

UNITAID AT



ACCELERATING INNOVATION IN GLOBAL HEALTH



**UNITAID AT 10:
ACCELERATING INNOVATION
IN GLOBAL HEALTH**

WHAT'S IN THIS BOOKLET?

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How Unitaid operates

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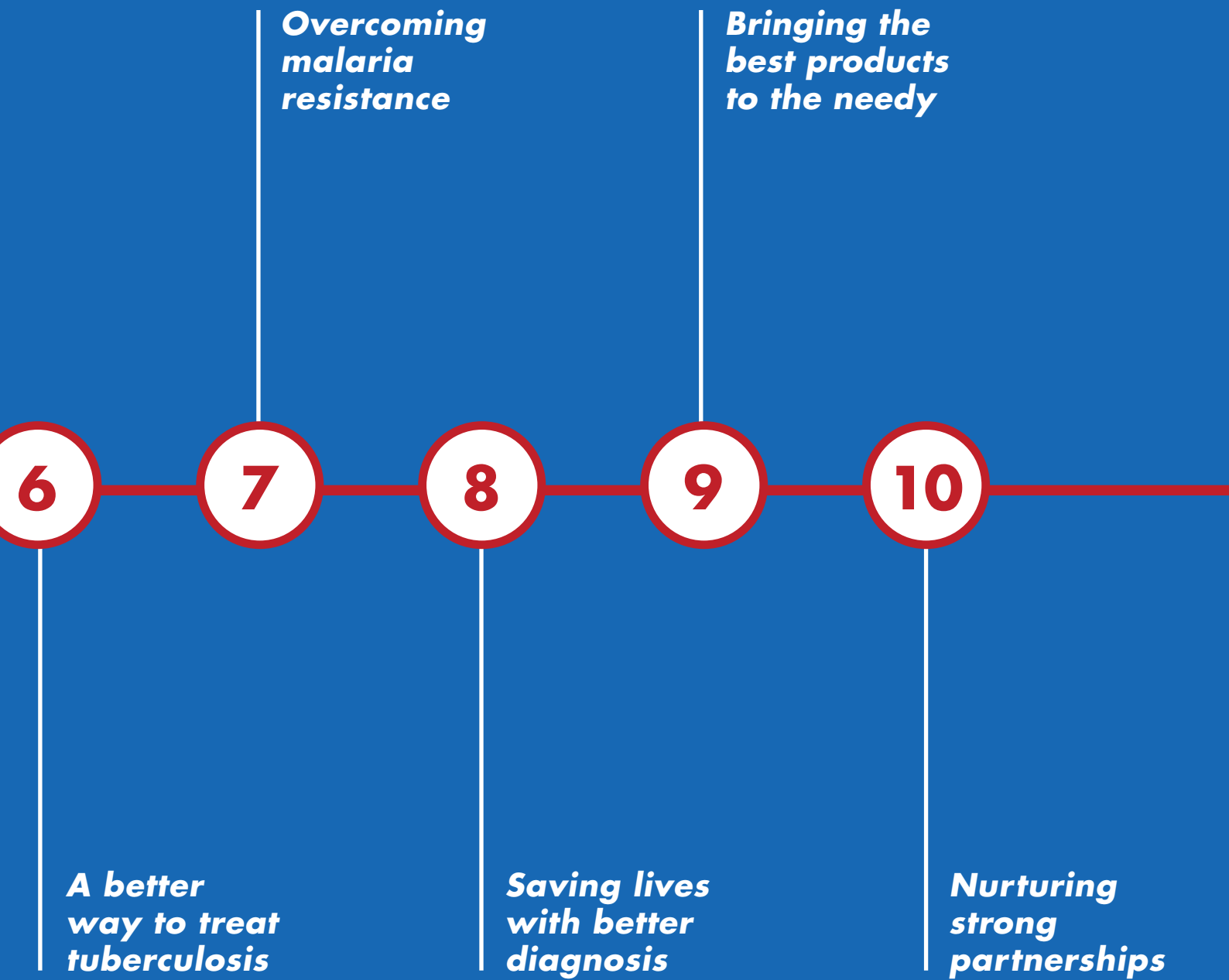
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Innovative ways of funding investments

