

CREATING THE TOOLS OF TOMORROW: INVESTING IN GLOBAL HEALTH R&D



Bill & Melinda Gates Foundation.

NEW TOOLS URGENTLY NEEDED

The progress we are making in global health was unthinkable a generation ago. In the coming years, we have an unprecedented opportunity to do more. New global health technologies can play a major role.

Despite the many medical advances made over the past half century, an estimated 15 million people still die every year from infectious diseases, maternal, infant and child health issues, and nutritional deficiencies.ⁱ To put this number in perspective, it would mean losing almost the entire population of the city of Shanghai, China, in a given year. Roughly half of those who die each year – 7.4 million – are children under the age of five.ⁱⁱ

The global health community is working to develop and deliver new and innovative tools to fight these diseases. But increased funding for global health innovation will be fundamental to developing new health tools and delivering them to people in need worldwide.

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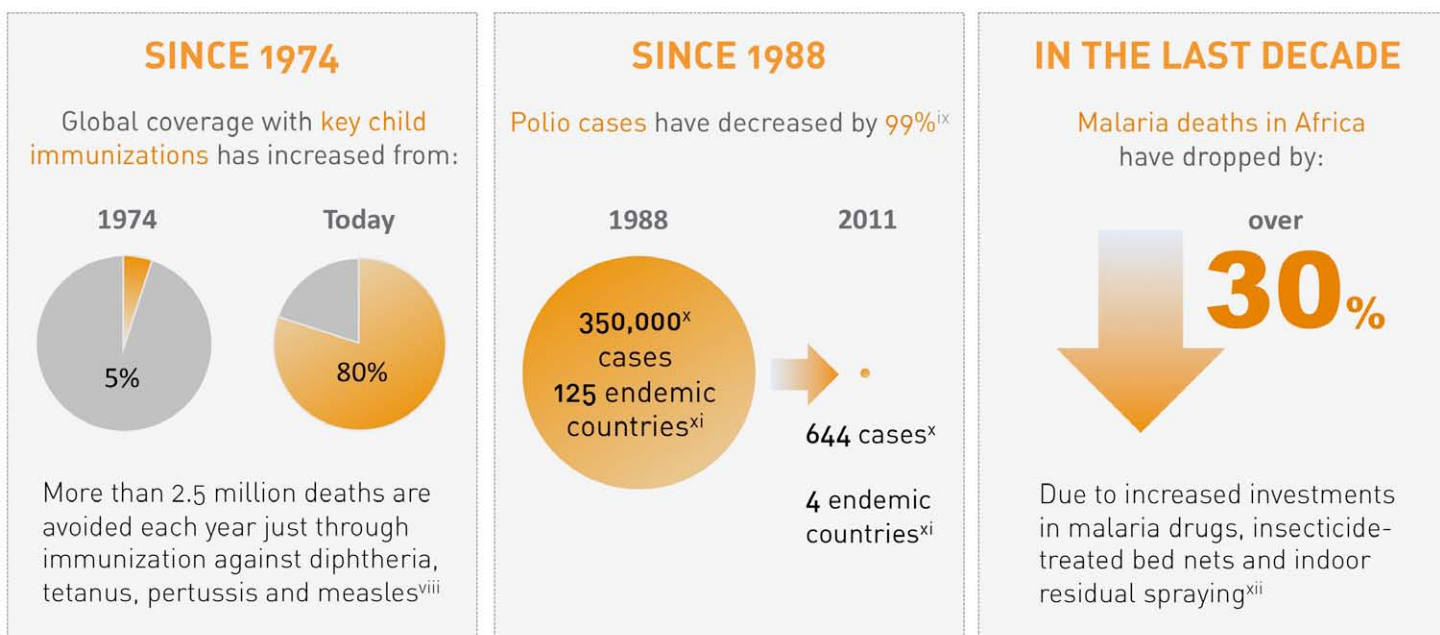
INNOVATIONS IN GLOBAL HEALTH RESEARCH

The world has seen substantial progress in reducing death and illness globally. In 1960, 20 million children under the age of five died annually. Fifty years later, in 2010, fewer than 8 million children under five died.ⁱⁱⁱ In the last decade, deaths caused by malaria in Africa have declined by more than 30 percent.^{iv}

New tools against diseases like smallpox, cholera, HIV/AIDS, malaria and sleeping sickness have played an important role in bringing down mortality and morbidity. In modern history, such technologies have proven their ability to cure and even eradicate diseases.

