







# **Dr Tedros Adhanom Ghebreyesus**

Director General, World Health Organization

Since its creation, Unitaid has been supporting countries to access innovations that save lives. WHO is proud to work with Unitaid to identify gaps and design interventions that are most needed to protect and promote health. By working to make sure innovations do not get stuck on their path to scale-up, the entire global health system benefits from Unitaid's model.





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### **Dr Philippe Duneton**

**Executive Director, Unitaid** 

WHO plays a critical role in shaping and informing Unitaid's investment ideas, and ensuring that evidence generated from Unitaid investments is rapidly translated into global guidance, leading to national policies which meet the needs of the most under-served populations.

# Innovation and access: the need for life-saving health products

Developing critical health innovations – tests, treatments, and other essential medical products - costs billions each year. Yet people in low- and middle-income countries do not have access to such life-saving interventions due to factors including high prices, unsuitable product design, regulatory obstacles, manufacturing bottlenecks or a lack of quality assurance. The level of investment needed to ensure equitable access to these new health products has fallen short – leaving millions of people vulnerable to disease and infection.

Innovation is essential if the world is to get ahead of evolving diseases, outpace drug-resistance, build resilient primary healthcare, and increase the effectiveness of the global health response to the most serious and debilitating diseases.

When everyone everywhere has access to better and more effective tests, treatments, and tools – at affordable prices – millions more people will be connected to lifesaving care.

Investment in innovation AND access will ensure that every dollar invested yields a maximum return.



### **WHO & Unitaid**

# A unique global partnership making access to innovation possible

Established in 1948 as the coordinating authority for health within the United Nations, the World Health Organization (WHO) provides leadership on global health matters, shapes the health research agenda, sets norms and standards, articulates evidence-based policy options, provides technical support to countries, prepares for and responds to health emergencies, and monitors and reports on health trends. WHO gathers the world's top experts to examine critical health issues, define the best solutions and deliver the strongest evidencebased guidelines while strengthening partnerships with countries.

Unitaid, a WHO hosted partnership, was created in 2006 to accelerate access to vital medicines, diagnostics and other health products which are fit for purpose and affordable for people and communities who need them most. Unitaid expands access to best-in-class health products to fight HIV, tuberculosis (TB), malaria, and HIV co-infections and co-morbidities such as cervical cancer and hepatitis C, to improve the health of women and children, and to respond to emerging or future global health emergencies.

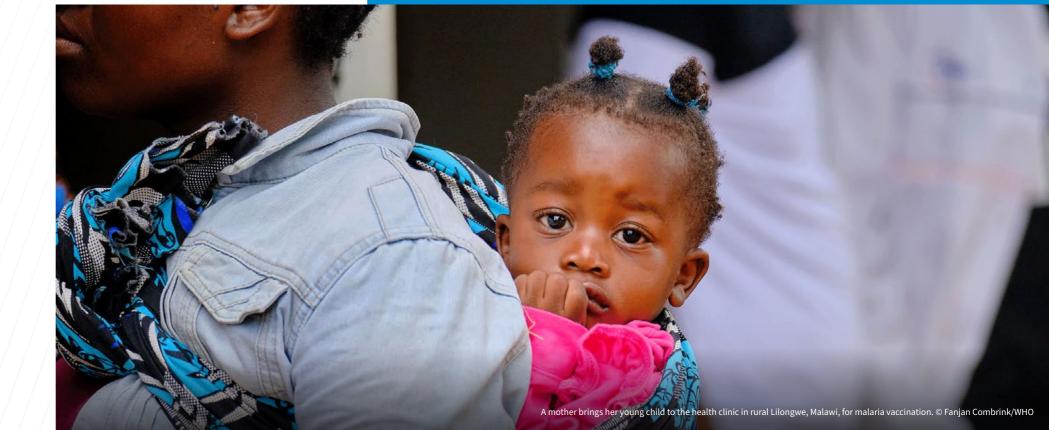






# **Transforming health care**

Together, WHO and Unitaid are transforming the healthcare of millions of people in low- and middle-income countries. The two organizations ensure that innovations in HIV, TB, malaria, hepatitis C, cervical cancer, maternal and child health and global health emergencies are translated into public health policy that have global impact.



