmaceutical companies, NGOs, research institutes, and the Bill & Melinda Gates Foundation. The strategy was to create an inclusive decision-making body to bring new coordination to a disjointed, inefficient marketplace.

How GAVI Works

GAVI invites the 75 poorest countries in the world to develop plans and submit proposals for increasing vaccine coverage and use of newer vaccines. An independent committee made up largely of developing-country public health experts then reviews and makes recommendations on the proposals. GAVI's board then meets to review the recommendations. Once the board approves a proposal, it requests that the GAVI Fund release payment.

To increase the efficiency of the market, GAVI looks across all the approved plans to forecast how many doses of each vaccine will be required overall. This demand-forecasting helps guarantee an adequate supply of vaccines. We hope that over the long term it will also reduce unit prices.

Two Shots in the Arm

In January 2005, the foundation announced a second \$750 million grant to support GAVI's work. This time, the grant will spread out over 10 years, rather than five. In the alliance's first five years, the foundation's funding accounted for half of GAVI's resources. In its next 10 years, we hope our funding will account for less than 20 percent.

One promising approach to bringing in new and more-predictable funding for immunization through GAVI is the International Finance Facility for Immunization (IFFIm), an idea developed by economists and health



experts and championed by Gordon Brown, chancellor of the British treasury. The IFFIm will collect pledges from donor governments, turn these pledges into bonds, sell the bonds in capital markets (just like a standard corporate or government bond), and use the proceeds to provide a large infusion of money for immunization. IFFIm has already collected \$3.5 billion in pledges from eight middle- and high-income countries, including greatly expanded commitments from two countries (the United Kingdom and France) that have already supported GAVI and four countries that have not contributed to GAVI previously.

Results

- The GAVI Alliance estimates that its work has helped prevent approximately 1.7 million deaths and that it is poised to help prevent well over 5 million deaths during the next 10 years.
- More than 115 million additional children have been reached with new vaccines, including those for hepatitis B, Hib, and yellow fever.
- 15 million additional children have been reached with basic vaccines.
- Since 2000, the funding for immunization in the countries that GAVI focuses on has more than doubled—from \$1.1 billion to \$2.5 billion a year.

Key Lessons

- Sometimes you have to be the first dollar in.** When the foundation made its \$750 million contribution to the GAVI Fund in 1999, we were its only funder, and we did not require that the grantee match our commitment (as we often do today). It was a risky bet—and other contributions to GAVI were initially slow to come in. It is now clear, however, that the foundation's early contribution worked to jumpstart worldwide progress on immunization, which proved to be an effective way of bringing other donors to the table.
- "Five years only" does not work.** One of the key assumptions underlying the business model for GAVI was that the alliance would help a country introduce a new vaccine such as Hib by providing it for free for five years—during which time the price would come down—and then the country and donor governments would be willing and able to step in to sustain the program. GAVI planned to continue to support the immunization needs of each country, but it would refocus its resources to support the introduction of another needed vaccine on the country's priority list. This approach has not worked as planned. Vaccine prices did not decline as anticipated, and in some cases actually went up. Although many countries increased their spending on immunization, they were unable to increase their funding to meet the higher cost of the new and improved immunization program. And some traditional donors that we hoped would lend support have redirected vaccine funds to other pressing health needs. As a result, GAVI has recently launched a new model we hope will work better. Rather than providing free vaccines, GAVI is now requiring countries to "co-pay" from the start—that is, to assume a small percentage of the cost of the program right away, with the percentage increasing every year.
- GAVI did not pay enough attention to developing-country priorities.** Driven in large part by the foundation's eagerness (even impatience) for results, GAVI often moved at a pace that made it impossible to get full buy-in from developing countries. For example, in the early years of the alliance, GAVI convinced some countries to introduce a \$3.50-a-dose vaccine that was available right away and protected children against five different diseases. Some countries preferred a vaccine that was not immediately available and protected against only four of these diseases but cost only \$1.25 a dose. Now that the five-year introductory period is up, some of these countries are reluctant to pick up the costs of the \$3.50 vaccine. They rightly say, "It wasn't our idea in the first place."
- Funding operating expenses is essential.** The foundation was initially reluctant to allow GAVI to use a significant amount of our funding to support grantee operating expenses—as opposed to purchasing vaccines. But we've learned that funding operating expenses is vital for getting new entities up and running, for attracting donors that have greater funding restraints, and for giving grantees the ability to innovate. For example, our operating support enabled GAVI to work with legal and financial experts to develop the initial conceptual framework for the IFFIm and make it a reality. IFFIm would not have been born without this support.
- GAVI was too narrowly focused.** From the start, GAVI has recognized that funding vaccine purchases alone would not allow the 75 poorest countries in the world to overcome their infrastructure challenges, so it has provided "immunization system support" to help countries improve their ability to deliver vaccines to a large portion of their children. GAVI has learned that in many cases the ability of the country to reach more children is not related simply to its immunization program. Broader health-system failures are often to blame. So GAVI has now expanded its funding criteria and set aside about half of its resources to help meet broader health-system needs. Under the new criteria, for example, countries can now apply for support for improving the frequency of supervisory visits to remote health clinics or for reforming the system for repairing and maintaining the vehicles used for delivering vaccines and other health supplies to rural areas.