Making life-saving drugs affordable and accessible





Newly wed couple, Leroy Godzi, 24 and Tilda Mutatandadzi, 18 arrive at a rural mobile health clinic for a confirmatory HIV test in Zimbabwe. They were motivated to carry out an HIV self-test in their village, thanks to Unitaids funding.

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Eric Gauss

THE ROLE OF UNITAID AND WHY IT MATTERS

*“Unitaid is ground-breaking in the way it raises funds and spends them in support of innovative health solutions for those in need. **It is a political idea that has proved its effectiveness in the field.**”*

Philippe Douste-Blazy,
Founding Chair of Unitaid, 2006-2016

Deaths from HIV/AIDS, tuberculosis and malaria have halved from 6 million a year in 2000. This turnaround was no accident. It was spurred by visionary political leadership, galvanising a big increase in funding and a surge of innovation that have brought about dramatic gains in availability of effective new treatments.

Unitaid, often working behind the scenes with its partners since its creation 10 years

ago, has been at the centre of this success story. Innovation is written into Unitaid’s genetic code. More than half of Unitaid’s funding is from a tax on airline tickets, pioneered by France.

At Unitaid, we invest in developing and unlocking markets to make health innovations widely accessible. We do this by funding the final stages of research and development of drugs. We

also help to produce data supporting guidelines for their use; to conduct operational research; and to break down intellectual-property barriers. With the support of Unitaid funding, a new medication or public health technology can reach markets in developing countries quickly at an affordable price.

Once health commodities have been made affordable through Unitaid’s work, their introduction

“Unitaid has made it possible to carry out a revolution in public health in developing countries, especially Africa.”

Former French President Jacques Chirac, who played a crucial role in establishing Unitaid

on a large scale is funded by governments and initiatives such as the United States President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, TB and Malaria (The Global Fund).

Why Unitaid’s work matters

Making the best medicines less expensive and accessible is a big part of the global success story of the past 15 years. A core part of Unitaid’s work has been simplifying treatments so that patients can take as few pills as possible, thereby helping them to stick to their treatment more easily. Other priorities have been to formulate child-friendly treatments and come up with

diagnostics that can be used in remote places that are far from hospitals and health clinics.

Unitaid’s work matters because the rate of increase in international investments in HIV, tuberculosis and malaria, which surged over the past 20 years, is slowing considerably. As funding flatlines, squeezing every drop out of available resources is going to be essential to achieve global health goals. Innovation is the lynchpin of our efforts to be more efficient and cost-effective in our response to disease, especially at a time when resistance to tried-and-tested tools is an emerging danger that threatens to derail progress.

“They look at all the different medicines that are being used for the diseases of the poorest, particularly malaria, HIV and TB and they go and think about: How could the prices be brought down? Or is there a paediatric formulation that’s missing?”

Bill Gates, Co-Chair and Trustee, Bill and Melinda Gates Foundation, speaking about Unitaid’s role

18-year-old Marvel Dzapasi is in fourth year of high school. When he grows up, he wants to be a computer analyst. Through strong partnerships, Unitaid supports millions of people in developing countries to achieve their dreams.

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Eric Gauss



INNOVATIVE WAYS OF FUNDING INVESTMENTS



The air ticket levy can range from US \$1 for economy-class tickets to approximately US \$40 for business and first-class travel. Passengers in transit are exempt and countries themselves can decide what rate and ticket class they would like to include.

63%

of the US \$2.5 billion that Unitaid received from 2006 to 2015 came from air ticket levies.