# Accelerating access to health innovations



### **WHO & Unitaid**



#### **HIV & co-infections**

- HIV effective prevention, testing, diagnosis, treatment, and care
- Hepatitis C driving elimination through prevention, testing and treatment
- Cervical cancer and Sexually Transmitted
   Infections increasing access to screening and treatment methods



#### Tuberculosis (TB)

- Preventing TB transmission among high-risk groups
- Improving access to new detection tools
- Accelerating adoption of new drugs and treatment regimens



#### Malaria

- Introducing and optimizing prevention tools
- Improving access to quality case management and care
- Piloting of new vaccines



#### Women & children's health

- Improving access to better tools for safe pregnancy and birth
- Eliminating neonatal HIV, syphilis, hepatitis B and Chagas
- Improving child survival with triage and better treatment tools



#### **Respond to global health emergencies**

- COVID-19 improving diagnosis and quality of clinical care
- · Expanding access to medical oxygen



#### **Cross-cutting technologies & topics**

- Ensuring quality assurance of medicines and diagnostics
- Expanding and optimizing self-testing and integrated diagnostics
- Developing long-acting products, digital health and other new technologies



WHO and Unitaid maximize their combined comparative advantage to make a difference and identify game-changing health solutions. Unitaid provides financial support to those partners best qualified to put key innovations into practice and deliver high-quality research. WHO accelerates the development of policies and guidelines based on all available evidence including information generated by Unitaid's network of implementing partners.¹ WHO supports countries to adapt these policy recommendations to the local context and update national strategic plans so that better health solutions can be scaled up through national health budgets and with funding from partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

### **WHO & Unitaid**



Bold investments by Unitaid, provide invaluable information, experience and evidence on how to deliver best-in-class test, treatments and tools in a safe and acceptable way to people who need them the most. Through Unitaid's market-shaping activities, people get access to these products at a fraction of the original price. Without Unitaid, it would take years for people living in resource-limited settings to benefit from affordable and quality-assured life-saving innovations.

### Dr Meg Doherty, Dr Tereza Kasaeva and Dr Daniel Ngamije Madandi

Directors of WHO's Global Programmes on HIV, Hepatitis, Sexually Transmitted Infections, Tuberculosis and Malaria



Convening of experts and countries by WHO achieves consensus on the priority strategies needed to improve the health and lives of billions of people. WHO's evidence-based guidance leads the way forward. Without WHO, countries would not benefit from global policies and guidelines on the best tests, treatment and tools, nor would they have access to technical cooperation to quickly adopt the best disease prevention, control and care strategies. WHO and Unitaid work together on a daily basis to make this happen.

#### **Robert Matiru**

Director of Unitaid's Programme Division

<sup>&</sup>lt;sup>1</sup> https://unitaid.org/our-projects/grantees

### **WHO & Unitaid**

# Working towards the health-related Sustainable Development Goals (SDGs)

Poverty is one of the major social determinants of health. Low- and middle-income countries are increasingly at greater risk of crises caused by conflict and political, socioeconomic, and environmental factors, such as climate change, which also impact health and health services.

Progress towards achieving the healthrelated SDGs was off-track even before COVID-19. However, the pandemic further stalled progress and starkly exposed the dramatic inequality in access to care between high- and lowincome countries, and between rich and poor people.

Essential services for HIV, TB, malaria, hepatitis C and other infectious diseases, as well as sexual, reproductive, maternal, newborn, child and adolescent health were severely disrupted.

In 2021, 10.6 million people fell ill with TB, almost half a million people developed drug-resistant TB, and the global tally of malaria cases reached 247 million. WHO estimated that 38.4 million people were living with HIV and 58 million people had chronic hepatitis C virus infection in 2019.