- **Creating an alliance of existing entities was a better strategy than building a new entity.** Global partnerships such as GAVI often run the risk of being slow and bureaucratic, and initially we considered funding a new, independent organization rather than an alliance of existing organizations. But as the old African proverb says, “If you want to go fast, go alone. If you want to go far, go together.” Each of GAVI’s partners has a unique role, and brings essential relationships and insights to the table. For example, WHO and UNICEF have been working on the ground for decades in the world’s poorest countries and have trusted relationships with health ministers in places where no one has ever heard of GAVI.



Next Steps

The foundation is very proud of GAVI’s progress to date. Bill and Melinda Gates have said, “Supporting children’s immunization is undoubtedly the best investment we’ve ever made.” But we recognize that there are a number of ways, in addition to the ones mentioned above, that the alliance can grow stronger and achieve even greater results over the next 10 years.

We will work closely with GAVI to learn how best we can help speed up the introduction of new vaccines under development. Over the next five years, it is likely that there will be a number of new vaccines appropriate for use in the poorest countries of the world, such as those for rotavirus, pneumococcal disease, meningitis, and Japanese

encephalitis. GAVI is taking innovative steps to cut the amount of time it takes to ensure that the world’s poorest citizens benefit from these vaccines as well.

We will also use our advocacy voice to help GAVI raise awareness of the large funding gap that remains. Immunization programs will need an additional infusion of \$11 billion to \$15 billion for vaccines over the next 10 years. If the international community and developing country governments are able to raise this additional funding, they will be able to save 10 million lives.

Web Sites

- GAVI Alliance:
www.gavialliance.org
- World Health Organization:
www.who.org
- UNICEF:
www.unicef.org
- The World Bank Group:
www.worldbank.org

Supporting Development of a Vaccine for Malaria, the Deadliest Disease Among Africa's Children

Results of the RTS,S trial have reinvigorated the field of malaria research and development and helped demonstrate that an effective malaria vaccine is indeed possible.



PHOTO COURTESY OF PATH. RICHARD LORD, PHOTOGRAPHER

Program Area

Global Health

Our Goal

Help the Malaria Vaccine Initiative (MVI) move promising malaria vaccine candidates through the development process and make effective vaccines accessible to people in developing countries.

Our Progress in Brief

MVI currently supports the development of 15 malaria vaccine candidates. The candidate that is furthest along, RTS,S, which was developed by GlaxoSmithKline Biologicals (GSK), showed encouraging results in a recent trial in young children in Mozambique.

We made a grant to MVI in 2005 to support RTS,S's continued development as a vaccine for those most affected by the disease: infants and young children in malaria-endemic countries. If RTS,S continues to meet its milestones, GSK will apply for a license for it to be used among children in Africa, and the vaccine could be incorporated into national immunization programs soon thereafter. RTS,S would be the first human vaccine for a parasitic disease.

However, malaria is an extraordinarily complicated disease, and a single promising trial doesn't guarantee that RTS,S will ultimately prove effective. Moreover, the vaccine confers only partial protection against the disease. MVI continues to manage multiple research-and-development projects in addition to RTS,S in the expectation that scientists can improve it or develop a better vaccine.