When the governments of Brazil, Chile, France, Norway and the United Kingdom created Unitaid in 2006, little did they imagine that 10 years later, the 'air ticket levy' would have stood the test of time, and remained stable in the face of a crippling economic crisis.

Of the US \$2.5 billion in contributions that Unitaid received from 2006 to 2015,

63 per cent come from air ticket levies.

When a passenger buys a ticket in a country that implements the levy, US \$1 of the ticket price goes to Unitaid. The simple act of taking a flight has turned passengers into contributors, and in turn financed investments that have shaped markets for critically-needed tests and treatments.

Thanks to the leadership provided by France, the number of countries using the air ticket levy has expanded from 3 countries in 2006, to 10 in 2016: Cameroon, Chile, Congo, France, Guinea, Madagascar, Mali, Mauritius, Niger and South Korea. Norway allocates part of its tax on CO₂ emissions.

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A doctor smiles before conducting an HIV test at a rural health outreach clinic in Godzi village of Zimbabwe. Unitaid supports diagnostics at points where communities tend to seek them most.

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A nurse in Kara Suu hospital in Kyrgyzstan. Through the Unitaid-funded endTB project, MSF is introducing new drugs in the country, where one in four patients newly diagnosed with tuberculosis has a multidrug-resistant strain of the disease.

© Vincent Tremeau/
MSF

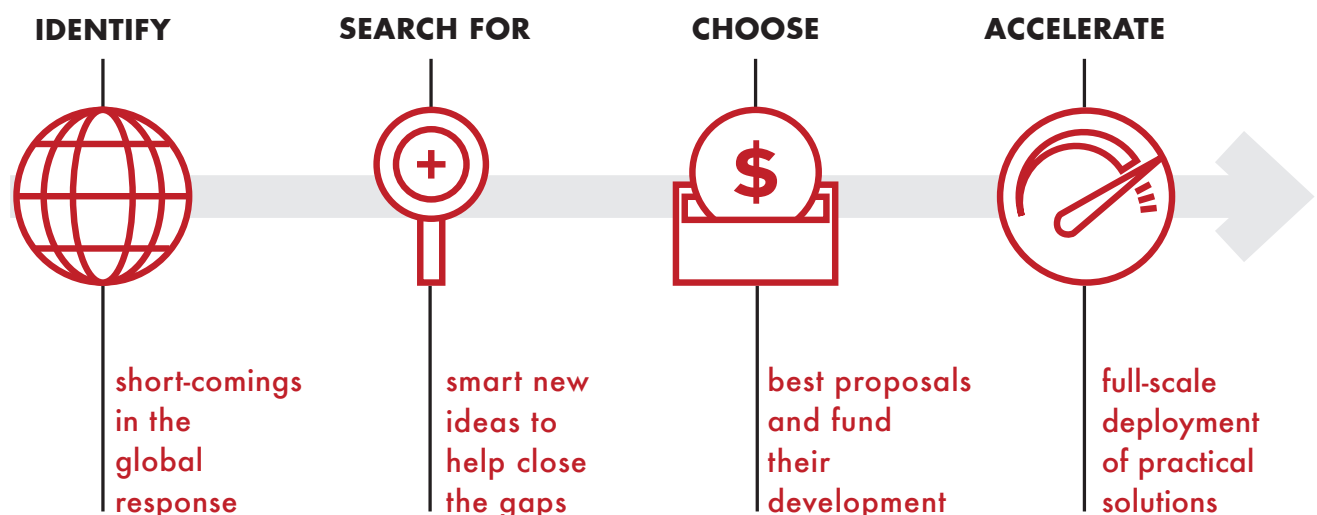
HOW UNITAID OPERATES

Unitaid invests in new ways to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly and effectively.

Here is how we do it:



Unitaid collaborates with global health partners and governments to:



— MAKING LIFE-SAVING — DRUGS AFFORDABLE AND ACCESSIBLE

60%

reduction in prices due to Unitaid's funding for adult second-line antiretrovirals, which also got more people on treatment and promoted competition.