In 2021, HIV, TB, malaria, hepatitis C and cervical cancer combined caused an estimated 3.5 million deaths globally.

Low- and middle-income countries around the world face the greatest burden of disease and death, and the highest rates of mortality caused by complications from pregnancy or childbirth, and cervical cancer. More than 90% of total under-5 deaths occurred in low- and middle-income countries in 2021.



# Access to critical health products for people who need them the most

The need for equitable access to affordable and effective quality health products has never been greater. Better health interventions will be key to getting the world back on track to achieve better health for all.

However, innovation means more than new products; it also means collaborating in new ways, bringing additional voices to the table, and forging new partnerships to shape the products, ensuring that those who should benefit are also part of the innovation process. This holistic approach will help improve access for all and build trust in new products.

# Game-changing health solutions

Since 2017, WHO has facilitated the design and delivery of more than 160 Unitaid-funded research studies to inform product approval, introduction and scale-up. More than 60 new WHO policy recommendations or guidelines have been published, leading to an unprecedented scale-up of game-changing health solutions, technologies, and approaches to prevent, diagnose, treat, and care for HIV, TB, malaria, cervical cancer, hepatitis C and COVID-19.

# HIV prevention 2022

countries adopted policies for oral PrEP

**3.3m** people were using PrEP by end of 2022

# From evidence to policy and global health impact - better health solutions delivered in LMICs

Unitaid-funded projects generate evidence:
WHO formulates policies and guidelines for implementation: scale up is
facilitated by countries and partners, such as the Global Fund

HIV self-testing

16m
kits were procured for HIV self-testing

102
countries had adopted HIV self-testing policies

HIV treatment 2022	Advanced HIV disease	2022	TB preventive treatment	2022	Childhood TB	2022	MDR-TB	2	2021
LMICs adopted the use of dolutegravir for adults  75  LMICs adopted dolutegravir for infants and children	99  LMICs fully adopted the WHO recommended package of care for perwith advanced HIV		78 countries using short-course prev treatments for TB in 2022, up from 52 in 2021 and 37 in 2020		countries are using friendly TB medicine  81 countries buying ch friendly second-line TB drugs	es ild-	bedaq MDR-T regime shorte more e	ries included uiline in their B treatment ens, allowing for r, less toxic and effective MDR-TB gement	

Hepatitis C	2016-2021	Cervical cancer	2019-2022	Malaria vaccine	2023	Vector control	2018-2022	Malaria chemoprevention	2021
1.5 - 5.2 the number of tested for hepa increased from 5.2 million	people titis C	wo for <b>1</b> Ur	momen were screened r HPV  4  nitaid-supported untries	children reached life-savir malaria soon mil more wil benefit	with ng vaccine, lions	14 cou 70% of malari <b>60 n</b>	ere ed across ntries with global a burden	45m children received S  160m malaria inf prevented since 2013	fections

## **Empowering solutions**

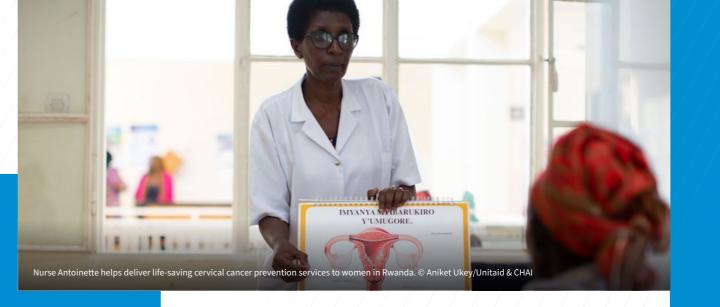
### **Self-testing for HIV**

Long distances, inconvenient opening hours, stigma and discrimination have created barriers to people learning their HIV status. Knowing your status means that people with HIV can access antiretroviral therapy for their own health, and access prevention to protect partners and infants. Self-testing increases access to an HIV testing option which is safe, confidential, and convenient.