The Challenge

When Dr. Johan Strömberg Nörklit, a Swedish physician, first arrived on the island of Zanzibar off the coast of Tanzania in 2000, he was confronted by women who pleaded to be sterilized. He first assumed it was because they lacked access to birth control and wanted to avoid having more children. But when he asked why, their replies shocked him—they said they couldn't bear to lose more children to malaria.

In Mozambique, one in five children dies by the age of 5. A great many of these children die from malaria, the disease that kills the most African children. About 2,000 African children die from malaria every day.

At the Centro de Investigação em Saude de Manhica (CISM) in southern Mozambique, where scientists conducted the RTS,S trial, the tragedy of these deaths and the hope that they might be prevented give the work an extraordinary sense of urgency.

Everyone who works at CISM knows dozens of families that have been torn apart by malaria. “Those children in the hospital are looking at us, telling us to put more effort, more resources, more brains, more research, to come out with solutions,” the center’s director, Pedro Alonso, has said. “They are a constant reminder of all that needs to be done.”

A Growing Problem

In recent decades, drug-resistant strains of malaria emerged, killing more people and further complicating efforts to control and prevent the disease. At the same time, research on malaria vaccines continued to proceed slowly, rarely advancing beyond the laboratory and into product development.

The commercial market for a vaccine in rich countries is very small—it would consist primarily of the military and travelers willing to take the time and expense to get immunized—so pharmaceutical companies didn’t have a market incentive to concentrate resources on developing one. To make matters worse, the scientific challenges of coming up with a vaccine for such a biologically complex parasitic disease are immense.

A vaccine isn’t the only way to fight malaria. People can give themselves some protection from the mosquitoes that transmit the disease by sleeping under insecticide-treated bed nets and spraying their homes with insecticides. Drugs can save people who contract malaria. But even a partially effective

vaccine would be a major advance in the fight against a disease that infects between 350 million and 500 million people every year. The ultimate goal, of course, is a highly effective vaccine that would end malaria as a public health problem.

The Response

In 1999, a group of malaria vaccine experts submitted a white paper to the foundation arguing that preventing malaria must be a “global priority” and proposing an “independent organization in control of adequate resources, with a sole mandate to develop, test and field promising malaria vaccines.” Later that year, we made a \$50 million grant to the Seattle-based organization Program for Appropriate Technology in Health (PATH) to create MVI. We have since made two additional grants to MVI for a total commitment of \$257.6 million.

MVI’s mission is to accelerate the development of promising malaria vaccines and to ensure that these vaccines are accessible to the people in developing countries who need them. To fulfill this two-part mission, MVI takes a two-pronged approach. First, it provides resources to help candidates move out of the laboratory to development and to clinical trials. Second, it conducts research and builds relationships with key health organizations and governments in developing countries to help make sure that vaccines will be introduced and distributed.

A Promising Candidate

The most advanced candidate that MVI has supported, known as RTS,S, was originally developed by GSK in the 1980s as a vaccine for travelers. The vaccine showed convincing protection in trials involving adult volunteers in the United States.

Subsequently, in a larger trial involving semi-immune adult men in the Gambia in 1998, it proved partially effective: It protected about 70 percent of the trial participants from infection, but only very briefly; the protection waned after just two months. Since travelers are less interested in a malaria vaccine that isn’t completely effective, it was obvious that the market for RTS,S would be limited to Africa, where the impact of the disease is greatest.

However, there was enough data to suggest that RTS,S might provide more effective protection in immune-naïve children—those whose immune systems are not already primed to fight infection—in malaria-endemic regions. That’s why, in 2001, MVI and GSK formed a partnership to develop the vaccine for children in developing countries.

The Need for Partnerships

Developing a vaccine for any disease is risky and expensive, and drug companies like GSK are accountable to their shareholders. Funding from MVI can decrease the risk for vaccine developers. However, MVI must also ensure that these investments result in vaccines that are affordable in the developing world. Developing-country governments can't commit to buying vaccines they can't pay for.

These goals aren't easy to reconcile, which is why partnerships between the pharmaceutical industry and the public sector have been rare. And yet partnerships are absolutely essential to vaccine development for neglected diseases. The public sector can help drive research and conduct clinical trials, while the capability to develop and manufacture vaccines on a large scale rests almost exclusively with industry.