Polio paralyzed or killed as many as 500,000 people per year at its peak. In the years since the widespread introduction of a safe and effective polio vaccine, the number of reported cases has dropped over 99 percent, with fewer than 700 cases reported globally in 2011.^{v, vi}

This dramatic improvement would not have been possible without investments in the science and technology that led to the advancement of an effective vaccine that was inexpensive, easy to administer and readily accessible to the world's poorest populations.



IN MODERN HISTORY, NEW TECHNOLOGIES HAVE PROVEN THEIR ABILITY TO CURE AND EVEN ERADICATE DISEASES.



A house-to-house polio vaccination team member gives a child polio vaccine drops in a home in the slum of Kamla Nehru Nagar. Bill & Melinda Gates Foundation.

PARTNERSHIPS THAT DELIVER

Global health research and development (R&D) partnerships work with industry, communities most affected, and academic research and policy experts to accelerate the development of drugs, diagnostics and vaccines for diseases that disproportionately affect developing countries. A Product Development Partnership or PDP is one type of partnership. By pooling scientific, technical, clinical development and policy experience to manage and advance promising technologies, PDPs and other partnerships have had numerous successes, clearly showing that the R&D partnership models work.

During the last decade, these partnerships have developed new technologies to combat malaria, tuberculosis, sleeping sickness, cholera, Japanese encephalitis, meningitis, visceral leishmaniasis and Chagas disease. Forty-five vaccines, drugs, diagnostics and preventatives have been developed to-date. Of these, 17 were specifically developed by PDPs, including several major breakthroughs.^{xii, xiii}

- ▶ New and improved antimalarial combination drugs have been developed by the Drugs for Neglected Diseases *initiative* (DNDi) and Sanofi with 130 million treatments made available since 2007;^{xiv}
- ▶ Novel pediatric antimalarial drugs were advanced by Medicines for Malaria Venture (MMV) and Novartis with more than 100 million doses delivered since 2009;^{xv, xvi}
- ▶ A new cholera vaccine with a longer duration of protection in children was developed by the International Vaccine Institute and has been approved by the World Health Organization;^{xvii, xviii}
- ▶ A detection diagnostic, GeneXpert, was developed by the Foundation for Innovative New Diagnostics (FIND) and delivers results that diagnose tuberculosis and detect drug resistance in two hours, compared to older tests that took two months;^{xix} and
- ▶ A new meningitis A vaccine that costs less than 50 cents per dose (see right).^{xx, xxi, xxii}



A young girl receives MenAfriVac™ shot as part of Burkina Faso's meningitis immunization campaign. The World Health Organization

A Meningitis Vaccine for Africa

Every year, meningococcal A epidemics claim thousands of lives in sub-Saharan Africa. In one of the deadliest epidemic seasons, 1996-1997, the disease killed more than 25,000 people and sickened 250,000.

As a result, the Meningitis Vaccine Project (MVP), a Product Development Partnership (PDP) collaboration between PATH and the World Health Organization, was created to develop a new, affordable preventive meningitis A vaccine for the meningitis belt of Africa. In 2010, MVP rolled out MenAfriVac™, at a cost of less than 50 cents per dose.

Nearly 20 million people were vaccinated in the 2010-2011 epidemic season. Not a single person who was vaccinated came down with meningitis A, which accounts for most of the cases of meningitis in the region.



One Woman's Story: A Need for New TB Tools

Mildred Fernando, 29, an accountant from Manila, Philippines, lived with a killer disease – extensively drug-resistant tuberculosis, or XDR-TB – not once, but twice. After years of treatment, she is healthy today for the first time since she was 19 years old.

In many countries, more than half of those with XDR-TB do not survive; many abandon treatment, which can last up to two years. Mildred is fortunate. She also is strong. She took her medication faithfully, even though it made her sick and weak.

Mildred's story shows how critical it is to develop new tools to fight diseases.