In 2015, only one low- and middle-income country had a policy for HIV self-testing and there were no supporting WHO guidelines. By demonstrating cost-effective ways to deliver the tests to affected people and communities, Unitaid generated evidence which informed new WHO guidelines, and countries were supported to adopt and scale-up use of affordable WHO prequalified HIV self-tests.

By the end of 2022, 102 countries had HIV self-testing policies and about 16 million self-testing kits were procured. The successful roll-out of HIV self-testing has led WHO to develop guidelines, product development and implementation tools for self-tests for hepatitis C, syphilis, and COVID-19.



# Offering choices: pre-exposure prevention for HIV

HIV prevention efforts stalled in 2021 with 1.5 million new infections worldwide that year – the same as 2020. With 4000 new infections every day in 2021, key populations (sex workers, men who have sex with men, people who inject drugs, people in prisons and transgender people) and their sexual partners accounted for more than 70% of HIV infections globally.

When WHO released new guidelines in 2022 for the use of an intramuscular injectable cabotegravir (CAB-LA) - as pre-exposure prophylaxis (PrEP) for HIV - it increased the HIV prevention options available, offering the choice of long-acting, safe and highly effective protection. Studies found that use of CAB-LA resulted in a 79% relative reduction in HIV risk compared with oral PrEP, as adherence to taking daily oral medication was often a challenge.

WHO, Unitaid and partners are working to accelerate access to different PrEP choices.

# Self-sampling for cervical cancer prevention

Approximately 604 000 new cases of cervical cancer were recorded in 2020, resulting in over 340 000 deaths; 90% of deaths occur in low- and middle-income countries. At the same time, cervical cancer is highly preventable and treatable. When women have access to early screening, diagnosis and treatment, the risk of cancer is reduced, and health outcomes improved. WHO and Unitaid have worked closely on screen-and-treat approaches which include self-sampling methods for testing for human papillomavirus (HPV) – the virus that can cause cervical cancer.

Self-sampling empowers women to take control of their own health, is more respectful of women's privacy, avoids invasive procedures, and frees up overburdened nurses from having to conduct pelvic examinations and collect the sample themselves. Overall, one million women in 14 low- and middle-income countries have been screened for cervical cancer through the integrated prevention programme, with the majority of those who tested positive receiving treatment. The COVID-19 pandemic has spurred efforts to accelerate HPV self-sampling introduction globally; it is now considered a key element in scaling up screening coverage.

## **Child-friendly solutions**

#### **HIV treatments**

Young children are particularly vulnerable to infectious diseases. Developing specifically designed child-friendly medicines is critical to ensure they can be treated effectively.

The lack of appropriate paediatric medicines has meant that existing treatments are often rejected by children, due to the bitter taste or the difficulty in trying to administer crushed adult doses.

Of the 1.8 million children living with HIV around the world, just half are diagnosed and on treatment, while 85 000 babies and children die each year unnecessarily from HIV.

In 2021, Unitaid and WHO launched a strawberry-flavoured, dispersable formulation of dolutegravir – WHO's recommended best-in-class treatment for HIV – which was developed to address the barriers that stop young children accepting HIV medication.



### **TB treatments**

TB kills nearly 600 children and young adolescents every day and is a major cause of child mortality worldwide. Most deaths occur in children under the age of five and almost all the children who die from TB receive suboptimal treatment or none at all.

About 30 000 children and young adolescents develop multidrug-resistant TB (MDR-TB) each year, but only 5000 are treated due to poor access to diagnosis as well as treatment limitations.

Until recently, due to a lack of child-friendly formulations, caregivers had to split and dissolve bitter-tasting adult tablets, often unacceptable to children and their families, which lead to imprecise dosing, poor outcomes, and risk of drug resistance. In 2013, Unitaid invested in the development of child-friendly dispersible fixed-dose combinations for children below 25 kg with drug-susceptible TB. However, limited evidence was available on the dosages and safety of medicines needed to treat MDR-TB in children and newborns.