In 2003, MVI, GSK, and other partners launched a trial to assess RTS,S's effectiveness. More than 2,000 children between the ages of 1 and 4 received three doses of RTS,S, and the six-month results were very encouraging. The group of children that received RTS,S showed a significant reduction (30 percent) in malaria cases compared with a control group, and the number of severe cases declined 58 percent. In a follow-up study at 18 months, the results were similar: Clinical cases were reduced by 35 percent, and severe cases were reduced by 49 percent.



In October 2005, on the heels of these positive results, we made a \$107.6 million grant to MVI to help it and its partners bring RTS,S through a series of additional trials and eventually to licensure, should it continue to meet its milestones.

Results

- RTS,S is the most promising malaria vaccine candidate to date. Results of the RTS,S trial have reinvigorated the field of malaria research and development and helped demonstrate that an effective malaria vaccine is indeed possible.

- MVI manages 14 projects in addition to RTS,S. It is critical to work on multiple vaccine candidates, no matter how promising the data on RTS,S. The vaccine could fail in subsequent trials, or there may be another vaccine that would prevent more disease. It is particularly important to manage a stream of activities because the most effective vaccine may involve a combination of candidates or even another scientific or technical approach.

Key Lessons

- **The vaccine development process is complicated and more expensive than we anticipated.** Nobody thought it would be cheap or easy, but the complexity of developing RTS,S has been instructive. The broader partnership involved in the effort includes about 10 African research centers that will run trials, as well as GSK, MVI, the foundation, and many experts in the field. A whole program of trials in Africa will be necessary to generate data to support the licensure of a new vaccine.

These trials will assess the vaccine's efficacy for children younger than 1 and will also evaluate whether RTS,S can be administered alongside the standard infant vaccines.

Moreover, malaria follows diverse epidemiological patterns. In some regions, transmission of the disease is intense and seasonal; in others, it is low-level and chronic. Some areas are hyperendemic, which means transmission continues at a high rate throughout the year. We need to see how the vaccine works across a broad range of environments.

And these are only the scientific challenges. To help countries adopt the vaccine, trials also have to take a variety of cultural, political, and social factors into account.

- **There is an urgent need to improve the process for licensing products that benefit only developing countries.** It is unclear which organizations could provide the necessary regulatory oversight for RTS,S. The FDA does not have a mandate to regulate products that will not be used in the United States or by the U.S. population. (It often does so for drugs, since they may be available to travelers who live in the United States. Vaccines, however, are different because they're intended for use in healthy children.)

Since MVI and its partners are working toward a vaccine that would benefit children in the developing world, it wouldn't necessarily fall within the FDA's purview. It is possible that a vaccine would be approved through a mechanism established between the World Health Organization and the European equivalent of the FDA (EMA).

And even after a malaria vaccine is approved, the challenge will be to get it licensed by individual countries' regulatory authorities. Most national drug-regulatory authorities in the developing world simply aren't equipped to evaluate and approve the use of a novel vaccine. Moreover, the decisions made by one national regulatory agency will not necessarily be acceptable to another, so the imprimatur of one nation won't automatically spur widespread licensure.

The hurdles malaria vaccines encounter will not be unique. Approval of novel products created solely for the developing world—and not for dual use in both rich and poor countries—will be a major challenge for the entire global-health community. The foundation, MVI, and its partners are talking to the FDA about options for the future.

- **We can't guarantee a vaccine will be used.** MVI has put a lot of time and effort into engaging developing-country governments and international health organizations to determine whether countries will adopt a malaria vaccine—especially if it is only partially effective.

But nothing will be certain until an actual vaccine is available. The foundation, as well as MVI and its partners, must consider how a potential vaccine would fit into national strategies to fight malaria, given that countries have a range of options to prevent and control the disease. These considerations must be reevaluated continually as new information becomes available.

- **It is very difficult to get pricing, supply, and other aspects of an access strategy right.** Many factors go into determining what the price of a vaccine should be, including supply and demand and the real cost of the product. These are hard to predict, however. Demand forecasts, for example, are often unreliable.

While all the partners are committed to the principle of an accessible and affordable vaccine, it isn't always clear where to set a price that is reasonable for both the manufacturer and developing countries. In short, to make partnerships work, the partners must occasionally negotiate on the basis of imperfect projections and without the benefit of hard data.