A decade ago, Dr. William Musoke was offering his adult patients first-line HIV treatment free of charge at the Mildmay health centre in Kampala, Uganda. However, the second-line drugs that patients needed if the treatment was failing were prohibitively expensive, leaving Dr. Musoke with little to offer but sympathy.

All that changed in 2007, when Dr. Musoke's clinic started providing free second-line treatment, as a result of Unitaid's funding to the Clinton Health Access Initiative (CHAI).

Better prices, better treatments

The programme brought down prices by up to 60 per cent for adult second-line antiretrovirals and also promoted competition with more generic manufacturers joining the fray and producing a range of second-line regimens. In 2011, a leading second-line regimen containing Tenofovir cost about US \$527 per patient per year, down from US \$1500 per year in 2006, largely due to Unitaid-funded CHAI's efforts to increase volumes

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12-year-old Progress Magaya walked for an hour with her grandmother from Nyariri village to reach the Dumbo health clinic in rural Zimbabwe. She contracted HIV from her mother. Today thanks to reductions in prices, Progress can start treatment at the clinic and enjoy a good quality of life.

© Unitaid/
Eric Gauss





and competition, develop sources with lower prices for raw materials and improve the chemical process.

With the number of producers rising and prices falling, thousands of patients per year were able to switch to life-saving second-line medicines.

Treatment also got better. For instance, in 2010, two second-line antiretrovirals were launched that did not require storage at low temperature. These “heat-stable” drugs allowed for simpler delivery and storage for the first time. Besides, these new combinations also meant fewer tablets, making medication more tolerable and easier to administer, thereby helping people living with HIV to stick to their treatment.

Transition to long-term funding

Unitaid grants are intended to be transformational and catalytic. To maximize public health impact, the grants are designed to transition to other funding sources once new health solutions have been adopted and introduced in low and middle-income markets. For

example, the Unitaid-funded CHAI project, which helped Dr. Musoke, ended in December 2012 with all 25 countries able to transfer funding support to either their own national governments or grants from The Global Fund or the US President’s Emergency Plan for AIDS Relief (PEPFAR).

Medicines Patents Pool

In 2010, Unitaid created and invested in the Medicines Patent Pool (MPP) to negotiate voluntary licenses for HIV medicines. This gave generics manufacturers the opportunity to produce and supply affordable versions of patented drugs. Today about 95 per cent of adults with HIV live in developing countries that are covered by MPP licenses.

In addition, MPP’s work on Tenofovir has made it even more widely available and resulted in savings of US \$195 million from 2012 to end 2015. Tenofovir is now included in the preferred first-line treatment recommended by the World Health Organization (WHO), and used by a majority of the 17 million people on HIV treatment.

95%

of adults with HIV live in developing countries that are covered by licenses of the Medicines Patents Pool, which was created by Unitaid.



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A South African girl holds a tablet specially adapted to treat children with tuberculosis in Delft. South Africa is preparing for the uptake of these medicines.

© TB Alliance/
John-Michael
Maas

THE QUEST FOR BETTER MEDICINES FOR CHILDREN

US \$600 million

invested by Unitaid to improve treatments and diagnostics for children living with HIV.

Drugs are most often designed for adults, which can lead to dosage problems for kids. With little incentive for manufacturers to produce child-friendly drugs, parents have to crush bitter-tasting pills to get the right doses for their children. Such ad hoc formulations are difficult for children to tolerate, or even swallow in the first place.

Recognizing the needs of children with HIV

Over the years, Unitaid has committed more than US \$600 million to improve treatment and diagnostics for children living with HIV. Unitaid was one of the first donors to recognize that the paediatric HIV market does not meet the needs of children

living with HIV in developing countries. As a result of Unitaid's investment, drug makers have brought more effective formulations to the market, making paediatric HIV treatment much more affordable.