In 2019, Unitaid investment generated new evidence and informed WHO recommendations on the use of bedaquiline in children under 6 years and delamanid in children under 3 years. This has made it possible to build all oral regimens for children with MDR-TB of all ages, and is a major step forward, compared to the past, when they were receiving painful injectables with bad side-effects.

### Solutions for tackling resistance

As drug and insecticide resistance grows, new tools are required to maintain the protection and treatment efficacy of a myriad of essential health interventions.

### **Double protection insecticide treated nets**

The recent WHO recommendation for a new class of mosquito net that uses two active ingredients – pyrethroid and chlorfenapyr – provides double protection against malaria in areas where mosquitoes have already developed resistance to pyrethroids. Trials of the dual active ingredient insecticide-treated

nets reduced malaria infections by approximately 50% among children between the ages of 6 months and 10 years. Unitaid contributed to playing a catalytic role in the introduction of the new nets, including market interventions to support affordability.



# Revolution in the treatment of MDR-TB

MDR-TB takes a heavy toll on people affected by TB, communities, and healthcare systems. Previously, conventional drugs used to treat drug resistant TB were ineffective. Treatments could last up to two years, cause terrible side effects like permanent hearing loss and kidney failure, require thousands of pills and painful injections, and cost several thousands of dollars per person.

A Unitaid-funded project treated 3000 MDR-TB patients across 17 countries in a substantial observational study and conducted a clinical trial of 750 patients in seven countries. The evidence derived from the project informed WHO guidelines and the use of shorter, more effective, less toxic, all oral treatment for all people suffering from drug-resistant TB. The data is providing critical insight to guide the use of new and repurposed medicines across diverse populations, including people in treatment for HIV, diabetes, and hepatitis C, as well as in pregnant women and children, who are often excluded from studies.



### At scale delivery solutions

# Seasonal malaria chemoprevention reaching millions of children

Malaria continues to be a leading cause of death in young children. A child dies every minute from infections caused by malaria-transmitting mosquitoes. Delivering effective malaria prevention and protection for millions of children has been an ongoing challenge for the global health community.

In the Sahel region of Africa, most malaria cases occur during the rainy season. A decade ago, some 25 million children under 5 in the Sahel needed seasonal malaria chemoprevention (SMC) to protect them from the disease. WHO recommended SMC in 2012, and in 2013, less than 4% of under-fives were receiving this protection.



Unitaid funded the world's very first evaluation of the effectiveness of SMC on a large scale. The project delivered prevention treatment to more than six million children across seven countries in the Sahel, proving that large-scale administration of seasonal malaria chemoprevention is feasible and cost-effective, with a strong public health impact. The project also motivated more manufacturers to enter the market for child-friendly, palatable, easy-to-administer medicines for seasonal prevention treatment. Over the past decade, SMC coverage has surged, reaching a record 45 million children in 2021 compared to just over one million in 2013. This intervention is now a cornerstone of malaria control programmes in 15 African countries. Unitaid, WHO and partners accelerated access to a robust, resilient intervention which has high impact; SMC is expected to see continued growth, protecting even greater numbers of children from malaria.



# **Expanding access to the best available HIV treatment dolutegravir**

Since 2018, WHO HIV treatment guidelines recommended the use of dolutegravir in fixed-dose combination with other medicines as the preferred first- and second-line treatments for adults and adolescents living with HIV. These recommendations also applied to children weighing at least 20 kg, for whom adult tablets could be used. In November 2020, a dispersible generic pediatric formulation became available and this recommendation was further extended to all young children.

These new dolutegravir-based HIV anti-retroviral treatment medicines promised more effective, less toxic treatment, and Unitaid was quick to intervene and help accelerate access, avoiding the delays experienced in the earlier years of the HIV epidemic. Through early market introduction, price negotiations and catalytic procurement efforts, the best available HIV treatments were both affordable and reached low- and middle-income countries in record time. To close the gender gap in medical access, Unitaid also funded critical research to ensure that pregnant women were protected with the highest quality medicines to prevent mother-to-child transmission of HIV – a key route of infection in sub-Saharan Africa.