- **Effective collaboration between academic researchers and industry is critical.** In the past, public-sector scientists made important advances but often lacked the resources to develop products from them.

MVI's product-development-oriented approach has helped researchers focus their attention on developing candidates that would meet strict regulatory and ethical standards. For example, products are now being developed in compliance with the FDA's Good Manufacturing Practices, and in recent years clinical trials have been increasingly well-designed.

MVI will continue to try to bridge the gap between these two key parties to the vaccine-development process.



What's Next

Although the RTS,S trial results were unprecedented, it was only one trial in one region of Africa. Subsequent RTS,S trials will take at least five years to complete, and the candidate will have to meet many milestones over those years.

While clinical development of the vaccine continues, MVI and GSK will continue to work together to ensure that, if the vaccine is successful, an adequate supply will be available for countries to deploy as soon as possible. To this end, GSK is developing a manufacturing facility that will be capable of supplying the RTS,S vaccine to meet the global need.

We will continue to evaluate MVI's other projects and consider what else should be done to manage the risk of failure, including, for example, alternative approaches and technologies and research to find ways to harness the immune response.

Enlisting States in Preparing All Students for College and Careers

Without deep engagement by the public sector, the foundation's efforts will do little to bring about wholesale change.



Program Area

U. S. Programs: Education

Our Goal

Build momentum at the state level for dramatically increasing the number of students who graduate from high school ready for success in college and careers.

Our Progress in Brief

In February 2005, a three-year process of grantmaking and relationship-building by the foundation culminated in the first National Summit on High Schools, which was attended by 45 of America's 50 governors. Although the impact of any single event is hard to gauge, this summit could prove to be a turning point in a growing national campaign to redesign high schools. In the wake of the summit, more than half the nation's governors committed to reforming their states' policies to help raise graduation rates and improve students' preparation for college and careers.

The Challenge

The story of the American high school is a tale of an institution that has not kept pace with a changing world. Today's employers need workers who can break down complex problems, use math as an analytical tool, and communicate effectively. Yet only one-third of all students entering high school this year will graduate with a high-quality education that provides these kinds of skills. Another third will graduate unprepared for college or careers. One third will drop out entirely.

The first group will have what it takes to succeed in a global economy. The second two groups, which consist mostly of low-income and minority students, will struggle simply to make a wage that can support a family.

Millions Left Behind

Cesar Gomez, a 17-year-old from Los Angeles, is typical of the millions of students who are falling through the cracks every year. Neither his mother, who works in a garment factory, nor his stepfather, who works for a meat-packing company, finished high school. Cesar wanted to be the first. But almost as soon as he entered high school, his troubles began. Nearly 5,000 students crowded the halls, and many of the kids were older, bigger, and intimidating. Classes were dull. Cesar began ditching school with friends and doing graffiti. A counselor told him he was good for nothing and would end up in jail.

To get back on track, Cesar switched schools—and lost a year of credits in the process. The new school was no better. He remembers some teachers just sat in the front of their classes and told students to open their books and read. He dropped out in his junior year.

Redesigning for Today's Demands

Cesar was one of the 1 million students who drop out every year. One of the main reasons so many students leave school is that our high schools were designed 50 years ago to meet the needs of another age. Even when they are working exactly as designed, most high schools do not teach students what they need to know in today's global economy.

Many countries around the world have reinvented their education systems to become more competitive, while the United States has held steady. The U.S. once led the world in high school and college graduates. Today, eight other nations have a greater percentage of young adults who have graduated from high school, and we have dropped from first to fifth in the percentage of young adults with a college degree.

Over the past five years, the foundation has invested more than \$1 billion to help redesign the American high school for the demands of the 21st century. We are supporting more than 1,800 high schools—about half are totally new, and the other half are existing schools that are being redesigned. The common denominator among these schools is that they are built on what we call “the new three Rs”—a rigorous curriculum for all students, relevant classes, and meaningful relationships with adults who push all students to achieve.

The Need for Champions

But we recognize that our grants alone cannot possibly solve this enormous national challenge. The schools we support represent less than 10 percent of America's public high schools.

Without deep engagement by the public sector, the foundation's efforts will do little to bring about wholesale change.