In 2013, WHO's new guidelines for paediatric HIV care significantly increased



Two-year-old Kamaragi was reeling with severe malaria when he was brought to the Luweero Hospital in northern Uganda. Fortunately for him, he was given injectable artesunate, a new malaria treatment that can bring children back from the brink of death. Unitaid has invested to make this treatment widely available.

200,000

estimated lives could be saved per year if African National Malaria Control Programmes use new treatment for severe malaria on a large scale.

the number of young children recommended for treatment and called for affordable child-friendly formulations.

To implement these guidelines, Unitaid, the Medicines Patent Pool (MPP), CHAI, the Drugs for Neglected Diseases initiative (DNDi) and WHO created the Paediatric HIV Treatment Initiative.

First adapted tuberculosis drug for children

In December 2015, Unitaid, together with TB Alliance and their partners, launched the first specially adapted medicine for children with tuberculosis, following the introduction of new WHO guidelines. The investment by Unitaid was a significant breakthrough for 1 million children who are estimated to get tuberculosis every year.

Protecting children from malaria

Unitaid funding is also targeting children under 5 years of age, who account for more than two-thirds of all deaths from malaria. A US \$34 million grant from Unitaid has enabled the adoption of products to treat severe malaria, which most often strikes at young children under 5 years of age.

Through this grant, an estimated 100,000 additional lives had been saved in Uganda, Kenya, Nigeria, Cameroon, Ethiopia and Malawi by end 2015. Larger-scale treatment, to be adopted by National Malaria Control Programmes in Africa, could save an estimated 200,000 lives per year. Another Unitaid grant delivers preventive malaria treatment to the hardest-to-reach children in rural areas of Africa's SAHEL region.



*A child in Mali
receives her
first dose of
medication
meant to prevent
seasonal malaria.*

© CRS/
Sylvain Cherkaoui

A BETTER WAY TO TREAT TUBERCULOSIS

*Simplified tuberculosis treatment can make the market for tuberculosis medicines **less fragmented, leading to better procurement processes.***

In the last 25 years, deaths from tuberculosis have halved and the number of cases has fallen by 42 per cent. Despite these successes, more than 1.5 million people still die from this curable disease every year. Far from being eliminated, tuberculosis has overtaken HIV as the deadliest infectious disease worldwide.

Of the estimated 9.6 million people who developed tuberculosis in 2014, some 480,000 cases were resistant to first-line drugs. Existing treatments for multidrug-resistant tuberculosis are long, toxic, often ineffective and can cause

severe side effects, including acute psychosis and deafness. Only half of those who take treatment get cured. Drug resistance threatens to stall, or even to reverse progress unless shorter, more effective treatment regimens are introduced.

Unitaid is driving change by investing in shorter and better ways to treat tuberculosis. In 2015, Unitaid committed US \$60 million to speed access to better, shorter treatments for multidrug-resistant tuberculosis – including combinations that use two new drugs - bedaquiline and delamanid - the first to be developed in almost 50 years.

The endTB project aims to speed access to these new drugs. In addition, a clinical trial could result in a new regimen that is simpler, less toxic, uses all-oral drugs instead of injections and could lead to higher cure rates.

Simplified tuberculosis treatment can make the market for tuberculosis medicines less fragmented, leading to better procurement processes. The endTB project is shaking up the market for tuberculosis drugs in partnership with Partners In Health (PIH), Médecins sans Frontières (MSF) and Interactive Research & Development (IRD).

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23-year-old Saba Hilemariome was in treatment for multidrug-resistant tuberculosis at the Alert MDR-TB Clinic in Addis Ababa, Ethiopia. Existing treatments are long, toxic and often ineffective.

© Unitaid/
Mulugeta Ayene





Lucas Ojoro, a reseller of artemisinin-based combination therapy, with a young customer on the outskirts of Kisumu town in Kenya. Unitaid invested in expanding access to this therapy, which is the first-line treatment for malaria.