As of June 2022, 110 low- and middle-income countries had transitioned to dolutegravir and an estimated 22 million people living with HIV were receiving dolutegravir-based antiretroviral therapy. According to WHO estimates, more than 90% of all people living with HIV who are on antiretroviral therapy, will be using dolutegravir-containing regimens by the end of 2023.

### **Quality assured health solutions**

Prequalification of medicines and diagnostic devices addresses a significant public health need – access to critical, quality-assured, safe health products in low- and middle-income countries.

Quality assurance of generic medicines creates price competition, and allows more medicines to be procured with available funds so that millions more patients living with HIV, TB or malaria can be treated. It also increases the uptake of medicines designed specifically to meet the needs of low- income countries – such as paediatric formulations, and combination therapies.



The role of WHO's prequalification programme, to increase the supply of quality-assured medicines and diagnostics, and build a more efficient marketplace for safe products, is vitally important. Unitaid has been providing financial support for

the WHO prequalification programme since 2006, enabling more than 418 medicines and over 97 diagnostic devices to be prequalified for HIV, TB, malaria, hepatitis C, cervical cancer screening, and most recently, COVID-19.



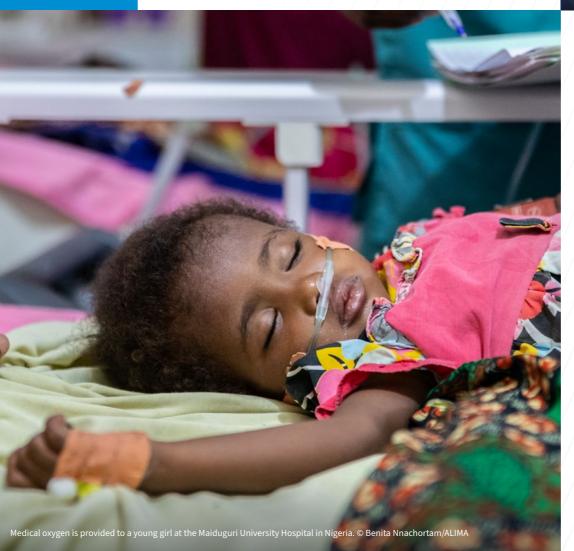
These included several "first ever" medicines, such as finished pharmaceutical products (FPP) for acute malaria, the first fixed-dose combination HIV product with ritonavir, dolutegravir-based fixed-dose combinations for HIV, a self-test for HIV, and a dispersible FPP for drug-susceptible TB, as well as rapid tests for malaria, HIV/Syphilis antibody tests and hepatitis C.

In 2017, WHO prequalified the first generic version of sofosbuvir, a critical medicine for the treatment of hepatitis C, as well as the first HIV self-test in a move to increase HIV diagnosis and treatment. WHO and Unitaid are working hand-in-hand to improve the management of both hepatitis C and HIV. For both diseases, long-acting formulations, such as patches or injections that can last weeks or months, are being developed to free people from daily pill regimens.

# Solutions to strengthen country responses

At the height of the COVID-19 pandemic, low- and middle-income countries struggled to meet demand for oxygen for their patients – many of whom were in respiratory distress and consuming up to ten 50-litre cylinders each day. Oxygen was the most critical treatment for people with severe COVID-19, yet supplies were unstable in many countries. Frequently the available oxygen was of poor quality and often worsened the state of the patient's health, and, unable to maintain oxygenation, many succumbed to the virus.

Unitaid and WHO were significant partners in the Access to COVID-19 Tools - Accelerator (ACT-A), and Unitaid chaired its COVID-19 Oxygen Emergency Taskforce. The Taskforce supported more than 120 low- and middle-income countries to identify country needs, connect countries to financing partners for their assessed oxygen requirements, rapidly make provision, not only for supplies and equipment – but also for the installation and repair of oxygen plants in key regional centers – and trained thousands of health workers and biomedical engineers. Unitaid and its partners also secured price reductions for medical oxygen following unprecedented agreements with the gas industry, ensuring countries had more equitable access.