Elected officials, especially at the state and local levels, have the power to build on what is working and to bring these new models to the students and families they represent. But first they will have to face up to the failure of America's high schools. They need to dispense with the idea underlying the old design—that we can train an adequate workforce by sending only a third of our students to college, and that the other students either can't do college work or don't need to. They need to recognize that every student can graduate ready for college and careers—and that the nation will lose its competitive edge if we don't give them the chance to do so.

The Response

“America's high schools are obsolete.” This is the statement that made headlines when Bill Gates spoke to the nation's governors at their National Education Summit in February 2005. But Bill's assessment of the crisis in America's high schools was even tougher than that one line conveys.

He told the governors, “When I compare our high schools to what I see when I'm traveling abroad, I am terrified for our workforce of tomorrow.” He said that elected leaders “should be ashamed [of] breaking our promise of a free education for millions of students.” This passionate declaration was the culmination of three years of effort to bring national attention to the plight of America's high schools and students.

Gaining Appreciation for Advocacy

In the foundation's early years, we assumed that our grants, some of which were among the biggest in their respective fields, would produce large, lasting impact. But we soon came up against the limitations of grantmaking and understood that without the engagement of the public and commercial sectors, our grants would always be just a drop in the bucket. The investment we'll make in U.S. education in the years ahead is less than one-quarter of 1 percent of the \$536 billion this nation spends on K-12 education every year.

In 2001, the foundation established a small office in Washington, D.C., and began to explore how to build new partnerships with governments and industry. One of our first goals was to use advocacy to put high schools on the radar for policymakers and to share the lessons—positive and negative—that we had learned in our own grantmaking.

Partnering With Governors

We soon realized that two organizations could help us reach the top decision-makers in all 50 states: the National Governors Association; and Achieve, a nonprofit started in the mid-1990s by governors and business leaders concerned about the state of American education. In 2002, we began providing funding to both these organizations in order to help their staffs develop deeper expertise in issues related to high schools.

Until that time, governors and other key decisionmakers had done a great deal to strengthen schooling between kindergarten and eighth grade, but they had not focused much attention on the high school years. We felt we could interest them in high schools if we could convince them that only a fraction of their students were graduating ready to join the workforce or attend college. Many of the governors simply did not know the extent of the problem. As we learned by sponsoring in-depth research on graduation rates by the right-of-center Manhattan Institute and the left-of-center Urban Institute, states were using a hodgepodge of inadequate measures to determine graduation rates. Some schools were reporting graduation rates of 95 percent even if they had a thousand people in ninth grade and only 250 people graduating in 12th grade.

A Summit Is Born

When Virginia governor Mark Warner was elected to chair the National Governors Association in 2004, we found the champion we were looking for. Governor Warner, who was a product of public schools and the first person in his family to graduate from college, had shown his interest in high school policy by pushing for reforms in Virginia focused on the 12th grade. He also was taking steps to explore a possible run for president in 2008.



Former Governor Mark Warner (D-VA) addresses the 2005 National Education Summit on High Schools.

With encouragement and financial support from the foundation, Governor Warner and Achieve President Mike Cohen set out to host a combined summit on high schools in early 2005 for the nation's governors and top business leaders. When they invited Bill Gates to speak, we saw it as an ideal opportunity for Bill to use his credibility as a leader in the knowledge economy and as a philanthropist to bring attention to the crisis in high schools.

The summit and Bill's speech generated far more attention to this crisis than we had expected. There were about 100 business leaders and governors in the room during Bill's speech. But his diagnosis of the problems—and his thoughts on promising approaches to solving them—reverberated far beyond the room. More than 27 million people saw an account of the speech in

newspaper reports, editorials, or television broadcasts.

Carrots for Commitments

To ensure that the summit would be more than just a collection of good sound bites, the foundation, the NGA, and Achieve used the occasion to launch a competitive grant program to encourage governors to make concrete commitments to change their states' education systems. To qualify for the grants, states would have to commit to five "non-negotiables," such as using one of a handful of highly rigorous methods of tracking graduation rates. We hoped to get applications from about six states for these NGA Honor States grants. Instead, 40 states applied, and 26 of them are now being funded (10 by the Gates Foundation and 16 by a consortium of seven other foundations).