© The Global Fund/
Thomas Omondi

OVERCOMING MALARIA RESISTANCE

Resounding success in the fight against malaria over the past 15 years has given the world much to celebrate. Since 2000, the number of people dying from malaria has more than halved. But these gains are now threatened. Mosquito populations around the world are developing increasing genetic resistance to insecticides used in indoor spraying and long-lasting insecticidal nets. If unchecked, this mounting resistance could see progress unravel.

A new generation of insecticides

New insecticides are urgently required to prevent widespread insecticide resistance. A US \$65 million investment by Unitaid is shaping a market for new insecticides that can be sprayed inside homes to kill mosquitoes. With Unitaid's intervention, the price of this new insecticide is expected to steadily decrease.

Lower prices could drive widespread availability across Africa beyond the 16 countries that will be supported through the Unitaid-funded programme.

In addition, the Innovative Vector Control Consortium (IVCC) and the President's Malaria Initiative (PMI) will speed up the development of new insecticides so that they can reach markets quickly. They will provide incentives for manufacturers, who are deterred by high product development costs and lengthy regulatory processes. With accurate forecasting of the demand for these insecticides, manufacturers could be persuaded to invest in production.

Affordable medicines to fight malaria

Antimalarial resistance is also a challenge in the treatment of malaria. Many of the older

antimalarial drugs are losing their efficacy at an alarming rate due to the malaria parasite's growing resistance to drugs. WHO recommends artemisinin-based combination therapy (ACT) as the first-line treatment for a deadly and widely prevalent strain of malaria caused by the *Plasmodium falciparum* parasite.

ACTs of quality are more expensive than older products and underused in sub-Saharan Africa where this deadliest form of malaria is rampant. A series of Unitaid interventions triggered considerable change. This included the funding of the Affordable Medicines Facility initiative, which helped to deliver over 400 million ACTs through a novel co-payment system with the Global Fund.

— SAVING LIVES WITH — BETTER DIAGNOSIS

16 million

GeneXpert cartridges were procured in 116 countries following reductions in the price of the cartridges, increasing detection rates of drug-resistant tuberculosis.

Without prompt diagnosis of a disease, there can be no treatment for those who need it. Every year, 3 million people die from HIV, tuberculosis and malaria, all of them diseases that are treatable if diagnosed in time. Yet, half of all people living with HIV and more than a quarter of the 9.6 million who get tuberculosis every year do not know they are infected and elude treatment.

Over the last decade, Unitaid has brought better, faster and simpler testing solutions to millions who require them, and made them more affordable.

Better detection of tuberculosis

Unitaid's EXPAND-TB project introduced new diagnostic platforms to detect multidrug-resistant tuberculosis to the

27 countries that account for 40 per cent of all cases worldwide.

Unitaid subsequently procured 1.4 million GeneXpert diagnostic machines for 21 countries. These machines detected 55,000 cases of drug-resistant strains of tuberculosis, each test taking only hours, instead of weeks.

Assistant researcher
Zelalem Yregal
holds up a
GeneXpert machine
cartridge at
Ethiopia's National
Tuberculosis
Reference
Laboratory.
GeneXpert
machines can
provide more
accurate results
for drug-resistant
tuberculosis in hours
instead of weeks.

© Unitaid/
Mulugeta Ayene.





33-year-old Zimbabwean Weston Kandawasvika conducts an HIV self-test on the outskirts of the capital, Harare. HIV self-testing has the potential to radically improve HIV testing amongst men in rural areas.

© Unitaaid/
Eric Gauss

US \$140 million

to test new diagnostics that provide results the same day in rural areas and communities.

Unitaid, the Bill and Melinda Gates Foundation and PEPFAR negotiated a 40 per cent reduction in the price of cartridges used in the machines in 145 countries, saving US \$55 million in the first 2 years after the price was cut. Since the price came down, more than 16 million cartridges have been procured in 116 countries, increasing detection rates of drug-resistant tuberculosis.