Things are changing – because of research. Researchers are developing new vaccines and effective and less cumbersome medicines to replace today's six-month treatment regimens – which can last much longer in the case of drug-resistant strains. Yet even with treatment, many patients, particularly those with co-infection with HIV, do not survive. Government and foundation funding is leading to this new promise. Ms. Fernando said more innovation is critical.^{xxiv, xxv, xxvi}

After 10 years of treatment, she said, "It's only now that I am starting to live. I just want to enjoy life."

POISED AT A HISTORIC TURNING POINT

Developing and developed countries alike are now at a historic turning point in global health. While a decade of unprecedented public and private commitment to fighting neglected diseases has brought immense progress, the need still remains for new innovations and continued funding to solve this generation's intractable problems.

An effective preventive vaccine could have a tremendous impact on preventing new HIV infections, while an effective microbicide would give women a new prevention tool they could control.

The current tools to fight malaria are working, but are not sufficient to achieve the long-term goal of eradication, as resistance to existing drugs and insecticides increases. A malaria vaccine is needed. In addition, new one-dose drug treatments could help combat parasite resistance that results from poor compliance with the current multi-day treatment regimens.

And many neglected diseases urgently need new technologies. In one example, current tools for diagnosing, treating and preventing visceral leishmaniasis (VL) are inaccurate, overly complex and expensive. The disease, also known as kala-azar or black fever, is fatal if left untreated, killing around 50,000 people per year.^{xxiii} A point-of-care test, a short-course oral treatment and an efficacious vaccine to prevent VL are all needed.

Partnering for Success: EDCTP

The European & Developing Countries Clinical Trial Partnership (EDCTP) is another example of a successful partnership for product development. With support from 16 European countries and the European Commission, its mandate is to accelerate the development of new clinical interventions to fight poverty-related diseases, particularly in sub-Saharan Africa, and to improve the quality of research in relation to these diseases.

This work includes 207 projects, including 52 clinical trials and integrated project grants; significant investment in African and European institutions; and co-funding from numerous third parties, such as pharmaceutical companies, foundations, PDPs and NGOs.^{xxvii}

For example, EDCTP provides co-funding for two ongoing Aeras-sponsored trials of the world's most clinically advanced tuberculosis vaccine candidates in Africa.^{xxviii}

THE NEED FOR NEW INVESTMENT

Unfortunately, the development of new global health products is at risk of being stalled due to insufficient funding. The R&D process can be costly. Estimates of the cost to develop a new drug or vaccine through the point of regulatory approval, including all research and clinical trials, are typically in the hundreds of millions of dollars.^{xxix}

For global health product development, R&D has traditionally been supported by the public sector, with private foundations playing a smaller but important role. In 2010, the public sector supported nearly two-thirds of global funding, or \$2 billion, almost all of which came from high-income governments.^{xxx} Funding from private foundations was \$568.1 million, approximately 18.5 percent of total global health R&D funding that year.^{xxxi} Together, support from governments and private foundations for global health research in 2010 was over 80 percent of total funding.

However, restrictions brought on by the global financial crisis have led to eight of the top 12 government funders reducing their support for neglected disease R&D in 2010.^{xxxii} In the same year, the philanthropic sector decreased its support by nearly \$80 million.^{xxxiii} Additional funding is urgently needed, both from those who have traditionally supported global health R&D, as well as new funders.^{xxxiv}

WE MUST INVEST IN R&D TODAY TO LAY THE FOUNDATION FOR THE NEW AND BETTER TOOLS OF TOMORROW.