In addition, 13 states representing a third of America's students announced that they would partner with Achieve and its American Diploma Project to raise their high school graduation requirements so that all high school graduates would have the skills necessary to be successful in college and work. Within a week, nine additional states made the same commitment. With funding from the foundation, Achieve is now providing hands-on assistance to help all 22 of these states make their pledge a reality. Prior to the summit, Achieve had predicted that only four states would participate.

Results

- Following the 2005 National Education Summit on High Schools, all 50 governors committed to adopting a common standard for calculating graduation rates. The new standard will create much greater transparency and accuracy in the reporting of graduation and drop-out rates.
- Prior to the summit, only five states had high school standards that ensured students would learn the skills necessary to be successful in college and work. Since the summit, 30 additional states are taking action to align their learning standards with the expectations of colleges and employers.
- At the time of the summit, only six states had high school tests in place that indicated whether students were ready for college-level work. In the past year, eight additional states have committed to adopting these assessments.

- Currently, only three states have data systems that can track individual students' progress from high school through college. Following the summit, 31 states are now in the process of creating this capacity. These systems provide critical information that states need in order to increase the number of students who graduate ready for college and careers.

Key Lessons

- **Policy change doesn't work according to strict schedules.** All the states we are working with have shown that they intend to adopt policies that will improve high school graduation rates, but many factors can make it hard to implement a plan of action. For example, some states' education agencies have limited staff capacity to take on new efforts. In other states, political will for these efforts has wavered as other pressing issues have commanded attention.
- **The foundation and its partners still have a long way to go to get legislators and boards of education engaged.** No single organization like NGA can possibly drive important changes in every state. Successful reform requires many different groups—governors, legislators, boards of education, chief state school officers, and others—to work closely on both the design and implementation of the reforms.
- **It has proved valuable to foster a network of states all working on the same reforms.** States participating in the NGA and Achieve projects get credibility from being part of a broad national movement. Having a critical mass of states that are making progress on tough issues also helps keep the pressure on the rest to act. And one of the most important sources of help for states is other states working on the same agenda. Leaders benefit greatly from learning about how other states designed policies, built political support, and planned for implementation.
- **States need more help than we anticipated.** Achieve and the NGA are providing significant technical support to the leadership teams that are implementing the action plans that emerged from the summit, but we all underestimated the number of states that would seek support. We also underestimated the depth of support individual states would need. They have needed not only help with identifying policy priorities but also technical guidance in developing their reforms, such as creating better assessments, determining how to best intervene in low-performing high schools, and communicating with citizens about what will be hard changes in their states. Both the NGA and Achieve are now working hard to add new staff and to identify better ways to help states prioritize.

- Our grants to Achieve and the NGA, involving dozens of states, have been hard for us to manage internally. Given the unexpectedly high demand from states, these grants have proven to be more complex and time-intensive to manage than we had expected. With limited staff to handle these grants, we have been stretched too thin to ensure that the sometimes difficult lessons states are learning are fed into our school- and district-level efforts.
- We must learn from mistakes and leave room for course correction. Our outside evaluations provide ample evidence that the work of high school redesign is very complex and that we have a lot to learn. They have shown that we have been less successful at redesigning old schools than in creating new ones. Classes—math classes in particular—in some of the schools we've funded have been less rigorous than those at comparison schools. And the evaluations have taught us that curriculum development is difficult and technical work—and that it is often best done across a network of schools, a district, or a state (rather than by individual schools alone).



Governors Bob Riley (R-AL), center, and Frank Murkowski (R-AK) greet Bill Gates during a break at the 2005 National Education Summit on High Schools.

Next Steps

Twenty-seven states have now made significant commitments to high school reform. However, there are no guarantees that all of them will implement their reforms successfully. It is incumbent upon the foundation to make sure that the NGA and Achieve apply the right level of pressure and support to keep the states on track.

Even if all these states prove to be successful, there will still be many others where these reforms are needed. We hope that a grassroots campaign known as Stand Up, launched in April 2006, will help build momentum by mobilizing millions of students and parents to demand high standards and quality high schools for all.

Five years from now we hope to look back at 2005 as the end of 20 years of stagnant graduation rates. We know that improvement won't be fast, but we hope that the National Summit on High Schools touched off an important trend.

Web Sites:

National Governors Association:
www.nga.org

Achieve:
www.achieve.org

Stand Up:
www.standup.org