Easier-to-use HIV diagnostics

One of the biggest challenges for health workers, especially in sub-Saharan Africa, is getting HIV diagnostics and treatment to people in remote locations. HIV diagnostic facilities tend to be located in big cities, far from rural areas. Patients often never get their results due to difficulty in travelling back to the centres.

Unitaid's response has been to invest more than US \$140 million to deliver new and easy-to-use diagnostic devices to rural areas that provide results the same day, allowing immediate initiation of treatment. The grants focus on newborn babies born to HIV-positive mothers as one in three infants born with HIV will die within 3 months, if untreated.

HIV self-testing

Unitaid is also funding the largest ever effort to kick-start wider use of HIV self-testing. Population Services International (PSI) and partners are distributing 750,000 HIV self-test kits in Malawi, Zimbabwe and Zambia to evaluate the best ways to enable self-testing in rural areas. The US \$23 million investment could help support global efforts to greatly increase the number of adults living with HIV who are aware of their status.



BRINGING THE BEST MEDICAL PRODUCTS TO THE NEEDY

Medicines and diagnostics play an important role in treating and healing people affected by HIV, tuberculosis and malaria. Many crucial medicines in developing countries, however, often don't meet global standards. Ensuring that medicines are of the highest standard is essential to success in the global response to the three diseases. Without approved quality products, treatment can be ineffective.

Unitaid is the main funder of a vital service provided by WHO to assess the quality,

safety and efficacy of medicines and diagnostics. Known as prequalification, the initiative provides global quality-assurance for health products. Since 2006, Unitaid has invested more than US \$100 million in WHO's Prequalification programme.

The WHO team follows strict criteria to evaluate products and to inspect manufacturing and clinical sites. The list of prequalified products is a useful tool for organizations purchasing medicines or diagnostics in bulk, such as

the Global Fund, UNICEF, the United Nations Development Programme, non-governmental organizations or national procurement agencies.

Today, thanks to this programme, millions of people in developing countries use more than 200 quality-assured medicines and 60 diagnostics for HIV, tuberculosis and malaria. In 2015, an estimated two-thirds of the 15 million people on HIV treatment were receiving WHO-prequalified antiretroviral drugs.

US \$100 million

invested by Unitaid since 2006 to help WHO check the quality of over 300 medicines and over 60 diagnostics.

NURTURING STRONG PARTNERSHIPS

Every successful health response is grounded in a variety of partnerships. Together with industry, pharmaceutical companies, governments, international organizations, academia, and research organizations, Unitaid contributes to the global response for HIV, tuberculosis and malaria. To ensure that Unitaid grants transition to other forms of funding and achieve maximum impact, Unitaid engages with health partners and major funders such as the Global Fund and US government partners.

A good example is Unitaid's support for TB Alliance and WHO that helped to develop the first new fixed-dose

combination for children with tuberculosis. At a meeting in March 2016 to steer the drug to children living in developing countries, a variety of partners came together to agree on steps to transition to the next phase. Working with these partners, the project implementers have now begun preparing countries to adopt this new child-friendly tuberculosis drug.

Through co-investments, Unitaid provides additional support, financial or in-kind, to ensure the success of grants along with other partners. For instance, Unitaid provides a co-payment to bring down the price of new and more effective insecticides for

malaria control in the short term. This will help IVCC, the US President's Malaria Initiative, Abt Associates, PATH and the Global Fund to work with industry and national malaria-control programmes to make alternative insecticides more readily available.

Robust partnerships are at the very core of the successes that have been achieved in the global public health response. Without them, Unitaid would have been unable to make a significant difference in the lives of people around the world.

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A technician reviews test results after using a Pima device for quick CD4 testing in Ethiopia. Across Africa, Unitaid's investments have helped to expand testing at points where people seek care.

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Gelise McCullough



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