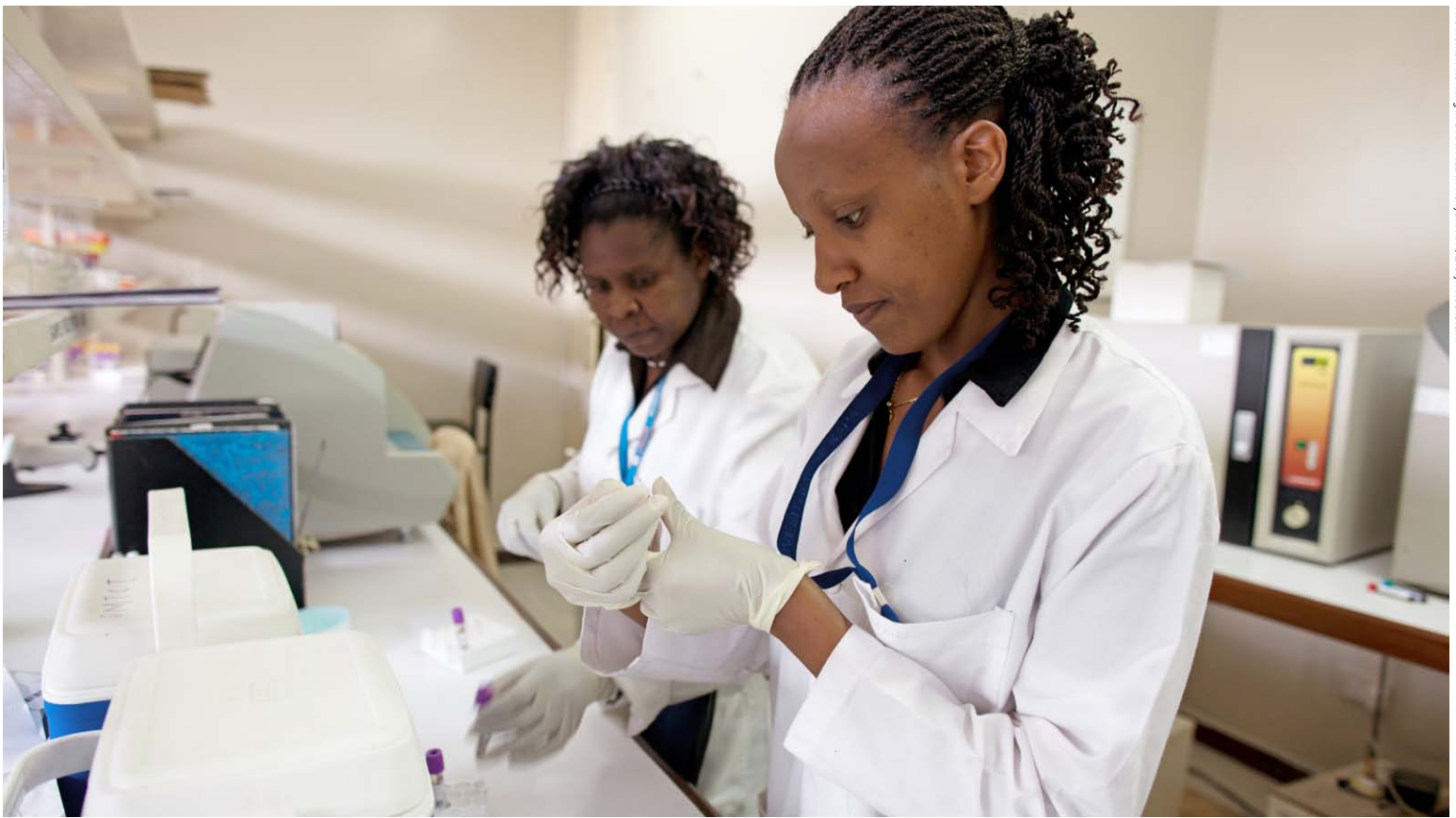
Watched by her 20-year-old mother Akhya, three-month-old Orpan receives her third dose of pertussis vaccine. Sarah Hogg Smith/ICM.

SUSTAINING THE MOMENTUM

Today, a strong pipeline of products is in late-stage development. While this is exciting news, it brings greater complexity, will require greater resources and also means growing costs. In addition, there are an increasing number of promising candidates to test as a result of early research – an indication that the portfolio of innovative global health products is maturing. Product development partners will be advancing these projects into clinical development in the next several years. These projects will need to pass through the necessary stringent safety hurdles that will increase their chance of becoming new drugs, vaccines, diagnostics and preventative therapies that will combat disease.

But funding for R&D for many diseases remains well below the levels needed to deliver new products to save lives. The long-standing funding gap for promising new drugs, diagnostics and vaccines is in danger of growing larger. Without sufficient resources, product developers will need to slow down or halt the development of promising new projects, putting in jeopardy the significant gains achieved during the past decade.

As long as the funding is there, innovations will keep coming every year. We need increased funding for global health R&D in order to sustain the momentum for new health tools, support innovations that are in final stages of development and deliver new products to people in need worldwide.



ENDNOTES

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