The Oxygen Emergency Task Force drew attention to the acute need for oxygen as an essential life-saving medicine for a range of conditions affecting newborns, children and adults – including pneumonia, TB and sepsis – and also as a lifeline for surgery, childbirth and serious injuries.

The World Health Assembly is now discussing ways to secure access to life-saving oxygen by adopting a resolution on increasing access to medical oxygen. At the same time, Unitaid, WHO and partners are launching the Global Oxygen Alliance, which will result in more governments, donors, and partners across the world focusing on this global health crisis and prioritizing improving oxygen availability.

### Better health solutions for the future

WHO and Unitaid are committed to making the best available health innovations accessible to the people who need them the most. Lessons will be drawn from the COVID-19 response to improve global cooperation, share data and know-how. WHO and Unitaid will promote the use of digital health technologies, support groundbreaking science advances

for innovations such as mRNA vaccines and monoclonal antibody development, and focus on developing simplified health approaches such as self-sampling, self-testing and long-acting technologies – as well as community, homebased and primary care delivery of health services.

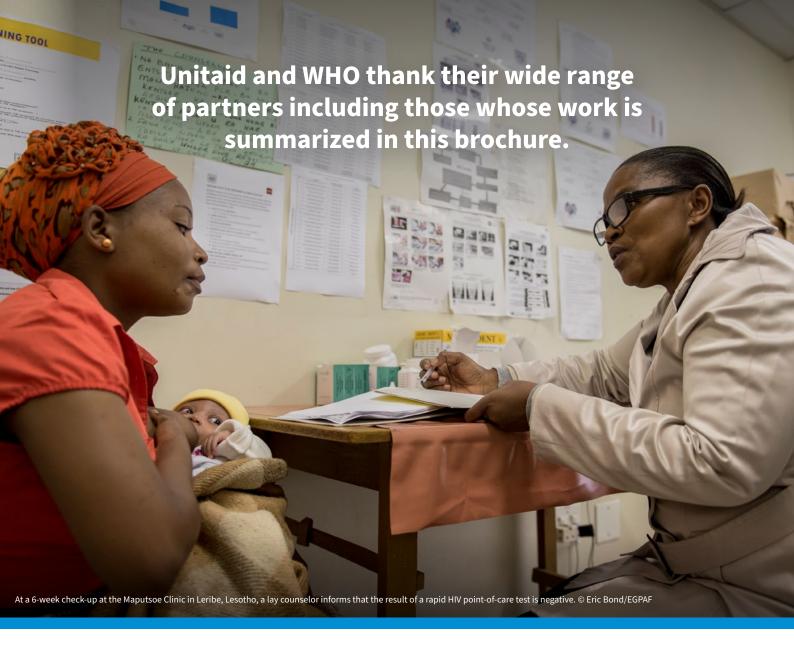
Specifically, WHO and Unitaid will ensure the development of better health solutions that can be scaled up in low- and middle-income countries by:

- Supporting upstream development and down-stream implementation of long-acting formulations for the prevention and treatment of major diseases
- Improving prevention and treatment of post-partum hemorrhage and pre-eclampsia to reduce maternal mortality
- Accelerating access to self-collection and HPV-based screening for cervical cancer prevention

- Accelerating access to tools that drive triple elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B
- Improving access to vector control and chemoprevention to prevent malaria
- 6 Improving malaria case management and mitigating resistance to antimalarial medicines
- Improving TB detection tools and approaches to massively advance TB prevention and treatment including for children and adolescents and for both drug-susceptible and drug-resistant TB



- Using innovative test, treat and care approaches to identify and treat thousands of mothers with Chagas disease, and their newborns
- Expanding access to medical oxygen by accelerating and enhancing the infrastructure introduced during the COVID-19 response
- Supporting sustainable investments in local and regional manufacturing, to build countries' resilience and greater self-sufficiency
- Reducing the carbon and environmental footprint of tests, treatments, and other essential medical products and improving the resilience of health systems to climate risks



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